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User-friendly design of a drug delivery system for Parkinson patients

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Abstract

The safe and economical use of medical devices requires high usability. Therefore, User Interface Design GmbH (UID) supported HSG-IMIT[1] in developing a drug delivery system for Parkinson patients. It is an innovative miniaturized drug delivery device for the insertion into the human oral cavity. HSG-IMIT developed the dose cartridge *BuccalDose* which is part of a dental prosthesis. The drug delivery is directed towards the buccal mucosa. The advantage is the high bioavailability obtained by trans-mucosal drug administration (inner cheek). By using an assistive tool the patient is able to insert and to remove the cartridge independently. The function of the base station is to identify and analyze the filling level of the cartridge. The main issue when designing the base station and the assistive tool was to maximize the ease of use and to minimize handling errors. The limited physical abilities of the patients were special requirements for the concept and the design process.

A team of product designers and usability engineers worked out several use cases and developed different interaction patterns. In the first draft the designers made rough scribbles. These designs were refined and afterwards transferred into true to scale product sketches to build up a 3D model. Furthermore, UID and HSG-IMIT created a Usability Engineering File according to the standard DIN EN 62366[2].

1 Introduction

HSG-IMIT developed telemedical system for remote drug delivery for the treatment of patients with Parkinson's disease. In order to match the system to the needs of elderly and impaired people as best as possible, HSG-IMIT asked UID's user interface experts to join the team.

The system's core element is a cartridge, the *BuccalDose*. It is integrated into a partial denture and continuously delivers liquid drugs directly to the buccal mucosa with extreme precision and without electrical energy. This ensures that the drug level remains constant as long as possible. The patients' quality of life improves and the risk of secondary diseases is reduced. The “assistive tool” supports patients in changing the cartridge, the base station indicates when it needs to be changed.

UID was assigned the task of developing a function and design concept for the base station and the assistive tool. The splash-proof system was to be designed in a way that would make handling easy and reduce the risk of operating errors. The patients' limited fine motor skills posed an additional challenge to our usability experts.

The article at hand shows the approach in the project and explains the different usability methods that have been used to develop a user-friendly medical device for Parkinson patients. In this project different methods of the user centered design process were used to transform the complex requirements into a profound concept and design.

Image 1 *BuccalDose* ensures safe and simple drug delivery.

2 Concept

During this project phase usability engineers defined a first concept, identified the primary operation functions, developed a persona and typical use scenarios as well as worst case scenarios. Furthermore, interface requirements were defined as required in the DIN EN 62366 (especially in the "application apecification").

2.1 Definition of first concept

First of all, the project team defined a first concept by the following approach:

- Review of several technical documents, such as functional and product specifications.
- Identifying several definitions such as the medical purpose, the patient population, the intended user profiles and the intended conditions of use.

The definition of a rough concept does also provide input for the application specification of the usability engineering file.

2.2 Primary Operating Functions

Usability experts identified frequently used functions and functions related to safety. "Functions" are in this case defined as typical tasks that are performed by the users every day. The primary operation functions are the basis for all further actions – e.g. they will be the basis for the validation activities (usability test), or in other words they will be the tasks listed in the test guideline.

2.3 Creation of a persona

On the basis of the intended user profiles a persona has been created:

- Erwin Müller, 68 years old
- Lives by himself in a two-room apartment
- Suffers from Parkinsons, degrees of severity 3 according to Hoehn & Yahr [3]
- In recent years his body movements slowed down significantly
- He has problems to keep the balance, especially if he stands over a longer period
- Along with other dysfunction, he has difficulties to chew, also because his jaw cracks

2.4 Creation of typical use scenarios

Based on the primary operating functions a typical use scenario has been created in which Erwin Müller plays a leading role. The following description shows an excerpt of such a scenario:

"Erwin Müller gets up at 6:15 am, as he does every day. He realizes he has difficulties to move his limbs. Therefore, he wants to insert a new cartridge with Ropinirol. […] Firstly, he removes his dental prosthesis […] He removes the old cartridge with the help of the assistive tool and puts it into the base station. This is important to determine the consumption data, as his doctor told him. […]"

The use scenario helps to identify ideas for further requirements. For example:

- Where to place the dental prosthesis?
- Does the user get feedback about the process of measuring? Does the user know when the measurments is completed?

