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State-of-the-art and User Requirements of Blood Glucose Measurement: Devices, Software and Services.

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Diabetes is an increasingly common illness that often requires regular measurement of Blood Glucose (BG). This Thesis discusses the state-of-the-art and user requirements of BG measurement, focusing on: BG meters, diabetes management software, and diabetes treatment guidelines and practices. Additionally, BG measurement quality definitions are discussed. The discussion on the state-of-the-art presented is primarily based on literature research. The requirements study is based on the results of a semi-structured interview of 8 subjects. The requirements of three user groups are discussed, i.e. doctors, nurses and diabetics. The requirements of the user groups are significantly similar. The current supply of BG measuring devices and services provides the bare minimum required for good quality BG measurement. The more advanced requirements elicited in this Thesis are mostly not met. The BG measuring devices and services are thus required to be more comprehensive and integrated. One of the key issues with BG measurement is motivating the diabetics to perform good quality measurements. Interesting topics for further research include the factors affecting patients' motivation.

Keywords: Diabetes, patient Self-Monitoring of Blood Glucose, Blood Glucose Meters, Diabetes Management Software, Diabetes Treatment and Guidelines, State-of-the-art, User Requirements, Semi-structured Interview, Human Centered Design

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Diabetes on jatkuvasti yleistyvä sairaus, joka vaatii yleisesti säännölliset verensokerin omamittaukset. Tämä Diplomityö tutkii verensokerimittauksen nykytilaa ja käyttäjätarpeita.. Erityisesti työ keskittyy verensokerimittareihin, verensokerimittauksen apuohjelmiin, sekä diabeteksen hoitosuosituksiin ja -käytäntöihin. Diplomityössä käsitellään lisäksi laadukkaan verensokerimittauksen määrittelyä Nykytilan analyysi perustuu valtaosin kirjallisuustutkimuksiin. Käyttäjätarpeiden kartoitus perustuu puolistrukturoituihin haastatteluihin. Haastatteluaineisto pohjautuu 8:aan haastatteluun, jossa haastateltiin kolmen eri käyttäjäryhmä edustajia: lääkäreitä, hoitajia ja diabeetikoita. Näiden käyttäjäryhmien käyttäjätarpeet ovat hyvin yhteneviä. Nykyiset verensokerimittauksen laitteet ja palvelut vastaavat hyvälaatuisen verensokerihallinnan vähimmäisvaatimuksiin. Nykyiset laitteet ja palvelut eivät vastaa Diplomityön esittelemiä vaativampia käyttäjätarpeita. Laitteiden ja palveluiden tulisi ola nykyistä kokonaisvaltaisempia ja integroituneita. Yksi verensokerimittauksen suurimmista haasteista on potilaan motivaatio mittausten laadukkaaseen läpivientiin. Potilaan motivaatioon vaikuttavien tekijöiden selvittäminen on yksi mielenkiintoinen jatkotutkimuksen aihe.

Avainsanat: Diabetes, Verensokerin Omamittaukset, Verensokerimittarit, Diabeteksen apuohjelmat, Diabeteksen hoitosuositukset ja -käytännöt, Nykytarjonta, Käyttäjätarpeet, Puolistrukturoitu haastattelu, Käyttäjäkeskeinen suunnittelu

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Abbreviations

ADA	American Diabetes Association
BG	Blood Glucose
BP	Blood Pressure
CGM	Continuous Glucose Monitoring
DESG	Diabetes Education Study Group
FIR	Far Infra-Red
HCD	Human Centered Design
IDF	International Diabetes Federation
ISO	International Standards Organization
Kela	Social Insurance Institution of Finland
MODY	Maturity-Onset Diabetes in the Young
NHI	National Health Insurance
NIR	Near Infra-Red
NKHC	NonKetonic Hypersmolar Coma
SMBG	Patient Self-Monitoring of Blood Glucose
STPD	Self-Treatment Product Distribution
UCD	User Centered Design

Key concepts

Diabetes Mellitus	Diabetes is a cluster of diseases caused by either the lack of insulin in the body the impaired effect of it, or both. Diabetes induces constantly high blood glucose levels. Diabetes is often divided into two main categories, type 1 and type 2 diabetes. Type 1 diabetes is caused by the destruction of pancreas' insulin producing cells, which leads to the lack of insulin. Type 2 diabetes is caused by insulin resistance (the impaired effect of insulin) and the inadequate insulin production in the pancreas. (Saraheimo, Mitä Diabetes on?, 2011)
Blood Glucose	Blood glucose is an essential nutrient of the cells in the body. Most of the carbohydrates in the blood stream are glucose. (Hiltunen, et al., 2005, p. 530)
Plasma-glucose	Blood consists of plasma, erythrocytes, leucocytes, platelet. (Hiltunen, et al., 2005, p. 434). Blood Glucose can be measured from either whole-blood or blood-plasma samples, plasma-glucose concentrations are approximately 10-15% higher than whole-blood glucose concentrations. Usually blood glucose concentration is reported as plasma-glucose concentration rather than whole-blood concentration, as plasma-glucose concentration is more important than whole-blood concentration. (Rönnemaa & Leppiniemi, 2011).
HbA_{1c}	HbA_{1c} is an acronym for glycohemoglobin. HbA_{1c} measures how much blood sugar is attached to the blood cells' hemoglobin. HbA_{1c} values are used for determining the average blood glucose levels of a patient. HbA_{1c} correlates with the average blood glucose of the previous 6-8 weeks. (The Finnish Diabetes Association, 2013)
Hyperglycemia	Hyperglycemia means high blood glucose levels. Hyperglycemia can be caused by lack of insulin, weakened effect of insulin, or both. Chronic hyperglycemia can lead to acute and chronic complications (Finnish Medical Society Duodecim, 2011a). (Finnish Medical Society Duodecim, 2011c)
Hypoglycemia	Hypoglycemia is an acute diabetes related complication where the diabetic's blood glucose levels are abnormally low (American Diabetes Association, 2013). Hypoglycemia is caused by over-effectiveness of insulin. Hypoglycemia symptoms can occur with glucose levels as high as 8-10 mmol/l with diabetics with poor treatment balance. (Finnish Medical Society Duodecim, 2011a)
Current Care Guidelines	Finnish clinical practice guidelines. They are developed by the Finnish Medical Society Duodecim in association with other medical specialist societies. Guidelines are intended to be used by all as a basis for treatment decisions. (Finnish Medical Society Duodecim, 2012)
Diabetes Treatment Guidance	Diabetes treatment guidance is a concept for empowering the diabetics to make treatment related decisions independently by teaching the tools and knowledge required to make these decisions (Finnish Medical Society Duodecim, 2011b). The aim of diabetes treatment guidance is to produce better quality of life and prevent acute complications with diabetics (Finnish Medical Society Duodecim, 2011a).
Treatment Balance	The stability of the illness induced by treatment. In the case of diabetes, HbA_{1c} is used as a reference for determining the state of treatment balance. (Finnish Medical Society Duodecim, 2011c)
Lifestyle Treatment	Lifestyle Treatment is essential in the treatment of diabetes, and it includes guidance on diet, weight-control, exercise, and consumption of alcohol and tobacco. (Finnish Medical Society Duodecim, 2011a)

Insulin, Insulin therapy	Insulin is a peptide-hormone that controls the blood glucose level (Hiltunen, et al., 2005, p. 511). Insulin therapy is a standard in the care of type 1 diabetics, type 2 diabetics may require insulin treatment at some stage of their illness (Mustajoki, Diabetes (sokeritauti), 2012). Insulin can be administered with an insulin pump or by injections. Insulin is administered to control fasting glucose levels (basal, long-term insulin) and to control the effect of meals on blood glucose levels (bolus, fast effect insulin). (Finnish Medical Society Duodecim, 2011a)
Patient Self Monitoring of Blood Glucose (SMBG)	SMBG is done by taking measurements of blood glucose levels. SMBG is important to all diabetics for estimating variation in blood glucose levels, the frequency of measurements needed is patient specific (Finnish Medical Society Duodecim, 2011a). The goal of SMBG is to help diabetics determine their blood glucose balance and help with treatment related decisions (Rönnemaa & Leppiniemi, 2011).
Non-Invasive Blood Glucose Measurement	Non-invasive blood glucose measurement does not require a blood sample for determining the glucose concentration of a patient. The glucose concentration is determined by either sub-dermal sensors (minimally invasive) or sensors that are not sub-dermal (non-invasive). (Klonoff, 1997)
Invasive Bloog Glucose Measurement	Invasive blood glucose meters require a blood sample to provide the estimate of blood glucose levels. This blood sample is applied to a test-strip which contains enzymes that react with blood glucose. The chemical reaction correlates with the glucose levels in the sample. (Ilanne-Parikka, 2010, p. 14)
Lancing device	A lancing device is a personal treatment device used for taking a blood sample for measuring blood glucose concentration. The lancing device uses lancets (needles that fit into the device) to puncture a small hole into the patient's skin, which is squeezed to acquire a blood drop. The blood drop is applied to the test-strip, which is inserted to the invasive blood glucose meter. Usually the depth of penetration can be modified in the lancing devices. (Ilanne-Parikka, 2010, pp. 14-15)
Test-strip	Test-strips are used in invasive glucose meters. The test strips contain enzymes that cause either a color (*photometric technique*) or electrical (*electrochemical)* reaction when blood is applied to them. Electrochemical sensors measure the changes in electrical currents, whereas photometric sensors measure changes in colors. (Ilanne-Parikka, 2010, p. 14)
Self-treatment Product Distribution	Each city and municipality is required by law to distribute products for self-treatment of various illnesses. In case of diabetes, specifically SMBG, blood glucose meters and test-strips are distributed free of charge. (1326/2010 Terveydenhuoltolaki, 25§)
Human/User Centered Design	An approach to system design aiming to make the system more usable. Key features of this approach include giving focus on the use of the system, inclusion of all stakeholders to the process, development of a solid understanding of the context of use, and applying user centered design methods. (ISO 9241-210:2010)
Stakeholder	The individuals and organizations that have an interest or are affected by the product or service. Stakeholders include the end-users, buyers, developers, distributors, and sellers. (ISO 9241-210:2010, p. 3; Ulrich & Eppinger, 2008, p. 48)

User Requirements	The user requirements of a specific system consist of functional and non-functional requirements (Benyon, Turner, & Turner, 2005, pp. 210-211; Rosson & Carroll, 2002, pp. 11-12; ISO 9241-210:2010, pp. 12-13). Functional requirements determine *what actions* the system *must* enable. Non-functional requirements concern with *how the actions are done*. (Benyon, Turner, & Turner, 2005, pp. 210-212)
Semi-Structured Interview	A semi-structured interview is a variation of interview technique. Semi-structured interviews utilize some pre-prepared questions and allow the interviewer to follow-up on additional interesting topics that emerge during the interview. (Benyon, Turner, & Turner, 2005, p. 216).
Meaning Coding	A method used for analyzing interview transcriptions. Involves categorizing segments of the transcriptions by using keywords describing the essence of the segment. (Kvale & Brinkmann, 2009, pp. 201-202)
Meaning Condensation	A method for analyzing interview transcriptions. Long phrases and segments are condensed into shorter sentences entailing the essence of the condensed issue. (Kvale & Brinkmann, 2009, pp. 205-206)

Fig. 0.1 shows how the key concepts presented above can be organized into five groups. Additionally to the relations depicted below, patient self monitoring of blood glucose is covered in the current care guideline on diabetes. Moreover, semi-structured interviewing is one method used in human centered design.

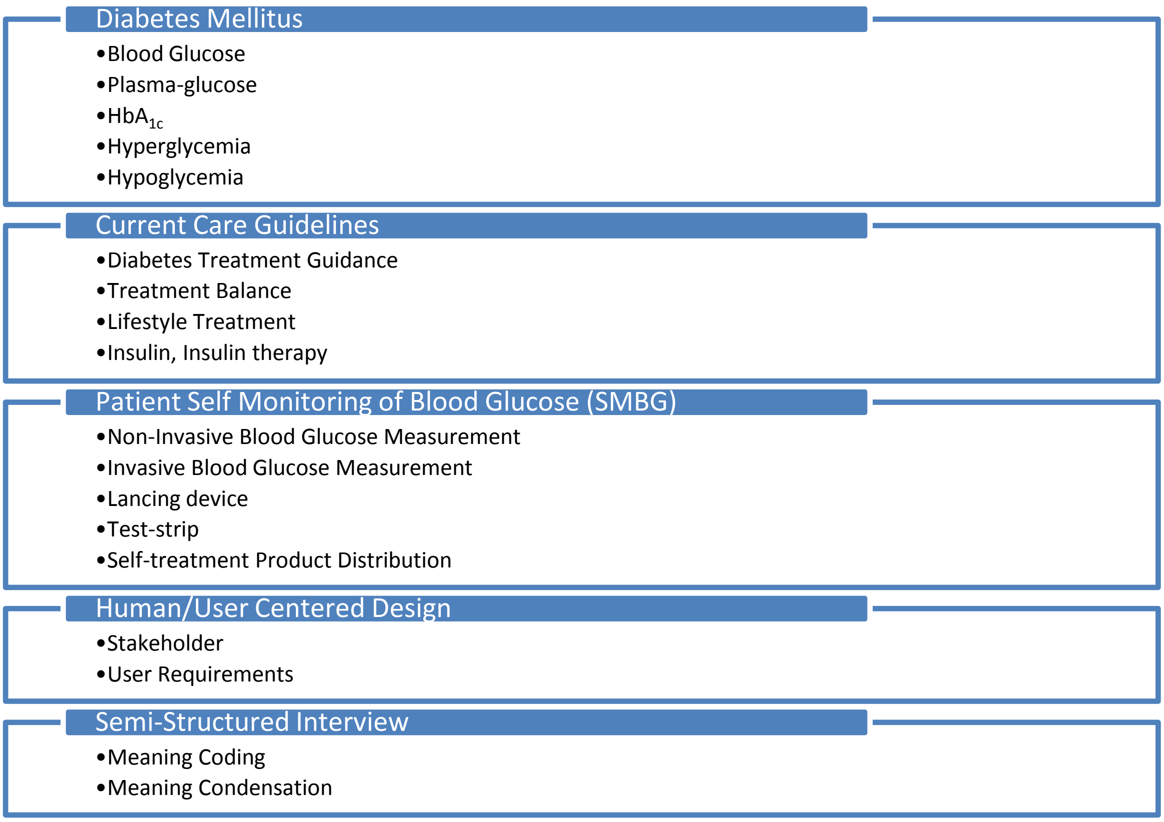

Figure 0.1 Organization of the key concepts

1 Introduction

Diabetes Mellitus is an increasingly common disease in Finland with estimated 10% of the population suffering from it (Koski, 2011, p. 6). In 2007 Finland had 300 000 diagnosed diabetics in treatment (Koski, 2011, p. 6). IDF (International Diabetes Federation) estimates that in 2011 there were 366 million diabetics globally, i.e. 8,3% of the global population. Furthermore, the IDF estimates that by 2030 the amount of diabetics rises to 552 million (9,9% of the population) (International Diabetes Federation, 2012). 8,3% of the population of the United States (25,8 million people) has diabetes, with an estimate of 79 million people with pre-diabetes (Centers for Disease Control and Prevention, 2011, p. 1).

Diabetes is a cluster of diseases caused by either the lack of insulin in the body or the impaired effect of it, or both. Diabetes induces constantly high blood glucose levels. Commonly diabetics are categorized to have either type 1 or type 2 diabetes. Type 1 diabetes is caused by the destruction of pancreas' insulin producing cells, which leads to the lack of insulin. Type 2 diabetes is caused by insulin resistance (the impaired effect of insulin) and the inadequate insulin production in the pancreas. (Saraheimo, 2011)

This Thesis discusses the topic of user requirements and state-of-the-art in blood glucose measurement. Blood glucose measurement is an integral part of diabetes treatment (Ilanne-Parikka, 2010, p. 5). Glucose can be measured either by the diabetics themselves with various types of blood glucose meters, or in the clinics and hospitals by medical professionals with blood tests. This thesis focuses on patient Self-Monitoring of Blood Glucose (henceforth SMBG), i.e. measurement of blood glucose by patients in various surroundings. Additionally this Thesis discusses issues closely linked to SMBG, i.e. *measurement devices* and *auxiliary software*, and *treatment guidelines* and *practices*. In the case of treatment practices and guidelines, focus is given on the respective applicable Finnish practices and guidelines.

The most common *measurement devices* are invasive and require a minimal blood sample, which is analyzed for glucose concentrations in a handheld device. Non-invasive devices extract the glucose concentrations via other measures without a blood sample, e.g., by using spectrometric techniques or by extracting interstitial fluids. Non-invasive blood glucose meters have been developed for decades, the earliest patent application found in the research of this Thesis was filed by W.F. March in 1974 (U.S. Patent No. 3,958,560, 1974). A commercially viable product is yet to emerge, most likely due to the technical difficulties.

Treatment of diabetes can be assisted with the use of various *auxiliary software*, e.g., applications for carbohydrate counting and software for analyzing blood glucose measurement results. Commonly the blood glucose meters have a memory which records a number of measurement results. These results can be downloaded into a computer via specific software. This software usually has further features for displaying and analyzing the results. Other relating software discussed in this Thesis include diabetes management applications. Mobile, web and desktop versions of these applications are commonly available.

The Finnish Medical Society Duodecim produces Current Care Guidelines on a number of health topics, including diabetes. The Current Care Guidelines are intended to be used as a reference for treatment practices (Finnish Medical Society Duodecim, 2012).

Fig. 1.1 summarizes the key topics discussed in this thesis. The topics are approached from two points of view: state of the art (Chapter 6) and user requirements (Chapter 5). Three topics of SMBG are discussed in this Thesis: the measurement devices, SMBG related software, and the treatment guidelines and practices in diabetes. In the discussion of the state-of-the-art of SMBG, the SMBG *devices* are divided into invasive (6.3.1) and non-invasive (6.3.2) devices. However, the *user requirements* of SMBG devices are similar regardless of the technology used to attain the Blood Glucose (BG) level (5.2.1). The state-of-the-art and user requirements of SMBG related *software* are divided into two categories: software for analysis and downloading of measurements from the meters (6.4.1 and 5.2.2), and the applications for treatment assistance (6.4.2 and 5.2.2). Treatment guidelines and practices are jointly discussed in Sections 5.2.3, 6.1 and 6.2.

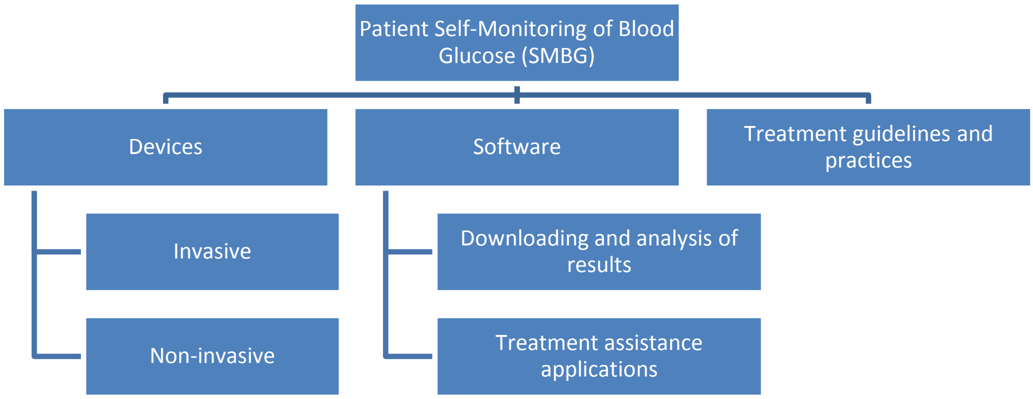

Figure 1.1 Topics of this Thesis

Fig. 1.2 depicts how the requirements of various user groups and the state-of-the-art of the issue can correlate. One objective of this Thesis is to discuss how overlapping the state-of-the-art and user requirements in SMBG actually are (6.5). Furthermore, this Thesis discusses how the requirements of the different user groups correlate (5.4). This Thesis focuses on the requirements of the doctors, nurses and patients. The user groups' requirements are discussed related to the topics in fig 1.1 and the state-of-the-art is divided according to the same topics. Additionally, this Thesis proposes a few possible means to meet the user requirements better.

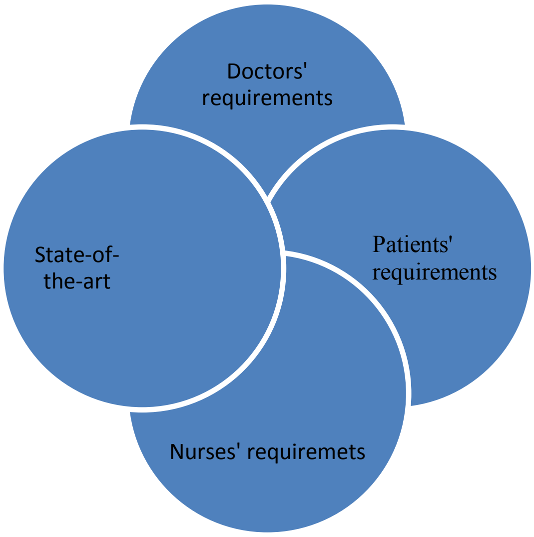

Figure 1.2 User requirements and state-of-the-art of blood glucose measurement

The research questions of this thesis are defined as follows:

1. *What are the important highlights of the Current Care Guideline and treatment practices on diabetes?*
2. *How could the current guidelines and treatment practices of glucose measurement be updated to meet the present requirements of the various stakeholders better?*
3. *What are the user requirements of glucose measurement and are there correlations between the requirements of the different stakeholders?*
4. *How could the devices and applications of glucose measurement meet the requirements of the users better?*

The first two questions are related to the Current Care Guideline, treatment guidance, and other treatment practices in diabetes. Special emphasis is given to the issues that are closely linked to SMBG, and the practices and guidelines in Finland. These questions are discussed by resolving the key stakeholders (i.e. doctors, nurses and diabetics) of the Current Care Guideline as well as by familiarizing the reader with the guidelines. In addition, common treatment practices are researched. Finally, the requirements of different stakeholders are discussed and comparisons made to determine how these guidelines and practices could be updated.

The latter two questions are more focused on SMBG and the relating devices, applications and treatment practices. The discussion includes the analysis of the different stakeholders of SMBG, their user requirements and the comparison of their requirements. The fourth question requires resolving how the current devices and applications meet the requirements of the user groups. After that, the discussion moves to some conceptual approaches in how the devices and applications could meet the requirements of SMBG better.

This Thesis is divided into six sections. Chapter 2 presents the relevant theoretical background required to understand the latter discussion on the Thesis. Background information is provided about diabetes 2.1), glucose measurement technologies (2.2), interview methods (2.3), and theory related to user requirements (2.4). Chapter 3 presents the research methods used to gather information for discussing the research questions. Semi-structured interviews (3.1) and user requirement elicitation (3.2) comprise the research methods. Chapter 4 presents the detailed results of the main research method in this Thesis, i.e. the semi-structured interview. Chapter 5 presents the user requirements interpreted from the interview results. The user requirements are divided to BG meter specific (5.2.1), software specific (5.2.2), and other (5.2.3) requirements. Additionally, the correlations of requirements between user groups are discussed (5.3). Chapter 6 discusses the state-of-the-art in current treatment practices (6.2), SMBG devices (6.3), and SMBG related software (6.4). The comparison of the user requirements and the state-of-the-art is performed in Section 6.5. Finally, Chapters 7 and 8 present the summary of this Thesis and discuss the key findings and limitations of this Thesis. Additionally, interesting topics for further research are presented.

2 Theoretical background

The discussion on the research questions requires analysis and understanding of the current treatment practices and guidelines for diabetes, and the currently available products and services to support SMBG. Furthermore, the discussion on the research questions needs analysis of the stakeholders (or user groups) for the issues mentioned above. Additionally, the analysis of the requirements of the various stakeholders is needed. Background information on diabetes (2.1) is presented to enable deeper understanding of the treatment practices and guidelines. Understanding of blood glucose measurement principles (2.2) provides a good basis for the discussion on SMBG devices. Interviewing is the main research method of this Thesis and it is addressed in Section 2.3. Human-Centered Design (HCD) (2.4) is presented as the theoretical framework for understanding the stakeholders and setting up the requirements analysis.

2.1 Diabetes

Diabetes Mellitus is an increasingly common illness in the Finnish population. Currently 10% of Finns (500 000 people) are diagnosed with diabetes and estimates suggest that the amount of diabetics in Finland may double in 10-15 years (Finnish Medical Society Duodecim, 2011a). 8,3% of the population of the United States (25,8 million people) has diabetes, with an estimate of 79 million people with pre-diabetes (Centers for Disease Control and Prevention, 2011, p. 1).

Diabetes is a cluster of diseases caused by either the lack of insulin in the body, the impaired effect of it, or both. Diabetes induces constantly high BG (Blood Glucose) levels. If fasting[1] plasma-glucose[2] levels are regularly over 7 mmol/l the patient is considered to have diabetes (Eskelinen, 2012). Plasma-glucose levels of 6,1-6,9 mmol/l suggest pre-diabetes[3] (Eskelinen, 2012). Diabetes can be divided into two main categories, type 1 and type 2 diabetes. Type 1 diabetes is caused by the destruction of pancreas' insulin producing cells, which leads to the lack of insulin. Type 2 diabetes is caused by insulin resistance (the impaired effect of insulin) and the inadequate insulin production in the pancreas. Type 1 and type 2 diabetes are the most common forms of diabetes, other types include gestational diabetes mellitus and MODY (Maturity-Onset Diabetes in the Young) (Finnish Medical Society Duodecim, 2011a). (Saraheimo, Mitä Diabetes on?, 2011)

Common symptoms of type 1 diabetes are fatigue, weight loss, increased thirst and urination. Typically these symptoms occur within a few weeks, and if treatment is not started early, this illness can be life-threatening. In addition to increased thirst and urination, symptoms of type 2 diabetes include fatigue after meals, irritability, aching feet, and tendency for inflammations. The symptoms of type 2 diabetes are usually rather mild, and it is often diagnosed by coincidence when blood tests are taken for other reasons. (Mustajoki, Diabetes (sokeritauti), 2012)

Diabetes increases risks of developing other diseases due to the continuously high BG of diabetics. The higher the BG is, the higher are the risks of developing chronic complications. The HbA_{1c}-test (glycohemoglobin) measures BG levels of a 2-3 month time period, and it is used to determine the average BG levels of a patient. Diabetes related complications include retinopathy (may lead to impaired vision (Seppänen, 2010)), nephropathy (may cause renal insufficiency), and neuropathy (causes aching and numbness especially in the lower limbs). Diabetes related complications are often caused by increased BG levels. (Mustajoki, Diabetes (sokeritauti), 2012)

Acute complications include hypoglycemia, ketoacidosis, and NonKetotic Hypersmolar Coma (NKHC). Hypoglycemia is a complication where the diabetic's BG levels are too low. It is caused by over-effectiveness of insulin and can even lead to unconsciousness. Ketoacidosis is

[1] Measurement taken in the morning before breakfast, Chapter 6.2 presents more detailed information of measurement practices.

[2] Blood Glucose can be measured from either whole-blood or blood-plasma samples, plasma-glucose concentrations are approximately 10-15% higher than whole-blood glucose concentrations. Usually blood glucose concentration is reported as plasma-glucose concentration rather than as whole-blood concentration, as plasma-glucose concentration is more important than whole-blood concentration. (Rönnemaa & Leppiniemi, 2011).

[3] Pre-diabetes precedes actual diabetes. Pre-diabetes suggests heightened risk of diabetes. (Eskelinen, 2012)

caused by the lack of insulin (leading to continuously high BG levels, chronic hyperglycemia) and often by serious dehydration. It can lead to coma or even death (American Diabetes Association, 2013). NKHC is caused by chronic hyperglycemia and dehydration, and the death rate of this complication is between 20-30%. (Finnish Medical Society Duodecim, 2011a)

Currently type 1 diabetes is unpreventable, whereas type 2 diabetes can be prevented with lifestyle changes. These changes include weight loss, cardiovascular exercising, and healthy diet. In addition, type 2 diabetes can be prevented with medication, although this is suggested to be used only when other attempts to prevent the illness fail. (Finnish Medical Society Duodecim, 2011a) (Mustajoki, Diabetes (sokeritauti), 2012)

The goal of treating diabetes is to prevent diabetes related complications and symptoms, in addition to achieving a good quality of life. Type 1 diabetes is without exception treated with insulin injections, whereas type 2 diabetes in the early stages might not require any medical treatment. Weight loss, exercising and dietary changes may keep the BG of type 2 diabetics in acceptable levels. However, type 2 diabetics can be treated with various orally administered pharmaceuticals. (Mustajoki, Diabetes (sokeritauti), 2012)

2.2 Glucose measurement technologies

SMBG is necessary in diabetes treatment (Ilanne-Parikka, 2010, p. 5). SMBG is conducted by either using BG meters or Continuous Glucose Monitoring (CGM) devices. BG meters and monitors can be categorized into *invasive* and *non-invasive* devices, which can be further categorized into a few sub-categories, as proposed in fig. 2.1.

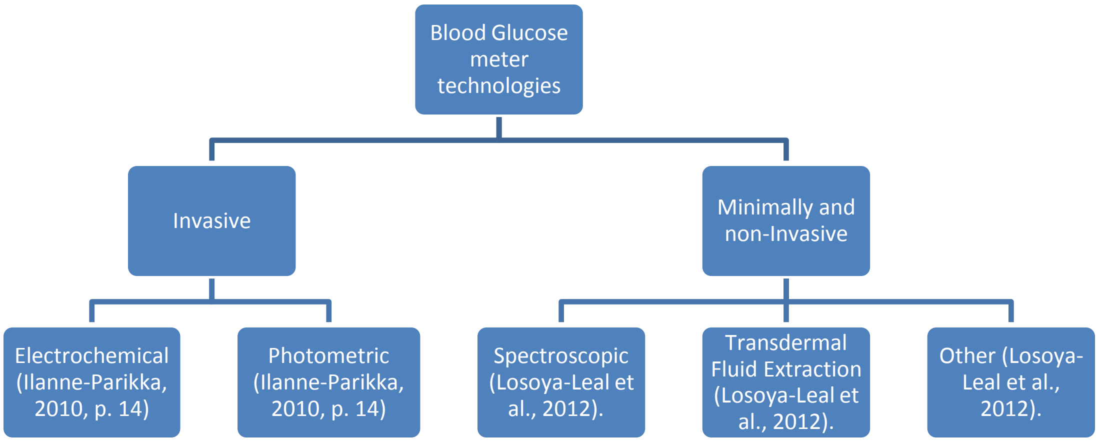

Figure 2.1 Blood Glucose measurement technologies.

2.2.1 Invasive technologies

Invasive meters require a blood sample to provide the estimate of the BG level. This blood sample is applied to a test-strip containing enzymes. The blood sample and enzymes cause either a color (*photometric technique*) or electrical (*electrochemical technique)* reaction. Electrochemical sensors measure the changes in electrical currents, whereas photometric sensors measure changes in colors. The chemical reaction and changes correlate with the glucose levels in the sample. (Ilanne-Parikka, 2010, p. 14)

The physical appearance of the invasive device is similar regardless of the technology used. Additionally, the procedure for acquiring the BG levels is similar as well. The basic procedure for determining the BG levels with invasive meters is:

1. Obtain a blood sample with a finger pricking (or lancing) device
2. Apply the blood sample to a test-strip
3. Insert the test-strip into the meter
4. The meter calculates blood glucose level of the sample
5. Read the result on the meter

Additional steps include: washing the test area before drawing blood, adding further information[4] (e.g., meal-pair markings) to the measurement taken which is useful for later analysis of measurement results, and disposing of the waste products (i.e. the used test-strip and occasionally the lancet).

