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# EMPATHIC-DESIGN ASSISTED BY THE KANO METHOD – A HUMAN-CENTERED DESIGN METHOD FOR MEDICAL DEVICES CONSIDERING PATIENTS

**Ahrens, Martin; Hehenberger, Peter**
Johannes Kepler University Linz, Austria

## Abstract

Every day we are confronted with new products and innovations. These may be based on known consumer demands or on industry innovations that give rise to new consumer demands. Usually, customers have little or no involvement in the product development process, which often results –as many well-known examples have shown –products that fail on the market.

First of all human-centered design requires studying the customers. Further, all the other influencers must be considered. All of these groups wish to be part of realizing the potential success of the product. In addition to investigating the importance of integrating the customer, we also provide an assessment of existing methods for customer integration.

Empathic design supported by the Kano method aims to be sufficiently intimate that latent customer requirements that have not previously been voiced can be identified in a structured form. The method was applied in a case-study in which an insulin pump was to be improved. Particular attention was paid to the requirements of diabetics who depend on insulin pumps for their whole lives. We present conclusions drawn from this case study and further aspects worth investigating.

**Keywords**: User centred design, Requirements, Medical device development, Empathic design method

**Contact**:
Martin Ahrens
Johannes Kepler University Linz
Institute of Mechatronic Design and Production
Austria
martin.ahrens@jku.at

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# 1 INTRODUCTION

## 1.1 Importance of Human-Centered Design

Survival in dynamic and turbulent marketplaces requires innovative products. Such products may fulfil new or as yet unknown consumer needs (Morris & Cormican, 2012). In the 1980s, Peters and Waterman stated in their book "In Search Of Excellence" that customer focus can contribute significantly to a company's success. Innovative and successful companies learn from their customers and offer unparalleled service, quality and reliability (Peters & Waterman, 1982). Numerous innovations that have failed in recent decades show that customer integration is important. Reinventions such as MiniDisc, netbook and pager did not survive, possibly due to a lack of or inadequate consideration of customer requirements and their integration in the product development process. In short, innovations are necessary for the survival of companies in modern marketplaces. Further, innovations may involve considerable risk, which may be reduced by employing human-centered design methods (Lüthje, 2004).

However, customer integration brings with it several additional questions and barriers. First, deciding at which stage of the development process customers should be integrated is not trivial. Second, the degree which customers are to be included must be determined. Identification and implementation of user requirements is therefore not a simple process, and one might wonder whether customers should be considered at all. Steve Jobs even said in a Business Week interview (Reinhardt, 1998, p. 1) that *“customers do not know what they want until you show it to them”*. Another problem with listening to customers was expressed by Ulwick (2002, p. 92), who said, *"Customers only know what they have experienced. They cannot imagine what they don't know about emergent technologies, new materials and the like"*. In this context, the human–machine interface (HMI) plays a key role. This means that not only functionality is essential, but also the handling of, and the communication with, the product.

Several important questions arise from this, which will be partially answered in this paper. First, we summarize commonly used methods for human-centered design. We then describe additional work that must be done before starting to use a particular method. Subsequently, we present a method that is able to identify in a hierarchical form not only conscious but also latent requirements.

## 1.2 Definition and Differentiation

We first provide some terms and definitions from the context of product development. Before customers become involved in the product development process, some facts about product position and definition must be determined. Clearly, stakeholders (e.g., persons or organisations) may have varying degrees of influence on the product development process. In this paper, we concentrate on the user and end customer, i.e., the human, and focus more on consumer goods than on industrial goods. That such a differentiation might be difficult is demonstrated by the case study presented in section 4.

**Definition and position of products.** Before human-centered design can be employed, the type of product must be defined. The aim in our case is to be sufficiently sensitized to know what is being talked about. Since finding such a definition is not always straightforward, Kotler and Keller (2006) therefore introduced product typologies, which can be specified by product properties and areas of application. Hence, each type of product is suited to a different strategic marketing-mix.

The typologies allow products to be characterized in terms of four major categories (Figure 1): A product can be a consumer and/or an industrial good, and it can be described as a material good and/or a service. It is important to know that these definitions are not mutually exclusive, and several may apply to a product. Take, for example, the vacuum cleaner: In private households, the vacuum cleaner is a consumer good and a material good, and additionally it provides a service. A vacuum cleaner used in companies is an industrial and material good that includes a service. In summary, we can say that the product definition depends on the customer. In section 4, we present a case study where this becomes clearly apparent.

