CHALMERS

Design of user interface for anaphylaxis auto injector

Master of Science Thesis

SOFIE WEIDENLÖV

Department of Product and Production Development
Division of Human factors
CHALMERS UNIVERSITY OF TECHNOLOGY
Gothenburg, Sweden 2014

Design of user interface for anaphylaxis auto injector

SOFIE WEIDENLÖV

Department of Product and Production Development
Division of Human factors
CHALMERS UNIVERSITY OF TECHNOLOGY
Gothenburg, Sweden 2014

Design of user interface for anaphylaxis auto injector
Sofie Weidenlöv

Gothenburg, Sweden, 2014
Chalmers University of Technology
Department of Product and Production Development
SE-41296 Göteborg
Sweden
Telephone: +46(0)736133003

Foreword

This report describes the product development process of a conceptual design made for an auto injector for acute, emergency, allergy use. The intention of this report is to describe the steps included in the product development process. It described the methods used for each step, how they were implemented and the results of each step, followed by a method discussion and a final conclusion. The results of the product development process are the two mock-ups; Electra Fusion, developed with a more realistic approach and the Microject Assembler that is developed with the future in mind.

I would like thank SHL for enable me to carry out my project at their site in Taiwan; providing me with equipment, materials and especially for assigning med two experienced and dedicated supervisors for my convenience. I would especially like thank Benson Chen and Dave Wang who always put their own work to aside to be there and support me every step of the way. I would also lite to extend a thank you to all the supportive people that volunteered to participate in the user study and tests. Finally, I would like to dedicate a special thank you to my supervisor Lars-Ola Bligård at Chalmers, Sweden, who also went the extra mile to help and support me along the way regardless of the time difference and day of week.

Thank you, thank you all!

Sofie Weidenlöv

Hsinchu, Taiwan, 14-06-06

Abstract

This report describes the product development process of two new interface designs of an auto injector for acute, emergency, allergy use. The project was sponsored by SHL goup in Taoyuan, Taiwan. The product development was carried out in eight steps; fields study, customer & user study, identification of customer needs, concept generation, concept evaluation & selection, concept testing that finally resulted in two final conceptual designs of the user interface. The first is called Electra Fusion and is based on and existing platform whereas the second design, called MicroJect Assembler, has a more futuristic approach. The project was mainly aiming at develop an interface design based on what the customers want and need in combination with user friendly directives. The development process did not focus on any mechanics but the user tasks needed to successfully give the injection. The result did fulfill its purpose do act as guidance as there has a great interest from highly important people though out this project but mainly to view the result. There will probably be more design solutions like Microject Assembler in the future as the pen injector has a very limiting effect on size and a reduction of size was the key point of all the customers that participated in the study. Finally, the major lesion learned during this project is how the Taiwanese corporate culture pursues.

Sammanfattning

Den här rapporten beskriver produktutvecklingsprocessen av två nya gränssnittsdesigner av en autoinjektor för akut, allergiskt bruk. Projektet var sponsrat av SHL gruop i Taoyuan, Taiwan. Produktutvecklingen utfördes i åtta steg: fältstudie, kund- och användarstudie, identifiering av kundbehov, konceptgenerering, konceptutvärdering & -val, testning av koncepten vilket resulterade i två slutgiltiga konceptuella designer av användargränssnittet. Den första gavs namnet Electra Fusion, vilken är baserad på en existerande plattform medan den andra som gavs namnet MicroJect assembler, är av en mer futuristisk karaktär. Projektet hade som främsta målsättning att utveckla en gränssnittsdesign baserat på vad kunden behöver och vill ha i kombination med vetenskapliga direktiv för användarvänlighet. Utvecklingsprocessen fokuserade inte på någon mekanik, dock fokuserade den bl.a. på de handlingar som användaren måste utföra för att kunna slutföra uppgiften att ge sprutan med ett lyckat resultat. Resultatet uppfyllde sitt syfte att fungera som vägledning då projektet väckt stort intresse bland högt uppsatta personer, både under projektets gång men främst vad det gällde resultatet. Troligen kommer det i framtiden att bli mer designlösningar som MicroJect Assembler då en pennformad injektor är begränsad i storlek och en reducering av storleken var en nyckelfråga för alla kunder som deltig i studien. Slutligen skall nämnas att den största lärdomen som dragits under projektet rör den Taiwanesiska företagskulturen.

Innehåll

1. Introduction 1

1.1. Background 1

1.2. Purpose 2

1.3. Objectives/problem formulation 2

1.4. Scope/delimitations 3

1.5. Actors and Stakeholders 3

2. Theoretical framework 4

2.1 Cognitive Processes and human information process 4

2.2. Stimuli & human senses 5

2.3. Perception 6

2.4. Attention 7

2.5. Mental Worklaod 8

2.6. Decision making 9

2.7. Memory functions 10

2.8. Human errors 11

2.9. Stress 12

3. Method 13

3.1. The product development process 13

3.2. Hierarchal Task Analysis 14

3.3. Cognitive Walkthrough 14

3.4. Interviews 15

3.5. KJ – Analysis 15

3.6. Metric list 15

3.7. Brainstorming 16

3.8. Brainwriting 16

3.9. Osborne's idea spurring checklist 16

3.10. Thumbnail sketches 16

3.11. Pugh matrix 16

3.12. Morphological matrix 16

3.13. Soft models 16

3.14. Computer Aided Design 17

3.15. Usability testing 17

4. Implementation 18
4.1. Field study 20
4.2. Customer / User Study 20
4.3. Identifying customer needs 22
4.4. Developing sub solutions 23
4.5. Concept development loop 1 23
4.6. Concept development loop 2 23
4.7. Concept development loop 3 24
4.8. Final results 27
5. Field study 28
5.1. Emerade 28
5.2. Adrenaline click 29
5.3. Twinject 30
5.4. Anapen 31
5.5. ConfiDose 32
5.6. EpiPen 33
5.7. Jext 34
5.8. Final analysis 34
6. Customer & User Study 36
6.1. Size 36
6.2. Hindrance 36
6.3. Appearance 36
6.4. User functions for children 36
6.5. Not inject into the heart 37
6.6. Expiration date 37
6.7. Assessing the drug 37
6.8. Practice or demonstration opportunity 37
6.9. Support for mental models 37
6.10. Instruction label 38
6.11. Lack of feedback when giving the injection 38
6.12. Finding the injector 38
6.13. Final analysis 38
7. Identifying customer needs 39
7.1. Number of doses to carry 39

7.2. Properties 39
7.3. Cover 39
7.4. Routines for expiration date and fluid 39
7.5. Practice 40
7.6. Convenience 40
7.7. Environment to be able to use it 40
7.8. Carrying 40
7.9. Storage 41
7.10. Use functions 41
7.11. Information on injection 41
7.12. Other information in conjunction with injection 41
7.13. Appearance 41
7.14. Other physical design 42
7.15. Functions and features 42
7.16. Before / after injection 42
7.17. Temperature 42
7.18. Final analysis 42
8. Developing sub solutions 43
8.1. Size & shape 43
8.2. Usage 44
8.3. Instructions 44
8.4. Injection fluid status 45
8.5. Expiration date 45
8.6. Practice/Demonstration 46
8.7. Appearance 46
8.8. How to carry the injector 47
8.9. Cover/Case 47
8.10. Carrying to disposal 48
8.11. Information in conjunction with the injector 48
8.12. Environment to use and store the injector in 49
8.13. Final analysis 49
9. Concept development loop 1 50
9.1. Puzzle pen 51
9.2. Air Tube 52

9.3. The player 53
9.4. MicroJect 54
9.5. One way griper 55
9.6. Oval run down 56
9.7. Robin Hood 57
9.8. Twister 58
9.9. BubblePen 59
9.10. Multiple ampoules 60
9.11. Punchliner 61
9.12. Superman 62
9.13 Final analysis 62
10. Concept development loop 2 63
10.1. Pugh matrix 63
10.2. Morphological matrix 63
10.3. Second loop concepts 64
10.4. Final analysis 71
11. Concept development loop 3 72
11.1. Electra Fusion 72
11.2. MicrojectAssembler 73
11.3. Final analysis 73
11.4. Concept testing 74
12. Final results 85
12.1. Electra Fusion – product specification: 85
12.2. MicrojectAssembler – product specification: 87
12.3. Instruction label – Electra Fusion 90
12.4. Analysis – Final results 91
13. Discussion 99
13.1. Overall discussion 99
13.2. The product development process 100
13.3. Filed study 100
13.4. Customer / User Study 100
13.5. Identifying customer needs 101
13.6. Generating sub solutions 101
13.7. Concept development loop 1 102

13.8. Concept development loop 2 102
13.9. Concept development loop 3 103
13.10. Concept testing 103
13.11. Concept testing – instruction label 103
14. Conclusion 105
References 106

Appendix 1 I
Appendix 2 III
Appendix 3 V
Appendix 4 VIII
Appendix 5 XXXV
Appendix 6 XXXIX
Appendix 7 LXIII
Appendix 8 XLV
Appendix 9 XLVI
Appendix 10 XLVII
Appendix 11 XLVIII

1. Introduction

This chapter aims at describing the importance of this project but also to explain the foundations of severe allergy, anaphylaxis and how the active substance in the allergy injector works. It will continue by describing the purpose of the project followed by objectives/problem formulation and scope/delimitations. Finally, there will be a brief discussion about actors and stake holders which in this case consisted of SHL group in Taoyen, Taiwan.

The following chapter consists of the theoretical framework used in order to understand the underlying cognitive processes that are affected by the interface design and chapter number three describes the methods used in this project.

Next chapter, implementation, provide detailed descriptions regarding how the methods were carried out. The continuing chapters from 5-12 presents the result of each step in the product development process, i.e. the results of the methods where chapter 12 presents the final results. The final results are then followed by a discussion of each step of the processes, starting with an overall discussion and this chapter is followed by a final chapter containing conclusions of both general and more specific character.

1.1. Background

There are 2,7 million people that consider themselves suffering from allergy in Sweden today. This is according to medeca.se a doubling that proceeded over the last 30 years and about 50% of the adolescent population consider them self to be allergic in some way. There is however less people that are being diagnosed by allergy today and according to slv.se about 15% of the population is being diagnosed with some kind of food related hypersensitivity.

Food allergy can be the cause of an anaphylactic shock that medeca.se describes as a life threatening allergy related reaction. It does not have to be caused by food only, a bee or a wasp sting are also possible causes together with latex, antibiotics and other medicine according to medeca.se. Even physical exertion and coldness could be possible causes. The webpage continues by explaining that an anaphylaxis reaction has both mild and critical symptoms. Examples of mild symptoms are; itching palms and soles, hives, a sense of stinging in the moth, nausea and vomiting etc. The more severe reaction that in some cases may be fatal are; hard to breath, swelling of the mouth and throat, a sudden debility accompanied by a sudden vertigo and finally a sense of a strong deterioration.

Anaphylaxis can be deeper explained by referring to medeca.se that states that the chock is caused by a sudden release substances from the cells to blood and the tissues. The released substances, mainly histamine, affects the blood vessels and causes a swollen mouth and throat, decreases the blood pressure which is when stomach pains could occur as well as dizziness and nausea.

The treatment of an anaphylaxis should according to medeca.se be started immediately by injecting adrenaline, intramuscularly. This is a short time solution which is why the second step is to consume cortisone pills and antihistamine. If the reaction has not been eased, a second injection should be given according to notalllergi.se.

When being diagnosed with severe and potentially deadly allergy the patient is prescribed auto injectors according to netdoktor.se. Medeca.se explains that the adrenalin contracts the dilated

blood vessels, relaxes the smooth musculature, which makes it easier to breath and stimulates the heart rate and prevent further swelling in the mouth and throat. It continues by stating that it is of highest importance to always carry these injections anywhere after being diagnosed with this kind of severe allergy.

There are many requirements that need to be fulfilled in order to have a well functioning allergy injector for acute emergency use. As an anaphylaxis reaction could result in unconsciousness, it is important that the injector is intuitive to use for any one, as the user may be a person without any experience of allergy and allergy injectors. Since the patient, the customer, need to carry these injectors at all time, they also need to have a physical design that matches this requirement. As medeca.se states that a second injection may be given after 15 minutes if no improvements, doctors recommend that two injectors are to be carries at all time according to Eva Thorelli (14-06-05) which also need to be taken into account when designing a new allergy injector.

There were many flaws and potential user error found when first analyzing the present injectors that are out on the market today. Most of those flaws were also confirmed later on when conducting the customer study but there were also additional flaws and disadvantages discovered during the customer study. There were both major and minor flaws but some could ultimately lead to serious consequences. One example of this is if the design of the injector is inconvenient to carry at all times and therefore left at home, or if the instruction label is too hard to read or comprehend. Flaws and disadvantages were found in these areas, among others, which is why there is a great need for a new design of these injectors that are based on what customers what but also on scientific research, methods, analysis and tests.

1.2. Purpose

This project was carried out for guidance purposes. The outcome of this project is a tool used to communicate what the customers want, to the industry, as the product development process, and hence the results, are mainly based on a customer study. The customers do however not have all the information regarding how to design an intuitive user interface which is why this project also created a user friendly interface based on scientific methods, analysis, tests and research, also for guidance purposes.

1.3. Objectives/problem formulation

The aim of this project was to carry out a product development process that that would result in a new interface design of an allergy injector used for acute emergency needs. The task included development of an executive design, a physical design and an aesthetic design of both the injector and the instructions. In order to fulfill this goal, a number of objectives were defined:

Objective 1: Defining the advantages and disadvantages of the existing product currently on the market

Objective 2: Firstly, deliver a list of user needs to consider when designing the injector and define what the customers want and what they need. Secondly, compliment the list of user needs with respect the situation the injector has to be used in and information based on scientific research with in human machine interaction.

Objective 3: Develop a range of possible interface solutions, based on the previous objects, resulting in either one or two physical mock-up designs.

1.4. Scope/delimitations

The scope of this project did not cover any material selection and it was decided at a later stage to limit the development process to the extent that no cases would be developed. It was at the same time also decided that the continued development should be focused on designing an injector for adults and adolescents and not for children as the needs of children differs from the needs of adults and adolescents. The scoop does however include solutions that may be slightly modified to also suit children and design solutions of an injector that may require a case, where only the injector is being developed. Finally the scope did not cover the development of a fully functional device, only a mock-up to illustrate the interface design.

1.5. Actors and Stakeholders

The only stake holder during this project has been SHL group in Taiwan. They have sponsored the project as they wanted to gain more knowledge of customer wants and needs. They were also interested in a knowledge exchange as they believed that a product development process may differ between what is taught at Chalmers University in Sweden compared to how it is carried out in Taiwan, especially since it may differ even more due to the different geographical positions.

SHL is a company that develops and produces medical technology. The company is originally Swedish founded and located in Stockholm; Sweden, Deerfiled; United States and Taoyen; Taiwan. They have 4 different focus areas called: SHL Medical, SHL Healthcare, SHL Technologies and SHL Pharma.

SHL Medical involves drug delivery systems such as auto injectors that are designed, developed and manufactured for biopharma and biotech customers worldwide. SHL Healthcare develop and produces equipment solutions for home, hospital and long term care use, with a focus ion patient comfort and functionality. The third focus area, SHL Technologies, provides contract manufacturing and engineer services for the production of medical technology and industrial products. Finaly, SHL Pharma, provides design, development final assembly, labeling and packing of drug delivery devices to the Pharmaceutical and biotechnology industries.

2. Theoretical framework

A human machine system is a system where humans and machines are interacting in an environment to solve or execute given tasks. Figure 2.1, displays a cyclic process where information, material and/or energy are being exchanged continuously during the interaction between the human operator and the technology, simultaneously under constant impact from the environment. The border between the technology and the human operator is to be viewed as the interface. (Bohgard et. al., 2008)

A human machine system needs to be useful in order to fulfill its purpose. Usefulness is divided into two different parts; utility and usability. Utility refers to the technical system; that it contains the correct functions and functionality. Usability means that the technology has to be easy and safe to operate for a target operator (Bohgard et. al., 2008).

The subject of human machine system is applicable and useful when developing technology that is to be used by a human operator. The following parts of the system must be considered in order to achieve a successful system, these are; human abilities, technology, environment and the challenges of the task (Bohgard et. al., 2008). Hence, the subsequent sections will explain theory regarding this.

2.1. Cognitive Processes and human information process

Human abilities include cognitive processes and refer to the processes involved when receiving information from the environment, through the five human senses, how the information catch attention and how it is perceived. It continues with how the information is processed by the memory functions and how decisions and actions are carried out (Boghard et. al., 2008).

According to Wickens and Hollands (2004) information is received as stimuli through the human senses and is perceived, through attention, with the help of the long term memory. They argue that once the information has been perceived, a decision is made that ultimately leads to a response that causes new stimuli. This process can be considered as a closed loop system. Further, the decision is affected by both attention and short term memory but does at the same time affect the short term memory itself. There is a closed loop of information exchange between the decision making phase and short term memory. The final sub-function of the information process is the closed loop between short term memory and long term memory. (Wickens & Hollands, 2004)

This is the essential foundation of the cognitive processes, according to Boghard et al, which was created in order to understand the underlying factors of interface design.. (2008). The embodied factors are described further down. There are however, many other factors to consider when designing an interface for a human machine system, but are all related to the information process.

As displayed in Figure 2.1, various design principles for displays, control buttons and levers should be considered as well as, mental models and mental workload. All these aspects are covered in Appendix Design principles and guidelines for HMI. The reason for regarding design principles for displays is that there is a lot of visual information to account for like the use of colors and appropriate font size etc.

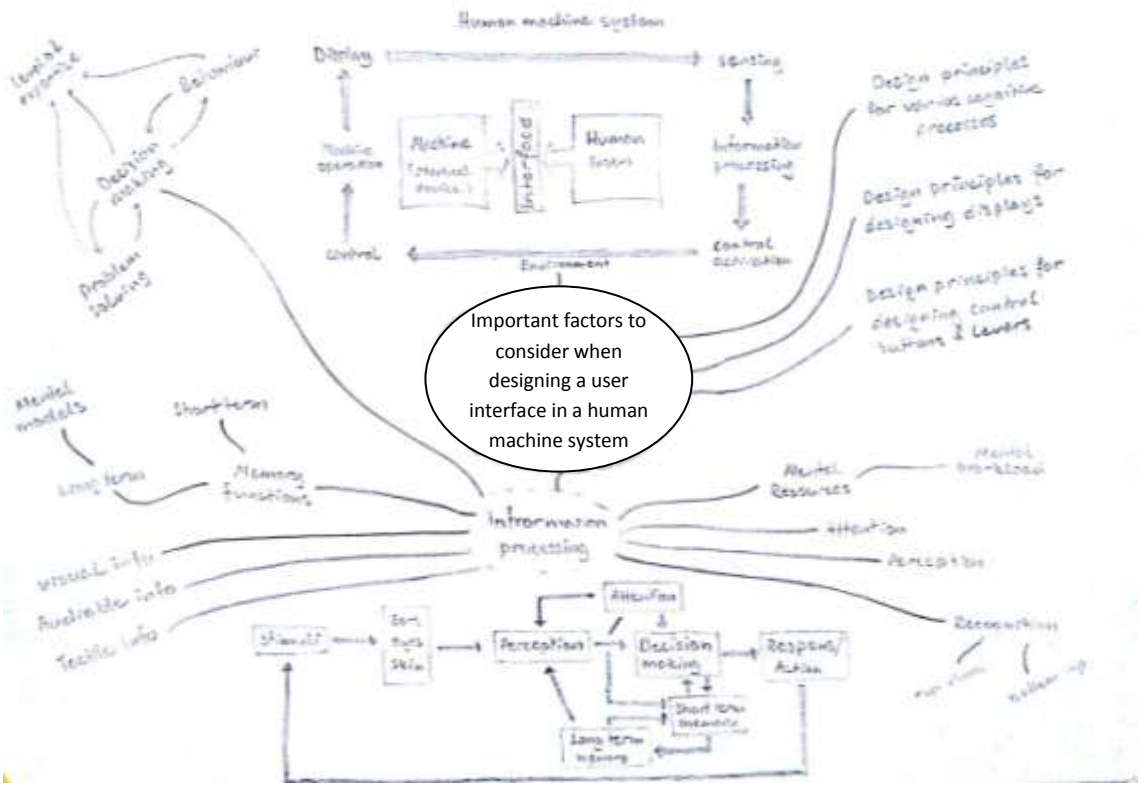


Figure 2.1 - Important factors to consider when designing a user interface. *Model of human machine interaction for medical devices. Adapted from Liu, (2009). Model of human information processing derived from Wickens & Hollands (2002).*

2.2. Stimuli & human senses

According to Robinson-Riegler and Robinson Riegler (2008) sensation include the process whereby eye, ear and skin receptors take the initial stimuli and register them in the chemical language of the nervous system that finally lead them to the brain where the process of perception transfers this electrochemical message into a rich percept. i.e. sensation is the input of a stimuli.

There are five basic human senses, according to Bohgard et. al. (2008); vision, audible , tactility, taste and smell. The last two senses will not be descried since they are not taken into consideration when designing the interface. Another human sense, the haptic sens, will however be mentioned and it is described by Bohgard et. al. (2008) as sub-sense of feeling that focus on pressure sensations and body movements.

2.2.1. Vision

Vision includes all stimuli that is processed by the eyes and is dominating the other senses according to Robinson-Riegler and Robinson Riegler (2008). About 80 percent of all the sensations are registered by the eyes but only in the field of 170° horizontally. Vision actively search for patterns and structures and important parameters for processing visual stimuli are contrast, luminance, colors, light, depth and detection of movements. (Bohgard et. al. 2008) The importance of colors that correspond to contrast will be described further in paragraphs later on.

Contrast
Contrast involves how differences between a brighter and darker surface are perceived. High contrast is essential in order to detect lines and shapes of an object. A high contrast makes it easier to distinguish between two objects. Poor lightning and conflicting colors frequencies has a negative effect on the contrast, while movements of the observed object enhance the perception of contrast. Raising age also affect the perception of contrast. (Bohgard et. al. 2008)

Accurate judgment of visual stimuli
Humans are usually good at distinguish between two sources of visual information if they are not looking too much alike, but it is harder to determine an accurate value of a coded stimuli like the height of a bar in a diagram. There are no guaranties that a person would be able to accurate determine more than 5 parameters. (Bohgard et. al. 2008)

2.2.2. Audible
The audible sense usually helps guiding vision to the right area of focus, since sound is most effective when it comes to catch the attention, i.e. it is a complementary sense to vision. Sound consists of mechanical vibrations in the air, which are registered by the ears. These vibrations are called sound waves and are defined by frequency and amplitude that determine the sound intensity. One of the most important functions of the hearing sense is the localization of sound and it is easier to localize a sound coming from the left or right than one coming from behind, above or in front of us due to the shape of the human head. (Bohgard et. al. 2008)

Even though vision dominates the audible sense, what happens when auditory and visual stimulus are in conflict is not always predictable, it depend on the situation which stimuli that will defeat the other but vision usually dominate in the end. (Robinson-Riegler & Robinson Riegler, 2008)

2.2.3. Tactility and haptic senses
Bohgard et.al. (2008) describes goal of the tactile as enabling the human being to understand when parts of the body is being under mechanical pressure or touch. They further states that it also includes the awareness heat, coldness, pain, itching and tickling. The human body can be trained to feel a depression of only 0.0005 mm on a flat surface and have 3 types of receptors (detects different stimulus); thermo, mechanics and free nerve ends. The thermo receptors detect changes in temperature, mechanic receptors detects touch, pressure and, vibrations and the free nerve ends detects pain or movements where the hair on the skin is being moved.

The haptic part of the tactile sense is according to Bohgard et. al. (2008) the science regarding the effects of body movements and touch. They continue by explaining that the haptic sense is composed by a tactile and a kinetic component that react to pressure on the skin and body movements in muscles, joints, tendons and extremities. The scientists mentioned above do also claim that a haptic user interface provide the user with a feeling that the objects on the screen has a physical mass and weight and makes a parallel to a video game with hand controls.

2.3. Perception
Like indicated above, perception refers to the psychological processes involved in the intermediate organization and interpretation of sensations according Robinson-Riegler and Robinson Riegler (2008). I.e. perception means that a person becomes aware of the the information from the environment that depend on the context different stimulus are currently in. Atkinson (2003) explains

it as the integration of sensory information together with the contents and meaning of what has been experienced and how that is being used. He also stat that the aim of perception is:

- Pattern recognition: Notice objects, remember them and understand the meaning of them.
- Localization: To determine where an object is located, distinguish it from the background, distance and movement
- Perceptual constancy: to maintain consistency of the mental image of the object even though the person is under the impression that is has changed.

2.4. Attention

Atkinson (2003) argues that the importance of attention is given when considering the aspect of perception. It becomes impossible to remember anything and understand the context of an object if it is not being noticed. En general rule between attentions and memory, is that when a person that is unaware it remember very little, if any, about the unintentional information. Things that are remembered unconscious come to the person's attention because the information usually is emotionally loaded somehow. Several scientists support this rule; Atkinson (2003) and according Robinson-Riegler and Robinson-Riegler (2008) among others.

The goal of attention is to focus on some stimulus and exclude others. There are two requirements regarding attention; it needs to be selective and shared. (Bohgard et. al. 2008)

2.4.1. Selective attention

Selective attention is when a person focuses on something in particular and discards everything else. (Atkinson, 2003) It is about allocating the mental capacity and determine what to focus on. (Boghard et. al. 2008) Atkinson (2003) claim that it is possible to fully understand the context of an object and understand where it is located by using selective attention. That also facilitates the memory of the object that can be of use in the future.

What information to focus on and what senses that will be activated is according to Bohgard et.al. (2008) determined by the following factors

- How prominent and distinct a signal is
- The expectations of the person
- The value of the information
- How demanding it is to obtain the information

2.4.2. Shared attention

This conception involves the ability to process information from one or several sources at the same time. This is not always possible, it depends on many factors and the factors that determine how hard this is to do are according to Bohgard et. al. (2008):

- Demand of mental resources
- Similarity of mental resources
- Alternation between different resources

The use of multiple recourses

According to Wicken's and Holland's (2004) 3-dimensional theory regarding the use of multiple resources, there are different cognitive resources in use when performing tasks that mainly uses information from different senses. I.e. different senses use different resources. It also explains that it is harder to perform different tasks that require the use of one category of the cognitive resources than to perform task that require different resources. Atkinson (2003) describes this by stating that it is very hard to listen to two stories at the same time, simply because both require the audible resource. He also states that it is easier to talk to a co passenger while driving because it demands the different recourses; audible and visual. However, Atkinson (2003) in consistency with Wickens and Hollands (2004) also argue that regardless of what resources a task demands, the human cognition can only handle so much when performing a task. This is explained by Atkinson (2003) as an overall limit of what the cognition is capable of processing and compares it to how a discussion with a driver immediately stops when the traffic situation drastically changes and the driver need to allocate all its cognitive resources to handle the difficult traffic situation. However, Atkinson (2003) also claims the level of expertise's correspond to how much of the cognitive resources that are needed for a certain task. As for the example of driver and the co passenger; a less experienced driver would not be able to focus as much on the conversation, than an experienced one, since the less experienced would need to allocate more recourses for driving.

2.5. Mental Worklaod

Ward (1996) mean that the use of multiple resources and the overall mental capacity are strongly related to mental workload and de defines capacity as "the upper limit of processing capability while resources represent the mental effort supplied to improve processing efficiency". This means that the use of similar resources/processes will increase mental workload as well as when the situation is of that character that it reaches the upper limit of the processing capability. However, Ward (1996) states that mental workload is not only task-specific but person-specific, depending upon motivation, applied strategies, mood state and the experienced load, it is possible to conclude that the operator itself is a big factor that affect Mental workload and the information intake for data processing.

The level of expertise can also be considered as a factor that effect mental workload since Rasmussen (1983) has concluded three levels of behaviors and actions, related to the level of expertise. A novice needs to actively think and solve problems to perform a task that is new and unknown. The more experience, the less thinking is required. Hence a more skilled operator would perceive less MVL than a novice since the tasks require much more resources and capacity for the novice to perform the task.

Young and Stanton (2002) notice a relationship between MWL and performance as reminiscent of a relationship between arousal and performance described by Wienberg & Gould (2003) who claim that arousal can be a positive thing for performance as long as the stress responses due to arousal do not turn out of control. Stress is according to Atkinson (2003) a result of arousal that occurs when the person experiences the demand of the task to be higher than its own perceived capacity. Hence, it is possible to assume that stress the level of expertise can affect the perception of the operator's own ability and thereby affect mental workload.

2.6. Decision making

As mentioned above, the level of expertise affects the amount of resources needed to perform a task and this has, according to Rasmusen (1983) , a crucial impact on the on the decision making phase of Wicken's and Holland's (2004) theory described in the cognitive process paragraph in this report.

Rasmusen's (1983) model gives a comprehensive view over how decisions are made depending on different the behavior that changes due to level of expertise. Bohgard et. al. (2008) state that it is crucial for a designer to have sufficient information about decision making in order to design a system that support relevant decisions.

There are three levels of knowledge based behaviors according to Rasmusen (1983):

- Skill based behavior (SB) – unconscious actions and actions of routine – Bohgard et. al. (2008) compares this to the action of opening a door.
- Rule based behavior (RB) – actions guided by rules, routines and old knowledge – Bohgard et. al. (2008) compare it to actions directed by traffic rules
- Knowledge based behavior (KB) – actions that require active thinking and problem solving – Bohgard et. al. (2008) compare it to actions taken in new or unfamiliar situations

Atkinson (2003) refers to this as we have either an automated behavior or a controlled behavior and that a task becomes more automated with practice. He continues by explaining that automated behavior require less cognitive resources, resources that could be used for another task simultaneously.

Rasmusen (1983) does also refer to the automated behavior but in terms of being skilled based and explain that the automated actions are triggered by perceptional signals which means that the short term memory can maintain most of its capacity.

The rule based behavior require more capacity from the short term memory but the actions are still based on what is stored in the long term memory. However, knowledge based behavior require mote of the mental resources and is used for problem solving. Problem solving is goal oriented and s problem solving plan is put together though a selections and tests that is evaluated when trying to solve the problem. This is executed by both mental and physical actions.

2.6.1. Problem solving

As described above, problem solving is a part of the knowledge based behavior according to Rasmussen (1983). There are two common models on the knowledge based level according to Bohgard et. al. (2008); normative and descriptive decision making. Normative decision making presuppose that human beings have unlimited mental resources and thereby are able to evaluate different arguments and alternative in order to mathematically calculate the maximum utility while making a decision. However, models of descriptive decision making is more frequently used when developing a human machine system since it is based on the fact that human beings actually have limited cognitive resources. The theories are also based on studies and descriptions of how human beings makes decisions in different situations. Bohgard et.al. (2008) describes that these theories exhibit that human beings use shortcuts, simple and incomplete procedures in order to select alternatives from a variety of environments. Human create a bias and uses rules of thumbs when making descions.

2.6.2. Mental limitations during decision making

Knowledge based decision making happens in three phases. Firstly, data and background information is collected from the environment and the critical point is that the information needs to be relevant. The information is then being interpreted in order to generate hypothesis, expectations and ideas about how different choices would affect the current situation. Finally, an action plan is crated based on the selections made. (Bohgard et. al. 2008)

2.7. Memory functions

The memory functions are necessary in order to learn, think and act. It enabled people to utilize earlier experiences. (Bohgard et.al. 2008) Time and context as well as emotions have a huge impact on what is being remembered. The memory process occurs in three steps: encoding, storage and retrieval. (Atkinson, 2003)

Encoding refers to the event when receiving information from stimulus trough attention and perception. Storage is about saving and organizing the information and retrieval occur when the stored information is being recalled. Repetition and exercise enhances the storage and retrieval process. (Atkinson, 2003) A cue is needed in order to recall the information according to Bohgard et.al. (2008).