2.2.2 Minimally invasive and non-invasive technologies

Minimally invasive and non-invasive meter technologies can be categorized into *spectroscopic*, *transdermal fluid extraction*, and *other* technologies (Losoya-Leal;Camacho-León;Dieck-Assad;& Martinez-Chapa, 2012), as shown in fig. 2.1. One definition of the difference between minimally and non-invasive technologies is that in the minimally invasive glucose monitoring the sensor is sub-dermal (located under the skin layer), whereas the non-invasive sensors are not sub-dermal (Klonoff, 1997, p. 436). An alternative division between these two is that the minimally invasive sensors measure glucose levels from fluids, whereas the non-invasive sensors measure glucose levels via other means (Newman & Turner, 2005). The major factor affecting the differentiation between these two techniques is the irritation discomfort caused by the measurement procedure. Drawing the line between these two is difficult, as even spectroscopic techniques can cause mild skin irritation (C8MediSensors Optical Glucose Monitor::FAQ, 2013)[5]. The main focus of this Thesis is in the user requirements of BG measurement. The differentiation between minimally and non-invasive technologies has little impact on the discussions of this Thesis, as the user requirements of BG measurement are presumably the same regardless of the measurement technology.

Spectroscopic

In the spectroscopic techniques, a beam consisting of a set of specific wavelengths is applied to the test area (e.g., skin or eye). The reflected and/or emitted light is analyzed. The spectroscopic technologies are: *NIR (Near Infra-Red), Raman, bio-impedance,* and *thermal emission (*or *FIR, Far Infra-Red)* spectroscopy, as depicted in fig. 2.2.

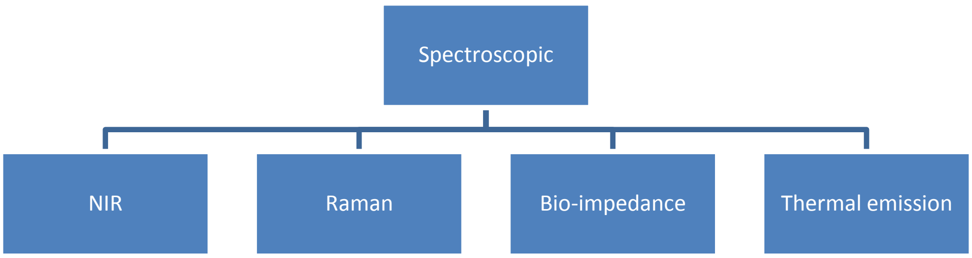

Figure 2.2 Spectroscopic technologies for non-invasive blood glucose meters (NIR = Near-Infra Red), modified from (Losoya-Leal; Camacho-León; Dieck-Assad; & Martinez-Chapa, 2012)

In *NIR spectroscopy* the wavelengths of the beams applied to the test area are commonly between 600nm and 2500nm. Glucose absorbs some specific wavelengths from the beam, and the change is measured either from the reflected light or from the light that passed through the test area. The weakness of this technology is that it requires frequent re-calibration (Klonoff, 1997), and it is vulnerable to interferences from other absorbing materials (e.g., muscles and bone) (Losoya-Leal;Camacho-León;Dieck-Assad;& Martinez-Chapa, 2012).

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[4] The additional information added to the measurements is discussed later on the Thesis, e.g., in Chapters 4, 5.2.1, and 6.3.1.

[5] C8MediSensor caused mild skin irritation and warming of skin, Chapter 6.3.2 discusses the state-of-the-art in non-invasive measurement devices. The website was no longer available on the 31st of October 2013, suggesting that yet another attempt on commercializing a non-invasive meter has failed. The most resent rumor found of the subject is that the company ran into financial difficulties (http://www.everydayupsanddowns.co.uk/2013/06/has-light-gone-out-on-c8-medisensors.html, last accessed in 12th of November 2013).

Raman spectroscopy applies beams between 785nm and 830nm to the test area. Some of the light undergoes frequency shifts, which correlate with glucose levels. These shifts are then measured and the BG levels are calculated. However, getting measurable shifts requires either long collection times or high-power lasers which can result in skin irritation and discomfort.

Bio-impedance spectroscopy applies small electric currents to the test area. The resulting voltage is proportional to the dielectric or dimensional changes of the test area. Blood analytes (including blood glucose) affect the dielectric properties at high frequencies. Thus the BG levels can be extracted with bio-impedance spectroscopy. (Tura;Maran;& Pacini, 2007)

Thermal emission spectroscopy measures mid-infra-red signals, between 5000nm and 12000nm (Klonoff, 1997). These signals are naturally emitted in humans, and they are affected by tissue composition and analyte concentrations. BG absorbs energy in a frequency band near 9400nm (Klonoff, 1997).Thus, changes in BG levels produce changes in the natural thermal emissions. The BG level is derived from these changes. A challenge with this technology is the small signal emission power of human thermal emissions (Klonoff, 1997).

Transdermal fluid extraction and other techniques

In transdermal fluid extraction, fluids are extracted from the tissue. The glucose concentration of that fluid is measured, which in turn is used to calculate the BG levels (Klonoff, 1997). Three techniques apply this basic principle: *reverse iontophoresis*, *sonophoresis*, and *dead skin thermal ablation*, as shown in fig. 2.3.

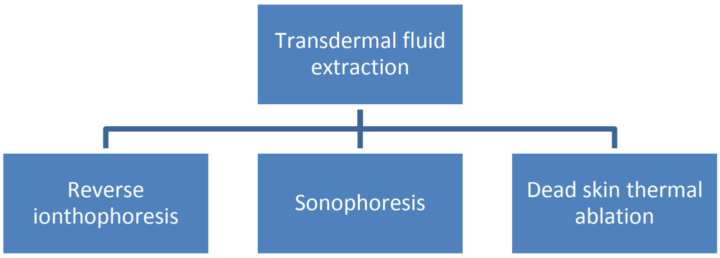

Figure 2.3 Transdermal fluid extraction techniques in non-invasive meter technologies, adapted from (Losoya-Leal; Camacho-León; Dieck-Assad; & Martinez-Chapa, 2012)

Reverse iontophoresis uses two electrodes to apply a small electric current to the test area. As charged ions move in the test area, an electro-osmotic solvent flows towards the negative electrode, and with it the glucose molecules. The amount of glucose that reaches the electrode is proportional to BG levels. At least one attempt of a commercial realization has emerged (GlukoWatch, see 6.3.2), which however, could not overcome the technical difficulties.

Sonophoresis applies ultrasound waves to the tissue at the test area producing micro-vibrations. This in turn increases dermal permittivity to interstitial fluids, enabling transportation of glucose to the sensors.

Dead skin thermal ablation enables glucose molecules to reach the surface of the skin by removing dead skin from a small area. A sensor is attached to the area with no dead skin and the sensor measures glucose levels of interstitial fluids, and BG levels are calculated.

Other technologies for non-invasive BG meters include *fluorescence, electromagnetic field variation,* and *polarimetry*. The basic idea behind the *fluorescence* based techniques is that glucose causes fluorescence in some component, the amount of fluorescence is measured. For example, in *tattoo-based fluorescence* a nano-sensor similar to tattoo-dye reacts with glucose, and it will fluoresce under infra-red light. This effect is proportional to BG concentrations. The e*lectromagnetic field variation* based technique relies on the fact that variations in BG levels affect the dielectric parameters of blood. The electromagnetic sensor measures these changes (e.g., conductivity), thus enabling non-invasive measurement of BG. *Polarimetry* is based on optical rotation of polarized light[6], which occurs when the light passes through optically active analytes, glucose in the case of BG measurement (Klonoff, 1997).

(Losoya-Leal;Camacho-León;Dieck-Assad;& Martinez-Chapa, 2012)

2.3 Interviews

Interviewing is a user-centric research method of gathering user data or even cultivating service development information. It is widely used in e.g., social sciences (Kvale & Brinkmann, 2009, pp. 12-14) and especially in user centered studies, see for instance (Benyon, Turner, & Turner, 2005, p. 216). An interview is a conversation between the interviewer and the interviewee, where usually the interviewer decides the topic to be explored and the interviewee provides further knowledge on the topic. The goal of interviews is to gather knowledge, either totally new or to confirm earlier knowledge. (Kvale & Brinkmann, 2009, pp. 1-10)

Interview methods can be categorized according to how structured they are. A questionnaire is the most structured form of interviewing, whereas unstructured interviews may not have explicit pre-prepared questions at all. Questionnaires produce simple consolidated data which is rather easy to handle and analyze, although the data may lack rich content. Moreover, questionnaires or structured interviews generally do not allow researchers to ask any clarifying questions. Semi-structured interviews follow some pre-prepared questions and allow the interviewer to follow-up on additional interesting topics that emerge during the interview. (Benyon, Turner, & Turner, 2005, p. 216).

Unstructured interviews provide the ability to discuss the topics more freely with the interviewee. Thus, the interviewees can point out, e.g., irrelevant topics in the interview or point out other issues that wouldn't emerge with other forms of interviews. This Thesis uses the semi-structured interview as the interview method.

2.3.1 Semi-structured interview

Kvale & Brinkmann (2009, p. 102) define the semi-structured research interview to consist of seven stages: (a) Thematizing, (b) Designing, (c) Interviewing, (d) Transcribing, (e) Analyzing, (f) Verifying, and (g) Reporting. Rubin & Rubin (2005) provide a guide for conducting interviews. From their description of the interview practice, the interview design can be divided into nine steps; (1) Deciding the topic of and what to interview, (2) Making the research questions that further clarify the subject of interest, (3) Selecting the sites for the interviews, (4) Choosing who to interview, and (5) Deciding and preparing the interview questions (Rubin & Rubin, 2005, p. 39). Next, after the interviews are conducted, (6) The interviews are analyzed by first (7) Transcribing the material and second (8) Extracting meaningful information from the material (Rubin & Rubin, 2005, p. 201). Finally, the results of the study are Reported (9) (Rubin & Rubin, 2005, p. 246). The framework provided by Kvale & Brinkmann (2009) is rather systematic and intuitive, and thus used as the reference framework in this Thesis.

Thematizing and *designing* the interview study concerns with initial preparations for the study. *Thematizing* the interview concerns with deciding the topics and motivation for the interview. *Designing* the interview consists of planning all the stages of the interview. The planning includes deciding how structured the interview is, how many interviewees to interview, how to transcribe, how analyze and verify the data, and finally how to report the results. The analysis of the material needs to be considered during the design of the interview in terms of the type of conclusion expected and other expectations of the results (Rubin & Rubin, 2005, pp. 53-56). Both Kvale & Brinkmann (2009) and Rubin & Rubin (2005, pp. 146-150) suggest the generation of an interview script for the *interviews*. The script can include the themes, questions, and checklists for the interview. (Kvale & Brinkmann, 2009, pp. 105-138)

Different methods of recording the interview are usually audio- and video recording, and taking notes. The selected recording method affects the interview situation, the material gathered in the interviews, and additionally the *transcription* of that material. A downside of taking notes is

[6] When a beam of polarized light passes through a fluid containing glucose the plane of polarization rotates. (Klonoff, 1997)

that it might interrupt the interview and disturb the conversation. Audio or video recording do not interrupt the interview situation but require more time in the transcribing phase. Furthermore, the use of electronic recording devices may impede the interviewer's memory of the interview situation. Transcription of the data should be started immediately after the interview situation. (Kvale & Brinkmann, 2009, pp. 177-183) (Rubin & Rubin, 2005, pp. 110-112)

The *analysis* of the material gathered during the interviews can be done in various ways and should be done throughout the interview study, even before all the interviews are conducted. Preliminary analysis of the early interviews can be used for focusing the research questions towards some more relevant topics (Rubin & Rubin, 2005, p. 54), thus affecting the later interviews. Rubin & Rubin (2005, pp. 206-216) suggest coding all of the interview material to enable systematic analysis. This may be realized by counting occurrences and keywords in the material. Another method is condensing long phrases in the transcriptions into shorter sentences entailing the main message (Rubin & Rubin, 2005, pp. 202-203; Kvale & Brinkmann, 2009, p. 205). (Kvale & Brinkmann, 2009, pp. 189-238)

Verification or validation of interview results can come from various sources. The expert experience of the interviewer (Kvale & Brinkmann, 2009, p. 248) or the interviewee (Rubin & Rubin, 2005, p. 64) can be a strong source of validity or credibility in itself. Validation can be done during the interviews (e.g., asking whether the discussions were understood or checking issues that appeared in previous interviews). Validation can be pursued after the interviews, e.g., by re-interviewing subjects or by trying to prove the result of the interview to be false; the logic being that if the result cannot be proven to be false, then the result must be true. Additionally, transparent reporting – i.e. clear reporting of the methods, the interview material, the source of the findings and the results – can provide further credibility to the results (Rubin & Rubin, 2005, p. 64). (Kvale & Brinkmann, 2009, pp. 241-260)

2.4 User Requirements

This Thesis uses the semi-structured interview method for gathering data for understanding the current state of BG measurement devices, software, practices and guidelines. Additionally the interview data serves as one source of gathering the user requirements. This section discusses different approaches for deriving user requirements for a specific product or service. First, the International Standards Organizations' (ISO) standard ISO 9231-210:2010 is discussed. Second, scenario based design is introduced. Other approaches and sources discussing user requirements are introduced as well. Finally, some insights from the various references are discussed.

Human-Centered Design (HCD) is best applied to a specific computer-based interactive system (ISO 9241-210:2010, p. 1). The focus of this Thesis is not on a specific interactive system, rather, the Thesis takes on a more holistic approach to BG measurement and the activities linked to it. Nevertheless, HCD is deemed to provide an useful insight to the issue of user requirements, which are in the core of the research questions (page 2). User-Centered Design (UCD) is an approach to designing systems that meet the actual requirements and needs of the users. Main features of UCD are (a) The active involvement of users in the process of understanding the requirements of both the user and users' tasks, (b) The iterative process switching between design and evaluation of that design, and the involvement of a multidisciplinary team in the design process (Vredenburg;Mao;Smith;& Carey, 2002).

2.4.1 ISO 9241-210:2010

The term Human-Centered Design (HCD) is advised to be used instead of UCD, as it emphasizes the involvement of other stakeholders in addition to just the end-user (ISO 9241-210:2010, p. 2). ISO 9241-210:2010 provides a set of principles to be followed in HCD (ISO 9241-210:2010, p. 5):

- the design is based on an explicit understanding of users, tasks, and environments;
- users are involved throughout the design and development process;
- the design is refined and driven by user-centered evaluation;
- the process is iterative;
- the design addresses the whole user experience; and
- the design team includes multidisciplinary skills and perspectives.

Although the whole process of designing an interactive system is not that relevant to this Thesis, the iterative process depicted in fig. 2.4 helps to understand the concept of HCD. The HCD process consists of six stages: planning, understanding the context of use, specifying the user requirements, producing designs, evaluating designs, and finally the process ends with a solution that meets the user requirements. The planning stage includes: (ISO 9241-210:2010, p. 10)

- identifying the appropriate methods and resources (both human and other) for the process,
- defining procedures for integrating HCD to other development activities,
- developing procedures for communication and feedback,
- agreeing on milestones for the activities described in the process, and
- agreeing on a suitable timeframe to allow iteration.

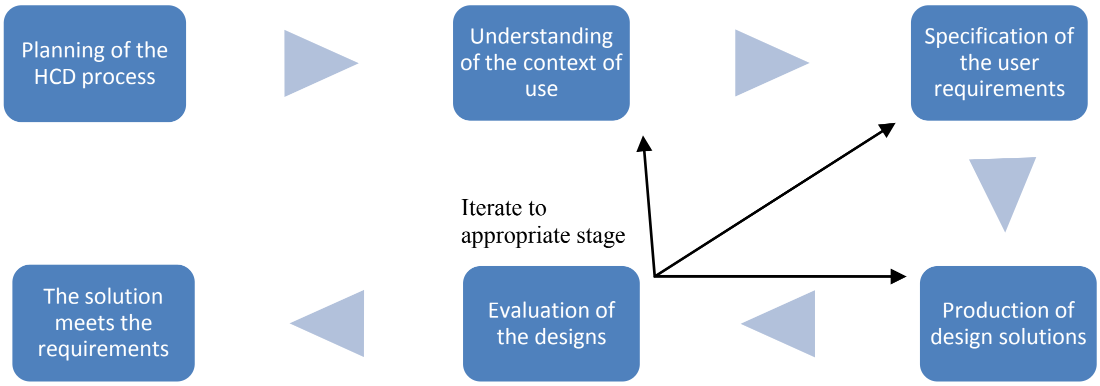

Figure 2.4 Human-Centered Design (HCD) process, adapted from (ISO 9241-210:2010, p. 11)

Understanding the context of use entails identifying the various user groups and stakeholders, the characteristics and the goals and tasks of those groups, and the use environment of the system. During the production of the designs special attention should be given to the user requirements. Additionally, the designs should be made concrete (e.g., by using prototypes or mock-ups). Evaluation of the designs should be based on the users perspective, e.g., with user-based testing or other user-centric evaluation methods. The evaluations can produce new information about the users, and feedback of the strengths and weaknesses of the design. Moreover, the evaluations can be used to assess whether the requirements have been met, and to compare different designs. If the evaluation of the design solutions shows some flaws in the results of the previous steps, the development process should iterate back to the step that produced the flaw. (ISO 9241-210:2010, pp. 11-17)

The specification of user requirements is the most relevant topic covered in the standard related to this Thesis. The user and other stakeholder requirements need to be identified whilst taking into account the restraints produced by the context of use. Focus should be given on the tasks and goals that need to be achieved. The specification of the requirements produced should include: (ISO 9241-210:2010, pp. 12-13)

- the context of use,
- the user requirements,
- requirements originated from other sources, e.g., organization, ergonomics, standards and guidelines, and
- usability requirements, objectives, and performance and satisfaction criteria.

The user requirements produced may be conflicting and often require doing tradeoffs. The conflicts need to be resolved and possible tradeoffs documented for future reference. The requirements need to be verified by relevant stakeholders and updated during the whole design process. (ISO 9241-210:2010, p. 13)

2.4.2 Scenario based design

Scenario based design is a popular UCD method. Scenario based design focuses on the goals of using a system, the tasks performed, and the context of use. The use of scenarios provides an insight on how the system is used, including (i) the interaction itself, (ii) the context of use, (iii) the people using the system, (iv) the use situation, and (v) the tools and other objects that are used during the interaction. (Rosson & Carroll, 2002, p. 1)

Scenarios provide a fast method for capturing usage possibilities and concerns of various stakeholders in early stages of the design process. Scenario based design can be used throughout the design process. The scenarios used in different stages of the design process have some differences. The various scenarios produced can be used as test cases for usability evaluations in every stage of the design process, thus supporting UCD. (Rosson & Carroll, 2002, p. 9)

Problem scenarios are used early in the design process focusing on stakeholder analysis and evaluating the negative and positive possibilities that result from the scenario. Problem scenarios provide an insight on the current usage situation and are the basis for iterative design producing design concepts. *The activity scenarios* describe how the stakeholders pursue their tasks, i.e., what activities are used to achieve the goals. Furthermore, activity scenarios focus on how the current paradigm might be enhanced and possibly shows totally new ways for users to pursue their goals. *Information scenarios* focus on how the design elements used for information exchange are produced. Additionally, the information scenarios are tested by using the activity scenarios, i.e. how one specific design would perform in the activity scenario described earlier. *Interaction scenarios* describe the concrete interactions between the user and the system. The previously produced scenarios limit the possible interaction scenarios that can be produced. *Usability specifications* are formed after all the scenarios are described. The specifications are task focused; each task is broken into subtasks and the subtasks are assigned with appropriate usability targets. (Rosson & Carroll, 2002, pp. 9-27)

Benyon et al. (2005, pp. 194-199) present four scenario types that can be used in the various stages of interaction design. Fig. 2.5 presents the four types of scenarios identified by Benyon et al. with the intended use of the scenarios. Advancing rightwards from user stories all the way to the use cases adds more detail and refinement into the design of the system. The relative size of the box suggests the relative amount of the different scenario types.

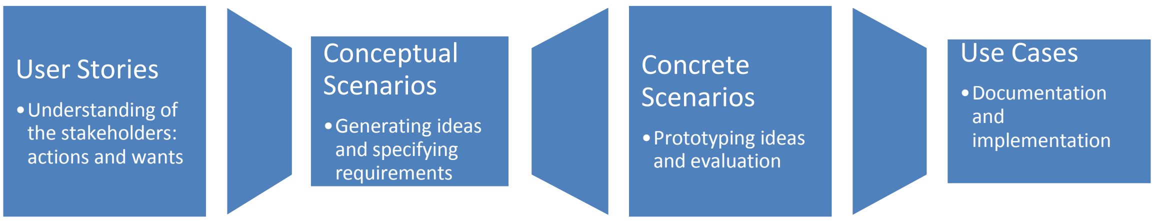

Figure 2.5 Scenarios in UCD, adapted from (Benyon, Turner, & Turner, 2005, p. 195)

User stories are primarily used for understanding all the relevant stakeholders of the system. The stories contain information of the activities of the users and the context in which these activities are performed. *Conceptual scenarios* are not as detailed as user stories. Rather, conceptual scenarios bind aspects of several user stories into fewer scenarios entailing the most relevant issues presented by the earlier scenarios. Conceptual scenarios are useful for generating ideas and specifying system requirements. *Concrete scenarios* are significantly more detailed than the conceptual scenarios. The conceptual scenarios are used as a basis for forming concrete scenarios. Concrete scenarios contain information on interface design and the actions of the user and the system. The amount of concrete scenarios is commonly larger than that of conceptual scenarios. *Use cases* combine many concrete scenarios into fewer descriptions of the interaction between the user and the system. The use cases commonly describe the tasks required to achieve the specific goals of the user. Additionally the use cases describe who performs the tasks, i.e. the user or the system. Scenarios can help with presenting user requirements (Benyon, Turner, & Turner, 2005, p. 226). (Benyon, Turner, & Turner, 2005, pp. 194-199)

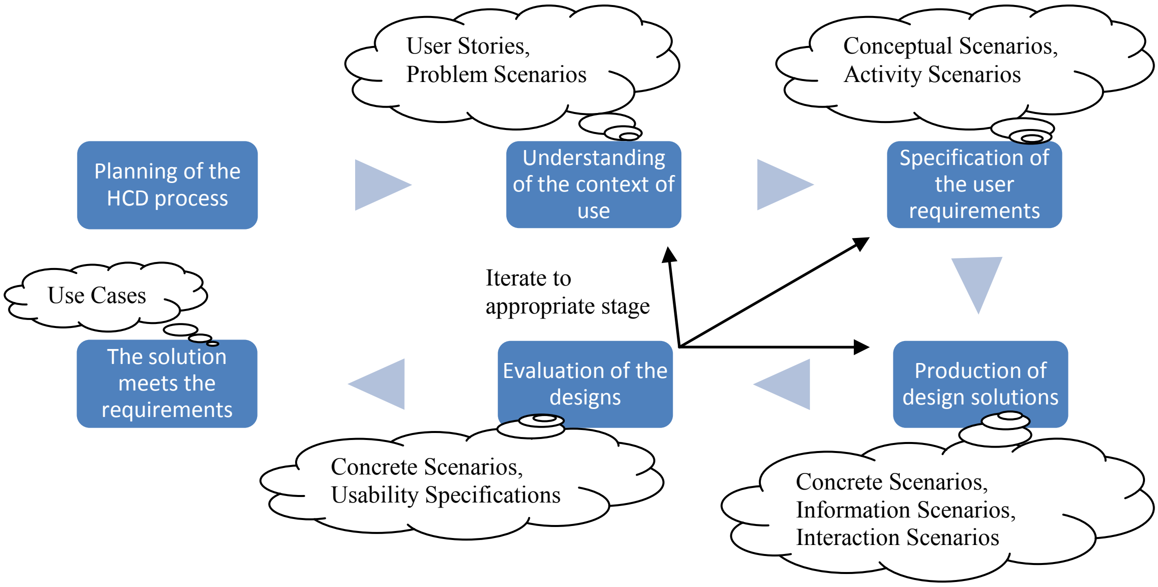

Figure 2.6 Use of scenarios in the ISO 9241-210:2010 HCD process

Both Rosson & Carrol (2002, pp. 9-27) and Benyon et al. (2005, pp. 204-206) present their versions of how to integrate the scenarios into the UCD process. In both of the versions the different types of scenarios are used in different stages of the process. Fig. 2.6 shows how the scenarios could be included into the general process of HCD presented in fig. 2.4. The general HCD process presented in ISO 9241-210:2010 provides merely a framework for the division of HCD activities, whereas the descriptions of scenario based design above provide some specific tools for performing the activities.

2.4.3 Gathering user requirements

The inclusion of all stakeholders into user requirements evaluation is recommendable (Benyon, Turner, & Turner, 2005, p. 37; Ulrich & Eppinger, 2008, p. 58; ISO 9241-210:2010, 2010, p. 11; Rosson & Carroll, 2002, p. 9). Interviews are proposed as one of the main methods of gathering user requirements (Ulrich & Eppinger, 2008, pp. 56-57; Benyon, Turner, & Turner, 2005, p. 216; Rosson & Carroll, 2002, p. 12). There are various other methods with which the end-users can be involved in the gathering of user requirements. Rosson & Carroll (2002, pp. 10-14) suggest using *the problem scenarios* for it. The use of scenarios in gathering the requirements is discussed by Benyon et al. (2005, pp. 217-218) as well; particularly as supplementary material while interviewing the users for visualizing the topics discussed. Along with scenarios, using early prototypes can help the interviewees visualize the topic discussed. Other means of gathering data for user requirements analysis include questionnaires and observations (Benyon, Turner, & Turner, 2005, pp. 220-225). Moreover, Benyon et al. (2005, p. 228) suggest that using more than one technique for gathering user requirements would provide a more comprehensive understanding of the use situation and user experience.

Regardless of the method by which raw data is introduced into the requirements gathering process, detailed data needs to be refined into a more abstract form describing the user groups. Again, a variety of techniques for this refinement are available, e.g., affinity diagrams, diagrams of stakeholder relationships, and hierarchical task analysis of activities. The generalizations of user groups are used in forming the problem scenarios introduced by Rosson & Carrol (2002, pp. 10-14). In the scenarios a set of hypothetical stakeholders are described – i.e. user stories are created as described by Benyon et al. (2005, pp. 195-196). In addition to general descriptions of the stakeholders, the scenarios describe problems that the stakeholders encounter during the story. The claims that are included in the scenario are analyzed using claims analysis. The claims and problems produced in this process are not requirements (or specifications of the system); rather the design solutions need to address the claims and problems described. (Rosson & Carroll, 2002, pp. 10-14)

Ulrich & Eppinger (2008, p. 55) propose a general process for the identification of user requirements and divide it into five steps: (1) Gathering raw data from users, (2) Interpreting requirements from that data, (3) Organizing the requirements into a hierarchical form, (4) Establishing the relative importance of the requirements, and (5) Reflecting on the results.

User requirements can be divided into latent and explicit requirements. Ulrich and Eppinger (2008, pp. 56-57) strongly advise to use interviews, focus groups or observing the users as the main methods of gathering raw data from the users. Identifying all the relevant user groups and stakeholders is critical. Interviewing representatives from all the user groups of the product or service produces a better understanding of all the requirements. Both observing users and interviewing lead users (or early adopters[7]) are good ways for indentifying latent requirements. (Ulrich & Eppinger, 2008, pp. 55-59)

Ulrich and Eppinger (2008, p. 62) advise to focus on users' tasks and goals. The requirements should be organized using two or more priority levels. In addition, grouping the requirements according to the issue they address is useful. Next the requirements should be arranged according to how important they are relative to each other. The relative importance can be determined either by the users themselves or the by the designers. Finally, the list of requirements and the process itself should be checked for any flaws. (Ulrich & Eppinger, 2008, pp. 62-67)

While Ulrich & Eppinger (2008, p. 62) suggest that only the stakeholders' tasks and goals should be taken into account while deriving the user requirements, other approaches take a different viewpoint. Generally, requirements of a specific system consist of functional and non-functional requirements (Benyon, Turner, & Turner, 2005, pp. 210-211; Rosson & Carroll, 2002, pp. 11-12; ISO 9241-210:2010, pp. 12-13). Functional requirements determine *what actions* the system *must* enable and are thus necessary for system usage. In contrast, non-functional requirements concern with *how the actions are done* and can be a compelling sales argument and can possibly affect the usability of the system to some extent. Essentially, extracting requirements for a system involve understanding what the users do and want to do, how they want to do it, and especially the problems with the current system usage. (Benyon, Turner, & Turner, 2005, pp. 210-212)

2.4.4 Context of use

Determining the context of use affects the actual solution provided to any problem, thus it is an integral part of understanding user requirements. E.g., screens of a system that are used in dim or extremely bright light conditions require a backlit screen, whereas screens used in specific and fitting light conditions do not require it. If the information visualized on the screen is private and it is accessed in public environments, the viewing angle of the screen needs to be narrow so that other people cannot read it.

ISO 9241-210:2010 defines the context of use to entail the characteristics of the users, tasks and environments. Understanding the context of use is essential in understanding the user requirements (ISO 9241-210:2010, p. 6). The use scenarios discussed by Rosson & Carroll (2002) incorporates context of use in the design process.

Benyon et al. (Designing Interactive Systems: People, Activities, Contexts, Technologies, 2005, pp. 29-39) provide a useful concept for understanding the factors that need to be considered when forming a view of the overall use scenario. The PACT-model (People, Activities, Context, and Technologies) approaches relevant issues in the context of use separately. They suggest separate analysis of the *people* affected by the system, the *activities* of people while using the system, the *contexts* of use, and the *technologies* affecting the system usage (Benyon, Turner, & Turner, 2005, p. 37).

[7] Everett Rogers ((Rogers, 1962), referenced in (Koetler & Keller, 2011)) divides consumers according to when they adopt the use of a product. The categories in order of how early the adoption is done are: innovators, early adopters, early majority, late majority, and laggards.

People

People have physical, psychological and usage differences, all of which affect the design of a system. E.g. differences in dexterity affect the optimal size and shape of buttons on a glucose meter. People have different capabilities in remembering e.g. when to take blood glucose measurements. Expert users require less instruction than novice users. (Benyon, Turner, & Turner, 2005, pp. 31-33)

Activities

The activities in performing a task have many characteristics. The most important is the overall purpose of the activity, e.g., knowing your BG level. Other important aspects of the tasks to consider are: the temporal aspects (e.g., how long is the interaction), the cooperativeness (individual vs. group activities), the safety concerns (e.g., how critical are errors in the system), and the content (e.g., the amount of information to be shown) of the activity. (Benyon, Turner, & Turner, 2005, pp. 33-34)

Contexts

The use context is defined to consist of three components; *physical environment, social context* and *organizational context*. The *physical environment* concerns with the physical surroundings of the use situation. Issues that require consideration include temperature, moisture, light, and how remote the location is. E.g., the glucose meter is used in a variety of physical environments with various conditions. The *social context* accounts for issues related to the people or other resources surrounding the use situation. E.g., manuals or other people can help with the use, auditory feedback may not be acceptable in some surroundings, or privacy issues come into consideration in social contexts. The BG meter is used both in private and crowded situations. The *organizational context* concerns with how the solution affects organizational structures. For instance, the solution provided to a problem may render some tasks unnecessary, e.g., automatic painting robots in car manufacturing can remove the need for human painters in the assembly line. (Benyon, Turner, & Turner, 2005, pp. 35-36)

Technologies

Usually interactive systems rely on a set technologies. Input devices are used to input data into the system. That data can be analyzed by the system, which is then shown to the user for interpretation. Additionally, communication between the system and the user and between the system and other systems needs consideration. Finally, the content inputted, analyzed and produced by the system needs to be relevant, up-to-date and accurate. E.g., the invasive BG meters take the test-strip as input, analyze them and then estimate the BG level of the blood. (Benyon, Turner, & Turner, 2005, pp. 36-37)

2.4.5 Discussion on the approaches to gathering user requirements

The terminology used in literature references varies slightly. ISO 9241-210:2010 uses the term HCD to describe a user-centered design process, whereas Benyon et al. (2005), Rosson & Carroll (2002), and Vredenburg et al. (2002) use UCD. However, there seems to be only little difference in the spirit of the definitions of HCD and UCD. Moreover, the practices of the HCD and UCD processes are remarkably similar. Both processes try to include all the relevant stakeholders and both distinct the user requirements into functional and non-functional requirements (Rosson & Carroll, 2002, pp. 9-12; Benyon, Turner, & Turner, 2005, pp. 37, 210-211; ISO 9241-210:2010, pp. 11-12). As depicted earlier in fig 2.6, the scenario based approaches using the term UCD can be incorporated into the HCD process presented by ISO 9241-210:2010. Additionally, the term *"human"* can be considered to hold the *"user"* as well. Thus, the term HCD can be seen as an upper-level term containing UCD and is therefore preferred in this Thesis.