**Definition and role of customers.** In a product development process, there are numerous stakeholders. Potential stakeholders are, for instance, persons, organisations, societies, and even the environment (Mitchell, et al., 1997), whose minimum expectations companies have to fulfil. The developing firm has the freedom to decide to what extent it satisfies its stakeholders (Kotler & Keller, 2006). The center of Figure 1 shows an example set of internal stakeholders. Of course, the customers and users are also essential stakeholders, but they are external. Ultimately, they determine long-term corporate success. As explained above, the question of who is the customer must be answered. The literature often uses the term “customer”, but closer inspection shows that the customer is not necessarily also the user: especially in the industry, there are also payers, buyers, decision-makers, users etc. (Kotler & Keller, 2006). Therefore, a company must define the customer it wants to reach. In our paper, the terms “customer”, “patient”, and “user (of a medical device)” are used synonymously.

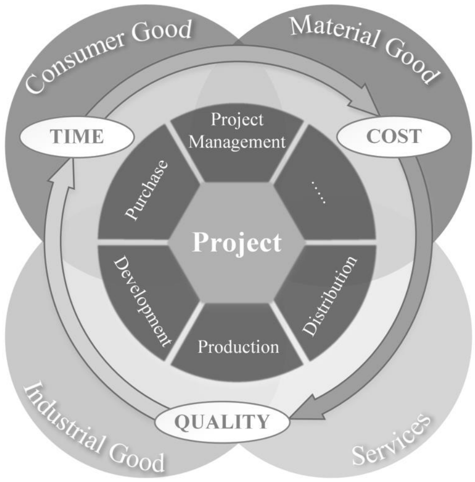


*Figure 1. Flower of definition in product development*

Although the focus of this paper is on the users, the Iron Triangle (Atkinson, 1999) of product development should be kept in mind in the development process. Its purpose is to help to develop a product at a given price with sufficient quality and in acceptable time. This is why this triangle is also included in the combined representation in Figure 1.

## 2 RELATED WORK AND STATE OF THE ART

Human-centered design in particular considers both the physical and the psychological needs of the user (Greenhouse, 2012). Since the methods used to involve users in the development process depend on the product, not every method is suitable for every product. This proposition can be proved, e.g. the customer of an industrial plant is steady in contact with the development team. But when you are developing a consumer product, the customers can be interviewed previously but not permanent during the development process. Another reason is the different stakeholders of different products. Stakeholders have more or less influence to a product development and so one method can be used easier than others. This section comprises two parts: First, we present an overview of general methods for analyzing user requirements. Then we describe specific methods for developing products in the medical device industry. The greatest challenge is always to find a method that translates customer needs into measurable variables (Wu, et al., 2005).

### 2.1 General Methods

The methods described in this subsection are commonly used both in research and practice to analyze and identify user requirements. Managerial economics gives advice such as "Get close to the customer" or "Listen to the voice of the customer", but – as Leonard and Rayport (1997) summed up in one sentence – "How can companies identify needs that customers themselves may not recognize?"

**Customer Observation.** Observing customers is an objective method, because the observer plays an active role and the users do not express their subjective perceptions. When users are being watched, their use of product functions can be identified. Otherwise emotional components related to the product, such as smell, sound, appearance, taste or texture, can be recognized (Berry, et al., 2002). Typically, two techniques called product clinic and empathic design are used in this context (Zogaj &

Bretschneider, 2012). Product clinic describes an approach in which the company must go through learning processes during product development in order to capture future customer requirements. Selected users are exposed to an artificial environment called the product clinic. The users are being observed while handling the company's own and competitor products in a laboratory setting. In the testing and comparison phase, the aim is to find a best-practice solution. The results are then used in the product development process employing, for example, reverse engineering (Wildemann, 1996). Empathic design, however, requires that customers be observed in their "natural" environment. In our case, is the user's own home – a familiar environment (Leonard & Rayport, 1997). Further information on empathic design can be found in section 3.1, as our method builds upon it.

**Customer Survey.** Another general method is the customer survey, where customers play an active role. Problems and wishes are addressed directly, but the success of the feedback heavily depends on the users' knowledge and their form of expression. It may happen that the results of a survey imply mostly product improvements and no concrete innovation. A disadvantage of this method is that users might be unable to find the right words to convey their needs. An advantage of the customer survey compared to customer observation is probably that customer needs can already be considered in the early phases of development.

