What does value-in-use assessment add to usability assessment of an artificial pancreas for type 1 diabetes patients in the Netherlands with different treatment conditions?

An experimental study in medical innovation management

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Abstract

Background - The artificial pancreas device (APD) is a breakthrough in diabetes treatment for type 1 diabetes patients. Inreda Diabetics developed one of these portable medical devices, which functions as a healthy pancreas by controlling blood glucose levels. The APD is not a cure, but could help patients in managing their condition effectively and efficiently. The APD could reduce medical costs and possibly delay or prevent early retirement. As the APD of Inreda is in the development phase, it should be optimized for use situations. Usability is important here, because it shows how well the functionality of the APD can be used by the user. However, the total experience of a product covers more than usability. The value of a product is determined by the user during usage (value-in-use). It is important to consider this user information to enhance a product, which is called co-creation. Despite this importance, a limited amount of studies is researching if and how the outcomes of the co-creation of value are beneficial. The goal of this study is to research if value-in-use assessment is an addition to usability assessment in the context of this medical innovation technology. This research will support the APD's application for a CE-mark.

Method - This study uses an experimental between-groups-design to qualitatively compare the concepts of usability and value-in-use. As treatment conditions could have an influence on the usefulness of the APD, differences between insulin pen users and insulin pump users were studied. Tasks with the APD were carried out by the participants. For the usability assessment a questionnaire and task checklist was used. Statistical analysis using the Wilcoxin Rank test and the Mann Whitney U test was used to assess differences between scores. The value-in-use assessment consisted of semi-structured interviews. After axial coding, content analysis was used for assessing value-in-use.

Results – A total of 32 type 1 diabetes patients from the Netherlands participated in the study, retrieved from the database of Inreda. Overall the usability was evaluated positively by type 1 diabetes patients and the tasks could be successfully executed. The APD was evaluated as inconvenient to carry by the patients. The value-in-use of the APD lies mainly in its ability to decrease the patient's dependency on procedures to regulate blood sugar. For insulin pen users the weight, size and tubes of the APD can lead to a loss of flexibility of movement. The APD does not influence the self-presentation, the decision-making or the ability to meet obligations of users, but could help in making decisions easier.

Conclusion - Diabetes patients do not only want tangible features, but also intangible experiences. The emotional and functional value proposition of the user continuously changes. Both assessments should be repeatedly assessed, during actual usage as well as during product development. Usability assessment is necessary to gain information on usability problems and task and product goals. Links between both assessments should be sought to fully understand the relevance of each issue and each situation. Value-in-use assessment is complementary to usability assessment. Concluding, the APD can positively influence diabetes regulation and life in general for a type 1 diabetes patient to a great extent. Ultimately, this influence is determined by the diabetes patient itself.

Keywords - value co-creation, value-in-use, usability, medical innovation management, diabetes, artificial pancreas

Executive summary

Goal of the study – This study provides an assessment of the additional value of considering the value-in-use of a product in comparison with considering usability. The context of the study is health care innovation technology, in specific the artificial pancreas device (APD). This research discusses the potential benefits of co-creation with patients. An integration model of value-in-use assessment and usability assessment is proposed for (health care) technology developers.

Findings – By considering value-in-use, a developer can gain information on the higher goals users want to reach while using a product. This assessment can provide information during actual usage, but also during product development. Although value-in-use is different for each individual, similarities can be found in groups. Based on the value proposition of the user, the developer can incorporate tangible features in the product to facilitate the goals of the user. Therefore, the developer should look for connections between the tangible features found in usability and the experiences mentioned at the value in use. While looking for these connections, the relevance of each situation should be monitored. This assessment should be made repeatedly, as value can change in time.

Recommendations – A integration model of both value-in-use assessment and usability assessment is proposed. This model considers the stages of the product development process of an initial idea, the design of the conceptual product, the testing of the product and the eventual usage of the product. The process is discussed below:

1. Product idea testing – Formative usability testing should be used to test potential usability problems. Based on these problems, interventions should be designed. Focus groups can be used to jointly develop an idea. Questionnaires could facilitate this process to address usability needs. The potential value-in-use of the product should be assessed in the focus groups based on previous experiences with current treatment methods and devices.
2. Design of a prototype – Formative usability testing in combination with a prototype must further assess usability problems. With the use of a prototype the value-in-use can be assessed for a range of real life test situations.
3. Testing of the product – When the conceptual product is ready, the summative usability should be tested on if the product reaches task or product goals. This could be done by using a task checklist. As the product is ready for launch, the value-in-use of the product should be tested in practice with a small sample of users. Diaries and/or (non)participant observation can be used to facilitate this articulation.
4. After market launch: Usage of the product - During actual usage forums, diaries and (non)-participant observation can also be used to monitor use in real usage situations repeatedly. This is both for summative usability assessment as well as for value-in-use assessment.

Conclusion – Developers should repeatedly consider usability assessment and value-in-use assessment. Co-creation with patients could create goodwill and allow for the joint development of more innovative ideas and products. For patients it is important that medical technology can facilitate treatment of illnesses in order to make life easier.

Preface

A year ago I started my Master in Business Administration at the University of Twente. During my search for a topic for my Master Thesis I came in contact with Ariane von Raesfeld, my professor of the course Business Development in a Network Perspective. After some time, Ariane presented me the opportunity to carry out a study for Inreda Diabetics. Inreda Diabetics was not a name I had heard of in the past. When I learned about the artificial pancreas they developed for type 1 diabetes patients, I became enthusiastic to study this device. I gained the opportunity to do something meaningful for people with a lifelong, demanding decease. Perhaps many people do not know about type 1 diabetes and what this implies for a person in daily activities. But during my study I learned about the opportunities the artificial pancreas could create for type 1 diabetes patients. When sending invitations for the study I saw the willingness of diabetes patients to have the opportunity to share ideas and have an influence on the development on the APD. All participants were anxious to participate, waiting from the moment they saw developer Robin Koops at 'De Wereld Draait Door' in 2011. In order to participate in the study, they covered great distances to have a small influence in the development of their potential future.

While being busy with completing my thesis, I was confronted with my prejudices about the ease in which daily activities can be executed. 'Normal' things are not just a matter of course. I became amazed about the perseverance of the person sitting in front of me. I learned that they are not diabetes patients. They have diabetes and that is certainly not who they are. Although diabetes might seem tolerable in general, having a decease day and night can feel like a burden. I learned I am lucky to not know the feeling. I would like to thank all participants of the study for giving me the insights I have today. It put my relatively unimportant issues into perspective, which gave me the drive to go on. For all the participating diabetes patients as well as for the diabetes patients waiting for the APD, I hope one day the APD will help you during daily activities.

As a final note, I would like to thank some other people which supported me during the writing of my thesis and my Master in general. Overall, I would like to thank Robin and Irene Koops, Caroline Gorter and the other employees of Inreda for the opportunity to help in the development of this device. Robin Barwegen, thank you for your time and explanation about the APD and diabetes. A thanks to my supervisors Ariane, Petra and Tamara for their honest and critical comments and their time. Max & Max, Marion, Nadine, Madelynn and Stephanie thank you for all the fun before, during and after the lectures. Nienke, thank you for exchanging stories about our theses, let us look forward to a much deserved holiday. Dad and Margot, thank you for helping me in determining what is important and what is not. Leon, Inge, Rob, Jesse and Wessel, although sometimes me talking about value-in-use and usability might seem complicated and exhausting to you, I do definitely think that this thesis might help you in understanding why I did. Lastly, I would like to thank my mother Harieke for being my sparring partner, both when I needed it and when I did not.

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Introduction

Type 1 diabetes is a demanding disease requiring patients to lead a disciplined lifestyle in order to avoid severe complications. People with type 1 diabetes have a lifelong autoimmune condition in which the normal blood glucose controlling mechanism does not work (The National Institute for Health Research Horizon Scanning Centre, 2015). Diabetes is one of the most underestimated sources of high costs in the Dutch medical world (4 Billion now, 16-19 Billion in 2020) (Booz & Co, 2011). Currently type 1 diabetes is treated with an insulin pump or pen. The discontinuation level of diabetes regulation devices, like insulin pumps and continuous glucose monitors is still very high and insulin pumps have seen to be malfunctioning in various studies (Fatourechi et al., 2013; The National Institute for Health Research Horizon Scanning Centre, 2015; Weissberg-Benchell, Antisdel-Lomaglio, & Seshadri, 2003). A new emerging area in medical devices research is the externally-worn closed loop artificial pancreas device (APD) for type 1 diabetes patients. The Dutch company Inreda Diabetics develops an APD, which is a portable medical device designed to function as a healthy pancreas by controlling blood glucose levels. The APD of Inreda is different from its competitors by being bi-hormonal, which implies that it works with insulin and its antagonist glucagon. Insulin decreases, whilst glucagon can increase blood sugar of diabetes type 1 patients (Inreda, 2015). Although the APD is not a cure, it should help patients to manage their condition effectively and efficiently (The National Institute for Health Research Horizon Scanning Centre, 2015). It could therefore reduce medical costs and possibly delay or prevent early retirement (Booz & Co, 2011).

Theoretical and practical relevance

As current medical devices are shown to be error-prone (Bastien, 2010), it is important to optimize the APD for working effectively and efficiently for patients. This study will support the application for a CE-mark for the APD. A provider of health care needs to interact with patients, as this is related to patient safety (Hardyman, Daunt, & Kitchener, 2015). In general, including the view of more transparent, smarter, demanding and networked customer is gaining importance, as the economic landscape is changing due to globalization and information technologies (McColl-Kennedy, Vargo, Dagger, Sweeney, & van Kasteren, 2012; Randmaa, Howard, & Otto, 2012). In order to prevent adverse consequences, it is necessary to detect error (Wiklund & Wilcox, 2005). This is particularly important, because the consequences in health care and for diabetes patients are high. Usability is how well a customer can use the functionality of a system (Nielsen, 1993), and therefore particularly important when studying the APD. In general, usability could affect repurchase intent, product returns and brand perception (Babbar, Behara, & White, 2002; Han, Hwan Yun, Kim, & Kwahk, 2000; Van Kuijk, Kanis, Christiaans, & van Eijk, 2007).

However, studies into usability changed. They emphasized a behavioral and emotional aspect (Han et al., 2000). Later, it was recognized the total experience of a product covers more than its usability (D. Norman, 2002). The value of a product used by the customer should also be taken into account (Anderson, Narus, & Narayandas, 2005; Wiklund & Wilcox, 2005). Considering value could create a competitive advantage for providers (Anderson et al., 2005). The value-in-use of a product is the the result of the process of cognitive assessment of a user's total service experience (Sandström, Edvardsson, Kristensson, & Magnusson, 2008). A destinctive aspect of value-in-use is the active co-creation of value by customers in interaction (Kowalkowski, 2011; Macdonald, Wilson, Martinez, & Toossi, 2011; S. Vargo & Lusch, 2004). Co-creation with patients could lead to improved medical status, greater physiological wellbeing and greater satisfaction for patients (Hardyman et al., 2015; Kowalkowski, 2011; Palumbo, 2016). Still, there is a limited amount of studies researching the outcomes of the co-creation of value in use (Voorberg, Bekkers, & Tummers, 2014; Witell, Kristensson, Gustafsson, & Löfgren, 2011). Various outcomes of the value co-creation process such as experiences, relationship value, services and new offerings for a product need to be studied (Ahrar & Rahman, 2014). This can be done by experiments in order to compare ideas from different orientations in a range of empirical contexts (Witell et al., 2011). It could be important to study the aspect of value-in-use when optimizing the APD, as value co-creation is the dominant paradigm for the National Health Service during the coming decade (The National Institute for Health Research Horizon Scanning Centre, 2015). Value co-creation in health care currently remains in the theoretical and experimental phase, and is therefore hard to assess (Hardyman et al., 2015). There is a need to better understand how patients can contribute to value co-creation, which can be done by using the patient's perspective (Hardyman et al., 2015; McColl-Kennedy et al., 2012; Zhang et al., 2015). This perspective could differ as treatment method could have an influence on the perceived usefulness and intention to use the APD (Uncu, 2014). Different patient perspectives therefore have to be taken into account.

Research aim and article structure

The goal of this study is to research if value-in-use assessment is an addition to usability assessment. This study first involves a literature study in order to give insights into the developments within usability, value-in-use and value co-creation. Then, the research design will be discussed: an experimental study looking into both assessments for different treatment conditions between type 1 diabetes patients. As a basis to study and compare these assessments, the first four research questions are drafted and used as a framework for comparison. The last two questions are drafted in order to assess if this type of co-creation with users is beneficial and subsequently how to integrate both assessments into the APD. This is examined in the discussion. In the last chapter the conclusion will be given. The research question and the subsequent sub-questions are as follows: <u>What does value-in-use assessment add to usability assessment of an artificial pancreas for type 1 diabetes patients in the Netherlands with different treatment conditions?</u>

1. What is the usability of the artificial pancreas for type 1 diabetes patients in the Netherlands?
2. Does a statistical significant difference exist in the usability of the artificial pancreas between the different treatment conditions of type 1 diabetes patients?
3. What is the value-in-use of the artificial pancreas for type 1 diabetes patients in the Netherlands?
4. Does a difference exist in the value-in-use of the artificial pancreas between the different treatment conditions of type 1 diabetes patients?
5. Is this type of co-creation with type 1 diabetes patients of an APD beneficial for the health care technology developer of the APD?
6. How can the value-in-use and usability' needs of type 1 diabetes patients be integrated into the APD?

Literature Review

The concept of usability

This paragraph will elaborate on the concept of usability. First, the variability in the concept of usability will be discussed. Then, the development of usability in time will be explained. Based on literature, usability as a construct will be reviewed.

Variability in usability - Usability was originally defined as product effectiveness and efficiency of use within a specified range of users, tasks, tools and environments (Randmaa et al., 2012). It can be seen as a generic term for ergonomic product quality in the field of Human Computer Interaction (HCI), and replaces ease of use and user-friendliness (Dzida, 1995; Nielsen, 1993). Within usability the context is important, as a product cannot be described as usable without mentioning the context of use (Maguire, 2001). The characteristics of the user, like experience, personal traits or cultural background should also be assessed (Kim & Christiaans, 2011). People's experiences change over time, where they are influenced by variations in contextual factors (Buchenau & Suri, 2000). A design should therefore be usable for as many users as possible, by considering a spectrum of users (Nielsen, 1993). Guidelines on usability exist, but there is no clear guideline on how to deal with this variability in design (ISO, 1998).

The development of usability in time - In early research usability was mainly concerned with the objective parts of effectiveness and efficiency (Nielsen & Levy, 1994). Subjective satisfaction was only a small part of it (Han et al., 2000). Where Nielsen (1993) considered dimensions like learnability, efficiency, memorability and errors, other studies show different usability dimensions such as ease of use, memorability, error rates and efficiency of use (Hix & Hartson, 1993; Shneiderman, 1992). In the last two decades, image (Ketola, 2002; Kwahk & Han, 2002) and emotional (P.W. Jordan, 2002) usability dimensions were added. Factors such as affect and helpfulness were taken into account by Kirakowski and Corbett (1993). Several usability measures were developed measuring emotional attributes, such as mental effort, flexibility, accuracy, affect and presentation (Chin, Diehl, & Norman, 1988; Keinonen, 1998; Lewis, 1995; Shneiderman, 1992). A new definition of usability was developed. Kwahk and Han (2002) defined usability as the extent on how well a product can satisfy a user both in terms of performance as well as image/impression (Han et al., 2000). The concept of usability has grown in recent years. Lewis (2014) noted the importance of distinguishing formative and summative usability, because it is important to use both to improve objective as perceived usability. Lewis (2014) explained summative usability as metrics associated with meeting global task and product goals. Formative usability was seen as the detection of usability problems and the design of interventions to reduce or eliminate their impact (Lewis, 2014).

Towards a usability construct – A systematic review of 100 articles on the usability of mobile devices of Coursaris and Kim (2011) divided usability into task-, user-, technology- and environmental characteristics. Within the review of those 100 articles they reduced usability to a total of 31 usability dimensions. This study shows that the most frequent used constructs are efficiency, errors, ease of use, effectiveness, satisfaction and learnability. Ryu (2005) developed the Mobile Phone Usability questionnaire (MPUQ), based on 21 dimensions of earlier questionnaires mentioned in the review of Coursaris and Kim (2011). The MPUQ is a three layered general usability framework. The main dimensions are effectiveness, efficiency and satisfaction. Underlying dimensions are the ease of learning and use, assistance of operation and problem solving, emotional aspect and multimedia capabilities, commands and minimal memory load, efficiency and control and a dimension especially for mobile phones. The MPUQ framework can be seen in Figure 1.