ISO 9241-210:2010 takes little stand on how the activities described in fig 2.4 should be performed. Fig. 2.7 presents a process for developing *user requirements*, combining the various approaches presented above. The arrow-shaped boxes present the stages of this process, and the boxes below them present some tools and methods that can be useful in these stages. Additionally to the tools and methods presented earlier, the *MoSCoW-rule* is introduced below.

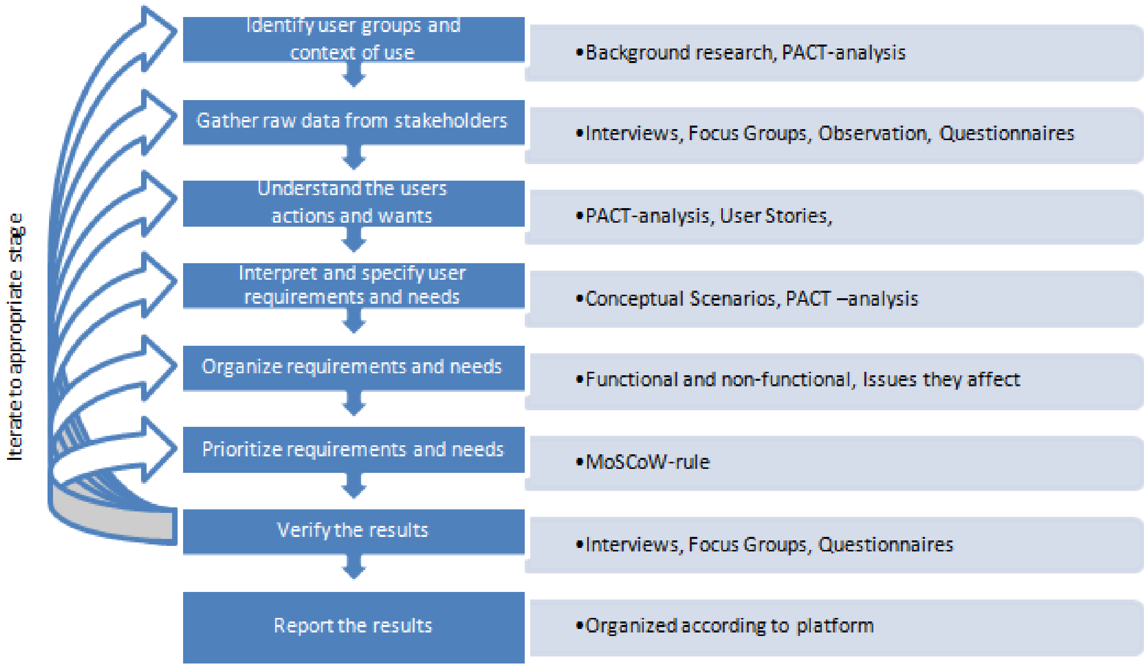

Figure 2.7 A process for developing user requirements

MoSCoW

The MoSCoW-method is one alternative for prioritizing requirements, providing intuitive terms for the priority levels. The four priority levels are *Must have, Should have, Could have,* and *Won't have this time.* The requirements prioritized as *Must* haves comprise the minimal requirements of the system; if those requirements are not met the system does not work and is effectively unusable. *Should* have requirements are extremely important and would facilitate the usage of the system. However, the system would function and be usable and useful without them as well. *Could* have requirements are clearly desired by the stakeholders and can be useful, although less useful than the *should* haves. The *won't* have requirements could be delivered but will not be delivered in the design and can wait for later releases. Nevertheless, listing them helps to clarify the scope of the project. Additionally they act as a reminder of requirements that consciously will not be met. The prioritization is made by the person who gathers the requirements. The requirements and the prioritization should be verified with the actual users and other significant stakeholders (Benyon, Turner, & Turner, 2005, pp. 213-214). (DSDM Consortium, 2008, pp. 64-65)

3 Methodologies

This Chapter presents the methods used in the research of this Thesis. Interviews (Chapter 2.3) are the main source of information, along with literature sources, web sources, and user manuals. Specifically, the interviews are the main source of information in gathering the user requirements (Chapter 2.4) of BG measurement.

3.1 Interviews

This Thesis relies on the seven stages of an interview study presented by Kvale & Brinkmann (2009) (Chapter 2.3.1). The theme of the interview study is *blood glucose measurement and the related user requirements*. The interviews were conducted with a semi-structured approach, with questions related to the following topics: (a) Current Care Guidelines and treatment practices, (b) Communication and information flow between relevant stakeholders, (c) SMBG and related devices, (d) Measurement data representation, (e) Web/mobile applications relevant for diabetes care, and (f) Problems with diabetes treatment.

Translations of the interview scripts are provided in Appendix A. Each of the interviewed user groups had a separate interview script. The scripts were used to guide the conversation into relevant topics and finally as a checklist to ensure that all relevant topics were covered. Each topic is investigated with focus on the current situation and problems, user requirements and future prospects. The interviewees consist of doctors and nurses specializing in diabetes treatment, and diabetics. In total, eight subjects were interviewed, three nurses and doctors, and two diabetics. Additionally one interview was performed in the early stages of the work of this Thesis. The interviewee had both medical and industry experience in diabetes treatment and BG meters, the objective of the interview was to help scope the theme of this Thesis.

The interviews were recorded by taking notes during the interviews. The decision not to take audio or video recordings was based on the time constraints and the personal experiences of the interviewer. Previous experiences on audio and video recordings suggested that the time available to conduct the study would be better used by conducting more interviews, rather than getting detailed transcriptions of them.

Immediately after each interview, the notes were refined and digested into a more structured form, i.e. *meaning condensation*[8] presented by Kvale & Brinkmann (2009, pp. 205-206). Meaning condensation facilitates the later more detailed analysis stage of the interview study. Knowledge obtained from earlier interviews was validated in later interviews, as suggested by Kvale & Brinkmann (2009, p. 253). Furthermore, statements of the current problems and future prospects were tabulated and keywords were added to each statement – i.e. *meaning coding*[9] (Kvale & Brinkmann, 2009, pp. 201-205) – to facilitate categorizing the statements.

3.1.1 Practical arrangements

The interviews were conducted between April and July of 2013. The analysis and reporting of the interviews of was conducted anonymously. The three doctors interviewed had a combined experience in diabetes treatment of 65 years. The three nurses interviewed had on average 15 years of experience treating diabetes. Two of the interviewed doctors work mostly on the public sector, and one has practice in several private clinics with no practice in the public sector. The nurses had all previously worked in the public sector, during the interviews they worked only in private clinics. The two interviewed diabetics had on average had diabetes for 35 years. The lack of patient material from the interviews is compensated by the use of another source[10], detailed explanations of this is given in the respective section (5.2.2, page 45).

[8] Rubin & Rubin (2005, pp. 202-203) discuss a similar approach where the interview material is broken into data units that describe, e.g., specific events, contexts or themes.
[9] Rubin & Rubin (2005, pp. 206-216) suggest coding of all interview material to facilitate the analysis.
[10] Additional information on the user needs (or rather, system requirements) of diabetes management applications was gathered via an Internet forum discussion on the subject. Available at (in Finnish): http://keskustelu.diabetes.fi/index.php/topic,1875892.0.html, last accessed 30th of October 2013.

The interviews were conducted in the most convenient location for the interviewees. In the case of medical staff, the interviews were conducted in their offices. The diabetics were interviewed either at their home or in a convenient café. A few of the subjects were rewarded with coffee for attending the interview. The majority of the interviews were conducted in approximately an hour, with one interview lasting a few hours. During the interviews, the interviewer took notes carefully, no recording devices were used. Immediately after the interview, the notes were digested into structured reports of the individual interviews. On one occasion, clarifications to the data gathered were asked via email.

3.1.2 Analysis method

Small-scale analysis was started immediately after the interviews in the form of structuring the notes into relevant categories, i.e. meaning condensation presented by Kvale & Brinkmann (2009, pp. 205-206). In total, the interviews produced forty pages of structured report material consisting of short summarizing sentences and bulleted lists. The claims of each interview were combined under common categories presented below.

> *Glucose Meters*: claims relating to the SMBG measurement devices. More specifically: important features and differences between them, choosing of a meter, and recommendations.
>
> *Measurement:* claims relating to the measurements, including no. of measurements, the relative importance of measurement types, patients' capability to interpret measurement results, and other important measurements besides blood glucose.
>
> *Measurement Data & Data Retrieval Software*: claims related to presentation of measurement results and data retrieval software. Subtopics include encountered presentation formats and preferences, important features in the software and presentation, and what is searched from the measurement result set. Additional subtopics related to data retrieval software include the use frequency, important features, problems, and suggestions.
>
> *Applications:* claims related to other software used in treatment. Topics covered under this category include the overall knowledge of the available applications, current application usage and frequency of use, recommendations, and common requirements.
>
> *Communication:* claims related to communication between stakeholders. Topics include the used channels, problems encountered, suggestions, and common requirements.
>
> *Guidelines:* claims related to the Current Care Guideline and treatment guidance and practices, including current state and usage, recommendations, opinions, and alternative sources of information used.

In addition to the categories above, all *problem statements* and claims related to *future prospects and wishes* were listed separately. *Meaning coding* (Kvale & Brinkmann, 2009, pp. 201-205) was used to categorize the statements and claims, i.e. primary keywords were added to each of the claims and statements. The primary keywords that are used consist of the categories presented above and additionally the keywords *knowledge* and *resources* are used. Secondary keywords further characterize the claims and statements. Detailed descriptions of the categories and keywords are provided as they occur in the analysis in Chapter 4. Listing each claim under common categories helped to form an overview of each of the issues covered in the interviews. Listing the problems and future prospects and hopes separately enables the more specific inspection of the current problems and hopes for the future. These approaches eventually led to the formation of user requirements (Chapter 5).

3.2 User requirements evaluation

Chapter 2.4 presents a few approaches to gathering user requirements and fig. 2.7 in page 15 presents one alternative for gathering user requirements. That process is used for gathering the user requirements in this Thesis, with the minor alteration of analyzing the context of use in the third phase of the process. Fig 3.1 shows which tools are used in this Thesis, where applicable.

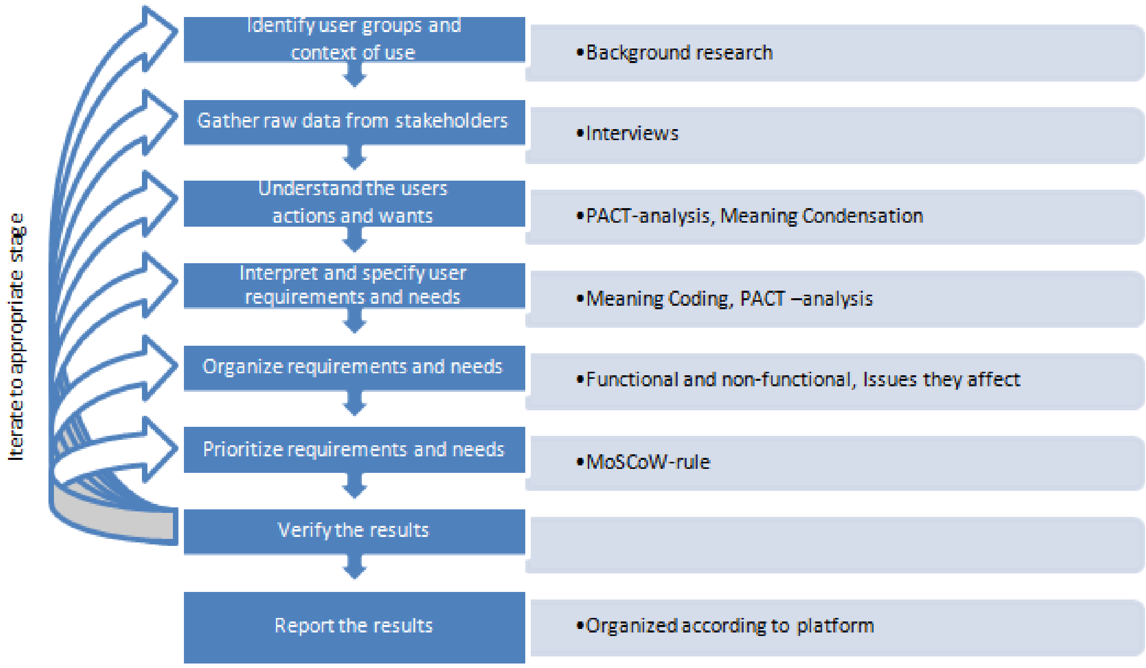

Figure 3.1 Gathering of user requirements in this Thesis

The relevant user groups were identified by doing background research on the meter technologies, diabetes treatment practices and guidelines, and diabetes in general (Chapters 2 and 6). In addition to the background research, interviews are the main method of gathering raw data of the users (Chapter 4). PACT-analysis (Chapter 5.1) and meaning condensation were used for analyzing the users' actions and wants. Meaning coding is the main method of analysis for interpreting and specifying the user requirements (Chapter 5.2). The requirements are organized according to the issue they affect, and they are prioritized according to the MoSCoW-rule. This Thesis is not a development project per se, thus the *Won't* category is left out. No decisions on which requirements will not be met are made. The verification of the requirements could be made by, e.g., further interviews. However, the value of verifying the requirements can be debatable. For instance, verifying latent user requirements can be difficult, e.g., in the late 1980s few were convinced that mobile phones would become as widespread as they are today. While scoping this Thesis, the verification phase was decided to be left for further research.

4 Interviews

The main research method of this Thesis is interviewing, the structure of the interviews, practical arrangements and analysis method is explained in section 3.1. This chapter presents the results and analysis of the interviews. They are presented categorized in relevant subthemes that emerged during the analysis. The results are later used for forming the user requirements in BG measurement (Chapter 5). First, a brief overview of the categories formulated in the analysis is presented (4.1). Second, this Chapter presents in detail the problems and future prospects and wishes found during the analysis (4.2). The issues are categorized according to the keywords used during the analysis. All of the information provided in this section originates from the interviews if not stated otherwise. Finally, a short summary of the interview results is provided (4.3).

4.1 Overview of the categories

Glucose Meters:

Not a single interviewee felt that they had the chance to affect meter choices. Rather, the choices are bound to the supply of the Self-Treatment Product Distribution (STPD, see Chapter 6.1 for further information). The interviewed doctors and nurses recommend only products that are available in the STPD of the municipality where the patient lives. The diabetics explained that they only used meters to which they get the test-strips free of charge from the STPD. If the limitations caused by the STPD would be removed, all-in-one type meters[11] would be most commonly recommended. However, the dominant opinion was that there are no significant differences between the meters available, i.e. all of the meters available in Finland enable good SMBG. However, the understanding of good SMBG may evolve as new products and services enable even better SMBG. Important meter features revealed during the interviews include: (a) *Discreteness*, (b) *Small size combined with a large display*, (c) *Ease of use, especially on the go*, (d) *Reliability*, (e) *Good*[12] *and sturdy test strips,* (f) *Relevant*[13] *marking options*, and (g) *The ability to add reminders onto the meter.*

Measurements:

Pair-measurements[14] are crucial in diabetes treatment. Both the Current Care Guideline of Diabetes (Finnish Medical Society Duodecim, 2011a) and the interviews support this claim. Solid and systematic measurements are required to ensure good quality treatment[15] (Ilanne-Parikka, 2010, p. 4). Additionally to meal and night-pair measurements, the interviewed diabetics took measurements when they didn't feel well, i.e. they felt that their BG level was low.

The interview material suggests that a large portion of diabetics take either too few or too many measurements. Estimates were that up to one third of diabetics take too few measurements, while some take up to 20 measurements daily. One of the interviewed doctors summarized figuratively that each measurement should eventually lead to an action or decision related to diabetes treatment. It is rather simple to deduct that the medical professionals need a certain amount of BG measurement data points to make proper conclusions of the state of the patients' diabetes. Too few measurements do not show how BG levels behave during the course of day. Although too many measurements may not impede treatment, they pose a major inconvenience and cost to patients. Each measurement is time consuming and more or less painful, and the average price of one test strip is 0,6 € (Chapter 6.3.1).

[11] All-in-one meters have additionally to traditional meters a lancing device for finger-pricking and a test-strip cartridge, enabling more effortless measuring. Further discussion is provided in Chapter 6.3.1.

[12] The interviewees gave some insight on what composes a good test strip, e.g., easy opening of the container and the test-strips stored in such a way that they can be easily inserted into the BG meter.

[13] The relevancy of marking options is discussed further later in the Thesis, e.g., in pages 38, 56, and 65, and in Section 6.3.1. The relevancy of marking options is in many respects user specific.

[14] Pair-measurements consist of two measurements around a specific event that effects the diabetics BG, e.g., a meal-pair-measurement consists of a measurement taken before eating and one measurement two hours after the meal. Chapter 6.2.2 in page 52 contains more information on SMBG practices.

[15] Chapter 6.2.2 provides more information on treatment practices related to SMBG.

The patients' capabilities to interpret and act based on the BG measurement results were deemed to be generally good. Usually diabetics that have lived with diabetes for a longer time had better capabilities. Moreover, the capabilities were described to be affected by how far in the treatment guidance[16] the patient is. One interesting observation provided by a doctor was that diabetics that were diagnosed in their childhood had better capabilities. The doctor continued that children with diabetes are usually treated in specialized clinics, whereas diabetics diagnosed as adults are treated in a variety of places. Thus, the quality of treatment of children with diabetes is rather consistent in contrast to the adult patients whose treatment quality may vary.

Other measurements that were commonly suggested to be incorporated into diabetics self-treatment were blood pressure and weight. However, one of the doctors strongly opposed any additions to the patients' workload. The doctor felt that the quality of measurement data was in many cases already poor and additional measurements could only make the situation worse.

Measurement Data & Data Retrieval Software:

The interviews suggest that the data retrieval software features[17] are not widely adopted, regardless of the software being available for several years. The software were described to feel unfinished and they were hard to use. Moreover, the functionalities and features of the software did not provide the means to achieve the goals that the users wanted to achieve (Chapter 5 presents more details on the user requirements).

The most commonly used data presentation type is paperback notebooks. The medical staff even encountered charts made by the diabetics themselves more often than the related software printouts. Whether, or how the diabetics use the software for their own purposes remains unclear, a questionnaire related to this would probably provide more data for a generalization.

Regardless of the data format used for analyzing the BG measurement results , the most valued qualities are that it's fast and easy to find significant information from it, it's fast and easy to use in general, and it offers flexible options for inputting additional data (such as the used insulin dose, carbohydrate consumption, or exercise information). The information extracted from the data includes hypo- and hyperglycemic measurement results and pair-measurement results. The main objective is to interpret trends from the data, e.g., common times of day when the hyperglycemic events happen. A diary or logbook type of data representations seemed to be the fastest and easiest ways enabling finding the most relevant care issues. Additionally color-coded diagrams (e.g., where different glucose levels are represented by different colors) were mentioned to provide good information.

Applications:

There are hundreds, if not thousands of different mobile or web-based applications designed to help diabetics with various aspects of their illness[18]. Some tackle a specific area of diabetes treatment (e.g., carbohydrate calculation) while others provide help with overall management of diabetes (more on these in Chapter 6.4.2). The interviews suggest that awareness of these products is rather low, i.e. the subjects had little knowledge of the available applications. Commonly recommended and used applications are different types of counters for e.g. carbohydrates or insulin dose. The medical professionals felt that the various applications are generally most useful with young adults who have recently been diagnosed with diabetes. Young diabetics were described to adopt the use of these programs more likely than the older ones.

[16] Diabetes treatment guidance is a concept for empowering the diabetics to make treatment related decisions independently by teaching the tools and knowledge required to make these decisions (Finnish Medical Society Duodecim, 2011b).

[17] Modern blood glucose meters have memory for storing measurement results. These results can commonly be uploaded into computers with USB-cables using specific software. The software is often manufacturer specific and free of charge. These software have features that allow the measurement data to be refined in several different ways (Chapter 6.4 in page 60 provides more details on this topic).

[18] Searching 'diabetes' on the 25th of April 2013 in the GooglePlay service – used by mobiles with the Android operating system – yielded over 2000 results. https://play.google.com/store

Moreover, diabetics with several years of experience with the illness have often already acquired the knowledge that the applications (e.g. counters) would provide.

Communication:

Although most of the interviewees did not explicitly describe problems with the current communication channels, the interview material suggests that problems are present. More specifically, communication between the doctors and patients seems to be problematic and the current channels were described to be insufficient. The appointments were described to be too short, phone calls inconvenient in many ways, and email too insecure. The communication between medical staff inside the clinics and hospitals was seen to be good by most of the interviewees. Another level of communication is the communication between clinics. One of the interviewed diabetics described an incident where two clinics gave conflicting care instructions to the same illness.

More indirect evidence of the insufficiency of communication channels between medical staff and patients emerged from comments on measurement results and treatment. Although the interviewed doctors and nurses clearly stated that they primarily looked for trends in the measurement data, the patients felt that the medical staff only gave attention to exceptional measurement results (i.e. hypoglycemic and hyperglycemic values). This controversy may result from various reasons and would require further research for comprehensive answers. One possible explanation might be as simple as the difference of expertise between the interviewed doctors and the doctors that treat the interviewed patients.

Guidelines:

The Current Care Guideline on Diabetes was without exceptions deemed to be good and up to date, although it is mostly applicable only to type 2 diabetics, thus for approximately to 85% of diabetics in Finland (Koski, 2011, p. 6). There are two versions available of the Current Care Guideline on Diabetes; a patients' version and a practitioners' version. Only one of the interviewed doctors advised patients to use either of these as a reference, and even that doctor did it on rare occasions. Half of the interviewed medical professionals use the practitioners' version as a reference themselves, while the rest assured to act according to the recommendations in it. The only problems seen with the guideline were that it is not applicable to all situations and patients, and that it's such a big collection that updating it is often tedious and slow. Section 6.2 discusses the Current Care Guideline on Diabetes further.

Considering the comments provided by the medical professionals, it should be no surprise that not one of the interviewed diabetics used the guideline. Moreover, all the interviewed diabetics had type 1 diabetes, thus only small sections of the guideline would be applicable. Furthermore, the patients felt that finding relevant information applicable to their specific situation is difficult. They described using the trial and error -method to find and test new treatment practices. Even the doctors and nurses preferred other sources of information to give to patients[19].

There is a clearly conflicting information here, on one hand the medical professionals claim that the Current Care Guideline is good and up to date, on the other hand the guideline is rarely used. The analysis of this topic would require further research focusing on this issue.

The guideline on Diabetes Treatment Guidance was considered to be good and up to date in every interview. Moreover, the clinic specific applications of the guideline were considered to be good as well. Although, some of the nurses said that the guideline is not applicable to all patients.

4.2 Problems and future wishes

In total, around 70 problem statements were recognized in the interview data. By combining similar statements, 40 problem statements were comprised. As mentioned in page 17, nine primary keywords (meaning coding) were formulated during the analysis and added to the

[19] Other sources mentioned were the Finnish Diabetes Association (http://www.diabetes.fi/en/finnish_diabetes_association), the Finnish Heart Association (http://www.sydanliitto.fi/home), and material provided by medical industry.

statements and claims. Some of the statements can be categorized to affect more than one issue covered by a single keyword. In these cases, the secondary keywords are presented next to the statement. Moreover, solving a single problem may affect more than one aspect of SMBG and diabetes treatment, producing an additional secondary keyword. Additionally, secondary keywords are used to describe other issues covered by the statement. The secondary keywords and the reasons why they are added are explained as they appear in the analysis.

A small portion of the interview was used to inquire opinions on future prospects and wishes for diabetes treatment. As a result, fifty statements related to future wishes were recognized. The wishes are compressed into over thirty statements by combining similar ones. These statements could have been transformed into problem statements by rephrasing them. However, presenting them separately allows deeper analysis of the themes by cross-referencing.

Next, each of the problem statement and future wishes that emerged during the analysis is explained in detail and possible implications of solving them are discussed. The statements are grouped according to the primary keyword. The order of the keywords (i.e. which is primary) is open for interpretation, the order used in this Thesis represents the author's opinion. The problem statements themselves originate directly from the interview material as well as the explanations.

Communication

The keyword "*communication*" is rather self-explanatory; problems listed under this keyword relate either to the communication *channels* used by the stakeholders or to the communication *between* the stakeholders. Table 4.1 presents the problem statements and future wishes categorized under this primary keyword.

Table 4.1 Problem statements and future wishes. Primary keyword: communication.

	Problem Statement	**Secondary Keywords**
1.	*Current communication channels are insufficient.*	patients
2.	*Patient information systems do not support communication.*	medical staff, software, resources
3.	*Communication between clinics and hospitals is insufficient.*	medical staff
	Future wish	
a.	*Better communication between doctors and nurses (e.g., getting consultations would be easier) would provide better treatment results.*	medical staff

The comments that produced Statement 1. discussed primarily the communication channels between patients and doctors. Solving this problem may very well improve patients' knowledge of their current state of health, treatment and measurement practices, or other issues. Improving knowledge of these issues eventually improves the patients' treatment and state of health.

Problem Statements 2. and 3. and wish a. are more focused on the communication between medical staff from different point of views. Solving these issues would provide medical professionals with alternative and possibly faster means of communication with other medical professionals. This could ease diagnosing and treatment, thus affecting eventually the patients' health. Wish a. further supports the claims of the problem statements and the analysis. However, it is worth noting that the majority opinion related to direct questions on communication between the medical staff inside clinics is positive (page 21). Nevertheless, by inspecting table 4.1 it is easy to interpret that communication between all stakeholders in diabetes treatment needs improvement.

Knowledge

The problems listed in this category relate to either know-how-type or skill-type knowledge. Table 4.2 presents five problems and three wishes identified in this category. Additional keywords further describe relations of the statements, including other connecting primary keywords.

Table 4.2 Problem statements and future wishes. Primary keyword: knowledge.

	Problem Statement	Secondary Keywords
1.	*Some patients' abilities to interpret BG measurements and act based on them are insufficient.*	patients, measurement
2.	*Carbohydrate counting is difficult for some patients.*	patients
3.	*Some patients do not learn all the functionalities of the meters.*	patients, meter, measurement
4.	*New patients learn slowly how to measure correctly.*	patients, measurement
5.	*Learning to use new treatment aids is difficult.*	medical staff, training
	Future Wish	
a.	*Concrete instructions on treatment of obesity are needed.*	medical staff, guidelines
b.	*Nurses should receive psychological training to help to tackle issues with patients' motivation.*	medical staff, motivation, training
c.	*Meters should alarm when high or low BG level is detected.*	patients, meter, feature

Problem Statements 1. to 4. and wish c. describe knowledge and learning difficulties encountered commonly with patients. Solving these problems would increase the patients' knowledge on various aspects of diabetes treatment. Solving problems 1 and 2 would directly alter the patients' use of insulin, which directly affects the patients' BG balance. Solving problems 3 and 4 would result in patients' taking better measurements and producing better measurement data. This would both affect the patients' SMBG and the medical professionals' capabilities to treat patients. Most of the available meters alarm when high or low BG is detected. Thus wish c. can be interpreted to show that not all users – be it doctors, nurses or patients – seem to know the features of the meters and monitors available, supporting problem statement 3. However, some of the meters do not have this feature. Therefore, wish c. could be interpreted differently and it could be assigned with the primary keyword *meter*.

Problem Statement 5. and wishes a. and b. concern the medical professionals' knowledge issues. Solving medical professionals' difficulties in learning to use new treatment aids would affect treatment in two ways. First, by increasing the medical professionals' capabilities to teach the use of the treatment aids designed for the patients. Second, by directly improving the professionals' capabilities to use aids designed to be used by themselves. Solving wish a. would help the professionals' with lifestyle treatment. Realizing wish b. would improve the nurses' capabilities to help patients with their motivation problems, thus affecting treatment directly.

Measurement

Problems related to the keyword *measurement* tackle issues of quantity and quality. Table 4.3 presents four statements that are closely knit to measurement. Additionally, all of the problems relate to patients' behavior. The two wishes listed in the table below provide an insight to possible solutions to the problems.

Table 4.3 Problem statements and future wishes. Primary keyword: measurement.

	Problem	Secondary Keywords
1.	*Some patients take too few measurements.*	patients, motivation
2.	*Some patients take too many measurements.*	patients
3.	*Some patients do not take measurements according to instructions or the measurements taken are irrelevant.*	patients, motivation
4.	*The marking options of measurements are not used.*	patients, meter, motivation
	Future Wish	
a.	*Programmable measurement schedules with reminders are needed.*	feature
b.	*Measuring and meters should be more discreet.*	motivation, meter

Problem Statements 1. to 3. are concerned with the quality and the amount of measurements. Taking too few measurements impedes the medical professionals' tasks of determining the state of the patients' diabetes and deciding on treatment. Taking too many measurements may not be that harmful albeit unnecessary. The third problem states that even if the correct amount of measurements are taken, timeliness and relevancy are equally important. Solving these problems can affect treatment in two separate ways. First, the solution can help the professionals' perform better with their tasks. Second, it can help the patients to get a clearer picture of their health thus helping self-treatment. Additionally, the solution may remove the diabetics' need to take futile measurements. The secondary keyword *motivation* is added to problem statements 1. and 3. as the interview material strongly suggests that the diabetics' lack of motivation can lead to poor quality of measurements.

Similarly to the problems explained above, the problem described in statement 4. can hamper treatment. The markings[20] in meters add relevant information to individual measurements, e.g., meal markings are commonly added to meal-pair measurements facilitating analysis of blood glucose behavior around meals. In addition, the patients' who regularly analyze their measurement history can have more difficulties determining their state of health if the marking options are not used. Thus, solving this problem could directly affect the treatment and state of health of many diabetics. Similarly to problems 1 and 3, the secondary keyword *motivation* is added to this problem as the interviews suggest that poor motivation can lead to the patient neglecting the use of marking options.

Wish a. proposes a solution to problems 1. and 3., possibly to problem 2. as well. If the patient would receive reminders – be it from the meter, smart-phone or any other device – the patient would more likely take the correct amount of timely and good quality measurements, thus facilitating treatment. Fulfilling wish b. can solve problems 1. and 3. indirectly. The interviews suggested that more discreet meters and measurement conventions could increase the patients' motivation and willingness to take proper measurements. Thus, more discreet measuring and meters could lead to the correct amount of good quality of measurements.

Meter

Table 4.4 Problem statements. Primary keyword: meter.

	Problem	Secondary Keywords
1.	*Interpreting trends in BG behavior directly from meters is difficult.*	presentation, analysis
2.	*Graphs that can be seen in some meters do not provide useful information.*	presentation, analysis
3.	*Meters' comment and marking options are bad.*	feature
4.	*The meter features are bad.*	feature
5.	*The meters are too slow and cumbersome.*	usability
6.	*Test-strips are hard to use and produce waste.*	test-strips
7.	*Finger-pricking is a huge discomfort to some patients.*	measurement
8.	*The meters available in the self-treatment product distribution provide too few choices.*	STPD
9.	*Self-treatment product distribution provides too few test-strips.*	STPD, test-strips
10.	*The meters provided in self-treatment product distribution are not the best available.*	STPD
11.	*Regular tendering of meters provided in the self-treatment product distribution results in having to change meter too often.*	STPD

Table 4.4 presents the problems under the category *meter* and consist of statements related to the devices used and available. The secondary keyword *presentation* is used on statements that describe the meter not showing issues that it should show. *Feature* is used on statements that

[20] Most of the current BG meters have marking options to create more detailed information related to a singular measurement. Chapter 6.3.1 (page 54) discusses the currently available meters and marking options in more detail.

describe issues with meter features. Two of the statements discuss the uncomfortable but necessary steps in using the meter (*test-strips* and *measurement*). The last problems listed under this category tackles one of the issues with the municipal self-treatment product distribution (STPD) (Chapter 6.1). Additionally it can be presumed that relatively better meters would induce better motivation to use the meters. Thus, most of the problems and wishes presented in table 4.4 and table 4.5 could have the secondary keyword *motivation*. However, determining what truly effects the patients' motivation would require research more focused on this specific issue.

The wishes related to meters are exceptionally presented in a separate table facilitating better visualization of the different types of wishes presented. The first three are more *general* wishes than the others. The secondary keyword *non-invasive* refers to non-invasive meters possibly fulfilling this wish. The wishes labeled as *improvements* concern with features that exist in some or all of the currently available meters. The label *new features* refers to wishes that would require the introduction of a totally new feature into the currently available meters.