There are two main memory storages; short term memory and long term memory and (Atkinson, 2003) is also open to the idea of a third memory a sensory one.

2.7.1. Short term memory (SM)

The short term memory coordinates old and new information, according to Atkinson (2003), and serves as a present memory according to Bohgard et.al. (2008). The later scientists explain this memory is active when the sensations are being processed, when a person is reflecting something and when the individual is focused on solving a problem. Hence, it is also called working memory. The short term memory only has capacity to store 7 +- 2 chunks, according to Atkinson (2003). He continues by explaining that experiments have been done on this topic where the participants were given a couple of randomized letters of which the participants remembered 7+-2. When they were given words the result was the same even though there were more letters to remember. If the words where put I categories of context, even more words were being remembered. Atkinson (2003) argue that it means we have a connection between the short term memory and the long term memory since some of the letters can be organized in to one chunk of the 7 +- 2 available.

2.7.2. Long term memory

The capacity to store data the in the long term memory is completely unlimited. The long term memory is storage of human experiences and is encoded through learning and practice. The information is stored in terms of categories and concepts that were available when the perception took place. The long term memory plays a central role during the perception phase described in Wicken's and Holland's (1983) model of information processing. The perceived stimulus are compared to information stored in the long term memory in order to understand and interpret the incoming information. This is very important for the process of recognition. (Bohgard et. al. 2008)

2.7.3. Mental models

A mental model is according to Bohgard et.al. (2008) "an intenternal representation of a system or entirety where the important aspects of the system and the relationship between them are stored in the long term memory". Mental models are used to simplify and predict different behaviors and actions in a dynamic procress. (Bohgard et.al.2008)

2.8. Human errors

Dekker (2004) presents two views at looking at human errors called "the old view" and another called "the new view". The old view considers human errors to be a cause of accidents and the system to be safe. This view looks at people as the biggest threat to safety and that the progress of safety would be to protect the system from unreliable humans. However, the author seems to sympathize more with the contradicting new view stating that human error is instead a symptom of trouble within the system. It also considers that safety has to be created by humans and thus is not inherent in the system. Furthermore the new view also considers human error as being systematically connected to the features of people's tools and that "progress on safety comes from understanding and influencing these connections", all in contradiction to the old view.

According to Kletz (2006), human error can be divided in to four categories similar to Reasons model;

- Mistakes – caused by the operators inability to know of what to do
- Violations – caused by a decision made by the operator to not do something that the operator know how to do
- Mismatches – causes when the operator lacks the ability do to do what needs to be done
- Slips and lapses of attention

Kohn (2000) states that "When a system fails, it is due to multiple faults that occur together in an unanticipated interaction, creating a chain of events in which the faults grow and evolve."

They all discuss different definitions of Human Error and they can all be related to Rasmussen's and Reason's models, just with different implications. Dekker (2004) seems to question whether there is such a thing as human error and would like to blame most errors on the system, whereas Kletz (2006) does not present any contradiction theories to the once that he is presenting. Kohn (2000) is not consistent with Dekker (2004) but very much in line with Dekker's view of how an error cannot be traced back to one single event and that it is hard to decide up on where the flaw is but also the conclusion that a lot of errors could depend on the system itself and not the human operator. However, Kohn (2000) seems to have no doubts that human error exists in contradiction to Dekker who seems to have more disagreement regarding this question.

If a further comparison was to be made between the researchers, between Kletz and Dekker in particular, one of the most distinguishing differences would be their ideas of human error preventions. Kletz has presented a list regarding accident preventions and most of the actions on that list have been dismissed by Dekker e.g. like the one regarding "rely on procedures" that Dekker believes would not remove all mistakes anyway.

2.9. Stress

Stress is described by McGrath (1970) as a state where there is an imbalance between the perceived demands of completing a specific task contra the perceived ability to complete it. Nervousness and anxiety are the result of an imbalance where the perceived demands are greater than the perceived ability. Feelings like unmotivation andboardness occure when the demands are perceived to be to low. Lasaruz (1999), illustrates stress like a seesaw where demand and personal resources need to carry the same weight in order to avoid stress.

2.9.1. Inverted U hypothesis

The inverted U hypothesis displays a curvilinear relationship between anxiety/arousal and performance which could look like an inverted U (Yerkes & Dodson, 1908). Some researches argue that this relationship could move along the x-axis to the right or left depending on the properties of the individual the design of the task. (Arent & Landers, 2003)

2.9.2. Individual zones of optimal function

Individual zones of optimal function (IOF) is a theory derived by Yuri Hanin (1978) that displays a relationship between emotions and optimal/minimal that depend on the individual. An individual can, according to the model, perform better or worse depending on the omtions of the individual and the intensity of them. The model focuses on the individual, subjective experience and declare that it is related to performance. It also states that there is a relationship with the perceived level of intensity of the emotion and the quality of the performance. The optimal intensity, high, low or somewhere in between, is determined by previous experiences of performance and the resources that are available at the moment. The chance of success is greater when in the optimal zone of intensity.

3. Method

The following chapter will describe the methods used during the development process. It will describe comprehensive methods as well as more specific methods and analyses. The methods are described in order of appearance.

3.1. The product development process

There are several comprehensive methods regarding how to carry out the product development process. The once described here are on one method presented by Ulrich and Eppinger (2012) and a second one illustrated by Bligård (2011).

3.1.1. The product development process according to Ulrich and Eppinger

The process starts by identifying user needs which is the foundation of the product specification, which is the next step. It continues with concept generation, which is followed by concept selection and finally concept testing. This will ultimately lead to a refined final concept. (Ulrich & Eppinger, 2012)

Figure 3.1. *The product development process by Ulrich and Eppinger (2012)*

3.1.2. The product development process according to Bligård

This process also include the actions of continues planning, data collection, evaluation and documentation throughout the development process. The steps included are firstly the identification of needs and secondly to design functions and tasks. This is followed by overall design and detailed design. The last two steps are construction and finally implementation. (Bligård, 2012)

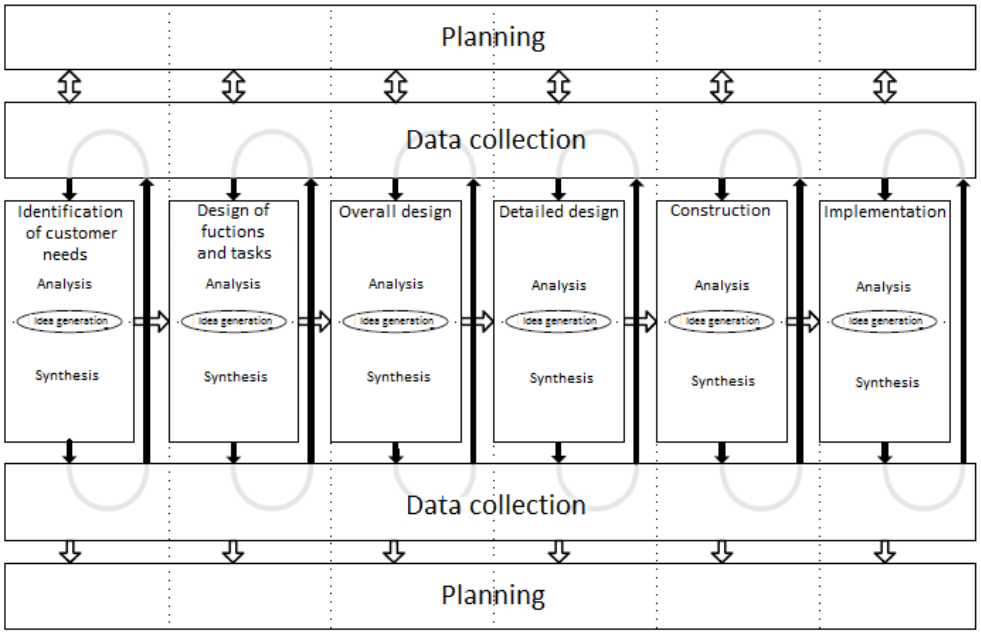


Figure 3.2. *The product development process by Bligård (2012)*

3.2. Hierarchal Task Analysis

The method constructs a hierarchal tree of the tasks, with the main functional task on top that branches off into levels of sub tasks, to provide a comprehensive over view of the tasks needed to complete the main functional task. (Boghard. et al. 2008)

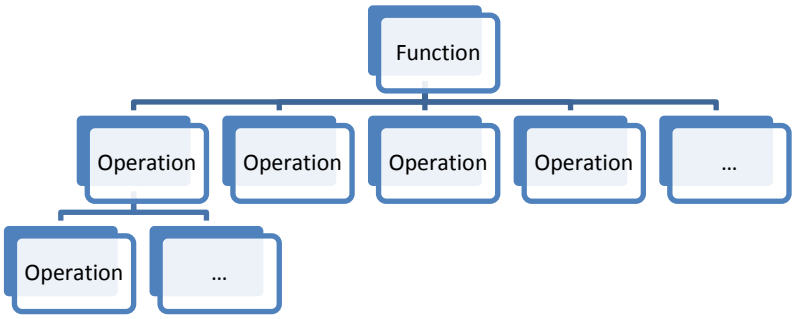


Figure 3.3. *Example of an HTA*

3.3. Cognitive Walkthrough

This analysis is described by Bligård (2011) as a simulation of the user's mindset when interacting with the machine. It is carried out by asking questions during every step of the way, for all the tasks needed to complete the main functional task of the machine. The questions are used to analyze if the user will carry out the right actions or not and what factors affects it.

There are two levels of questions to answer according to Bligård (2011):
Examples of level 1 questions; nodes and functions:

1. Will the user know that the function is available?
2. What kind of clues could the interface provide that revels that the functions is available?
3. How should the clues be designed for the user to associate the right clues with the right function?
4. How could the interface be designed in order for the user to receive sufficient feedback to understand the right function has been selected?
5. How should the interface be designed for the user to receive sufficient information to understand that the right function has been carried out?

Examples of level 2 questions; operations:

1. Will the user try to carry out the right action
2. What kind of clues could the interface provide so that the user will understand the right action is available?
3. How should the clues be designed for the user to associate the correct action with the correct result
4. In what way should the information be provided in order for the user to use it?
5. How should the interface be designed so that the user will receive sufficient feedback to understand that the correct action has been carried out?

3.4. Interviews

Interviews are one out of five exploratory and qualitative methods to use, in a market study, when gathering raw data from which customer need are to be derived from. (McQuarrie, 2012) also Ulrich and Eppinger (2012) mention this as a possible method when gathering raw data.

An interview, according to McQuarrie (2012), is a discussion with an individual customer. They are usually conducted in the customer's environment and last for 1-2 hours.

There are three different kinds of interview structures described by Bligård (2011). The fist on is structured interviews, the second is semi structured and the last one is unstructured interviews. The structured follows and interview guide where the question and the order of the questions are predetermined. This structure is often used for a questionnaire that according to Bligård (2011) and McQuarrie (2012) stats that questionnaires are qualitative method used to obtain raw data.

Semi structured interviews, according to Bligård (2011), means that questions are formulated before hand to maintain in track but with room to explore and follow through certain path initiated by the interviewee. Further McQuarrie (2012)explains that there are certain questions that are predetermined to make sure that at specific topics are covered but the order and the phrasing could differ depending on the interviewee. This structure is used more often during interview studies according to McQuarrie (2012).

Unstructured interviews are explained by McQuarrie (2012)to be ruled by the interview while the interviewer is more passive. The topic is governed by the interviewee and there are no questions prepared in advance. This interview structure is not suitable for product development purposes according to McQuarrie (2012).

3.5. KJ – Analysis

The KJ-analysis is used to compile a large amount of data to obtain an overview. It is a bottom-up strategy which means that it stats by looking at the details and works its way up to a comprehensive level. The result from the data collection is written down on paper notes and the notes are organized into categories that did not need to have existed before the compilation and are finally given a caption. (Bligård, 2011)

This method has many names as Ulrich and Eppinger (2012) refer to it as the step by step method and Bligård (2011) further explains that it is sometimes referred to as "the yellow note method" as post-it notes are commonly used when conducting as KJ-analysis.

3.6. Metric list

In a product development project carried and described by Dowling et. al. (2013) a metric list was established to determine the relative importance among the needs. The needs were weighted by using a scale from 1-3 where 1 stated the need was important, 2 that it was a very important need and 3 that the need was essential. Dowling et. al. (2013) did not use any customer surveys while establishing the metric list but relied on the knowledge within the team and help from different stake holders.

3.7. Brainstorming

Brainstorming is a session where a group of people are trying to gather as many ideas as possible in order to solve a predefined problem. During this session quantity is more important than quality and no criticism is allowed. The purpose of the methods is that the group members should inspire each other and all ideas are documented. (Österlin, 2010)

3.8. Brainwriting

This is an individual brainstorming where the ideas generated by one individual are documented in chronological order as they appeared. The purpose here is to avoid that the group members influence each other to obtain a larger deviation among the ideas. The ideas are then presented to the group after a certain time. One way to present the ideas is that everybody presents the first idea in their own list and when everybody has presented the first ideas the second is presented and so on. The purpose of this approach is that it increases the chance that all ideas are spoken and not discarded by the deviser him or herself. (Österlin, 2010)

3.9. Osborne's idea spurring checklist

The purpose of the checklist is to process the ideas from the Brainstorming and Brainwriting by asking the following questions in an attempt to generate further ideas that are all being documented and evaluated: Replace, Combine, Process, Scale down, Enlarge, Eliminate, Modify, Do the opposite? (Österlin, 2010)

3.10. Thumbnail sketches

According to Ulrich & Eppinger (2012) thumbnails sketches are made once the needs are interpreted as an attempt to find technical sub functions of the product. The sketches are fast and simple and used to mediate possible ideas and evaluations.

3.11. Pugh matrix

According to Ulrich & Eppinger (2012) the Pugh matrix is used to reduce the number of concepts and improve them. Futher Johannesson, et. al. (2004) explains that all relevant aspects should be covered but it should focus on the problem that the product should solve. The Pugh matrix is a weighting of different factors compared to a reference in a matrix. (Lars Trygg, 120919)

3.12. Morphological matrix

According to Johannesson, et.al. (2004), the Morphological matrix is used to combine different suggestions of sub solutions. They continue by explaining that to the left, in the matrix, is a column that lists the sub functions and to the right are lists of possible solutions to each sub function. Concepts of total solutions can then be derived from the matrix by combining the sub solutions together.

3.13. Soft models

Soft models are usually full scale models that are created by foam or have a foam core board. The method is used to evaluate concepts in three dimensions and enable touch, feel and modifications. The more complex the concept is to visualize, the more models are required. Even though the foam models are often quite rough, designers have used these kinds of models to assess size, proportion and shape etc. (Ulrich & Eppinger, 2012)

3.14. Computer Aided Design

According to Ulrich & Eppinger (2012) industrial designer can generate, display and rapidly modify their work on high resolution computer displays using computer aided design (CAD). It may be used generate control models or drawing and they continue by stating that it has the potential to generate a greater amount of detailed concepts more quickly.

3.15. Usability testing

According to the International Standards Organisation (ISO) usability is; *"the effectiveness, efficiency and satisfaction with which specified users can achieve specified goals in particular environments."* Jordan (1998) describes five components of usability; guessability, learnability, experienced user performance, system potential, Re-uasability. Guessability account for effectiveness of how a specified user can complete a certain task for the first time, relying on guessing s. Learnability accounts for how well a user has learnt to perform a specified task after only performing it once before. Experienced user performance means how well an experienced user could accomplish a certain task and system potential consider the extent to which the specified task could be completed. Finally, re-usability regards the extent to with specified users could complete the task after being away from the product for a certain time.

4. Implementation

The core structure of the product development process has been based on a combination of the procedure presented by Ulrich and Eppinger (2012) and Bligård (2011). Ulrich and Eppinger (2012) presents a number of steps as the key components of a product development process in large consistency of a process described Bligård (2011) that also presents documentation and evaluation in addition. Merging them together resulted in the following structure:

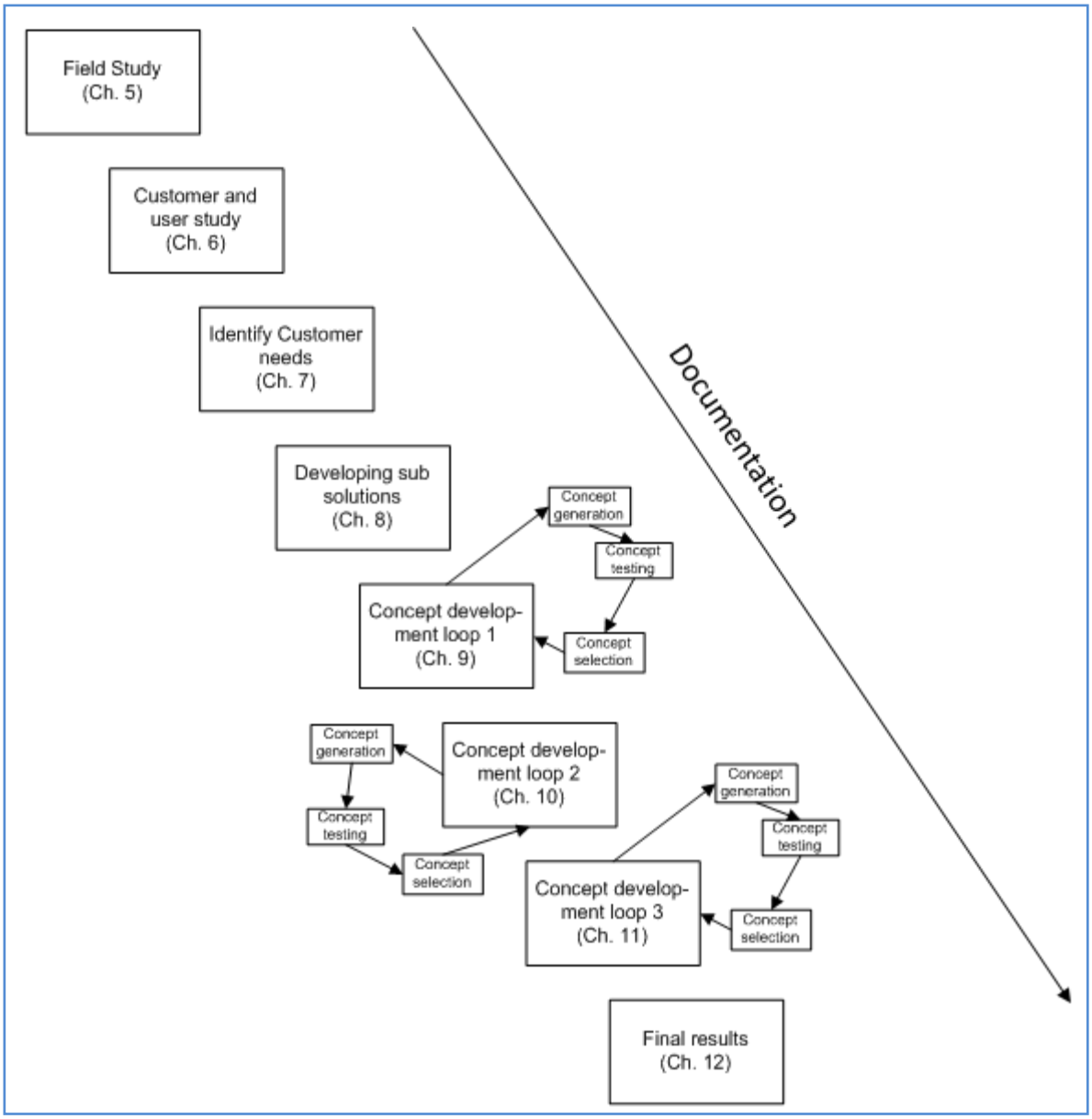


Figure 4.1. *The product development process derived from Ulrich & Eppinger (2012) and Bligård (2011). The results from each step in this process are presented in chapter 5-12.*

When merging these product development processes together there were a couple of key points that were decisive. Both were considered to be on very comprehensive levels where the one presented by Ulrich & Eppinger (2012) where found to be the most flexible. This argument is based

on an conclusion that believes that the oppreoces by Ulrich & Eppinger (2012) allows the process steps “over all deisgn” and “detailed design” and in some cases also “construction” described by Bligård (2011) to occur during both concept generation and concept selection stages of the Ulrich & Eppinger (2012) process.

As the project only aimed at develop a conceptual design the last step of the process described Bligårad (2011), implementation was not accounted for during the merging. The last step of the process by Ulrich & Eppinger (2012), final concept, and the second last step by Bligård (2011), construction, was considered to be equal. Final concept was however concluded to mediate a sense of closure as a concept and not a product was to be the final outcome of the project, which is why this is the name of the final step of the product development process of this project.

There are however some additions done to the product development process of this project which is the first two steps that were not derived from the other processes. The first step is the field study. This was added as it was considered very important to know the present products out on the market well, to know their flaw and strengths. This provide the opportunity to gain knowledge about what mistakes not to do and feasible sub solutions for further evaluation that could benefit the product development of a new concept. Is was also thought as an appropriate way to obtain an overview of more common problems, advantages and especially knowledge about how to use them as that may be crucial knowledge in order to design a concepts that could support mental models of the current customers.

The second step, Customer & User study, was added to the merged process as the whole development process of the concepts should be based on the customers and potential users. Hence, this step was considered to not only be a part of neither the step “Identification of user needs” (Ulrich & Eppinger, 2012) nor the step “Identification of customer needs” (Bligård, 2011) but deserved a step of its own. Regarding the third step, both customers and users were considered since this project distinguee between users and customers.

Another modification is made to the middle steps derived from Ulrich & Eppinger’s (2012) process that are called concept generation, concept selection and concept testing. These steps are now distributed over the three concept development loops, as shown in figure 4.1. as this has been carried out in an iterative process. The final loop contains more testing than the previous two as the concepts are taken to more systematic testing and hence need a more thorough evaluation than needed during the other steps. As the merged process has chosen to include evaluation throughout the whole project, in consistency with Bligård´s (2011) process it was found appropriate to enhance the statement of the evaluation during this step as it is of a more crucial character.

Data collection, planning and documentation has been carried out during the entire project but was not mentioned in the merge process. Documentation was considered redundant to include as this was thought of as implicit when pursuing this kind of project. Even though planning was carried out to some extension during the different phases of the project, most of the planning was carried out in advance which is why this was not mentioned in the merged process. Data collection was also mainly carried out in the first two steps that where added the merged process, hence it felt redundant to keep it as it was displayed in the process provided by Bligård (2011).

4.1. Field study

The first period of the product development process was dedicated to finding and investigating existing solution on the market. Six products were explored in total, but an additional one has been found and explored during the later stages of the process.

The method used to explore these products was Hierarchal Task Analysis (HTA), which according to Boghard et. al. (2008), is a useful tool when investigating the actions to perform in order to fulfill the main task of the product.

A second analysis, Enhanced Cognitive Walkthrough, was performed with the over view provided by the HTA. Cognitive Walkthrough was used to study each sub task to review the feedback status given before during and after an action has been preformed, but also if an action will be attempted or not.

No alternative methods have been found that was considered to be a more appropriate approach than HTA, but perhaps the use of Tabular Task Analysis (TTA. The TTA is more advanced, mapping cognitive processes together. One of the main reasons to conduct the HTA was to quickly gain an overview of the existing solutions on a more comprehensive level instead of receiving more specific data. The second reason was that the HTA was to be used as a foundation of which the ECW could be built on. The use of TTA was thought complicate the application of the ECW which is another reason for using the HTA.

There was however a close tie between the use of the ECW and the simplified method; Cognitive Walkthrough (CW) where only one level of questions are asked. During this stage, it was considered to be more preferable to conduct the enhanced analysis with the motivation that it will provide both more specific but also more general information about the tasks of the products which could be of use during the concept generation step.

4.2. Customer / User Study

When the investigation of the existing products was conducted by theoretical means, another part of the investigation took place. This time eleven people with severe allergies were interviewed with the help from a semi structured interview guide. The interviews lasted in between 26-73 minutes, depending on the interviewee.

The interviews were audio recorded, which is why only a few specific notes was taken during the interviews. However, a written compilation was made for each interview afterwards. The compilation followed the same structure for all interviews.

According to McQuarrie (2012), there are two kinds of approaches available when conducting a market study from which customer needs are to be derived. The approaches mentioned are; confirmatory and exploratory. As the product development is mainly based on what the customers want for their injectors, the exploratory approach was chosen for this research.

McQuarrie (2012) also stated that qualitative methods are suitable for the exploratory approach and lists the following qualitative methods: Secondary research, customer visits, interviews, observations and focus groups. Ulrich and Eppinger (2012) mention interviews, focus groups, observing the products in use and written surveys as methods from which needs could be derived.

Surveys are not recommended by Ulrich and Eppinger (2012) and McQuarrie (2012) does not consider them to be an exploratory method, hence it was discarded. Focus groups could have been interesting but since it is only a small percentage of the population that carry these injectors on a daily basis it became logistically difficult to organize this. Another disadvantage is that according to McQuarrie (2012) are focus groups more effective at exploring, defining and generating than identifying, describing and monitoring, which is the opposite purpose during this part of the project.

Hence, interviews and observing the product in use was considered the best alternatives for an exploratory investigation. As the products are single use injectors, it was hard to be able to observe the products in use, as the products are single use injectors, which is why the customers was asked to give instruction regarding how to use them in a case of emergency instead.

According to McQuarrie (2012) and Bligård (2011) there are three kinds of interview methods; structured, semi structured and unstructured. A structured interview has a fixed set of questions, prepared in advance with a specific order where as the order and formulation has room for deviation when conducting a semi structured interview according to Bligård (2011). The interviewer is more passive in favor for the interviewee to express him or herself during a structured interview and no questions are defined in advance according to McQuarrie (2012) who also means that this kind of interview is not suitable for product development purposes. Bligård (2011) further states that structured interviews are more suitable when quantitative data is requested . Hence, semi structured interviews was carried out which is in consistency with McQuarrie (2012) who claims that this is commonly used for interview studies.

4.2.3 Interviewees

There was a wide range of variety among the interviewees and both men and women were interviewed. Some were users, some were customers and some were both. Customers are people who need the injections and carry them with them but who have never had to use them. Users are people that have used an injection at least once, but who do not necessarily have to be a customer. A person can be both a user and a customer if this person need to carry injections and also has used it at some point. The youngest range of interviewees was children in the ages of from 2-7 years old, who were all assisted by their mothers. Then there were adolescents from the age of 12-18 years old followed by young adults from the age 20 and finally people in their thirties and forties. All the interviewees, but one, came from Sweden but they had various cultural backgrounds. One participant came from Finland.

The ideal aim was originally to gain as many participants as possible and with as diverse backgrounds as possible. There is however a limited amount of people struggling with this kind of allergy which was a hindrance when searching for participants. All people that sowed interest were welcome to join the study regardless of their backgrounds.

4.2.4. Interview guide

The interview guide was designed with input from the field study, and from supervisors within the industrial design sector and started with general questions regarding their allergy, the number of injectors they carry and how long they have been struggling with allergies. After that the questions got more specific; asking about when or if they have ever used the injectors, the frequency of it and the situation in which they had used them.

After that the subjects were asked if they knew how to give the injection the first time, what was hard and easy. They were also asked to give an instruction about how to use the injector during this part of the interview.

I the next phase the interviewees was asked even more specific questions by asking for example if they knew they knew where the expiration date was located or if they could tell if their injection fluid, the drug, was discolored or not by looking through the little window on the injector. However, some of the interviewees did not have injectors with a window.

In the final part questions of explorative kind was asked by asking questions about what the interviewees really thought about their injections. What the advantages and drawbacks was, if they ever had modified the injector in some way etc.

To view the full interview guide, see appendix 2.

The design of the interview guide was motivated by the knowledge of supervisors that had experienced that it was better to start with general questions and then work towards more leading questions in the end. They use this design, not to influence the answers of the interviewees in that aspect that they may answer what they believe the interviewer wants to hear. As it was of great interest to hear what the interviewees had to say, without affecting them, this approach was chosen when designing the interview guide. The leading questions in the end were asked based on some of the results from the HTA and ECW and included in the interview guide to make sure that these topics were treated.

4.3. Identifying customer needs

Once the interviews were conducted, they were transcribed and compiled one by one. Customer statements were then derived from each and every one of the compilations. The customer statements were all interpreted into customer needs, which were used in a KJ-analysis to map all the customer statements together.

During the KJ-analysis, the user needs were organized into categories. Redundant needs from one individual were discarded and popular needs among various customers piled up into stacks of needs regarding the same matter. These categories were after some modifications, during the later stages, the foundation of sub solutions which the concepts are built on.

After the KJ- analysis, a metric list was established, inspired by the one used by Dowling et. al. (2013), with the categories and their containing needs. The needs were, in the metric list, listed with ratings from 1 to 3 depending on the frequency of that particular need during the KJ-analysis. Needs interpreted from only one costumer were rated as nr 1 and considered important. Needs interpreted from 2-3 costumers were rated as nr 2 and thought of as very important and needs derived from four or more were rated as nr 3 which means that they were considered essential.

This course of action was motivated as the result of the interviews was a large amount of interpreted customer needs that somehow needed to be organized. With respect to this, it then seemed feasible to use a bottom up method to carry this out. That is why the KJ analysis was chosen. This reasoning is in line which both Bligård (2011) and Ulrich and Eppinger (2012) who both states that this is a method used for data analysis.

As there were a large number of needs they also needed to be weighted respectively in order to determine which needs that were more important than others. Not all could be heavily focused on as some needs are have a relatively high importance than others. As this product development process has chosen to focus on what the customers want, it was natural to let the customers also decide which needs that are more important and should be rated higher. Hence, the more customers that were stating the same thing, the higher the rating of that particular need got.

4.4. Developing sub solutions

In order to generate sub solutions, a brain writing followed by a brainstorming was carried out at first. The topics of the methods were based on the categories derived from the metric list of user needs and referred to as sub solutions. Some of the categories were discarded or partly discarded due to limitations of the project where as other were modified or added depending on other information or knowledge regarding the matter.

The brainwriting was not carried out by any stakeholders at the SHL but two designers participated in the brainstorming session at a later stage. Both the results from the brainwriting and the brainstorming where documented as mind maps. The mind maps were considered to provide a comprehensive overview.

The reason for conducting an individual brainstorming, brainwriting, before the brainstorming session was that, according to McGrats (1984), there are some studies that have showed that individuals can generate more and better ideas when working alone rather in a group. It was however considered to be important also have a brainstorming session in a group as Johannesson, Persson & Persson (2004) claims that, once a new idea is presented, then it is often easier to generate similar ideas or continue to enhance the ideas of others.

4.5. Concept development loop 1

During second phase of the concept generation, the merging of different sub solutions into 12 total solutions, Osborne's spurring checklist was considered as it was thought to be a preferable way to carry out one final evaluation before creating complete concepts.

The concepts were expressed by thumbnail sketches with written explanations the each sub problem, in consistency with the categories from metric list. Thumbnail sketches were used because this, according to Ulrich & Eppinger (2012), is a fast method that simply expresses ideas and evaluation possibilities.

After this step of the product development process, 11 concepts were to be narrowed down a smaller number of remaining concepts which would be further refined and merge in to 2 final concepts selected for testing.