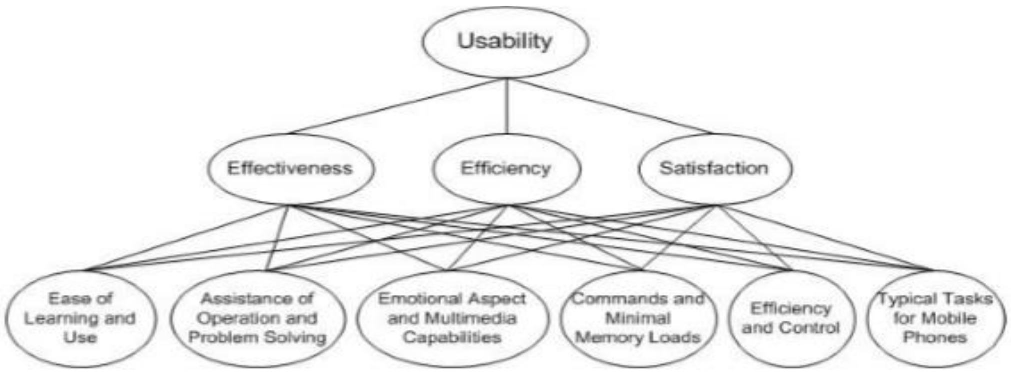

Figure 1. Mobile Phone Usability Questionnaire framework of Ryu (2005)

Changing the lens: The concept of value-in-use

This paragraph will elaborate on the concept of value-in-use. First, the more active role of the customer is considered. Second, the value-in-use process is examined. Based on literature, a value-in-use construct will be discussed by looking at different value dimensions.

The more active role of the customer in value-in-use - In marketing and business development studies it was shown that it is not tangible goods what the customer want, but what effect these products have on them (Randmaa et al., 2012), The function of a good is to provide a service with less identifiable emotions and experiences (Randmaa et al., 2012). As value is how well a market offering performs in a given customer application, the true value of a market offering can only be assessed through the lens of the customer (Anderson et al., 2005; Witell et al., 2011). Many interpretations of value exist. This can result in the re-interpretation and extension of the concept of value (Kukushkin, Otto, & Howard, 2015). Value in use is a frequently used, but still vague concept in management literature. Several perspectives arise, focused on the provider as well as the customer (Macdonald et al., 2011; Walter, Ritter, & Gemünden, 2001; Woodruff & Gardial, 1996). The view on value creation within both services as well for products, shifted towards service centered co-creation with users (the Service-Dominant perspective) (S. Vargo & Lusch, 2004). It was more focused on the customer rather than the provider (Kukushkin et al., 2015; Walter et al., 2001; Woodruff & Gardial, 1996). Still, critique on this perspective on value-in-use of Vargo & Lusch (2004) arised, because it was not considering the usage process of the customer, the achievement of the customer's outcome and the role of the relationship with the supplier (Macdonald et al., 2011). Later studies on value-in-use did focus on the outcomes of this interaction process between user and supplier. Within multiple studies value-in-use is seen as relative as it is not judged during purchase, but the valuation of products is determined by the individual situation of the customer (McColl-Kennedy et al., 2012; Raja, Bourne, Goffin, Çakkol & Martinez, 2013). The creation of value-in-use is seen as a multiparty process of interaction with the supplier and other stakeholders involved in the service network (de Castro-Ferreira & Menezes, 2015; Grönroos et al., 2013; Randmaa et al., 2012; Pfisterer & Roth, 2015). In health care this interaction is related with the successful management of chronic diseases (Mc-Coll-Kennedy et al., 2012; Zhang et al., 2015). Keep in mind that within health care the variation between patients' skill level, function and condition of use is important (Witell et al., 2011).

The value-in-use process - Sandström et al. (2008) made a framework considering both the individual situation of a user and the service experience while measuring value-in-use (Figure 2). Service in this context is 'the provision of the information to (or use of the information for) a consumer who desires it, with or without an accompanying appliance' (S. Vargo & Lusch, 2004). Within value-in-use the physical and technical enablers, like symbols or products, are the foundation for the functional and emotional value proposition of the user (Bitner, 1992). Within this last emotional value proposition personal feelings are important, because they are the resources in the form of knowledge and experience which create a lasting expression (Fisk et al., 2011). The purposeful integration of available resources represents the service experience that eventually could lead to value-in-use (Pfisterer et al., 2015). Helkkula, Kelleher, and Pihlström (2012) note that value is dependent on past, present and future imaginary experiences. The individual situation is important to consider, because value is relative to differences in customer interfaces, offerings, time horizons, relationship costs, trust and risk-taking (Johnson & Selnes, 2004) . Value may change over time (Macdonald et al., 2011).

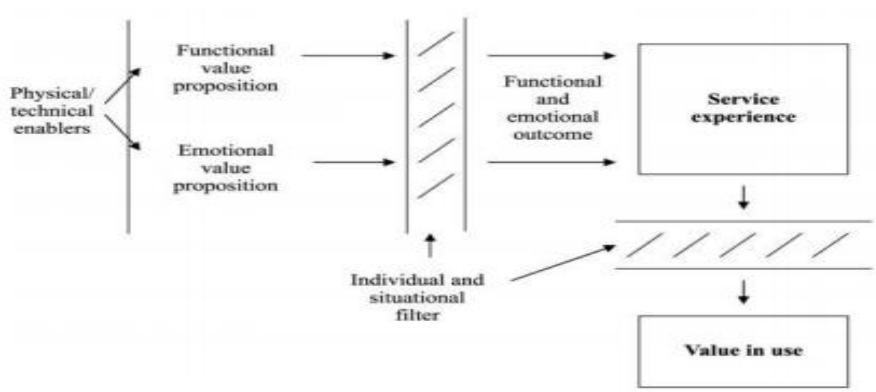

Figure 2. Value-in-use framework of Sandström et al. (2008)

Towards a value-in-use construct - Lai (1995) and Anderson et al. (2005) both proposed value as product benefits. These benefits could be functional, social, affective, epistemic, aesthetic, hedonic, situational, holistic, economic, technical and social. Holbrook (1996) based his typology on three dimensions: intrinsic/extrinsic, self-oriented/other-oriented, and active/reactive. These dimensions resulted in different types of customer values: efficiency, excellence in quality, politics (success), esteem, play, esthetics, morality, and spirituality. All these dimensions show the complexity of the concept of value (Hartmann, 1968; Sheth, Newman, & Gross, 1991; Sweeney & Soutar, 2001). Bick et al. (2014) studied the dimensions of value-in-use more deeply. In this value-in-use model new dimensions were created as well as earlier dimensions of Hartmann et al. (1968), Sheth et al. (1991) and Sweeney and Soutar (2011) were included. This resulted in a framework of 9 dimensions, which can be seen in Figure 3.

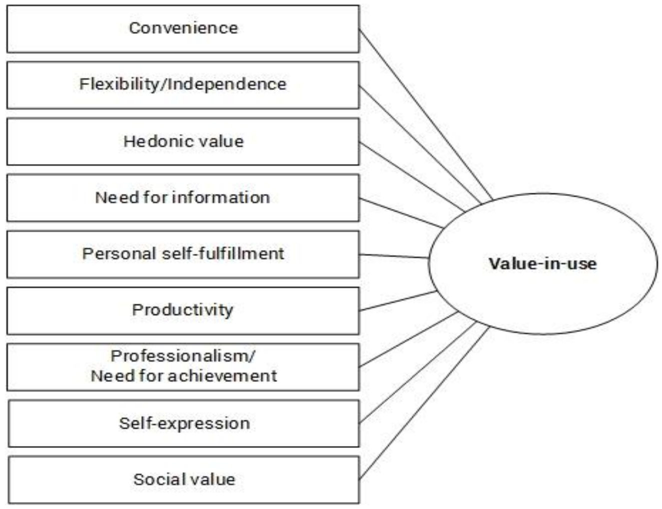

Figure 3. Graphical representation of the framework of the value-in-use dimensions, based on Bick et al. (2014).

A closer look: The concept of co-creation

One of the differences between usability and value-in-use is the active co-creation of value. This paragraph looks more deeply into co-creation. First, the user's role in co-creation is discussed. Then, the co-creation process is examined.

The importance of co-creation and the customers' role - Value co-creation or 'the active involvement of users' has been increasingly recognized as important in research and design. It can contribute to more effectiveness, efficiency, customer satisfaction, and citizen involvement, which was found in a systematic review of 122 articles on value co-creation by Voorberg et al. (2014). Co-creation with customers is becoming key in gaining a competitive advantage. It does not only provide revenue, but it is also a source of gaining product ideas, technologies and/or market access from customers (Kukushin et al., 2015; Voorberg et al., 2014; Walter et al., 2001). The co-creator is deployed in different ways. The customer and service-provider have different roles when co-creating value when they exchange resources within a service. They could be co-implementer, co-designer or could have many other type of roles (Agrawal & Rahman, 2015; Voorberg et al., 2014; Zhang et al., 2015).

The co-creation process and its conditions - In order to facilitate involvement properly Prahalad and Ramaswamy (2004) state co-creation needs to include Dialog, give Access, assess Risk-benefits, and have Transparency (DART) during co-creation, especially for people with a medical condition. Only when customers have clarity about their expectations about basic minimum requirements and excitement factors, and developers can meet those expectations, then it can lead to successful integration (Aarikka-Stenroos & Jaakkola, 2012; Agrawal & Rahman, 2015; Füller & Matzler, 2007). Aarrikka-Stenroos and Jaakkola (2012) described the co-creation process in more detail. They detailed a five step process of collaborative activities: diagnosing needs, dialogue, negotiation, evaluation of solutions and eventually choosing a solution. For health care there are three specific phases within this process of co-creation: preparation of health care, execution of usage and learning of patients' ideas as basis for innovation (da Silva & Farina, 2013). Organizations should be compatible to facilitate co-creation, but the environment is currently still seen as uncontrollable and unreliable. Citizens need to be aware they can influence a service (Voorberg et al., 2014). It should be kept in mind a value system is always understood as a set of interactions that can potentially create value, often resulting in unused potential (Kukushkin et al., 2015).

Summary: The concepts of usability and value-in-use

In order to clarify the different aspects of the concepts of usability and value-in-use a literature review summary and comparison has been provided in Table 1.

Table 1
Literature review summary of the concepts of usability and value-in-use

	Usability	Value-in-use
Field of Study	Goods-dominant logic based on tangible output and transactions (S. Vargo, Maglio, & Akaka, 2008)	Service dominant logic based on intangible output and exchange processes (S. L. Vargo & Lusch, 2008)
	Used in a larger concept of System Acceptability seen as one of the factors in Usefulness (Nielsen, 1993)	
	Important in both product design (Babbar et al., 2002) and as a purchasing factor (Han et al., 2000)	
Aspects of the concept	Ergonomic product quality (Dzida, 1995)	Influenced by both the functional as well as the emotional value proposition (Fisk et al., 2011; Sandström et al., 2008)
Value proposition	Based on a functional value proposition of efficiency and effectivity (Babbar et al., 2002)	Creating value is a process (Bick et al., 2014)
	The use of functionality (Nielsen, 1993)	Value is created in interaction with service-provider (McColl-Kennedy et al., 2012; Pfisterer & Roth, 2015).
	Moving towards including emotional value proposition of both performance as well as image factors (Han et al., 2000)	Valuation is not seen in isolation, but value creation is a multiparty process of interaction with the servicenetwork (de Castro-Ferreira & Menezes, 2015; McColl-Kennedy et al., 2012).
	Creating value is an outcome (Bick, Bruns, Sievert, & Jacob, 2014)	Not homogeneous process judged at purchase, but as a process using a product different for different individuals (Raja et al., 2013).
	Value is embedded in product (S. Vargo & Lusch, 2004).	
	Get rid of marginal features that have no value (Wiklund & Wilcox, 2005)	
	Formative and summative usability (Lewis, 2014).	
Influence of the customer	Take into account needs and wants of customers and transform these into operable product (Babbar et al., 2002)	Take the customers point of view (Anderson et al., 2005; S. Vargo et al., 2008; Woodruff & Gardial, 1996)
	Usability is how well the functionality of the product can be used by users and adapted to this (Nielsen, 1993)	Customer determines value when using product (S. Vargo et al., 2008)
	Should be designed to be usable for a spectrum of users (Nielsen, 1993)	Customer is co-creator of value (S. Vargo & Lusch, 2004)
	Point of view of customers' product evaluation (Keinonen, 1998)	Service experience of the customer (Fisk et al., 2011; Sandström et al., 2008)
	Reactive market orientation (Witell et al., 2011)	Proactive market orientation (Witell et al., 2011)
Context	Take into account context factors (Babbar et al., 2002; Buchenau & Suri, 2000; Maguire, 2001)	Take into account individual situation and context (Johnson & Selnes, 2004; Kukushkin et al., 2015; McColl-Kennedy et al., 2012; Randmaa et al., 2012; Sandström et al., 2008)
Importance of the concept	Disenchantment when adequate quality of use (P. W. Jordan, Thomas, McClelland, & Weerdmeester, 1996)	Create competitive advantage (Anderson et al., 2005; Witell et al., 2011)
	Product returns when expectations not satisfied (den Ouden, Yuan, Sonnemans, & Brombacher, 2006)	Gaining revenue (Wiklund & Wilcox, 2005)
	Repurchase intent and cross-purchasing, product returns, demand on customer support and brand perception (Van Kuijk et al., 2007)	Gaining product ideas (Wiklund & Wilcox, 2005; Witell et al., 2011)

Propositions

Based on the previous paragraphs the following propositions were developed to qualitatively assess differences between value-in-use assessment and usability assessment:

- **Proposition 1** focuses on the assessment within the product life cycle:
  - Value-in-use assessment focuses on the process of exchanging value during the actual usage of a product. Usability assessment focuses on incorporating usefulness into product design.
- **Proposition 2** focuses on the dimensions of both assessments:
  - Both value-in-use assessment as well as usability assessment incorporate functional as well as emotional dimensions and/or value propositions.
- **Proposition 3** focuses on the place of the customer in both assessments:
  - In value-in-use assessment, the customer actively creates the value of the product in interaction with stakeholders. In usability assessment, the stakeholder considers the customers' needs and wants when designing the product.
- **Proposition 4** focuses on the goals of both assessments:
  - The goal of value-in-use assessment is that an individual user values a product during usage. The goal of usability assessment is to develop a product usable by a broad spectrum of users in a spectrum of situations.

Methodology

Research design

The purpose of the study is to research if the value-in-use assessment adds to the usability assessment of an APD for type 1 diabetes patients in the Netherlands. The APD of Inreda Diabetics has been used in this study. The research design is a experimental study. A random selection of patients may have been preferred from a scientific point of view (Shadish, Cook, & Campbell, 2001). However, this preliminary study on the request of Inreda makes use of their database to retrieve patients. The design is a between-groups-design in which differences in treatment conditions of type 1 diabetes patients' usability and value-in-use are compared. It therefore controls for history, maturation and interaction effects of a pretest (Campbell & Stanley, 1963). For both groups, the dependent variables - usability and value-in-use - are studied and qualitatively compared, in order to determine the value of both concepts. The two conditions in this study are the two treatment conditions: patients using an insulin pen and patients using an insulin pump. First, the participants performed three tasks with the APD of Inreda. After the task simulation, the usability and value-in-use of the APD was assessed. For the usability measure an adapted version of the Mobile Phone questionnaire (MPUQ) of Ryu (2005) and a task checklist were used. For the value-in-use method semi-structured interviews were chosen, using an adapted codebook of Bick et al. (2014). A content analysis of the different dimensions was used to determine the value of the APD for the participants. Percentages of the quotes given at each dimension facilitated the content analysis. A schematic view of method used in this study is illustrated in Figure 4.