Table 4.5 Future wishes. Primary keyword: meter.

		Future wish	Secondary Keywords
general	a.	*Meters should be more accurate.*	accuracy
	b.	*Receiving BG levels should be effortless.*	measurement, non-invasive, motivation
	c.	*The meters should be easier and faster to use.*	usability
improvements	d.	*Adding reminders of measurements should be easy on meters.*	feature, measurement
	e.	*Meters should have bigger screens with nightlight.*	feature, usability
	f.	*Scrolling measurement results on meters should be easier.*	feature, usability, analysis
	g.	*Marking and commenting options on meters should be more useful and better.*	feature
	h.	*Adding markings to measurements on meters should be easier.*	feature, usability
	i.	*The possibility to comment on larger timeframes in meters is needed.*	feature
new feature	j.	*Warnings of overcorrecting with insulin should be added to meters.*	feature
	k.	*Blood pressure meters should be integrated to meters.*	feature
	l.	*Target range in terms of sugar amplitude should be added to meters.*	feature
	m.	*Meters should have an integrated cloth for wiping blood spatters.*	feature

Statements 1. and 2. describe problems with specific features of the meters. Enabling diabetics to interpret trends in BG behavior directly from the meters would remove the step of importing the measurement data into a computer. Thus, solving this problem would ease the *analysis* of the data and might affect treatment. Wish f. closely relates to this problem providing a simple and perhaps sufficient solution. However, moving the analysis options of the current data retrieval software into the meters only makes it faster to analyze the data, i.e. it does not add anything new to SMBG. Solving problem 1. might require further functionalities in the meters. Additional functionalities might impede its usability, thus impeding SMBG. Adopting HCD processes into the development is essential to ensure good usability. Problem 2 can be interpreted as an example of a poorly developed feature. The meters graphs are most likely intended to enable the analysis of the results on the meter. The solution produced apparently is not satisfactory and doesn't produce any additional knowledge. HCD processes might have helped with producing a more useful solution.

Problem 3. also describes a specific problem with currently available meters. Solving this problem could increase the use of commenting and marking options adding more detail to the data produced by measurements. As argued earlier in page 24 in problem no. 4 (*The marking options of measurements are not used),* providing better comment and marking options adds context to the measurements thus easing the analysis of them. Eventually this would produce better treatment from medical professionals and better SMBG as well. Wishes g., h., and i. all supplement problem 3 and fulfilling these wishes would result in better treatment of diabetes with the same arguments. Wish d. is similar to wish a. (*Programmable measurement schedules with reminders are needed)* in table 4.3 in page 23, and fulfilling it would provide better treatment with identical arguments.

Wish e. concerns with the meters interface. Having bigger screens would make reading the results and other possible matters easier. The nightlight would increase nighttime usability of the device. Fulfilling either or both of these wishes could make the meters easier to use and could improve SMBG. However, bigger screens can be conflicting with the request for smaller meters (page 19) and problem statement 5.

Problem statements 4. to 7. and wishes a., b. and c. are concerned with more general issues related to currently available meters. Thus, the possible solutions to the problems and wishes would be more general in nature as well. Additionally, the solutions could affect treatment by improving the patients' motivation to measure thus producing more timely and correct amount of measurements. As argued earlier in page 24, this would positively affect treatment of diabetes.

The remaining problem statements (8. to 11.) comment on the legislated municipal responsibility of providing all necessary treatment aids and medicine to specific diseases (Chapter 6.1). Providing better options to the meters available in the distribution and enough test-strips could increase the percentage of patients who take the correct amount of timely and good quality measurements. Better options enable the diabetics to choose more suitable meters meeting their specific needs, thus possibly improving their motivation to measure. The adequate amount of free of charge test-strips enables all diabetics to take the correct amount of measurements, regardless of their financial status. Additionally, the interview material suggested that these issues affect patients' motivation as well, thus affecting the measurements taken and ultimately treatment. Problem 11 discusses another aspect of the distribution. Municipalities are legally required to put the STPD products out to tender periodically. § 67 of the Act on Public Contracts (348/2007 Laki Julkisista Hankinnoista) states that direct award contracts may be used in social and healthcare services only if the arrangements for tendering, negotiation procedure, or change of the service provider would be unreasonable or inappropriate from the point of view of the client. The unfortunate result is that patients and medical staff may need to learn the usage of new treatment products rather regularly, the interview material suggests that a period of two years is rather common. Learning to use a new meter impedes (at least temporarily) the taking of measurements, which impedes the production of useful knowledge of the BG balance, which in turn impedes treatment.

The remaining wishes (j., k., l., m.) propose new features currently unavailable in BG meters. Warnings of overcorrection with insulin could prevent unnecessary use of insulin and produce more stable BG levels. Stable and low BG levels are considered to produce fewer complications and thus better state of health (Mustajoki, Diabetes (sokeritauti), 2012). The wish of integrating a Blood Pressure (BP) meter into glucose meters would enable measuring BP as conveniently as BG. However, the currently available technology for measuring BP would require the meter to be rather large. Fulfilling wish l. would visualize the stability of BG to patients', which might affect treatment. Wish m. is related to the necessary blood sample used in invasive meters. Taking a blood sample often leaves extra blood on the test area that is wiped off. The integration of the cloth would have little effect on treatment. However, some users may find it useful and it could prove to be a selling argument.

Resources

Table 4.6 presents seven problem statements and two wishes with the primary keyword resources. The claims mainly concern human resources, treatment hardware and practices, and other such issues.

Problem statements 1. and 2. seem conflicting at the first glance. Statement 1 claims that there are not enough nurses, whereas statement 2 claims that the nurses could take on more responsibilities. The interview material suggests that statement 2 concerns with the abilities of diabetes nurses and that these abilities are not utilized to the full extent. In contrast, statement 1 simply comments on the situation in specific municipalities where the resources are insufficient. Thus, statement 2 is most applicable in hospitals and clinics where there are enough nurses available and problems 1 and 2 are no longer conflicting. Solving either one of these problems by either producing more resources or by utilizing them better, would clearly affect treatment of diabetes directly. Wish b. provides one possible solution to problem 1. Wish a. further emphasizes the possibility to utilize nurses better.

Table 4.6 Problem statements and future wishes. Primary keyword: resources.

	Problem	Secondary Keywords
1.	*In some municipalities there are too few nurses to achieve proper treatment results.*	nurses
2.	*Diabetes nurses aren't utilized as much as possible and useful.*	nurses
3.	*Getting new medication to the National Health Insurance reimbursement system is too slow.*	Kela
4.	*Some problems in treatment cannot be recognized due to lack of proper tools.*	hardware, guidelines, knowledge
5.	*There are no clinics or hospitals that could treat all the diabetes related diseases.*	organization, knowledge
6.	*Current treatment practices do not apply to every situation and patient.*	knowledge
7.	*Patients receive feedback on measurements too slowly.*	patients, motivation, meter, communication
	Future Wish	
a.	*Nurses should have more possibilities to affect treatment.*	nurses
b.	*Group guidance should become more common to help to stretch resources.*	nurses

Problem statement 3. comments on the bureaucracy of the Social Insurance Institution of Finland (hence Kela). Development in the medical treatment of diabetes is continuous. The medications become available to the majority of diabetics in Finland when Kela accepts them as part of the National Health Insurance reimbursement system. Earlier availability of new medication would improve treatment of those diabetics who would get help from that medication.

Problems 4, 5 and 6 can all comment on the same issue. Problem 4 may well reflect on the issues stated in problems 5 or 6. Some clinics may lack the tools (e.g., diabetic retinophaty, damaged retina) for treating some diabetes related illnesses. On the other hand, some diabetes related illnesses may not be covered in current treatment practices and guidelines, thus the proper tools are lacking. Solving these issues would directly improve treatment of diabetics, although deeper analysis requires further information.

Problem statement 7. concerns with measurement feedback. The interviews suggest that receiving faster accurate feedback on measurements could improve the patients' motivation to measure properly. This would affect treatment positively as explained in earlier analysis. Additionally, purposeful content in the feedback would directly help diabetics. The reasons that feedback is currently not received at a satisfactory level can be argued to be related to at least the meters' technology or the lack of communication channels between the doctors and patients. The meters could have additional interactive features that would provide feedback on measurements.

Software

Software problems listed in table 4.7 relate to both the data retrieval software and applications for helping with dealing with diabetes. The first three of the six wishes concern with specific applications and the fourth is a general comment on current data retrieval software. The last two wishes vaguely describe the need for a more comprehensive service that would remove a vast amount of routine tasks from diabetics. The last two wishes can very well reflect the user requirements that are not fulfilled according to problem statement 3.

Problem 1 and the wishes d., e. and f. comment on communication between different devices and systems. Wish d. proposes the integration of one service that currently is available on e.g. smart-phones. Wish e. focuses on the same exact issue as problem 1, whereas wish f. is a vision of a more comprehensive service that could include data sharing with medical staff and patients, medical history, social interaction and many other features. Solving problem 1 – for example by fulfilling wish e. – would very likely increase usage of the analysis software for measurement results, which could improve the patients knowledge of his/her state of health. Fulfilling wish d. or adding other useful software into the meter could produce further information of the patients' lifestyle into the measurement results. This could help both the patients and the medical professionals to create a holistic view of the diabetic's state of health. Exercise trackers in particular can help patients' determine the needed insulin and carbohydrates. Additionally, exercise trackers can help with lifestyle treatment, which is particularly useful for type 2 diabetics. Producing a comprehensive cloud service could improve treatment by enabling better communication between patients and medical professionals, or by engaging the patients. Nevertheless, there are many possible pitfalls in this approach. Privacy issues and organization of the various components of the service are two examples of the challenges faced with this type of services. Especially the privacy issues are very complicated and require extreme care. A multitude of Finnish legislations discuss the right to privacy in Finland[21]. The data handled by healthcare professionals is in many cases most private.

Table 4.7 Problem statements. Primary keyword: software.

	Problem	Secondary Keywords
1.	*Inputting the same measurement results and other information into several places is too time-consuming.*	data retrieval, applications
2.	*The data retrieval software are hard to use and are not properly made.*	data retrieval
3.	*The data retrieval software do not meet the user requirements.*	data retrieval
	Future Wish	
a.	*Applications calculating and showing risks in not treating are needed.*	application
b.	*Applications supporting lifestyle treatment are needed.*	application, type 2
c.	*Retrieval software need better functionalities and features.*	data retrieval, feature
d.	*Exercise trackers should be integrated with other diabetes management hardware.*	application, meter, feature
e.	*Automatic data transfer between meters, smart-phones, IT-systems and other resources is needed*	data retrieval, application, meter
f.	*A comprehensive cloud service for diabetes management is needed.*	data retrieval, application, knowledge, communication

Both problems 2 and 3 relate to the data retrieval software and are connected to each other, albeit not strongly. Statement 2 refers to the user experience of the software, whereas statement 3 possibly refers to the features of the software or to other issues. Fulfilling wish c. could help solving problem 3. Providing a solution to problems 2. and 3. could produce better measurement data or facilitate analysis of that data.

Wishes a. and b. propose two specific requests for applications related to diabetes treatment. The first would be an application that could help prevent complications related to diabetes by showing specific risks that relate to not treating the illness properly. Wish b. proposes a set of applications designed to help with lifestyle treatment, one of the key means for treating especially type 2 diabetes. Fulfilling either one of these wishes would probably help with treatment of diabetes.

Patients

Problems with the primary keyword *patients* concern with several issues. Table 4.8 presents nine problem statements, five of which are directly related to *treatment.* One of the statements comments on either the patients' *knowledge* of the available resources or the patients' abilities to understand when help is needed. The problem with the keyword *presentation* discusses the possible dishonesty of patients. The problem statement with the keywords *communication, knowledge* and *presentation* can be caused by either communication problems between diabetics and medical staff, or by the lack of knowledge of the medical staff, or by the result presentation

[21] E.g., Personal Data Act (523/1999 Henkilötietolaki), Act on the Openness of Government Activities (621/1999 Laki viranomaisten toiminnan julkisuudesta), Act on the Protection of Privacy in Electronic Communication (Parliament, 516/2004 Sähköisen Viestinnän Tietosuojalaki, 2004)

format used by the patients. The last issue covered concerns with patients' *motivational* issues that were commented by all of the interviewed subjects. Only one wish directly related to the category *patients* was identified.

Table 4.8 Problem statements. Primary keyword: patients.

	Problem	Secondary Keywords
1.	*Some patients easily forget to inject meal-insulin.*	treatment
2.	*Often patients fear hypoglycemia, which leads to keeping BG consistently too high.*	treatment
3.	*Some patients correct high BG levels inefficiently and the results are not checked (i.e. measured).*	treatment, measurement
4.	*Overcorrection of high BG with insulin is common.*	treatment
5.	*Some patients do not treat themselves systematically.*	treatment
6.	*Not all patients seek help when measurements produce bad results.*	knowledge
7.	*Patients can falsify measurement results into paperback notebook markings.*	presentation
8.	*Diabetics feel that the medical staff only focuses on irrelevant single high or low measurements.*	communication, knowledge, presentation
9.	*Lack of motivation with patients is very common.*	motivation
	Future wish	
a.	*Faster feedback on good measurement or treatment results is needed.*	meter, communication, resources

Problem statements 1. to 6. focus on patients' actions in treating diabetes. Solving any of these problems would produce better treatment results. Eating increases the BG of diabetics, meal-insulin is injected as a countermeasure. Keeping BG consistently too high raises the risk of complications in diabetes (Mustajoki, Diabetes (sokeritauti), 2012). Effective correction of high BG would result in better treatment balance. Overcorrection with insulin can result in a roller coaster effect, where BG levels fluctuate when the patient injects too much insulin and then eats too much carbohydrate to compensate for it, further compensates with more insulin and so forth. Systematic treatment could produce more stable BG levels.

Problem statement 7. comments on one drawback of the popular traditional paperback notebook used for sharing measurement results with the medical staff. Falsifying the results hampers the treatment. The most outrageous falsifications are revealed with HbA1c tests[22]. One possible solution is to prefer the printouts of the retrieval software, which makes falsifying results more difficult. The solution would improve treatment, as accurate measurements produce more accurate knowledge of BG balance, which is key to good treatment.

Problem statement 8. discusses the diabetics' feelings on the medical staffs' focus on treatment. Perceived wrong focus may reduce the patients' motivation and thus impede the patients' willingness to treat his/her illness. The solution to this problem is related to inter-person communication and the execution depends on the reasons for this problem to occur. If the medical professionals focus on deviant values they could explain why it is done, which may reduce the frustration the patient experiences. On the other hand, if the staff is actually interpreting trends from the data while the patient feels that only deviant values are inspected, the communication between the doctor and the patient is probably of poor quality.

Problem statement 9. comments on patients lack of motivation, which seems to be the biggest issue in BG measurement encountered by the medical professionals. All commented on the motivational problems with many patients, additionally motivation issues affect many other problems as explained earlier. Solving this problem is of the utmost importance and would definitely improve treatment results. The solution would most likely require several components. One of those components could be more discreet meters, as discussed earlier in page 21 concerning wish b. in measurement related wishes.

[22] Measures BG levels from an extended time period, 6-8 weeks prior to test (Finnish Medical Society Duodecim, 2013)

Wish a. comments on the issue of many patients not knowing what the measurement results mean in practice or what actions they would require. Providing faster feedback on measurement results could motivate patients to measure more accurately and motivate them with treatment as well. The wish could be fulfilled by several means, e.g., by adding interactive feedback into meters or by providing better communication channels between patients and the medical staff. Many of the wishes presented in previous keyword-sections can help with the problems presented in table 4.8.

Future prospects and non-invasive devices

Table 4.9 presents future prospects envisioned by the interviewees. The first four statements envision how measurement and meters may evolve in the near future. The latter four statements represent the opinions on non-invasive devices. It is worth noting that most of the interviewees seemed to be rather indifferent of the non-invasive devices. This may be due to the troublesome history that non-invasive device development has had; so far not a single meter has proved to be commercially viable (see chapter 6.3.2 in page 58 for further details).

Table 4.9 Future prospects and statements on non-invasive devices.

Statement	Secondary keywords
CGM will become more available and common.	CGM
Multimodal measurement will become more common.	measurement, meter
Utilizing the immune system in meters will become more common.	measurement, meter
Sensor implants will become more common.	measurement, meter
The need for non-invasive meters is present.	non-invasive
Non-invasive monitors and meters are too expensive.	non-invasive
Non-invasive meters could help with motivation problems, e.g., by eliminating the need for finger-pricking.	non-invasive
Non-invasive meters and monitors can replace both the traditional meters and current CGM devices.	non-invasive

4.3 Summary / Highlights

The previous section presented all of the problems and wishes discovered in the research. Additionally, the section discussed how each problem and wish affects treatment. The affect was not always straightforward, rather, fixing one issue led to improvements on another issue and eventually to better treatment. E.g., providing better marking options can improve the diabetics' motivation to measure, thus producing more measurement results which can be utilized by both the medical professionals and the diabetics themselves. Additionally, providing better marking options can clarify the context of specific measurements, thus providing more background information for interpreting the behavior of BG. The actual solution to any of the problems presented above affects the path with which it affects treatment. The goal of treating diabetes is to prevent diabetes related complications and symptoms, in addition to achieving a good quality of life (Mustajoki, Diabetes (sokeritauti), 2012). Preferably, all development made in the field of diabetes care should lead to better treatment results, i.e. fewer complications, mitigation of symptoms and better quality of life for diabetics. Thus, all solutions provided for the problems above should aim to the same objective.

The interview material strongly suggests that one of the most important issues with current diabetes treatment is the patients' motivation. Strong support was found on the claim that motivation significantly affects measurement quality. Good quality and timely measurements are one of the key issues affecting good treatment results. The interviews gave two examples of issues affecting motivation. Meter quality and relevant feedback were considered to directly affect motivation. The actual realization of the feedback on measurements could link other factors to affect motivation as well. For instance, getting feedback directly from doctors would assign the 'feedback/motivation' combination to the *communication* category. A feedback component could alternatively be added to the data retrieval software thus resulting in the *software* category affecting motivation. Applications could affect motivation as well, e.g., the risk calculators mentioned earlier would increase the diabetics' knowledge of risks in not treating their diabetes. It can be assumed that knowledge of the possible outcomes of not treating oneself could motivate to put more effort in treatment. Additionally, it is likely that there are numerous other measures with which motivation can be affected, e.g., more engaging interaction in the treatment equipments. A full coverage of all the motivation related issues would require further research focused on the factors affecting motivation.

The most problematic topics seem to be the meters and measurement in general. These two categories are extremely closely tied together; meters are used to acquire measurements. The meter features are not good, and the currently available meters should be more accurate, faster and effortless to use. Especially marking and commenting options received negative attention. Using them is difficult and the options provided are in some cases irrelevant. Moreover, the available options are commonly not used properly and the timeliness and amount of measurements is often incorrect. Furthermore, the diabetics' capabilities to interpret the measurement results and make treatment decisions varies. The patients' knowledge of the meter features and how to take good quality measurements varies as well.

Communication between the patients and medical staff and amongst the medical staff needs refinement. Better communication channels may provide the means to enhance communication itself, although other measures – such as using layman terminology or other ways of ensuring that the patient fully understands what is discussed – may be useful as well.

The guidelines related to diabetes are seen to be in good shape, however, some updating might be useful. The guidelines are not used regularly, although treatment is arranged accordingly. New information on treatment is gathered from other sources, e.g., from patient material produced by other organizations, some of which may have conflicting interests (e.g. the medical industry wants to sell their product for profit). The conflicting information extracted from the interviews suggests one topic for further research, i.e. why are the Current Care Guidelines not used. Regardless of the information available and used in treatment, some patients do not systematically treat their diabetes. Other more specific treatment related problems include that of diabetics keeping BG levels constantly too high to prevent hypoglycemia.

The STPD system requires upgrading. The system is too rigid and does not allow patient specific treatment. Some diabetics require more test-strips than covered by the system. The legally mandated regular tendering of self-treatment products (§67 of 348/2007 Laki Julkisista Hankinnoista) can result in diabetics having to change their measurement devices more often than necessary. Additionally, some diabetics might benefit from using other meters than the ones covered by the system.

The low amount of nurses in some municipalities can impede treatment of diabetes. On the other hand, the nurses feel that they could be utilized even further and wish for more influence on treatment. Moreover, the nurses could benefit from further training on the treatment aids (e.g., software) used. Additionally, psychological training could help nurses with assisting diabetics who have motivational issues.

Diabetes related software requires updating as well. The currently available data retrieval software is generally of poor quality and not used by the clinics, traditional paperback notebooks are preferred. The applications helping diabetes management are not well known, although the material suggests that there is a need for such applications. Moreover, a comprehensive IT-system that would cover all the aspects of diabetes treatment could be extremely useful.

5 User requirements

The user requirements are gathered according to the process presented in Chapter 3.2. The three user groups inspected in this Thesis are doctors, nurses and diabetics. The context of use affects specific aspects of the solutions meeting the requirements. For instance, backlit screens are unnecessary in products that are used in specific lighting conditions. However, using the screen in extremely bright lighting or in darkness requires backlit screens. The raw data for gathering user requirements can be acquired by many measures; interviewing was selected in this Thesis due to its flexibility. In addition to the user requirements of glucose meters, software and guidelines, the interviews provided an insight to other issues as well. The interpretation and organization of the requirements is based on the interview material and results, although the author's personal qualities and experiences have some effect. The relational importance of the requirements is based on the interview material and results and affected by the author. The verification of the results usually includes the involvement of the various stakeholders affected by the solution.

First, this chapter presents the PACT-analysis on BG measurement (5.1). Second, the user requirements are presented. They are organized into five categories: the BG meters, data retrieval software, diabetes management applications, and treatment practices, guidelines and other issues (5.2). Third, the correlations of the requirements between the user groups are discussed (5.3). Finally, a short summary of the requirements is presented (5.4).

5.1 PACT-analysis

The theoretical background of the PACT-analysis is presented in Chapter 2.4.4. The analysis focuses on the three main stakeholder discussed in this Thesis, i.e. the doctors, nurses, and diabetics. Special focus is given to the three main issues discussed in this Thesis; glucose meters, diabetes related software, and treatment guidelines and practices.

5.1.1 People

The doctors, nurses and diabetics are the main groups using the meters, software, and guidelines on BG measurement. Other relevant stakeholders include the device and service manufacturers, retailers, various diabetes and other associations, and municipal officials in tendering, purchasing and health care.

The doctors are a diverse group. The main difference between doctors is the level of expertise in diabetes treatment, affecting their knowledge on the meters, software and guidelines. The doctors treating diabetes have various fields of specialty. Diabetes doctors, endocrinologists and general practitioners are likely the professionals that are most active in treating diabetes, thus the most knowledgeable in the treatment equipment and guidelines. That is, endocrinologists and diabetes doctors are extremely knowledgeable, and general practitioners can have good knowledge on diabetes treatment. Moreover, doctors are comfortable in using medical terminology. In contrast, stereotypical doctors generally are not the most computer-savvy, although comfortable using basic computer software. Thus, technical terminology might be out of their comfort zone and learning to use new technological equipment might be difficult for some. The age of the typical doctor treating diabetes varies, ranging from their 30s to late 60s. Generally doctors work individually and deduct diagnosis based mostly on their expertise and the patients descriptions of their symptoms.

The nurses treating diabetes are usually specialized in it, thus having good knowledge on the treatment equipment and guidelines. Similarly to doctors, the nurses are comfortable using medical terminology. Furthermore, the nurses are generally familiar with basic computer software and usage. However, nurses cannot be generalized to be tech-savvy and learning to use new technologies might be challenging to some nurses. Especially when considering the age differences of diabetes nurses, ranging from mid-20s to late 50s. Eyesight might present some restrictions to designs. Nurses are comfortable in giving basic instructions to diabetics, although more challenging issues are usually solved by the doctors. Moreover, the medical profession is extremely hierarchical and the responsibilities amongst the staff are usually specified clearly.

Type 1 diabetes does not discriminate, and the patients come in all sizes and shapes. The diabetics could be categorized at least according to age and how long they have had diabetes. The youngest patients may be under 10 years old and the oldest over 80. The younger patients are generally more tech-savvy than the older patients. Moreover, eyesight issues become more common with older age and along with diabetes related complications. Additionally, diabetics are prone to suffer from neuropathic symptoms, e.g., joint pains in carpal tunnel syndrome. Diabetics who have suffered from the illness for longer periods of time are more likely to be familiar with diabetes specific medical terminology. Moreover, their knowledge of treatment practices, equipment and guidelines becomes better. Type 2 diabetes is unusual in the youth, and type 2 diabetics are more commonly overweight and suffer from other issues caused by overweight.

5.1.2 Activities

Focus is given to the activities related to BG meters, diabetes management software and treatment guidelines. Generally speaking, the overall purpose of every activity mentioned above is the treatment of diabetics.

The doctors rarely use the BG meters or diabetes management software. However, they need access to the information generated by the meters and software. Usually this is delivered either in a printout from the software or in paperback notebook format, rarely digitally. Patient information systems are used regularly for, e.g., managing patient information and printing prescriptions. The guidelines can be accessed via the Internet, the use frequency and how long it takes to retrieve relevant information from them depends on the doctor's level of expertise. Usually the doctors have a busy schedule and fast usage of any equipment is of the essence. The relevant information to the treatment of any specific patient is commonly retrieved alone and before the patient appointment, thus the information retrieval can be an undisturbed activity. The information is comprised of text, tables and diagrams. Additional sources of information include the Finnish Heart Association (http://www.sydanliitto.fi/home), the Finnish Diabetes Association (http://www.diabetes.fi/en/finnish_diabetes_association), and scientific journals.

The nurses guide diabetics with the use of the glucose meters during appointments. This is a collaborative activity where the patient asks for more detailed information on specific issues. The nurses generally are familiar with the meters used by their patients and do not need to fetch related information during the appointment. However, misinformation on the usage of meters can lead to false measurement results, which in turn can lead to incorrect treatment. Thus, it is important that no mistakes are made during the instruction session. In case of the measurement data, the nurses get either a pre-prepared document of the measurement data or they retrieve the data from the meter using the meter specific software. If the data is retrieved during the appointment, the information may be browsed on screen or a report of the measurements is printed out. The printout is likely to be taken always as it may be used for making notes for the patient or future doctor's appointment. Mistakes in the data retrieval and analysis process can lead to false interpretations of the measurement results. Thus, the software cannot allow wrong actions. The length of the appointment can vary from 20 minutes to an hour, during which collaborative actions to guide the patient are taken. The relevant information in the treatment guidelines can be accessed before the appointment. The amount of information retrieved depends on the nurse's expertise level. Additional information may be retrieved during the appointment if some unexpected issues rise up during the appointment.

The diabetics use the glucose meters frequently. Depending on the specifics of their illness (type, sugar balance), the instruction is to take measurements from 4 times a week to over 6 times a day (table 6.2, page 53). The whole measurement procedure should takes less than 5 minutes and can be disturbed depending on the context of use. Taking a blood glucose measurement with invasive devices[23] is uncomfortable and can be socially inconvenient for some diabetics, thus requiring some privacy. Correct measurements are imperative for proper treatment, thus the meters shouldn't allow any incorrect actions. Incorrect actions may lead to false interpretations of measurement data. The data retrieval software can be used, e.g., on a monthly or weekly basis, for importing measurement data from the meters. This is most likely done on the diabetic's personal computer in home settings, where interruptions may occur, e.g., by a crying baby. The measurement results are browsed on screen for relevant information. Focus is given on

[23] Chapter 6.3 discusses the types of meters available and developed, invasive devices require a blood sample.

interpreting trends in BG behavior and exceptionally high or low BG values. The measurements require further context to facilitate the interpretation, such as time and date, day of week, activity around the time of measurement (e.g., meals, exercise), exceptional situations (e.g., the flu), and other relevant issues. As with the meters, incorrect actions in the use of the software can lead to false interpretation of the measurements. Thus, the possibility of incorrect actions should not be allowed in the software. Other diabetes management software is rarely used, partly due to the limited selection available. The guidelines are most likely used early after the diagnosis of diabetes. As the diabetic becomes more accustomed with the illness, relevant information on treatment is gathered from other sources, including the doctors, nurses, associations and by the trial- and error -method. The information provided in the guidelines is too generic in nature for many of the patients and may not apply to the patient's specific requirements. Additional sources of information include the Finnish Heart Association and the Finnish Diabetes Association. Furthermore, forums and other Internet sources are used to get opinions from peers.

5.1.3 Contexts

The doctors and nurses treat diabetics mostly in their offices during the appointments. They have a desk for using their computer and the patient sits opposite of them. If the measurement data is browsed on screen, it might be useful to enable the patient to see the same information, either on a secondary screen or by enabling the rotation of the screen. Additionally, the guidelines can be read on screen as well. The nurses need enough space on the desk to present meters and instruct their usage. The nurses and doctors work in a highly hierarchical organization where the responsibilities between them are divided rather clearly. Thus, any new solutions provided for diabetes treatment that involves the participation of medical staff needs to consider the division of responsibilities within the medical profession. The nurses may use group guidance where multiple[24] patients are given diabetes guidance simultaneously. On these occasions the ability to display information on a large display could be useful.

The diabetics can use the meters and diabetes management applications on a variety of surroundings. Measurements are taken indoors and outdoors, in home, office and other settings, and in a variety of environmental conditions. Lighting conditions may vary from total darkness in the night to extremely bright light under the midday sun. The surroundings may be extremely noisy (e.g., a bus stop during rush hour) or demand utter silence (e.g., in a library). Moreover, measurements may be done in solitude (e.g. at home) or in a crowd (e.g. at a cafeteria). Thus, all the extremes of the possible context need to be considered. The data retrieval software is used most commonly in familiar home settings, as is information searching. Depending on the computer, the software may be used on a desk or in a sofa or other home settings. Although it may be a calm setting, distractions are possible.

5.1.4 Technology

The doctors and nurses use most commonly desktop PC-computers with a mouse, keyboard, and high-speed Internet connection. Additionally, smart-phones are rather common in Finland. Other technological equipment used include BP-meters, eye examination devices and other medical devices. The BG devices in use are invasive due to the self-treatment product distribution and the unavailability of non-invasive devices.

The diabetics can use a variety of computers on different operating systems; desktops, laptops, and tablets, and operating on Windows, Linux, or Mac OS environments. Smart-phones are common especially with young users. On the other hand, some users may not have computers or smart-phones at all. Diabetics often have BP-meters and scales as well.

The invasive meter technology poses some limitations to the context of use. The operation temperature is usually between 5°C and 45°C. The meters have limitations in terms of air humidity (e.g., between 10%-90%) and altitude (e.g., under 3000m) as well. Additionally, the test

[24] The Diabetes Education Study Group (DESG) recommends to keep group sizes between 10 and 15 people, with smaller subgroups (5 to 8 people) used for practical exercises (The Diabetes Education Study Group, 2002). In the Finnish translation of the document the suggested size of the group is 6-8 people with smaller groups for practical exercises (Suomen Diabetes Education Study Group ry, 2002).

strips need to be stored in certain conditions as well, commonly in room temperature and away from too humid environments. Generally, the computers have Bluetooth and/or infrared interfaces enabling wireless data transfer. USB-ports are an industry standard. Most of the currently available meters use wired USB connection for data transfer.

5.2 Requirements

The DSDM Consortium (2008, p. 64) advice to use the highest priority level – *must have* – on requirements that are critical to the system, i.e. if they are not met, implementing the system becomes futile. Thus, one could deduct that if there are BG meters and software assisting their usage, no unsatisfied *must have* type requirements can exist. Pedantic use of the MoSCoW-method would in the case of BG meters produce only one abstract requirement – *The meter must enable blood glucose measurement* – which can be further developed into more specific requirements, e.g., *measurement results must be interpretable.* However, advances in technology and implemented systems can reveal latent requirements, which were not considered in the development of the current systems. Moreover, the usage of the MoSCoW-method can be interpreted differently, i.e. developing *new* systems is futile if they do not provide advantages in comparison to old systems. Thus the *must haves* would be the requirements that must be satisfied in order to produce relevant *advantages* in comparison to existing systems and the development of the system would be purposeful.