4.6. Concept development loop 2

The first evaluation resulted in the reduction of concepts in a way that only sex concept reamind which was the base for the next evaluation and selection point where the six concepts where optimized into two concepts.

To reduce the 11 concepts and narrow them down to 6 remaining concepts for further evaluation, a Pugh matrix was and a morphological matrix was used. The Pugh matrix was used by using the one of

the existing products out on the market, the EpiPen, as reference and the sub solutions that scored worse than the EpiPen's were discarded. The sub solutions of each concept were listed in the columns to the right of sub problem it should solve. The sub solutions were reworded a "+" if it was considered better than the sub solution of EipPen, a "-" of it was considered worse or given "0" if the sub solutions was equal.

The Pugh matrix was used since it appeared to be a proper method to quickly reduce the number of concepts but yet had the possibility to account for a large set of metrics with detailed specifications. It was chosen over another method, the eliminations matrix explained by Ulrich & Eppinger (2012) that also could have been used during this stage. The reason for choosing Pugh matrix over the elimination matrix is based in the fact that the elimination matrix uses less specified criteria where as the Pugh matrix refer to more detailed criteria which was preferable in this case. However, the Pugh matrix have a disadvantage as it, according to Ulrich & Eppinger (2012), does not regard the individual ranking between the metrics. This was however not regarded as problematic enough to use the elimination matrix instead.

The once that scored better than EpiPen's were used in the Morphological matrix that were used to combine 6 new and refined concept. One of the concepts from the early concept phase was however still thought feasible as a total solution according to the total score of the Pugh matrix and was passed on the second loop concept phase without modifications. Hence, only 5 new concepts were created with the help of the Morphological matrix.

The decision to use morphological matrix to combine total solutions is mainly based on the fact that the Morophological matrix is a great tool to obtain a comprehensive view over a large set of sub solutions and organize data according to Johannesson et.al. (2004). They continue by explaining that it reduces the chance that combinations of sub solutions are being omitted which is yet another argument for selecting this method.

The 6 new concepts were all created as soft models, in addition to thumbnail sketches, using foam to create them. This was done in order to express the concept in a third dimension, enabling evaluation by touch and feel but also evaluation of modifications which are in consistency with Ulrich & Eppinger (2012).

Another motive for creating foam models was the before creating the models, evaluation regarding different dimensions needed to be done. This was important as dimensions had not yet been considered at this point. The dimensions were crucially needed in order to proceed with further development.

4.7. Concept development loop 3

After the development of the second loop concepts there was an internal evaluation meeting at SHL with the same two designer present as the for the brainstorming session in the previous step of the development process. The aim of the meeting was to select two or possibly three concepts for further testing by having a group evaluation of the six remaining concepts. The original thought was to only produce one final concept but as it turned out to be two kinds of core ideas of the remaining concepts, both found interesting to take to testing, it was decided to use to development approaches and develop two final concepts instead of one. The concepts closer to one approaches was merged together by using the concept that was considered to be the best in total as the core structure and

adding preferable features and functions from the others. In the end, one concept from each approach was selected for testing.

The reason for not passing the concepts though any further loops of concept is that it probably would not lead to any optimization of the concepts but a greater number of concepts that risked being equally good. At this point it was thought to be a better approach to have a discussion with more experienced designers and use their input to narrow the number of concepts down.

4.7.1. Computer Aided Design

Computer Aided Design (CAD) was used to create visual 3D models of the two concepts before the concepts were tested.

It was decided to use CAD drawings at the point where the concepts needed to be used for testing. Even if the Ulrich & Eppinger (2012) claims it is a rapid method it still take a lot more time to develop CAD models than thumbnail sketches and foam models which is why it had not felt motivated to do so before this stage of the process. The reason or this is that all the involved parties where familiar with the previous concepts and the creation of CAD models would have been redundant and less time efficient than the thumbnail sketches and foam models. However, when it was time to test the concepts, they needed to be mediated to others that were not familiar with the concepts nor the previous development process which is why it was considered motivated to create CAD drawing as they are more accurate than both thumbnail sketches and foam models.

4.7.2. Concept testing

The aim of this chapter is to describe how the usability tests were carried out for the selected concepts. It also aims at describing how the instruction label of the final realistic concept that was tested even though this test was carried out after the final concept had been physically 3D modeled in order to place the instruction and other labels on the injector before testing.

Usability testing of the injector

Once the final two concepts were selected for testing, a usability test was designed and preformed with focus on guessability. As the product should be able to be use for the first time in an emergency situation, by perhaps an inexperienced user, it became clear that the guessability part of the concept of usability had to stand in the center of attention during the testes.

The tests were divided into three parts: one general part and then two more specific parts, A and B, with more explicit questions regarding guessability. The general part had four questions regarding what the subjects thought it was, where to inject, how to hold it and how to use it. Part A contained questions about where specific features where located or if they even existed where as part B asked questions about what they thought were the function of features that were obvious. To view the test guide, see appendix 12.

The subjects were given CAD drawings of plain injectors without instructions but also soft models to touch, feel and further explore during the general part of the test as well as for part A. There were two CAD drawings of each concept; one drawing in 2D perspective with given and accurate dimensions and one larger drawing with a 3D perspective without given dimensions. The soft models and CAD drawings was accompanied by an example of an instruction label and other features to be printed on the injector which was placed on one of the CAD drawings during part B. Part B was only carried out for the realistic concept as it was yet to determine, by the test results, whether or not

there should be any labels on the body of the futuristic concept. The subjects where given CAD drawings with the labels only after the general part and part A were carried out and were not on display throughout the entire test. The two concepts were also tested separately, starting with the realistic concept. This order was consistent during all the tests.

It would have been interesting to conduct a experienced user performance test and most certainly a re-usability test to observe how a customer, that has some kind of experience with emergency allergy injectors would handle the injector after a relative time as that would have been much more like a real case. In reality, the customer may practice at a doctor's office when first being diagnosed with the allergy and then has to use it years later. Both of these test were however impossible to carry out due to lack of customer in the local area where the final parts of this project were carried out.

Usability testing of the instructions label of the final concept

When the changes, based on the results of the above described testing, of the injectors were made it was time to focus on the instruction label. It was already determined that no instruction label was to be designed for the final futuristic concept as it were to be placed in a case or as a separate sheet inside of the case. Since the instruction label would depend on the case it was discarded due to the limitations of not including development of a case in the project.

The tests of the instruction label were made on both the new instruction but also on the existing product EpiPen, for reference. The purpose of the test was to verify that the new instruction label was comparatively faster to interpret than the one for EpiPen and hence could be perceived in less than 20 seconds. Hence tests of the EpiPen were carried out first to obtain a suitable time to use when testing the new instruction label.

EpiPen

The test consists of 2 parts where two test subjects carried out the first part and an additional set of two test subjects carried out the second part.

The purpose of the first part is to get an idea about how long time a user need to fully assimilate the instruction label to perform the correct action in order to complete the task of injecting successfully. This is done by handing the injection the test subjects and let him or her study the instruction label for as long as he or she may want. When they think they understand enough to retail the instruction they were instructed to say "stop". Their time was noticed individually and used as a reference base for the next part of the test. Finding the instruction label was also included in the task of part one and included in the time.

During the second part, two new subjects were tested based on the results from part one. A maximum time of how long time it is appropriate spend in order to find and understand the instruction label is determined by using the times from the previous test. The maximum time was determined before the second test starts.

The subjects were given the injection, and at the same time, a timer was started. After 25 seconds, which was the maximum time decided before the test, the timer rang and the subjects were told to put the injection away and retell the instructions.

Instruction label of the final realistic concept

The test was carried out in the same way as for the second part of test conducted on EpiPen. The first part of the test conducted on EpiPen was considered to be redundant as the purpose was the evaluate if the new label was faster to interpret than the instructions of EpiPen. It would however have been interesting to conduct tests on the instruction labels of other present injectors but as the number of possible test persons was scarce it was not possible. The number of possible test subjects was limited as it was a predetermined requirement that the test persons were to be native speaker of the language in which the instructions of the injectors were written in. This requirement was settled as the test result was regarded as being more accurate if the test subjects were given the same conditions while performing the tests. Hence, it would have been less valuable to have used an instruction label written in English to non native speaker since they have different language skills. The only two instruction labels available was the one for EpiPen and the label for Emerade. The instruction label of Emerade was in English and hence discarded while the instruction label of Epipen was available in both Swedish and Finnish. There were access to Swedish and Finnish test subject, however a limited amount due to the geographical area, that could be used for testing, which is why the test was carried out on EpiPen only.

4.8. Final results

The final results are the results of the tests described in the previous section but also the products of the entire product development process, described in this chapter. All the methods and actions described above have contributed to the final results, which will be presented in chapter 12. Final results. For a thorough description of the product development process in total, see the beginning of this chapter where this is regarded.

5. Field study

A field study was conducted in order to understand the product but also to reveal pros and cons with these injectors not conduct the same mistakes again. It was also used as inspiration as the results also revealed feasible features. The filed study involved finding and investigating the products currently out on the market by using Hieratical task analysis (HTA) and Enhanced cognitive walkthough.

5.1. Emerade

The following section describes the field of application, functions and features and the results of the HTC and ECW analyses of the auto injector Emerade.

Field of application

According to emerade.com “Emerade is an adrenaline auto-injector used for the emergency treatment of severe acute allergic reactions (anaphylaxis) to foods, medicines or insect stings. It can also be used for exercise induced anaphylaxis”. The website also explains that Emerade is a single dose medical device. It has no storage condition stated but one; do not to let it freeze.

Function & Features

According to the instructional video at emerade.com the device has tree actions to complete before the adrenaline is successfully injected:

1. Remove the Needle Shield at the needle end
2. Press the needle end towards the outer side of the thigh
3. Hold for 5 seconds

CW & overall analysis

The Emerade received relatively high values on both task/function and operation, especially for the operation to remove the cap and pull the injection out at the end. It also scored highly on the operation to place the injection on thigh due to the illustrative picture on the instruction label. The total score was however damaged due to some individual flaws about like the lack of feedback to communicate that the injection is done injecting and the task has been completed.

Figure 5.1. *Emerade*

The advantage of this injection is its shape and instruction label. It is a smooth pen shape with a cap at the needle end. The cap has a label saying: “1 remove Needle shield” with an arrow showing which to pull the cap of. This gives a very small chance of misunderstandings. The following two steps of the instruction label is given as illustrations, apart from many other with just key words like “press” and “Hold 5 sec” along arrows showing directions. This makes it easier for the user to interpret the instructions as pictures are interpreted faster than text (Schimidt & Wrisberg, 2007). However, the instruction to hold for 5 seconds need to be enhanced since this is the major error that all first time user conduct according to the customer study.

5.2. Adrenaline click

The following section describes the field of application, functions and features and the results of the HTC and ECW analyses of the auto injector Adrenaline click.

Field of application

According to epinephrineautoinject.com “Adrenaclick is an emergency injection (“shot”) of epinephrine. It is a medicine used for life-threatening allergic reactions such as severe swelling, breathing problems, or loss of blood pressure. Allergic reactions can be caused by stinging and biting insects (bugs), allergy injections, food, medicines, exercise, or unknown causes.” It is single dose injection that needs to be properly disposed after usage, a container for transportation to disposal unit is provided with the injection.

Function & Features

According to the self-administration video at adrenalineclick.com the injection has five actions to complete before the Epinephrine is successfully injected but explain it as two steps:

1. Check the injection fluid before use – should be clear
2. Pull of the gray socket at the needle end of the injection
3. Pull of the slightly smaller gray socket at the rear end of the injection
4. Place the needle end against the middle and outer side of the thigh
5. Press down hard
6. Hold steady for 10 seconds
7. Pull out the injection
8. Check if needle is exposed = the dose has been I

It has a dispose case, a window to show the status of the liquid before use and does not require that the injection place is rubbed after injection.

CW & overall analysis

This injection had a moderate score in total. The large number of operations to perform is also a factor to consider apart from the results of the CW itself. It scores particularly high regarding the operation to pull off a big gray socket that covers up the needle almost like a cap but also for removing the cap in the rear. Probably due to illustrative pictures, but they are quite small which is why the Emerade has been given higher scores for this operation.

Figure 5.2. *Adrenaline click*

One dangerous factor was reviled during the CW and that it might be hard to understand in what end the needle is located since there are one gray socket in both ends. Otherwise it shares the same strengths and weaknesses as the other injections.

5.3. Twinject

The following section describes the field of application, functions and features and the results of the HTC and ECW analyses of the auto injector Twinject.

Field of application

According to twinject.ca, “Twinject is indicated for the emergency treatment of severe allergic reactions including anaphylaxis to stinging insects & biting insects, foods, latex, allergen immunotherapy, other allergens and drugs”. It is available in the format of 0.3mg and 0.15mg epinephrine. Need to be disposed after usage. A cover I provided to the auto injector.

Function & Features

It is both an auto injector, for the first dose, and can be dissembled to a manual injector for a possible backup dose.

According to the instructions at twininject.ca, the first dose is given by five actions:

1. Pull of the socket at the needle end of the injection
2. Pull of the slightly smaller socket at the rear end of the injection
3. Place the needle end against the outer side of the thigh
4. Push hard against the thigh
5. Hold for 10 seconds

There is no button and it has a window to show the status of the liquid before use.

According to the instructions at twininject.ca, the backup dose is given by actions:

1. Unscrew and remove the red tip
2. Pull syringe from barrel
3. Remove the yellow collar by sliding it off the plunger
4. Put needle in to thigh
5. Push the plunger all the way

It has a plunger and a clear syringe to view the solution as it injects.

CW & overall analysis

The cognitive walkthrough of Twinject only analyze the second dose since the first dose is given exactly like Adrenaline click.

Figure 5.3. *Twinject, first dose*

Firugre 5.4. *Twinject, second dose*

The second dose of Twinject has the lowest total score of all the investigated product since it is not obvious even to a person who are used to allergy injections that there is a second dose inside. This

does not support mental models that according to Atkinson et. al. (2003) is a mental representation of how things work and how they function in relation to each other. As no other injection share the same solution it is fair to conclude that a user does not expect to disassemble or would clearly understand how to disassemble the injection to be able to reach the syringe and inject properly. It is however, from a user perspective desirable to save space which is why it was found to be an interesting solution.

5.4. Anapen

The following section describes the field of application, functions and features and the results of the HTC and ECW analyses of the auto injector Anapen.

Field of application

This is a single use auto injector of epinephrine (a.k.a. adrenaline), used to reverse anaphylactic shock. It needs to be properly disposed after use. It is short lasting, which is why the patient needs to be taken into medical care immediately after the injection. There are three different levels of Epinephrine in the Anapen that are suitable for different bodyweights: 150mikrg (12-15kg), 300mikrg(25 and higher), 500 (60kg and higher). (anapen.co.uk)

Function & Features

According to the instructional video at anapen.com, there are four actions to complete before the Epinephrine is successfully injected:

1. Remove the black socket at the needle end
2. Remove the black cap covering the read button at the rear end
3. Place the Anapen on the outer side of the thigh with the needle side facing down towards the thigh.
4. Press the red button in the other side of the injector

It has a button but no window to show the status of the liquid before use.

CW & overall analysis

The overall score for Anapen is in consistency with the Adrenalin Click, moderate. Most of the operations have received moderate scores as well. A drawback with this injection is that it seems to be harder to find the rear end than for the other products, again in consistency with Adrenalin Click since it also has safety levers to remove in both ends. Both levers have the same color which might contribute even more. The most intuitive feature concluded from the CW is the button. With or without removing the black cap, it looks like a button. The fact that it is red enhances the mediation of the button. Red is according to Boghard et. al. (2008) a color that interprets like danger or stop etc. which is why it is also fair to say that the red color of the button signalize that something drastic will happen when pushed.

Figure 5.4. *Anapen*

Other weaknesses and strengths, is in consistency with the general description in the beginning of this chapter.

5.5. ConfiDose

The following section describes the field of application, functions and features and the results of the HTC and ECW analyses of the auto injector ConfiDose.

Field of application

According to westpharma.com, West's systems are applicable to a range of specific therapeutic areas, including diabetes, oncology, autoimmune diseases and vaccines.

It is a single dose device and need to be disposed after usage. A large tube is provided together with the injection for carriage the used injector.

Function & Features

According to the instructional video at West's Facebook site, there are six actions to complete before the Epinephrine is successfully injected:

1. Remove the large and clear plastic cover, covering the needle and half of the injection
2. Twist the blue outer layer if the upper part of the pen until a green marker turns from one indicated location to the other.
3. Locate the injection vertically (not mentioned where) with the needle side down
4. Press the green button in the rear end
5. Look at the clear part of the injection where the solution is displayed as it is being pushed down through the injector by a force
6. Hold steady while the solution is being pushed down

It has a button and a large clear 360 part serving as a window to show the status of the liquid before and during use. It also has a retraction feature of the needle so the needle is protected before and after injection

CW & overall analysis

Again very moderate results but this injection provides sufficient feedback to understand that the injection is completed in that way that the needle is retracted when done injecting apart from the other injections. Another advantage is the transparent lower part of the body that enables the user to watch the injection fluid as it passes through the injection. Else see it scores quite average but a bit lower when it comes to locate the rear end. Probably since the green button at the rear end could be mistaken for a needle cover or a plug to pull out to reveal the needle. The same goes for the operation to find the green marker, in the second step described above. The total solution of having to twist the injection to activate it is not preferable from a user perspective since it does not support mental models as no other injection has the same sub solution. Markers can also be hard to find as they are relatively small. Another drawback with this injection is the six operations to preform before done injecting that makes it less desirable to use in a case of emergency where the user need to be able to give the injection as fast as possible.

Figure 5.5. *ConfiDose*

Furthermore, this injection scores critically regarding the operation to place the injection on thigh as the instructions given do not emphasize this enough. Many of the other injections would benefit from a further enhancement of this factor, but usually they have at least a picture, that is an attempt to emphasize it. This injection does not, hence the critical score.

5.6. EpiPen

The following section describes the field of application, functions and features and the results of the HTC and ECW analyses of the auto injector EpiPen.

Field of application

Both injectors are used for allergic emergencies but carries different levels of Epinephrine. They serve type 1 allergy emergencies for to insect stings or bites, foods, drugs, and other allergens but also treats idiopathic or exercise-induced anaphylaxis. They are of single dose kind, and need to be disposed properly after use. They are only short lasting why the patient needs to be taken into medical care immediately after the injection. (www.dailymed.nlm.nih.gov)

Function & Features

According to the instructions for usage on the injection itself (EpiPen300 mikrog, 2013), the injection has four actions to complete before the Epinephrine is successfully injected:

1. Remove the blue socket on top of the injection
2. Place the orange part (the needle side) at a distance of about 10cm from the outer side of the thigh
3. Pound the injector pen against the outer side of the thigh.
4. Hold the pen steady for 10 seconds.

It has no button but do have a window to show the status of the liquid before use.

CW & overall analysis

The injector score a little lower than the others due to its unclear instructions. All the instruction are available, but the label alternate between Swedish and Finnish, which in combination with very small characters, makes it hard to both read and focus on the important pictures.

The result show that it is easy to find the needle end due to the orange tip and the label stating “needle end” whereas the hardest operation to complete or even understand how to do is to check the injection fluid. It is just a small window in the middle of the extensive amount of text and even though it has a label on one of the two sides, it is hard to detect. Even if the label is detected it is hard to know how to check the fluid as it simply states “dispose if fluid is discolored” and there is no reference to show how the injection fluid should look when it is not discolored. The same problem applies for all the injection that has this kind of window function.

Another problem with this injection is that the instruction labels tell the user to place the orange tip 10cm from the outer part of the thigh before pounding it. This part need to be enhanced not for it to simply blend in along with the massive text flow on the injection. The same enhancement needs to be done to communicate to hold the injection steady for 10 seconds. when injecting.

5.7. Jext

The following section describes the field of application, functions and features and an overall analysis of the auto injector.

Field of application

Jext contain a sterile adrenaline solution in an auto injection to use in case of emergency. It is a single dose adrenaline that is injected in the outer part of the thigh, intramuscular injection. Jext is being used for emergency treatment of sudden life-threatening allergy reactions (anaphylaxis chock, anaphylaxis) caused by a bug sting or bite, aliment, medicine or physical endeavor. (www.fass.se)

Function & Features

According to the instructions on medicininstruktioner.se the injection has tree actions to complete before the Epinephrine is successfully injected:

1. Remove the yellow socket at the rear end
2. Press the needle end towards the outer side of the thigh
3. Hold for 5 seconds

It has no button but a window to check the injection fluid.

Overall analysis

This injector was found at a later stage, during the interviews. It share the same average strengths and weaknesses as the other injections and there are no new levers, trigger functions nor activation features that has not yet been investigated for some of the other products, which is why Jext has not been analyzed with Cognitive Walkthrough.

The product has however, been analyzed in comparison to the other injections and their CW analysis. Like EpiPen, there is a lot of text with small characters but there are no mix of dual language here. The contrast between the back text and the red background, also stresses the eyes which might have a negative impact in a case of an emergency where the user already is in stress. Furthermore, the pictures are slightly unclear, like many of the other injections, to illustrate how to remove the yellow cap and press against the thigh. The positive side of this injection is the few steps to go through before injection is complete. Another advantage is the 5 second rule instead of 10 as for the others.

5.8. Final analysis

The field study reviled seven existing products on the market. They were all shaped pens or tubes, but otherwise differed in appearance, user functions and trigger functions.

The different trigger functions found when investigating these products were:

- Pound the injection on to the thigh
- Press the injection against the thigh
- Push button at the rear end
- Normal hospital syringe with a manual plunger

The different activation functions and safety levers found when investigating these products were:

- Remove cap or socket either in rear or front end, or both
- Twist part of the injection
- Disassemble the used injection to find a new dose inside
- Collar to remove over needle
- Manual plunger

For complete HTA trees, see appendix 3.

The main common problems found by the ECW were the lack of sufficient feedback to tell the user that the injection is done and the task complete, but they also have problems to clearly express where the injection should be injected. However, the test results also display a different view, where the operation of placing the injection on the thigh scores relatively high. However, this is probably due to the nature of the CW where only a certain kind of questions is asked in a way where not all factors are considered. During the user study, in a later stage, it was discovered that many people were uncertain about what part of the body to inject in. Hence, this is a big problem regardless of the fairly good results from this analysis. Another common problem found, is to communicate that the user should hold the injection for ten or sometimes five seconds before pulling it out, in order to give the whole dose.

For complete ECW score for all the individually, investigated auto injectors, see Appendix 4.

6. Customer & User Study

The customer/user study revealed much useful about what the user think about their products, how they would like them to look like, color and shape, how they wish that they would function and what they want them to communicate and much more. It also provided information about what they dislike about their products, malfunctions and user errors etc.

Not all the products from above had been handled by the users or owned by customers but some were familiar with AnaPen, some with EpiPen and some other with Jext. Some had experience from two injections and in rare cases, all three.

6.1. Size

The main thing that was brought up by the customer was that it is too big to be convenient to carry around at all times. Especially since most customers carry two injectors and in rare cases even three or four. Some explained how they sometimes leave them at home because they have nothing to carry them in. Some of these customers had also experienced the drama of having an allergy reaction but with the injection still at home. They feel that they are too big to fit an average pocket of neither trousers nor jackets and thus hard du carry with them. Other talked how they were sick of carrying a bag, one woman said, “I wish I could just wear a dress in the summer without having to bring my bag with me”. There were also people who had started to buy other kinds of trousers or jackets, with big pockets.

6.2. Hindrance

Children felt particularly disturbed by this. They felt like the injections were a hindrance when they go out to play or practice sports. They were also a bit embarrassed have them, especially in the beginning of puberty. They did not want to carry the big and clumsy injections on them when they were going to discos and the same apply for adults when they go out to dinner or clubs at night.

6.3. Appearance

Most customers wanted them to be very discreet, not to reveal what it is but in contradiction yet signalize the severity of the condition and what it is used for. Some of the adults felt that the injections looked too much of a toy and that they were taken seriously when displaying them to others. The smaller children however, wanted them to look even more like toys, preferably with pictures to distract them when forced to use it. Some boys, especially young and adolescents said they would like it to be “cooler” and a suggestion to make the injector body transparent to view the inner mechanism came up. They explained that they would like to feel a sense of pride to own it.

6.4. User functions for children

Regarding user functions, it became clear that many of the small children could not give the injections themselves. Either it was too complicated or physically too hard for them to activate the trigger function. This was a very difficult question. The assisting parents interpolated that they wanted the child to be able to handle the injector but yet not, both for safety reasons.

6.5. Not inject into the heart

The interviews also revealed that most people think that the injection should be injected in the heart. All interviewees where asked if they at some point had been asked if the injection should be injected in to the hart and almost all interviewees were familiar with this misunderstanding in some way. Hence, thins sends clear signals that this is something that needs to be very well communicated on the injection, in order to clearly explain to a user who might think differently that the injection should be injected in the thigh.

6.6. Expiration date

Other interesting facts were that many of the expiration dates was hard to find or maybe even to read. When the interviewees were asked if they could find the expiration date, one person could not even find it with guidance and some other realized that their injection had expired when asked this question. It was at least one customer of each injection brand who discovered this, which is why it is fair to conclude that the communication of expiration date need to be enhanced regardless of the brand of the injection.

6.7. Assessing the drug

When asking about the window to control the injection fluid, the drug, (for those that had injections with a window) it became clear that no one was certain whether or not the injection fluid was discolored or not. There are no guidance to understand what discolored means, just a label that says “change if discolored” and some also have “or cloudy” or “or contains particles in it” in addition. This indicates that some kind of reference is needed in order for the user to understand when there is something wrong with the injection fluid.

6.8. Practice or demonstration opportunity

Another frequent answer was about the willingness to practice which is not provided by the single use injectors on the market today. Since the injection is only given in rare cases there are no customers that could be considered skill based users which would be preferable due to the severity of the reaction. Hence may customers would like to be able to practice more often. Some had never practiced at all. At least they wanted to be able to watch and or show a demonstration video to their friends and loved ones.

6.9. Support for mental models

Since it is very important to know how to use the injector, many users would like a new injector to have a similar course of action as their current injector. This is very contra dictionary since many complained about the user functions of their current injector. But it is clear that they all want the injector to be intuitive to use. Another compliant was about the instruction labels, EpiPen in particular. There is very small font size and partly in Finnish, partly in Swedish. No one really thought that it could be read by elderly or even people in the upper middle age, if they did not wear glasses.

6.10. Instruction label

When discussing instructions and label on the injections it became clear that some people whated more information than provided in the injector. It was not clear where this information should be located; it did not necessarily have to be placed on the injector. Examples of the information requested were information about pregnancy and injecting, after care and general information about the drug and the medical condition etc.

6.11. Lack of feedback when giving the injection

Furthermore, it became clear that the current injectors had problems with providing sufficient feedback regarding when the injection starts, when still injecting and finally when the injector is done injecting. A majority had experienced that the injection had been pulled out too fast and some of the drug had gone to waste as it continued to inject outside the thigh. Some had experienced this during an actual case of emergency and other when practicing on for example dishrags. This seemed to be a big problem even though all the injectors have instruction that says “hold for 10 seconds”. It should be mentioned that some injectors only need to be held for 5 seconds. And again, since people practice at home with real injections, it clearly indicates that customers really want to practice. One of the mothers, assisting here child during the interview even said that her husband, the father of the child, had tried an expired injection on himself to practice. Hence this is an important matter.

6.12. Finding the injector

Finally, many had a great concern whether or not a random person would be able to find the injection in a case of emergency since there barely says what the injection is for in the injector. It usually says what the injection is for but with very small font size.

Of causer other important things like how the injector has to with stand certain surroundings; climates, weather, temperature, dust and dirt etc was brought up during the interviews as well.

6.13. Final analysis

All these subjects that were brought up during the interviews needs to be further processed in order to use the information properly. As the final aim was to create an interface design that was based on the customers, this information needed to be thoroughly evaluated. Hence, it was time to conduct further methods to organize the information and derive user needs on which the concept generation could be based on.

7. Identifying Customer Needs

The interpreted needs, derived from the customer and user study, were organized under a range of categories that were later used as foundations of sub solutions that combined together would a complete total solution. This chapter will account for the categories but not for each and every individual need. To view the complete metric list containing all the needs, see appendix Metric List – Customer/user needs.

7.1. Number of doses to carry

The first category simply evolves how many doses the customer need to carry. Some need to carry as much as three doses whereas some only need one. The most common number of doses was found to be two and hence it is very important to keep this in mind when designing the injector. Five out of the six investigated injectors only contain one dose, hence the customer need to carry two injectors. This will affect the size of the total package of two doses, as it will be larger, which is not feasible from a customer point of view according the interview results that were mentioned in the previous chapter.

7.2. Properties

None of the three user needs scored higher tank level 1, important. Two out of the three was however taken rather seriously as similar needs were found under for other categories where as one was ignored due to the limitations of the project. The two more serious needs were about providing secure impression about safety catchers and that the injector should not be mistaken for something else. Especially the last one has been found under other categories that indicate that there is a need for the injectors to communicate what it is for.

This however is in great contradiction to other needs found under other categories that states that the injector should be discreet or be distracting. The reason for this contradiction depend mainly on the fact that customer of all ages were interviewed. Children want them to distract them and look like toys and adults want them to communicate the severity and what it is used for whereas some adolescents want them to be discreet.

7.3. Cover

The cover category did not score particularly high either and was later discarded due to limitations of the project that narrowed it down to only include the injector itself and the instruction label. It did however survive the first loops of the concept generation phase and the main focus here was the make sure that the cover did not make the total package larger than necessary.

7.4. Routines for expiration date and fluid

It became clear during the interviews that there was a need for routines both for checking the expiration date and for assessing the status of the injection fluid, the drug, even though routines from checking the expiration date scored a lot higher. Later on it was also determined that a routine from assessing the injection fluid was not necessary but some kind of aid that could assist the assessment was definitely needed.

7.5. Practice

As mentioned in the previous chapter; customers want to have an opportunity to practice or at least be able to watch a demonstration, which is why these needs scored highly. The need to practices scored however, even higher than the need to watch a demonstration and resulted in the highest priority; essential needs.

7.6. Convenience

This category only contains one need that was found to be very important. This is a need for a place to store a specific kind of medicine in conjunction with the injection. All customers of these injectors also need to carry cortisone as it removes the cause of the reaction and the injection only relieves the symptoms for a short while. It is therefore important to always carry cortisone as well as the injectors since the reaction will most likely come back after a short while if no cortisone is ingested. The most common cortisone medication in Sweden is Betapred that comes in flat packing's of 10 pills that all need to be consumed in order to stop the reaction and remove its cause. Sometimes even more pills need to be taken and hence also carried around.

Because of this many on the customers wanted some where to store their cortisone in conjunction with their injector(s). This is probably not to hard to understand as they always bneed to carry the cortisone with them to. Many people want to have all their medications together. Some has made their own bags and covers or modified tailor made covers from the injector companies just so that they can keep is all at one place.

7.7. Environment to be able to use it

There were a lot of environments mentioned during the interviews, in which some of the customers had used the injectors in. hence it became clear that the injectors need to be able to be used in various environment. Most importantly in hot and cold environments since most of the current products cannot be kept in extreme temperatures for longer periods of time.

7.8. Carrying

This category contains a great amount of various needs. The essential needs, are the obvious need that the injector has to be convenient to carry at all times. Number two is again about size that appeared to be the key question in common for all the users. Under this category it was communicated as a need to fit an average pocket. Another very important need was a need for carrying without wearing special cloths or bags. Along with the reduction of the cover focus this part lost some focus as well since the most of the sub solutions for carrying where solved by a certain case. It should however be clarified that attention has been paid to this matter throughout the concept generation phase even if some of the solutions had to be sorted out due the limitations regarding casing.