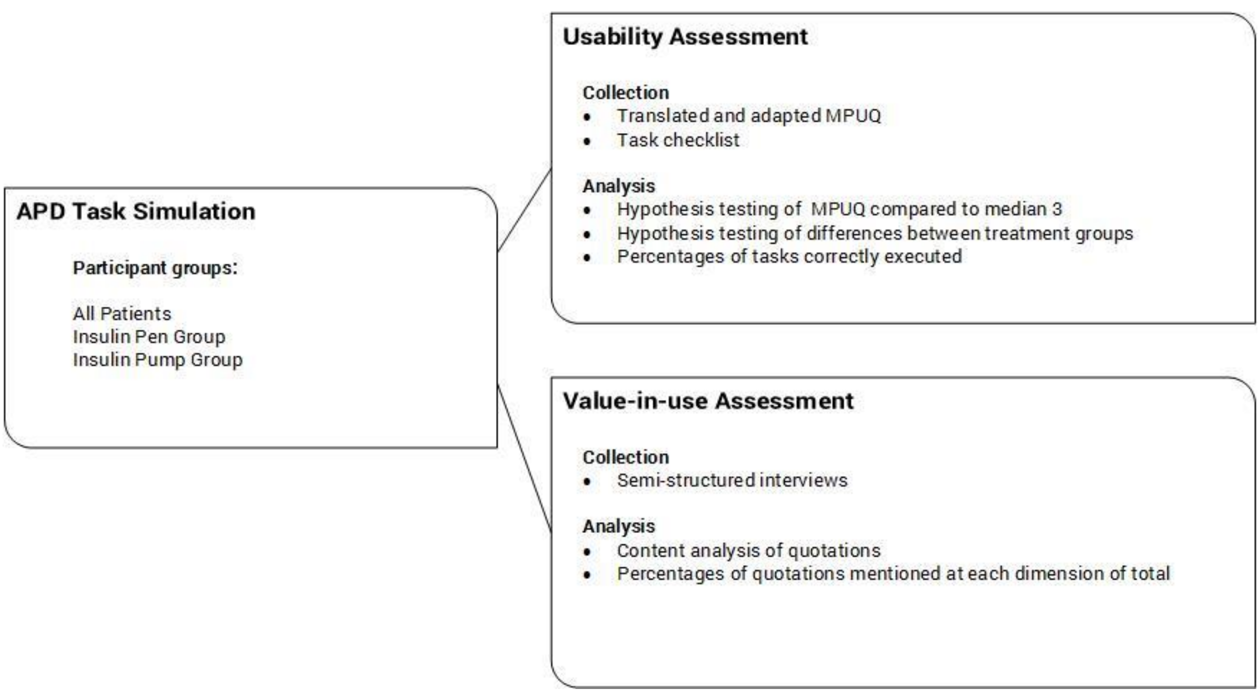

Figure 4. Schematic view of the study: Procedure, data collection and analysis

Subjects

Dutch type 1 diabetes patients were retrieved from a database of Inreda. Patients that previously participated in a clinical test with an APD were excluded, because this could influence their test result. The sample size threshold of Albert and Tullis (2013) of 20 participants was used in this study, because this number of participants can account for at least 95% of the total problems in a study. Female and male patients aged from 18 till 70 were included in the sample. In order to participate, patients needed to have at least one-year experience with their current diabetes treatment (insulin pen or insulin pump). Two groups were formed in accordance with research of Uncu (2014) that states that previous treatment method may influence the intention to use and usefulness of a product. The patients were not randomly invited by email. Participants were selected by convenience sampling. They were placed into the one of the two treatment groups, insulin pen or pump, based on their current treatment method. This is based on data collected in a demographics questionnaire. The demographics questionnaire is based on questionnaires in the studies of Hüsgen (2015) and Uncu (2014). All participants gave their written consent prior to the study after being informed about the procedure of the study. The invitation, the demographics questionnaire and the written consent form can be found in Appendix 1.

Data collection

Tasks

In this study a fixed set of three tasks was developed. These tasks cover for the main functions of the APD. These tasks were chosen in consultation with experts within Inreda. They are in correspondence with typical risky problems with insulin pumps found in earlier literature (Liljegren, Osvalder, & Dahlman, 2000; Vicente, Kada-Bekhaled, Hillel, Cassano, & Orser, 2003). The first task was a test-task to let participants become familiar with the artificial pancreas. When the tasks are executed, use-related hazards are also assessed to validate the safety of the medical device (Kaye & Crowley, 2000; Schmettow, Vos, & Schraagen, 2013). A checklist was used to measure how effective the tasks can be executed. Every subtask was documented for every participant. This documentation was taken into account when determining the usability of the APD. A checklist for all subtasks within the three tasks can be found in Appendix 2. The three tasks to be carried out are:

1. Connect a heartrate belt to the artificial pancreas
2. Replace the insulin ampule of the APD
3. Replace the batteries of the artificial pancreas

Usability assessment: Development of the questionnaire

Choice for usability assessment - Next to the task checklist, a questionnaire has been chosen as the method to measure usability. A questionnaire improves users' ability to provide design recommendations, affects the user's decision-making process for comparative evaluation, gives quick feedback and is often used in health IT (Kushniruk, Patel, & Cimino, 1997; Ryu, Babski-Reeves, Smith-Jackson, & Nussbaum, 2007; Yen & Bakken, 2012). The MPUQ of Ryu and Smith-Jackson (2006) is chosen as a starting point for our questionnaire. This is the most complete usability questionnaire, which includes most dimensions that are mentioned in the review of Coursaris and Kim (2011). This questionnaire complements automated evaluation methods as it provides user-centered values and emotional aspects of a product (Ryu, 2009). The validity of the MPUQ as a psychometric instrument was supported in previous studies (Ryu & Smith-Jackson, 2006). An adapted version of the MPUQ has been used in clinical decision making in the area of anesthesia monitoring, and proofed promise to use the MPUQ in health care monitoring (Karlen et al., 2011).

Characteristics of the questionnaire - This questionnaire is an adapted version of the MPUQ. The questionnaire is translated to Dutch, according to the international guidelines for intercultural translation of health related questionnaires (Beaton, Bombardier, Guillemin, & Ferraz, 2000; Guillemin, Bombardier, & Beaton, 1993). It consists of 58 questions with a categorical 1 to 5 Likert scale (1 – Never and 5 – Always). The questionnaire consists of 6 dimensions, which are the dependent variables who account for usability as a construct (Figure 1). The amount of questions for each dimension is illustrated in Table 2. The specific category for the tasks for mobile phones was adapted to be relevant for the APD-device. In this study an explanation possibility was given after every dimension to study the reason for a certain score on one of the dimensions of the MPUQ. This eliminates the risk of not knowing the reason for an answer (Kushniruk et al., 1997). The MPUQ and all questions can be found in Appendix 4.

Questionnaire examination procedure - A factor analysis was executed for every sub-scale to check if the factor structure corresponds with the factor structure of the original MPUQ. The variance explained by each factor was over 40 percent for all factors and therefore acceptable (Table 2). To determine the extent to which the items in the questionnaire correspond to each other in this population, the internal consistency of the items and the dimensions was studied. The Cronbach's alpha (α) for the total questionnaire was determined at 0.951. All 6 factors had an alpha above 0.7, the acceptable threshold according to Terwee et al. (2007). The Cronbach alpha for each factor can be seen in Table 2. To further strengthen the questionnaire, the corrected item total correlation was studied to determine which items do not correspond with the scale (below 0.3 indicates that the item does not correspond well with the overall scale), and therefore have to be deleted from the questionnaire (Field, 2013). In total 14 questions have been deleted from the original MPUQ. The correlated item total correlations of the 6 factors and their α if item deleted can be seen in Appendix 3, along with further explanation about the deleted items. Based on a Mann-Whitney U Test, there is no significant influence of order of method on the scores of all 6 categories and the total score on the MPUQ (sig. > 0.05).

Table 2

Operationalization of the concept of usability: Original MPUQ questions (N), adapted MPUQ questions (N), Cronbach's alpha of the adapted MPUQ and the variance explained by each factor of the MPUQ.

Dimensions (categories)	Original MPUQ (N)	Adapted MPUQ (N)	Cronbach's Alpha (adapted MPUQ)	Variance explained by factor (%)
ELU: Ease of Learning and Use	23	20	0.920	43.3
HPSC: Helpfulness and Problem Solving Capabilities	10	8	0.805	51.8
AAMP: Affective Aspect and Multimedia Properties	14	12	0.845	44.0
CMML: Commands and Minimal Memory Load	9	5	0.727	49.3
EC: Efficiency and Control	9	7	0.721	40.5
TTAP: Typical Tasks for the Artificial Pancreas	7	6	0.734	51.7
Total	72	58	0.951	-

Value-in-use assessment: Development of the interviews

Choice for value-in-use assessment - For measuring value-in-use a semi-structured interview was used. Interviews allow for identifying complex needs and perspectives of users (experts in their field) and provide rich data needed for capturing both unknown latent and known needs within value-in-use (Witell et al., 2011). A disadvantage is that results could be biased by the researcher during interviews and while interpreting, as well as results cannot be compared (Bick et al., 2014; Manning & Stage, 2003; Wahyuni, 2012). Our interviews are semi-structured, which are known as a hybrid type of interview which lies between structured and in depth interviews (Saunders, Lewis, Thornhill, & Wilson, 2009). It offers the merit of using predetermined questions and topics and keeps flexibility by letting interviewees talk freely (Wahyuni, 2012). It is therefore considered appropriate for this type of research. Percentages of the amount of quotations will facilitate the analysis to be able to compare treatment groups.

Characteristics of the interviews - The value dimensions identified by a value-in-use study of smartphones of Bick et al. (2014) were used as a starting point for the interview guide. The value dimensions of Bick et al. (2014) were adapted and complemented. The value dimension Health Benefits was added, as the product is a technology for medical treatment. This resulted in a total of 10 value dimensions. A total of 23 value aspects were used during the analysis of the interview data. The total operationalization of the interview guide can be seen in table 3.

Interrater-reliability examination - The interrater-reliability has been calculated by hand using the Cohen's kappa method, mentioned as the most widely used inter-rater reliability index (Gisev, Bell, & Chen, 2013). Overall inter-rater agreement was established at 0.78, using a second coder with the academic degree (Master of Science). Using the acceptance-standard of Neuendorf (2002) of 0.7, this can be seen as substantial.

Table 3

Operationalization of value-in-use, divided into value dimensions and value aspects

Value dimensions	Definition of dimension	Value aspects: Codes
Convenience	The user appreciates a comfortable and carefree usage as well as convenient handling.	• The level of cognitive effort and other positive aspects • The duration and speed of usage • The issues and concerns with the APD
Flexibility/ independence	The user wants to be unrestricted, flexible, and independent of location and other devices as possible during usage.	• Decreased dependency on procedures/others and increase of flexibility of movement • Increased dependency on procedures/others and decrease of flexibility of movement
Health Benefits	The users feels the device brings benefits to their health.	• Stability of blood sugar • Risk of complications • Physical activity
Hedonic value	The user wants to have fun, enjoy entertainment, and relax from stress.	• Fun • Relaxation
Need for information	The user wants to be consistently informed, he or she wants to enhance knowledge, be up to date, and know what is happening around him or her	• Information needed/given by APD • Information not needed
Personal self-fulfillment	The user wants to unfold and pursue personal interest and own hobbies.	• Change in the ability of pursuit of personal interests • No change in the ability of pursuit of personal interests
Productivity	The user wants to better organize and arrange his or her daily routines and pursues clear goals and plans.	• Change in decision-making, organization of daily activities, productivity • No change in decision-making, organization of daily activities, productivity
Professionalism/Need for achievement	The user wants to act dutifully and strives for achievement and professionalism by meeting his obligation.	• Change in the ability to meet obligations • No change in the ability to meet obligations
Self-expression	The user wants to be perceived and seen by others; the user wants to show others what he or she is like and satisfy the need to communicate.	• Change in self-presentation, social life, communication with others • No change in self-presentation, social life, communication with others
Social value	The user appreciates interaction with social contacts, the user wants to maintain relationships, keep in contact with friends and family, and communicate with them.	• Negative aspects for peers • Acceptance of peers • Social-emotional benefits for peers

Procedure and Analysis of data

<u>Test Environment for Performing Tasks</u>

Procedure - The participants were placed in the room where three tasks were programmed into the simulation. Instructions for the tasks were presented on the display of the AP. The participants were instructed not to ask for advice during the task. The tasks could be carried out independently to not let participants get stuck during the procedure. The study was conducted at Inreda in Goor in the Netherlands in a quiet room. Before participating in the study the participants received a small explanation, which can be seen in Appendix 5.

Analysis of data - Every task was documented in the task checklist, which served as support material to analyze the usability of the APD. Every task consisted of sub-tasks. Percentages for the successful completion of the total, each task and each sub-task were calculated. This is important for providing a reproduction of the situation and facilitate reliable analysis of participants' problems (Kaufman et al., 2003; Kushniruk et al., 1997). During the task, the researcher was in the room to document. To design the procedure of the tasks, the study of Schmettow et al. (2013) was used as a guideline.

<u>Questionnaire Procedure and Analysis of Data</u>

Procedure - When the participants indicated the three tasks were completed or when they felt stuck and could not proceed, they continued either with the questionnaire or with the interviews. These were randomly distributed. Participants had the ability to ask questions during taking the questionnaire, when they did not understand an item in the questionnaire.

Analysis of data - In this study, the Likert measure is considered as ordinal data and therefore non-parametric tests were used. This choice is strengthened by G. Norman (2010), as it cannot be guaranteed that the distance between 1 and 2 is the same as between 4 and 5. Under normal conditions, non-parametric tests use rank, median or range with tabulations, frequencies, contingency tables and chi-squared statistics (Allen & Seaman, 2007). However, there is chosen to use means in this study to show differences in groups. Although the distance between numbers cannot guaranteed, for this study this is irrelevant, because the computer only deals with numbers and differences to make conclusions. Within earlier studies using the MPUQ, means have also been used (Karlen et al., 2011; Ryu, 2005), strengthening the choice for means. Differences are considered significant if $p < 0.05$. SPSS software, version 21, was used for data analysis. The MPUQ was presented to the participants using the program Limesurvey (2.50+). This program can easily transport data to SPSS. Two hypotheses were drafted to test the first and second sub-question. For the first question '*What is the usability of the artificial pancreas for type 1 diabetes patients in the Netherlands?'* the Wilcoxon Rank Test was used to compare the usability to the median of the 5 answer categories. The alternative hypothesis was that the total usability of the artificial pancreas for type 1 diabetes patients was not equal to 3. The second question of '*Are there statistical significant differences between the usability outcomes of the different treatment conditions in type 1 diabetes patient groups?'* the Mann Whitney U test was used, as the data of the two groups is considered as unpaired. The alternative hypothesis, which has been drafted based on the study of Uncu

(2014) was that for the artificial pancreas there were significant differences between the usability outcomes of the different treatment conditions in type 1 diabetes patients.

Interview Procedure and Analysis of Data

Procedure - Before the interview, the participants were briefed and got information about the aim of the interview. This aim of the interviews focused on the value participants attributed to the APD during usage. The confidential, anonymous and voluntary nature of the study was emphasized during the briefing. Even though the consent form was signed, the participant was asked again if the interview could be recorded. A written interview guide was used as a checklist to cover all value dimensions. The actual questions were based on the natural rhythm of dialogue, based on guidelines of Dooley (2001). Both past and present experiences with their diabetes regulation devices as well as future imaginary experiences with the APD were discussed in the interviews, based on literature of Helkkula et al. (2012). The interviews were structured into open-ended questions about the value-in-use of the tasks and the different value dimensions. Follow up questions served to assess why participants valued or did not value certain aspects. This structure is developed according to guidelines of Wahyuni (2012). The conceptual interview guide was discussed with experts of Inreda before being accepted into the study, and can be found in Appendix 6.

Analysis of data - After the data from the interviews was collected, the interviews were fully transcribed and coded. After transcribing, the data was checked with the audio tape for accuracy. The raw-text based data from the interviews was axial coded by the researcher in order to make connections between categories. The total amount of quotations for each dimension was used as a basis for establishing frequently mentioned dimensions. By using a content analysis, the data collected on each dimension was assessed on a qualitative level. Constant comparative analysis was executed by analyzing patterns and themes within the data. This method is preferred when trying to reveal important differences, concepts, processes and experiences in a systematic way (Boeije, 2002; Wahyuni, 2012), and therefore of use in this study. Linguistic details as laughter were deleted, because only the content of the interview was of interest. As the interviews are confidential and anonymous, information identifying the participant was omitted. This information was replaced with a unique code, which is based on guidelines of Wahyuni (2012).

Results

Participants

A total of 212 patients from the database from Inreda were sent an invitation for the study. This invitation was sent on April 4th 2016. The response rate of the invitation was 38.2%. A total of 36 participants was scheduled, where 4 participants cancelled due to private circumstances. Participants came from 10 of the 12 different provinces in the Netherlands, excluding Friesland and Zeeland. The study included 32 type 1 diabetes patients (17 women, 15 men, M *age* = 43,9 years, age range: 19-67 years). The study was performed in the period of April 23th 2016 until May 26th 2016. The insulin pen group consisted of 13 participants (6 women, 7 men, M *age* = 46.7 years, age range: 19-67 years). The insulin pump group consisted of 19 participants (11 Women, 8 men, M *age* = 42.0 years, age range: 21-62 years). Participants were randomly placed in groups in which the procedure of the study differed. This to study the influence of procedure. The interviews - questionnaire group consisted of 16 participants (9 women, 7 men, M *age* = 45.4 years, age range: 19-62 years). The questionnaire - interviews group did also have 16 participants (8 women, 8 men, M *age* = 42.3 years, age range: 21-62 years). The demographics can be seen in Table 4. The Kolmogorov-Smirnov test, Shapiro-Wilks Test and degree of skewness and kurtosis showed statistical support for the normality of both gender, educational level, age, years of treatment method and years of diabetes. Missing data was imputed by the mean of the item score.