In addition to constructing the requirements according to the MoSCoW-rule, this Thesis uses a grade system to further show the relative importance of the requirements. Requirements graded with the number four are the most important requirements, whereas grade one refers to less important requirements. The requirements are commonly prioritized by the researchers that gather the requirements (Chapter 2.4). The priority levels are affected by the potential influence and complexity of the possible solution. Naturally, the prioritization of the requirements is affected by the author's opinions. The validation of the requirements could be done by, e.g., further interviews. This Thesis focuses on the unsatisfied requirements discovered during the analysis. A vast majority of the requirements presented originate directly from the problems and wishes presented in Chapter 4.2, while others were merely inspired by the findings. Next, every requirement that was elicited in this Thesis is presented. The requirements are organized and presented as meter specific (5.2.1), software (5.2.2) and other (5.2.3) requirements.

5.2.1 Meter requirements

Table 5.1 presents 30 glucose meter related functional and non-functional[25] user requirements arranged according to their relative priority. Along with the each of the requirement the source, type, and priority level of the need and requirement is presented. E.g., in requirement no. 2 the source *measurement 1, 2, 3, a* refers to the problems 1, 2, and 3, and wish a in the *measurement* section of Chapter 4.2. Requirement no. 2 is a functional need of priority level 3. The requirements are organized in the table according to their priority level, the higher the priority number, the more important the requirement is. They are presented organized according to the main issue they affect, i.e. *feedback, reminders, markings, interpretation and analysis, general, data transfer,* and *other.*

Some of the requirements are conflicting, that is fulfilling one may impede the fulfillment of another. One of the basic functional requirements for meters is having fast and effortless use, supported by simplified design and simple interaction. As some of the requirements would require more complex interaction, they might conflict with requirement no. 10. Therefore, fulfilling any requirement involving new and more complex features requires special consideration on simple and easy interaction.

[25] Functional requirements determine *what* actions the meter should enable, whereas non-functional requirements describe *how* the actions are performed. Chapter 2.3 discusses the theoretical background of user requirements.

Table 5.1 User requirements concerning glucose meters

	Source	Need	Functional or non-functional	Priority
1	patients 2	*Meters should warn users if consistent high or low BG values are detected.*	functional	3
2	measurement 1, 2, 3, a, meter d, patients 3	*Meters should remind users to measure.*	functional	3
3	measurement 4, meter 3, g, h, i	*Measurement marking options should be relevant.*	functional	3
4	meter e	*Meters should have large displays with nightlight.*	functional	3
5	resources 7, patients 2, a	*Meters should provide feedback on measurements.*	functional	3
6	measurement 1, 3, 4, patients 9	*Meter feedback should motivate users with their measurements and treatment.*	non-functional	3
7	software 1, patients 7	*Meters should have wireless interfaces for exporting measurement data.*	functional	3
8	knowledge 3	*Meter functionalities should be intuitive.*	non-functional	3
9	measurement b	*Meters should be more discreet.*	non-functional	3
10	meter 5, b, c	*Meters should be fast and effortless to use.*	non-functional	3
11	knowledge 1, patients 2	*Meters should assist diabetics in interpreting measurement results.*	functional	2
12	knowledge c, PACT	*Meters should clearly and visually alarm when high or low BG is detected.*	functional	2
13	measurement 1, 2, 3, a	*Meters should have programmable measurement schedules.*	functional	2
14	measurement 4, meter 3, g, h, i	*Measurement marking options should be modifiable by users.*	functional	2
15	meter j, patients 4	*Meters should warn the user when overcorrection with insulin is suspected.*	functional	2
16	meter l	*Meters should have a BG target range feature in terms of sugar amplitude.*	functional	2
17	software 1, e, patients 7	*Meters should automatically export data into other services.*	functional	2
18	patients 1	*Meters should remind diabetics to inject meal-insulin.*	functional	2
19	meter a	*Meters should be more accurate.*	non-functional	2
20	meter 1, 2, f, patients 2	*Meters could support analysis of measurement data.*	functional	1
21	meter 1, 2	*Meters could refine measurement data into useful charts and graphs.*	functional	1
22	patients 6	*Meters could advice patients to seek help if poor BG balance is detected.*	functional	1
23	knowledge 4	*Meters could assist diabetics with measurement practices.*	functional	1
24	measurement 4, meter 3, g, h, i	*Meters could automatically suggest relevant marking options on measurements.*	functional	1
25	measurement 4, meter 3, g, h, i	*Meters could learn the user's measurement and marking routines and suggest relevant markings.*	functional	1
26	meter k	*Meters could have integrated blood pressure meters*	functional	1
27	meter m	*Meters could have an integrated cloth for wiping blood spatters.*	functional	1
28	need no. 27	*Meters could use mobile networks for automatic data transfer.*	functional	1
29	software b, d	*Meters could have integrated applications helping with lifestyle treatment.*	functional	1
30	software a, b, d, e, f, patients 5	*Meters could have a smart-phone-like ecosystem, where applications helping with various issues could be downloaded into meters.*	non-functional	1

Requirements – feedback

Requirement 1. originates from the *patients* section's problem "*Often patients fear hypoglycemia, which leads to keeping BG levels consistently too high"* (page 29). The requirement states that the meters should warn when consistent high or low BG levels are detected, which may decrease the average BG level of patients. Lower average BG level is considered to prevent diabetes related complications (Mustajoki, Diabetes (sokeritauti), 2012), thus this is considered to be a high priority requirement.

Requirement 5. is an abstract representation of other requirements (at least nos. 1, 6, 12, 15, and 22) requesting feedback on measurements. It originates directly from wish a. in the patients section – "*Faster feedback on good measurement or treatment results is needed"*. Faster feedback was linked in the interviews as one possible way to affect motivation. The patients' motivation was recognized to be imperative for good quality measurements and treatment, thus this issue is of the highest priority.

Requirement 6. is non-functional and it emphasizes that the feedback should motivate the users. It was inspired by issues that were considered to be affected by the patients' motivation (e.g., problem no. 9 in table 2.8, page 29). The question of *how* the meter should motivate the users requires further research. Nevertheless, possible solutions to this are discussed in Chapter 8.1. The high priority of this requirement is based on the same arguments as with requirement 5. above.

Requirement 12. is an adaptation of wish c in table 4.2 – '*Meters should alarm when high or low BG is detected*'– with the addition of the alarm being clear and visual. The research revealed that nearly all of the current meters show some type of alarm when hypo- or hyperglycemic BG levels are detected (Chapter 6.3.1), this requirement emphasizes that the alarm should be distinct. The alarm is suggested to be visual as it is often more discreet than auditory alarms. Priority level two was give to this requirement as it could be incorporated into the solution to requirement 11. Meters should assist diabetics with interpreting measurement results.

Requirement 15. originates directly from wish j in the meter section of Chapter 4.2. It states that the meters should warn the users of overcorrection with insulin. The meter could possibly detect when measurements are taken temporally close to each other. Moreover, the interviews suggested that large variation of BG levels in these measurements is a revealing sign of overcorrection. When these are detected, a simple dialog that would encourage the diabetic to rethink his/her treatment actions could produce more stable BG. Therefore, this requirement is considered to of some importance and priority 2 level.

Requirement 22. is inspired by a problem statement commenting on patients' actions when consistent poor BG balance is present. The requirement states that the meters could encourage the diabetics to seek help when poor BG balance is suspected. A simple verbal suggestion on the meters screen could suffice. Priority level 1 was assigned as requirements changing other patient behavior are determined to be more useful.

Requirements - reminders

Requirement 2. originates from problem statements and wishes related to the timeliness and correctness of measurements taken. It suggests that the meters should remind the users to measure. Some of the meters have this feature available and it should be an industry standard. Furthermore, this feature should be intuitive, easy and fast to use– as should the meter in general, requirement 8. This requirement is of high priority, as such a feature can help diabetics to take the correct amount of good quality timely measurements and it is relatively easy to implement.

Requirement 13. originates directly from wish a. in the measurement section. It suggests the inclusion of programmable measurement schedules in the meter. The schedules can help patients make good quality measurements. However, measurement reminders (requirement 2.) are considered to be relatively more important, thus this requirement receives a mid-scale priority level.

Requirement 18. is inspired by a single problem statement commenting on some patients' forgetting to inject meal-insulin, and suggests a reminder for it. This is one alternative of meter feedback; the meters could prompt the reminder immediately after pre-meal measurements. Priority level 2 was given as this affects only insulin-treated patients.

Requirements - markings

Requirement 3. originates directly from the *meter* section's wish "*Marking and commenting options on meters should be more useful and better"* and other problems and wishes discussing marking options. The requirement asks for relevant marking options which produce in depth context to each measurement facilitating the analysis of measurement data. Good quality analysis of measurement data helps with diabetes treatment, thus this is considered to be a high priority requirement.

What is a relevant marking option varies between diabetics. Modifiable marking options (requirement 14.) could provide the relevancy required from marking options. Priority level 2 is given to requirement 14.; it is merely one solution for making markings more relevant.

Requirement 3. discusses the need of relevant marking options, and requirement 14. presents one solution to the problem. Requirements 24. and 25. propose further measures for providing relevant and useful marking options, i.e. automatic suggestions for markings possibly based on the meter learning the users routines. Additionally, these requirements propose measures for speeding up the procedure of marking measurements.

Requirements – interpretation and analysis

The functional requirement 11. is inspired by the problem statement "*Some patient's abilities to interpret measurements and act based on them are insufficient"* in the knowledge section. Patients having difficulties with these issues can benefit from the meter helping them with interpreting measurement results (requirement 11.), and maybe even suggest possible actions. A simple example of the suggestions could be the following dialog box on display after low BG value is detected: *'Your blood sugar level seems to be low, perhaps you should eat something?'* As this was not considered to be a widely spread problem amongst the diabetics[26] this issue received the middle range priority level.

Many of the current meters have a feature in which the sugar amplitude target range can be fixed into lower and upper limit. Requirement 16. originates directly from wish l. in the meter section, and suggests that the target range should rather be determined in terms of variation, e.g., a variation smaller than 10 mmol/l could be a good target for some patients. This requirement was not considered to be of the highest priority and neither of the lowest, thus a mid-range priority level was defined for this requirement.

Requirement 20. was inspired by a few comments on the features of the current meters used for analyzing measurement results. It suggests the meters supporting the analysis of measurements, which would enable the diabetics to analyze measurements on the go. However, the diabetes related software might be a more suitable platform for deep analysis. Thus, this requirement receives the lowest priority level.

Requirement 21. is extremely closely linked to requirement 20., proposing one way to enable analysis of measurement data. The charts and graphs suggested are already in use in data retrieval software and other diabetes related applications (Chapter 6.4).

Requirements - general

Requirement 4. is a slightly modified version of wish e. stated in the meter section, "*Meters should have bigger screens with nightlight"*. This feature directly affects meter's use in dim light-conditions, and can help the visually impaired to use the meter, and is thus of the highest priority. Determining the sufficient size of the display would require further research. This requirement may conflict with requirement 9., where the discreet meter is considered to include the small size of it. As usual in product development, some compromises are required with these requirements.

Requirement 8. is rather abstract and states that all functions of the meter should be intuitive. Intuitive interfaces can remove the need to learn the usage of the device all together, thus helping all users of the system. Therefore, it is reasonable to presume that this would provide better quality measurements. Thus, this issue receives the highest priority.

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[26] The ability to interpret measurement results and act based on them was deemed to be good in general, page 20.

Requirement 9. is similar to the wish "*Measuring and meters should be more discreet"* in the measurement section of Chapter 4.2. Discreet meters would make measuring more discreet, thus facilitating measuring in socially inconvenient situations. This in turn would provide better quality measurements used in analyzing BG balance. Therefore, the high priority is given.

Requirement 10. demands fast and effortless use of meters. It originates from statements and wishes directly commenting on the issues of meter usage, and it should be considered in all requirements describing interaction or meter usage. Again the high priority is given due to the solution to this requirement possibly increasing meter usage, thus providing more measurements to be analyzed and better treatment results.

Requirement 19. asks for more accurate meters. Although no clinical evidence that it would provide better treatment results is available (Heinemann, 2013), the interviews suggest that patients' treatment decisions, such as insulin injections and carbohydrate intake, might be affected by more accurate measurement results. Thus, this requirement receives level 2 priority.

Requirement 29. suggests the integration of applications that help with lifestyle treatment into the meters. It is inspired by two wishes in the software section, both concerning with lifestyle treatment. An integrated exercise or weight management application could motivate the patient to give more attention to lifestyle treatment. Moreover, if these applications were available and used, the medical staff would have concrete data of lifestyle treatment issues available when treating the patient, which could be useful. Regardless, these types of applications are available on smart-phones and other devices, thus priority level 1 was assigned to this issue.

Requirement 30. is inspired by all statements and wishes on applications. It suggest adopting a similar ecosystem approach of smart-phones into BG meters and services. Independent application developers could produce services to the meters that could possibly affect treatment or meter usage. However, the relative low volume of users might be an unattractive quality of application development for glucose meters. Moreover, the wireless automatic data transfer from meters to smart-phones would enable better usage of current diabetes management applications, producing in essence the same functionalities as if the application would be on the meter. Thus, priority level 1 is justified.

Requirements – data transfer

Requirement 7. is inspired by comments on the effort required to use current data retrieval software, and it requests wireless data transfer of measurement data. Although wireless interfaces do not necessarily reduce the number of tasks required for data transfer, the interfaces would enable automatic data transfer and possibly other features. Thus, this requirement receives its high priority level.

Requirement 17. suggests automatic data connection between the meters and other services. It originates directly from wish e. in table 4.7 in page 28. Fulfilling requirement 7. is necessary for fulfilling this requirement. Automatic data transfer would remove the need for connecting the BG meter to computers for measurement data transfer and analysis. Additional services could be developed as well, e.g., transmitting measurement results directly to the caregivers' mobile-phones (e.g., child-patients and the elderly might benefit from this). Priority level 2 was give for this functional requirement as it can affect every diabetic. However it is possible that it would not significantly improve treatment results.

Requirement 28. is one possible solution for requirement 17. It suggests the use of mobile networks for automatic data transfer, which would enables a host of applications in diabetes treatment. One possible application could be centralized monitoring of patients requiring close care, e.g., the elderly. However, the inspiration and main idea behind this requirement is that of automatic data transfer to current diabetes management applications and caregivers. However, automatic data transfer can be enabled by other cheaper means as well, thus this requirement receives the rather low priority level 1.

Requirements - other

Requirement 23. suggests that the meters could assist with measurement practices. Proper measurement practices were commented to be a challenge for some new diabetics. The meter could show an interactive guide for e.g., the first 30 measurements to assist with this issue. However, persistent guides on screen can become irritating quite fast. Additionally, adjustments on diabetes treatment guidance might produce better results, thus priority level 1 is reasonable.

Requirement 26. emerged from one of the diabetics interviewed asking for integrated BP meters into the BG meters. However, radical technological advances are required for the integration of BP-meters into BG meters. Moreover, one of the doctors interviewed would strongly object to this, as acquiring proper measurements form patients is difficult enough with current systems. Additional measurements might impede the objective of getting better quality BG measurements. Therefore, this requirement is conflicting with requirements proposing easier and faster use of BG meters. Thus, priority number 1 was given for this issue.

Requirement 27. was proposed by one diabetic asking for an integrated cloth for wiping blood spatters. As invasive meters require blood samples, some residue blood is usually left on the test area. This residue blood is either licked or wiped off, thus many diabetics carry some sort of cloth along with their other measurement equipment. The integrated cloth does not affect treatment in any way and is thus a priority 1 requirement. Furthermore, some diabetics might find the integrated cloth to be useless and perhaps even unhygienic.

5.2.2 Software requirements

This section discusses the user requirements related to data retrieval software and diabetes management applications. Table 5.2 present the requirements originating and inspired from the interview analysis organized by the estimated priority level. The requirements are presented in more detail organized by the main issues that they affect, i.e. *communication, interpretation and analysis, cross-platform communication, general* and *other*.

Requirements - communication

Patient information systems are already used for some type of communication, requirement 3. proposes that they should support it even further. At each appointment the medical staff updates information of the patient into the system. This information is accessible to other treatment professionals as well, at least within the clinic. As the patient information systems are already in frequent use, they could just as well provide additional communication channels. This requirement was inspired by the second problem statement in the communication section. Priority level 2 is assigned for this issue. However, privacy issues and secure data transfer are critical in fulfilling this requirement as patient information is considered to be extremely personal. Additionally, the legal requirements on privacy need consideration.

Requirement 15. is inspired by communication issues discovered in the research. Diabetes management software could be an ideal channel for simple communication related to measurements. If patients would frequently upload measurement results onto the software (better yet, automatic data transfer) doctors or nurses could comment on the current situation before an appointment. Additionally, the medical staff could follow-up on recent treatment advice. The possible applications are numerous. However, the usage of such a feature might pose some problems in terms of pricing, i.e. *who would pay for such a service and how much?* Nevertheless, this kind of a feature could be useful and a priority level 1 is assigned to it.

Requirements – interpretation and analysis

Requirement 1. is essential for the usage of diabetes management software, thus it received the highest priority level and '*must'* status. It is rather vague and states that the software should help with interpreting measurement data. It takes no stand on *how* that data would be interpreted. Table 5.4 in page 45 presents additional requirements gathered from a web-forum related to this issue. Additionally, the other requirements in this sub-category present an alternative on *how* the diabetes management software could help patients with interpreting and analyzing BG measurement data.

Table 5.2 User requirements related to diabetes management software

	Source	Need	Functional or non-functional	Priority
1	knowledge 1, patients 6	*Diabetes management software must help patients to interpret measurement data.*	functional	4
2	software 3, c	*Diabetes management software should automatically search and detect trends in BG behavior.*	funcitonal	3
3	communication 2, 3, a	*Patient information systems should support communication, even between clinics and hospitals.*	functional	2
4	knowledge 2	*Applications should help with carbohydrate counting.*	functional	2
5	knowledge 4, measurement 1, 2, 3	*Diabetes management software should contain guides on correct measurement practices.*	functional	2
6	knowledge c.	*Diabetes management software should highlight low and high BG values.*	functional	2
7	patients 2, 6, 7, 9, a	*Diabetes management software should give patients feedback on measurement results.*	functional	2
8	patients 2	*Diabetes management software should detect problems in BG balance and warn about it.*	functional	2
9	Measurement 1, 2, 3, a	*Diabetes management software should have a feature for programming measurement schedules and reminders.*	functional	2
10	All	*Diabetes management software should be available on all platforms (mobile, desktop, web, tablets, meters, others).*	functional	2
11	meter c, software 1, 2, e	*Diabetes management software should receive automatically measurement data from meters.*	functional	2
12	software 2, 3, c	*Diabetes management software should be customizable.*	functional	2
13	software 2	*Diabetes management software should be easy and fast to use.*	non-functional	2
14	software f	*Diabetes management software should provide a comprehensive package that supports all aspects of diabetes treatment.*	non- functional	2
15	communication 1, 2, 3, a, resources 2, a, patients 6, 8	*Diabetes management software could provide communication between doctors and patients and other stakeholders.*	functional	1
16	patients 5, 6	*Diabetes management software could contain guides on diabetes treatment.*	functional	1
17	Measurement 1, 2, 3, a, patients 3	*Diabetes management software could remind users to measure e.g. with SMS.*	functional	1
18	patients 1	*Diabetes management software could remind users of other treatment related issues.*	functional	1
19	meter 3, 4, d, g, h, I, j, l, Measurement 1, 2, 3, a	*Diabetes management software could be used for customizing meter functionalities.*	functional	1

The wish that inspired requirement 2. – *Retrieval software need better functionalities and features* – comments on the current software and their functionality. The requirement states that the software should automatically detect different types of trends. This feature would definitely be useful, although it may be difficult to develop. Automatic interpretation could be done for, e.g., BG behavior in meal-pair measurements, exceptional weekdays or time of day in terms of BG behavior, and irregularities in measurements. A rather high priority level 3 was assigned to this requirement as the author is confident that this feature would be extremely useful, if implemented properly.

Requirement 6. provides a rather simple and partial solution to requirement 2. suggesting highlighting exceptional measurement results. That can make the analysis phase faster, at least in terms of finding the exceptional measurement results. This feature is extremely simple to implement, but it probably is not that beneficial. In fact, a simple implementation is already in place in some of the current software, where data points are presented in a color coded diagram; the target range is coded in one color and ranges above or below the target range are presented in other colors. Fig. 5.1 shows one example of this type of presentation, where high values are in a yellow background, low values in red background, and values in target range are presented in front of a green background. More complex solutions may further facilitate analysis of measurements. This requirement is assigned with a priority level of 2.

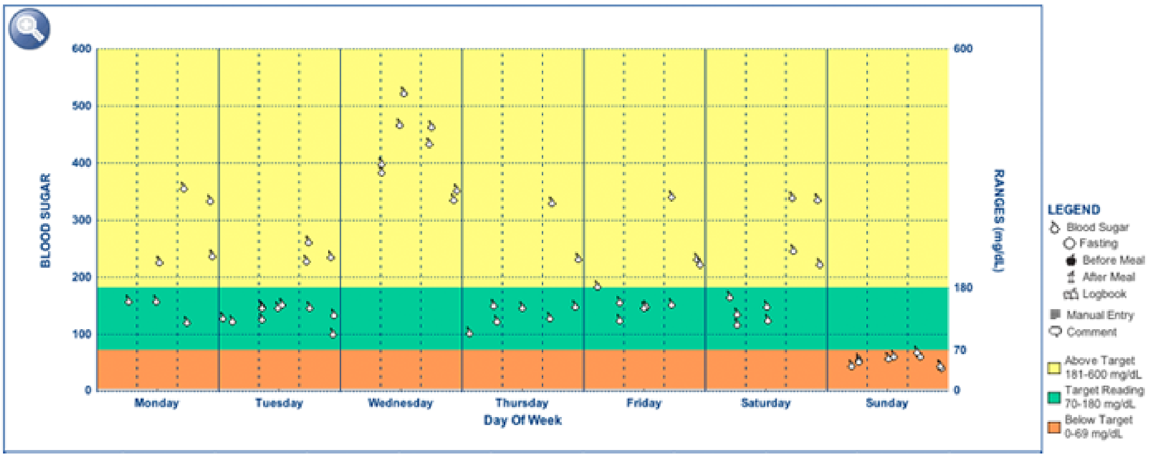

Figure 5.1 Example of a diagram in Bayer Glucofacts Deluxe software[27]

As all other feedback related requirements, requirement 8. is closely knit and partially similar to the feedback requirements in the meter section. The requirement states that the software could automatically analyze the measurements and provide feedback based on that analysis. For example, if the software detects that the diabetic has consistently too high BG values (problem 2 in table 4.8, page 29) the software could, e.g., produce a pop-up screen informing that such a problem has been detected and suggest that corrective measures would be taken. Priority level 2 was assigned to this requirement.

Requirements – cross-platform communication

Requirement 9. originates from a wish commenting on measurement schedules (wish a. in table 4.5). It suggests a feature for programming measurement schedules and reminders. The software would be a convenient interface for the programming if the simple interface of the meter is of higher priority. Priority level 2 was assigned, as this could prevent problems related to patients' measurement quality (relevancy, timeliness and correct amount).

Other treatment related issues include insulin injections and taking medication. Requirement 18. suggests that the software could remind of such issues. The inclusion of this service into the diabetes management software could be better suited for those type 2 diabetics who do not measure that often. The meter would be a more convenient platform for this requirement for patients who measure often, e.g., nearly all type 1 diabetics. Thus, the priority level 1 is reasonable.

The usage of the software is more flexible and thus more frequent if it is available on multiple platforms, as suggested by requirement 10. Therefore it is reasonable to suspect that the overall user experience of the software would be better by fulfilling this requirement. Thus, priority level 2 is justifiable.

Similarly to requirement 9., using the software interface for customizing the meter features (requirement 19.) enables keeping the meter interface as simple as possible. Thus, this feature implemented on the software can prove useful. Priority level 1 was assigned as the interface or platform used for customization can be a matter of personal preferences as well. Moreover, the meter features should to be usable independently on the meter, thus the customization feature should be available on the meter as well.

[27] Image source: http://www.bayercontour.com/Blood-Glucose-Monitoring/DiabetesManagementSoftware/Glucofacts-Deluxe/Screens/Screen2, retrieved 28.10.2013

Requirement 11. can be seen as the bare minimum in automatic data transfer suggesting automation between the software and the meters. Automatic receiving of data would remove the tedious work of manually uploading measurement results from the meter to the computer. Automatic data movement to other services and platforms enables further features.

Requirements – general

Requirement 12. suggests that the software should be customizable. Diabetics have different preferences and requirements relating to the diabetes management software. For instance, some diabetics' BG reacts to stress strongly while others do not. Thus, while analyzing the measurement results some diabetics would find it useful to be able to separate '*stress*'- results from others, and other diabetics would not use this feature at all. In addition to treatment related requirements, diabetics have different preferences on how these actions should be done, i.e. non-functional requirements[28]. Priority level 2 was assigned to this issue as it could significantly affect the user experience of this software.

Requirement 13. concerns with on all the aspects of the management software suggesting easy and fast use. According to problem no. 2 in table 4.7, the current software are not easy and fast to use. Some other requirements affect this requirement directly – e.g., automatic data transfer – and this requirement should affect the *how* question on each action and task done with the software. Priority level 2 was given as this affects tremendously the usage of the software.

Requirement 14. is inspired by wish f. in the software section of Chapter 4.2. It suggests that the software should be a comprehensive package including, e.g., such services as treatment guides, meter management, prescription storage, communication channel with medical staff, lifestyle treatment applications, data sharing with relevant stakeholders, etc. Priority level 2 was assigned to this requirement as it could affect a diversity of issues in diabetes treatment, while the implementation of such a system is extremely challenging.

Requirements – other

Requirement 4. is more related to smart-phone applications and directly inspired from a single problem. It suggests that carbohydrate counting applications are needed. Carbohydrate counter applications are already available[29]; perhaps the counting measures could be made even easier and incorporated to other applications as well. Good estimation of the consumed carbohydrates is essential in insulin treated diabetes (Finnish Medical Society Duodecim, 2011a). On the other hand, the interviews suggested that carbohydrate counting skills develop rather quickly. Thus, priority level 2 was assigned to this requirement.

Similarly to requirement 23. in table 5.1, the software could contain guides on measurement practices (requirement 5.), perhaps even interactive tutorials. Incorrect measurement practices can influence the accuracy of the measurement (Ginsberg, 2009), therefore priority level 2 on requirement 5. seems reasonable. Moreover, as argued earlier these guides are most useful in early diabetes treatment; as the diabetic becomes more accustomed with measuring blood glucose the usefulness of these guides declines fast. Similarly to requirement 5., requirement 16. can help diabetics with treatment. It suggests the inclusion of diabetes treatment guides into the software. However, the interviews suggest that the current care guidelines on diabetes treatment are not useful to all patients. Moreover, the guidelines are not required that often and other sources are used more often (Chapter 4.1). Section 5.2.3 discusses requirements related to guidelines and other issues further.

Requirement 7. suggests faster and relevant feedback on measurements incorporated into the software and is similar to requirement 5. in table 5.1. The diabetes management software is simply another possible channel for this feedback. Moreover, the software enables more comprehensive feedback; as requirement 15. (page 40) claims even the medical staff could

[28] These requirements were not researched in this Thesis and would require a more user-centered approach. E.g., the contextual design method presented by Beyer & Holtzblatt (1999).

[29] E.g., Medtronic Inc. provides carbohydrate counting games designed to help diabetic children with carbohydrate counting: http://www.lenny-diabetes.com/games-n-apps.html, last accessed 28.10.2013.

provide the content of the feedback. Priority level 2 is given for this requirement as it could affect treatment directly and additionally the patient's motivation, while the cost-structure of this service can be troublesome.

Requirement 17. is more of a solution proposition to problems related to patients' measurement quality proposing the use of SMS for reminders. However, better and cheaper solutions include applications and the meter itself producing these reminders, thus a rather low priority is given to this requirement.

Additionally to the software requirements discussed above, a majority of the requirements discussed in the meter section are easily adapted for smart-phone applications. Table 5.3 below presents the requirements that are adaptable into smart-phone application requirements are presented, along with the reference page number for further information. Unlike the other requirements tables, this is not arranged according to the priority level. Rather, the requirements that concern the same issues are presented next to each other. Detailed explanations of the requirements are significantly similar to those presented in the meter section (5.2.1), thus the explanations are not presented here.

Table 5.3 Application requirements, adapted from table 5.1

		Need	Reference	Priority
Feedback	1	*The application should warn users if consistent high or low BG values are detected.*	meter 1, p. 37	3
	2	*The application should provide feedback on measurements.*	meter 5, p. 37	3
	3	*The application feedback should motivate users with their measurements and treatment.*	meter 6, p. 37	2
	4	*The application should clearly and visually alarm of high or low BG.*	meter 12, p. 37	2
	5	*The application should warn the user when overcorrection with insulin is suspected.*	meter 15, p. 37	2
	6	*The application could advice patients to seek help if poor BG balance is detected.*	meter 22, p. 37	1
Reminders	7	*The application should remind users to measure.*	meter 2, p. 37	3
	8	*The application should have programmable measurement schedules.*	meter 13, p. 37	3
	9	*The application should remind diabetics to inject meal-insulin.*	meter 18, p. 38	2
Markings	10	*The application marking options should be relevant.*	meter 3, p. 38	3
	11	*The application marking options should be modifiable by users.*	meter 14, p. 38	2
	12	*The application could automatically suggest relevant marking options on measurements.*	meter 24, p. 38	1
	13	*The application could learn the user's measurement and marking routines for suggesting relevant markings on measurements.*	meter 25, p. 38	1
Interpretation and analysis	14	*The application should assist diabetics in interpreting measurement results.*	meter 11, p. 38	3
	15	*The application should have a BG target range feature in terms of sugar amplitude.*	meter 16, p. 38	2
	16	*The application could support analysis of measurement data.*	meter 20, p. 38	1
	17	*The application could refine measurement data into useful charts and graphs.*	meter 21, p. 38	1
General	18	*The application functionalities should be intuitive.*	meter 8, p. 39	3
	19	*The application should be fast and effortless to use.*	meter 10, p. 39	3
	20	*The application could include feature helping with lifestyle treatment.*	meter 29, p. 39	2
Data transfer	21	*The application should automatically export data into other services.*	meter 17, p. 39	2
	22	*The application could use mobile networks for automatic data transfer.*	meter 28, p. 39	1
	23	*The application could assist diabetics with measurement practices.*	meter 23, p. 40	1

Although the requirements in table 5.3 are phrased to suit the requirements related to diabetes management applications, they could be generalized to other SMBG devices and services as well. E.g., any device or service providing feedback on measurements should consider the requirements 1-6. Development of data retrieval software should consider at least all other requirements than those related to reminders. Although as argued earlier, the data retrieval software or other applications linked to the SMBG devices could be used as the interface for programming measurement schedules and reminders. Moreover, overall synchronization between diabetes management applications, meters, data retrieval software, and possible other devices and services can be extremely useful.

Additionally to the requirements interpreted from the interview material, an Internet forum discussion was used for gathering requirements that are specific for data retrieval and analysis software. The topic was initiated on the 6th of May 2013 by an eager software developer who wasn't content with the current supply on BG management services. He asked the diabetics on the forum for requirements for such a service. The functional requirements produced are presented in table 5.4. The forum discussion was analyzed similarly to the interview material, and the method is presented in Chapter 3.2, page 18. The first three requirements relate to inputting data into the service. The next batch of requirements concerns data presentation or plotting of measurement data. Requirements no. 10 and 11 relate to commenting of the measurement data points. The following two requirements concern with presentation as well, more specifically with what types of summaries need to be visualized. The rest of the requirements are more miscellaneous in nature.