**Co-Creation.** The terms Co-Creation and Co-Design flow over the world. Companies, their staff and customers are working together to develop a joint product. On the one hand the company gets the needs of the customer and on the other hand the customer gets the product he really needs. We can call this a typical win-win situation. Francis Gouillart goes beyond this and speaks concerning to Co-Creation of the "Real Social-Media-Revolution", where all stakeholders are interconnected (Gouillart, 2012).

**Quality Function Deployment - QFD.** Quality Function Deployment (QFD) is not a typical tool for identifying user requirements. Akao's definition is that QFD plans and develops quality functions of a product according to the customers' required quality characteristics (Saatweber, 2011). We include QFD because it is a powerful tool for translating the voice of the customer into the language of engineers (Akao, 1992). Another reason why QFD is presented here is that in some approaches it was combined, for instance, with the Kano model (Chaudha, Jain, Singh, & Mishra, Integration of Kano's Model into quality function deployment (QFD), 2010) (Sireli, Kauffmann, & Ozan, 2007) (Lai, Xie, & Tan, 2004) (Shen, Tan, & Xie, 2000). An analogous method is proposed in subsection 3.3. Further literature on QFD is collected in (Chan & Wu, 2002), which contains over 650 publications from several sources.

Moreover there is a multiplicity of methods e.g. the lead user method (von Hippel, 1986). A lead user hurries ahead the requirements of the mass and receives a great benefit if the product satisfies his requirements. After lead users are selected, they are systematically involved in the product development process.

## 2.2 Specific Methods

The specific methods we employ are those of human-centered design in relation to developing medical devices. It is well known that human-centered design is a very complex process, for example, when one takes into account that several stakeholders are interested in product specifications and, indirectly, also in the product development process. The development of medical devices involves so many different stakeholders that the situation is further complicated.

Extensive searches of the published literature revealed little on concrete procedures for involving patients in product development processes. Experience shows that in many cases they are not involved at all. The reason might be that there are so many stakeholders, such as health professionals, health insurers, and regulations governing medical products that take priority. At best, patients are included when the design brief is fixed. As Martin et al. stated, "This may be because medical devices are frequently technology driven rather than resulting from an identified unfulfilled need" (Martin, et al., 2008, p. 275).

Martin et al. (2012) found that Garmer et al. (2004) have so far provided the most notable study on methods for collecting user requirements of medical devices. Note that these methods are used for existing devices, with the aim of developing advanced versions. No published research (at least none that could be found in a literature search) has so far identified user requirements for a completely novel product. This opinion was shared by Martin et al. (2012).

The next section is the heart of this work and presents a consolidation and expansion of existing methods in order to specifically identify the requirements of patients (i.e., users of medical devices).

# 3 EMPATHIC DESIGN EMPLOYING THE KANO METHOD

As described in the previous section, patients are typically only included in product development processes when the design brief is already fixed. It has been stated (Martin, et al., 2008, p. 275) that this is due to technological standards and various priorities of stakeholders. Our method aims to improve existing medical devices. Note that the users of medical devices include both health personnel and patients. Since the patients have no way to express their needs, they are the main focus of our method.

The design method aims primarily at medical devices that are used 24/7 by patients who self-administer medication for chronic conditions. Our experience shows that patients prefer being able to self-medicate, but that they are often confronted with technology that is not user-friendly or is inconvenient in daily use. Through years of experience, patients develop strategies to avoid typical issues or learn how to deal with them. The aim at this point is to find a tool or method for detecting latent needs. Another method subsequently integrates and addresses these needs. Empathic design assisted by the Kano method seeks to support a typical requirements survey to detect more and, in particular, subconscious needs, and to do this in a structured way.