Table 4
Demographical representation of participants: Total, insulin pen and insulin pump

	Gender	N (%)	Educational level	N (%)
Total (N = 32)	Male	15 (46.9)	Basisonderwijs	0 (0)
	Female	17 (53.1)	Voortgezet onderwijs	5 (15.6)
			Middelbaar Beroepsonderwijs	13 (40.6)
			Hoger Beroepsonderwijs	12 (37.5)
			Wetenschappelijk onderwijs of hoger	2 (6.3)
Insulin Pen (N = 13)	Male	7 (53.8)	Basisonderwijs	0 (0)
	Female	6 (46.2)	Voortgezet onderwijs	3 (23.1)
			Middelbaar Beroepsonderwijs	6 (46.2)
			Hoger Beroepsonderwijs	4 (30.8)
			Wetenschappelijk onderwijs of hoger	0 (0)
Insulin Pump (N = 19)	Male	8 (42.1)	Basisonderwijs	0 (0)
	Female	11 (57.9)	Voortgezet onderwijs	2 (10.5)
			Middelbaar Beroepsonderwijs	7 (36.8)
			Hoger Beroepsonderwijs	8 (42.1)
			Wetenschappelijk onderwijs of hoger	2 (10.5)

In years	Age (range)	Diabetes (range)	Method (range)	Median		
				Age	Diabetes	Method
Total, Mean	43.9 (19 - 67)	23.6 (4 - 52)	13.1 (1 - 45)	46.5	21.5	8.5
Insulin pen, Mean	46.7 (19 - 67)	21.4 (4 - 52)	18.8 (4 - 40)	49.0	16.0	16.0
Insulin pump, Mean	42.0 (21 - 62)	25.1 (6 - 45)	9.2 (1 - 45)	45.0	22. 0	5.0

MPUQ - Usability questionnaire

<u>Usability of the APD: All patients</u>

Questionnaire - For the MPUQ questionnaire the Wilcoxin Rank Test was used. This allowed for examining whether the usability of the artificial pancreas for type 1 diabetes patients is significantly higher than the median 3. Mean scores were calculated for the total usability score and for each of the 6 dimensions. The alternative hypothesis is that the total usability of the artificial pancreas for type 1 Diabetes patients is not equal to 3. A Wilcoxin Rank Test revealed a significant difference between the total MPUQ score for type 1 diabetes patients and the median 3 (mean = 4.14, SD = 0.41, Sig. = 0.000) as the significance is below 0.05. All 6 categories of the MPUQ showed significant difference with the median 3 as their significance was below 0.05. The total usability score and the score for all of the 6 categories scored significantly higher than the median 3. The mean scores (M), standard deviation (SD) and significance (Sig.) can be found in Table 5. Therefore, it can be said that the alternative hypothesis is sustained for the score in total as well as for each of the 6 dimensions. When studying the usability of the participants on dimensional level, the factor AAMP scores the lowest among the type 1 diabetes patients with a score of 3.57. When looking at the item level can be seen that AAMP 1 – Is the size suitable for carrying the device (mean = 2.52, SD = 1.29) and AAMP 5 – Does the color make the product attractive (mean = 2.31, SD = 2.09) have the lowest scores within AAMP. AAMP5 is statistically significantly lower than the median 3. Participants experienced the color of the APD as unattractive. However, only a small amount of participants mentioned this in the comments. They did state that the color of the APD is not of great importance, but that the functionality is crucial as it could help them in their medical treatment. AAMP 1 – if the APD is convenient to carry - scores statistical significantly lower than the median 3 (Sig. = 0.041). Therefore, the size of the APD is considered as inconvenient to carry for participants. This is articulated by 34.4 percent of the participants in the comments of the questionnaire. An illustration of a comment: *'The device is still too big and cumbersome. A smaller device, more gracefully designed and a less notable color would be nice (P4)'.*

Task checklist - The checklist shows that 72.9 percent of the participants could successfully complete the tasks overall. A percentage of 90.6 percent of the participants could successfully complete the first task – activating the heartrate belt. A total of 43.8 percent of the participants could successfully complete the second task– replacing the insulin ampule. This was due to the last step in the task process. Also 43.8 percent of the participants was able to let the canule drip in order to remove the air in the tube. Most participants did not properly check if the canule had dripped. The second task was not considered as successfully completed when this vital step could not be completed by a participant, as this could result in safety issues. Participants also had problems with the whether they should change the infusion set during the second task. This was only successfully completed by 56.3 percent of the participants. By pressing 'yes' instead of 'no' participants became confused, because the APD had already communicated to them to remove the canules in earlier stages of the task. However, this was not vital for safety and therefore not vital in completing the second task in total. The last task – replacing the batteries – was successfully completed 84.4 percent of the participants. One problem was raised within this task. Although the manual stated that the battery cover should be used to remove the batteries, only 43.8 percent of the participants used this cover.

Conclusion - The results of the MPUQ and the total percentage of successfully completed tasks overall provide evidence that the usability of the artificial pancreas is evaluated as positive by type 1 diabetes patients in the Netherlands. Alterations should be made to ease the canule dripping procedure, as this is vital to the safety of the patient's treatment.

Usability of the APD: Insulin Pen and Insulin Pump

Questionnaire - For assessing differences between the insulin pen group and the insulin pump group the Mann Whitney U test was used. The alternative hypothesis of that there were significant differences between the usability of the artificial pancreas of the insulin pen group and the insulin pump group was examined. The Mann Whitney U test revealed no significant difference between the insulin pen group and the insulin pump group on the total MPUQ score (M *pen =* 4.03*,* M *pump* = 4.21, Sig. = 0.170). No significant differences were found between the insulin pen and insulin pump group for all 6 dimensions of the MPUQ, as their significance was above 0.05. Although not significant the insulin pump group scores slightly lower on all 6 dimensions. It can be said that the alternative hypothesis is rejected for the total score as well as for all 6 dimensions. The mean score for both the insulin pump group and the insulin pen group (M), their standard deviation (SD) and significance (Sig.) can be found in Table 5. When studying the groups on dimensional level the AAMP scores lowest for both groups. This is in accordance with results for the total participant group. When looking deeper into the scores of the MPUQ on an item level, three items which were deleted, showed to have significant differences across the 2 groups. On the first item on whether the help during the tasks is useful the insulin pump group scores significantly lower than the insulin pump group (HPSC1) (M *pen =* 3.71*,* M *pump* = 4.60, Sig. = 0.007). On the items mentioning if there is an index for the tasks (CMML3) and the data (CMML4), the insulin pump group does also score significantly lower than the insulin pump group. When looking at items within our questionnaire the insulin pen group scores significantly lower on whether the brightness makes the product attractive (AAMP6) (M *pen =* 3.61*,* M *pump* = 4.26, Sig. = 0.045). These aspects could possibly be explained, as insulin pump users have experience with the brightness of the screens of insulin pumps, with task and data indexes on their current devices and with current manuals for their insulin pumps. They are therefore able to compare these, where insulin pen users cannot. A quote of a member in the insulin pump group is for example: *'Pleasant control for somebody who already works with insulin pumps (P16)!'*

Task checklist – Both groups could complete all tasks successfully in general. Based on the percentages a small difference can be seen in overall completion. Where 66.7 percent of participants of the insulin pen group could successfully complete the tasks, 77.2 percent of the participants in the insulin pump group could. When looking deeper into this difference, task two must be studied. At the second task insulin pen users scored notably lower, where only 23.1 percent of the participants of this group could successfully complete the task. A total of 57.9 percent of the insulin pump users could successfully complete the task. The largest difference between both groups can be seen at whether the canule dripped (*insulin pen* = 23.1%, *insulin pump* = 57.9%). This task is vital for safe treatment with the APD. An explanation for this differences can be sought in the comments within the MPUQ by the patient groups. A total of 31.6 percent of the insulin pump group mentioned that their experience with their pump helped them during the task. A number of 38.4 percent insulin pen group explained that their lack of experience with similar systems like the insulin pump or lack of experience with the terminology of the artificial pancreas was a disadvantage when completing the tasks. Distinctive for the insulin pen group are quotes as '*What is a canule? Not clear (P13).'* and '*I think it is quite a lot, when you are only used to an insulin pen (P28)'.* Several other remarks can be made. For the second task, both groups showed low scores on whether the infusion set should be replaced (*pen* = 53.8%, *pump*= 57.9%) and they did not use the battery cover for removing the batteries (*pen* = 38.5%, *pump* = 47.4%). This is comparable to the total for all participants. The completion scores on the first and third task are comparable between groups. For the first task 89.5 percent of the insulin pump users and 92.3 percent of the insulin pen users could successfully complete the task. A number of 84.6 percent of the insulin pen users could complete the third task successful, where 84.2 percent of the insulin pump users could.

Conclusion – Although the checklist shows differences between the two groups in successfulness of completed tasks, no statistical evidence is provided that there is a difference in usability between the insulin pen group and insulin pump group on a total MPUQ level or on a factor level. On an item level differences were found between groups. The scores on the task checklist for all patients, the insulin pen group and the insulin pump group can be found in Appendix 7.

Table 5

Usability scores for total MPUQ and for each dimension: Mean (M), Standard deviation (SD) and Significance (Sig.) for all patients, insulin pen users and insulin pump users

	All Patients			Insulin pen		Insulin pump		
	M	SD	Sig.	M	SD	M	SD	Sig.
Ease of Learning and Use	4.2488	0.53	0.00	4.1638	0.44	4.3070	0.59	0.17
Helpfulness and Problem Solving Capabilities	4.1257	0.55	0.00	4.0690	0.37	4.1714	0.65	0.32
Affective Aspect and Multimedia Properties	3.5700	0.68	0.00	3.3684	0.71	3.7078	0.64	0.24
Commands and Minimal Memory Load	4.2984	0.47	0.00	4.2383	0.39	4.3395	0.52	0.43
Control and Efficiency	4.2736	0.50	0.00	4.1473	0.49	4.3601	0.49	0.21
Typical Tasks for the Artificial Pancreas	4.3190	0.42	0.00	4.2102	0.50	4.3935	0.35	0.22
Total	4.1393	0.41	0.000	4.0312	0.33	4.2132	0.45	0.17

Value-in-use

<u>Value-in-use of the APD: All patients</u>

In order to assess the value-in-use of the artificial pancreas for type 1 Diabetes patients in the Netherlands all 32 interviews have been transcribed and coded. This resulted in a total of 1299 quotations. A total of 32 interviews were conducted. Whereof 31 interviews conducted face-to-face and 1 interview conducted by phone.

Convenience – A number of 23.8 percent of the quotations coded mentioned the convenience of the APD. Participants thought the APD was easy to use as it takes low cognitive effort when using the product. The APD was experienced as having a low duration and quick speed of usage (N = 145, 11.5%). A quotation to illustrate these findings: *'I thought it was quite handy. It is almost idiot-proof. Easy. I would say that almost everybody can use it* (P1)'.

Overall the tasks were experienced as easy to complete. Participants thought their speed of usage could increase if they used the APD more often: '*I think the more often you use it, the faster it goes* (P13)'. However, participants did encounter issues and problems during the use of the APD. Most mentioned was the large size and heavy weight of the device. This was often mentioned by participants: '*Yes, indeed. The battery system needs to be replaced. It really needs to be easy to secure. I would not know where to put that thing. In this case. It is certainly too heavy. I hate the color* (P20)'. Other frequently mentioned problems were the inability of participants to replace the insulin ampule and/or batteries, problems participants have with needles in the stomach during usage, concerns of participants about if the device fails or problems participants have with the size of the characters on the screen (N = 156, 12.0%). An example: *'The display should be really clear. My eyes are bad. Many diabetics have poor eyes. There should be something to enlarge it? The screen or a part of the screen. I think that would be better* (P21)'.

Flexibility/Independence – A total of 24.5 percent of the quotations coded mentioned the flexibility/independence aspect. The value of the APD lies mostly in its ability to decrease the participants' feeling of dependency on others and procedures (N = 208, 16.0%). To illustrate this potential experience of freedom: '*Yes, it makes your life so much easier. Because now you constantly have to watch what you are eating and doing in order to gain the right amount of insulin. And if that thing does what is says it does, you do not have that anymore* (P23)'. Still, for the participants the use of the APD can also increase the dependency they feel on the device for regulating their Diabetes. The device and tubes could restrict flexibility of movement (N = 110, 8.5%). Mentioned by many participants is the potentially restricted feeling during activities: '*Well, when I am playing with the kids, definitively in the beginning, you have all those things on your body. '…' It is always stuck on your body with a needle inside of you* (P18)'. For the participants this is a consideration. Eventually for most participants the independency the APD could bring is considered as most important: *'I think I would be more dependent on the device, but more independent in my daily activities. I am faster in saying: 'Oh, I am going to work out now'. Not that I have eaten and have to wait for an hour '…' Everything that is not regulated, deregulates. So I think it would definitely give me freedom at those moments* (P20)*'.*

Health benefits and Hedonic Value – All participants agree that the artificial pancreas could provide a more stable blood sugar (N = 59, % = 4.5). This could help in decreasing the risk of complications (N = 39, % = 3.0). Due to these aspects the artificial pancreas could ensure a certain degree of relaxation for the participants (N = 50, % = 3.8). An example of a statement regarding this aspect: *'Look, sometimes I do have a low blood sugar, that is the reason I check myself so often. It would give me lots or relaxation, to know that does not happen anymore* (P3)'.

Need for Information – In general participants would like to have little or no information and let the device regulate their blood sugar (N = 51, 3.9%). A quote of a participant 23 illustrates this finding: '*If the device is running, I would not like to know anything, because when I do I am still busy with regulation my diabetes'.* Participants do indicate that their trust in the APD has to be gained during usage, and they would still like to have to possibility to check the blood sugar in daily activities and during problems. Especially in the beginning of their usage of the APD (N = 108, 8.3%). Most participants indicate when starting to use the APD, they are likely to check the reliability of the APD by manually controlling the blood sugar: '*I think that you will regularly check yourself in the beginning. How high is it?*

And how do I feel? If that works for a couple weeks, month or a few months, and it is always is 4 and 8 as it supposed to be. Then that is normal again and you will probably check less manually or maybe even never again (P17)'.

Personal self-fulfillment - Participants think the APD could to a small extent increase their ability to pursue personal interests (N = 41, 3.2%). This is illustrated by participant 27 who indicates that the APD decreases the unconscious amount of risk participants take into account when pursuing personal interests with their current method: '*Sure, I think that after a while you will be able to go back to before you had diabetes. Excluding some moments when you still have to check. That is part of it. However, for everything else you should be able to approach your limit to make sure you are developing again. Physically, but also spiritually. Right now you always have that fear during physical activities.'*

Productivity – Using the APD does not influence decision-making, organization of daily activities and productivity in general for participants (N = 41, % = 3.1). Based on the quotations given by different participants the APD could mainly raise the productivity during a state of hypo- or hyperglycemia: '*Yes, I think so. If you are better in your sugars, you will feel better physically and mentally. I do think you are more productive then* (P26).' When looking at daily activities, participants state daily activities and decisions could become easier when using the artificial pancreas (N = 58, % = 4.5). To illustrate this: '*Not different decisions, but easier decisions. You do not have to think where you are at that point and it is therefore easier to decide if you want to ride your motorcycle or to work out* (P15).'

Self-expression and Professionalism – For participants, the self-presentation, social life and communication with others (N = 60, % = 4.6) or ability to meet obligations (N = 31, % = 2.4) is not influenced by their usage of the APD. Most participants indicate they would not present themselves differently with or without an APD, both in private and work circumstances. Some quotes to illustrate this are: *'No, sometimes you have to arrange some extra things when you are going abroad for instance, but that is also necessary with this device '…' However, that is more about the person, and less about the device. At the moment diabetes does not stop me in what I am willing to do* (P4)' or '*I do not feel I present myself as a diabetes patient. That is not how I am '…' I would not present myself any different* (P25)'.

Social value – Participants agree that their peers would accept their potential use of the APD. The use of the APD could also potentially result in social-emotional benefits for peers. Most participants mention that the APD could also bring relaxation for friends and family. This is illustrated by the following quotation: '*If I am feeling better, I think my surroundings will start to notice that. That is good for everybody* (P30).'

Conclusion – An overview and conclusion for the participants on all dimensions is illustrated in Table 6. The percentages and amount of quotations for all value dimensions and value aspects can be found in Appendix 8.

<u>Value-in-use of the APD: Insulin pen and insulin pump</u>

In order to assess whether there are differences in the value-in-use outcomes for the different treatment conditions among type 1 Diabetes patient groups, a comparison between both groups was made. This resulted in a total amount of 493 quotations for the insulin pen group and 806 for the insulin pump group. In this paragraph only the dimensions with differences in groups will be discussed.

Flexibility/Independence – A difference can be seen between groups when looking at the percentage of quotations within the dimension of flexibility and independence (*pen =* 30.4%, *pump* = 20.7%) When looking deeper into that difference, several remarks can be made. The insulin pen group experiences the use of the artificial pancreas to a greater extent as a potential increase in their dependency on the device. It could also decrease their flexibility of movement to a greater extent in comparison to the insulin pump group. Explanations given by insulin pen users are the low degree of experience they have with carrying a device and/or their current choice to use a pen to not wear a device. An illustration of these aspects: '*Yes. That is also one of the reasons for why I do not have an insulin pump. Because you are attached to it all day and all night. When you want to swim? Then you should disconnect it. That it also something you have to do with this device. And how does it proceed? I can imagine that the device can't handle that. It is not waterproof. '…' At that moment nothing is controlled (*P21)'.