Table 5.4 BG management service requirements, gathered from a forum discussion topic[30]

		Need	Priority
input	1	*The service should have a feature for importing measurements from other sources (e.g. Excels)*	2
	2	*The service must support inputting of medication intake, laboratory results, BS, carbohydrates, insulin, and exercise information[31].*	4
	3	*The service must enable inputting data separately, e.g., carbohydrates without BS-reading.*	4
plotting	4	*The service should produce a plotted BS graph (y-axis = sugar level, x-axis = time).*	3
	5	*The plotted BS graph should automatically add trend lines when enough data is available.*	2
	6	*All graphs and reports must have a modifiable timeframe of analysis.*	4
	7	*The service should plot carbohydrate intake and absorption rate.*	3
	8	*The service should enable plotting of several trend lines and issues on the same graph.*	2
	9	*The service should enable color coding of measurements according to target values.*	3
comment	10	*The service should have a feature for commenting measurements.*	3
	11	*The service should enable commenting of longer timeframes at once (e.g. by color-coding).*	2
summary	12	*The service should produce a summary of daily carbohydrate intake and bolus-insulin intake with carbohydrate/bolus-ratio, and basal-insulin separately.*	3
	13	*The service should produce a summary of average BS-values in different time-scales and pair-measurements.*	3
other	14	*The service could enable programmable measurement schedules.*	1
	15	*The service could enable making reminders for measurements.*	1
	16	*The service should have a feature for exporting data and graphs.*	3

5.2.3 Requirements related to guidelines and other issues

The third matter of interest in this Thesis is the guidelines and treatment practices related to diabetes. This section discusses the user requirements of these issues. Table 5.5 presents the requirements related to the guidelines on diabetes treatment. The requirements propose some updates that could be added to the guidelines. None of the interviewees had specific requests on updates to the guidelines. However, the analysis of the material suggests that the updates listed below could prove to be beneficial.

[30] Source: http://keskustelu.diabetes.fi/index.php/topic,1875892.0.html, needs were gathered on the 20th of October 2013, last accessed on the 29th of October 2013

[31] The Current Care Guideline on Diabetes suggests that continuous BG monitoring benefits from added information of carbohydrate intake, insulin intake, and performed exercises. (Finnish Medical Society Duodecim, 2011a)

Table 5.5 Requirements relating to guidelines

No.	Source	Requirement / Need	Priority
1	knowledge 1, 4	*The patient versions of guidelines should give more information on measurement techniques.*	2
2	knowledge 1, 4	*The patient versions of guidelines should give more information on interpreting measurements.*	2
3	measurement 1, 2, 3	*The patient versions of guidelines should contain more information on measurement practices.*	2
4	patients 9	*The guidelines could contain more information on how treat motivation issues.*	2
5	guidelines, resources 6	*The treatment guidelines could be more comprehensive.*	1
6	knowledge a	*The guidelines could contain information on treatment of obesity.*	1
7	meter j, patients 1, 2, 3, 4, 5, 6, 7, 9	*The guidelines could contain information on the most common patient misbehavior (e.g. overcorrection with insulin).*	1
8	software f	*The guidelines could be linked into diabetes management software.*	1
9	guidelines	*Distribution of guidelines from various sources could be centralized into a single service.*	1

Requirements 1., 2. and 3. discuss the patient versions of the current care guidelines. Requirements 1. and 2. are inspired by problems related to patients' knowledge on *measurement technique* and *interpretation of measurement*. If the guidelines would include more information on these topics, the patients' knowledge on these issues could be better, thus producing better quality measurements and improving the patients' ability to interpret measurement results. Requirement 3. is inspired by problems on the quality and amount of measurements that patients do. Better knowledge on measurement practices can remove human error from the accuracy of the measurements, e.g., proper hand washing before measurements improves the accuracy (Ginsberg, 2009).

Requirements 8. and .9 propose a solution for sharing the knowledge on the guidelines to patients. Requirements 4.-7. discuss the practitioners' versions of the current care guidelines. Requirement 4. originates from the common problems with patients motivation. The diabetes nurses could benefit from more knowledge and tools to recognize and treat motivational issues. Requirement 5. is more abstract in nature commenting on the general comprehensiveness of the current guidelines. Requirements 6. and 7. propose yet more suggestions on what information could be added into the guidelines. Obesity problems are rather common with type 2 diabetics. Descriptions of the signs and results of common patient mistakes can help the medical staff to identify these problems and treat them.

Table 5.6 presents the rest of the requirements gathered in the analysis that were not considered to come under any of the other categories. The column *category* groups the requirements according to the issue they concern. The requirements in the category *practices* comment on issues that should be changed in current treatment practices. The category *resources* contains requirements that comment on various issues related to human and other resources. Requirement 12. could easily be categorized under *practices,* however, it only proposes the use of new tools (*software*) in current treatment practices. The rest of the requirements comment on the STPD practices and generally demand for more flexibility in the distribution.

Table 5.6 Requirements, other

No.	Source	Category	Requirement	Priority
1	resources 3	Kela	*Getting new medication to the National Health Insurance reimbursement system should be easier and faster.*	2
2	meter 6, 7	meters	*Non-invasive meters should become available.*	2
3	patients 7	practices	*Use of diabetes management software should be encouraged and supported in treatment practices.*	3
4	measurement	practices	*Treatment of all diabetics could be centralized to specialized clinics.*	1
5	knowledge b	resources	*Nurses should receive psychological training to help to deal with patient's motivation issues.*	3
6	resources 5	resources	*Diabetes clinics should have more cooperation with special fields treating common complications in diabetes.*	3
7	resources 1, b	resources	*There should be more diabetes nurses available.*	2
8	resources 2, a	resources	*Workload analysis on diabetes nurses should be done in order to determine whether they can take on more responsibilities*	2
9	knowledge 5	resources	*The use of new treatment aids could be trained more properly to medical staff.*	1
10	knowledge 3, 4	resources	*The use of treatment aids could be trained more properly to patients.*	1
11	applications	resources	*Diabetes nurses could receive training on possible useful and available diabetes treatment applications.*	1
12	resources b, a, 7	software	*Video conferencing or virtual environments could be used in treatment guidance, especially in group guidance.*	1
13	meter 9	STPD	*STPD should be more flexible in distributing test-strips.*	3
14	meter 8	STPD	*STPD should provide more meter options for patients.*	2
15	meter 11	STPD	*Patients should be able to receive test-strips to a meter of their choice in STPD.*	2
16	meter 8, 9, 10	STPD	*STPD could be more flexible regarding the distribution diabetes treatment supplies in general.*	1

5.3 Correlations of requirements between user groups

One of the main interests of this Thesis is how the requirements of different user groups correlate. The correlation of the requirements of different user groups has two dimensions, i.e. *how similar they are* and *how similar is the relative importance of the requirements*. The interpretations of the correlations depend on the viewpoint of the analysis. A narrow scope would present clear differences in the user requirements. For instance, the doctors and nurses rarely use the BG meters, hence, the conclusion could be that they have little or no user requirements on that issue. However, both the doctors' and nurses' tasks become easier with better quality measurements. Thus, it's rather easy to conclude that fulfilling the requirements of the diabetics' would benefit the doctors and nurses as well. Thus, the interpretation could be that the requirements of the doctors, nurses and diabetics correlate strongly. Furthermore, all of the categories and subcategories on user requirements presented earlier received input from all the user groups interviewed, suggesting some amount of positive correlation.

Chapter 6.5 presents a summary of the most important requirements presented and compares those requirements to the state-of-the-art of the current devices and services. The state-of-the-art in the current SMBG devices and software is compared to the requirements presented in table 6.9 in page 66. The requirements in that table are grouped according to which part of SMBG they affect, i.e. *(1) Data Interpretation and analysis, (2) Data Transfer, (3) Feedback on measurements, (4) General issues, (5) Markings, (6) Reminders,* and *(7) Meter specific issues.* Table 6.10 in page 68 presents other significant requirements that emerged in this Thesis, and they are categorized to sub-groups *(8) Kela, (9) STPD, (10) non-invasive meters, (11) treatment practices, (12) communication issues, (13) resources,* and *(14) guidelines.* The correlations are investigated separately for each of these 14 issues. Figure 5.2 shows the results of the correlations analysis.

Appendix B contains more detailed versions of table 6.9 and table 6.10 with information of the correlations, which were used to produce fig. 5.2. The requirement was deemed to be similar to the user groups if it could directly affect all user groups. Unequal requirements didn't affect at least one user group. The difference of relevance of the requirement between user groups was approximated by estimating the importance of the requirement to each user group separately. Next, the standard deviation of the estimated values was calculated. The most extreme *'unequal relevance'* means that the requirement is either extremely important to one group while it's not important to the rest of the groups, or the requirement is not important to one group while being extremely important to the rest of the groups. *'Equal relevance'* means that the importance of the requirement is exactly the same for all user groups.

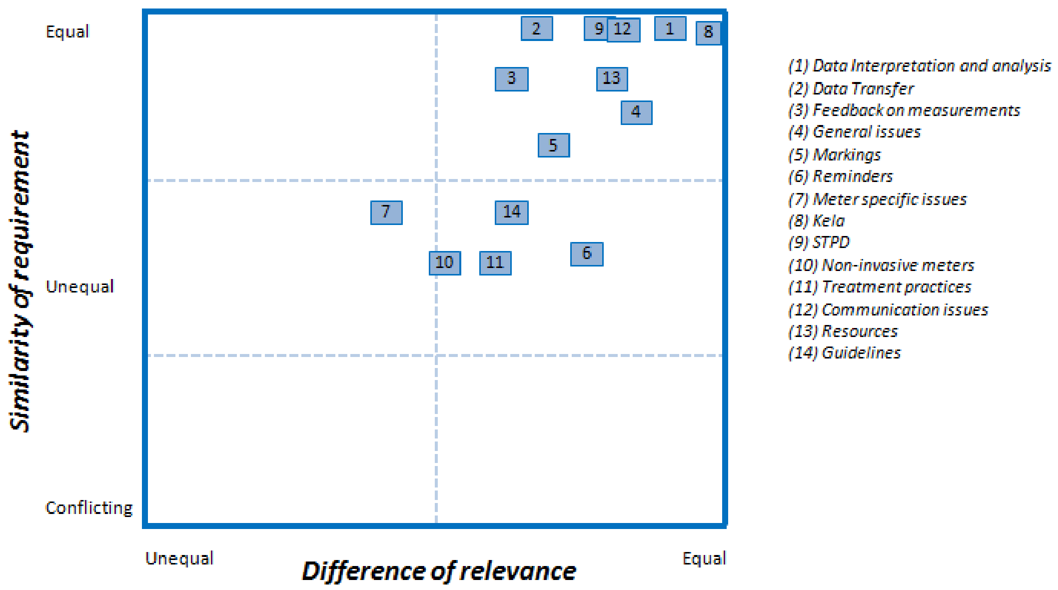

Figure 5.2 Correlations of requirements

The results of the analysis are based on the expert opinion of the author. The results of the analysis on the similarity *of the requirements* between the user groups is more valid than the results of the *difference of relevance* between the user groups. The similarity is determined by the sources of the requirement, i.e. the source(e.g., a doctor) of the problem or other statement that produced the requirement. However, the relative importance of the requirement is based on the author's estimate of the situation, which is based on the interviews. True validity on both of these issues could be acquired by further research; e.g., a questionnaire designed to research these issues on all of the requirements could produce relevant information with fairly little work.

The slightest confliction between requirements is found on the requirements of meters being small and discreet, and the meters having a large screen. Otherwise, no clear conflictions are found. Nine of the fourteen requirement categories are more equal than unequal in terms of similarity. The most unequal requirement categories are meter specific (7, 10) and concern with reminders (6), i.e. diabetics are more affected by these issues than the other groups. Furthermore, the majority of the requirements on guidelines (14) are specific to the patient versions. The treatment practices (11) related requirements affect the nurses more than other groups. The rest of the requirements are more or less equal to all groups.

Moreover, the majority of the requirements are more equally relevant than unequally relevant to the user groups. Only the meter specific requirements (7, 10) are clearly more relevant to the diabetics than other groups. The equality of the relevance is due to the authors' point of view that most of the requirements affect in some way each of the user groups, thus even meter specific requirements are somewhat relevant to doctors and nurses as well.

5.4 Summary / Highlights

A total of 111 requirements were presented in this section, many of which are significantly similar and applicable to a number of services and devices in SMBG. In some cases the requirements were presented separately for different platforms as they receive different priority levels according to which service or device they are applied to. As said earlier, this section does not provide a full set of functional system specifications. The scope of this Thesis is not the generation of system specifications for SMBG devices and services. Rather, this Thesis focuses on unsatisfied user requirements. Additionally, this section focuses on the requirements that surfaced from the interview material. The interviews by nature support the unveiling of unsatisfied requirements. Surprisingly, the majority of the requirements that emerged are functional, suggesting that the current devices do not allow the users to monitor their BG levels as thoroughly as wanted. Although, non-functional requirements emerged as well. Moreover, different research methods might have produced more detailed information of the non-functional requirements. E.g., observation could have shown how BG measurements are currently taken and contextual inquiry[32] could have revealed how the users would want to take BG measurements. A vast majority of the requirements are similar between the doctors, nurses and diabetics.

[32] Contextual inquiry is a sub-method in the contextual design method. Simplified, it combines observation and interviewing; the users are observed while completing actual tasks and questions clarifying the motives, tasks and objectives are asked as they emerge. (Beyer & Holtzblatt, 1999)

6 State-of-the-Art of glucose measurement

This Chapter presents the state-of-the-art of diabetes treatment practices, BG measurement devices, and diabetes related software. Additionally, the service concept of BG measurement in discussed (6.1). The discussion on the treatment practices focuses on the guidelines and practices in Finland (6.2). Both the invasive and non-invasive devices are discussed in Chapter 6.3. Finally, Chapter 6.4 discusses the state-of-the-art of diabetes related software.

6.1 Service concept

This Chapter discusses the service concept in BG measurement. In addition, the business model of the BG measurement industry is discusses. Although the focus of this Thesis is on the Finnish diabetes treatment, parts of the analysis are applicable in other regions as well.

6.1.1 Patient self-treatment product distribution

This Thesis focuses on diabetes treatment in Finland. According to § 24 the Finnish Health Care Act (1326/2010 Terveydenhuoltolaki) the municipalities are responsible for arranging the health care of inhabitants in their regions. According to § 25 of the Health Care Act (1326/2010 Terveydenhuoltolaki) treatment equipment prescribed in treatment plans of chronic illnesses is included in the medical treatment service. Additionally, according to § 5 of the Social and Health Care Client Fees Decree (9.10.1992/912 Asetus sosiaali- ja terveydenhuollon asiakasmaksuista) the treatment equipment is included in the medical treatment service and free of charge. Thus, the municipalities are required by law to provide diabetics with the necessary BG meters, test-strips, lancets, insulin syringes and other equipment needed in diabetes care. Additionally, Kela partially reimburses necessary medicine expenses of the medicine prescribed by doctors to treat an illness as long as the Pharmaceuticals Pricing Board has confirmed that particular medicine to be reimbursable (The Social Insurance Institution of Finland, 2013). The result is that all the necessary expenses for treating diabetes are covered by others than the diabetics themselves. As the focus if this Thesis is on BG measuring rather than on medicinal treatment of diabetes, focus is given on issues affecting BG meters, test-strips and other relating issues.

The Ministry of Social Affairs and Health of Finland has released an information letter in June of 2013 for municipalities concerning the self-treatment product distribution. One key topic of the letter is that self-treatment product distribution should be fitted to the patient's individual requirements and be based on medical professional's assessments. Another key message is that the total costs of patient self-treatment are lower than that of hospital treatment, regardless of increases in self-treatment product distribution costs. One of the interviewees articulated the exact same claim as well. Furthermore, the municipal or other guidelines on product distribution cannot override the individual needs of any patient, thus test-strip needs exceeding the recommendations in the Current Care Guideline on Diabetes should be met (table 6.2 in page 53 provides more information on the recommendations of the guideline). Moreover, regardless of tendering of the self-treatment products, individual needs regarding the hardware should be met. Thus, one can claim that the Ministry of Social Affairs and Health has tackled some of the issues discovered during the research, i.e. the problems and requirements related to STPD. (Ministry of Social Affairs and Healt of Finland, 2013)

6.1.2 Service concept

Currently the most usual combination of products provided by meter manufacturers is comprised of the BG meter, tests-strips, lancing devices, lancets, calibration solvents, and data retrieval software. Often the BG meter and data retrieval software is offered free of charge, at least to diabetics. Analysis of the cost structure of the products provided by meter manufacturers clearly shows that the test-strips provide the most revenue of the products. On average, a BG meter costs 23,2€ for consumers while the average annual costs of BG measurement rises to 1398€ (Chapter 6.3.1). Service costs of meters are likely to be rather low, as the meters themselves are relatively cheap. Moreover, regular tendering of meters can lead to the patients receiving new meters before they malfunction. Thus, the income received from test-strips should cover nearly all of the development costs of SMBG services.

Key stakeholders making decisions on which meters (and more importantly, test-strips) are taken into the STPD are: the municipality's tendering official, the doctors and nurses producing advisory reports for the tendering process, and the operative purchasers. Patients can affect these decisions by complaining on the currently available products. The tendering official responsible for the tendering of medical devices can ask the medical professionals for opinions on the meters available and what should be considered in the tendering process. The purchasers can give their opinions on manufacturers that they have worked with. Additionally, the municipal council makes final decisions on the budget for devices, thus indirectly providing the price-range in which the purchases need to be made.

Other stakeholders related to the service concept of diabetes treatment include the doctors and nurses. The doctors and nurses collaborating with the patients make the final decision on which meter is used in treatment. Although, the diabetics usually have few choices on the meters. Diabetics can either choose to use the meters provided in the self-treatment product distribution, or alternatively pay for the measuring equipment themselves –and pay an average annual cost of 1398 € (table 6.3 in page 54 provides more information of the cost structure of BG meter usage).

Moreover, the software for diabetes management are currently not included in the treatment equipment defined in the legislation. Thus, finding a willing purchaser to pay for these services may prove to be difficult and the costs of developing proper data retrieval software needs to be covered in other payments. Perhaps for that very reason the current software seem to be of poor quality. The purchasing of comprehensive diabetes management software can potentially become even more complex, as the price of such programs could presumably be rather high.

6.2 Treatment practices of diabetes

The Finnish Medical Society Duodecim produces Current Care Guidelines for diabetes, amongst other diseases. All the information is easily available via the Internet to all who are interested in the subject (http://www.kaypahoito.fi/web/kh/suositukset/naytaartikkeli/tunnus/hoi50056). However, some of the information is designed to be used by the medical professionals only (e.g., Finnish Medical Society Duodecim, 2011a), and the versions intended for patients are provided on some topics, e.g., for diabetics (Finnish Medical Society Duodecim, 2011c). In the case of diabetes, the patient version offers significantly less information than the practitioners' version. Hence, the practitioners' version is used to obtain relevant information of the treatment practices of diabetes from doctors' or nurses' point of view in this Thesis.

Treatment of diabetes is rather complicated and can involve use a combination of medication, lifestyle treatment, and other methods. This Thesis focuses on the user requirements of BG measurement. Hence, focus is give to issues related to that in the treatment guidelines.

Diabetes is treated by several methods, out of which lifestyle treatment is mentioned to be essential (Finnish Medical Society Duodecim, 2011a). Lifestyle treatment consists of e.g., loss of weight, increasing physical activity, and diet therapy. Type 2 diabetes can even be prevented by these measures, whereas type 1 diabetes cannot be prevented. (Finnish Medical Society Duodecim, 2011a)

6.2.1 Diabetes treatment guidance

Diabetes treatment guidance is a method to help diabetics to self-manage the illness. The aim is to give diabetics the tools to make their own choices regarding diabetes treatment in their everyday lives. The treatment guidance is continuous and has instructions regarding the order in which the topics need to be covered. Although the guidance is meant to be planned ahead, treatment guidance is tailored for each patient individually and should cover current issues. Table 6.1 presents the issues that should be covered early in the treatment guidance. (Finnish Medical Society Duodecim, 2011b)

Table 6.1 Issues to be covered in treatment guidance upon diagnosis of diabetes (Finnish Medical Society Duodecim, 2011b)

Insulin-treatment	Diet-treatment and orally medicated
Injecting insulin	The importance of treatment regardless the lack of symptoms
SMBG	Diet
Carbohydrate assessment and calculation	The significance of medical treatment
Recognition and treatment of hypoglycemia	SMBG

Treatment guidance is intended to continue throughout the diabetics' lives. The aim is to cover all of the relevant topics during the first year of the illness. Afterwards the focus of the guidance moves to updating information and covering topical issues. Topics that are recommended to be covered in treatment guidance are: (Finnish Medical Society Duodecim, 2011b)

- Diabetes as an illness, complications related to diabetes and treatment of those
- Goals of treatment and means to reach them
- Healthy life habits
- SMBG and utilizing the results of it
- Self-adjustment of insulin treatment in varying situations
- Hypoglycemia
- Chiropody
- Welfare
- Treatment related stress and load (how to recognize it and cope with it)
- Alcohol consumption
- Contraception

6.2.2 Patient self-monitoring of blood glucose (SMBG)

It is recommended for diabetics to measure regularly their BG levels. Generally the most important measurements are so called pair-measurements, i.e., meal and night pair measurements. Each pair measurement consists of two individual BG measurements. The first measurement for a meal pair is taken before eating a meal, the second two hours after eating. A night pair measurement consists of one measurement before going to sleep, the second directly after waking up, before breakfast. The Current Care Guideline on diabetes recommends taking additional measurements in the following cases and situations: (Finnish Medical Society Duodecim, 2011a)

- risk of hypoglycemia
- changes in life conditions (e.g., travel)
- acute illnesses
- medical procedures
- temporary use of medical substances that effect glucose metabolism
- pregnancy and nursing

The treatment guidelines list further cases when BG levels need to be checked, applying to patients who use medication that increases the risk of hypoglycemia: (Finnish Medical Society Duodecim, 2011a)

- when suspecting hypoglycemia
- before using a motorized vehicle
- while performing high-risk tasks
- in exceptional physical stress

The complications induced by hypo- and hyperglycemia are described in page 4. Table 6.2 presents the average glucose measurement needs and test-strip usage in various cases.

Table 6.2 Plasma-glucose measurements and test-strip needs, translated from (Finnish Medical Society Duodecim, 2011a).

	Situation	Objective	Measurements	Objective in terms of blood glucose levels	Test-strips required weekly	Length of measurements
Long term needs	Established type 1 diabetes or complicated type 2 diabetes	Detecting changes in blood-glucose balance	Meal-pair and Night-pair measurements	Rises in glucose levels during meal no more than 2-3 mmol/l, night glucose levels stable	35	permanent
	Established type 2 diabetes (no insulin usage)	Detecting changes in blood-glucose balance	Meal-pair and Night-pair measurements	Rises in glucose levels during meal no more than 2-3 mmol/l, night glucose levels stable	12	permanent
	Established uncomplicated type 2 diabetes (with insulin treatment)	Detecting changes in blood-glucose balance	Meal-pair and Night-pair measurements	Rises in glucose levels during meal no more than 2-3 mmol/l, night glucose levels stable	20	permanent
Temporary additional needs	Fine-tuning of mealtime insulin dose	Determining after-meal hyper- or hypoglycemia	meal-pair measurements	No changes after meal	14	about 4 weeks
	fine-tuning of basic insulin dose	Determining changes in blood glucose levels during the night	night-pair measurements	stays stable through the night	10	about 4 weeks

The American Diabetes Association (ADA) recommendations for SMBG differ from those of the Finnish Medical Society Duodecim slightly. ADA recommends patients on either insulin pump or multiple-dose insulin therapy to measure their BG before meals and snacks, prior to bedtime and exercise, when suspecting low BG, after treating low BG, and prior to critical tasks (American Diabetes Association, 2013). Additionally, ADA recommends postprandial (after meal) measurements occasionally (American Diabetes Association, 2013). In total, this would result in 6-8 daily (or 42-48 weekly) measurements for patients on insulin pump or multiple-dose insulin therapy (American Diabetes Association, 2013), whilst the Finnish measurement practices results in 35 weekly measurements (table 6.2). In contrast to the Finnish Medical Society Duodecim's recommendations, ADA recommends meal-pair measurements occasionally and night-pair measurements are not mentioned at all. Nevertheless, night-pair measurements are taken in practice if the patient takes a pre-breakfast measurement and bedtime measurements.

ADA takes no clear stand on SMBG with type 2 diabetics who are not on insulin therapy. Rather, the paper presents a few researches with contradicting results on the benefits of SMBG with non-insulin treated type 2 diabetics, suggesting that no conclusive evidence of the effectiveness of SMBG in non-insulin treated type 2 diabetics is available. One research suggests small benefits with slight changes (-0,25%) in HbA1c after 6 months of regular SMBG ((Farmer, Perera, Ward, & al., 2012), referenced in (American Diabetes Association, 2013)). Another research presents that the effects of SMBG are small after 6 months and diminish further after 12 months ((Malanda, et al., 2012), referenced in (American Diabetes Association, 2013)). The Current Care Guideline on Diabetes similarly claims that SMBG provides no benefits if the diabetic has had diabetes for over a year, the diabetics HbA_{1c}- value is good and no medication that increases the risk of hypoglycemia is used (Finnish Medical Society Duodecim, 2011a). (American Diabetes Association, 2013)

Both the Current Care Guideline on Diabetes (Finnish Medical Society Duodecim, 2011a) and the interviews suggest that the meal- and night-pair measurements are essential in diabetes treatment, whereas ADA recommends occasional meal-pair measurements (American Diabetes Association, 2013). Table 6.2 is used as a reference for the number of BG measurements in various cases.

6.3 Devices

This chapter presents the results of the state-of-the-art investigation on the BG meters. First, a set of invasive meters are discussed. Second, development projects on non-invasive meters are presented.

6.3.1 Invasive devices

A total of 37 invasive BG meters were included in the research of this thesis. This section discusses some basic features of the meters and the costs of measuring BG. The vast majority of the meters included are marketed in either the EU or USA. More meters are available in these markets, and on the scale of worldwide markets even more meters would emerge. However, 37 meters is considered to provide a sufficient picture of the current supply on invasive BG meters. All information of the meters was acquired from the manufacturers' websites, owner's manuals and brochures. The price information on the meters, test-strips and lancets was gathered from various sources during May of 2013, and doesn't necessarily match the current prices of the products. Moreover, various campaigns and such can deliver the products at significantly lower prices. Furthermore, the Finnish municipalities most likely buy in bulk based on the results of the public tendering process, thus reducing the price they pay for the products. Regardless of the possible inaccuracies in the price comparison, it does enable an understanding of the total costs and cost structure of blood glucose measurement.

Table 6.3 presents the average prices of the meters, test-strips, lancets and annual costs. Price information was not available for all of the meters included in this Thesis, and the average costs and prices are calculated from the available information. The annual usage costs of the devices were calculated by assuming five daily measurements[33], and it includes the price of the device, test-strips, and lancets. It is clear that the sales revenue from the meter itself is irrelevant. The majority of manufacturers' revenue seems to come from the continuous purchases of test-strips and lancets. Lifescan even provides meters free-of-charge for the diabetics (http://www.lifescan.fi/ourproducts/where-to-obtain) (Cilag GmbH International, 2012).

Table 6.3 Average prices of invasive meters, test-strips, and lancets

Meter	(50) Test-strips	(50) Lancets	Annual costs
23,2 €	31,2 €	6,4 €	1398 €

Chapter 4.1 discusses the results of the interviews. Important features of BG meters include (page 19): *(a) discreteness; (b) small size of the meter combined with a large display; (c) ease of use, especially on the go; (d) reliability; (e) good and sturdy test strips; (f) relevant marking options;* and *(g) the ability to add reminders onto the meter.* Investigation of some of these features would require analyzing the physical meters, perhaps even performing some small-scale usability evaluations. Due to the time-constraints of this Thesis, such measures were considered to be too tedious. However, certain aspects of some of the issues can be inspected by other measures, i.e. by inspecting technical information of the meters.

[33] As according to the Current Care Guidelines test-strip needs of established type 1 diabetics and complicated type 2 diabetics (table 6.2, page 53).

Table 6.4 Invasive measurement devices

Manufacturer	Device	Annual usage cost	All-in-one	Screen/ port light	Feedback of blood-sample[34]	Calibration[35]	Meal + other markings	Reminders / day	modifiable BG tresholds	Size[36]	Weight (g)	Other
Abbot Diabetes Care	FreeStyle Lite	1799	no	yes / yes	SV	auto	0	4	no	S	31,2	
	FreeStyle Freedom Lite	1799	no	no / no	SV	auto	0	4	no	S	45,4	
	Precision Xceed	1914	no	yes / -	SV	man.	0	No	no	S	46	ketone monitoring
Bayer HealthCare	Contour	1303	no	no / no	SV	auto	yes + 0	1	yes	M	47,5	
	Contour XT	1303	no	no / no	SV	auto	yes + 0	1	yes	M	47,5	
	Contour Next USB	1332	no	yes / yes	SV	auto	yes + 2	1	yes	XS	11	
	Contour Link	1350	no	no / no	SV	auto	yes + 0	1	yes	L	52,7	link to insulin pumps
	Breeze 2	1303	no	no / no	SV	auyo	0	no	no	XL	102	
ACON Diabetes Care	On Call Plus	1015	no	no /no	S	auto	0	no	no	M	50	slow (10s) test
	On Call Advanced	1088	no	no / no	SV	chip	yes + 0	5	yes	L	66	
	On Call EZ	1015	no	no / no	V	chip	0	no	no	XS	30	small (30) memory, slow (10s) test
	On Call Resolve	**1383**	no	yes / yes	V	auto	yes + 0	5	no	L	52	
	On Call Vivid	**1285**	no	yes / yes	V	auto	yes + 0	5	yes	L	52	
	On Call Xp	**1396**	no	no / no	V	chip	0	no	no	M	50	
iglukos	2in1 smart	**1469**	no	yes / no	V	auto	yes + 1	-	-	XS	12	uses iPhone display
AccuCheck / Roche	Mobile	1541	yes	yes / -	SV	auto	yes + 0	7	yes	XL	150	After meal reminder
	Aviva Nano	1632	no	yes / -	SV	chip	yes + 0	4	yes	S	40	After meal reminder
	Aviva	1632	no	no	SV	chip	no + 1	4	no	M	60	
	Compact plus	1361	yes	yes / no	SV	auto	0	3	yes	XL	147	
	Performa Nano	1284	no	yes / no	SV	chip	yes + 0	4	yes	S	40	After meal reminder
	Performa	1284	no	no	SV	chip	no + 1	4	yes	M	62	
	Advantage	1155	no	no	ST	chip	no + 1	no	yes	M	57	discontinued
	Active	**1396**	no	no	SV	chip	0	no	no	L	57	discontinued
LifeScan, ONeTouch product family	UltraEasy	1371	no	no	T	man.	0	no	no	S	40	
	Vita	1498	no	no	V	auto	yes + 0	no	no	XL	58	
	Ultra2	1389	no	yes / no	T	man.	yes + [illegible]	no	no	L	43	modifiable comments
	Select	1384	no	no	T	man.	yes + 0	no	no	L	52	
	VerioPro	1394	no	yes / yes	VT	auto	yes + 2	no	yes	L	85	detects glucose trends
	VerioIQ	1409	no	yes / yes	VT	auto	yes + 0	no	yes	M	18,7	detects glucose trends
	UltraSmart	1469	no	yes / no	T	man.	yes + 2	no	yes	XL	73,7	discontinued
	Ultra	1409	no	no	T	man.	0	no	no	M	48,2	discontinued in the US
	Horizon	**1396**	no	no	T	man.	no + 1	no	no	S	-	
	SureStep	**2110**	no	no	T	man.	0	no	no	L	108	slow (15-30s) test
Mendor	Discreet	**1296**	yes	yes / no	V	auto	no + 1	no	no	L	28	
Ypsomed	mylife Pura	**1396**	no	yes / -	ST	auto	0	no	no	S	53	
	mylife Unio	**1234**	no	yes / -	T	auto	yes + 3	4	no	XS	-	
	mylife puraX	**1396**	no	yes / -	ST	auto	0	no	no	S	53	

[34] S = sound, V = visual, T = test-strip scale

[35] auto = automatic, man. = manual, chip = code chip

[36] Evaluated in cubic centimeters, dimensions proved to be difficult to compare. XS < 50 cm^3, S = 50…75 cm^3 , M = 75…100 cm^3 , L = 100…150 cm^3 , XL > 150 cm^3

Table 6.4 presents the 37 invasive blood glucose measurement devices with relevant information of the devices. However, it is worth noting that table 6.4 is not intended to be used as a reference for choosing meters. Whether a meter is good for one individual diabetic can be affected by many other issues. Some of the annual usage costs of the meters are in bold typeface. The cost calculations of these meters include at least one price component calculated by taking the average price of that component from the information available on other meters.