7.9. Storage

A number of places to store the injector ere mentioned during the interviews which is why there are many needs regarding storage. None of them scored higher than number 1; important. It is however very important that the injections could be stored at any of the places mentioned by the customers. The reason for the low score had probably something to do with the customers different preferences regarding where to store their injectors. One customer stored them in the kitchen, another in the bedroom; another stored them at work or in the bathroom etc. It is thereby very hard to receive a high score for the individual needs of this category even though it is obvious that they need to be able to be stored at the places mentioned.

7.10. Use functions

The two essential needs of this category is that the injector has to be intuitive to use and support mental models of current injectors that the customer is used to. Other need, rated as important needs are for example that it needs to be able to be handled by a child whereas another need is for it to be childproof. This displays a very difficult task when designing producers as there are contradicting needs of this characters that need to be accounted for.

7.11. Information on injection

This is one of the largest categories, containing more of the very important needs than the other categories and three essential need. The first one has again to do with the lack of feedback to assess whether or not the injection fluid, the drug, is doable or not. The need is to clearly indicate when the injection fluid is not doable. Another previous discussed matter has again been interpreted to a different need stating that there is a need for the injector to clearly indicate what it is for and communicate the severity of the reaction.

During the interviews there were as mentioned, lots of uncertainties regarding the instruction labels and one very important need is that the font size should be suitable for reading on an average arm distance. Other very important needs regarding the instruction label are that the instructions should be sufficient and clear as well as easy to interpret. An additional very important need is to clearly emphasize that the injection should be given in the thigh.

7.12. Other information in conjunction with injection

There are only the but one essential need covered here which is a need for over all information. Like explained in the previous chapter, many of the customers requested extra information that what was available on the injection or the packing. It was however not implied where this information should be available which is why the need for this information was interpreted to be in conjunction with the injector instead of on the injector itself.

7.13. Appearance

The needs interpreted for this category is again of a contradictory kind especially depending on the age of the interviewee but also gender seemed to have had some impact. They differed from a need for a serious impression or a “cool” impression. Other needs differed from distracting to discreet.

7.14. Other physical design

The differences between this category and Appearance is that the needs here are of a more abstract kind than the concrete once in the previous category. The essential needs her are a need for a convenient shape for daily carrying and the second one was simply a need for it to be small. Like stated before, the size has an impact on many needs derived from the customer study but it also is a need in itself.

Very important needs under this category are also related to size and say that the injector should fit movement patterns of adolescents and children and also be no hindrance when dancing. Why dancing became a very important need is probably related to side tracks that occurred while talking to young adults and adolescents about their hobbies and interest, where dancing and clubs and shool discos came up during some of the interviews.

7.15. Functions and features

Essential functions and features is that the injector need to clearly communicate when it is starting to inject, when it is injecting and when it is done injection. Another essential need is again related to the expiration date where there is a need for a function that could communicate when the injection has expired.

7.16. Before / after injection

There are only two needs here where one is considered important and on very important. The important one is however essential as Anders Skoglind (2014) explains that there are ISO legislations for this matter. The need is that it should be safely carried to disposal after use.

It is not to strange that this was not one related of the most frequent customer statements as this is related to what happens after use. A large amount of the customers had never used an injector and hence probably never thought about this at all which is why only one of the users mentioned it.

7.17. Temperature

The temperature category could have been placed as a sub group to the environment category as it also expressed the need for the injectors to be able to withstand heat and cold. The reason for distinguish between the categories is that the environment category refer the environment in which the injector should be able to be used in whereas this category refers to the temperature in which the injection should be able to be doable in for longer periods of time.

7.18. Final analysis

Even though lots of needs and problems were defined there were still no ideas how to deal with them further. Many were extremely contra dictionary and others where hard to define whether or not they should be taken into account at all. The scope of the project was yet to be determined as there was an urge not to limit the creativity in the beginning of the concept generation phase. With or without clear boundaries it was time to start thinking about how to accommodate the needs of the customers use the ideas as a foundation of possible limitations. The next step was the concept generation step that started by generating sub solutions that would correspond to the customer needs.

8. Developing sub solutions

The first phase of the concepts generation step was to generate sub solutions and the results will be displayed in this chapter. They will be presented in mind maps which were the direct result of the brainwriting method and brainstorming session.

The problems that the sub solutions were to solve was in consistency with the categories of the metric list but with some modifications in some categories. The problem categories are; size & shape, usage (including trigger function, how to communicate where the needle is, how to communicate the injection time and safety levers), how to monitor the medicine (fluid), how to enhance the communication regarding expiration date, opportunity to practice and/or watch video, appearance (differ depending on children, adults or adolescents), how to carry, cover/casing, how to safely carry the used injector to disposal and finally how to communicate additional information that was further requested during the customer study. These categories will be used further in this report as they are the core composition what problems this project was to accommodate for. Cover/casing will however not be regarded during the later phases of the concept generation step as limitations were made after the Second loop concept generation phase. Another limitation, to not focus the development on designing an injector for children, were made after the early concept generation phase which is why the later phases uses the category “appearance” without any sub headlines. The brainwriting and brainstorming sessions resulted in the following possible solutions:

8.1. Size & shape

The mind map displayed in Figure 8.1. displays possible ideas regarding what size and shape the injector should have. Size and shape were combined to one problem category since the shape ultimately affects the size. To only use size as one category was considered rather uninteresting as the mind map only would include words like; “Big” or “small”, which was not regarded as a proper solution to the size problem. The combination of the two did however provide wide range of possible solutions for both size and shape.

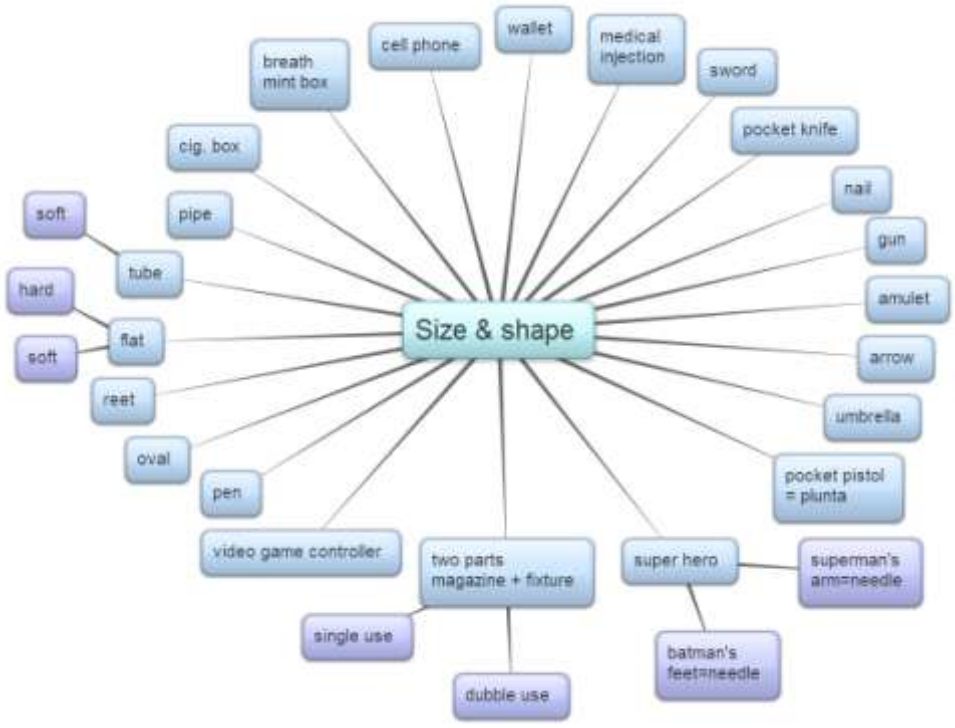


Figure 8.1. *Sub solutions regarding how to solve the sub problems size and shape*

8.2. Usage

This sub problem branched off in to four new sub problems that were considered individually. The four sub problems to account for were, as shown in figure 8.2.; what trigger function to use, how to communicate when starting to inject, when still injection and when done injecting. It also regards how to communicate where the needle is and what safety levers to use.

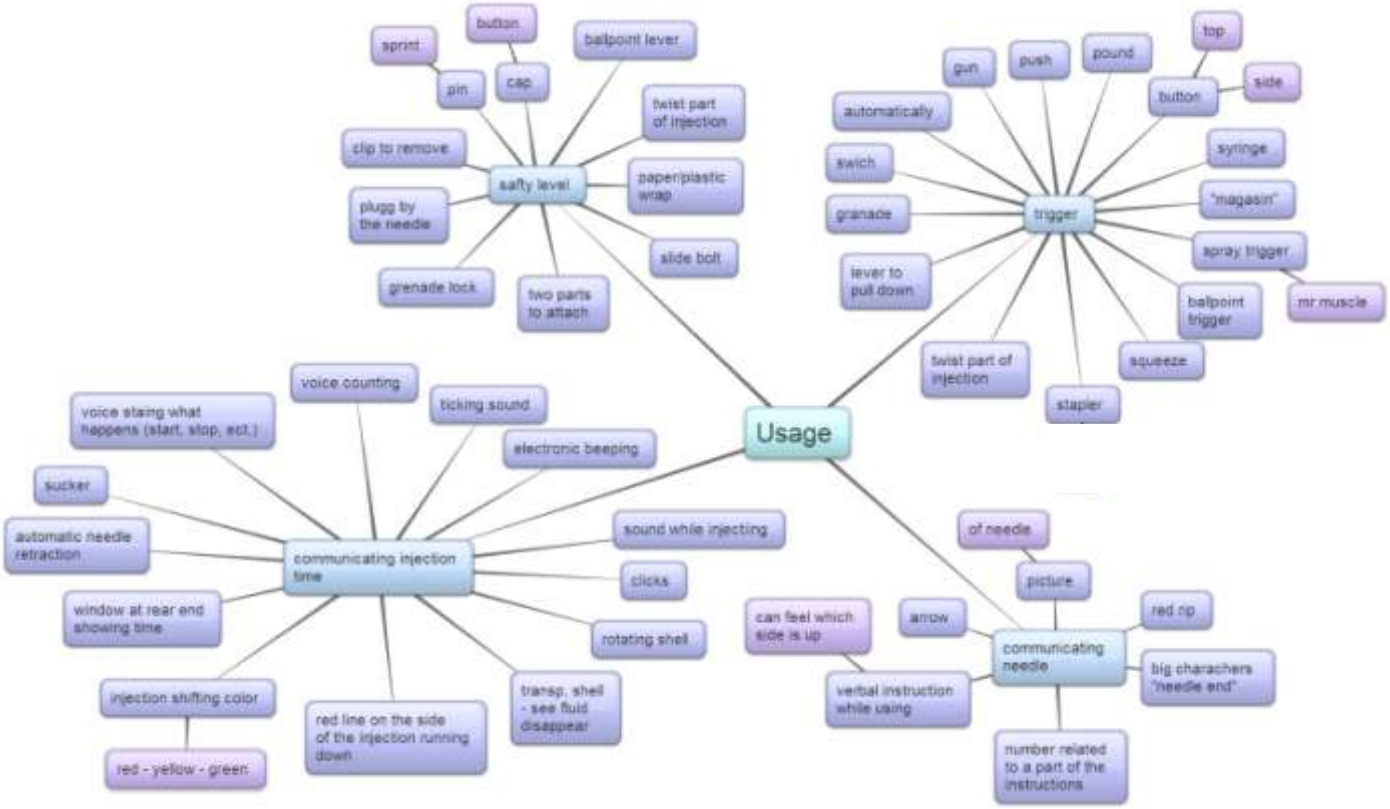


Figure 8.2. Sub solutions regarding how to solve the four different aspects of the sub problem usage

8.3. Instructions

The instruction problem did also branches of in to three sub problems and possible solutions can be viewed in figure 8.3. The tree branches considered were; what instructions to communicate, how to communicate them and for whom the instructions are for.

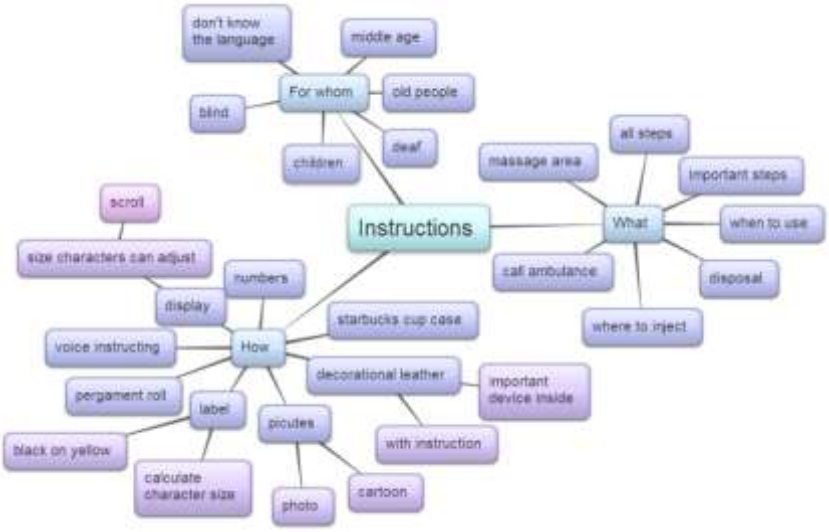


Figure 8.3. Sub solutions regarding how to solve the three aspects of instructions

8.4. Injection fluid status

All injectors need to have a window to monitor the medicine status by observing the medicine fluid, sometimes also called injection fluid and instructions in the injectors instruct that the injector should be replaced with a new one if the injection fluid is cloudy or discolored. It became clear, during the customer study, that none of the customers were completely sure how to monitor the medicine status which is why Figure 8.4. represents possible solutions to this problem.

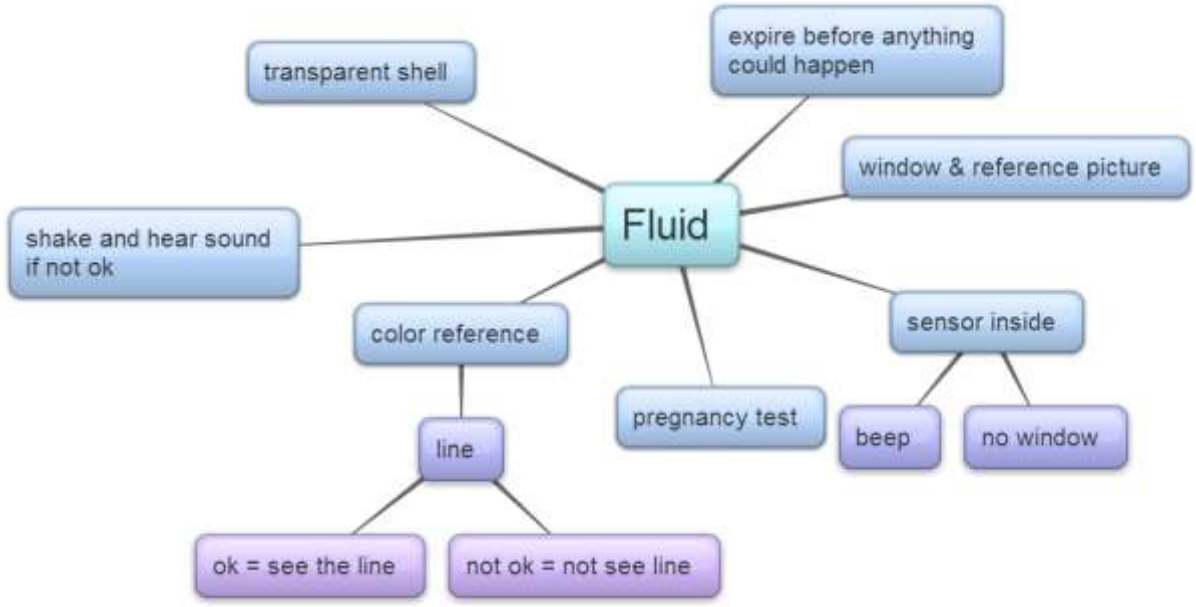


Figure 8.4. *Sub solutions regarding how to solve the sub problem of how to communicate the status of the injection fluid, the drug*

8.5. Expiration date

Another problem to solve was how to communicate the expiration date. There was also a certain need for reminders when the injector was about to expire which is why figure 8.5. also contains possible ways to accommodate for that.

Figure 8.5. *Sub solutions regarding how to solve the sub problem of how to communicate when the injection has expired*

8.6. Practice/Demonstration

This sub problem was originally divided in to two categories but it was regarded beneficial to use the same mind map for both as some of the possible solutions apply for both problems. The ideas regarding how to meet the needs of these sub problems can be found in Figure 8.6. below.

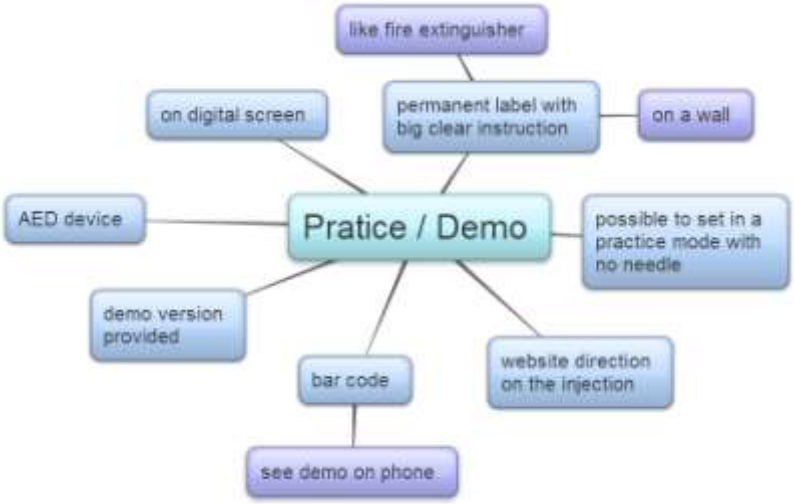


***Figure 8.6**. Sub solutions regarding how to solve the sub problem; lack of practice or demonstration*

8.7. Appearance

This sub problem branches of into five new sub problems. They can, as displayed in Figure 8.7. be divided into two groups; three of the new sub problems are affected by ages and the other group has more to do with how the appearance can affect the communication of what the injector is for and the severity of the condition. The sub problem of appearance has the most contra dictionary sub solutions as the needs of appearance differs a lot between the ages and in some cases also by gender. This is why limitations had to be made which in this case resulted in narrowing the focus area to only involve adults and adolescents. This limitations were made at the end of the Early concept generation phase.

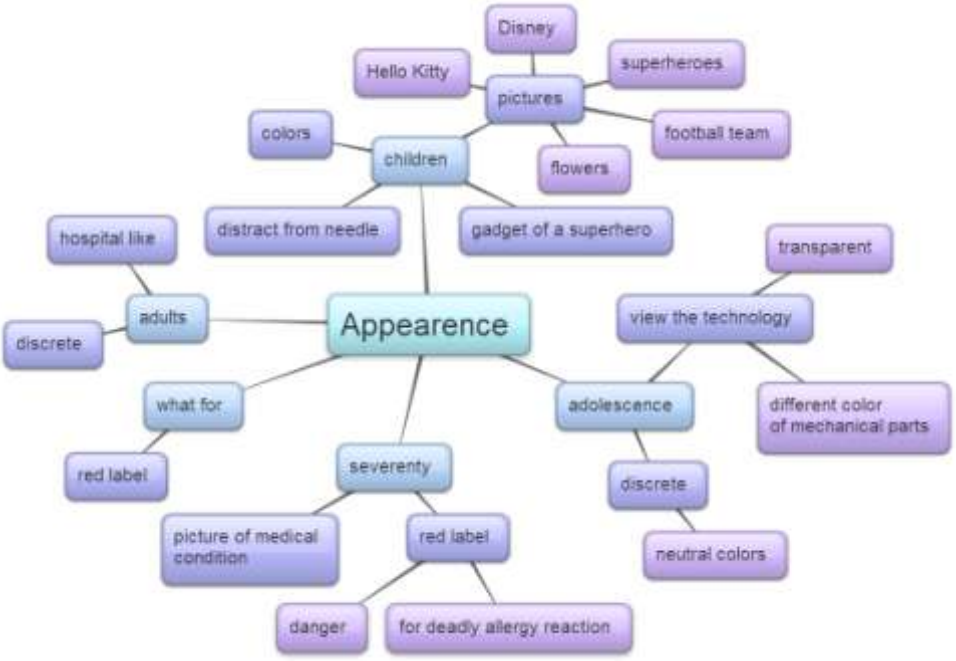


***Figure 8.7**. Sub solutions regarding how to solve the five aspects of Appearance*

8.8. How to carry the injector

The injector should as mentioned before be carried at all times which is why it was important to derive possible ways to carry the injector. The different ideas are shown in figure 8.8.

***Figure 8.8**. Sub solutions regarding how to solve the sub problem of how to carry the injector at all times*

8.9. Cover/Case

This sub problem was considered during the first loops of the concept generation step but delimited in the later stages as this would involve an additional product development process in order to make sure that fulfill its purpose. This limitation was made to assure that the product development of the injector was not conflicted as that was the main purpose of this project. There were however ideas about casings and covers which can be seen in figure 8.9. and some of these have inspired the final result as well as it was determined that there was room for solutions that did not need a case or a cover.

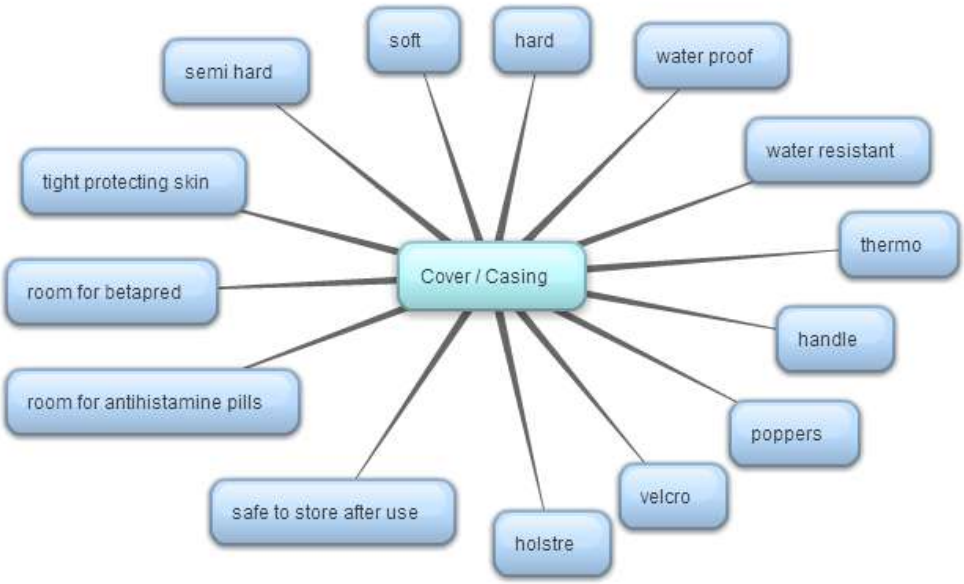


***Figure 8.9**. Sub solutions regarding how to solve the sub problem of cover and casing*

8.10. Carrying to disposal

Figure 8.10. displays possible ways regarding how to carry the used injector safely to disposal without any risk of being stung by the used needle.

***Figure 8.10**. Sub solutions regarding how to solve the sub problem of carrying the injector to disposal after use*

8.11. Information in conjunction with the injector

There were many requests about other information than instructions that came up during the customer study which is why one sub problem is called information. Different ideas regarding what information to display is shown in figure 8.11. This sub problem was later changed and regarded how and where to display this information as it seemed very difficult to fit all this information on the injector itself.

***Figure 8.11**. Sub solutions regarding how to solve the sub problem of what other information than instructions should be communicated in conjunction with the injector*

8.12. Environment to use and store the injector in

The categories of problem regarding the environment to use the injector in and the environment to store the injector in has not been considered here as the injector must be able to be both used and stored in all the places that was brought up during the interviews and far more. These categories are therefore all ready requirements and all sub solutions derived in the following steps need meet these requirements. Hence, they are not subjects of the following procedures.

8.13. Final analysis

This first phase of the concept generation step was later used as a base for the following concept generation. One sub solution from each mind map where used in combination with each other to create total design solutions. In rare cases two or more sub solutions from the same mind map were used to satisfy some specific needs.

Not all of these sub solutions were used during the early concept generation, only the ones that seamed feasible or made satisfying combinations. The morphological matrix, used during the second loop concept generation, were also extended by some of the preferable sub solutions from the mind maps that had not fitted in to any combinations during the early concept generation and hence not used.

9. Concept development loop 1

The following concepts are the first concepts derived from the sub solutions on the mind maps. They are presented as thumbnail sketches, see previews in figure 9.1. below, with a product specification and some highlights regarding the specific concepts. Not all sub solutions was selected to be part of the concepts and some sub solutions may have been added along the way of creation. The following concepts have been created by merging one sub solution from each mind map to combine a set of sub solutions into one total solution. In some cases more than one sub solution from each mind map were used in combination to facilitate the solution even more.

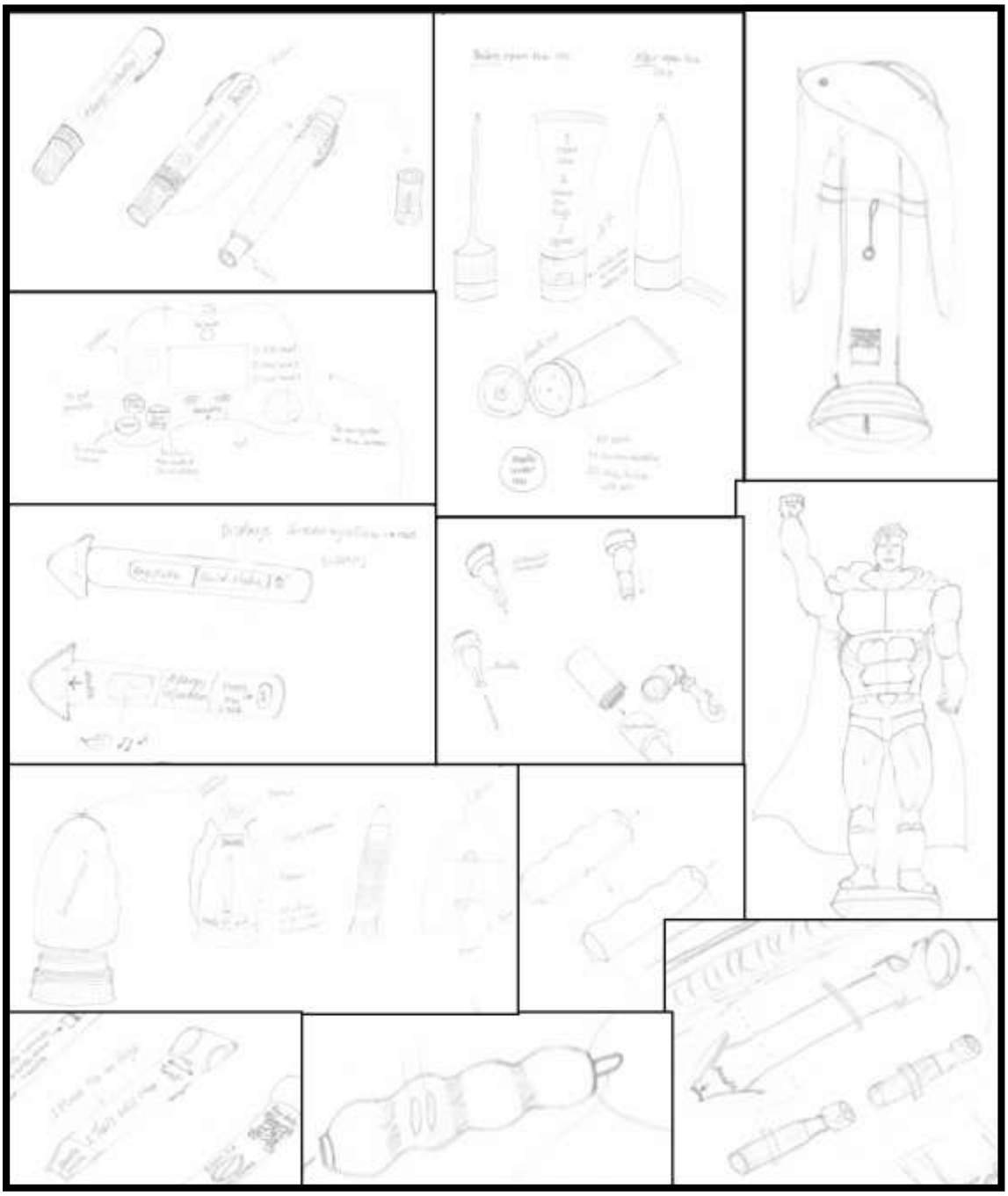


Figure 9.1. *Miniature thumbnail sketches of the early concepts.*

9.1. Puzzle pen

Figure 9.2. displays the first concept created, called puzzle pen. One of the key factors was the safety lever that made sure that the injection could not be triggered if the cap was not removed and also placed at the rear end and used as a button. All existing product has a safety catch that need to be disassembled. This was designed as it was regarded to be easier that something would accidentally would be removed compared to accidentally assembled. Other new ideas to use a reference picture for comparison when monitoring the medicine status; see the pen picture in the middle of figure 9.1.

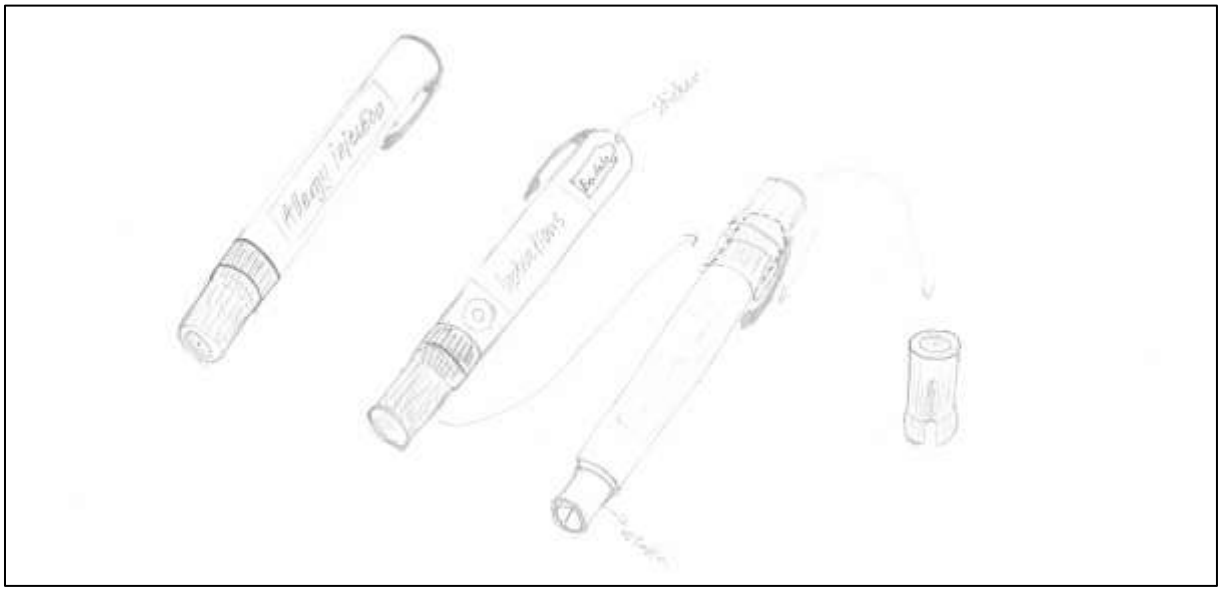


Figure 9.2. *Puzzle pen concept*

Singe or multi use	Single use
Size and shape	Whiteboard pen but shorter, body (without cap) length of an average hand
Usage	
Trigger	Button; the cap has to be put on the rare end on a special way indicated by the clip
Com. Injection time	Ticking sound when injecting
Com. needle	Intuitive shape
Safety levers	Cap, two parts need to be assembled
Instructions	On injection
Practice/demo	Guide to information website on package, not on injection
Fluid	Window, ref. pic.
Expiration date	- Green label in the rear end, a sticker that could be peeled of and put in calendar - Permanent label underneath
Appearance	Adults: Discrete look like a pen Children: could be covered with cartoon characters etc, could have different colors Adolescents: Could be either in neutral colors or transparent Severity: Big red label the com. what it is for
Carrying	Pen clip, fit in average pocket (breast pocket, front pocket of trousers to be safe)
Case/Cover	No cover, cap is enough
Disposal	Cap is being put back over the needle

9.2. Air Tube

The second concept, shown in figure 9.3. were made with an idea to make the comcept discret, designing it to look like an ordinary tube of lotion. It could also be produced with funny pictures and in dirfrent colors for children.