Controversially, insulin pen users articulate to a greater extent that the use of the APD can potentially give them a feeling of a decreased dependency of others/procedures compared to insulin pump users. Insulin pen users do also mention that the APD could potentially lead to an increase in flexibility of movement (*pen =* 10.5%, *pump* = 7.2%). Therefore, for insulin pen users the APD could increase, whilst also decrease dependency and flexibility of movement. An explanation for this conversion is that for insulin pen users, even though the APD stabilizes their blood sugar, their current insulin pen is seen as less invasive. An example of an insulin pen user considering this aspect: '*You have to have the APD with you. So, using an insulin pen is much easier. But maybe, if I have an APD, I will think 'Why did I not do that any sooner?' (P28)'.* Also, insulin pump users mention that the insulin pump already facilitates a certain amount of tasks and independency in comparison with the insulin pen. Insulin pen users do not have this experience. An illustration of a comment of an insulin pump user: *'Yes, I think so. The insulin pump is already great. I have had an insulin pen, but the insulin pump is great. Because it does already take over a lot of things.'…' I think if I would have an artificial pancreas it would be a lot easier (P12)'.*

Need for information – Insulin pen users articulate to a greater extent their need for information when using the APD, compared to insulin pump users (*pen =* 5.8%, *pump* = 9.8%). An explanation for this difference can be found within the fact that the insulin pump group already has experience with a similar device and with problems that occur with these devices. A quotation to illustrate this aspect: '*In the beginning you probably would want to see what the device does. '…' But I do not think it is an ideal control system. He will probably spin out of control once in a while. Then you should be able to react and check the history what happened* (P29)'.

Other aspects – When looking at the decision-making, the organization of daily activities and productivity a difference can be seen between groups in percentage (% *insulin pen = 5.0, % insulin pump = 8.9).* However, based on the answers of the different groups no explanation for this difference was articulated, and this is therefore comparable to the total for all participants. Also, no differences were found in the health benefits the APD brings, the fun and relaxation the APD could give, the ability of the participants to pursue their personal interests or to meet obligations with the APD. This is all comparable to the value propositions mentioned by all participants. No difference can be seen in self-presentation and communication of participants when using the APD as well as the acceptance of the APD by peers. The APD helps in treating diabetes, but does not influence the personality of the participant.

Conclusion - Within Table 6 the conclusion per value dimension can be found for all type 1 diabetes patients. The conclusion also shows where differences were found between groups.

Table 6

Overall conclusion per value dimension: All type 1 diabetes patients and difference in treatment conditions with total amount of quotations (N) and percentage (%)

	N (%)	Overall conclusions:
Convenience	309 (23.8)	Participants indicate the APD is easy to use and has a low duration of usage. Although, still a relatively high amount of problems and issues are mentioned, mainly concerning the large size and weight. No difference between treatment condition was articulated
Flexibility/ independence	318 (24.5)	Participants indicate the APD allows for independency in daily activities and freedom of movement. This feeling of independency is higher for insulin pen users as the insulin pump does already facilitate a certain amount of tasks and independency. Although, it is articulated that carrying the device decreases the flexibility of movement due to the size and weight of the device and the tubes attached, which is mentioned more by insulin pen users.
Health benefits	117 (9.0)	Participants indicate the APD stabilizes the blood sugar, decreases the risk of complications and provides the ability to increase physical activity if participants want to. No difference between treatment condition was articulated.
Hedonic value	57 (4.4)	Participants indicate the APD brings relaxation for participants due to the function of stabilizing the blood sugar. It can bring more fun into the lives of participants, although participants indicate they do not let their diabetes influence their amount of joy. No difference between treatment condition was articulated.
Need for information	164 (12.6)	Participants indicate they want to have the ability to check blood sugar during daily activities and during problems, mainly in the beginning of using the APD. More insulin pump users than insulin pen users indicate this aspect, possibly explained by insulin pump users already having experience with problems occurring in these devices and therefore want to have information regarding its functioning. It is also articulated no further information is needed as the APD is experienced as a device taking over their current regulation function.
Personal self-fulfillment	50 (3.8)	Participants indicate the APD could to a small extent improve the participants' ability to pursue their personal interests. No difference between treatment condition was articulated.
Productivity	97 (7.5)	Participants indicate that the APD does not influence their decision-making, organization of daily activities and productivity. The APD could only influence productivity in a state of hypo- or hyperglycemia. It is also indicated the APD makes it easier to make decisions. No difference between treatment condition was articulated, although there is a difference in percentage between groups found.
Professionalism/ Need for achievement	31 (2.4)	Participants indicate the APD does not influence their ability to meet obligations. No difference between treatment condition was articulated
Self-expression	93 (7.2)	Participants indicate the APD does not influence their self-presentation, communication with others and social life. No difference between treatment condition was articulated.
Social value	63 (4.8)	Participants indicate the APD is accepted by peers in general and could possibly bring social-emotional benefits for peers. No difference between treatment condition was articulated.

Discussion

Discussion and theoretical contribution

Summary

This study researched whether value-in-use assessment is an addition to usability assessment. The context of the study is a medical technology, the artificial pancreas. Different treatment conditions in diabetes type 1 patients in the Netherlands were studied. For the purpose of readability, the research question is repeated:

'What does value-in-use assessment add to usability assessment of an artificial pancreas for type 1 diabetes patients in the Netherlands with different treatment conditions?'

In order to test this, the first four sub-questions were drafted. These were used as a framework for studying value-in-use assessment and usability assessment. When looking at those questions independently several remarks can be made. The overall usability was positively evaluated by the type 1 diabetes patients. Overall the tasks could be successfully completed. Participants evaluated the device as too heavy to carry. The canule dripping procedure could not be successfully completed by a large share of the participants, which is important as it is vital to the safety of diabetes treatment. No differences between treatment conditions were found, except for differences on item level. Insulin pump users assessed the help during the tasks as more positive than insulin pen users. Less insulin pen users succeeded in letting the canule drip. An explanation is derived from the low experience of pen users with such devices. The value-in-use of the APD for type 1 diabetes patients lies mainly in the independency which the APD provides in daily activities. The APD could give a higher flexibility of movement. This results from a better regulation of the blood sugar. More insulin pen users experience carrying the device and its tubes to a greater as a feeling of decreased flexibility of movement. This was compared to insulin pump users. The APD does not influence decision-making, self-presentation or the ability to meet obligations. It could help the type 1 diabetes patient in making easier decisions. To study if value-in-use assessment adds to usability assessment four propositions were made. These will be discussed independently in order to provide a complete answer on the main question.

Proposition 1: The assessment within the product life cycle

'Value-in-use assessment focuses on the process of exchanging value during the actual usage of a product. Usability assessment focuses on incorporating usefulness into product design'.

The findings of this study indicate that incorporating value-in-use assessment during product development can already give information about the value proposition of the product. Value-in-use can not only be assessed during actual usage, as stated by MacDonald et al. (2011) and McColl-Kennedy et al. (2014), but also during product development. As an example: The pursued functionality for the stabilization of the blood sugar can potentially lead to an experience of independency in daily activities and flexibility of movement. Therefore, value-in-use can indeed be seen as a process, as proposed by Bick et al. (2014). The technology developer can incorporate certain features into the product based on the expected value propositions of the user. Assessing value-in-use to facilitate this exchange process can certainly lead to the incorporation of tangible features. Value-in-use is therefore not only about intangible output and exchange processes as proposed by S.L. Vargo and Lusch (2008). By incorporating the feature of constant information of the blood sugar value, patients are potentially more relaxed. The usability needs' and wants' of the user should be taken into account during product design to develop an operable and usable product. Still, it should be realized that needs can change over time. It is advisable to choose specific moments to assess the needs and wants of users. Usability should be assessed formative as well as summative to product development. This is consistent with Lewis (2014). By using the combination of a questionnaire and task checklist, usability problems can be detected and task and product goals can be checked. Customers have goals about the outcomes of their usage. These goals, considering objective benefits and personal values, can have causal links (MacDonald et al., 2011). Value-in-use assessment can help in establishing links with usability problems regarding attributes of the product. For example: this study's usability assessment showed patients thought the device was too heavy to carry and within the value-in-use assessment patients mentioned the high weight gave them a feeling of decreased flexibility of movement.

<u>Proposition 2: The dimensions of both assessments</u>

'Both value-in-use assessment as well as usability assessment incorporate functional as well as emotional dimensions.'

Both assessments take into account functional as well as emotional dimensions. This corresponds to literature of Babbar et al. (2002), Fisk et al. (2011), Han et al. (2000) and Sandström et al. (2008). Usability might seem to move towards emotion according to Han et al. (2000), but the focus is still on the functional aspect within this study and in literature in general. The focus of value-in-use lies mainly on the emotional value aspect. In this study only the aspect of convenience focused on the functional proposition. It is important to not only look into the tangible goods, but also the effect a product can give. Value-in-use assessment does study these effects, as patients want to reach goals by using the device. For example: for patients these goals are control of the blood sugar and more independency in daily activities. This corresponds with literature of MacDonald et al. (2011) that customers are willing to pay for certain features as these can be associated with higher goals in their mental model. It is therefore important to also include emotional dimensions next to functional value proposition when assessing a user's needs and wants.

<u>Proposition 3: The place of the customer in both assessments</u>

'In value-in-use assessment, the customer actively creates the value of the product in interaction with stakeholders. In usability assessment, the stakeholder considers the customers' needs and wants when designing the product.'

In this study's usability assessment, several important problem areas were found. For example: the task checklist shows users had trouble with determining whether they should replace the infusionset. Futhermore, most users were not able to let the canule drip. And finally, the battery cover was not always used to remove the batteries. When considering the usability of product, the usability of a product is more complex than only considering these functional issues when considering the needs and wants of users. Developers need to know how use situations influence a specific usability issue. According to van der Bijl-Brouwer (2013) this defines the success of a product. The user is directly and indirectly influenced by his/her experiences, cultural background and personal traits (Kim & Christiaans, 2011; Nielsen, 2002). For example: For a patient previously experienced hyper- or hypoglycemia's may influence the information they demand when using the APD. However, the importance of each situation is relative and can change. This should be monitored. This change can be illustrated by the users' need for information. As an example: Users require more information on their blood sugar during first usage of the APD. This need will decrease when the device works as patients expect. This example shows that for value-in-use, the value of a product is continuously created through interaction with others. Both the users' usability needs and value-in-use needs should be repeatedly assessed. In the end usability assessment and value-in-use assessment only provide recommendations for the designer. Ultimately, to what extent these needs and wants are considered when a product is designed is up to the developer.

Proposition 4: The goals of both assessments

'The goal of value-in-use assessment is that an individual user values a product during usage. The goal of usability assessment is to develop a product usable by a broad spectrum of users in a spectrum of situations.'

The APD is positively evaluated and no significant differences between treatment groups were found. These findings indicate that the APD is usable for a broad spectrum of users. This is needed to be effective and efficient according to Randmaa et al. (2012). However, actual effectiveness can be different from the perceived usability. For example: the APD was evaluated as positive, but more than half of the participants was not able to let the canule drip or remove the batteries properly. Even if this is vital to safe diabetes treatment. It is therefore important to measure perceived usability and actual effectiveness within the spectrum of users. The value of a product is judged differently for each individual, according to Raja et al. (2013). Within this study that finding should be nuanced. Similarities in value-in-use can be found for different user groups. To illustrate: Insulin pump users want more information than insulin pen users. As insulin pump users have more experience with diabetes regulation devices, they also have encountered more problems with such devices. The value-in-use perspective can give additional insights into value aspects during individual usage, but also the usage of the APD by groups.

Practical inferences

Practical inferences for developers

In this last paragraph the integration of the value-in-use and usability needs of type 1 diabetes patients will be discussed. To illustrate the benefits of co-creation, a practical framework for this integration process is proposed. It should be kept in mind that this study is focused on the health care market, with diabetes in particular. However, the findings discussed can also be relevant for developers of other (health care) technologies. This paragraph will focus on general inferences for developers. Developers can benefit from formative and summative usability assessment when developing products. The design of a product should be iterative, corresponding with Lewis (2014), as needs can change. When designing a product quantitative and qualitative methods should both be used and potential links between these methods should be sought by the technology developer. In order to find out all basic minimum requirements mentioned by Füller and Matzler (2007), emotional and functional value propositions should be taken into account. Usability assessment and value-in-use assessment can lead to the determination of additional and complementary requirements. A process of integration of these assessments was developed by the researcher, which can be used by (health care) technology developers before, during and after the development of a product (Figure 5).

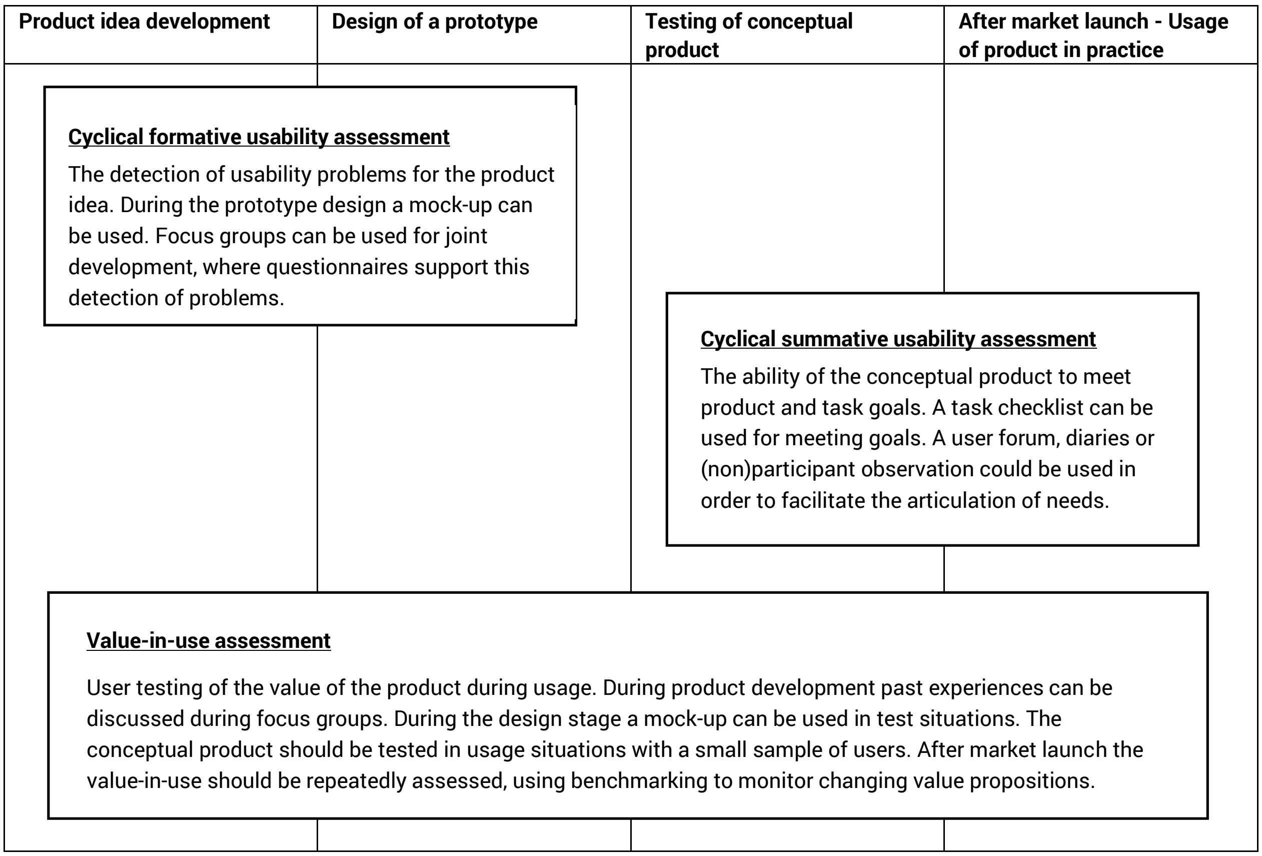

Figure 5. The product development process: Integrating usability assessment and value-in-use assessment

Formative usability assessment - Within the process developers need to include an iterative circle in the process, in which both summative usability assessment, formative usability assessment and value-in-use assessment take place. Past, present and future imaginary experiences should be discussed to understand relevant use situations. Developers should test their initial product idea by iterative formative tests of detecting usability problems. A potential solution could be to organize focus groups with users to test a product idea on usability problems. During the development of a prototype a mock-up could be used. A usability questionnaire, similar to that in this study, can be used during these focus groups to support the detection of usability problems.

Summative usability assessment - After a (conceptual) product for the market is developed, summative usability tests can demonstrate if users are able to reach task and product goals. This could be done by using a task checklist. The product for market is designed based on outcomes of product and task goals. During actual usage a use forums or support archives can be developed. Users could keep diaries to monitor changing needs. (Non)-participant observation can also be used to monitor use in real usage situations. Here users have to ability to articulate needs regarding a product. By letting multiple experts in the field discuss problems, innovative ideas can be jointly developed.

Value-in-use assessment - The developer should facilitate conditions under which users can articulate their value-in-use. This should be done throughout the development and usage process, as value can change. A solution for facilitating these conditions is to regularly invite users to articulate the value they award to a product. This could be done by focus groups, diaries of (non)participant observation. These discussions should be used as a benchmark to develop a timeline of the changing value. In this stage the developer can see the user as co-innovator, co-ideator, co-evaluator and co-tester of the product.