## 3.1 Empathic Design

In recent years empathic design has gained increasing attention in the field of user-centered design. Its strength lies in identifying numerous conscious and latent needs by means of observing and interviewing customers. Some authors (Postma, et al., 2012) even claim that empathic design enables creative understanding of user experiences for product development. Creative understanding means comprehending cognitive and emotional needs with the potential to translate them into user-centered products (Wright & McCarthy, 2005). Although many top engineering and design companies and some forward-thinking developers are aware of empathic design, it is not commonly used. This is regrettable, because applying this technique allows important customer needs to be identified at relatively low cost and risk. Observing users while they use a product in their own environment can provide clear, fundamental information (Leonard & Rayport, 1997). If one considers usability, for example, customers can be watched when they are turning on a new electrical device to assess whether finding and operating the power button is intuitive. This is just one simple example, but evaluating the results is not always straight forward, especially when the usability of something as complex as the human–machine interface (HMI) of a software product is to be determined. It is, however, possible to obtain fast and clear feedback. An additional difficulty is that product developers must be experienced in applying empathic design and very familiar with the product in order to benefit from the technique. It should also not be forgotten that empathic design is not a panacea, but a tool – a means to an end (Morris & Cormican, 2012).

Empathic design allows a minimum of five types of information to be elicited that cannot otherwise be identified by standard methods such as surveys and market research. However, empathic design does not replace standard methods, but complements them for increased retrieval of essential information. The five types of information are (Leonard & Rayport, 1997):

- Triggers of use: What motivates a customer to use the product?
- Interaction with the user's environment: Is the product suited to the user's environment?
- User customization: Do users modify the product to improve it for their particular application?
- Intangible attributes of the product: Does the product have a unique emotional feature?
- Unarticulated user needs: Do users have problems using the product that have not been communicated back or of which they are aware?

The implementation of empathic design can be structured into four steps, as shown in Figure 2.

In summary, one of the main challenges is finding and choosing highly trained personnel who are familiar with the product and related functions. Furthermore, precise knowledge of the customer base and its typical needs is required. Observing users in their familiar environment is complex, and the best results can probably be achieved when users are unaware of being watched.

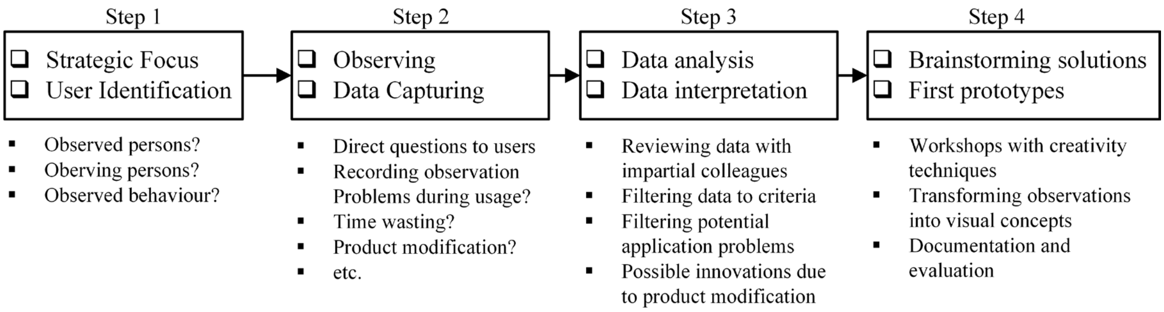


*Figure 2. Process of empathic design based on (Lüthje, 2007) and (Morris & Cormican, 2012)*

### 3.2 Kano Method

Let us assume that a great number of customer needs have been collected. Clearly, product properties that better satisfy customer needs yield higher customer satisfaction. Note, however, that the correlation between performance and satisfaction is less straight forward than it might seem. Kano's model successfully categorizes product characteristics and their influence on user satisfaction (Kano, et al., 1984). Applying this model therefore allows us to identify the attributes most critical to optimally satisfying customer needs. Kano's Theory of Attractive and Must-Be Quality divides customer requirements into three different groups (Chaudha, et al., 2010):

1. Must-be requirements: are those that users expect to be fulfilled, and if this is not the case, they will be dissatisfied and quickly lose interest in the product. However, meeting these requirements does not contribute significantly to customer satisfaction.
2. One-dimensional requirements: are explicitly requested by the customer, and satisfaction increases linearly with the degree of their fulfilment.
3. Attractive requirements: customers do not expect these to be satisfied. However, their fulfilment is likely to generate great satisfaction, especially when it comes as an unexpected pleasant surprise. Not fulfilling these requirements does not result in dissatisfaction.