This concept is also equiped with a bar code that could be scanned for genreal information, expiration date and to watch en instruction video.

This is the first concept that also concider using multi modality to communicate when starting injectiong, while still injectong and when done injecting.

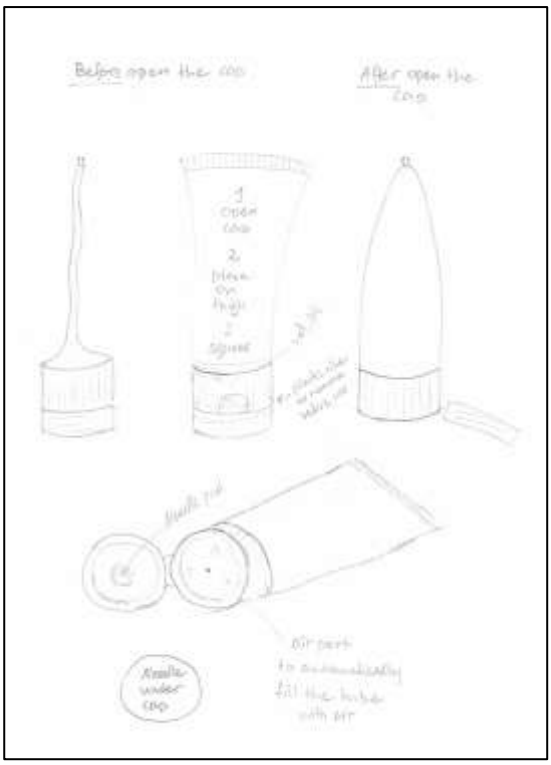


***Figure 9.3**. Air Tube concept*

Singe or multi use	Single use
Size and shape	Tube
Usage	
Trigger	Squeeze
Com. Injection time	Click when staring, click when finished, a deluxe version would play a song and have a blue light at the bottom when injecting
Com. needle	Intuitive shape, Big characters on cap
Safety levers	Plastic rib bon to cover cap opening and a cap
Instructions	Numbers pictures text
Practice/demo	Info on the back with directions to a web page with demo
Fluid	Transparent bottom part where the fluid is, a ref. pic. above to compare to
Expiration date	Barcode on the back to that can be scanned with a cellphone and the exp. date will be uploaded to the calendar or to an app with additional information and demos that also sends warnings when the injection in about to expire
Appearance	- Adults: discrete - Children: Colors and pics. possibility - Adolescents: discrete - Severity: Red label; “emergency allergy injection”, perhaps pictures on reaction depending on size
Carrying	Average front or back pocket
Case/Cover	No need for; water resistant (plastic body), semi hard. (Could be created to store other meds)
Disposal	Close the lid to cover the needle

9.3. The player

The player, displayed in Figure 9.4. was the delux concept that would sucessfully solve all problems expect maybe for being descret enough for adults. This is the first multi use device, usually they are singel use devices, which was an attempt to reduce the costs as this would be a rater pricy product. This concept was however discared by the stake holders that did not believe in this very futuristic concept.

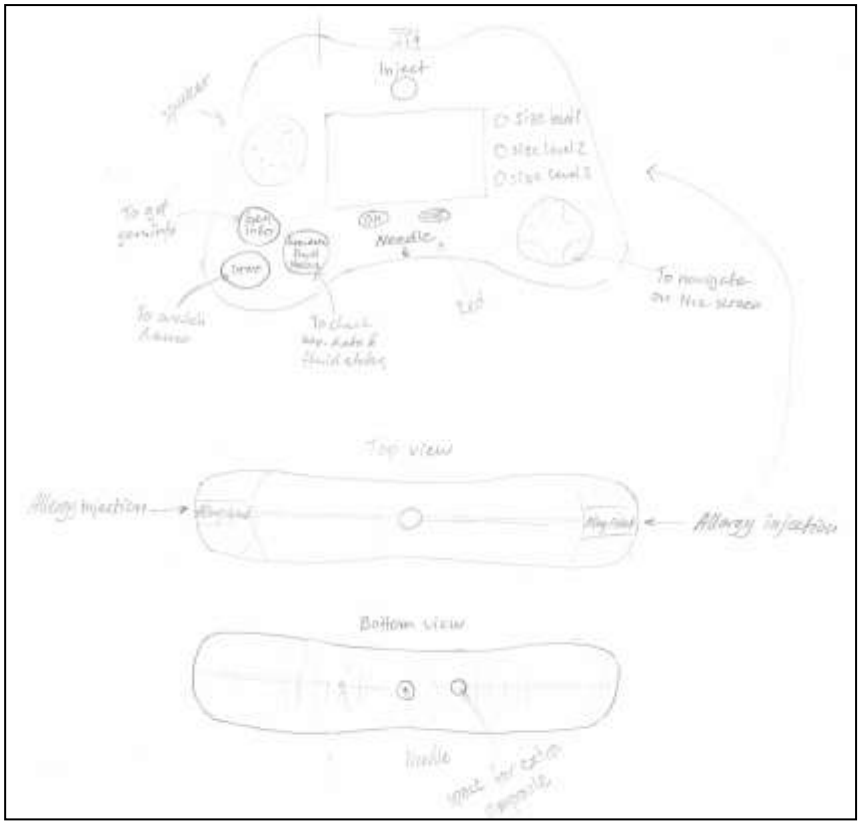


Figure 9.4. *The player concept*

Singe or multi use	Multi; Uses brail, verbal instruction, pictures and text → Suitable for both blind and deaf, have room in the back for betapred
Size and shape	Game control
Usage	
Trigger	Button
Com. Injection time	Verbal (speaker), count down on screen
Com. needle	Characters and arrow
Safety levers	Automatic
Instructions	Verbal & on screen. Different font sizes can be chosen
Practice/demo	Button to press for demo on the screen, can also be set in practice mode
Fluid	Press button to receive fluid status on screen and verbally
Expiration date	Press button to receive expiration date status on screen and verbally – also send expiration sdate info via email when closer to expiration
Appearance	Adults: No opinion Children: Distract from needle, could be colorful with pictures on the back. A special kids edition could be made with a fun video clip to watch while injecting Adolescents: could be transparent Severity: red label on the side to com. what it is for
Carrying	In a case attached to belt or straps on bag, should be able to carry in average pocket
Case/Cover	Tailor made, water prof, preferably transparent
Disposal	Needle and ampoule (attached to needle) can easily be removed and put in storage units within the device

9.4. MicroJect

This concept where the first in line of a small range of more realistic concepts for the future inspired by the skin penetration device used when taking a blood sample from a finger.

MicroJect was design to mainly accommodate the need of many to have a smaller injector.

The small needle cover to the left in Figure 9.5. was later discarded.

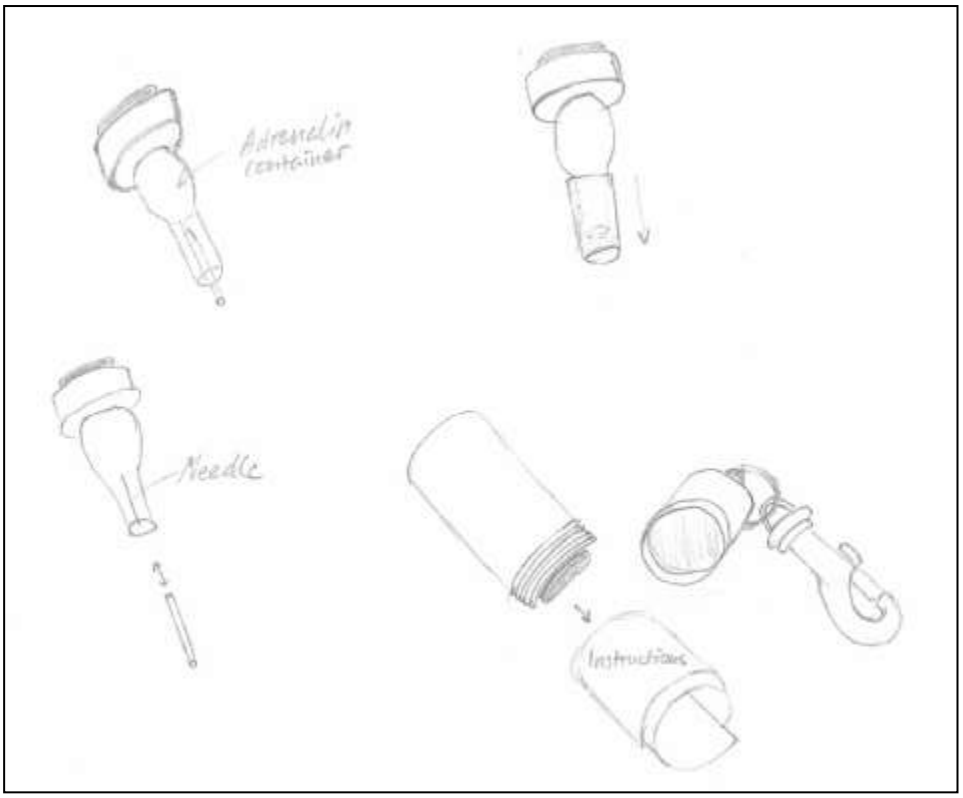


Figure 9.5. *MicroJect concept*

Singe or multi use	Single alt multi use
Size and shape	Small mushroom
<u>Usage</u>	
Trigger	Button
Com. Injection time	- The button forces the fluid to inject and it cannot be pushed faster than the fluid is being injected - The fluid container is transparent, hence it is easy to observe the process
Com. needle	Either the needle is visible → transparent pipe or state “needle” on pipe
Safety levers	Need to use force to be able to break lever and start injection, safe cover
Instructions	On an external piece of paper inserted in the cover (kinder egg wise)
Practice/demo	Guide to demo video online
Fluid	Transparent container – ref pic. in the external instruction sheet
Expiration date	Label on top of the button – with sticker
Appearance	Adults: Looks hospital like, serious but with discreet cover Children: may be less appealing to children but the cover could be colorful with pictures Adolescents: interesting because of the mechanics, but also discreet Severity: The appearance communicate medical device, cover label “allergy injection”
Carrying	In keychain, straps on cloths, in front pocket, jacket pocket and much more
Case/Cover	Rounded metal pipe cover, screw lid with key ring and
Disposal	Put injection back in case

9.5. One way griper

This concept, displayed in figure 9.6. was mainly design to view the sub solution to have a sheet that pulled out from a paper roll which means that the instructions could be bigger and more sufficient than if limited by the size of the injector. The other sub solution for display is the use of a finger grip to indicate how to hold the injector.

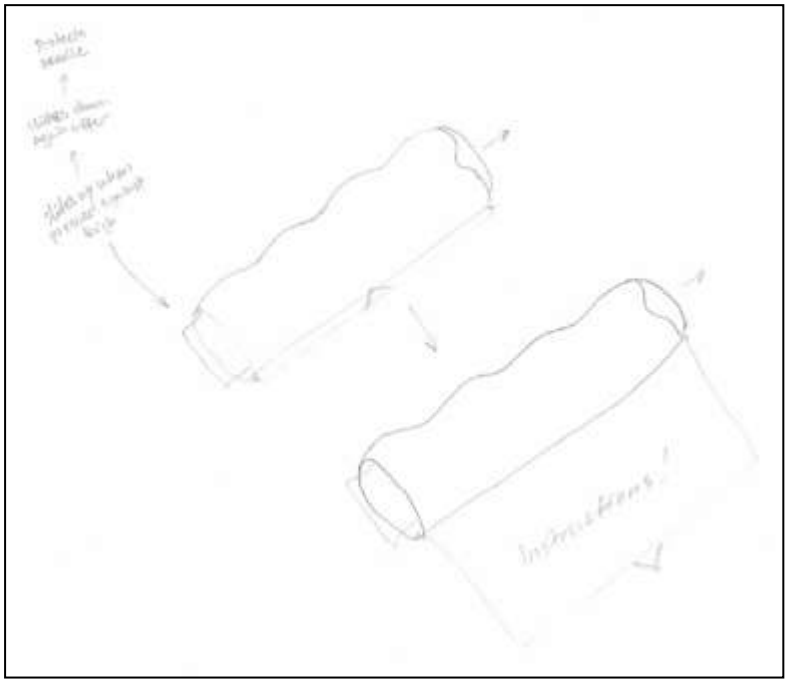


Figure 9.6. *One way gripper concept*

Singe or multi use	Single
Size and shape	Oval rounded section surface, ergonomic for average hand to grip, grip for fingers on one side to know what side to be up front (right handed persons)
Usage	
Trigger	Pound
Com. Injection time	Clicks
Com. needle	Labe “Needle end”
Safety levers	A cap to be removed in the rear end
Instructions	A pullout curtain with instructions and other useful information
Practice/demo	Guide to webpage
Fluid	No need for checking - stable
Expiration date	On the safety cap
Appearance	Adults: serious Children: could ha lots of pictures Adolescents: could be transparent Severity: “Allergy injection” on the side
Carrying	In a cellphone case
Case/Cover	Cellphone case
Disposal	There is a lever in the needle end that slides up when pounded against the thigh and then it slides down again protecting the needle. It can only slide up once.

9.6. Oval run down

The concept in Figure 9.6. is a total solution using many sub solutions that at the time were considered more preferable. One of these was how to communicate when injecting in order for the user not to pull out the injector before it is done injecting. The idea was to have line in the middle as shown in Figure 9.7. that would slide down while injecting, indicate the level by shifting color from green to red. Another solution displayed is the oval shape that might would result in an reduction of length causing a more comfortable design.

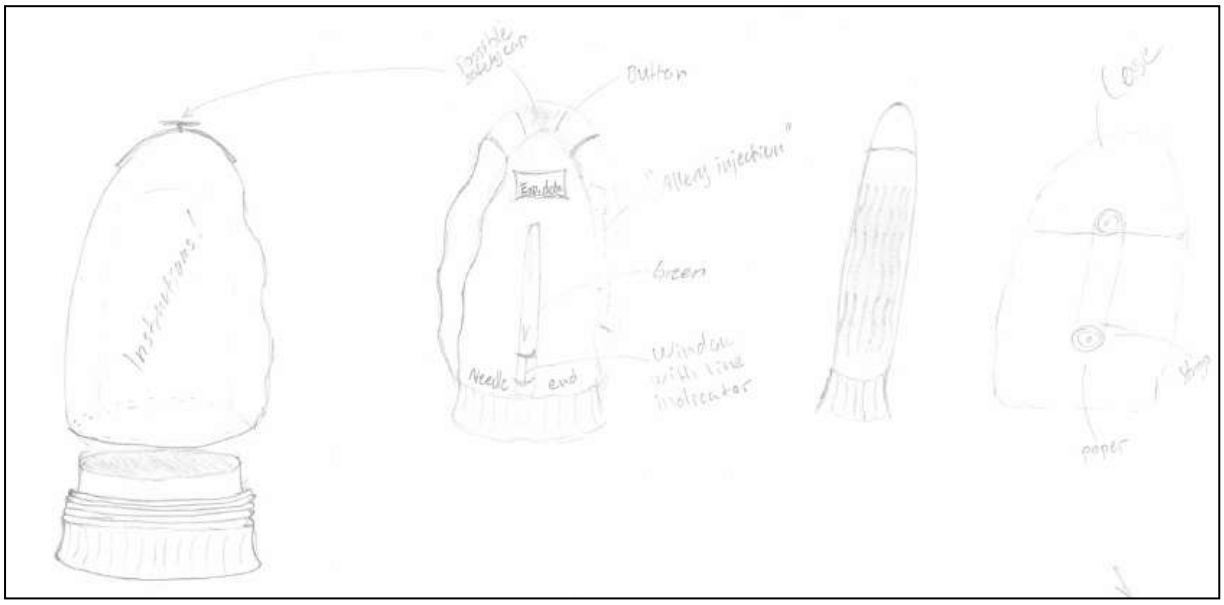


Figure 9.7. *Oval rundown concept*

Singe or multi use	Has the potential to be both
Size and shape	Oval, fit average hand, grip on left side to com what way to hold it
<u>Usage</u>	
Trigger	Button
Com. Injection time	- line that runs down green → red - click when needle comes out
Com. needle	Label on the bottom; “Needle end”
Safety levers	- screw stopper for needle - small resistant when removing the lid, as a plug - possible safety cap on button if needed
Instructions	Numbers, pictures, text on the back
Practice/demo	Website direction on the back
Fluid	Window with a green line, if the green line is not visible →warped fluid
Expiration date	Big label up front
Appearance	Adults: Discrete but a bit hospital like Children: Quite distracting, multiple color possibility Adolescents: Discrete, possibly ta haw transparent parts Severity: Big label on the side “Allergy reaction”
Carrying	On cloths, bag or belt, fit average pocket.
Case/Cover	Tight, transparent, protecting skin with poppers (additional poppers provided to put on cloths or bag) and strap to put either on cloths, bag or in belt.
Disposal	Put on screw stopper again

9.7. Robin Hood

This concept is dsigned as an arrow and is more focused on children using an undermaing shape aming other things. It is the first concepts that are thought to play a song while injectiong to distract from the serious situation but also to communicate the time span of when it is injecting. there is also an attempt to accommodate for the need to store other medicine; cortisone and antihistamine in conjution with the injector as displayed to the right in figure 9.8.

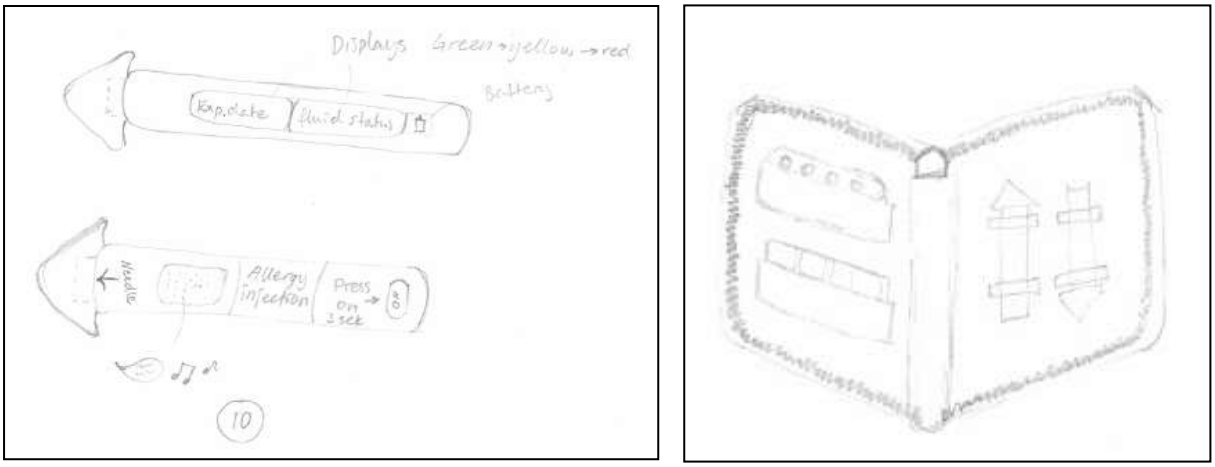


Figure 9.8. *Robin Hood concept*

Singe or multi use	Single
Size and shape	Arrow, fit average hand
Usage	Power on button to press first after which verbal instructions are given
Trigger	Automatically or pressure
Com. Injection time	- Song/tone is playing while injecting – good for patients who do not inject themselves - Count down on a display in top of injection - Click in the beginning
Com. needle	Label at the end “needle end” together en arrow underneath
Safety levers	Button, cap
Instructions	Verbal only, apart from the power on instruction
Practice/demo	Could have the opportunity to set in a practice mode
Fluid	A display shows the fluid status by text and colored background that goes from green→yellow → red
Expiration date	A display shows the exp. date by numbers and colored background that by time goes from green→yellow → red
Appearance	Adults: Real device, (could think it is too much like a toy) Children: Distracting sound Adolescents: Interesting because of technology Severity: Both information in large characters on the injection but also outside the case
Carrying	In bag, strap or belt
Case/Cover	Case with zipper that fit two injection, betapred and antihistamine
Disposal	Arrow tip shaped cover could be put back on

9.8. Twister

The Twister concept, in figure 9.9. uses a different trigger function than any of the existing products as the rear end need to be twisted in order to inject. It also has a function to safely retract the needle after use.

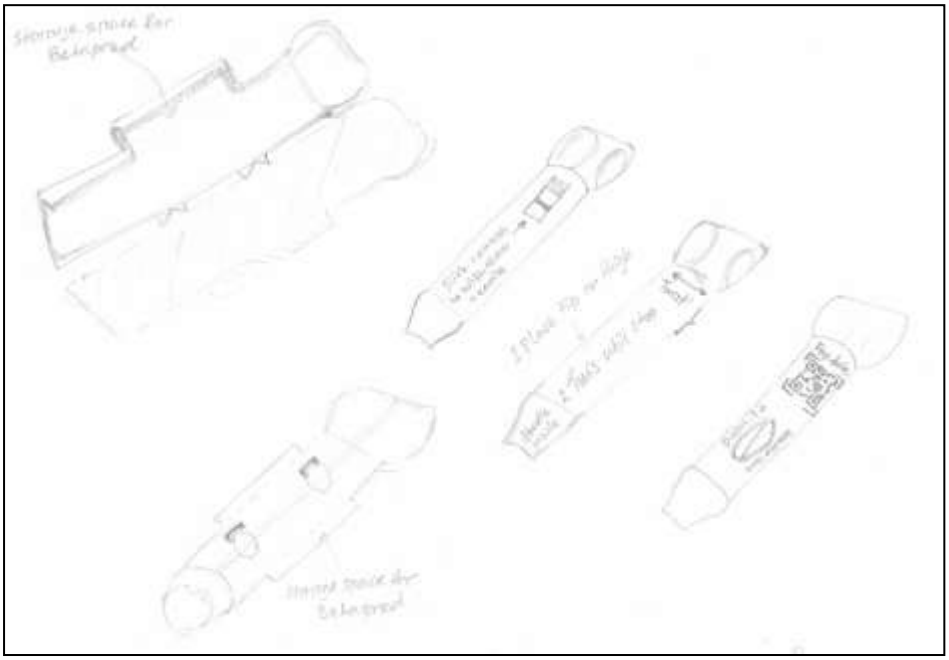


Figure 9.9. *Twister concept*

Singe or multi use	Single
Size and shape	Pen, fit in average hand
Usage	
Trigger	Twist
Com. Injection time	The lever shall not be able to be twisted faster than the fluid is injected and the instruction says you should twist until it stops
Com. needle	The nozzle is red and labeled “Needle inside”
Safety levers	Need to use a force to break the safety lever for it to be able to twist
Instructions	Instructions: 2 step instruction on the side of injection, text and possibly pictures
Practice/demo	Demo provided when scanning bar code on the back
Fluid	Window, similar design as “Molly”, one diagonal line is always for display. If another diagonal line in the opposite direction occurs → Dispose it!
Expiration date	A label on injection above bar code, but also to register in cellphone calendar
Appearance	Adults: Quite serious Children: lever can come in different colors Adolescents: appropriate level of seriously Severity: Stated “allergy injection” on the side
Carrying	In average pocket
Case/Cover	Slim case cover with storage space for Betapred
Disposal	Disposal: Slide lever to manually withdraw the needle back into the pen

9.9. BubblePen

The idea when designing this concept was mainly to use the sub solution of carrying the injector as a necklace and how the trigger button could be disassembled and put over the needle as displayed in figure 9.10. This concept was however discarded before the next phase as it was considered dangerous to have a sharp object attached to the neck. Another contributing factor was that it was a risk of being stung by the needle when trying to put the button over the needle as a needle cover.

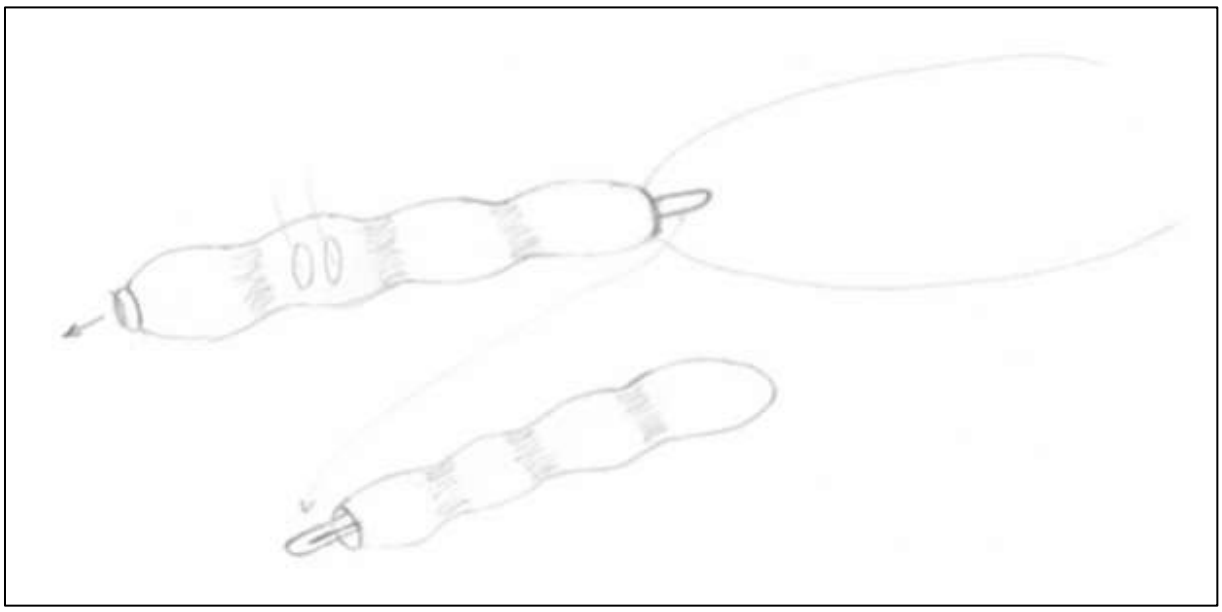


Figure 9.10. *BubblePen concept*

Singe or multi use	Single
Size and shape	Pen, narrow, average hand
Usage	
Trigger	Ballpoint pen button
Com. Injection time	Clicking sound till done
Com. needle	Label “Needle end”
Safety levers	Plug to pull out that cover needle
Instructions	One instruction at each convex wave
Practice/demo	Information about webpage
Fluid	Window and ref. pic.
Expiration date	At the top in big protruding letters
Appearance	Adults: discrete, not look like a toy Children: Funny shapes, could be colors as well Adolescents: could be transparent Severity: states allergy injection
Carrying	In a ribbon around neck or where ever preferred. Or tied to preferred item.
Case/Cover	Slime custom made plastic transparent cover
Disposal	The ballpoint button can be removed and put over needle

9.10. Multiple ampoules

As shown in Figure 9.10. this is a total solution regarding casing and carrying but also using the idea of having to assemble to part in order to inject. There is also room for other medicine in the case.

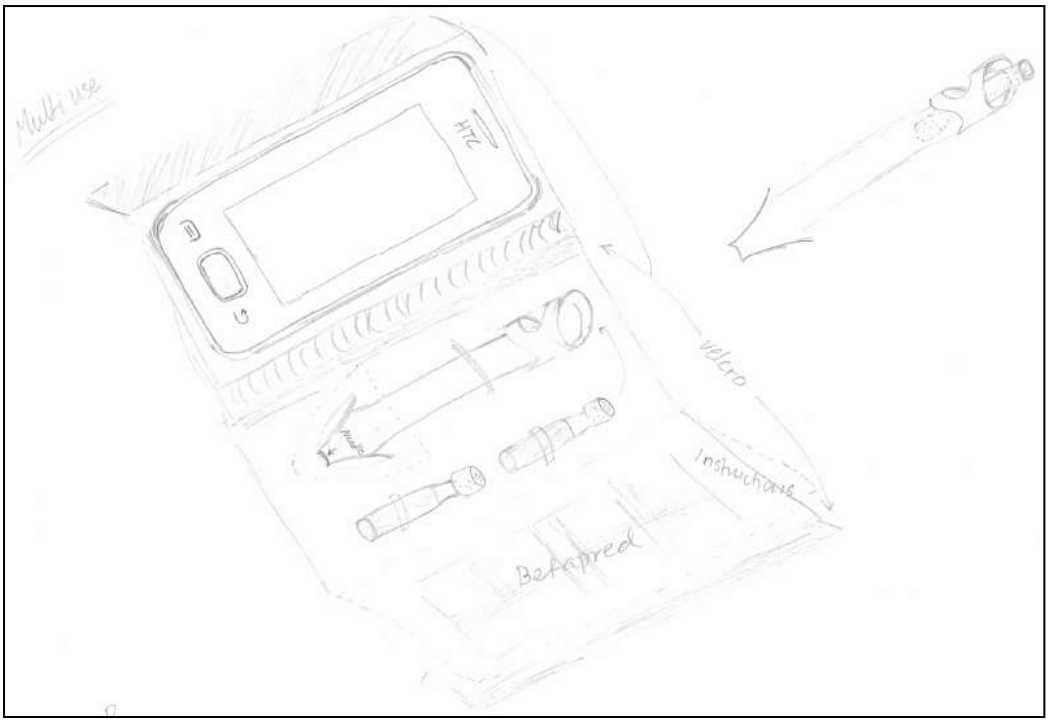


Figure 9.10. Multiple ampoules concept

Singe or multi use	Multi: After first use the ampoule could be removed and a new one inserted. After use, the rear end part needs to be twisted to withdraw the needle and release and at the same time push up the used ampoule so it can be removed.
Size and shape	Pen in two parts
Usage	
Trigger	When inserting magazine
Com. Injection time	watch the injection fluid pass, blue light to lighten the fluid, lights off when done – of out of battery → only watch fluid pass
Com. needle	Arrow and text label, perhaps red/orange tip
Safety levers	Two parts to attach
Instructions	On a sheet in the case, Short cuts on injection
Practice/demo	Guides to a website on instruction sheet
Fluid	Visible in the ampoules, clear instruction on instruction sheet how to check it
Expiration date	Label on the ampoules
Appearance	Adults: Hospital like, serious, discrete in its case Children: easy to use but might be frightening Adolescents: Same as adult but could also be found exciting Severity: in case and on injection, red label
Carrying	Along with cellphone
Case/Cover	Included in a cellphone case with storage space for betapred and an external instruction sheet, either to be loos or attached. The sheet provide instructions on the first page and general information on the back
Disposal	Twist the rear end part to withdraw needle

9.11. Punchliner

The Punch liner uses many of the highly rated sub solutions but did not make it very far as being a concept of its own. It utilizes a safety grip where two lever need to be squeezed in order to trigger. There is a sucker that will stick on to the leg while injecting and then release when the injector is done injecting. The case has as displayed in Figure 9.12. a magnet for it to be attached and possibly stored on the fridge for example but the case does also have a strap for it to be carried in the best or on a strap of a bag for example.