Conclusion: The benefits of this type of co-creation – By using this type of co-creation the market as well as the users are repeatedly assessed for changes. A positive side-effect is that by involving users in the development process, this will likely create goodwill for the developer of the product. In the medical setting where users are waiting for a solution to their illness there is a great willingness to co-create a product with a developer. Ultimately, learning from patients' ideas by co-creating with them could lead to more innovative ideas and solutions regarding a product.

Practical inferences for the APD and diabetes treatment

Although the APD is assessed as usable, several recommendations can be given based on solutions given by participants. For the APD the weight and size should be reduced by Inreda, according to the questionnaire. Solutions given by patients are decreasing the amount of needles in the stomach, smaller insulin and/or glucagon ampules, smaller batteries or having a smaller device with a remote controller. Another solution proposed is for Inreda to search for possibilities to place the APD on other areas on the body, which is possible with current insulin devices. In order for the APD to be readable for users with eye problems the developers of the APD should include a function to enlarge the screen. When looking at the tasks patients completed with the APD, several remarks can be made. The information about whether or not to replace the infusion set should be made more prominent, as not to confuse the patients during the task. Also, more information should be given on letting the canule drip and using the battery cover for removing the batteries. This could be done by giving a visual overview of all the components of the APD in the manual. This could also help insulin pen users with learning the names of the components of the APD. In order to provide safe diabetes treatment, it is important for users to be able to let the canule drip.

Another possible solution proposed by us is to integrate the APD with a smartphone or smartwatch to create a portal with accessible information for users. With an app on the smartphone/smartwatch users are free to share information with acquaintances and watch the trend of their blood sugar. The app enables users of the APD to discuss with other diabetes patients how situations can be handled best, like going for a swim or going on vacation. This information can be used by developers. Information on the app can also help in creating and spreading more accessible knowledge on diabetes type 1 and what it implies. In the future this app can possibly be used by practitioners during their treatment for both adults as well as for making information understandable for children with diabetes. By integrating the APD with a smartphone/smartwatch the weight and size could potentially be significantly reduced. This could also increase the feeling of flexibility of movement for users. This possible solution should be studied to find out to what extent integration is possible. As most patients have a higher need for information when starting to use the APD, the technology developer should facilitate the information needed by patients during the transition to the APD.

Research limitations and directions for further research

Every research has its limitations, including this research. The limitations of this study will be discussed in this paragraph. A mixed-method approach was chosen to measure the concepts of usability and value-in-use. Qualitative research has the advantage of a richness in data and is useful for social observations - although is it prone to interpretation error. Quantitative data are easier to aggregate, compare and summarize (Babbie, 2015; Van Kleef, van Trijp, & Luning, 2005). Due to these choices both concepts could only be compared on a qualitative level. However, a quantitative measure was used for the usability assessment, as this is intrinsic to the concept. For the same reason a qualitative measure was used for the value-in-use assessment.

A possible point of criticism is, that a power analysis was not performed when starting the study. A minimal number of 20 participants reported by Albert and Tullis (2013) was used instead. The number of participants in this study was too low to execute a factor analysis for the total usability measurement. However, on a subscale level factorial analysis showed substantial variances explained by each factor. The factor structure was also determined earlier in the medical context in a study of Karlen et al. (2011). For further research, the recommendation is given to use a larger sample size to increase the validity of the study.

It could be criticized that the value-in-use and the usability measured in this study was based on the usage of the APD during one point in time. However, they are in accordance with typical problems with current insulin pumps (Liljegren et al., 2000; Vicente et al., 2003), and reflect the most important real life situations. The needs, wants and value in actual situations can change over time, and a longitudinal study should be performed in order to assess the value in use and usability of the APD during longtime usage. This study can serve as a starting point for comparison.

A direction for further research could be to study how to develop and integrate the APD with an app. A potential focus is on how information in the app can facilitate easier communication between users and acquaintances. Another focus can be how to make information on diabetes and the APD accessible for children. A different direction could be how to integrate the app and the APD into the diabetes treatment given by practitioners. Further research could also focus on how to extract usability information of a user forum. This should be studied in order to assess how ideas can best be jointly developed, and could increase the insights of benefits of co-creation in time. Theoretical research should look more deeply into both value-in-use assessment and usability assessment in other contexts. Other studies within other context could be compared to this study. Overall, this study is a firm basis for further research to take full advantage of value-in-use assessments in product design.

Conclusion

The value proposition of the user is continuously changing. The user's value proposition is dependent on past, present and future experiences. The interaction with other stakeholders in a service network can influence these experiences when using a product. The need for information of users can always change in time. Use situations are dynamic and therefore value-in-use should be repeatedly assessed. Value-in-use assessment of a product with patients can be seen as beneficial, both during the development phase as well as during actual usage. In all stages of the product life cycle it could give insights into more aspects than the mere functional product. The importance of experiencing certain feelings is crucial for users, beside the usability of the product. Certainly as diabetes is a not a 9 to 5 job, the feeling of independency in daily activities is crucial for diabetes patients. Not only tangible product features are needed, but also intangible experiences as freedom of movement for diabetes patients. If a user wants to gain a certain experience, the product should certainly usable as well as safe. Usability assessment is necessary, because it could provide information on usability problems and task or product goals. Links between both usability and value-in-use assessment should be sought to understand situations relevant for users. Developers need to know how these use situations influence the relevance of usability issues. Value-in-use assessment is complementary to usability assessment, and either have to be measured in order to gain a full understanding of the functional and emotional value proposition of the user. The APD is to a certain degree an extension of the user. To what extent the user lets his or her life influence by the APD is up to the individual user. Although the APD can be helpful in facilitating life in general for a diabetes patient, ultimately medical technology is not crucial for the user as a person.

References

Aarikka-Stenroos, L., & Jaakkola, E. (2012). Value co-creation in knowledge intensive business services: A dyadic perspective on the joint problem solving process. *Industrial Marketing Management, 41*(1), 15-26. doi: http://dx.doi.org/10.1016/j.indmarman.2011.11.008

Agrawal, A.K., & Rahman, Z. (2015). Roles and Resource Contributions of Customers in Value Co-creation. *International Strategic Management Review, 3*(1–2), 144-160. doi: http://dx.doi.org/10.1016/j.ism.2015.03.001

Ahrar, N., & Rahman, A.A. (2014). Review on DART model used in value co-creation for evaluation of e-service system. *International Journal of Managment, IT and Engineering, 4*(2), 409-415.

Albert, W., & Tullis, T. (2013). *Measuring the user experience: collecting, analyzing, and presenting usability metrics*: Newnes.

Allen, I., & Seaman, C. (2007). Likert scales and data analyses. *Quality Progress, 40*(7), 64.

Anderson, J., Narus, J., & Narayandas, D. (2005). *Business Marketing Management: Understanding, Creating and Delivering Value*: Pearson Education (US).

Babbar, S., Behara, R., & White, E. (2002). Mapping product usability. *International Journal of Operations & Production Management, 22*(10), 1071-1089. doi: 10.1108/01443570210446315

Babbie, E. (2015). *The practice of social research*: Cengage Learning.

Bastien, C. (2010). Usability testing: a review of some methodological and technical aspects of the method. *International journal of medical informatics, 79*(4), e18-e23.

Beaton, D., Bombardier, C., Guillemin, F., & Ferraz, M.B. (2000). Guidelines for the process of cross-cultural adaptation of self-report measures. *Spine, 25*(24), 3186-3191.

Bick, M., Bruns, K., Sievert, J., & Jacob, F. (2014). Value-in-use of mobile technologies. *Wirtschaftsinformatik, 56(6)*, 381-391.

Bitner, M.J. (1992). Servicescapes: the impact of physical surroundings on customers and employees. *The Journal of Marketing*, 57-71.

Boeije, H. (2002). A purposeful approach to the constant comparative method in the analysis of qualitative interviews. *Quality and quantity, 36*(4), 391-409.

Booz & Co. (2011). Diabetes Care in the Netherlands: Improving Health and Wealth.

Buchenau, M., & Suri, J. F. (2000). Experience prototyping. *Proceedings of the 3rd conference on Designing interactive systems: processes, practices, methods, and techniques*, 424-433.

Campbell, D. , & Stanley, J.C. (1963). Experimental and quasi-experimental designs for research. *Handbook of research on teaching*, 171-246.

Chin, J.P., Diehl, V.A., & Norman, K.L. (1988). *Development of an instrument measuring user satisfaction of the human-computer interface.* Paper presented at the Proceedings of the SIGCHI conference on Human factors in computing systems.

Coursaris, C., & Kim, D. (2011). A meta-analytical review of empirical mobile usability studies. *Journal of usability studies, 6*(3), 117-171.

da Silva, A., & Farina, M. (2013). The Medical Encounter: Building Co-creation Capabilities in Healthcare Services.

de Castro Ferreira, L.M., & Menezes, J. (2015). Value-in-use in a B2B food service logistic context. *Tourism & Management Studies, 11*(1), 146-152.

den Ouden, E., Yuan, L. , Sonnemans, P. J. J., & Brombacher, A. C. (2006). Quality and reliability problems from a consumer's perspective: an increasing problem overlooked by businesses? *Quality and Reliability Engineering International, 22*(7), 821-838.

Dooley, K. (2001). *Social research methods* Vol. 4. U. S. River (Ed.)

Dzida, W. (1995). Standards for user-interfaces. *Computer Standards & Interfaces, 17*(1), 89-97. doi: http://dx.doi.org/10.1016/0920-5489(93)E0069-E

Fatourechi, M., Kudva, Y., Murad, M., Elamin, M., Tabini, C., & Montori, V. (2013). *Hypoglycemia with intensive insulin therapy: a systematic review and meta-analyses of randomized trials of continuous subcutaneous insulin infusion versus multiple daily injections*.

Field, A. (2013). *Discovering statistics using IBM SPSS statistics*: Sage.

Fisk, R.P., Patrício, L., Edvardsson, B., Ng, G., Zhi Min, C., Firth, R., & Yi, D. (2011). Does service-dominant design result in a better service system? *Journal of Service Management, 22*(4), 540-556.

Füller, J., & Matzler, K. (2007). Virtual product experience and customer participation—A chance for customer-centred, really new products. *Technovation, 27*(6), 378-387.
George, D., & Mallery, M. . (2003). *Using SPSS for Windows step by step: a simple guide and reference* (Vol. 4). Boston: Allyn & Bacon.
Gisev, N., Bell, J. S., & Chen, T. (2013). Interrater agreement and interrater reliability: Key concepts, approaches, and applications. *Research in Social and Administrative Pharmacy, 9*(3), 330-338. doi: http://dx.doi.org/10.1016/j.sapharm.2012.04.004
Guillemin, F., Bombardier, C., & Beaton, D. (1993). Cross-cultural adaptation of health-related quality of life measures: literature review and proposed guidelines. *Journal of clinical epidemiology, 46*(12), 1417-1432.
Han, S. H., Hwan Yun, M., Kim, K.J., & Kwahk, J. (2000). Evaluation of product usability: development and validation of usability dimensions and design elements based on empirical models. *International Journal of Industrial Ergonomics, 26*(4), 477-488. doi: http://dx.doi.org/10.1016/S0169-8141(00)00019-6
Hardyman, W., Daunt, K.L., & Kitchener, M. (2015). Value Co-Creation through Patient Engagement in Health Care: A micro-level approach and research agenda. *Public Management Review, 17*(1), 90-107.
Hartmann, R. (1968). *The structure of value: Foundations of scientific axiology*. Carbondale: Southern Illionois Press.
Helkkula, A., Kelleher, C., & Pihlström, M. (2012). Characterizing value as an experience: implications for service researchers and managers. *Journal of Service Research*, 1094670511426897.
Hix, D., & Hartson, H. (1993). *Developing user interfaces: ensuring usability through product & process*: John Wiley & Sons, Inc.
Holbrook, M. B. (1996). Special Session Summary. Customer Value–A Framework for Analysis and Research. *Advances in consumer research, 23*(2), 138-142.
Hüsgen, R.L. (2015). A virtual reality test of the usability of an artificial pancreas with diabetes 1 patients as co-creators.
Inreda. (2015). De kunstmatige alvleesklier: Over de ontwikkeling van een medisch hulpmiddel dat de glucoseregulatie van diabetespatiënten overneemt.
ISO. (1998). *ISO 9241-11: Ergonomic Requirements for Office Work with Visual Display Terminals (VDTs): Part 11: Guidance on Usability*. Geneva, Switzerland: International Organization for Standardization.
Johnson, M. D., & Selnes, F. (2004). Customer portfolio management: toward a dynamic theory of exchange relationships. *Journal of Marketing, 68*(2), 1-17.
Jordan, P. W., Thomas, B., McClelland, I. L., & Weerdmeester, B. (1996). *Usability evaluation in industry*: CRC Press.
Jordan, P.W. (2002). *Designing pleasurable products: An introduction to the new human factors*: CRC press.
Karlen, W., Dumont, G., Petersen, C., Gow, J., Lim, J., Sleiman, J., & Ansermino, J. (2011). *Human-centered phone oximeter interface design for the operating room.* Paper presented at the International Conference on Health Informatics.
Kaufman, D., Patel, V., Hilliman, C., Morin, P., Pevzner, J., Weinstock, R., . . . Starren, J. (2003). Usability in the real world: assessing medical information technologies in patients' homes. *Journal of biomedical informatics, 36*(1), 45-60.
Kaye, R., & Crowley, J. (2000). Medical device use-safety: incorporating human factors engineering into risk management. *Food and Drug Administration*.
Keinonen, T. (1998). *One-dimensional usability: influence of usability on consumer's product preference*: University of Art and Design.
Ketola, P. (2002). *Integrating usability with concurrent engineering in mobile phone development*: Tampereen yliopisto.
Kim, C., & Christiaans, H.H.C.M. (2011). *Usability problems: The influence of user diversity.* Paper presented at the Proceedings of IASDR2011, the 4th World Conference on Design Research. Delft, the Netherlands: TU Delft.
Kirakowski, J., & Corbett, M. (1993). SUMI: The software usability measurement inventory. *British journal of educational technology, 24*(3), 210-212.
Kowalkowski, C. (2011). Dynamics of value propositions: insights from service-dominant logic. *European Journal of Marketing, 45*(1/2), 277-294.
Kukushkin, M., Otto, T., & Howard, T.J. (2015). Value-centric business development: descriptive and prescriptive research into five different companies. *Proceedings of the Estonian Academy of Sciences, 64*.
Kushniruk, A., Patel, V., & Cimino, J. (1997). *Usability testing in medical informatics: Cognitive approaches to evaluation of information systems and user interfaces.* Paper presented at the Proceedings of the AMIA annual fall symposium.

Kwahk, J., & Han, S.H. (2002). A methodology for evaluating the usability of audiovisual consumer electronic products. *Applied Ergonomics, 33*(5), 419-431. doi: http://dx.doi.org/10.1016/S0003-6870(02)00034-0
Lai, A. W. (1995). Consumer values, product benefits and customer value: a consumption behavior approach. *Advances in consumer research, 22*, 381-381.
Lewis, J.R. (1995). IBM computer usability satisfaction questionnaires: psychometric evaluation and instructions for use. *International Journal of Human-Computer Interaction, 7*(1), 57-78.
Lewis, J.R. (2014). Usability: Lessons learned… and yet to be learned. *International Journal of Human-Computer Interaction, 30*(9), 663-684.
Liljegren, E., Osvalder, A., & Dahlman, S. (2000). *Setting the requirements for a user-friendly infusion pump.* Paper presented at the Proceedings of the Human Factors and Ergonomics Society Annual Meeting.
Macdonald, E. K., Wilson, H., Martinez, V., & Toossi, A. (2011). Assessing value-in-use: A conceptual framework and exploratory study. *Industrial Marketing Management, 40*(5), 671-682.
Maguire, M. (2001). Context of use within usability activities. *International Journal of Human-Computer Studies, 55*(4), 453-483.
Manning, K., & Stage, F. (2003). What is your research approach? *Research in the college context: Approaches and methods*, 1931.
McColl-Kennedy, J.R., Vargo, S.L., Dagger, T.S., Sweeney, J.C., & van Kasteren, Y. (2012). Health care customer value cocreation practice styles. *Journal of Service Research*.
Neuendorf, K. (2002). *The content analysis guidebook*: Sage.
Nielsen, J. (1993). *Usability Engineering*: Morgan Kaufmann Publishers Inc.
Norman, D. (2002). *The Design of Everyday Things*: The Perseus Book Group.
Norman, G. (2010). Likert scales, levels of measurement and the "laws" of statistics. *Advances in health sciences education, 15*(5), 625-632.
Pfisterer, L., & Roth, S. (2015). Customer usage processes A conceptualization and differentiation. *Marketing Theory*.
Prahalad, C. K., & Ramaswamy, V. (2004). Co-creation experiences: The next practice in value creation. *Journal of interactive marketing, 18*(3), 5-14.
Randmaa, M., Howard, T.J., & Otto, T. (2012). *From product centered design to value centered design: understanding the value-system.* Paper presented at the 8th International DAAAM Baltic Conference.
Ryu, Y.S. (2005). Development of usability questionnaires for electronic mobile products and decision making methods.
Ryu, Y.S. (2009). Mobile phone usability questionnaire (MPUQ) and automated usability evaluation *Human-Computer Interaction. New Trends* (pp. 349-351): Springer.
Ryu, Y.S., Babski-Reeves, K., Smith-Jackson, T.L., & Nussbaum, M.A. (2007). Decision models for comparative usability evaluation of mobile phones using the Mobile Phone Usability Questionnaire (MPUQ). *Journal of Usability Studies, 3*(1), 24-39.
Ryu, Y.S., & Smith-Jackson, T.L. (2006). Reliability and validity of the mobile phone usability questionnaire (MPUQ). *Journal of Usability Issues, 2*(1), 35-53.
Sandström, S., Edvardsson, B., Kristensson, P., & Magnusson, P. (2008). Value in use through service experience. *Managing Service Quality: An International Journal, 18*(2), 112-126.
Saunders, M., Lewis, P., Thornhill, A., & Wilson, J. (2009). Business Research Methods. *Financial Times, Prentice Hall: London*.
Schmettow, M., Vos, W., & Schraagen, J. (2013). With how many users should you test a medical infusion pump? Sampling strategies for usability tests on high-risk systems. *Journal of Biomedical Informatics, 46*(4), 626-641. doi: http://dx.doi.org/10.1016/j.jbi.2013.04.007
Shadish, R., Cook, D., & Campbell, T. (2001). Experiments and Generalized Causal Inference in Experimental and Quasi-Experimental Design for Generalized Causal Inference. *Houghion Mifflin, New York*, 1-35.
Sheth, J.N., Newman, B.I., & Gross, B.L. (1991). Why we buy what we buy: a theory of consumption values. *Journal of business research, 22*(2), 159-170.
Shneiderman, B. (1992). *Designing the user interface: strategies for effective human-computer interaction* (Vol. 3): Addison-Wesley Reading, MA.
Sweeney, J.C., & Soutar, G.N. (2001). Consumer perceived value: The development of a multiple item scale. *Journal of retailing, 77*(2), 203-220.