Further elements mentioned by Kano, such as indifferent, reverse, and questionable requirements, are not considered in more detail here, as they are not relevant to the combined method we present below. From the information provided above follows: It makes no sense to fulfil one-dimensional or attractive requirements before all must-be requirements are satisfied, because even one ignored must-be requirement can suffice to obviate all higher-order needs. Furthermore, the Kano method considers product quality to be dynamic. This means that, over time, attractive properties may become one-dimensional and subsequently must-be properties. A typical example is the antilock brake in the automotive industry. The Kano method allows complex product properties to be structured in a relatively simple way. However, according to Kano, if customers are involved in structuring their own requirements with the help of this method, the results may heavily depend on the number and different types of customers.

### 3.3 Empathic design assisted by the Kano Method

A search of the literature showed that not only are methods often combined, the Kano method in particular seems to be favored for this purpose. It was integrated with QFD, for instance, in (Sireli, et al., 2007) (Chaudha, et al., 2010) (Lai, et al., 2004) (Shen, et al., 2000), and with FMEA in (Shahin, 2004). We did not find examples of its integration with other methods, but empathic design is frequently the topic of publications (Postma, et al., 2012) (Leonard & Rayport, 1997), so further combinations like empathic lead users (Lin & Seepersad, 2007) can be expected in the near future. Our search identified one publication where empathic design was used in the medical device industry (Morris & Cormican, 2012). Generally we can claim that the Kano method and the empathic design are famous tools and they are well-established in academia and industry. Kano published his method already in the 80s (Kano, et al., 1984) but a combination of Kano and empathic design could not be found till now.

The presented method demonstrates a possible additional benefit when combining fitting methods. As you can see in Figure 3, they are supporting each other. The method we present is intended for the development of medical devices, which are usually not mass products. The basic requirement is that the product is capable of managing a particular disease. Not every method can therefore be used in the human-centered design of medical devices. Hence, we present a combination of methods for involving users (i.e., patients) in the product development process and discuss how the design of existing products can be advanced by integrating patient needs. More precisely, we present a method that detects unknown and unconscious patient requirements in a structured way.