Discreteness can be considered to be affected by the size of the meter and other measuring equipment, the speed of the measurement procedure, and the type of interaction while using the meter. Columns *all-in-one, size,* and *weight* can are considered to affect the discreteness of the meter. Specifically, factors *the size of the meter and other equipment* additionally to *the speed of the measurement procedure.* A meter is defined to be *all-in-one* if the test-strips and lancing device is integrated to the meter. The *size* column is naturally used for assessing the sizes of the meters as well, unfortunately only few of the meter manufacturers provided comparable information of the display sizes. Thus, this information is omitted from table 6.4.

Issues that affect the ease of use of the meter are listed in columns *all-in-one, screen/port light, feedback of blood sample size,* and *calibration.* The screen/port light column lists which meters have a backlit screen and which have a lit test-strip port. A backlit screen and port ease the measurement especially in dim conditions. The type of feedback the meter gives on the size of the blood sample can be visual on the test-strip, visual on screen, auditory, or a combination of these. The required amount of blood varies between meters; the majority of the meters require a sample of 0.5µl. The meter needs to be calibrated each time a new batch of test strips is used on it due to the measurement technology. Calibration removes inaccuracies in measurements resulting from variation in test-strip quality. The calibration can be automatic, require manual entry of a sequence of numbers, or it can involve inserting a small code chip into the meter.

The relevancy of the different marking options highly subjective to the diabetic's personal preferences, lifestyle and treatment. However, meal-marking is universally relevant amongst all diabetics. *Meal-marking + other marking options* column lists whether the meter has meal marking options or other making options. Note that possible other markings can be used for meal-markings if no designated meal marking option is available.

Reminders were considered to be important as well, and it is listed in the reminders/day column. The reliability of the meters is not discussed in this section, neither is the test-strip quality. These issues are not researched as they would have required substantial efforts and the resources available did not allow these efforts. Reminders are available in 16 out of the 37 meters evaluated. Designated meal-marking options are included in 18 of the meters. By including the meters with some other marking options the number rises to 22. 13 meters had a reminder feature and some marking option. The amount of reminders and marking options that are found varies from 1 to 13.

Out of the meters included in table 6.4 only three can be considered to be *all-in-one* type. Out of these, only Mendors' Discreet is clearly designed to be all-in-one. Others can be described to have the lancing device "glued on", as shown in fig. 6.1. In addition, Bayer HealthCare Breeze2 has a test-strip cartridge of 10 strips, but as it lacks an integrated lancing system. Out of the meters shown below, only Accu-Check Mobile has a lancet cartridge. The use of the other two meters requires loading lancets more often.

18 of the meters presented in table 6.4 have backlit screens, out of which only six have a test port light. All of the meters provide some feedback when enough blood is drawn, 29 of the meters inform when enough blood is drawn by other means than the test-strip scale. Calibration is fully automatic in 19 of the meters, code chips are used in ten meters, and completely manual calibration is required in eight meters. 15 of the meters provide some means for the modification of glucose thresholds.

Figure 6.1 All-in-one meters (from left): Mendor Discreet[37], Accu-Check Compact Plus[38], Accu-Check Mobile[39]. Not in scale.

Out of the 37 meters, only four[40] have both port and screen lights, provide easy blood-sample size feedback, and have automatic calibration and modifiable glucose thresholds. The annual costs of these meters are between 1285 € and 1489 €, which is rather close to the average costs of the meters. None of these meters are all-in-one, but two of have reminders and marking options (shown in fig. 6.2). They differ in portability and screen size, where Bayer's' Contour Next USB is more portable and ACON Diabetes Care's On Call Vivid has a larger (thus more easy to read results) screen.

Figure 6.2 Meters with most features (from left): On Call Vivid[41], Bayer Countour Next USB[42], not in scale

In conclusion, it is obvious that a vast majority of the meters do not meet the requirements presented in Chapter 4.1 in page 19 and in table 5.1 in page 35. However, many of the meters meet some of the requirements. This is not to say that On Call Vivid or Contour Next USB are the best meters available for all diabetics. It is important to note that different users benefit from different features and qualities in a BG meter. Thus, the buying decision is based on issues that may include some of the requirements elicited in this Thesis in addition to other issues.

[37] Image source: http://darmedical.ru/d/143498/d//mendor_discreet_black.png

[38] Image source: https://images.accu-chek.com/images/products/metersystems/compactplusgt/nbg_compactplusgt_face_mg_l.png

[39] Image source: https://images.accu-chek.com/images/products/metersystems/mobilelcm/mobile-LCM_l.png

[40] Contour Next USB, On Call Vivid, OneTouch VerioPro, OneTouch VerioIQ

[41] Image source: http://www.aconlabs.com/images/ocv.jpg

[42] Image source: http://www.digas.gr/images/thumbs/20130308152647641538900Contor%20Next%20USB%20frontal.jpg

6.3.2 Minimally an non-invasive device

During the research of this Thesis, a total of 31 attempts on creating non-invasive or minimally invasive meters and monitors were discovered from reliable sources. The inclusion of unverified references of companies developing non-invasive meters would increase the number even higher. However, it is extremely difficult to find comprehensive information even of the meters that are included in this Thesis. Thus, the more unreliable sources (lacking good quality information) for non-invasive technologies were omitted.

Out of the 31 references to non-invasive meters, 17 are either actively developed or currently sold in some regions. Table 6.5 presents the 17 active non-invasive or minimally invasive meter projects and relevant information about them. Comprehensive information of all of the meters was not found, probably due to the early development stage of the meters. Either the companies are reluctant to give detailed information of the meter, or they cannot yet provide information on certain details (e.g., if they do not know yet whether calibration is required).

Out of the 17 meters presented in table 6.5, four either already have a CE approval or expect to receive it during 2013. Seven of the 17 meters are either conducting or starting clinical trials, the rest are a bit further away from production. Only one of the meters is currently available in some markets (TensorTip, sold only to type 2 diabetics). Apart from 2 minimally invasive exceptions (Symphony CGM and Senseonics), all of the meters are non-invasive. NIR is the most popular technology (7 meters) and Raman Spectrometry is next with 3 meters. Nine of the meters can be used for CGM, out of which three can be used for spot measurements. Four of the meters can be used only for spot measurements, while five of the meters are designed only for continuous measurement. Test areas include abdomen, fingertip, earlobe, arm and eye, the selection of the test area does not seem to correlate with any of the other properties of the meters. Out of the 17 meters, 13 are designed to be portable, and thus may (at least partly) replace the need for the traditional invasive SMBG devices.

In addition to the 17 devices that are actively developed, the research revealed 14 attempts to develop non-invasive meters. Nevertheless, these remaining 14 meters have been either discontinued or their development has been cancelled in the past. A list of these attempts on non-invasive meters is provided in Appendix C.

Tura et al. investigated the subject of non-invasive technologies and meters in 2006 (Tura;Maran;& Pacini, 2007). They found in total 16 references to development projects in non-invasive meters. Out of these 16 projects only three are currently developed (GlukoTrack, NBM, and Symphony CGM). Sontra Medical that originally developed the Symphony system merged with Echo Therapeutics Inc. in 2007 (Echo Therapeutics Inc., 2007). Interestingly, all of the three projects mentioned above use different techniques for glucose measurement (table 6.5).

Some of the devices listed by Tura et al. (2007) have been sold but discontinued later. GlucoWatch was sold for five years until Animas Corporation decided to stop sales in July of 2007. GlucoWatch was a wearable wristband that used reverse ionthophoresis for glucose measurement. GlucoWatch encountered numerous problems related to accuracy and performance, particularly when users sweated. (The Diabetes Mall, 2007)

Pendra by Pendragon Medical Ltd. used bio-impedance spectrometry for extracting blood glucose values. Pendra was a wearable wristband (as GlucoWatch), and was discontinued in 2005 due to performance issues. DiaSensor by BICO Inc. was a rather large device that used NIR spectrometry. It was sold in Europe in the turn of the 21st century. However, no company website is available or any other evidence that would support active sales of the product presently. (Tura;Maran;& Pacini, 2007)

The rest of the meter projects presented by Tura et al. had neither FDA nor CE approvals during the study, and more recent information of the projects was not found. Out of the ten remaining meters four were based on NIR spectrometry and two on reverse ionthophoresis. The remaining four companies developed meters based on photoacoustic spectrometry, thermal spectrometry, interstitial fluid extraction, and bio-impedance spectrometry. (Tura;Maran;& Pacini, 2007)

Table 6.5 Actively developed minimally and non-invasive glucose meters

Product / manufacturer	Approvals / status	Invasiveness	Technology	Readings	Test site	Portability	Calibration	Other	Source
C8MediSensor / C8MediSensors	CE mark	Non-invasive	Raman Spectromentry	Continuous	Abdomen	Yes	Periodic baseline measurements	Causes mild skin irritation. Web-site down. Apparently company has ran into some difficulties and the meter is not sold anymore.	(C8MediSensors, 2013)
TensorTip / Cnoga Medical	CE mark	Non-invasive	NIR	Spot & continuous	Fingertip	Yes	Initial 2 week calibration period	Price 1500 $, sold to type 2 diabetics only. Continuous reading only 10 min at a time	(Cnoga Medical Ltd., 2013)
NBM (Noninvasive blood monitor) / OrSense Ltd	CE mark	Non-invasive	Occlusion Spectrometry (patented NIR)	Continuous	Fingers root	Yes	No	Not sold yet. 30s lag time in reading	(Orsense Ltd., 2013)
GlukoTrack / Integrity Applications	CE mark	Non-invasive	Ultrasonic, thermal, electromagnetic	Spot & continuous	Earlobe	Yes	once a month, takes 1.5 h	-	(Integrity Applications Ltd., 2013)
Symphony CGM / EchoTherapeutix	Clinical Trials	Minimally invasive	Dead skin thermal ablation	Continuous	Abdomen	Yes	-	Targets hospital usage first	(Echo Therapeutix, 2013)
Glukometer / Grove Instruents	Clinical Trials	Non-invasive	NIR (with patented optical bridge)	Spot	Fingertip / earlobe	Yes	-	20s to get reading	(Grove Instruments Inc., 2013)
MD-Watch / BioImpedance General Ltd	Starting clinical trials	Non-invasive	Bio-impedance	Continuous	Wrist	Yes	-	-	(Big Bio-Impedance General Ltd., 2013)
Diramed	Prototyping / clinical trials	Non-invasive	Raman Spectromentry	-	-	Development in progress	-	Seems like for the moment prototypes only for hospital equipment	(DIRAmed Llc., 2013)
NBCM / LightTouch Medical Inc	-	Non-invasive	Raman Spectromentry	Spot	Fingertip	No	No	3 min to get reading	(LightTouch Medical Inc., 2013)
Senseonics Inc	Clinical Trials	Minimally invasive	Fluorescent glucose chemistry / interstitial fluids	Continuous	Upper arm / abdomen	Yes	-	Implantable sensor, lasts for six months. Smartphone display for readings	(Senseonics Inc., 2013)
I-SugarX / Freedom Meditech Inc	Investigational device	Non-invasive	NIR	Spot	Eye	Yes	-	-	(Freedom Meditech Inc., 2013)
St. Louis Medical Devices, Inc.	Investigational device	Non-invasive	NIR	-	Finger	-	-	Developed in University of Missouri	(The Curators of the University of Missouri, 2012)
Photonic Glucose Sensor (PGS) / Cybiocare	Clinical Trials	Non-invasive	NIR	Continuous	Upper arm	Yes	Daily	Measurements every 5 min	(CYBIOCARE, 2010)
Quantum Catch	Active development	Non-invasive	NIR	Spot	Eye	Yes	-	10 s measurement time	(Quantum Catch Llc., 2013)
Eyesense	Planned product launch in 2014	Non-invasive	Autofluorescence	Spot & continuous	eye	Yes	-	20 s measurement time. Implantable sensor to the eye.	(Eyesense GmbH., 2013)
Lein Apllied Diagnostics	Active development	Non-invasive	-	-	eye	Yes	-	-	(Lein Applied Diagnostics Ltd., 2013)
Apex Biotechnology Corp.	Active development	Non-invasive	-	-	-	-	-	-	(Apex Biotechnology Corp., 2010)

In conclusion, nearly all of the theoretically available technologies for producing non-invasive blood glucose meters have been tried in practice. At the moment not one of the attempts on non-invasive meters has proved to be commercially viable, although continuous development is made on many projects. The meters that have received either some approval or are performing clinical trials can be considered to be further in the development than the other meters. The meters with CE mark all use different technologies. At the moment only one meter available for purchase (TensorTip by Cnoga Medical), C8MediSensor was marketed for a few months and the company seems to have gone bankrupt[43].

6.4 Software

This Chapter presents the state-of-the-art in diabetes related software. The software included are *data retrieval and analysis software* and *mobile diabetes management applications.* Additionally to these software, web-based BG management services are available, some of which are included in the section as they have mobile versions of the service.

6.4.1 Data retrieval and analysis software

Although the meters for BG measurement without any exceptions include a display for reviewing the measurement results, they are not the primary means of browsing and analyzing measurement data. Many BG meter manufacturers provide software for downloading measurement data from their meters. These same software often provide means for analyzing that data as well. Regardless of this opportunity, the traditional paperback notebook remains as the prevalent tool for storing and analyzing measurement data. The interviews suggested possible reasons for the rather small adoption of the software; they were commented to be hard to use and that they had an unfinished feel to them.

Table 6.6 shows a short comparison of seven of the available software for downloading and analyzing measurement data from BG meters. All the information of the software was gathered from the manufacturers' software website or user manuals when available (during August of 2013). Five main qualities were selected to table 6.6. The selected qualities support the type of use that is wished from the software by the users. Mobile applications may increase the use of the software (software requirement 10. *Diabetes management software should be available on all platforms*, page 42). The ability to import from a variety of meters may increase adoption by practitioners. Importing from a file may provide a workaround method for that issue, and it is one of the requirements listed in table 5.4 in page 45. Markings are mandatory to categorize the results, the specific marking options selected to table 6.6 seemed to be the most important ones (table 5.4). The software provide a variety of printable reports, the features selected to the table reflect the results of the user requirements analysis (table 5.4). Finally, the communication section shows whether the software supports information flow from the doctor to the patient and vice versa (requirement no. 3 in table 5.2). The information flow may be as simple as the doctor having access to the patients' measurement results, or the doctor having the ability to comment on the results. As with table 6.4, table 6.6 below is not intended to provide a comprehensive comparison of the software to help with choosing which software would suit which user. Rather, table 6.6 is intended to act as a visualization of the current supply in diabetes management software.

Table 6.6 shows the differences between the seven investigated software. Sinovo's SiDiary has more features than the other software in the comparison. This may be due to the fact that Sinovo is a software manufacturer that does not produce meters. Hence, Sinovo can specialize in software development , while the others develop hardware as well. Mendor along with Sinovo provides support to multiple manufacturers devices, a feature that allows the medical staff to learn the use only one program in BG management.

[43] The company website was no longer available on the 31st of October 2013, suggesting that yet another attempt on commercializing a non-invasive meter has failed. The most resent rumor found of the subject is that the company ran into financial difficulties (http://www.everydayupsanddowns.co.uk/2013/06/has-light-gone-out-on-c8-medisensors.html, last accessed in 12th of November 2013).

Table 6.6 Software for downloading and analyzing measurement data

	Manufacturer - Software	Abbot Diabetes Care - Copilot/Freestyle AutoAssist	Bayer HealthCare - Glucofacts Deluxe	Acon DiabetesCare - On Call Diabetes management software	AccuChek - Smartpix	LifeScan - OneTouch Diabetes Management Software	Mendor - Balance	Sinovo - SiDiary
	Mobile Application	no	no	no	no	no	no	yes
	Import from other manufacturers devices	no	no	no	no	no	yes	yes
	Import from file	yes	no	no	no	no	no	-
Markings / data entry	**meal-pair**	yes	yes	yes	yes	yes	yes	yes
	night-pair	yes	yes	yes	no	no	yes	yes
	excersice	yes	no	no	yes	yes	no	yes
	comment	yes	yes	no	yes	yes	no	yes
	medication	yes	no	no	yes	yes	no	yes
	lab-test	yes	no	no	no	no	no	no
	insulin	yes	no	no	yes	no	yes	yes
	carb	yes	no	no	no	no	no	-
Reports	**logbook / diary**	yes	yes	yes	yes	yes	yes	yes
	graphs	yes	yes	yes	yes	yes	yes	yes
	trendlines	no	no	yes	no	no	yes	-
	statistics	yes	yes	yes	yes	yes	yes	yes
Communication	**Doctor->patient**	yes	no	no	no	no	no	no
	Patient->doctor	yes	no	no	no	no	yes	yes

The practitioners focus on meal and night-pair measurements, hence these are the most important markings from their point of view. Only AccuCheck and LifeScan do not provide a designated marking option for night-pair measurements. Meal-pair measurement markings are in all the investigated software. The patients seemed to value most the free commenting option, which is available in all but Abbot Diabetes Care's and Mendor's software. The rest of the marking options have the next priority level, and are useful in showing the amount of features in the software.

The software provided a multitude of printable reports. Different manufacturers used different names for similar report types, the ones listed above are the most commonly sought after according to the interviews and the user requirements analysis. A Logbook/Diary form of report does not differ significantly from the traditional paperback notebook format, and it is available in all of the software. The use of charts and graphs divided opinions during the interviews; most seemed to find them useful but no consensus was found on the type of graph that would the best. All of the software provided a variety of graphs to be printed and analyzed. The statistics report typically includes at least the amount of measurements, average result, standard deviation, and the percentage of measurements that were in the defined target range (e.g., between 4 and 15 mmol/l). The dataset included in the statistics was software specific and all of the software provided some type of statistics in the reports.

Abbot Diabetes Care's products' options for communication channels are rather versatile, enabling even data sharing between health care professionals in addition to data sharing between doctors and patients, and vice versa. Mendor and Sinovo enable data sharing from the patient to the doctors.

One important aspect of the products is not included in this comparison. The interviews suggested that the currently available software is not used due to the poor usability of the products (Chapter 4.1, page 19). Performing a usability evaluation on all the seven included software would have been too time-consuming. Moreover, the interviews suggested that usability is a major issue with all of the products that the subjects had encountered. Thus, the usability evaluation is omitted. Nevertheless, one can generalize that the more features any product or service includes, the more challenging achieving good usability becomes. Table 6.6 lists only the most common features of the software investigated.

6.4.2 Mobile Diabetes Management applications

The interview results suggest that awareness of diabetes management applications is rather low. However, the need for all-inclusive application or software to help with diabetes management is present (e.g., table 5.2 and table 6.9). During the interviews rumors about software development of such services were heard. Unfortunately, follow-ups on these rumors yielded no results and detailed information of the development cannot be revealed. Nonetheless, there are some available applications attempting to answer to the need of a comprehensive diabetes management application. The results of the interviews clearly show that such software should operate on a mobile platform. Therefore, mobile diabetes management applications currently available are discussed in this section.

There is a multitude of diabetes-related software available for different devices. Searching "diabetes" (on the 25th of April 2013) in GooglePlay service – used by mobiles with the Android operating system – yielded over 2000 results. Comprehensive diabetes management applications need to have functionalities to analyze BG levels. Thus, this section focuses on mobile applications that allow storing of BG test results. Three of the most popular mobile platforms are included in this research; Android, iPhone, and Windows Phone. Google Play (for Android, https://play.google.com/store), Markets (http://www.windowsphone.com/en-us/store/overview) and iTunes (http://www.apple.com/itunes/, for iPhone) were used for searching applications for this part of the research. These services were searched with the phrase *"diabetes log"* on the 25th of April 2013. Ten of the most popular results were included in the research. Information available on either the applications website or the information sheet provided in the platforms service were used to create a view of the currently available mobile services in the area of diabetes management. Table 6.8 presents the most relevant information used in the analysis. It is important to note that this section does not take any position on which application would be the best available. The main aim is to provide an overview of the currently available software, enabling evaluation of whether there are any applications answering – if even remotely – to the requirements related to this subject. Moreover, development of mobile applications is by nature extremely fast-paced and more comprehensive applications may be available by the time this Thesis is published. Moreover, the applications listed in table 6.8 may have new versions released with significant improvements.

Chapters 4.1 and 5.2.2 listed problems and requirements related to applications amongst other issues. Covering all of the requirements related to diabetes management applications in table 6.8 is deemed to be unnecessary. Focus is give to the requirements that at least one of the applications addresses. From Chapter 4.1 the inclusion of various counters (e.g. carbohydrate or insulin counters) is listed in the table. As suggested by table 4.7 in Chapter 4.2 (page 28), table 6.8 evaluates whether the applications address the need for aiding with lifestyle treatment and whether they provide a comprehensive service. Table 5.3 presents a comprehensive list of requirements that are related to applications. Out of these the inclusion of *reminders, relevant marking options, supporting of data analysis,* and *exporting* features are discussed. Additionally, two columns superficially discuss the general requirement of ease of use of the applications. Table 6.7presents a summary of the topics covered in this section.

Table 6.7 Issues covered in diabetes management application analysis

Issue	Columns in table 6.8 addressing the issue
Carbohydrate counters etc.	Other (other)
Lifestyle treatment aids	Tracking (weight, exercise, pulse)
Comprehensiveness of the application	All
Need for reminders	Other (reminders)
Relevancy of markings	Tracking
Support of analysis	Analysis
Exporting features	Other (exporting, report printing, sharing)
Ease of use	Input method, online sync.

Before presenting the summary of the contents of table 6.8 it is important to note that there are a few weaknesses with the information on the table. First, all the information on the table was gathered via Internet sources during July of 2013, i.e. developer websites and marketplace information sheets. Not one of the applications was evaluated physically by the author. The information available on the web-sources is rather scarce and some applications may include features that the table does not list on them. Moreover, application development is extremely fast-paced and new releases may result in some information on table 6.8 being outdated. Nevertheless, table 6.8 provides means for analyzing the current supply on diabetes management applications.

Only three of the applications in table 6.8 enable other than manual data entry which affects the ease of use of the application. However, manually adding data in the application is significantly more convenient than it would be in the data retrieval and analysis software discussed in Chapter 6.4.1. The mobile application is accessible to the user practically all the time, as mobile phones are usually accessible whenever a measurement is made. Thus, manual data entry can be done simultaneously to the measurement. Regardless, automatic data transfer – ideally continuous as discussed earlier the meter requirements section in page 39 – would simplify the use of the application. However, 13 of the applications transfer the data automatically to an online server, 5 of them for backup. 7 of the applications that automatically transfer data into an online server can be used on another platform as well (tablet, web, or PC), suggesting that the data is automatically uploaded to these other devices and interfaces as well.

All of the applications enable tracking of BG and carbohydrates. Weight can be tracked in 13 applications and exercise in 17, supporting lifestyle treatment. Medication usage (at least insulin) can be tracked in 23 of the applications, BP in 12 and HbA1C in 7 of the applications. All of the applications that can track HbA1C can track BP and medication as well, providing comprehensiveness in terms of medical tracking. 17 of the applications enable some type of exercise tracking[44], weight tracking is possible in 13 of the applications. 5 of the applications enabled both these tracking features and additionally tracking of pulse. However, not a single one of the applications had an integrated exercise tracker similar to, e.g., Sports Tracker[45]. The exercise tracker applications commonly use the smart-phones GPS feature and some can even be connected to a pulse meter providing a comprehensive service for analyzing exercises. This type of a feature was wished in diabetes management equipment (e.g., page 25).

9 of the applications supported the use of reminders. Most of the applications seemed to provide tools for analyzing the data included in the application (graphs in 22, logbooks in 21, and statistics in 16). Definitive information supporting this claim was not found on the rest of the applications. However, it is likely that those applications provide some mean of analysis as well.

11 of the applications provided some additional features adding to the comprehensiveness of the service. 14 of the applications enabled data sharing by email, 5 with a server based approach, and 1 on social media. Only 5 of the applications provided no means for exporting the data out of the application, i.e. printable reports, or exporting the data via email, or into a tabulated format.

[44] At least input of exercise information into BG measurements

[45]http://www.sports-tracker.com/, website accessed on the 30th of October 2013

Table 6.8 Diabetes management applications

Software name	General			Tracking[47]						Analysis			Other				
	Input method	Online sync	Platforms	Pulse	BP	Medication	Weight	hbA1C	Exercise	Graphs	Logbook	Statistics	Reminders	Other[46]	Sharing	Eporting	Reports
Glucool Diabetes Premium	man.	yes	mobile	no	yes	yes	yes	yes	yes	yes	-	yes	yes	IDE	email	yes	yes
OnTrack Diabetes	man.	yes	mobile	yes	yes	yes	yes	-	yes	yes	yes	-	yes		-	yes	yes
Glucose Buddy	man.	yes	mobile / PC	no	yes	yes	yes	yes	yes	yes	yes	yes	yes		no	yes	yes
Track3 Diabetes Planner	man.	no	mobile	no	no	yes	no	no	yes	yes	yes	yes	no	ND, CC	email	yes	yes
HelpDiabetes	man.	no	mobile	no	no	yes	no	no	yes	-	yes	-	no	ND, IDE, CC	no	yes	no
Sugar log	man.	no	mobile	no	no	no	no	no	no	yes	yes	yes	no		no	no	no
SiDiary Diabetes Management	man. / auto	yes	mobile / PC	no	yes	yes	yes	no	yes	yes	yes	yes	no		no	yes	yes
Diabetes Log	man.	no	mobile	yes	yes	yes	yes	yes	yes	-	yes	-	no		email	yes	yes
dbees.com Diabetes Management	man.	yes	mobile / PC / web	yes	yes	yes	yes	yes	esy	yes	yes	yes	yes	CC	realtime, server	yes	yes
Diabetes UK Tracker	man.	no	mobile	no	yes	yes	yes	yes	no	yes	yes	yes	no		email	yes	yes
Diabetes Manager	man.	no	mobile	no	no	no	no	no	no	-	-	-	no		email	yes	no
Diabetes log book	man.	no	mobile	no	no	yes	no	no	yes	-	yes	yes	no		no	no	no
DiaLog - Diabetes Log	man.	no	mobile	no	no	yes	no	no	yes	yes	yes	yes	no		email	no	yes
DiaCheck	man.	no	mobile	no	yes	yes	yes	no	no	-	-	-	no	ND, CC	no	no	no
Glucose Tracker Plus	man.	yes	mobile	no	no	no	no	no	no	yes	yes	-	yes		server	yes	yes
VitalCheck	man. / bluetooth	yes	mobile / web	yes	yes	yes	yes	no	yes	-	-	-	no	ND, CC	no	yes	yes
Diabetes Diary	man.	no	mobile	no	no	no	no	no	no	yes	yes	yes	no		email	yes	yes
Glukobook	man.	yes	mobile / web	no	no	yes	no	no	yes	yes	yes	-	no		realtime, server	yes	yes
Glucotracker	man.	no	mobile	no	no	yes	no	no	no	yes	yes	yes	no		no	no	no
TrackMyDiabetes	man.	yes	mobile	no	no	yes	no	no	yes	yes	yes	-	no		email	yes	no
TactioHealth	man.	yes	mobile / tablet	yes	yes	no	yes	no	yes	yes	-	yes	no	ND	email	yes	yes
Diabetes Log	man.	no	mobile	no	no	yes	no	no	no	-	-	-	no		email	yes	no
Glooko Logbook	man. / auto	yes	mobile	no	no	yes	no	no	no	yes	yes	yes	no	ND, CC	email	yes	yes
Diabetes In Check	man.	no	mobile / tablet	no	no	yes	no	no	yes	yes	-	-	yes	ND, CC	not specified	yes	yes
Diabetes:360	man.	no	mobile	no	no	yes	no	no	yes	yes	yes	yes	yes	ND, IDE, CC	server	yes	yes
Glucose Tracker	man.	no	mobile	no	no	yes	no	no	no	yes	-	yes	no	ND	no	no	no
LogFrog DB	man.	yes	mobile	no	yes	yes	yes	yes	yes	yes	yes	-	yes		no	yes	yes
Glucose Companion Free	man.	no	mobile	no	no	no	yes	no	no	yes	yes	yes	yes		email	yes	yes
Diabetes+	man.	no	mobile	no	yes	yes	yes	yes	no	-	-	-	no		email	yes	yes
GlucoSweet	man.	yes	mobile / tablet	no	no	no	no	no	no	yes	yes	-	no		email, server	yes	yes

46 Additionally to the tracking features listed all applications enable tracking of BG and carbohydrate intake

47 ND = Nutritional Database, IDE = Insulin Dose Estimator, CC = Carbohydrate Counter

The most comprehensive service is provided by '*dbees.com Diabetes Management',* which addresses all of the issues discussed in the four paragraphs above. The least comprehensive services were *Sugar log, Diabetes Manager* and *Glucose Tracker.* The rest of the applications covered some of the areas discussed above, while leaving other areas with less focus. However, it is worth repeating that the research on these applications merely scratched the surface and the results drawn here are not conclusive. Moreover, some might value the simplistic design and ease of use more than the comprehensiveness of the features included in the application. Nevertheless, one conclusion can safely be made; the research suggests that no applications covering all the requirements presented in Chapter 5.2.2 are available at the moment.

6.5 State-of-the-art versus user requirements

Chapter 4 presents the interview results and more importantly, the problems with current devices, services and practices. These problems and other interview results were transformed into user requirements for SMBG devices (5.2.1), services (5.2.2), and practices (5.2.3). The state-of-the-art of SMBG devices (6.3), services (6.4), and practices (6.1 and 6.2) is presented as well. This chapter presents a comparison of the state-of-the-art and user requirements in SMBG devices, software and treatment guidelines and practices. Summaries of the key user requirements on SMBG are provided to enable the comparison.

6.5.1 SMBG devices and software

Table 6.9 presents a summary of the user requirements on SMBG devices and software. The requirements are organized according to the issue that they are related to. Separate priority levels are given for meter based, application based, and data retrieval software based solutions where applicable. The column *current solutions* comments on the state-of-the-art of BG measurement devices and services regarding that specific requirement. Current *meters,* data retrieval *software,* or *applications* can provide a solution to the requirement. The use of brackets specifies whether a partial solution is available, or if the solution is provided by only some of the meters, applications of software. In other words, the lack of brackets means that a full solution to that requirement is commonly adopted in current meters, software or applications. E.g., in need no. 1 *(meter)* means that current meters partially assist interpreting measurement results, i.e. the results can be browsed on the meters and some summary reports are available. The word *software* without brackets means that most of the current data retrieval software assists with the interpretation of measurement results. The priority columns show the authors opinion on how important the need is in various solution platforms. By using the categorization of requirements in table 6.9, some conclusions of the state-of-the-art of BG meters and SMBG software, and the user requirements in the current solutions can be made. Next, the state-of-the-art and user requirements are discussed device and service specifically.