Terwee, C., Bot, S., de Boer, Mi., van der Windt, D., Knol, D., Dekker, J., . . . de Vet, H. (2007). Quality criteria were proposed for measurement properties of health status questionnaires. *Journal of clinical epidemiology, 60*(1), 34-42.

The National Institute for Health Research Horizon Scanning Centre. (2015). Artificial pancreas device systems in development for the closed-loop control of type 1 diabetes.: University of Birmingham.

Uncu, C.E. (2014). *The effect of stakeholders' general beliefs of technology on perceived usefulness and eventually intention to use a product in medical innovation management: A review of type 1 diabetes patients and physicians in the Netherlands.* University of Twente, Enschede.

Van Kleef, E., van Trijp, H., & Luning, P. (2005). Consumer research in the early stages of new product development: a critical review of methods and techniques. *Food quality and preference, 16*(3), 181-201.

Van Kuijk, J.I., Kanis, H., Christiaans, H.H.C.M., & van Eijk, D.J. (2007). *Usability in product development practice: After sales information as feedback.* Paper presented at the Proceedings of IASDR Conference on Design Research. Hong Kong: Polytechnic University.

Vargo, S. L, & Lusch, R. F. (2008). Service-dominant logic: continuing the evolution. *Journal of the Academy of Marketing Science, 36*(1), 1-10.

Vargo, S., & Lusch, R. . (2004). Evolving to a new dominant logic for marketing. *Journal of marketing, 68*(1), 1-17.

Vargo, S., Maglio, P., & Akaka, M. A. (2008). On value and value co-creation: A service systems and service logic perspective. *European management journal, 26*(3), 145-152.

Vicente, K., Kada-Bekhaled, K., Hillel, G., Cassano, A., & Orser, B. (2003). Programming errors contribute to death from patient-controlled analgesia: case report and estimate of probability. *Canadian Journal of Anesthesia, 50*(4), 328-332.

Voorberg, W.H., Bekkers, V.J.J.M., & Tummers, L.G. (2014). A systematic review of co-creation and co-production: Embarking on the social innovation journey. *Public Management Review*(ahead-of-print), 1-25.

Wahyuni, D. (2012). The research design maze: Understanding paradigms, cases, methods and methodologies. *Journal of Applied Management Accounting Research, 10*(1), 69-80.

Walter, A., Ritter, T., & Gemünden, H. G. . (2001). Value creation in buyer–seller relationships: Theoretical considerations and empirical results from a supplier's perspective. *Industrial marketing management, 30*(4), 365-377.

Weissberg-Benchell, J., Antisdel-Lomaglio, J., & Seshadri, R. (2003). Insulin pump therapy: a meta-analysis. *Diabetes care, 26*(4), 1079-1087.

Wiklund, M. E., & Wilcox, S. B. (2005). *Designing usability into medical products*: CRC Press.

Witell, L., Kristensson, P., Gustafsson, A., & Löfgren, M. (2011). Idea generation: customer co-creation versus traditional market research techniques. *Journal of Service Management, 22*(2), 140-159.

Woodruff, R. B., & Gardial, S. (1996). *Know your customer: New approaches to understanding customer value and satisfaction*: Wiley.

Yen, P., & Bakken, S. (2012). Review of health information technology usability study methodologies. *Journal of the American Medical Informatics Association, 19*(3), 413-422.

Zhang, L., Tong, H., Demirel, H.O., Duffy, V.G., Yih, Y., & Bidassie, B. (2015). A Practical Model of Value Co-creation in Healthcare Service. *Procedia Manufacturing, 3*, 200-207. doi: http://dx.doi.org/10.1016/j.promfg.2015.07.129

Appendix

Appendix 1a: Invitation Patients

Beste heer/mevrouw,

Graag willen wij u uitnodigen voor een onderzoek met betrekking tot de ontwikkeling van de kunstmatige alvleesklier van Inreda Diabetic B.V. De kunstmatige alvleesklier is bedoeld voor de verbetering van de behandeling van diabetes. Tijdens dit onderzoek gaat u twee taken met de kunstmatige alvleesklier uitvoeren, waarna u een vragenlijst over de bruikbaarheid van de kunstmatige alvleesklier invult en waarbij u een kort interview wordt afgenomen over de waarde tijdens het gebruik van de kunstmatige alvleesklier. Dit onderzoek zal bij elkaar ongeveer anderhalf uur duren.

Dit onderzoek is opgezet vanuit de afdeling Bedrijfskunde van de Universiteit Twente als afstudeerproject, waarin samen wordt gewerkt met Inreda Diabetic B.V.

Het doel van dit onderzoek is om inzicht te krijgen in hoe uw mening ten opzichte van de bruikbaarheid en de waarde tijdens gebruik van de kunstmatige alvleesklier verwerkt kan worden in de kunstmatige alvleesklier van Inreda Diabetic B.V.

Omdat dit een afstudeerproject betreft, zouden wij u vriendelijk willen vragen zo snel mogelijk te reageren omtrent uw deelname aan het onderzoek. Begin hier alleen aan als u voldoende tijd heeft. Uw gegevens zijn volledig anoniem.

Wilt u aan het onderzoek deelnemen?

Vul dan de vragenlijst in, beschikbaar via de volgende link: ? . Aan de hand van deze vragenlijst zal er bepaald worden of u geschikt bent voor het onderzoek en zal er verder contact met u worden opgenomen. Indien u nog vragen heeft, kun u altijd mailen naar r.s.meeringa@student.utwente.nl.

Alvast hartelijk dank voor uw medewerking,

Remi Meeringa, Universiteit Twente

Dr. A.M. von Raesfeld, Universiteit Twente

cPhd T. Oukes, Universiteit Twente

Manon Spin, Universiteit Twente

Robin Barwegen, Inreda Diabetic B.V.

Appendix 1b: Demographics questionnaire

Vult u de volgende vragenlijst in om te bepalen of u geschikt bent als patiënt voor het onderzoek. U zult geïnformeerd worden over de selectie kort nadat u de vragenlijst heeft ingevuld.

1. Heeft u diabetes type 1?	○ Ja ○ Nee
2.Hoe veel jaar heeft u al diabetes type 1?	……………………………..
3.Wat is uw geslacht?	○ Man ○ Vrouw
4.Wat is uw leeftijd (in jaren)?	……………………………..
5.Wat is uw hoogst genoten opleiding?	○ Basisonderwijs (Groep 1 t/m 8) ○ Voortgezet onderwijs (VMBO, HAVO, VWO) ○ Middelbaar beroepsonderwijs (MBO) ○ Hoger beroepsonderwijs (HBO) ○ Wetenschappelijk onderwijs (WO) of hoger
6.Welke methode gebruikt u op dit moment om diabetes te behandelen?	○ Insuline pen ○ Insuline pomp ○ Insuline pomp en CGM (Continue Glucose Monitor) ○ Anders …………….
7.Hoe lang gebruikt u uw methode al? (In jaren)	……………………………..
8.Heeft u deelgenomen aan een klinische test met de kunstmatige alvleesklier?	○ Ja ○ Nee
9.Bent u bereid om voor het onderzoek naar Inreda (Goor, Overijssel) te reizen?	○ Ja ○ Nee
10. Hoe mag er contact met u worden opgenomen?	○ Email: ……………… ○ Telefoonnummer: ……………

Appendix 1c: Informed Consent Form

Informatie

Betreft: Deelname aan een onderzoek naar wat de uitkomsten van het gezamenlijk creëren van de kunstmatige alvleesklier met patiënten als u op het bedrijfsmodel van Inreda Diabetic B.V. zijn. Goor, April 2016.

Geachte mevrouw/heer,

In samenwerking met Inreda Diabetic B.V. gaat Universiteit Twente een onderzoek uitvoeren naar de usability en de waarde tijdens gebruik van de kunstmatige alvleesklier van Inreda Diabetic B.V. Dit onderzoek wordt uitgevoerd ter verbetering van het gebruiksgemak van de kunstmatige alvleesklier en ter verbetering van de behandeling van type 1 diabetes patiënten. Wij zijn blij dat U wilt meewerken aan dit onderzoek.

Wat zijn de consequenties als u deelneemt aan dit onderzoek?

U zult eerst twee taken met de kunstmatige alvleesklier moeten doorlopen, waarna u een vragenlijst over de bruikbaarheid van de kunstmatige alvleesklier invult en waarbij bij u een interview zal worden afgenomen die betrekking heeft op de waarde tijdens gebruik van de kunstmatige alvleesklier. Dit onderzoek zal ongeveer anderhalf uur in beslag nemen.

Wij verzekeren u dat met u gegevens vertrouwelijk wordt omgegaan. Voor het geval dat u meer informatie wil over het onderzoek, kunt u contact opnemen met onderzoeker Remi Meeringa, Student Msc. Business Administration, email: r.s.meeringa@student.utwente.nl.

Wij hopen u voldoende geïnformeerd te hebben. Wilt u vervolgens de volgende pagina ondertekenen?

Met vriendelijke groet,

Remi Meeringa, Universiteit Twente

Dr. A.M. von Raesfeld, Universiteit Twente

cPhd T. Oukes, Universiteit Twente

Manon Spin, Universiteit Twente

Robin Barwegen, Inreda Diabetic B.V.

De instemmingsverklaring/informed consent

Naam onderzoek: Onderzoek naar de usability/value-in-use van type 1 diabetes patienten van de kunstmatige alvleesklier van Inreda Diabetic B.V.

Naam deelnemer

- Naam: ……………………………………………………………………….
- Plaats: ……………………………………………………………………….
- Datum: ………………………………………………………………………

- Ik verklaar dat ik de informatie horend bij de studie naar de uitkomsten van het gezamenlijk creëren van de kunstmatige alvleesklier met patiënten op het bedrijfsmodel heb begrepen.

- Ik begrijp dat deelname aan het onderzoek vrijwillig is en dat ik mij op elk moment zonder opgave van redenen uit het onderzoek kan terugtrekken.

- Ik weet dat voor dit onderzoekgegevens van mij gebruikt worden voor wetenschappelijk onderzoek en eventueel gepubliceerd worden.
  Hiermee stem ik in, mits mijn privacy gewaarborgd wordt.

- Ik geef hierbij uit vrije wil mijn toestemming om deel te nemen aan dit onderzoek.

Handtekening patiënt: ………………………………………………………………….

Naam onderzoeker

- Ik bevestig hierbij dat ik aan bovengenoemde patiënt de procedure voldoende heb uitgelegd.

Plaats/datum: ………………………………………………………………….

Handtekening: ………………………………………………………………….

Appendix 2: Checklist Participants

		Correctly executed:
Task 1	Press 'Sleutelicoon'	
Connect heart rate belt to AP	Press heartrate	
	Press OK for activating heartrate	
	Hartslag shows 'in bedrijf'	
	Task successfull	
Task 2	Press 'Insulineicoon'	
Replace insulin ampule	Disconnect tubes of canule	
	Reversal of 'aandrijfstang'	
	Press no at 'Do you want to change infusionset?'	
	Disconnect ampule	
	Put ampule in	
	Put adapter back on	
	Tightening of 'aandrijfstang'	
	Press Test repeatedly	
	Canule drips	
	Task successfull	
Task 3	Use 'batterijsleutel' as lever	
Replace batteries	Use battery cover for removing batteries	
	Remove batteries	
	Put batteries in	
	Put cover correctly on	
	Task successfull	

Appendix 3: Internal consistency: Correlated item total correlations and α it item deleted of the adapted MPUQ

Item	ELU		HPSC		AAMP		CMML		CE		TTAP	
	CITC	α if deleted	CITC	α if deleted	CITC	α if deleted	CITC	α if deleted	CITC	α if deleted	CITC	α if deleted
1	.527	.876	-.046	.740	.512	.776	.485	.613	.744	.361	.257	.734
2	.423	.877	.712	.609	-.250	.838	.579	.594	-.255	.713	.521	.655
3	.649	.870	.390	.655	.517	.776	.344	.644	.414	.503	.776	.609
4	.705	.869	.610	.623	.552	.774	.270	.656	.118	.586	.309	.717
5	.735	.871	.416	.657	.349	.790	.245	.660	.225	.554	.333	.716
6	.653	.870	.513	.635	.634	.774	.503	.594	.319	.525	.597	.666
7	.698	.869	.557	.624	.539	.774	.176	.686	.705	.430	.629	.668
8	.666	.869	.721	.606	.338	.792	.390	.628	.360	.519	-	-
9	.663	.871	-.180	.805	.485	.783	-	-	.148	.568	-	-
10	.394	.878	.615	.623	.658	.768	-	-	-	-	-	-
11	-.110	.897	-	-	.643	.767	-	-	-	-	-	-
12	.361	.879	-	-	.659	.770	-	-	-	-	-	-
13	.795	.866	-	-	.359	.791	-	-	-	-	-	-
14	.613	.871	-	-	.193	.801	-	-	-	-	-	-
15	-.188	.897	-	-	-	-	-	-	-	-	-	-
16	.432	.877	-	-	-	-	-	-	-	-	-	-
17	.492	.875	-	-	-	-	-	-	-	-	-	-
18	.486	.875	-	-	-	-	-	-	-	-	-	-
19	.617	.872	-	-	-	-	-	-	-	-	-	-
20	.511	.875	-	-	-	-	-	-	-	-	-	-
21	.619	.873	-	-	-	-	-	-	-	-	-	-
22	.637	.873	-	-	-	-	-	-	-	-	-	-
23	.093	.885	-	-	-	-	-	-	-	-	-	-

Note. CITC = Corrected Item Total Correlation. ELU = Ease of Learning and Use; HPSC = Helpfulness and Problem Solving Capabilities; AAMP = Affective Aspect and Multimedia Properties; CMML = Commands and Minimal Memory Load; CE = Control and Efficiency; TTAP = Typical Tasks for the Artificial Pancreas.

$^{\alpha}$n = 32.

Further explanation:

In order to provide a high internal validity of the questionnaire, there was looked into the corrected item total correlation (CITC). For this measure items below 0.3 were deleted, as this indicated they did not correspond with the overall scale. The Cohen's kappa was also used to test the internal correlation between items in a scale. George and Mallery (2003) indicate an alpha below 0.5 is unacceptable. Items below this threshold were deleted. The variance explained by each factor was also discussed.

<u>Ease of Learning and Use (ELU)</u>

- Item 11, 15 and 23 were deleted as their alpha if item deleted was below 0.5.
- The Cronbach's alpha of this scale is 0.920.
- ELU accounts for 43.3% of the variance of the 20 items.

<u>Helpfulness and Problem Solving Capabilities (HPSC)</u>

- Item 1 and 9 were deleted as their alpha if item deleted was below 0.5.
- The Cronbach's alpha of this scale is 0.805.
- HPSC accounts for 51.80% of the variance of the 8 items

<u>Affective Aspect and Multimedia Properties (AAMP)</u>

- Item 2 and 9 were deleted as their alpha if item deleted was below 0.5.
- The Cronbach's alpha of this scale is 0.845.
- AAMP accounts for 44.0% of the variance of the 12 items.