2.5 Worst case scenarios

Based on identified risks of the risk management file, the following worst case scenarios have been set up:

- Forget to readout the cartridge
- Remove the cartridge in the mouth
- Not able to open the packaging

2.6 Definition of user interface requirements

Derived from use scenarios, conditions of use and the intended user profile user interface requirements have been defined. The list below shows some examples of such requirements:

- Degree of severity 3: Patients with degree of severity 3 shall be able to use *BuccalDose* independently.
- Splash-proof: *BuccalDose* has to be splash-proof because of saliva and cleaning.
- User guidance: *BuccalDose* shall indicate what the user has to do next.
- Memory function "medication": User shall be reminded to remove the cartridge.
- Forget to measure: User shall be reminded that the last cartridge has not been readout.

2.7 Concept workshop

Two product designers and a usability engineer developed some first concepts by conducting a walkthrough through the primary operating functions and with the help of the identified use scenarios.
These concepts were created in a brainstorming session. Afterwards the concepts were compared to the user interface requirements.

3 Design

3.1 Scribbles and storyboard

The designer scribbled the concepts and created a storyboard which explains a concept by showing all contained handling steps. The handling steps are again based on the

primary operating functions. In several iterations the concepts were discussed. Thus, the primary operating functions could be reduced to fewer handling steps.

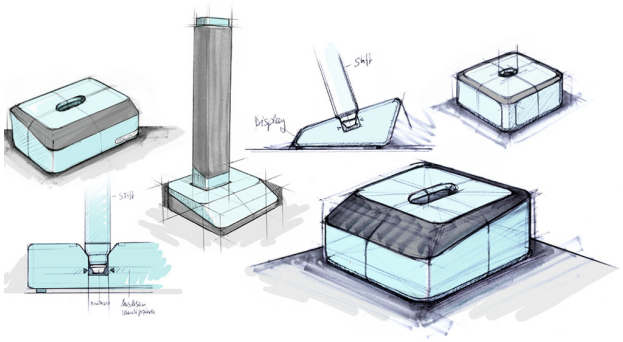

Image 2 Designers first drafted scribbles of their ideas

3.2 Interim Workshop

In a workshop with HSG with an interdisciplinary team consisting of designers, project managers, usability engineers and engineers the different concepts were discussed and merged to one concept that has been further refined during after the workshop.

2.3 Drawing 3D Design models as master

The product designer drawed a 3D model that has been used as a master for setting up the CAD Data for the device. Later on a rapid prototype has been build up based on these data.

Image 3 The *BuccalDose* system at a glance

4 Testing

The next step is that the user interface requirements will be verified in a clinical trial. Therefore, it is possible to optimize usability and further adapt it to its intended users.

5 Conclusion

When designing a medical device understanding the user's needs is one of the most important aspects to improve the usability and to meet the requirements of the DIN EN 62366.

The assistive tool disposes of large grips, perfectly adapted to patients with limited fine motor skills, who can hold the tool with their entire hand. The button, located on its top side, is beveled so it can be pressed more easily. The cartridge's receptacle is slightly indented to ensure it stays in place even in the event of sudden movements. The colors of the assistive tool and the base station match.

The base station provides the patients with as much information as possible. Instructions in the form of large icons and sounds support them in every phase. Large step-by-step icons at the front support them when the cartridges need to be changed. The base station's design is minimalist and appealing at the same time, and thanks to its small dimensions, it can easily be stored, even on narrow bathroom shelves.

A reader module at the base station identifies the cartridge every time it is changed and measures the drug amount delivered. Doctors can access this information remotely.

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