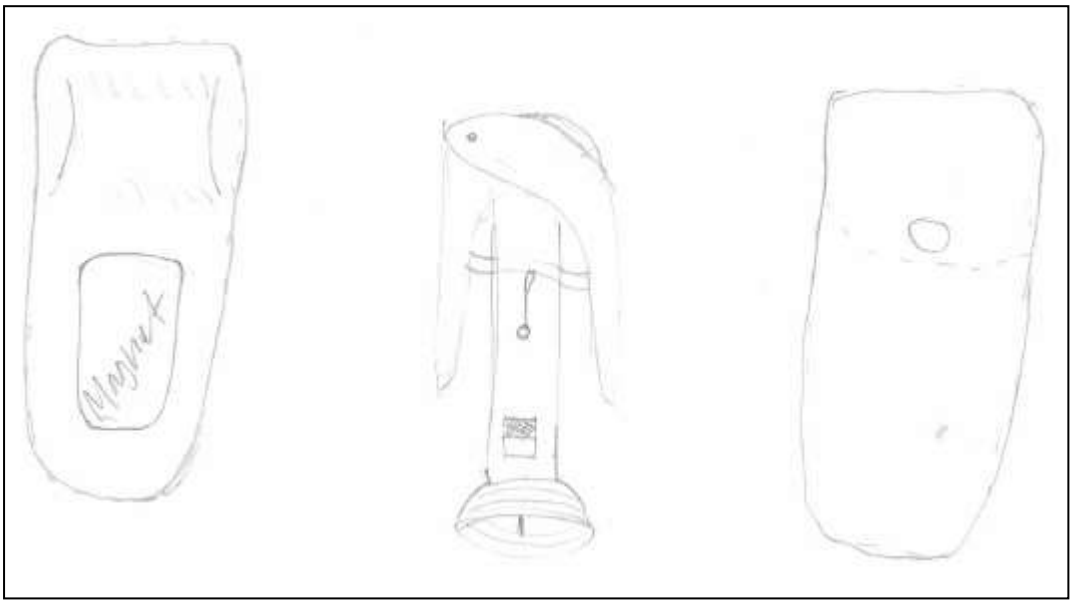


Figure 9.12. *Punchliner concept*

Singe or multi use	Single
Size and shape	Wine opener
Usage	
Trigger	As a punch
Com. Injection time	Sucker that relieves when done, the arms of the punch also releases from its tight position
Com. needle	Label
Safety levers	A string to unleash the arms. Squeeze the arms in to the injection to activate
Instructions	The 3 steps in text and pictures on injection, additional instructions on external sheet in the case
Practice/demo	Guide to website
Fluid	Window that will turn the same as a ref. pic. if scattered
Expiration date	Label or barcode at the top of the rear end
Appearance	Adults: Discrete in its case. Quite serious Children: Could have different colored parts Adolescents: Could be transparent Severity: small sized letters on injection, big letters outside case
Carrying	In average pocket, belt, on refrigerator
Case/Cover	Rounded bag, closed with a popper
Disposal	Needle withdrawal when arms are turned upwards like on a corkscrew

9.12. Superman

Figure 9.13. *Superman concept*

This concept, shown in Figure 9.13., was design for children but limitations were made during this phase which is why there are only a few ideas regarded here which is that this concepts could either have been designed as a pure case or as an injector. The needle can come out from the raised hand of from the bottom if it would have been designed as an injector. The trigger function could be to punch or pull the raised arm etc.

The super man concept was the last developed concept that was an attempt to match the needs younger children who wanted their injectors to be distracting but yet deliver a sense of pride etc. During the customer study it became clear that there was a need for an injector more suited for children in many aspects. There are many challenges into making an injection suitable for children and many contra dictionary needs that would have impacted the development process. This is why the early concepts also resulted in a limitation of the project to only involve the development of an injector suitable for adults and adolescents but with some reservations for possible solutions that could be made for the injector to also be more suitable for children. An example of a reservation like that is that the color of the material could be changed or even transparent or that the instruction label could be changed to something more child friendly. Other parameters like the need from children to have a distracting injector wile injecting was yet regarded as this could be applied to adults to.

9.13 Final analysis

The early concepts managed to use most of preferable the sub solutions but some did however remain unused. Most of the unused did however make it to the second loop of concept generation and where used together with the used sub solutions in the morphological matrix. Only two concepts remained from the early concepts which was MicroJect and Multiple Ampoules that was slightly improved and came to be known as Assembler instead. Parts of the other concepts did remain but they were all recombined into a smaller number of concepts for further improvements. The following phase of the concept generation step is the second loop concept generation.

10. Concept development loop 2

The second loop concepts are the results of the Pugh matrix and Morphological matrix and the thumbnail sketches can be found in appendix Second Loop Concepts. The chapter will start by a general analysis and presentation of the individual results of the Pugh matrix and morphological matrix respectively. They will be followed by a presentation of the resulting six concepts which will be presented in consistency with the presentation of the early concepts but where the thumbnail sketches are replaced by photographs of the soft models.

10.1. Pugh matrix

The result of the Pugh matrix can be studied in detail in appendix Pugh Matrix but a summary of the results will be given in this paragraph.

Out of the total 185 sub solutions that were used in the early concept, 136 scored better than the EpiPen and were passed on to the Morphological matrix. This section will give a short presentation regarding the future of the concepts that received the highest and lowest scores.

The player received the highest score among the concepts but was discarded by the stakeholders at SHL. The concept evolved a lot of technology and would have been a very expensive injector and thereby considered unrealistic and ruled out. The two second best concepts were MicroJect and Robin Hood. MicroJect were passed on to the next round without any modifications while Robin Hood where taken apart and the plus rated sub solutions were used in the Morphological matrix. The reason for not preserving the Robin Hood concept was because it was possible to disassemble this concept into sub solutions that were fairly easy to combine with other sub solutions. The sub solutions of MicroJect was however harder to combine with other as the together form a rather unique total solution.

Superman was the concepts that scored the least which was not surprising as the limitations of not developing an injector for children were decided up on before the concept was even finished. The second lowest scoring concept was the twister. The main feature of Twister was however still taken in the picture as this feature, the trigger function, was rather unique as none of the existing solutions on the market uses it.

No other concepts where taken into account as total solutions. However, like stated before, the 136 sub solutions that scored better than EpiPen were subjects of the Morphological Matrix.

10.2. Morphological matrix

Out of the 136 sub solutions that scored better than EpiPen, 98 unique sub solutions were found and used in the Morphological matrix. As some of the early concepts shared the same sub solutions, the number had to be reduced as redundant sub solutions were ruled out.

Not all the entire sub solutions were used to combine new concepts as the purpose of using this method was to reduce the number of concepts to half of the original amount. Hence, 5 new concepts were created by combining the sub solutions that was regarded to be most preferable among the customers but also with respect to the condition in which the injector may need to be used.

To view the full Morphological Matrix, see appendix Morphological Matrix and to view which sub solutions that was considered to me the most preferable, see appendix Morphological Matrix – preferable sub solutions.

10.3. Second loop concepts

The following concepts were generated by merging the preferable sub solutions from the Morphological Matrix together in to five total solutions. Only one, MicroJect, remained unmodified from the early concepts.

To view thumbnail sketches of the second loop concepts, see appendix Second Loop Concepts.

It should also be mentioned that the injectors have different sizes of their syringes. Singalong, Twoister, Elektra and Hand grenade are created with a 1ml. syringe and MicroJect and assembler are created with a 0.3ml syringe. There is also one creation called Elektra Mini that are supposed to have only a 0.3ml syringe, which could be used as reference for the other 1ml syringe concepts for evaluation of the size as this seem to be a key point to the customers.

The dose required for these kinds of injections are only 0.3ml but yet it appears like the existing products out on the market today are using a 1ml container anyway. There were few answers internally to why the 1ml syringe was used but there were indicators saying that the 1ml syringe was required earlier, to obtain a decent life span but there were also others that provided the opposite information which is why both where tested in order to see what impact it may have on the size of the injector.

The sizes of the injectors that contain a 1ml syringe are based on rough measurements of one of the smallest injectors at SHL in order to be as accurate as possible regarding the size but yet as small as possible, hence the choice of the platform. Regarding the size of Elektra mini there has been a deduction in half of the length of the inner mechanics as the reduction of the syringe has been scaled down to a third of its original size. The reason for not scaling the inner mechanics in to a third of its original size is a quality assurance matter as it was considered important to ensure that the inner mechanics would deliver the drug even though it had been scaled down. Limitations where therefore made to only scare it down a half of the original length to ensure that the drug would be delivered.

10.3.1. SingAlong

This concept, in picture 10.1. can be seen as a further development of the oval run down concept from the previous phase. The previous concept was more rounded which made it larger when using this platform. A round shape might decrease size if using another platform, not yet developed. The injecting indicator has been improved with a light diode and a song or tune that plays while injecting.

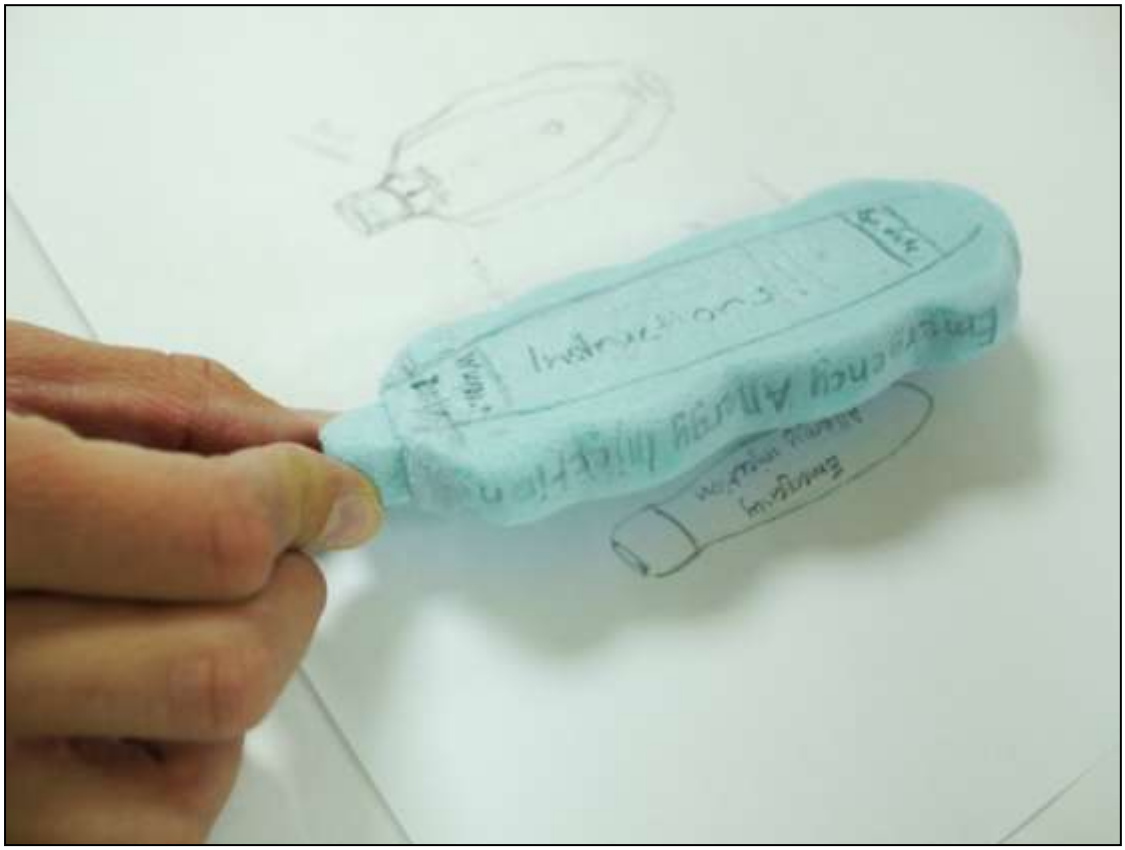


Figure 10.1. *SingAlong concept*

Injection type	Auto injector
Size and shape	Oval
Trigger	Button
Com. injection time	Song/tone = line with a running light
Com. Needle	Text label at the bottom + arrow
Safety levers	Plug button (plastic ribbon)
Instructions	On injection
Practice/demo	Guide to webpage
Fluid	Ref pic
Expiration date	Permanent exp label, protruding letters
Com. what it is for	Label along the sides
Exposed needle protection	Automatically withdrawn
Carrying	Clip

It should however be mentioned that the foam model was accidentally twice as wide as it should have been which need to be take into account when viewing Figure 10.1.

10.3.2. Twoister

This is the second edition of the concept Twister but with a slimmer design, see figure 10.2. It is equipped with a QR-code that can be scanned to benefit from many different features. One of the safety levers is the seal used for un opened soda bottles which was later considered excessive. Another new sub solution was to have instructions underneath the cap which was later discarded.

Figure 10.2. *Twoister concept*

Injection type	Manual injector
Size and shape	Oval pen
Trigger	Twist – manual trigger
Com. injection time	Transparent lower part; see fluid move and twist until it reaches a red black line – will be resistance in the twist function
Com. Needle	Label on cap
Safety levers	Plastic ribbon line on soda bottles + extra resistance in the beginning of the twist to break internal safety lever
Instructions	On injection
Practice/demo	Barcode + app
Fluid	Ref picture around the lower upper part of the injection newt to the transparent part
Expiration date	Barcode
Com. what it is for	On injection
Exposed needle protection	Cap
Carrying	Key ring (+ chain)

10.3.3. MicroJect

As mentioned several times before; the concept MicroJect remained untouched from the early concepts to the second loop concepts and the foam model representing it is shown I figure 10.3.

***Figure 10.3**. MicroJect concept*

Injection type	Manual alt auto injector Single alt multi use
Size and shape	small mushroom
Trigger	Button
Com. injection time	- The button forces the fluid to inject and it cannot be pushed faster than the fluid is being injected - The fluid container is transparent, hence it is easy to observe the process
Com. Needle	Either the needle is visible; transparent pipe or state “needle” on solid pipe
Safety levers	Need to use force to be able to break lever and start injection, safe cover
Instructions	On an external piece of paper inserted in the cover (kinder egg wise)
Practice/demo	Guide to demo video online
Fluid	Transparent container – ref picture in the external instruction sheet
Expiration date	Label on top of the button – with sticker
Com. what it is for	The appearance communicate medical device, cover label “allergy injection”
Exposed needle protection	Put injection in case
Carrying	In case; rounded metal pipe cover, screw lid with key ring and safety hook

10.3.4. Assembler

This is the new Multiple Ampoules comcept and as seen in figure 10.4. and 10.5. the lengt has been greatly reducted as the 0.3. ml syrigne did not require it to be larger. This is however not based on any platform and the dimensions of any iner michanisms are unknwoned. Hence, it might would have had to be slightly bigger depending the inne mechanics.

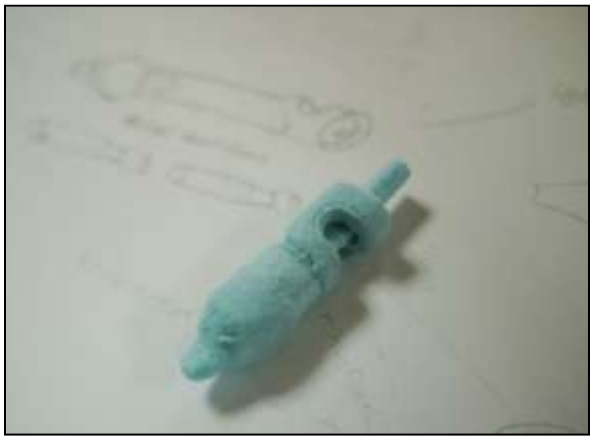


Figure 10.4. *Assembler concept, assembled*

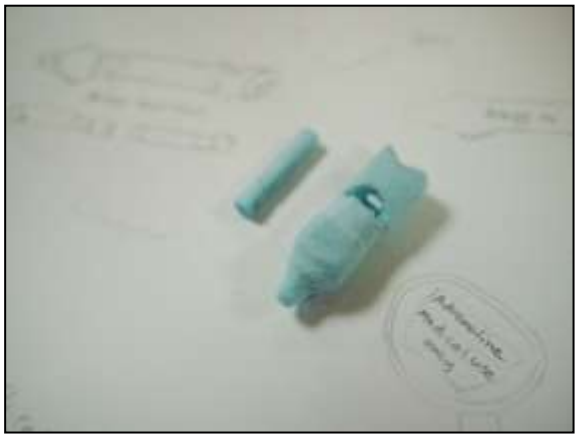


Figure 10.5. *Assembler concept, before assembly*

Injection type	Manual or Auto injector – multi use
Size and shape	Crayon
Trigger	When inserting Ampoule
Com. injection time	Verbal, light, count down
Com. Needle	Label on nozzle + arrow
Safety levers	Ampoule to assemble
Instructions	Key instructions on injection + external sheet
Practice/demo	Possible to set in practice mode with fake ampoule (no needle)
Fluid	Ref picture on external sheet, clear ampoules
Expiration date	Sticker + permanent label on ampoules
Com. what it is for	Label on both injection and ampoules
Exposed needle protection	Needle withdraws when ampoule is removed (need to screw up the ampoule)
Carrying	Pref. in a case

10.3.5. Elektra

The Elektra was made in two versions, one with a 1ml syringe and one with a 0.3ml syringe as shown in figure 3.6. and 3.7. respectively. Elektra is a further development of the previous Elektra with for example a speaker and a display with diodes and finally a vibrator that are to be used in combination to communicate that it is injecting. The vibrations were later discarded though they probably would cause discomfort to the patient.

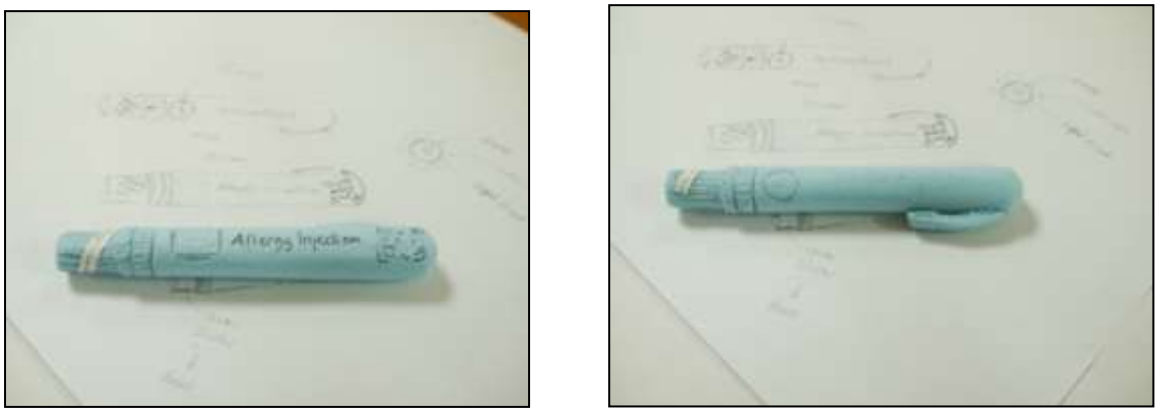


Figure 10.6. *Elektra concept*

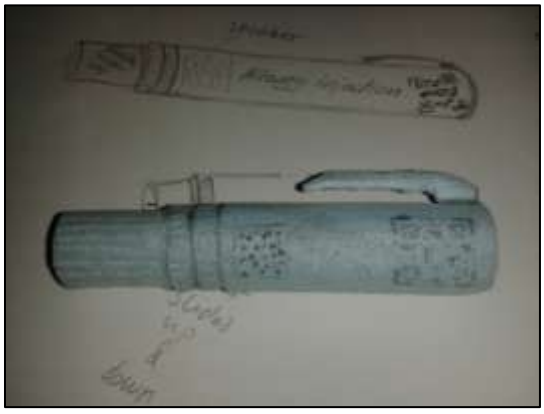


Figure 10.7. *Elektra Mini concept*

Injection type	Auto injector
Size and shape	Felt pen
Trigger	Press; needle cover slides up
Com. injection time	Countdown on display, light, vibrations
Com. Needle	Text label on cap, arrow on cap, colored cap
Safety levers	Cap activates trigger function, start the verbal instructions
Instructions	On injection
Practice/demo	Barcode →app →demo
Fluid	Protruding window, ref picture
Expiration date	Barcode; expiration date
Com. what it is for	Red letters; emergency allergy injection
Exposed needle protection	Needle cover slides down + cap
Carrying	Pen clip

10.3.6. Hand grenade

The Hand grenade concept, in figure 10.8. was also based on the same existing platform as some of the other which forced the shape to be much straighter than round. It could have remained its shape by using a so far unknown technology/mechanics, in consistency with Singalong concept. The important sub solutions to point out here of the communication of the expiration date which is done by using a sticker that could be removed and place else were, perhaps in a paper calendar, but also by having a permanent label underneath.

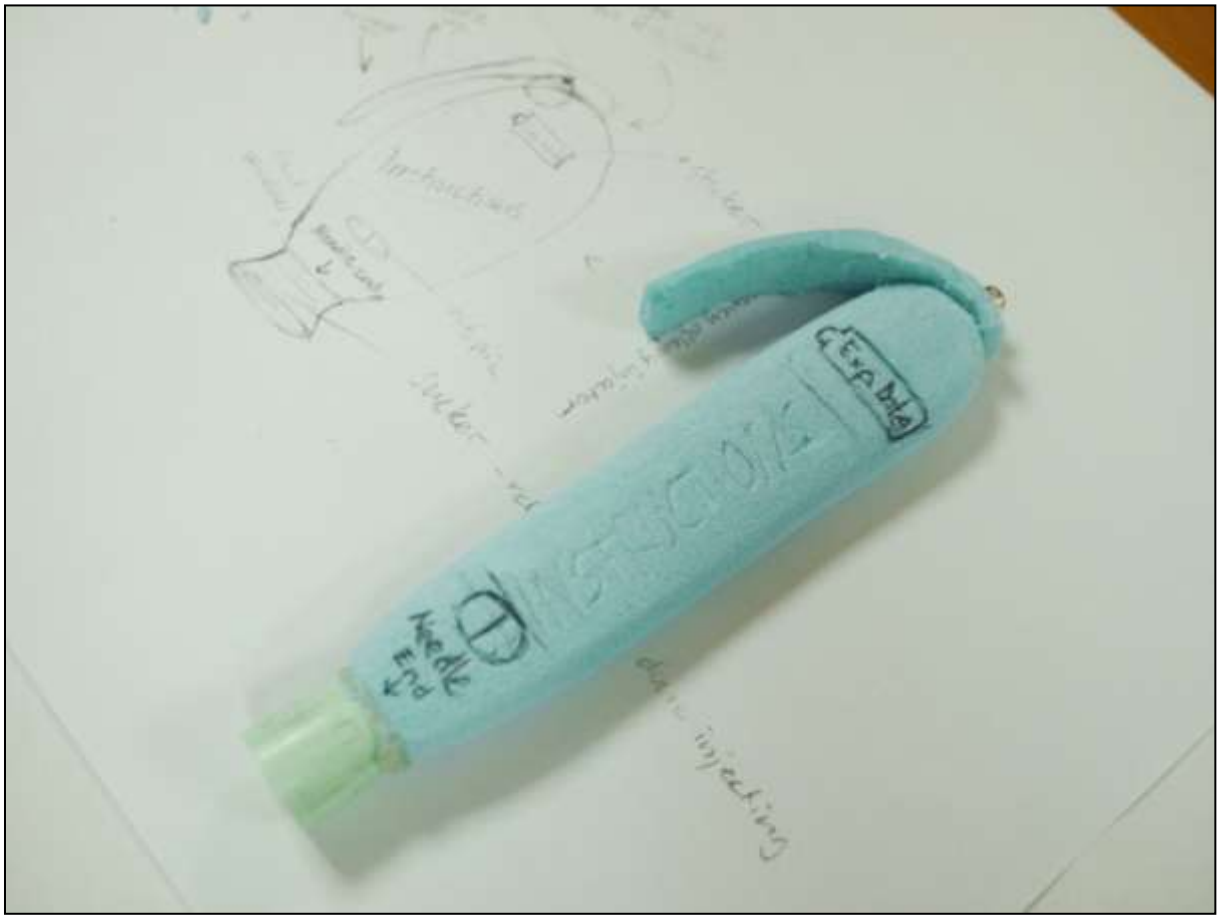


Figure 10.8. *Hand grenade concept*

Injection type	
Size and shape	Oval slim
Trigger	1 ever to push/grip
Com. injection time	Sucker and arm relieves when done injecting
Com. Needle	Arrow + text label at the bottom
Safety levers	Sprint to pull out above the arm to activate the arm and sucker
Instructions	On injection
Practice/demo	Guide to web page
Fluid	Ref picture
Expiration date	Perm label + sticker
Com. what it is for	Big red label on the side
Exposed needle protection	Automatic withdraw + cap
Carrying	Possible to add poppers at the back

10.4. Final analysis

The use of the matrixes wan an effective tool to the number concepts from the early concept generation phase but yet optimizing the new concepts. Many of the concepts from created in the second loop phase looked similar to some of the early concepts and were also referred to as improvements of the previous concepts. This is however not entirely correct as most of the sub solutions has been changed for most of the concepts but there are a lot of similarities in shape and some key features that survived the matrixes which creates this illusion. It was however a found to be a more beneficial approach to view them as during these development phases as this made it easier to remember them.

It was during this phase that the concepts could be evaluated in 3D but also by touching for the first time as soft models were created. It contributed to a whole new level of examination and rough dimension need to be determined. This made parts of the further evaluation easier as it was obvious that some concepts were un able to be shaped as they were first indeed and hence lost parts of their value. There was however a need for more evaluation before two final concepts could be designed and selected, which is why a groups discussion was held internally together with two design engineers at SHL. This phase is referred as the concept selection phase which is part of both the concept generation step and the concept selection step.

11. Concept development loop 3

During the internal discussion with the two designers at SHL, it was determined to develop two final concepts for testing with two different approaches; a realistic approach and a futuristic approach.

The core ideas that dominated the six concepts were; one that was based on a platform at SHL where the technology already existed to produce the injector and the other was a more explorative one, with no defined ideas regarding how to solve the mechanical problem. Since the project was limited to only focus on the functional design and not the inner mechanics, there was no specific time dedicated to problem solving of the inner mechanics.

11.1. Electra Fusion

The realistic approach is based on the concept Electra where the choice was to use the 03.ml syringe and 12mm needle. The modifications made, by adding functions and features from the other realistically oriented concepts was, among other things, to let the grip from SingAlong be an optimal extra feature if wanted by the customer. The grip should be an individual part that could be assembled or disassembled by the customer him or herself. Another added feature was to use the PET bottle seal solution for the cap from the Twoister. A second feature influenced b Towister was that the instructions were decided to be located inside the cap on an external sheet. The solution to have a removable sticker of the expiration date, with a permanent sticker underneath, used on the Hand grenade we the final addition to the Electra that was renamed to Electra Fusion. No other features was changed apart from this but one; the vibration that was supposed to assist in the mediation of the information that the injector was injecting was discarded since it be uncomfortable for the patient. The functional design of the original Electra did still apply for Electra fusion.

Electra Fusion was then 3D modeled in a CAD based software after a thorough investigation of the dimensions of the platform which it was based on, see figure 11.1. and 11.2. The dimensions were then scaled down to half of its size but for the syringe that was scaled down to a third.

Figure 11.1. *Electra Fusion – with cap*

Figure 11.2. *Electra Fusion – Without cap*

For detailed computer added sketched displaying dimensions etc, see appendix 6.

11.2. MicrojectAssembler

The Futuristic approach is mainly based on the Assembler concept. The only modification done to the Assembler is that the grip was enhanced to facilitate the understanding of how to hold the injector while injecting but also to help communicating where the needle was located, see figure 11.3. This was inspired by the Microject which is why the new concept was renamed to MicrojectAssembler. The functional features of MicrojectAssembler is the same as for the previous Assembler concept.

Figure 11.3. *MicrojectAssembler*

For detailed computer aided sketched displaying dimensions etc, see appendix 7.

11.3. Final analysis

The combination of the four realistic concepts provided the concept Electra fusion with features from the remaining three concepts. Even though this was the most optimized concept with the most optimized sub solutions there were no guaranties whether or not it would actually work out in reality. The same applied for MicrojectAssembler. It was now time to conduct some testing on other people to se how intuitive the interface actual was. And as it turned out; some of the features from both Electra Fusion and MicrojectAssembler were disregarded after testing loop where as others where enhanced. The following phase of the concept development loop 3 is referred to as concept testing, where usability of the two selected concepts were tested, which is the final part of the entire concept development of this project.

11.4. Concept testing

The following chapter will reveal the test results from the usability testing. The results from each question are followed by an analysis of the results and finally statements of what actions to take based on the analysis.

This chapter will also describe the results from the tests made with the help of the instructions label of EpiPen which was the foundation of the test of the instruction label of Electra Fusion. The results from testing of the instruction label of Electra Fusion are also described below.

12.4.1. Electra Fusion – General part

Body part to inject in: All subjects were insecure about were to inject. Half of the Swedish subject thought initially hart but they all also mentioned leg or thigh as a possible part to inject in. Only one mentioned more than two possible body parts. 3 out of 4 Taiwanese subjects thought thigh. However, they are more familiar with injections the Swedish subject which is why they might already knew the correct answer.

Analysis: It is not obvious that the injection should be injected in the thigh.

Action: Clear instruction on the injection stating where to inject

Grip: 5 out of 8 believe it is the intended grip. One out of these five changed its mind after reasoning about the small size of the pen and changed to a pen grip.

Analysis: There is a need for an extra instruction as the shape are not intuitive enough. Since 62,5 of the subjects could guess the right grip, it should be easy to understand it with some extra guidance. The shape however should not be changed as it has been proven intuitive for other important factors, e.g. where the needle is etc.

Action: Clear instructions with illustrative picture; how to hold injection

How to use: They all guessed the intended needle end but else differed in their descriptions. It was clear that they all was looking for a button, they either thought that the intended display in the rear was a button or the intended window/windows or both. One out of the eight did however draw the conclusion that there was no button. They also did not know the hold the injection for 10 seconds while injecting.

Analysis: It is interesting that they all were looking for a button as a trigger function. If they would have been actual customer the test result would probably would have had another outcome since most of the injections on the market do day do not have a button. Hence, the mental models of an actual user will probably not include a button. However, the ordinary random person will have to rely on its own mental models and in this case it is probably a mental model of how a pen works. Not all pens have buttons but as the subject understand that they had to trigger it somehow, they all seemed to think that a button was the only possible solution. Hence, having a button would probably be the most intuitive way to trigger the injection for a non customer. This should not be too much of a problem for the actual customer neither since they have probably have the same mental models about pens as a random person. Another implication is that there have been injections on the marked before that did have buttons and many customers have used these injections.
It might be a bit odd that the subjects did not think about holding the injection steady on the thigh

for some time to let in inject properly. This in combination with the results from the fields study indicates that there is a need for an enhanced instruction about this.