<u>Commands and Minimal Memory Load (CMML)</u>

- Item 4 and 7 were deleted at first as their alpha if item deleted was below 0.5.
- After further study item 3 was also deleted as this item alpha was also below 0.5.
- The Cronbach's alpha of this scale is 0.727.
- CMML accounts for 49.3% of variance of the 5 items.

<u>Control and Efficiency (CE)</u>

- Item 2 was deleted as the alpha if item deleted was below 0. 5.
- Item 4 was deleted as it showed a high inter-item correlation with item 6 and is therefore repetition.
- The CITC of item 5 is below the threshold of 0.3, but was sustained because of its relevance.
- The Cronbach's alpha of this scale is 0.720.
- CE accounts for of 40.5% the total variance of the 7 items.

<u>Typical Tasks for the Artificial Pancreas (TTAP)</u>

- Item 1 was deleted as the alpha if item deleted was below 0.5.
- The Cronbach's alpha of this scale is 0.734.
- TTAP accounts for of the total variance of the 6 items.

<u>Total scale</u> - The α of the adapted MPUQ is 0.951 (N = 58).

Appendix 4: MPUQ questionnaire

Number	Question
ELU1	Is het bedienen van dit product gemakkelijk te leren?
ELU2	Is dit product voldoende gemakkelijk in gebruik?
ELU3	Wordt er in voldoende mate rekening gehouden met de gebruikersbehoeften?
ELU4	Is het relatief eenvoudig om van het ene deel van de taak naar het andere onderdeel te wisselen?
ELU5	Kunnen alle handelingen op een zelfde systematische manier uitgevoerd worden?
ELU6	Zijn de handelingen bij dit product eenvoudig en niet ingewikkeld?
ELU7	Kunnen de taken snel, doeltreffend en efficiënt uitgevoerd worden?
ELU8	Is het makkelijk om bij de informatie te komen die je van het product nodig hebt?
ELU9	Is de organisatie van de informatie die op het productscherm staat duidelijk?
ELU10	Heeft het product alle functionaliteiten en mogelijkheden die je verwacht bij dit apparaat?
ELU11	Vind je het gemakkelijk om te onthouden hoe je de taken moet uitvoeren met dit product?
ELU12	Is de interface van dit product duidelijk en begrijpelijk?
ELU13	Zijn de karakters op het scherm gemakkelijk te lezen?
ELU14	Is het gemakkelijk om het product in te stellen?
ELU15	Kun je het product makkelijk regelen, controleren en bedienen?
ELU16	Is het makkelijk om te navigeren tussen de (sub)menu's, pagina's en het scherm?
ELU17	Zijn de manieren om gegevens in te voeren voor dit product eenvoudig en bruikbaar?
ELU18	Heeft het oplichten van het keyboard en het scherm nut?
ELU19	Is de benaming van de commando's goed gekozen?
ELU20	Is het vinden van nieuwe functies eenvoudig genoeg?
HPSC1	Is de presentatie van de informatie over het systeem voldoende duidelijk en begrijpelijk?
HPSC2	Geven de documenten en de handleiding bij dit product voldoende informatie?
HPSC3	Zijn de berichten ten aanzien van het voorkomen van fouten toereikend?
HPSC4	Helpen de foutmeldingen je daadwerkelijk met het oplossen van problemen?
HPSC5	Is het gemakkelijk om een actie te corrigeren als je een foutmelding hebt ontvangen?
HPSC6	Is de terugkoppeling over het afronden van de taken duidelijk?
HPSC7	Geeft het product alle informatie die nodig is om het apparaat op de juiste manier te gebruiken?
HPSC8	Geeft de hulp tijdens de taken voldoende keuzemogelijkheden voor alle aspecten van het product?
AAMP1	Zijn de afmetingen geschikt om het product mee te nemen of ergens op te bergen?
AAMP2	Vind je dit product aantrekkelijk en aangenaam?
AAMP3	Voel je je op je gemak en zeker van jezelf wanneer dit product gebruikt?
AAMP4	Maakt de kleur het product aantrekkelijk?
AAMP5	Maakt de helderheid het product aantrekkelijk?
AAMP6	Zijn de kwaliteit en de grootte van de afbeeldingen op het scherm goed?
AAMP7	Is het aantal beschikbare kleuren voldoende?
AAMP8	Word je er enthousiast van als je dit product gebruikt?
AAMP9	Zou je het product missen als je het niet meer had?
AAMP10	Zou je trots zijn of ben je trots op dit product?
AAMP11	Voel je je hip als je dit product draagt?

AAMP12	Kun je je eigen waarschuwingstoon kiezen met dit product? Zo ja, zou dat een bruikbare en prettige functie voor jou zijn?
CMML1	Is de manier waarop de menu's zijn ingedeeld voldoende logisch?
CMML2	Past het ontwerp van de grafische symbolen, pictogrammen en labels in voldoende mate bij hun betekenis?
CMML3	Zijn de logo's voor de menukeuze zorgvuldig bedacht?
CMML4	Helpt het als het commando op het scherm wordt opgelicht?
CMML5	Zijn de MENU knoppen gemakkelijk genoeg te vinden voor alle functionaliteiten?
CE1	Is de reactietijd en de display waarop de informatie verschijnt snel genoeg?
CE2	Is de hoeveelheid informatie die op het scherm verschijnt voldoende?
CE3	Is de manier waarop het product werkt in het algeheel consistent?
CE4	Geeft het product de gebruiker toegang tot de applicaties en data door weinig aan te hoeven klikken?
CE5	Kunnen alle taken met het product op een gemakkelijke manier worden uitgevoerd?
CE6	Is het product betrouwbaar?
CE7	Is het gemakkelijk om met dit product gegevens uit te wisselen met andere producten (bijv. computer, PDA, en andere mobiele producten)?
TTAP1	Is het gemakkelijk om de canule te plaatsen?
TTAP2	Is het gemakkelijk om de infusieset te plaatsen?
TTAP3	Is het gemakkelijk om de adapter te plaatsen?
TTAP4	Is het gemakkelijk de sensor te vervangen?
TTAP5	Is het gemakkelijk om gemiste taken af te lezen?
TTAP6	Is het gemakkelijk om de sensor te calibreren?

Appendix 5: Explanation given before participating in study

Beste (naam),

Voor uw deelname aan het onderzoek bent u ingepland op de volgende datum: (DATUM). U wordt om (TIJD) verwacht. Het onderzoek zal plaatsvinden in Goor (Overijssel) bij Inreda Diabetic B.V. Inreda Diabetic B.V. zit aan de **Klavermaten 65-5, 7472 DD, te Goor.**

Wat wordt er van u verwacht en wat houdt het onderzoek in?

Het onderzoek is een samenwerking tussen Universiteit Twente en Inreda Diabetics ter verbetering van de kunstmatige alvleesklier en dient ervoor om de kunstmatige alvleesklier beter af te stemmen op patiënten. Het onderzoek zal ongeveer anderhalf uur duren. Het zal bestaan uit 2 taken die u uit gaat uitvoeren met de kunstmatige alvleesklier. Nadat u dit heeft gedaan, zal er bij u zowel een vragenlijst over het gebruiksgemak van de kunstmatige alvleesklier en een kort interview over de waarde tijdens het gebruik van de kunstmatige alvleesklier worden afgenomen. Na afloop van het onderzoek zal uw data verwerkt worden. Het onderzoek loopt tot eind Juni. Mocht u meer willen weten over de resultaten van het onderzoek, kunt u dit altijd aangeven tijdens het onderzoek.

Zorg dat u op tijd aanwezig bent. Mocht u toch verlaat zijn, dan kunt u mij altijd bereiken via mijn telefoonnummer: ----------. Wilt u meer informatie over de kunstmatige alvleesklier of over Inreda Diabetic willen hebben, dan kunt u een kijkje nemen op: http://www.inredadiabetic.nl/wordpress/nl_NL/. Mocht u nog meer vragen hebben, beantwoord ik ze graag.

Met vriendelijke groet,

Remi Meeringa
Student Msc. Universiteit Twente

Appendix 6: Interview guide value-in-use

- Introductie
    - De onderzoeker vertelt over het doel van de studie: Het onderzoeken van de waarde tijdens gebruik van de kunstmatige alvleesklier
    - De onderzoeker vertelt dat er vertrouwelijk om zal worden gegaan met de gegevens en dat het onderzoek volledig vrijwillig is. De participant mag op elk moment van het interview stoppen.
    - De onderzoeker vertelt dat het interview opgenomen zal worden en vraagt nogmaals om toestemming.
- Begin interview
    - Introductie van vragen door: Hoe ging het uitvoeren van de taken?
- Gebruiksgemak
    - In hoeverre kostte het u mentale moeite om de taken uit te voeren? Waarom? Welke aspecten wel en welke aspecten niet?
    - In hoeverre kostte u het fysiek veel moeite om de taken uit te voeren? Waarom? Welke aspecten wel en welke aspecten niet?
    - Vond u het uitvoeren van de taken lang duren? Ging dit gemakkelijk/moeilijk? Waarom? Wat ging hierin makkelijk/moeilijk?
    - Heeft u nog wat toe te voegen aan het gebruiksgemak van de kunstmatige alvleesklier?
- Flexibiliteit/Onafhankelijkheid
    - Heeft de AP invloed op hoe afhankelijk u zich van de kunstmatige alvleesklier voelt als u deze zou gebruiken voor u ziekte? Wat vindt u hiervan?
    - In hoeverre verwacht u dat de kunstmatige alvleesklier uw onafhankelijkheid beïnvloedt? Waarom verwacht u dat?
    - In hoeverre verwacht u dat u flexibeler in uw algemene leven bent als u de kunstmatige alvleesklier gebruikt? Waarom verwacht u dat? Op welke gebieden verwacht u dat?
    - Heeft u nog wat toe te voegen aan de flexibiliteit/afhankelijkheid van de kunstmatige alvleesklier?
- Hedonische waarde
    - In hoeverre brengt de kunstmatige alvleesklier u plezier? Waarom vindt u dat?
    - In hoeverre geeft de kunstmatige alvleesklier u rust/ontspanning? Waarom?
    - Heeft u nog wat toe te voegen aan gevoelswaarde van de kunstmatige alvleesklier?
- Informatiebehoefte
    - In hoeverre vervult de kunstmatige alvleesklier uw informatiebehoefte? Waarom?
    - In hoeverre heeft u het gevoel dat de kunstmatige alvleesklier uw kennis vergroot? Waarom?

- In hoeverre heeft u behoefte aan aanvullende informatie tijdens het gebruik van de AP? Wat voor informatie, in welke vorm en waarom?
- Heeft u nog wat toe te voegen aan informatiebehoefte die u heeft met betrekking op de kunstmatige alvleesklier?

- Zelfontplooiing
  - In hoeverre heeft de AP invloed op of u zichzelf kan ontplooien? Waarom vindt u dat?
  - In hoeverre zou de kunstmatige alvleesklier u kunnen ondersteunen in uw zelfontplooiing? Hoe verandert dat voor u uw levenskwaliteit en mogelijkheden?
  - Heeft u hier nog wat aan toe te voegen?
- Productiviteit
  - Heeft de AP invloed op beslissingen in uw leven en omgang met uw diabetes? Waarom?
  - Heeft de AP invloed op het bewaren van belangrijke data over uw ziekte? Waarom? Wat vindt u hiervan?
  - Heeft de AP invloed op het organiseren van uw leven? Waarom?
  - Heeft de AP invloed op het managen van uw tijd? Waarom?
  - Heeft de AP invloed op uw productiviteit? Waarom?
  - Heeft u hier nog wat aan toe te voegen?
- Professionaliteit
  - Heeft de AP invloed op het volbrengen van uw verplichtingen in uw professionele- of privéleven?
  - Heeft u nog wat toe te voegen?
- Self-expressie
  - Heeft de AP invloed op hoe u uzelf presenteren? Waarom?
  - Heeft de AP invloed op het communiceren van belangrijke informatie naar anderen? Waarom?
  - Heeft de AP invloed op in hoeverre u zichzelf kan zijn en uzelf kan uitdrukken? Waarom?
  - Heeft de AP invloed op hoe u zich gedraagt in openbare situaties? Waarom?
  - Heeft u nog wat toe te voegen?
- Sociale waarde
  - Wat zal uw omgeving van het gebruik van de AP vinden?
  - In hoeverre denkt u dat het gebruik van de AP invloed heeft op contact met anderen?
  - In hoeverre heeft het gebruik van de AP invloed op uw sociale leven?
- Eind van het interview
  - De onderzoeker bedankt de participant en vraagt of er nog opmerkingen/vragen zijn.

Appendix 7: Checklist Tasks: Percentage of correctly carried out tasks for All patients, Insulin Pen and Insulin Pump.

		Total (%)	Insulin Pen (%)	Insulin Pump (%)
Task 1	Press Sleutelicoon	93.8	100.0	89.5
	Press Hartslag	93.8	100.0	89.5
	Press OK for activating Hartslag	90.6	92.3	89.5
	Hartslag shows 'in bedrijf'	90.6	92.3	89.5
	Task successful	90.6	92.3	89.5
Task 2	Press Insulineicoon	100.0	100.0	100.0
	Disconnect tubes of canule	90.6	84.6	94.7
	Reversal of 'aandrijfstang'	100.0	100.0	100.0
	Press no at 'Do you want to change infusionset?'	56.3	53.8	57.9
	Disconnect ampul	93.8	92.3	94.7
	Put ampul in	93.8	92.3	94.7
	Put adapter back on	93.8	92.3	94.7
	Tightening of aandrijfstang	100.0	100.0	100.0
	Press Test repeatedly	100.0	100.0	100.0
	Canule drips	43.8	23.1	57.9
	Task successful	43.8	23.1	57.9
Task 3	Use batterijsleutel as lever	71.9	76.9	68.4
	Use battery cover for removing batteries	43.8	38.5	47.4
	Remove batteries	84.4	84.6	84.2
	Put batteries in	84.4	84.6	84.2
	Put cover correctly on	81.3	84.6	78.9
	Task successful	84.4	84.6	84.2
Total (%)		72.9	66.7	77.2

Appendix 8: Value-in-use scores: N and % for All Patients. Insulin Pen Group and Insulin Pump Group

Value dimensions	Codes	All Patients		Insulin Pen		Insulin Pump	
		N	%	N	%	N	%
Convenience	Total	309	23.8	113	23.6	195	24.2
	Increase Duration and Speed of Usage	8	0.6	4	0.8	4	0.5
	Issues and Concerns during Usage of the APD	156	12.0	50	10.1	106	13.2
	Low Cognitive Effort/Duration and Speed of Usage and other Positive Aspects of Product	145	11.1	60	12.1	85	10.5
Flexibility/ Independence	Total	318	24.4	151	30.4	167	20.7
	Increase Dependency and/or Decrease Flexibility	110	8.4	52	10.5	58	7.2
	Decrease Dependency and/or Increase Flexibility	208	16.0	99	20.0	109	13.5
Health Benefits	Total	117	9.0	37	7.5	80	9.9
	Increase Stability of Bloodsugar	59	4.5	22	4.4	37	4.6
	Increase Physical Activity	20	1.5	5	1.0	15	1.9
	Decrease Risk of Complications	39	3.0	10	2.0	29	3.6
Hedonic Value	Total	57	4.4	20	4.0	37	4.6
	Increase Fun	10	0.8	7	1.4	3	0.4
	Increase Relaxation	50	3.8	15	3.0	35	4.3
Need for Information	Total	164	12.6	56	11.3	108	13.4
	Information Needed/Given using the APD	108	8.3	29	5.8	79	9.8
	No/Little Information Needed during Use	51	3.9	23	4.6	28	3.5
Personal Self-Fullfillment	Total	50	3.8	15	3.0	35	4.3
	Increase Ability of Pursuit of Personal Interests	41	3.1	14	2.8	27	3.3
	Unchanged Ability of Pursuit of Personal Interests	9	0.7	1	0.2	8	1.0
Productivity	Total	97	7.5	25	5.0	72	8.9
	Unchanged Decision-making. Organization of Daily Activities and Productivity	41	3.1	8	1.6	33	4.1
	Changed Decision-making. Organization of Daily Activities and Productivity	58	4.5	18	3.6	40	5.0
Professional/ Need for Achievement	Total	31	2.4	6	1.2	25	3.1
	Increase Ability to Meet Obligations	18	1.4	3	0.6	15	1.9
	Unchanged Ability to Meet Obligations	13	1.0	3	0.6	10	1.2
Self-Expression	Total	93	7.1	42	8.5	51	6.3
	Unchanged Self-Presentation. Social Life and Communication with Others	60	4.6	23	4.6	37	4.6
	Changed Self-Presentation. Social Life and Communication with Others	33	2.5	19	3.8	14	1.7
Social Value	Total	63	4.8	27	5.4	36	4.5
	Negative Aspects for Peers	3	0.2	0	0.0	3	0.4
	Increase Social-Emotional Benefits for Others	29	2.2	17	3.4	12	1.5
	Acceptance of Peers	31	2.4	10	2.0	21	2.6
Total - All		129 9	100	493	100	806	100