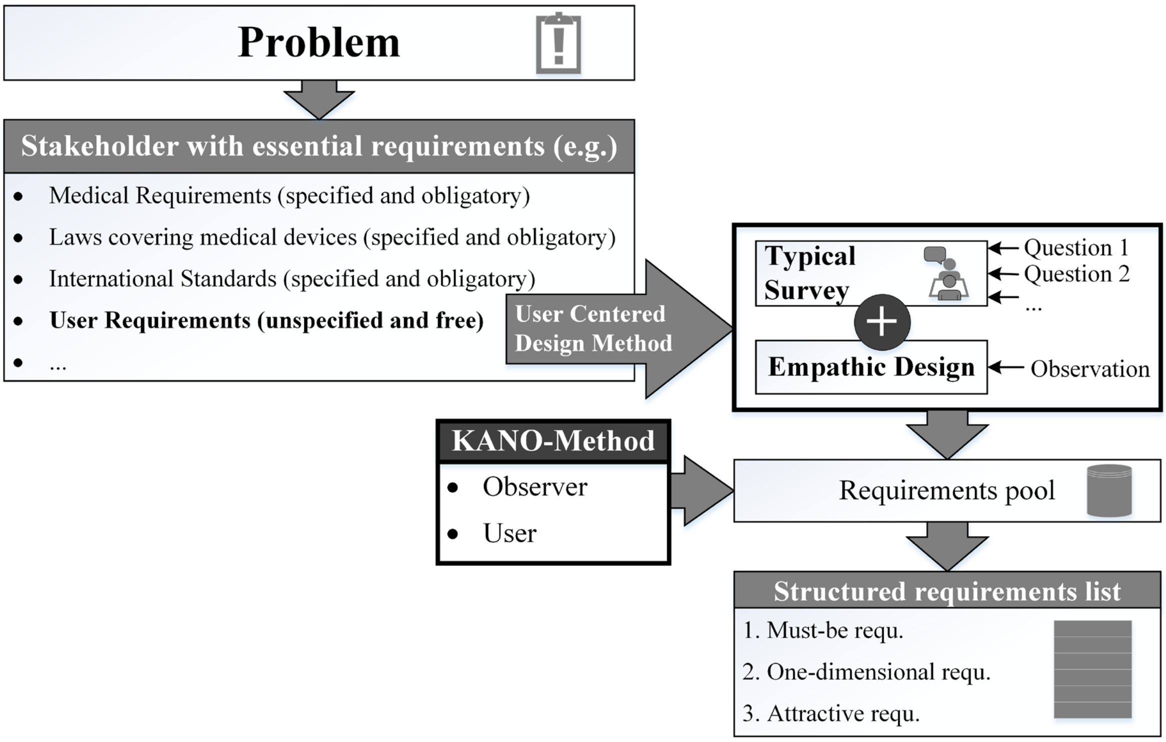


*Figure 3. Empathic Design assisted by the Kano Method*

The first step is a typical survey with selected questions, which is then expanded by means of empathic design. In the final step, the observer and the patient use the Kano method to structure the requirements thus collected. Empathic design makes it possible to recognize hidden and (often) unknown needs. Observing the patients allows identifying the strategies they employ when confronted with problems. Observation clearly requires in-depth knowledge of the product in order for latent needs to be detected. An important step is structuring the requirements pool, which contains many needs. In collaboration with the patient, the observer classifies the needs according to the Kano method into must-be, shall-be and can-be requirements. This allows focusing primarily on the must-be requirements and considering the remaining needs to create more customer satisfaction. Interestingly, as a result of this method, patients feel not only more satisfied, but also more confident– a key achievement in the context of medical devices. Our method provides a relatively easy way to involve patients, with the result that patients' trust in their medical devices and customer loyalty increase at comparatively low cost and with moderate time and effort.

## 4 CASE STUDY

The following case study focused on an insulin pump for medicating patients suffering from the chronic autoimmune disorder diabetes mellitus type 1. Diabetes mellitus is caused by a congenital genetic defect resulting in insufficient insulin production by pancreatic cells. An insulin pump allows insulin to be injected continuously into the body, thus imitating a healthy pancreas. However, the blood glucose level must be monitored, so the patient knows whether to inject insulin or to eat (see Figure 4). As previously mentioned, the typical users of this type of pump – the patients – are usually not involved in its development process. Patient integration could, however, be valuable, because an insulin pump is a product for very intimate and personal use. Patients must trust the device completely because they rely on it continuously.

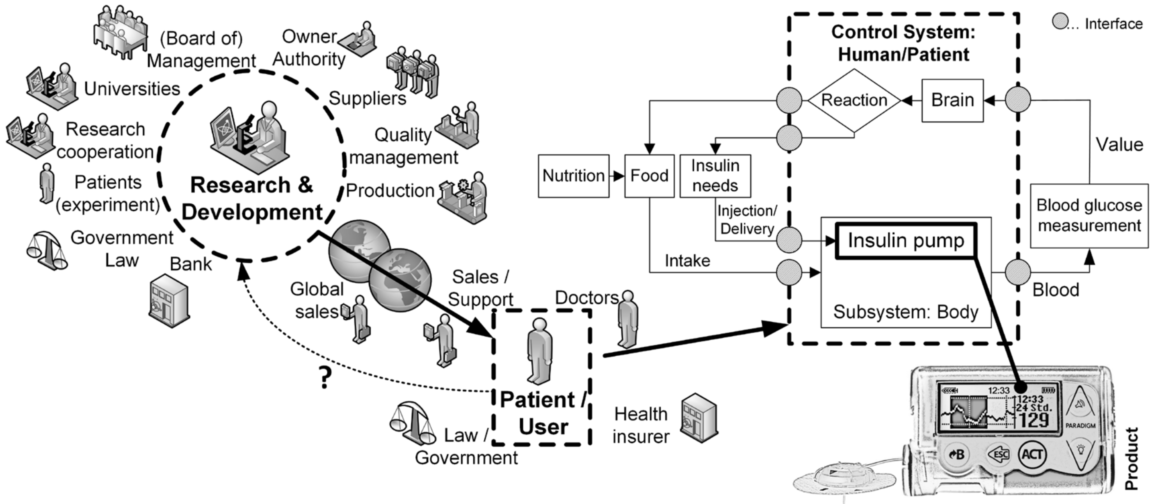


*Figure 4. Insulin pump, stakeholders and control loop in a holistic system overview*

A challenge in our context is the large number of different stakeholders in addition to patients, as shown in Figure 4. Healthcare professionals, medical device legislation, international standards, health insurers, etc. all seek to influence product specifications. Though we focus on the patients, the other stakeholders should also be borne in mind.