Action: Change the location of the display and use button as trigger function. Place a large instruction along the side of the injection stating that the injection need to be held steady for 10 seconds while injection before pulling the injection out.

11.4.2. Electra Fusion – Part A

Needle: All subject guessed the right end. However, there were some who were insecure about whether or not it was hidden underneath a cap or not.

Analysis: The intuitive shape of a pen, signalized where the needle was. Help from bottom up and top down processes. Bottom up = know where the edge of a marker pen is. Top down conclude that it is a needle instead with the help from the context

Action: None

Button: All but one think that it is a one or more buttons. All but one, out of the subjects who think that there is a button, believes that the button is the display in the rear end. Two believe that the window(s) are buttons to.

Analysis: Firstly, it was almost impossible to perceive that the rear end, extruded part was a display only by viewing the CAD drawings and the foam models. Hence, it is not valid to conclude that the actual display will be mistaken for a button, only by judging from these test results. However, the same conclusion of how the pen shape is intuitive enough to guide the user to find the needle end, could apply here as well. As many ballpoint pens and markers have buttons it might be less favorably to have a feature with a shape that looks similar to a button. Even though the shape is different from most buttons on pens, the shape itself was obviously close enough for the subjects to conclude that it was a button.
Another way of looking at it is that the subject where looking for a button to use as a trigger function. It might depended on it shape of a pen or that it would be strange to have a trigger function where the user pound the injector in to the thigh to trigger it. Most of the subject looked surprised when they were told the right trigger function. It is fair to guess that some subjects never had heard about such a trigger function before. However, The Taiwanese engineers more used to injections were familiar with the trigger function but 3 out of 4 yet looked surprised when told about the intended trigger function.
Either way, it might be a more intuitive trigger function to have a button instead. That will however add one more step before the injection is complete which is not preferable. But it is better that the user, who might be a person with no experience of allergy injections, easily understand how to use it. The trigger function is the most crucial operation in the task of giving the injection and it is hazardly to have a trigger function that a possible user does not even have a mental model to support.

Action: Extrude the shape of the button even more and use it as a button instead of a display. Place the display elsewhere.

Cap: All subjects but one thought that there was a cap. There was however some uncertainties in most cases, but when they had to decide they all said that there was a button.

Analysis: The reason for the doubts is probably that they perceived the cap as shorter than a cap on original markers. If the cap would have been longer an also clearly cover a small lover part of the lower (needle) end it probably would have been easier to conclude that there was a cap.
It will intrude on the space for instruction if the cap will cover more of the surface. However, one of the male subjects thought it was too short to grip around and did not think that was the intended grip, which is why it might be a good idea to extend the length in favor for both the instructions, the extension of the cap and to make it more grip friendly for users with large hands. It could have serious consequences, if accidentally inject in any part of the hand due to a too small injection. Even though it will increase the size, which is the main concern of all interviewees from the user study, it is always important to prior safety first. Increasing the length will reduce the risk a user injury and at the same time contribute to a more user friendly interface with indirectly will reduce the risk of a possible user error while performing the task of giving the injection.

Action: Enlarge the cap and extend the length of the injection. Make the cap longer but also a slightly larger diameter for it to look like it covers a small part of the lower (needle) end. Make the body longer in favor for the extension of the cap, space for instruction and large handed users.

Instructions: They all thought that the instruction should be on the injection more or less. No one seemed to even think about having injections inside the cap to fold out. Someone even mentioned that it should not be any instructions to fold out while in the serious event of having a person with a severe allergy reaction.

Analysis: It might not be preferable to have the instructions under the cap since no one seems to expect that. The injections out on the Swedish market today do not have instructions underneath their caps neither which is why it does not support the mental models of the users neither. However, the interviewees from the users study requested more general information. Some of these test subjects were also talking about after care etc and to have more detailed instructions somewhere else than on the injection. They still meant that there should be very simple instruction on the injection even though there was an extra sheet with instructions somewhere else. It could be a good idea to have more detailed instructions under the cap, but also some more general information about after care etc. Since the cap will be pulled of anyhow, the information note will be found. But since it might not be the first place that the user will look, it is probably good to have instructions in the injection as well. The user might not even look at the note in a moment of panic.

Action: Have instructions; illustrative pictures and keywords on the injection. More detailed instructions, general information and after care will be placed underneath the cap.

11.4.3. Electra Fusion – Part B

Window with reference picture: There were many different theories regarding the window. They all had different ideas but some ideas were similar in that way that many thought that it was some kind of indicator. Some thought it was to see medicine, others to see that the injection was complete, maybe even see the needle etc. But there were also some subjects who thought it was a button ar buttons, either activation buttons or trigger buttons. They did not really consider the reference picture at all and some did not realize that there were two windows.

Analysis: Firstly, it should to be stated that it was slightly hard to see that the window was transparent from only looking at the CAD drawings. It will be much clearer that it is a window in

reality. However, the round shape with the picture, looking like a dot in the middle, might increase the chance of perceiving it as a button. Secondly, it was not originally intended to have two windows like shown on the CAD drawings, which is why the blue foam model only had one window, which might confused the test subjects.
If the edge of the window would have been extruded from the body, it would probably look less like a button since it would be hard to press the small area of the window, if there is an extruded circle around it that the user's fingertip would have to fit in to.

Action: Extrude the edge of the window by 1.5 mm.

RQ-Code: Everybody understood that the RQ code was intended to be scanned with a cell phone and they all thought that it was to get extras information about instructions and more general information. Most of the subjects thought that it could also be instructions about the injection itself. Other frequent suggestions were that it gave information about the brand, medicine and the expiration date but there were also thoughts about how it could be liked to a webpage with more information or an app and somehow also provide a demonstration video.

Analysis: As all the test subjects was under the age of 35 and educated in the technology sector, which might had an impact on the fact the 100% of the test subjects were right regarding how the use RQ-code. However, the fact that they all also expected to gain extra information, regardless of the content, may have other reasons than youth. Most of the interviewees from the field study requested more information than what was given on the injections today. Maybe people want to know more by nature and therefore search for a source of more information.

Action: Place a label in conjunction with the RQ-code stating: "Scan for more info"

Pen clip: All but one mentioned that the open clip could be used to carry it in on some way. Most of them pointed or mentioned breast pocket but also the collar of a shirt was mentioned. None of them thought that it had any other function even though some were specifically asked if they thought so. However, many of the subjects, including the subject who did not mention that it could be used to carry in a pocket, thought that it gave the pen a more intuitive shape and helped them to determine in which end the needle and the thought button was. Some also meant that this was a functions in itself.

Analysis: It is fair to conclude that the pen clip actually does communicate useful information since most of the subjects thought that the pen clip made the shape more intuitive. The fact that all subjects also guessed correctly regarding where the needle was strengthens this theory even more. Since no one doubted that the pen clip could have any other function, even when specifically asked, it is probably designed in a way that prevents the user from believing otherwise.

Action: None.

Display: All subjects but one thought it was a button

Analysis: See the analysis regarding buttons in Part A 1.

Action: See the action regarding buttons in Part A 1.

Speaker: Only one subject thought it could be something like a speaker; that it might play a song or e tune while injecting. The other hade different ideas but no one had a clear picture of what it was. Two subjects did not have any clues at all. A few thought it was to enhance the button and few others thought it could have something to do with twisting tings, maybe what they thought was a button. One subject thought it might be a lever for air pressure and another one thought it had something to do with indicating time as it was 12 dots. In total, two subjects thought it had something to do with indicating the time while injection.

Analysis: As mentioned before, not all things are realistically presented on the CAD-drawings, which may have had an impact on the results of this part of the test to. However, the speaker need to be relocated, since the improvement of the injection will include a button in the rear end. It is not preferable to have a speaker that will be covered by a thumb. A relocation of the button to the side of the injection will also enable the speaker holes to change shape to look more like a speaker. However, it is not curtained that a user will understand that there is a speaker at all because it is not something that the user expects the injection to have. It does not matter if it is a user who is familiar with injections or not. If not familiar it will fall back on its mental models of a marker pen. A marker pen does not usually have a speaker. Hence, it is not something that the user is looking for. The bottom up processes may have a clue about the size and shape but the co working top down processes will probably guide the human information process to come to the conclusion that a speaker does not belong on a pen and therefore conclude that it is something else. However, since this is an automatic feature that only exists to facilitate the counting operation when injecting and hence it not a crucial feature, its recognition is subordinated. Especially, since the sound of it will reveal its function. This is why it is better to make sure that the speaker is located at a place where it will be heard instead of paying too much attention to how well it is recognized.
Places where there are spaces available, on the body, are probably in both ends. When the subject held the injection correctly it was obvious that they tried to hold their hands in the middle of the body, leaving a few millimeters of the body visible on both sides. Since the body will be longer with the new improvements, more space will be left on both sides. With the new improvement to have a button in the rear will probably lead to that the user will have a grip that leaves a little more part of the body visible in the rear end since it will be more comfortable to hold it and press the button at the same time. This will leave more space for a possible speaker in the rear end, but still on the body.

Action: Place the speaker in the upper end, but on the body and not on top.

Expiration date: All subjects but two, thought it was the expiration date, the others thought it was a product number or a serial number respectively. Most of them did not have any clues about the tag. One thought that the label could be removed to see something else and a second one thought it was a sticker to remove in order to see the expiration date which the subject felt was very odd.

Analysis: The two subjects who did not think of it as an expiration date might would have thought differently if would have been an actual sample of an expiration date number instead of only X:es. Since 80% had no doubts it meant that the design of the expiration date label was relatively feasible. The sticker function however, needs to be enhanced, as well as the function of it. If the tag would have been red and clearly represented in a way that it would have been possible to see that the tag was not glued on and loose, it could have had another out come on the test. Since this is not a crucial

feature it should not be enhanced by another text label as this might interfere with more important information like user instructions etc.

Action: Make the tag red and almost curled in order for the user do perceive that there is a tag.

Additional analysis: It might be preferable that the needle automatically with draws when done.

11.4.4. MicrojectAsembler – General part

Grip: Half of the subjects guessed the intended grip. However, one of the others found a different way of grip that would work just as fine as the originally intended grip. The other three subjects had different ideas, whereas two out of these three held it upside down thinking that the needle was in the rear end.

Analysis: It was hard to see, from the drawings and CAD models, that the tube was a medicine container. Hence, the mistakes of concluding the incorrect needle end. However, there were some doubts for a few of the subjects even though they concluded the intended needle end. This indicates that the grip need to be more enhanced.

Action: Enhance the grip more by hollow out the space for the point and long finger.

How to give injection: Most of the subjects who got the needle end right had a pretty good idea of how to give the injection even though some of them mistook the orange part for being a cap and added that as an extra step. They also understood that they should press the tube down but not all the way, then put on thigh and then push it the whole way.

Analysis: the most crucial part of giving this injection is that the tube should not be pressed down the whole way until the injection is places on the patient's thigh. Since, practically all of the subjects, who got the needle end right, also understood this, this must mean that the interface is sufficient in this matter.

Action: Give clear instructions in conjunction with the injection, regarding the crucial procedure of inserting the tube.

11.4.5. MicrojectAssembler – Part A

Needle: Like stated before, two out of the eight subjects had the wrong idea about the needle end.

Analysis: The result may depend on the fact that it was hard to understand that the tube was a medical container and the lack of this knowledge may have had an impact on the results. The tube is not transparent on the CAD-drawings, which it should be on the real product. It might also need to be indicated where the needle is, somewhere on the injection.

Action: Make sure to have a transparent tube. Indicate where the needle is by adding a label in conjunction with the needle stating “Needle end”.

Button: Again the same eight subjects, who guessed the correct needle end, also thought that the tube had the function of a button.

Analysis: This probably means that if the user know where the needle is, then it is relatively easy to understand that the tube has the same function as a button.

Action: Give clear instructions in conjunction with the injection, regarding the crucial procedure of inserting the tube.

Cap: Five of the eight subjects thought that there was a cap. There were however uncertainties regarding this matter on both sides. They were confused regarding whether or not the orange part was a cap or not. Some also changed their minds along the test. One of the five who thought there was a cap had the wrong idea about the needle end and thought that the tube was the cap. The remaining four thought that the orange part was a cap.

Analysis: It looked like a joint between the orange part and the white part on the injection body. Hence, it may have looked like a cap that could be removed.

Action: Change the color appearance so that the white smoothly fade to orange and remove the line that looks like a joint.

Instructions: Seven of the subject thought that the instruction should be on the flat side of the injection even though it is very small. Some said that it should be a small, single words description with two or three pictures. Others said that more sufficient instructions could be placed on the packing and one thought that the instructions were inside the tube.

Analysis: Maybe people want to be sure that they have the instruction and for that reason still want them to be on the injection regardless of how small it may be.

Action: Place a single worded instruction with pictures in the injection but also have more sufficient instruction on the case or the packing.

11.4.6. MicrojectAssembler – Part B

Transparent part: There were some questions about this and it is clear that many of the subjects did not know if this part had any function at all. But there were one who thought that this was something to twist, although in this case the subject thought it was to activate it. Another thought it was a stand for the medicine tube.

Analysis: This is a shape that the user is not familiar with which is probably why they did not guess the correct action.

Action: Clear instructions how to use it should be placed on the packing.

11.4.7. Instruction label

As mentioned before, the testing sequences of the instruction label of Electra Fusion will be described in this chapter together with the pretest made on EpiPen. The tests on the EpiPen was the foundation of the test designed for the new instruction label for Electra Fusion. Nine people participated in the tests in total and they are referred to as TPX, where TP stands for "test person" and X represents the number of the order in which they were tested in.

Instruction label of EpiPen

There were three test subjects that took the first test of the EpiPen. Two Swedish persons and one who was Finnish. During the first test of the EpiPen , the subjects were told to locate and read the instructions, displayed in figure 11.4. and once they felt as they had perceived the instructions they instructed to say the word "stop". The time was documented and notes were taken regarding how well they could retell the instructions. Figure EpiPen instruction label show the appearance of instruction label which the test subjects were to find and comprehend. Here are the results of the first test round:

Figure 11.4. *EpiPen instruction label*

TP1: 55.88 seconds, correct, but was a little vague regarding the trigger function; weather to pound the injection against the thigh or if it was enough to just put the injection against it.

TP2: 26.20 seconds, did not say anything about holding it for 10 seconds, else correct but a bit vague in total.

TP3: 45.8 seconds, believe incorrectly that the blue part is a button to push and did not mention the anything about holding it 10 cm away from the thigh before pounding it again the thigh which the subject evidently did not think was the trigger function. The subject did however start to read on the back of the injector which may have increased the stress level.

This was considered to be a relatively realistic test round as the subject got a little anxious just knowing that they were being timed which could correspond to a real situation that involves a great amount of anxiety due to the serious circumstances of the situation. The fact that one of the subjects also started to read on the back of the injector is also a proof of the challenges of finding the instruction and how that may delay the process of giving the injection.

The result of the first part was, like mentioned before, used to determine a specific amount of time that the following three test subjects were given to find and comprehend the instruction of the EpiPen. As the purpose of this test is to gain test results that could be compared to the results from the test of the new information label of Electra Fusion, the time was determined to only 25 seconds. The reason for this was that the aim of the new instruction label was that it would be able to be perceived in about half of the time as the one for EpiPen which based on the test results from part one would be about 25 seconds when accounting for the errors that were made by the test subjects when retelling the instructions. Hence, it was interesting to find out how much information that would have been left out if only given 25 seconds. This could also create a situation with some similarities to the real situation as the subjects were being even more stressed out due to the short amount of time, a stressor that is highly present in a real scenario. In some cases, an increased amount of stress could lead to and increased performance according to Atkinsson (2007) as long as the perceived ability is in balance with the demands. If the demands are perceived higher that the ability to complete the task, the level of performance will decrease. This is also something to account for while designing the instructions and hence it was of great interest to study the results from this test:

TP4: Almost correct but did not say how long the injection should be held not did the subject say anything about calling for ambulance after use. The subject did however emphasize that the injection should be held for some time, the subject just did not say for how long.

TP5: Correct but said that the injection should be held steady for 20 seconds instead of 10.

TP6: Correct but forgot to mention to hold the injector 10 cm away from the thigh before pounding it against it.

The part found interesting after monitoring the results is that the general impression of confidence was better when the time was limited and it was almost the same error that were made when retelling the instructions. This may have been a result of an increased anxiety that according to Atkinson (2007) could increase the performance. The reason for the common misunderstandings or oblivion, regarding the time span to hold the injection while injecting and the distance from which the injection should be held from the thigh before pounding, may have something to do with potential flaws in the design of the instructions.

Instruction label of Electra Fusion

The instruction label of the Electra Fusion was tested by the same procedure as for the second tests of EpiPen where the subjects were given the injection and had 25 seconds to locate and perceive the instructions. After the 25 seconds they reported what they remembered without watching the instruction as the same time.

This time, the instructions were in English and the test subjects were not English speakers by mother tongue. Four out of the six subjects were Swedish and were fluent in English where as the other two were Vietnamese and not fluent in English. The Vietnamese Subjects communicated their results in a combination of Chinese, English and body language but it was not a hindrance when receiving their response regarding retelling the instructions.

The subjects were also from different academic backgrounds but they were all students. There were three engineering students, one in law and two that was conducting language studies.

All Test subjects gave the correct explanation after the 25 seconds, but one who forgot about how long time to hold the injection for when injecting. This could depend on the fact that the time is mediated as a second task of the third, the final step, on the instruction label. This is the only step that has two tasks and there is no firm distinction between them, like it is between the previous steps. The reason for this particular design was not to confuse the user to think that it was a fourth step as the two tasks need to be carried out simultaneously.

In total the results were extremely positive and some of the subject even put the injector, with the instruction label, away before the time was up but yet delivered a detailed and confident, correct explanation. The time was noted for two for these cases who gave the injector back after 17 respectively 20 seconds but there were also other subjects who considered themselves dome before the time was up but yet kept the injector for the rest of the time as well.

Again the, great results could have been a result of the increased amount of anxiety that increased the performance but as they were all correct, but an insignificant part of one test, it is fare to conclude that it also was a result of the interface design of the instruction label. This especially since the previous test with EpiPen was made on native Swedish speakers that had to understand an instruction label written in their native language, Swedish, where as the instruction label of the that Electra Fusion could be successfully assimilated by non native speaker English speakers. The fact that people that are not even fluent in English could give a correct description enhances this conclusion even more.

One of the main differences between the EpiPen and the instruction label of the Electra Fusion is the increased focus on the use of explaining pictures in favor of text. The instruction label of EpiPen has a lot of explaining text, in very small characters and only a few pictures that are relatively vague. It also has text written in both Finnish and Swedish which contribute to the confusion that many of the test subjects reported after the tests with the EpiPen which is eliminated on the instruction label of the Electra Fusion. The dual language also conduces to decreasing the characters which makes them harder to read. According to Boghard et. al. (2008) is there a special relationship between the font size and the reading distance that needs to be accounted for. This factor is poorly accounted for when it comes to the instruction label of EpiPen but taken seriously when designing the new label as this was something that was highly mentioned during the interviews. The relationship can be found in Appendix 1. There was however one factor that was equally regarded in the design of both labels which is the use of black color on a yellow background which according to Boghard et.al. (2008) provides the greatest contrast.

The final advantages of the instruction label of Electra Fusion compares to the one for EpiPen are the distinction between the steps that clearly divide the instructions into four tasks. The other advantage

is that the instructions are horizontally represented instead of vertical. As most information or text is vertically represented it is fare to conclude that it is relatively more generic to read horizontally and hence faster to interpret. The clear distinction between the tasks communicated as steps are also more supportive for the human cognitive recourses as Atkinson (2007) explains that the human mind can process 7 +-2 units at the same time. This means that the almost all people can process at least 5 tasks but human mind can actually process even more information if this information could be categorized in to one of these units which according to Boghard et. al. (2008) is called chunking. As the instruction label of EpiPen does not have a clear distinction between the tasks there is a lack of sufficient chunking which forces the cognition to process a relatively un organized information which ultimately takes more time. Even though the instruction label of EpiPen actually only explains three steps it takes longer time to assimilate that the other display that communicates an additional step, probably because of the clear distinction between them that assist in the organization of the tasks. That there is also explaining text in another language for all tasks on the instruction label of EpiPen is most likely counteracting when the cognition tries to organize the data. The only advantage found with the EpiPen label is that it only explains three steps which may have little to with the design of the label as it is a result of the functional design but as the human cognition are capable of processing at least five things at the same time it should be even less problem processing four and evidently it was not at problem, based on the test results.

12. Final results

There are two final concepts that have been derived from the original thirteen concepts. An iterative evaluation process has narrowed them down to these final two. These two concepts have been tested on random people but also on engineers who are used to work with different medical injectors, which ultimately resulted in the following two final concepts:

12.1. Electra Fusion – product specification:

This injector is the more realistic concept based on one of the smallest platforms at SHL group, see picture 12.1. The dimensions of the size were based on a theory that the inner mechanical parts could be scaled down to half its sizes, since the syringe for this injector only contain a third of the amount of medicine as an original injector does. It is determined to be an auto injector with a 12 mm needle, penetration depth of 8 mm and a 0.3 ml syringe.

Figure 12.1. *Electra fusion with cap on*

Figure 12.2. *Electra Fusion with cap off, orange needle cover visible*

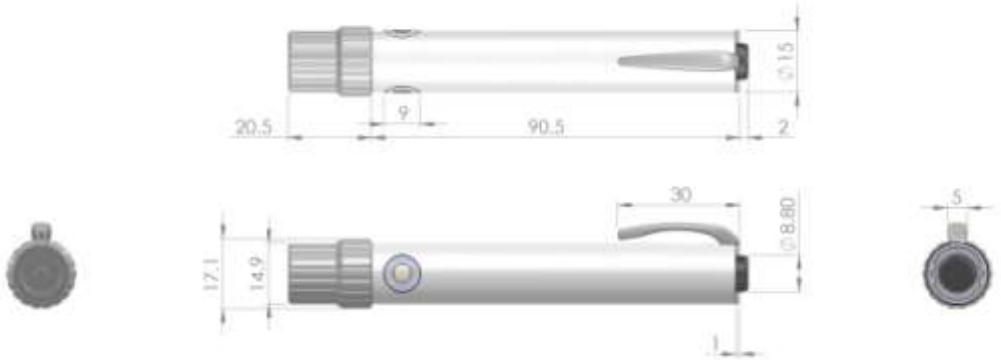


Figure 12.3. *Dimensions of Electra Fusion, with cap on*

Figure 12.4. *Dimensions of Electra Fusion with cap off, orange needle cover visible*

User instructions:

1. Remove cap
2. Place the injector on the patients thigh so that the yellow needle cover is retracted into the body of the injector, which activates the button
3. Press the button
4. Hold steady for 5 sec.

Dimensions: See CAD drawings; Figure 13.3 and 13.4.

Shape: Marker pen; see CAD drawings; Figure 13.1 and 13.2

Trigger function: Button

Safety levers: Remove cap and then push needle cover inside the injector body to activate the button

Communicate the injection time: Verbal count down from a speaker underneath the pen clip and a diode ring in the rear that indicates each second with a blink. The ring will be lit for the entire last second and for one an additional second after be for it turns of to indicate that the injection time is up.

Exposed needle protection: Needle cover slide down over the needle and cannot slide up again. The cap can also safely be put back on and provide extra protection. For example protect the patient's or the user's cloths or bag from remaining medicine that might drip off the needle.

Communicate where the needle is: The intuitive shape of the pen in addition to the positioning of the pen clip provides an intuitive understanding of which end the needle is located. To enhance the message even more, the cap will have a label stating "Needle under cap", that also includes an arrow, in the direction of a needle.

Monitor medicine status: Two rounded windows on the injection body, each containing a reference picture in the middle communicating what the medicine look like when it is adequate. There are two windows in order to allow light to shine through which will make it facilitate the operation of monitor the medicine.

Carrying: In pen clip

Instructions: On injection, numbered pictures with keywords.

Communicate what the injector is for: Big label on the side of the injector.

Communicate where the injection should be given: On the instructions

Expiration date: Sticker with date, which could be removed and put in to a calendar, permanent label with date underneath. Also a QR code on the injection could be scanned in order to receive the date into an electronic calendar but the QR code is also connected to an app that could provide reminders.

Practice: The QR code can be scanned to be directed to either a web page or an app, where it is possible to watch a demonstration video.

General information: The QR code can be scanned to be directed to either a web page or an app, where it is possible to obtain more general information about the product, medicine, after care etc.

12.2. MicrojectAssembler – product specification:

This is auto injector based on a theory that the medicine can be injected by using compressed air. It has a 0.3 ml syringe that is to be assembled and used as plunger as well.

Figure 12.5. *MicrojectAssembler with the medicine container assembled (Correct color scheme)*

Figure 12.6. *Medicine container before assemble*

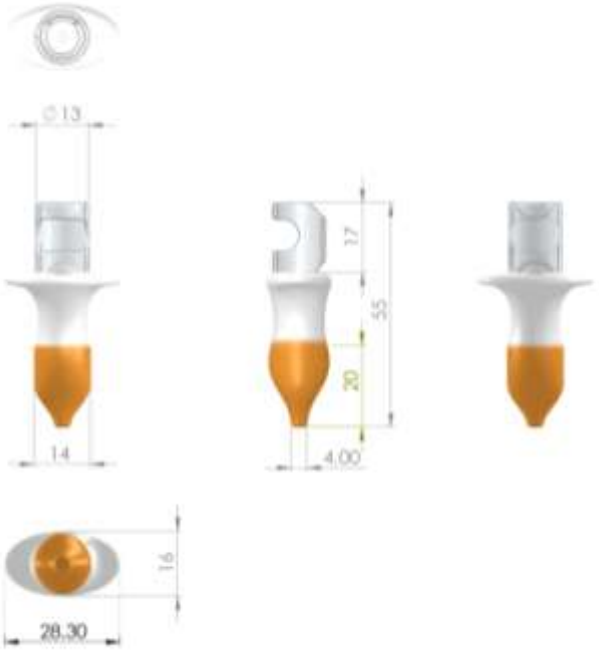


Figure 12.7. *MicrojectAssembler before the medicine container has been assembled (incorrect color scheme)*

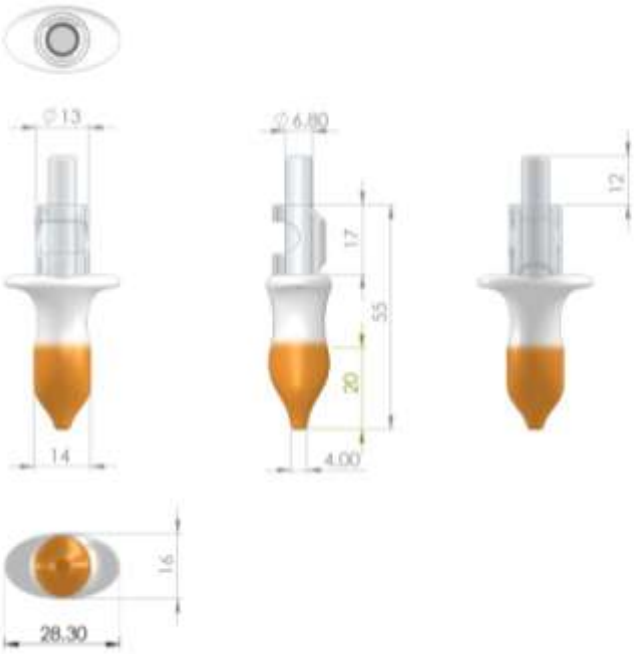


Figure 12.8. *Dimensions of MicrojectAssembler (incorrect color scheme)*

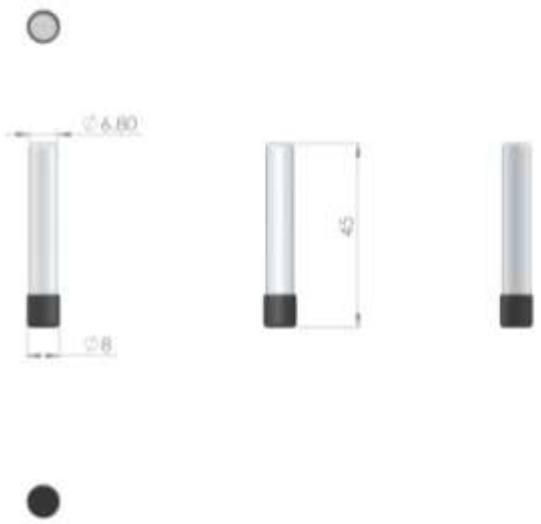


Figure 12.9. *Dimensions of the medicine container*

User instructions:

1. Place the injector on the patients thigh
2. Insert the syringe until a click sound appears (and the needle comes out)
3. Hold for 5 sec.

Or:

1. Insert the syringe half way or as far as it goes until resistance appears
2. Place the injector on the patients thigh
3. Press the syringe down until a click sound appears (and the needle comes out)
4. Hold or 5 sec.

Dimensions: See CAD drawings, Figure 13.7. – 13.9

Shape: Jelly fish and tube; see CAD drawings, Figure 13.5. and 13.6.

Trigger function: Syringe used as a but ton

Safety levers: Syringe must be assembled before it can be triggered. The injector can only be trigged by using the syringe.

Communicate the injection time: Transparent syringe, possible to watch while the syringe is being emptied

Exposed needle protection: Automatic needle with draw

Communicate where the needle is: Safety orange tip to signalize that there is something to warn about but also a label stating “Needle end” to enhance the signal.

Monitor medicine status: Transparent syringe to watch the medicine and a reference picture on the external instruction sheet to compare it to.

Carrying: In a container with the possibility to add a safety hook or key ring

Instructions: Small key words and possible pictures on the injector

Communicate what the injector is for: Big label on the container

Communicate where the injection should be given: On the instruction sheet

Expiration date: Sticker and permanent label on each syringe

Practice: QR code on the external instruction sheet that can be scanned to be directed to either a web page or an app, where it is possible to watch a demonstration video.

General information: The QR code can be scanned to be directed to either a web page or an app, where it is possible to obtain more general information about the product, medicine, after care etc.

12.3. Instruction label – Electra Fusion

The instruction label of Electra Fusion is designed according to the design principles and guidelines for human machine interaction (HMI) that are to be found in appendix Design for HMI. The only design part not covered by the appendix is the use black text on a yellow background which according to Boghard et. al. (2008) provides the best contrast.

The final step of task three is an attempt to improve the mediation of the information to hold the injection for 5 seconds while injecting. This has been poorly emphasized on most of the existing injectors and this task scored poorly when they were tested in the field study. This was also the one thing that most customers failed to communicate when they were give to task to act as they were to give instructions regarding how to give the injection. This was also something that was often forgotten or poorly communicated by the test subjects of the EpiPen instruction label. The reason for the green color on the watch and the number was that it is thought to draw attention to it. Red would have been the best color to use in order to draw attention but that also communicates danger according to Boghard et. al. (2008). They instead state that green communicates safety or “ok” which is why it was used instead.

Figure 12.10. *Instruction label of Electra Fusion.*

12.4. Analysis – Final results

This chapter will discuss the final result with respect to the given objectives of the project. It will mainly focus on the second objective, the list of user needs derived from the user study. This list will be the core structure of this discussion but objective 1; the analysis of the existing products on the market today will also influence the discussion to a reasonable extent, together with the complimenting parts of the list that refer objective 3; knowledge about the situation in which the injector will be used in. As there are many factors to discuss, only the needs rated with an importance level of 2 or higher will be discussed.