Meters

In terms of BG measurement data *interpretation and analysis* the currently available meters do not meet the requirements. The only means for interpretation and analysis are browsing of measurement results and retrieving a summary report of the measurements from the meter memory. *Data Transfer* requirements are not met at all. The measurement data is transferred wirelessly and requires significant efforts. The *Feedback* requirements are barely or partially met. Most of the current meters provide a feature that shows whether the BG measurement taken is in target range or not and whether the size of the blood sample is large enough, other type of feedback was not encountered in this Thesis. Regarding the *General* requirements, the meters are evolving towards more discreet, faster and effortless measurement. All-in-one meters can be claimed to be the closest of meeting these requirements. The *Marking* requirements are not really met. Although, the relevancy of the marking options is often patient specific, thus the ability to modify the marking options would be extremely useful. Some of the meters provide options to make *Reminders* for measurements. Even rudimentary programmable measurement reminders were encountered in some meters. Only some of the meters provided features that meet some of

Table 6.9 Summary of the user requirements for SMBG devices and software

			Priority			
		Need	Meter	Apps.	Ret. software	Current solutions
Interpretation and analysis	1	*The solution needs to assist diabetics with interpretation of BG measurement results.*	2	3	4	(meter), software
	2	*The solution needs to support analysis of measurement data.*	1	2	4	software, (apps.)
	3	*The solution needs to have a BG target range feature in terms of sugar amplitude.*	2	2	3	-
	4	*The solution needs to refine measurement data into useful charts and graphs.*	1	3	4	(software), (apps.)
	5	*The solution needs to automatically search and detect trends in BG behavior.*	1	2	3	-
Data Transfer	6	*The solution needs to be automatically linked to other services.*	2	3	3	(apps.)
	7	*The solution needs to provide communication between doctors and patients and other stakeholders.*	-	1	1	(software)
Feedback	8	*The solution needs to provide feedback on measurements.*	3	3	2	(meter)
	9	*The feedback should motivate users with their measurements and treatment.*	3	3	3	-
	10	*The solution needs to detect problems in BG balance and warn about it.*	2	2	2	-
	11	*The solution needs to warn users if consistent high or low BG values are detected.*	3	3	2	-
	12	*The solution needs to clearly and visually alarm when high or low BG is detected.*	2	2	2	meter
	13	*The solution needs to warn the user when overcorrection with insulin is suspected.*	2	2	-	-
	14	*The solution needs to advice patients to seek help if poor BG balance is detected.*	1	2	3	-
General	15	*The functionalities of the solution need to be intuitive.*	3	3	3	-
	16	*The solution needs to be fast and effortless to use.*	3	3	3	(meter)
	17	*The solution needs to assist diabetics with measurement practices.*	1	1	2	-
	18	*The solution needs to have integrated applications helping with lifestyle treatment.*	1	3	2	(apps.)
	19	*The solution needs to function on multiple platforms.*	1	2	2	(apps.)
	20	*The solution needs to be customizable.*	2	3	2	(apps.), (software)
	21	*The solution needs to be comprehensive and regard several aspects of SMBG.*	1	3	2	(apps)
Markings	22	*Measurement marking options need to be relevant.*	3	3	3	(apps.), (meter), (software)
	23	*Measurement marking options need to be modifiable by users.*	2	2	3	(apps.), (software)
	24	*The solution needs to automatically suggest relevant marking options on measurements.*	1	2	2	-
	25	*The solution needs to learn the user's measurement and marking routines and suggest relevant markings.*	1	2	2	-
Reminders	26	*The solution needs remind users to measure.*	3	3	1	(meters), (apps.)
	27	*The solution needs programmable measurement schedules.*	2	2	-	-
	28	*The solution needs to remind diabetics to inject meal-insulin.*	2	2	-	-
Meter specific	29	*Meters should have large displays with nightlight.*	3	-	-	(meter)
	30	*Meters should be more discreet.*	3	-	-	(meter)
	31	*Meters should be more accurate.*	2	-	-	-
	34	*Meters could have a smart-phone-like ecosystem.*	1	-	-	-

the *Meter specific* requirements. That is, some of the meters provided backlit displays and some of the meters can be claimed to be discreet. Although more accurate meters can affect the used insulin dosage, there is no clinical proof that better accuracy would better treatment results (Heinemann, Lodwig, & Freckmann, 2012).

Data Retrieval Software

The current data retrieval software provide some features that meet the requirements of BG measurement data *interpretation and analysis.* More focus should be given on the type of graphs and charts presented in the software. Additionally, intelligent automation of the analysis (e.g., searching of trends) would be useful, especially for diabetics who haven't yet acquired the knowledge and skills for proper interpretation of BG measurement results. Only two of the software in this Thesis provided some type of *data transfer* between doctors and patients, thus partially meeting the requirement of supporting communication between different stakeholders. The software provide no *feedback* on BG measurement results. Only some of the software enable rudimentary customization. The *Markings* in the software are somewhat modifiable in some of the software, thus partially meeting the requirement for relevancy. Currently the link between software and meters is only one way, thus any measurement reminders cannot be planned and made on the software.

Applications

The current diabetes management applications provide some basic tools for *interpretation and analysis* of BG measurement results, i.e. a partial solution to the need. *Data Transfer* is automatic to some extent in a handful of the applications, although truly automatic data transfer between meters and applications – let alone the data retrieval software – is yet to be developed. The *feedback* provided in the applications is non-existent. Some of the applications are more customizable than others, and some even function on multiple platforms and have built-in applications assisting with some aspects of life-style treatment. However, even the currently available technologies enable development of more comprehensive and better solutions than the ones found in this Thesis. The relevancy and modifiability of the *markings* in current applications varies greatly. Similarly, *reminders* are available in a few of the applications.

6.5.2 Other (guidelines, practices, other)

In addition to discussing the BG measurement devices and SMBG related software, major discussion topics of this Thesis are the current treatment practices and guidelines. Additionally to issues related to practices and guidelines, other topics emerged during the research of this Thesis. Table 6.10 presents the key user requirements of these topics. According to the interview results, all of the requirements presented below are unsatisfied. The complexity of satisfying the requirements varies, requirements nos. 1, 2, 3, 5, 6, and 7 are most likely rather difficult to satisfy. Additionally, updating the Current Care Guidelines may prove to be difficult as well. The Current Care Guidelines are intended to contain evidence-based practice guidelines (Finnish Medical Society Duodecim, 2013). Thus, usually updating them requires either evidence that the issue affects treatment or support from experts on the field of diabetes treatment. Requirement no. 4 can be relatively easy to meet, although the nurses may be reluctant to encourage the use of diabetes management software unless it is proven to affect treatment.

Table 6.10 Summary of other user requirements

Category		Requirement	Priority
Kela	1	*Getting new medication to the National Health Insurance reimbursement system should be easier and faster.*	2
STPD	2	*STPD should be more flexible in distribution of all treatment hardware.*	3
meters	3	*Non-invasive meters should become available.*	2
practices	4	*Use of diabetes management software should be encouraged and supported in treatment practices.*	3
communication	5	*IT systems and other treatment software should support communication*	2
communication	6	*Communication between the stakeholders should be better.*	3
resources	7	*Diabetes clinics should have more cooperation with special fields treating common complications in diabetes.*	3
resources	8	*Nurses should receive psychological training to help to deal with patient's motivation issues.*	3
resources	9	*Diabetes nurses should be utilized further where possible and more nurses should be available where needed.*	2
guidelines	10	*The patient versions of guidelines should give more information on measurement techniques.*	2
guidelines	11	*The patient versions of guidelines should give more information on interpreting measurements.*	2
guidelines	12	*The patient versions of guidelines should contain more information on measurement practices.*	2
guidelines	13	*The guidelines could contain more information on how treat motivation issues.*	2

7 Summary

This Chapter presents a summary of the issues discussed in this Thesis. First, the sections discussing each of the research questions are referenced. Second, the user requirements and the state-of-the-art of BG measurement devices, services and related guidelines are compared and discussed. Third, the correlation of requirements between the user groups is discussed. Finally, other key findings of this Thesis are presented.

7.1 Research questions

The research questions of this thesis are:

1. *What are the important highlights of the Current Care Guideline and treatment practices on diabetes?*

2. *How could the current guidelines and treatment practices of glucose measurement be updated to meet the requirements of the various stakeholders better?*

3. *What are the user requirements of glucose measurement and are there correlations between the requirements of different stakeholders?*

4. *How could the devices and applications of glucose measurement meet the requirements of the users better?*

Section 6.2 discusses the highlights of the Current Care Guidelines and treatment practices on diabetes (question 1). Section 6.5.2 based on the requirements presented in section 5.2.3 discusses possible updates to the guidelines and treatment practices (question 2). Sections 5.2.1, 5.2.2, and 5.3 discuss the user requirements of SMBG devices and software (question 3). Section 6.5 discusses research question 4, based on the requirements (Sections 5.2.1, 5.2.2, and 5.3) and state-of-the-art (6.3 and 6.4).

7.2 User requirements and the state-of-the-art

A total of 111 user requirements were elicited in this Thesis, tables 6.9 (*Summary of the user requirements for SMBG devices and software*, page 66) and 6.10 (*Summary of other requirements*, page 68) present summaries of the user requirements elicited in this Thesis. Out of the 47 requirements included in the summary, only 17 are partially satisfied by the current options in SMBG devices and software. None of the requirements on treatment guidelines and practices are satisfied.

The 34 user requirements for SMBG devices and software (table 6.9) are grouped into seven categories; *Interpretation and analysis, Data Transfer, Feedback, General, Markings, Reminders,* and *Meter specific.* The current software provide some solutions to the requirements in the category *interpretation and analysis,* the diabetes applications[48] and meters provide only partial solutions to a couple of the requirements. The *data transfer* requirements are not met, current applications provide some automatic data transfer to cloud services, and the current software provide some rudimentary communication channels between doctors and patients. The requirements for *feedback* are in practice not met at all. While the feedback on measurements should have more content and be relevant, the current meters provide merely simple warnings of high or low BG values. The *general* requirements are only partially met, e.g., some meters are fast to use, some applications have integrated services to help with lifestyle treatment, and some parts of the software are customizable by the users. *Marking* options are key to analysis of measurement data, the requirements related to this are barely met. Some meters and services provide some relevant marking options, even some type of commenting or modification modes are available on some applications and software. Nevertheless, more effort should be put on enabling relevant user modifiable marking and commenting options. The *reminders* can help diabetics to produce good quality measurements. Some of the meters provide functionalities on

[48] Mobile phone applications in this context.

this subject, reminders should be an industry standard. Moreover, further functionalities in measurement reminders are sought by the users. Half of the *meter specific* requirements are met by some meters, i.e. some meters have big screens with nightlight and some meters are relatively discreet.

This Thesis focuses on the unsatisfied user requirements elicited during the research. Nevertheless, it is important to note that most of the current meters and other systems enable fair quality SMBG meeting the bare minimum set of requirements for it. The more advanced features described in the user requirements could motivate the users, ease the measurement procedure, and enable better SMBG. Most of the advanced features described in this Thesis are not provided in the current devices and services. Producing some of these features can be rather difficult (e.g., automated marking options), while developing others is easier. Especially the interactive, motivating and relevant feedback on measurements, possibility to add reminders, and user modification are some of the technically simpler features to produce and equally important. However, the content of these features requires careful consideration and should be extremely relevant. Additionally, communication between the BG meters and diabetes management applications and software should be considered. Automatic communication is possible with current technologies. Developing a viable business case providing these functionalities can be a challenge.

7.3 Correlations between the requirements of different user groups

The correlations of the requirements of different user groups are open to interpretation. That is, the conclusions on this matter depends on the point of view taken on the inspection of the correlations, or how strictly the user groups affected by requirements are defined. E.g., the medical staff doesn't use the BG meters but their work is affected by the quality of measurements taken by the diabetics. Thus, the qualities of the meters affect the work of the medical professionals. Therefore, many of the user requirements related to BG meters can be interpreted to affect doctors, nurses, and diabetics. On the other hand, the diabetics are the main user group of the BG meters, and thus the majority of BG meter related requirements should be considered to be only the diabetics' user requirements. Inspecting the user requirements more specifically poses yet another difficulty in determining the correlations of the user requirements. As table 6.10 shows, many of the requirements discovered in this Thesis can be adapted to various platforms. The platform used to produce the solution partly determines the user groups affected. For instance, requirement 2. (*The solution needs to support analysis of measurement data)* in table 6.10 can be incorporated into the meters (affecting diabetics), diabetes management applications (affects diabetics), or data retrieval and analysis software (affects all user groups).

Nevertheless, the requirements between the three user groups investigated (doctors, nurses and diabetics) are remarkably similar. Moreover, not a single user requirement is conflicting with a requirement of another user group investigated in this Thesis. The only partially conflicting requirements are those of simple use and added features – i.e. adding features usually means added complexity in the system. Fig 5.2 in page 48 depicts how similar the user requirements of different user groups are. Moreover, the user requirements are so similar that all the requirements included in this summary are adaptable to all user groups.

7.4 Key findings

In addition to the comparison of user requirements and state-of-the-art of current devices and services, this Thesis revealed other interesting findings in the subject of diabetes treatment and SMBG. Perhaps most importantly, the quality of measurements taken – i.e. correct number of timely and relevant measurements – is affected greatly by two factors: motivation and STPD. The issues with STPD are rather simple; the meters available in the distribution restrict the choices of meters for patients. Thus, the diabetics may not be able to use the most suitable meter for their specific needs. Moreover, the number of test-strips distributed can limit the number of measurements taken, thus impeding SMBG. As mentioned earlier (page 50), the Ministry of Social Affairs and Health has taken some steps to correct the situation in Finland.

The diabetic's motivation seems to be another major factor greatly affecting SMBG. The interviews strongly supported that nearly every diabetic suffer of poor motivation at some point of their treatment. Poor quality measurements and in some cases even total lack of measurement data reveal the patient's poor motivation. Improved functionality and ease of use of the SMBG devices and services may decrease the threshold of measuring. Furthermore, motivating feedback could improve the diabetic's willingness to keep measuring even when motivational issues are encountered. Moreover, interactive feedback that is concurrent and relevant could even act as a countermeasure for motivational issues. However, motivational issues should be handled on all fronts, and the technology-focused solutions should be considered as the tools supporting better motivation. The solution to motivational problems should not be limited to the meters and services; motivational problems can require psychological focus as well. The nurses might benefit from psychological training, and improvements on communication between the medical staff and patients might affect motivation as well. Moreover, peer-support may be extremely useful.

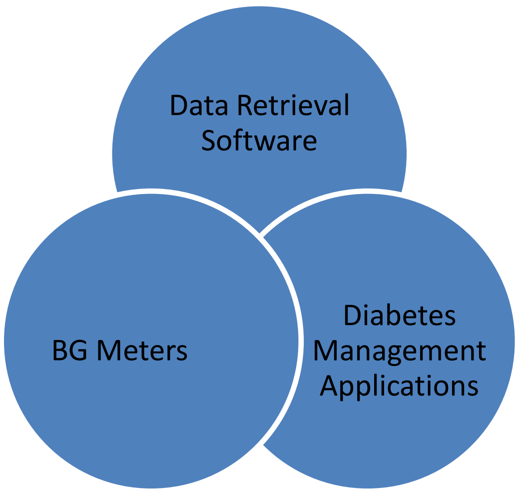

Figure 7.1 Current convention on SMBG device and service integration

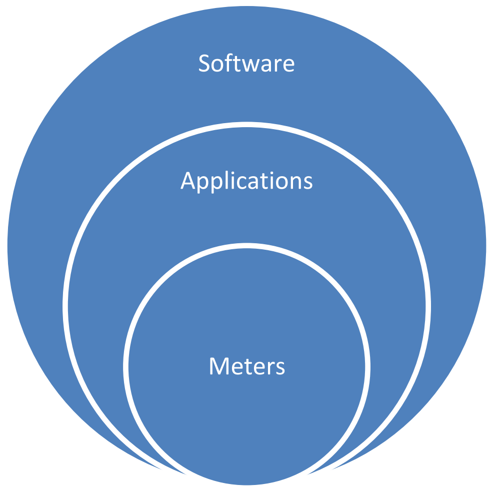

Figure 7.2 Preferred integration of SMBG devices and services

The quality of BG measurements and motivation is affected by the SMBG devices and services. The current convention of SMBG devices and services is more or less as depicted in fig. 7.1. The diabetes management applications, data retrieval and analysis software, and BG meters currently operate rather separately. The most evident link between the systems is the diabetic manually transferring data from one service to another. Additionally to the measurement data, the markings and possible comments on the measurements are transferred. Based on this study, the concept should evolve towards the one depicted in fig 7.2, where the applications, software and meters provide the an integrated service with different levels of finesse. The meters would provide the basic functionalities, applications a bit more features and functionality, and the software would enable a full service. Full integration would result in the data input being done only once.

8 Discussion

8.1 Motivation

As argued earlier, the diabetic's motivational problem is one of the key issues in current SMBG conventions. The interviews suggested the use of feedback on BG measurements to help with motivation problems. This Thesis argues that better SMBG devices and services affect motivation as well. Gamification is presented as another approach that may improve motivation. Gamification can be considered to provide one type of engaging feedback. Moreover, the incorporation of relevant information into the content of the feedback given on the meters may improve patients' motivation.

Gamification can be defined as *"the use of game design elements in non-game contexts"* (Deterding, Dixon, Khaled, & Nacke, 2011), i.e. adopting concepts conventionally used in game design in the design of other services and systems. Another approach does not limit gamification to game-design elements and argues that there is not a well-defined set of game-design elements (Huotari & Hamari, 2012). Although a well-defined set of game-design elements may be hard to define, elements that are commonly used in games include: the use of badges, leader-boards, levels, time constraints, limited resources, turns, and setting clear goals (Deterding, Dixon, Khaled, & Nacke, 2011).

Leader-boards could be used for encouraging diabetics towards better quality measurements; e.g., leader-boards for the timeliness of meal-pair measurements. Additionally, doctors could set measurement goals – e.g., in terms of BG level or number of measurements - for the diabetic and badges could be rewarded to the diabetic according to how close to the objectives he/she gets. Progress bars could be adopted in the early use of the meter, e.g., to show how many of the meter features have been used – i.e. how well the meter functionalities have been learned. The opportunities provided by gamification are numerous. In fact, gamification is already in use in some diabetes related applications (e.g., http://www.lenny-diabetes.com/carb-counting-with-lenny.html).

However, the use of gamification in the context of SMBG would require careful consideration and further research. Diabetes is a serious illness and the diabetics are not a homogeneous user group. While the young diabetics might find it fun to earn badges for their BG measurements, the more grown up diabetics may not enjoy it.

8.2 Limitations of this Thesis

The small number of diabetics interviewed in this Thesis can be a major limitation. Generalizing the interview results is demanding and requires further research, e.g., more interviews. Validation of the requirements is not completed in this Thesis and left for further research. In practice, the interview material was validated during the interviews themselves, i.e. while taking notes the issues were confirmed verbally with the interviewees. Nevertheless, the interpretation of the material into user requirements is not formally validated. Thus, the user requirements presented in this thesis require critical observation. The limitations of this Thesis can be addressed through further research. If the reader is interested to use the requirements listed in this Thesis as a basis for development of SMBG devices and software, further validation by, e.g., a questionnaire is recommended.

8.3 Future research

Additionally to the user requirements of SMBG devices, software and guidelines, this Thesis discussed other interesting topics. The motivational problems with diabetics seem to be one of the major contributors to poor quality measurements, which in turn impede treatment. A comprehensive research of the motivation with diabetics could prove to be beneficial for further development of the treatment practices and the SMBG devices and software. First, direct evidence of the frequency of motivation issues amongst diabetics should be acquired, e.g., with a more comprehensive sample of diabetics. Second, the underlying issues causing poor motivation can suggest means for solving the problem. Third, the research should cover how different approaches (i.e. devices, software, treatment practices, etc.) could affect motivation.

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Appendix A

This appendix contains the interview scripts used in the research of this Thesis.

Doctors

Background information:

- How long have you practiced in the field of diabetes? Do you keep practice in the public or private sector?
- What type of diabetics do you treat most often (type 1 or 2)?

Meters:

- Are there any essential differences in the BG meters available?
- Which of the BG meters features or qualities are essential?
- Do you get to affect the meters that the patients choose to use?
- Are there any shortcomings in the current BG meters? Any improvements required?

Measurement:

- What is essential in measuring BG?
- What are the most common problems in BG measurement?

Measurement data:

- Are the measurement results good in general? In terms of timeliness, relevancy or amount?
- What is the most common format of presentation of measurement results? Should the most common format be different? Do you advice patients on the presentation format?
- What do you look for in the results? Is it easy to find these issues?
- What other measurements besides BG should be connected to BG measurements?

Guidelines on treatment practices and treatment guidance:

- Do you use the treatment guidelines? E.g., the Current Care Guidelines?
- Do you recommend others to use the guidelines? E.g., patients?
- What is your opinion of the current guidelines?

Patients:

- Are motivational problems common with diabetics?
- Are the patients in general capable of interpreting the measurement results?

Diabetes related software:

- Do you recommend patients to use software and applications that help with diabetes treatment? Which?
- Do you feel that there is a need for such software and applications?
- What is your opinion of the data retrieval software? Do you use them?

Communication:

- With whom do you discuss the treatment of patients?
- To whom does the information of the treatment of a patient go to?
- What type of communication channels do you use?

Other:

- Are there any other specific problems or issues that should be discussed?
- Do you have some ideas on how the current services and devices should be updated?
- Is there some specific issue that requires updating?
- What would be the best way to produce SMBG services?
- What do you think the state-of-the-art will be in 10 years?
- Do you have an opinion on non-invasive meters?
- Do you have any questions?

Nurses

Background information:

- How long have you worked in the field of diabetes? In the public or private sector?
- What type of diabetics do you treat most often (type 1 or 2)?
- How many different meters do you encounter in your work?
- How many software (data retrieval and other) do you encounter in your work?

Meters:

- Are there any essential differences in the BG meters available?
- Which of the BG meters features or qualities are essential?
- Do you get to affect the meters that the patients choose to use? Who chooses them? What issues affect the choosing of a meter?
- Are there any shortcomings in the current BG meters? Any improvements required?

Measurement:

- What is essential in measuring BG? Which are the essential markings? Essential times-of-day for measurement? Are there any general rules for measuring?
- What are the most common problems in BG measurement?

Measurement data:

- Are the measurement results good in general? In terms of timeliness, relevancy or amount?
- What is the most common format of presentation of measurement results? Should the most common format be different? Do you advice patients on the presentation format?
- What do you look for in the results? Is it easy to find these issues?
- Are there any differences on how the data or what type of data should be presented to doctors, nurses or patients?
- What other measurements besides BG should be connected to BG measurements?

Guidelines on treatment practices and treatment guidance:

- Do you use the treatment guidelines? E.g., the Current Care Guidelines?
- Do you recommend others to use the guidelines? E.g., patients?
- What is your opinion of the current guidelines?

Patients:

- Are motivational problems common with diabetics?
- How do you help the patients with motivational problems?

Diabetes related software:

- How would you describe your knowledge of the current supply on diabetes assistance applications?
- Do you recommend patients to use software and applications that help with diabetes treatment? Which?
- Do you feel that there is a need for such software and applications? What type?
- What is your opinion of the data retrieval software? Do you use them?

Communication:

- With whom do you discuss the treatment of patients?
- To whom does the information of the treatment of a patient go to?
- What type of communication channels do you use?

Other:

- Are there any other specific problems or issues that should be discussed?
- Do you have some ideas on how the current services and devices should be updated?
- Is there some specific issue that requires updating?
- What would be the best way to produce SMBG services?
- What do you think the state-of-the-art will be in 10 years?
- Do you have an opinion on non-invasive meters?
- Do you have any questions?

Patients

Background information:

- How long have you had diabetes?
- How many diabetes related devices and services do you use?
- Would you describe yourself as tech-savvy?
- How many measurements should you take on average? How many do you take?

Meters:

- How do you choose your meter? Who or what affects the choice? Who makes the final decision?
- What meter do you currently use? How many have you used before?

- What’s good/bad about your current meter? How would you improve it?

Measurement data:
- What do you look for in the data? Is it easy to find?
- How do the measurement results affect your treatment?
- What would you change about data presentation? In the meter? Software?

Communication:
- To whom do you tell about your treatment and measurement results?
- Should this information sharing be easier?
- Do you have to share information with someone you wouldn’t want share it with?
- What would you change about information sharing?

Diabetes related applications:
- Do you use diabetes related applications? Which? What benefits do you get from using them?
- What type of applications would you want to use? How would you improve the applications?

Motivation:
- Why do you measure your BG? What are your objectives in measuring BG?
- Have you had problems with motivation? Who helps you with motivation issues?

Treatment practices and guidelines:
- How has the treatment guidance worked in your case?
- How would you describe your treatment guidance?
- What do you think of the treatment guidelines? E.g., the Current Care Guideline?
- Do you have any wishes related to these issues?

Other:
- What improvements would you want in the field of diabetes treatment?
- What would you like to be removed from the current diabetes treatment issues?
- What do you think of the non-invasive meters?
- Do you have some other improvement ideas?
- Are there any other topics that should be covered?

Appendix B

This appendix contains the tables used for determining the correlations of the user requirements.

Table B.1 Summary of user requirements on SMBG devices and software with the values used for determining the correlation of the requirements

		Need	Similarity	Doctors (relative importance)	Nurses (relative importance)	Diabetics (relative importance)	Standard Deviation	Normalized SD
Interpretation and analysis	1	*The solution needs to assist diabetics with interpretation of BG measurement results.*	2	4	4	4	0,00	
	2	*The solution needs to support analysis of measurement data.*	2	4	4	4	0,00	
	3	*The solution needs to have a BG target range feature in terms of sugar amplitude.*	2	1	1	3	1,15	
	4	*The solution needs to refine measurement data into useful charts and graphs.*	2	3	3	3	0,00	
	5	*The solution needs to automatically search and detect trends in BG behavior.*	2	2	2	3	0,58	
		AVERAGE	**2**				**0,35**	**0,15**
Data Transfer	6	*The solution needs to be automatically linked to other services.*	2	1	2	4	1,53	
	7	*The solution needs to provide communication between doctors and patients and other stakeholders.*	2	3	3	3	0,00	
		AVERAGE	**2**				**0,76**	**0,33**
Feedback	8	*The solution needs to provide feedback on measurements.*	2	2	2	4	1,15	
	9	*The feedback should motivate users with their measurements and treatment.*	1	2	2	4	1,15	
	10	*The solution needs to detect problems in BG balance and warn about it.*	2	1	1	3	1,15	
	11	*The solution needs to warn users if consistent high or low BG values are detected.*	2	1	1	2	0,58	
	12	*The solution needs to clearly and visually alarm when high or low BG is detected.*	2	1	1	3	1,15	
	13	*The solution needs to warn the user when overcorrection with insulin is suspected.*	2	1	1	2	0,58	
	14	*The solution needs to advice patients to seek help if poor BG balance is detected.*	1	2	2	3	0,58	
		AVERAGE	**1,75**				**0,89**	**0,39**
General	15	*The functionalities of the solution need to be intuitive.*	2	3	3	3	0,00	
	16	*The solution needs to be fast and effortless to use.*	2	3	3	3	0,00	
	17	*The solution needs to assist diabetics with measurement practices.*	1	1	2	3	1,00	
	18	*The solution needs to have integrated applications helping with lifestyle treatment.*	1	1	2	3	1,00	
	19	*The solution needs to function on multiple platforms.*	2	2	2	3	0,58	
	20	*The solution needs to be customizable.*	2	2	2	3	0,58	
	21	*The solution needs to be comprehensive and regard several aspects of SMBG.*	2	4	4	4	0,00	
		AVERAGE	**1,71**				**0,45**	**0,20**

		Need	Similarity	Doctors	Nurses	Diabetics	Standard Deviation	Normalized SD
				relative importance				
Markings	22	*Measurement marking options need to be relevant.*	2	3	3	3	0,00	
	23	*Measurement marking options need to be modifiable by users.*	2	2	3	4	1,00	
	24	*The solution needs to automatically suggest relevant marking options on measurements.*	1	1	2	3	1,00	
	25	*The solution needs to learn the user's measurement and marking routines and suggest relevant markings.*	1	1	1	3	1,15	
		AVERAGE	**1,5**				**0,79**	**0,34**
Reminders	26	*The solution needs remind users to measure.*	1	3	3	4	0,58	
	27	*The solution needs to have programmable measurement schedules.*	1	2	2	3	0,58	
	28	*The solution needs to remind diabetics to inject meal-insulin.*	1	2	2	3	0,58	
		AVERAGE	**1**				**0,58**	**0,25**
Meter specific	29	*Meters should have large displays with nightlight.*	1	0	0	3	1,73	
	30	*Meters should be more discreet.*	1	0	0	3	1,73	
	31	*Meters should be more accurate.*	2	1	1	2	0,58	
	34	*Meters could have a smart-phone-like ecosystem, where applications helping with various issues could be downloaded into meters.*	1	0	1	3	1,53	
		AVERAGE	**1,25**				**1,39**	**0,60**

Table B.2 Summary of other user requirements with the values used for determining the correlation of the requirements

Category		Need	Similarity	Doctors	Nurses	Diabetics	Standard Deviation	Normalized SD
				relative importance				
Kela	1	*Getting new medication to the National Health Insurance reimbursement system should be easier and faster.*	**2**	3	3	3	**0,00**	**0,00**
STPD	2	*STPD should be more flexible in distribution of all treatment hardware.*	**2**	2	2	3	**0,58**	**0,25**
meters	3	*Non-invasive meters should become available.*	**1**	1	1	3	**1,15**	**0,50**
practices	4	*Use of diabetes management software should be encouraged and supported in treatment practices.*	**1**	1	2	3	**1,00**	**0,43**
communication	5	*IT systems and other treatment software should support communication*	2	3	3	2	0,58	0,25
	6	*Communication between the stakeholders should be better.*	2	3	3	2	0,58	0,25
		AVERAGE	**2**				**0,58**	**0,25**

resources	7	*Diabetes clinics should have more cooperation with special fields treating common complications in diabetes.*	2	3	3	2	0,58	0,25
	8	*Nurses should receive psychological training to help to deal with patient's motivation issues.*	1	2	3	2	0,58	0,25
	9	*Diabetes nurses should be utilized further where possible and more nurses should be available where needed.*	2	2	3	3	0,58	0,25
		AVERAGE	**1,75**				**0,58**	**0,25**
guidelines	10	*The patient versions of guidelines should give more information on measurement techniques.*	1	1	2	3	1,00	0,43
	11	*The patient versions of guidelines should give more information on interpreting measurements.*	1	1	2	3	1,00	0,43
	12	*The patient versions of guidelines should contain more information on measurement practices.*	1	1	2	3	1,00	0,43
	13	*The guidelines could contain more information on how treat motivation issues.*	2	2	3	2	0,58	0,25
		AVERAGE	**1,25**				**0,89**	**0,39**

Appendix C

Table C.1 contains the information found of the inactive non-invasive development projects.

Table C.1 Inactive non-invasive development projects

Product / manufacturer	Approvals / status	Invasiveness M = Minimal, N = non-invasive	Technology	Readings	Test site	Portability	Measurement time / interval	other	Source
GlukoWatch / Animas Corportaion	discontinued in 2007	M	reverse iontho-pharesis	continuous	wrist	yes	10 min	unreliable readings	(Tura;Maran; & Pacini, 2007)
DiaSensor / BICO Inc.	Approved, withdrawn	N	-	spot	forearm	no	2 min	not for all patients, company out of business	(Tura;Maran; & Pacini, 2007)
Pendra / Pendragon Medical Ltd.	discontinued in 2005	N	Bio-impedance	continuous	wrist	yes	-	company bought by Solianis, not info on that available	(Tura;Maran; & Pacini, 2007)
Aprise / Glucon Medical Ltd.	-	N	photo-acoustic	continuous	-	yes	10-15 min	no info of ever reaching markets, or of FDA	(Tura;Maran; & Pacini, 2007)
Glucoband / Calisto Medical Inc	no info	N	Bio-electro-magnetic resonance	spot	wrist	yes	3-8min	no info of ever reaching markets, or of FDA	(Tura;Maran; & Pacini, 2007)
SpectRX Inc.	develops non-invasive cancer detection applications (Guided Therapeutix Inc, 2008)	M	interstitial fluid extreactio n (similar to symphony cgm)	-	-	yes	-	no info of ever reaching markets, or of FDA	(Tura;Maran; & Pacini, 2007)
SugarTrack / LifeTrack Systems inc	no info	N	NIR	spot, continuous with 5 min intervals	earlobe	yes	1 min	no info of ever reaching markets, or of FDA	(Tura;Maran; & Pacini, 2007)
Symphony / Sontra Medical	Probably same as symphony TCGM								(Tura;Maran; & Pacini, 2007)
DreamBeam / Futrex Medical Instrumentation Inc	develops body composition analyzers, NIR (Futrex Inc.)		most likely NIR		finger	yes			(Tura;Maran; & Pacini, 2007)
GluCall / KMH Co. Ltd.	no info	M	interstitial fluids / reverse iontho-pherisis	continuous	wrist	yes	20 min	sensor must be changed every 6 h	(Tura;Maran; & Pacini, 2007)

Product / manufacturer	Approvals / status	Invasiveness M = Minimal, N = non-invasive	Technology	Readings	Test site	Portability	Measurement time / interval	other	Source
GluControl GC300 / ArithMed GmbH	no info					yes			(Tura;Maran; & Pacini, 2007)
Hitachi Ltd	no new info	N	Thermal emission (FIR), photo-metric	spot	fingertip		5 min		(Tura;Maran; & Pacini, 2007)
Sysmex Corporation	R&D on minimally invasive technologies (Sysmex Corporation)					yes			(Tura;Maran; & Pacini, 2007)
TouchTrack Pro 200 / Samsung Fine Chemicals Co. Ltd.	was sold in 1998, 30 000 US$								(Tura;Maran; & Pacini, 2007)