In order to test our method, we asked a patient with diabetes, who agreed to be interviewed. Of course, this is only an example evaluation a large number of patients would be needed to draw well-grounded conclusions that could be used in the development process. As shown in Figure 3, we began by conducting a typical survey comprising two relatively general questions:

- *What is important to you when you use the insulin pump?*

The response included the following keywords: maximum reliability, 24h service, user-friendly, exact insulin delivery, robust construction, resilience to heat and cold (sports, holiday), key lock, alarm in case of fault (amount of insulin, insulin delivery, battery…)

- *What would you like in an ideal insulin pump?*

The response included the following key words: smaller size and light construction, waterproof, fully automated insulin delivery, integrated blood glucose monitoring, without catheter tube

In the next step, empathic design was used to detect latent user needs. The results are from continuous observation of the patient's daily routine using the insulin pump.

Several hours after the patient had placed a new catheter, the device sounded an alarm for faulty insulin delivery. It was observed that the patient was unsettled by the alarm and searched his/her conscience for incorrect behavior (nutrition, insulin delivery), when in fact the insulin supply tube was blocked. This was detected by measuring the back pressure. Such an incident could be particularly serious for very young patients, because they need relatively little insulin; therefore, the flow problem is recognized even later, and the missing insulin will later cause blood glucose to increase. The main requirement identified in this context is therefore a very fast-reacting alarm when insulin delivery is faulty.Another point we identified concerned hypoglycemia (low blood glucose). The usual procedure in this case is to eat food high in carbohydrates and to interrupt the continuous insulin delivery. It often happens that a patient feels stressed in such a situation and forgets to manually stop insulin injection. The requirement identified here is automatic interruption of insulin delivery. This in turn requires continuous glucose monitoring to react to changes in the blood glucose level.

Further, we found that long-term users of insulin pumps complain about annoying security queries. These queries give new users a sense of security, but irritate long-term users. A possible requirement is therefore to create a two-mode system that satisfies both types of user.

As shown in Figure 3, in the next step the total requirements pool was structured according to the Kano method. Observer and patient worked together and arranged the requirements as follows:

1. *Must-be requirements:* maximum reliability, 24h service, exact insulin delivery, robust construction, resilience to heat and cold, alarm in case of fault, **very fast alarm in case of faulty insulin delivery, automatic interruption of insulin delivery in the case of hypoglycemia**
2. *One-dimensional requirements*: user-friendly, key lock, **integrated blood glucose monitoring, waterproof**
3. *Attractive requirements:* **fully automated insulin delivery, without catheter tube, smaller size and light construction, two-mode system (new/long-term user)**

The words indicated in bold are features not yet realized completely and reliably in existing insulin pumps. Since some of these points were classified as must-be requirements, it is clear where development should start. We are confident that it is thus possible to achieve results in the short term and with relatively little effort. It is widely recognized in the field of medical devices that product reliability and resulting customer satisfaction in the form of confidence are paramount.

It is important when newly identified requirements are considered and solutions implemented that existing product properties are not impaired. One difficulty in this context is translating patient needs into technical functions, because patients usually know little about the potential of technologies. Furthermore, critical consideration must be given to the numbers and types of patients involved. The results obtained can depend, for example, on the age of the customers interviewed or on how long they have been using the product. Our case study focused only on one patient, but there are many other important stakeholders. Now we can argue that the answers are obviously, but the interviewed person is a real diabetic which uses an insulin pump for over a decade. If the answers are really foreseeable, why the engineers do not succeed the implementation of the requirements. Maybe the answer is, that they do not know the patients real needs. We sought to demonstrate that the end user is often forgotten or not considered sufficiently in product development processes. The distinguishing feature of our method is that it identifies more requirements than a typical survey. Furthermore, an additional advantage employing the Kano method is that the users can influence the priority with which their needs are addressed. Implementing their requirements guarantees customer satisfaction.

## 5 CONCLUSIONS AND FUTURE WORK

As only one patient was considered in the case study, the results presented here are not intended as recommendations to manufacturers for further development. However, the case study demonstrates ways to quickly arrive at results when conducting a broad-based study. Further, it shows the flexibility of the method presented and that it is possible to identify unknown requirements with relatively little effort. The method may not be practical for mass-market consumer products, because the clientele is so extensive and diverse that the results are probably equally disparate. Future work could include broader based studies or tests of the method on other products. Further extensions to the method are also possible. In conclusion, customers who rely on a medical product day in and day out are insufficiently involved in the product development process, although they – as patients –must trust and work with the medical devices to treat their diseases.

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