12.4.1. Electra Fusion

The interface design of Electra Fusion could be considered an improvement of the pen injectors out on the market today. It is smaller, more intuitive to use for an inexperienced user and has been designed according to methods and guidelines for human machine interaction. This section will analyze the sub solutions of different levels of the design of Electra Fusion starting with the sequence of tasks that needs to be fulfilled in order to successfully give the injection.

Since the injection is to be given in a time of emergency it is fare to conclude that it also will contain a lot of stress, both for the user but also for the patient, that could be the same person. Several researchers like Atkinson (2007), Arent and Landers (2003) to mention some, states that stress can have a negative impact on performance if there is an imbalance between the perceived ability and the demand from the task, where the perceived ability is perceived lower than the demand from the task. This is directly related to mental workload which affects the perceived ability. Mental workload ins in its turn related to the use of multiple resources where Ward (1996) mean that the human cognition only has a limited amount of recourses to use and a stressful situation like this may uptake a large amount of the resources for some users as all the scientists agree that stress, MWL and the cognitive capacity differ between individuals.

Since there may be a small amount of resources left to perceive and complete the task of giving the injection, it is important that the sub tasks are intuitive to carry out both by an experienced and an inexperienced user. Therefore it was considered to design the tasks with respect to an un experienced user but yet account for the support of mental models of the customers that are already used to how their injections works to smooth the transmission. The reason for choosing to focus on a design for inexperienced users was further strengthen by the fact that most customers have never used their injectors.

The development work focused on designing a sequence of task with as few tasks as possible, to reduce the mental work load and also the time the patient has to wait before the injection is completed. EpiPen scored the highest during the HTA analysis as it has fewer actions to carry out then the other investigated devices. The EpiPen is triggered by pounding the injector against the thigh and reduces the two steps, of placing the injection on the thigh and then carry out some trigger task, into one task. The fact that it does not have a cap to remove makes it even less troublesome.

However, as there was a need for the user to have a secure impression about safety levers it was determined to use a cap. The existing Products Emerade and Anapen does also use caps but they scored poorly on the EWC regarding if the user will understand and/or try to carry out the right task, in this case remove the cap before use. Possible reasons for these results were the shape and color

schemes of the injectors which is why the Electra Fusion has a typical shape of a marker pen which with a clearly visible cap that also where enhanced after the final tests.

The second additional task of Electra Fusion compared to EpiPen is the separation of the task to place the injector on the thigh and then use a trigger function in this case a button. The trigger function of EpiPen was as stated before thought to be the trigger function of Electra Fusion as well. After the final testing it became clear that people were looking for a button which is why it was decided to use a button as trigger function instead. It is true that less tasks to carry out is better but if the tasks are not intuitive enough for an inexperienced user to carry out it might be better to add an extra task if that makes the sequence of tasks easier to carry out. Experienced users, customers and related people with experience of injectors should also be able to adapt to this sequence of actions as it supports mental models of some of the existing injectors like Anapen and ConfiDose but also partly supports mental models of the others. It mainly supports mental models of how to use a marker and/or a ballpoint pen which is a possible reason why the most of the test subjects thought it was a button to trigger. This yet another reinforcement to support the decision to use a button as a trigger function. The support of mental models will decrease the mental workload which will decrease the stress level in that way that the demand of the task will be perceived lower. Stress, as mentioned before, could have a positive impact on performance but as this is a very important situation it might be better to use every mean to decrease the perceived demand from the task as it is more likely that the severity of the situation pushes the user over to the right side of Yerke's & Dodson's (1908) inverted U-hypothesis.

The shape has also been considered from an intuitive perspective. As mention above, it is probably relatively easy to understand that the caps should be removed and thereby probably that also easy to understand the needle is underneath. To reduce any final doubts about where the needle is, it was decided to also use a label and an arrow stating "needle under cap". The letters on the label is however smaller than what is recommended by Boghard et.al. (2008) as the font size as been calculated to for a reading distance of 71cm. This is a result or the compromise made between many important factors and the fact that seven out of the eleven customers explicitly said that they wanted a small injector but all 11 indicated this in different ways. Another factor considered for the intuitive shape is the use of the clip as a sub solution to carry the injector. A pen clip may not be the most efficient sub solution for this matter but it contributes to making the injector more intuitive to use. It could be considered to use a kind of solution that appears to be a pen clip but with a possible buckle that could be used to safely carry it in a belt or strap on a bag for example, with no risk of falling off. The pen clip in combination with the cap does however reduce the need for a cover. Even though the scope of this project did not include a development of a cover it is from a user perspective positive not to have a cover as a cover may be less intuitive to remove than a cap and the instructions are visible at all times.

Another thing that would be visible at all times without a cover is the label with large red letters stating "Emergency allergy injector". It has been placed clearly visible horizontal along the body of the injector in order to communicate what it is for in a case of emergency when the injection has to be found quickly. The use of the red color is that it, according to Boghard et.al. (2008), communicates danger. One problem that was bought up by some of the customers during the interviews was that they wanted the injector to give a serious impression as they had experienced difficulties when it comes to be taken seriously. Some had experienced that others had thought that their current

injectors were toys and hence it became even more substantial to accommodate for this problem, which is why this information got an even larger share of the surface area of the injector, than actually needed to be read from a distance of 71cm.

There has also been a discussion whether or not to put a medical cross on the outside of the pen clip. This might conflict the discretion of the design which is not preferable as many of the customers wanted it to be discrete. It would probably from a user perspective be better to have the cross when in the situation of finding the injection fast.

If continuing to discuss the size it should be mentioned that a large step has been taken towards reducing the size by using a syringe that only contains 0.3 ml instead of 1 ml as the injectors normally contains today. 0.3 ml is the dose needed according to the pickings' of the auto injectors out on the marked today but they all contain 1 ml which makes the injector larger. When trying to find out why the 1 ml syringe was used instead of a 0.3 ml syringe, there were many different ideas regarding this issue. The search was done internally and some stated that there could be problem with the durability of the medicine. Other meant that it could have something to do with patents or the fact that this has never been tried before. Finally there were indications saying that it there were no production lines for a 0.3 ml syringe today and hence not considered feasible to change. Probably due to the small amount of customers compared to the costs of the change. However, there were finally also great indications uttering that a 0.3 ml syringe would be durable with today´s technology. As no accurate information was provided whether or not the 0.3 syringe could be used, it was decided to create a concept with a 0.3 ml syringe as the concepts it supposed to be a guide line displaying what the customers want. Since a key issue for the customers appeared to be about minimizing the size, it was considered justified creating a smaller concept with at 0.3 ml syringe.

The appearance questions, that was partly mentioned earlier was one of the toughest tasks as the opinions of the customers had a great diversity, mainly depending on age. The most of the adults and some of adolescents wanted a discreet injector whereas the children wanted a more playful and distracting design, which is why some of the age categories hade to less focused on. It was however still hard to accommodate all wants and needs even though the project was limited to adults and adolescents. This was solved with a compromise where the colors of the injector was neutral and discreet, the shape of the pen could also contribute here but there are also possibilities to use other colors than white and gray, even use a transparent material to view the inner mechanisms which would be highly appreciated by young boys and male adolescents according to what was said during the customer study.

The present colors; white and gray do however have another purpose. The injector is very similar to a marker or a ballpoint pen and there may be a risk of misuse due to this. To compensate for this it was decided to try to design a marker pen that no one would like to use. Most people will most likely use a marker pen that is black, clue, green or red in order to use the colors to draw attentions to what they have written. This the reason for choosing light gray as cap color as less people would choose to use a light gray marker. White was then chosen as a background color, not to interfere with the indication that it is a gray pen. The changes of color schemes may have a higher chance of resulting in misuse, which ironically would be worse for children that are the age category that would potentially benefit from the change of colors.

Other contra dictionary difficulties have been related to size. As mentioned before, all the interviewees from the customer study wanted a smaller injector than what they have to day. The want it to fit an average pocket so that no extra bag would have to be carried and then also fit their movement patterns and be no hindrance when they are living their daily life. It should with other words be convenient to carry at all times. Since there are recommendations, as mentioned before, of the size of letters to be read from a certain distance, the instruction label had limitations regarding the dimension. It could have e slightly smaller but on the expense of what key words to use on it. Hence, one of the factors that hindered the reduction of the length of the injector was the size needed for the instruction label. Due to the pen shape, there also had to be a compromise between a small size and the fact that the injector needed to be safely grasped by an average hand without risk of injecting into the lower hand of the user if the hand is bigger than the injector is long.

It would however also have been preferable if there would have been a shape of a grip on the opposite side of the instruction, not to interfere with them but mainly to indicate that the pen should be held with the whole hand, and not like an ordinary pen which is indicated by the shape. This unfortunately forgotten when creating the final CAD drawings but would be strongly recommended if this design is ever to be implemented.

Another drawback with having an injector as small as possible was that there was no space left on the injector body to have an extra label stating “inject into other part of the thigh” as was decided up on earlier. This could be a problem as information sating that people has different ideas were derived from the customers study. The information on the instruction label could probably be considered comprehensive enough.

The instruction label was however designed with font size as mentioned before which is preferable and the balance between the size of the injector and the size of the instruction label was considered to be in balance. The instruction label has been clearly divided into three tasks where the third task has been divided into two subtasks. The design of clearly expressing 3-4 tasks has been based on the knowledge of memory functions explained Atkinson (2003), who states that the human mind can process 7 +-2 units at the same time. The use of 4 tasks to carry out has been explained above but the decision to clearly separate the four tasks has not been mentioned. It is simpler to remember the 7+-2 units if they are clearly defined. They are harder to perceive, if they are described in a continuous flow of information where the user first has to cognitive organize the tasks and put them in to separate available resources. One down side by dividing the third task in to two subs task is that the second task may lose focus when reading the instructions as it may seem like some extra information that are not as important as the first part of the third task. This has been accounted for by using green color to indicate the time span but where yet found to be the only error made during the last round of tests of the label. This error was however only done by one test subject.

This error is however more forgiving as the injection time is also communicated by visual and audible means. The speaker is strategically positioned under the pen clip for protection but also as it seemed like less of a chance that it would be covered by a hand while using. This was the reason for moving it in the first place as the rear end will be covered by the thumb. The diode ring that will be lit while the injector is still injecting was however placed on top as it may give shining light even though a finger may be placed on top. Usually the entire area of the rear will not be covered which is why it was justified to place the diodes there. The sound would however have suffered if parts of the speaker

would have been covered. The use of multiple resources to communicate this very important information, that what one of the flaws found both when investigating the existing devices but also during the interviews, depend on the fact that it is according to Wickens and Hollands (2003) easier to process information at the same time if using different cognitive recourses. As it further is meant to communicate the same information it is fare to conclude that the information will be better perceived by using to channels of stimuli and hence room for both selective and shared attention.

If considering the instruction label further it is also designed not only by using written instructions as an illustrative picture was thought to communicate the instruction better as it may be faster to perceive, especially in a stressful situation nut also for people struggling with reading difficulties. The use of block font color on a yellow background is based on the fact that it according to Boghard et. al. (2008) provides the best contrast.

Other important issues to discuss are the sub solutions developed to solve the problems with finding and remembering the expiration date and how to monitor the medicine status. There are regulations stating that these kind of injectors need to have a window to view and monitor the medicine. The existing products that are equipped with a window states something similar to “change to a new injector of the fluid is discolored or cloudy” but there are no reference to compare to, which is why Electra fusion is equipped with a reference picture in the middle of the window for comparison. Due to the strive to keep the size of the injector as small as possible there had to be yet another compromise in that way that there were no room for any explanations about changing the injector if there was a mismatch between the reference and the fluid. Hopefully, people will understand that there is something to be taking into account if the fluid suddenly does not match reference. This was made as it was considered less important to have an explanation about this on the injector compared to the other information that at communicated in the injector and that it also was important not to compromise that information in any way.

Information regarding this should however be available in the packing but more importantly when scanning the QR-code with a Smartphone. There should be less s for a customer or user to understand the meaning of the QR-code as many products are equipped with a QR-code today. If not used to the QR-code, most of the information could be found on the injector or the packing as well. Other problems solved by the QR-code are the expiration date issue and the need for more sufficient but also general information. The QR-code should be combined with an app that could contain a lot of extra information about after care, general information about allergies etc but also provide reminders when it is time to change the injector which is a great complement to the sticker on the side of the injector body. It should be rather easy to find the expiration date without having scanned the QR-code; some people may not even have a Smartphone, which is why it was also placed on the body of the injector. The communication is also further enhanced by a sticker with the expiration date placed on top of a permanent label. This enables the customer to remove the sticker at place it in a physical calendar or anywhere the customer wants. It was considered important to have a sufficient solution to make sure that no customers carry an expired injection, as it is rather important to change an injectors that has expired, which is why there are many ways to prevent this using this design. The color scheme of the expiration label is also based on the contrast relationship explained above but with a red tip of the tag to indicate that it can be peeled off.

The final issue that the QR-code is to solve is the need for practice or at least watch a demonstration video without having to search the web for a video. Most customers wanted to be able to practice but it was found to be very inconvenient to design an injector that also could be set in a practice mode as it would have a negative effect on other important needs like size for example. Hence, it was considered to better to design a solution where demonstration could easily be watched.

The QR-code may however have some down sides. There is a risk of a misunderstanding that the QR-code should be scanned for directions in a case if emergency, even though the instruction label cover almost a third of the surface area of the injector body. This may result in a delay in the process of giving the injection, which is why it could be argued that the QR-code could be placed on the packing instead. The customer study did however reveal that most customers does not carry their injectors in the packing which counter acts the other problems that the it was supposed to solve. Hence, it might be a good idea to have the instructions as the first page of the app in case of any misuse in the terms of using the QR-code for instructions.

Safety lavers have been briefly discussed above and there is one final safety lever that has not been mentioned yet; the needle cover. The needle cover is the orange part that can be viewed in figure XX. This part has to be completely pushed inside the injection body in order for the button to be activated. The needle cover slides back over the needle afterwards and protect the needle from exposure so that no one accidently will get plunged by it after use. This in combination with the cap was considered to be a sufficient solution regarding how to carry the injection to disposal. The needle cover is an extra prevention for the user not to get stung when outing the cap back on. The cap should be put back on to prevent any remaining medicine to escape.

The original reason for using the needle cover was that it would cover the needle and that manual penetration would apply. When it became clear that a button would be use, and thereby use automatic penetration, there was a great reasoning regarding what to do with the needle cover. The first idea was to only use the task of removing the cap as a safety catch as it may be unclear and hard to communicate that the needle cover has to be pushed inside the body of the injector when pushing it against the thigh. Since the needle cove provides an extra security not to accidentally trigger the injector and facilitated the after use it remained.

Finally, it is time to focus the attention to some of the needs that has not been regarded during the development of the interface design but yet should be take into consideration. There were a lot of needs regarding temperature and environment to both store and use the injectors in. Since the scope of this project did not include material selection, it was not possible to consider temperature an environment but it is clear that the injections need to withstand heat and could higher than 25°C and 8°C. They should at least withstand 25 degrees more both up and down the Celsius scale. Regarding environments to use and store in, it is fair to say that they should function within any common environment of the customer's daily lives. It would be preferable if there were special extra covers or casings for customers that are working etc. in extreme environments and it would be suitable if they were provided by the same company as the one that provide the injectors.

12.4.2. MicrojectAssembler

The design on MicrojectAssmebler is an attempt to think outside the box as all the investigated injectors has been designed like pens. It is there by not bounded to use the same technology as a pen injector would have to use even though the technology may differ among them. The technology of MicrojectAssembler is not yet developed as it was not covered by the scope of this project. The vision is however to use compressed air in the plunger but exactly how that is to function is unclear.

A new world of possible designs opens up when taking a step back from the pen shaped injectors. There can be other shapes, other sizes, other trigger functions and so on when starting to think in other directions but it is of course important to consider the user needs.

The sequence of tasks to fulfill before injecting successfully was found to be quite intuitive based on the results of the user tests. Some subjects were however insecure about whether or not it had a cap, which is why the color design was changed to a fading color transmissions rather than a firm boarder. This in combination with the change to safety orange (#FF6700) which according to colors.findthebest.com is the color used for road works, was thought to enhance the conclusion that the there is no cap and that the needle are down at the bottom there the color is most intense. The use of “safety orange” is an attempt to support mental models as this color probably is associated with attention and perhaps also danger. The increasing intensity of this warm color was also aiming at communicating where the needle is located.

The design also enables a smaller total solution with multiple accessories that could be stored either together or separated in order further reduce the size burden. This could be discussed further if ever designing a case but the risk of misplacements of parts has already been discussed. When the customers where asked if they ever forget their injectors there were non who said that they did if they did not do it on purpose. There for it is fair to conclude that it is deeply rooted within their memory that it has almost become a skilled based behavior, which is why the use of multiple parts should not be a problem.

The problem with providing a secure impression about safety catchers is probably better organized for MJA that has two parts to assemble before injecting, hence there is no risk of accidentally trigger the injector. There is how ever a risk of accidentally trigger the injection when in the process of actually giving the injection as the syringe accidentally may be pushed all the way down before it has been placed on the thigh. This is a risk that has to be mediated through sufficient instructions, perhaps by audio means in the future but this is however yet the weakest part of the interface design. It should be emphasized that this design would not have been the same if it was not for the results or the user tests where a majority found it to be intuitive enough and actually performed the right sequence of actions.

Some problems share the same sub solutions as Electra Fusion like, a sticker and permanent label on the medicine container, a reference picture for the medicine fluid and the reasoning of the Appearance depending on age. The same discussion applies for these factors as for the same above.

The communication of the injection time is however different as it is possible to watch the medicine as the liquid level decreases. It would probably be more effective so also further enhance this communication, perhaps by the use of lights and or sound as for Electra Fusion. Since it is a future

concept it is possible to consider the use of batteries to enhance many features and functions. Any changes in this area would impact the size but as it comes in pieces it should be less of a problem.

One sub solution that could be considered better than the one for Electra Fusion is the way in which the injector communicates when it is done injection. When done injecting, the needle is automatically withdrawn in to the body again, which is probably the ultimate way of communicating when it is done injecting as the needle is no longer available. This sub solution was considered for Electra Fusion as well but there were indications say that it would increase the total size which is why it was finally discarded. The sub solution corresponds to the problem of carrying the injector safely to disposal as the needle is no longer disposed. A case would however be needed du fully complete the task as there may be some leakage of medicine after use.

Other problems that would be solved by a case is where the instructions should be, how to communicate the instructions, communicate what it is for and the severity and finally a possible QR-code for general information, expiration date and demonstrations etc.

13. Discussion

This chapter starts with an overall discussion followed by a general discussion about the product development process in total. The general discussion is followed by deeper discussions about the methods used in each step of the process.

13.1. Overall discussion

The purpose of this project, to communicate to the industry, what the customer wants and needs are considered fulfilled as this project was carried out in corporation with one of the major companies that develop and produces auto injectors for this purpose. The company, SHL group, has been involved throughout the process and a great interest from highly important people within the company has developed along the way. The interest did not only include the staff in Taiwan; where two major presentations were given regarding the process and the results, but also members of the staff at their site in Sweden. Finally it became clear that the CEO had a particular interest in the final results by actively attending the final presentation and also functioned as a sounding board during the project, which further proves that the purpose has been fulfilled.

Regarding the objectives of the project, to firstly define pros and cons with the present solutions on the market, it is fair to say that it was fulfilled with the help of the methods HTA and ECW. They clearly revealed preferable and less preferable sub solutions of these products.

Secondly, the objective was to deliver a list of customer needs which can be viewed in Appendix 5, which represents the metric list of weighted need on which the concept generation was based on. Hence this objective has been fulfilled.

Finally, the last objective was to develop a range of design solutions which has been done and they can be viewed in Appendix 11 but also in Appendix 7. This objective did also include coming up with one or two final designs which can be found in Chapter 13 – Final results.

There have been many obstacles to overcome like for any other research. The first step is to find someone that could sponsor the project and then do deliver. It is a great responsible that rest on the shoulders of the product developer once the stake holders has been convinced to act as sponsors. The responsibility becomes even greater if the product development process is supposed to be a standalone projects which it was in this case. The fact that it was carried out in an East Asian corporation where both cultural differences and language barriers affected the project resulted in even more obstacles to overcome.

The greatest lesion learn during this project is to quickly adapt to new cultures and how to work around language barriers. It is important to stay open minded and try to remain calm when things changes or do not go the way there where intended to. This applies for all projects of course, but in particular when working in a different culture where things that are thought to be self-explanatory actually are not. Thereby a unique opportunity to gain knowledge about new ways of thinking is given if open to it. It does not have to be wrong just because it is different, it might even be better. That is probably the most useful wisdom of all.

However, the Taiwanese culture is very open and empathic which is why, there has been very little influence on the project in total. The way of thinking when carrying out certain methods and other

parts of the project has been affected as there was a continuous dialog and evaluation presented though out the project. This was a great combination as they where rather unfamiliar with the Swedish used methods, which gave the project a new dimension.

This is one of the factors that contributed to that the objectives were met. Other factors were the great sense of responsibility to company and even more importantly a willingness to work hard for intrinsic values as well.

13.2. The product development process

The overall impression is that the product development process derived from Ulrich & Eppinger (2012) and Bligård (2011) was an appropriate approach for this project. However, there are always some things that could have been better. The first thing is that one step should have been highly dedicated to construction as this was a very time consuming part which did not have the space it needed during the process stages. Another implication is that planning could have been included like it is on the process illustrated by Bligård (2011). It was very easy to make plans in the beginning but as the project went on more planning was found to be needed and many changes was made to the original plan like the decision to create final concepts for both a futuristic and one realistic design.

13.3. Filed study

HTA and ECW were found to be use full tools during the investigation of the already existing products. They were however rather extensive and time consuming compared to the useful outcome. The use of HTA corresponded quite well to the expectations and was not as time consuming as ECW. ECW did however provide greater feedback, especially regarding some of the key issues in common for most of the products out on the market today. This feedback was highly accounted for during the product development process of this projects and may have been regarded less without the results from the ECW. The general results from the ECW could however have been obtained by using a lower number of questions as it was a great amount of recurrence throughout the analysis, which is why it probably would have been more suitable to only conduct the CW instead. The thorough investigation of each task of the HTA did however gain information about particularly beneficial or non beneficial sub solutions that otherwise would have been lost. This information has been considered during the concept generation step but also during some of the later stages.

13.4. Customer / User Study

The following chapter discusses the method used during the customer and user study with respects to outcome and expectations. The only method used for this phase was semi structured interview.

13.4.1. Semi structured interviews

The information obtained by the interviews was of great help during the later stage, where the customer needs had to be defined. The semi structured procedure, in which the interviews were conducted, facilitated the compilation the interviews on both individual and comprehensive level. Due to this structure, there was also room for side tracks which was relatively easy to organize using the semi structured method. There was a great deal of important information obtained during these side tracks that would have been lost if a more structured procedure would have been used. Hence, the use of the semi structured method matched the expectations and even perceived to be a better

aid when it came to the specific part of organizing side tracks that did not naturally belong to any subject of the interview guide.

The only drawback identified regarding the use of the semi structured guide, and the designed one in particular, may have been that some of the interviewees stopped themselves in the middle of a reasoning regarding a side track, mainly as they knew that there were more questions to be asked and answered. Possible reasons could have been that they were stressed out, worried that the interview would take too much time, either for them self of by courtesy, or both. This is likely to be a reason as the interview guide was quite extensive in its nature and the interviewees where informed that the interview should only up take around 40 minutes to an hour of their time. Another possible reason for dropping a side track may have been that the interviewees thought that their side track subject was of no use or less interesting to the project.

13.5. Identifying customer needs

There were two methods used when identifying customer needs; KJ-analysis and metric list. They are both discussed below.

13.5.1. KJ-analysis

The KJ-analysis where the first step to categorize the needs of the customers and the outcome corresponded to the expectations. This is based on the fact that the categories derived during this method were used as the foundation to all sub solutions during the concept generation and concept selection steps which were found to be a proper aid during these steps. No drawbacks have been considered of using this method.

13.5.2. Metric list

This was an appropriate approach and the outcome was very easy to follow. The weighting has influenced the product development process and made it easy to understand the important focus areas. All methods has however flaws which in this case meant that very important needs where sometimes only said by one customer which led to very low ratings for some needs that deserved a higher score. This was however accounted for during the rest of the product development process. Needs that were considered important based on knowledge of the conditions and from stakeholders, but yet received low scores where cared for throughout the concept development. There were also some needs that were not even derived from the customers that also were accounted for due to the same matter as explained above. However, it should be mentioned that this could be considered to be a very subjective course of action but was yet found appropriate at this stage of the process as it is based on hard fact and knowledge.

13.6. Developing sub solutions

A brief method discussion about the expectations of methods used during the phase of generation sub solution will be displayed below.

13.6.1. Brainstorming & brainwriting

The use of brainstorming as a creative tool was found to be an appropriate tool not at least with the brainwriting conducted in advance. This especially since it was a method that all participants in the brainstorming session were familiar with it. It was time efficient since no time had to be spent on explanations etc, even though the participants came from different backgrounds and even nationalities but it also generated a wide range of ideas in a relatively short time session of 1.5 hours.

One factor that could have been optimized was that none of the designers at SHL, who participated in the brainstorming session, did conduct any brain writing in advance, as they had other prior engagements.

13.6.2. Osborne's idea spurring checklist

The method completed its purpose but was however a bit redundant in this process as most of these factors were subconsciously processed throughout this step of the process. Since this list was continuously accounted for, there was no actual need to document any specific results from this checklist rather than documenting the total result from all the methods used during this step of the process.

13.7. Concept development loop 1

Only one method was used during generation of early concepts which is to draw thumbnail sketches. This method was also used during the second loop of concept generation.

13.7.1. Thumb nail sketches

This was found to be a very appropriate method to use the express the first two loops of concepts as they had to be derived and visualized with in a very short period of time. It was also preferable as it was easier for other evolved parties to understand the concepts when a viewing a picture rather than only a written explanation. It was however necessary to also have a written explanation in addition, to fully understand the entirety of each concept.

13.8. Concept development loop 2

The following paragraph discusses the methods used during the second loop of the concept generation step. The methods used during this phase were; Pugh matrix, Morphological Matrix and Soft models.

13.8.1. Pugh matrix & Morphological matrix

About half of the sub solutions from the early concepts survived the Pugh matrix and were transferred to the morphological matrix. It was perhaps too many sub solutions that did survive which is why the elimination matrix by Ulrich & Eppinger (2012) could have been considered in addition as it may had sorted out some more. However, as it is a method the uses relatively rough criteria probably would not have been time efficient to conduct this method to. This, especially since the morphological matrix provided such extensive over view of the remaining that it was very uncomplicated to sort out the most feasible sub solutions and combine them in to new concepts, regardless of the remaining amount of sub solutions from the Pugh matrix. Hence the Morpgological matrix was a very useful tool at this stage in the project

13.8.2. Soft models

The use of soft models was a good choice of method especially during that time in the project. Six concepts was a proper amount of concepts to model. More concepts would have taken more time than what would have been valuable. If it would have been done later on in the concept generation phase, it would probably have resulted in loss of relevant evaluation output as the modeling of these concepts gave a great amount of feedback about the concepts.

13.9. Concept development loop 3

No scientific methods were used during this phase, instead a group discussion was found to be the best solution to reduce the six remaining concepts in to two final concepts for testing. The outcome of the group discussion met the expectations as it fulfilled its purpose of reduces six concepts into two. It could be argued that an elimination matrix according to Ulrich & Eppinger (2012) could have been used instead but as stated before, it was considered to be a rather rough method. Compared to the discussion with two experienced designers it felt as the group discussion gave a better and more time efficient result than what could have been provided by an elimination matrix.

13.10. Concept testing

During the concept testing phase preparations was done to facilitate the testing step. Computer Aided Design was the only additional aid used in combination with the soft models.

13.10.1. Computer Aided Design

The use of computer aided design (CAD) to create more detailed sketches that also provided the potential of receiving a sense of 3D feeling when viewing the drawings fulfilled its purpose. The CAD drawings were used during the user the following testing phase as was highly appreciated among the test subjects. It was the right decision to create the CAD drawings before the tests as they gave a clear picture over the concepts that need to be communicated to the test subjects. There was no need for CAD drawings before this stage of the process as the previous concepts did not need to be communicated to any one unfamiliar with them.

13.11. Concept testing – instruction label

This chapter will account for the usability testing of the selected concepts and the instruction label. The first paragraph regards the testing of the selected concepts and the second regards the instruction label.

13.11.1. Selected concepts

The guessability test gave an expected result with respect to the conclusions made regarding necessary changes in the aesthetic and functional design of the injector. It was however a small deviation between the test groups which could have depended on the technical skills of the engineer students that were used as un experienced users and the lack of experience of allergy auto injectors from the engineers that were used to represent experienced users and vice versa.

It has to be taken into account that the test groups consisted of subjects educated within the technical sector. This may have impacted the results that otherwise would have been different. It would have been optimal to have subjects with different backgrounds. It would also have been optimal conduct the test on real customers. This was however impossible due to geographical and social limitations. The test was carried out in an area where people with food allergy are scarce; hence there were no access to customers. Social limitations, meaning that there was a social lack of people from other academically backgrounds in the environment in which the test was conducted in, forced the study to be performed on people in with a technical background. The subjects did however have a great deviation in their fields of expertise which in combination with a consistency in the language among each group could be considered indicators of higher validity among the test results.

13.11.2. Instruction label

The tests of the instruction label preceded better that excepted and the same applies for the results. Thirty seconds was the original idea of how long it would take to fully assimilate the instruction label of the realistic concept but as it turned out it only took somewhere in between 17-25 seconds. It could have been discussed whether or not the tests were needed to carry out for the EpiPen as the same result could have been obtained by conducting the same two tests as used to test the EpiPen. It was however considered to be of great interest to have a product for reference especially for comparison of the interface design.

14. Conclusion

The number one conclusion is that the most important factor, when designing a device like this is to have a customer focus. Secondly, it is important to gain knowledge about the situation and usage. Thirdly, it is crucial to design the product according to guidelines and principles for human machine interaction.

The purpose has been achieved, as highly important people within this industry took special interest in this project, and especially to the results. The objectives have also been fulfilled and opportunities were given, were the corresponding results of the objectives were communicated.

Regarding the future, it has been concluded that devices like this will probably not have the ordinary pen shape, like Electra Fusion, as it limits the length of the injector. The future will probably hold solutions that are more in line with MicrojectAssmebler as it allows new ways of designing the shape which will ultimately affect the size.

There is one final conclusion left to state that is by far the most important one to communicate: Just because something is different, it does not have to be wrong, it could in fact be better. This is applicable both for new ways of thinking regarding products and design but also for personal and cultural differences. There are so many problems that could be solved if people would just stay open minded and have mutual respect for each others' differences.

References

Anapen. (2009) *Anapen*: http://www.anapen.com (2013-10-30)

Atkinson, R. H. (2003). *Introduction to Psychology.* Stanford; Cengage Learning.

Arent, M., & Landers, M. (2003). *Arousal, anxiety, and performance: a re-examination of the inverted-U* hypothesis. *Inist, 74*, 436-444.

Bluemner, E. (2008). *Methods and Application of Creativity in Product Design:* www.productdesignresources.com (3 June 2013).

Bohgard, M., Karlsson, S., Lovén, E., Mikaelsson, L. Å., Mårtensson, L., Osvalder, A. L., et al. (2008). *Arbete och teknik på människans villkor*. Solna: Prevent

Dey Pharma L.P. (2010) *EPIPEN - epinephrine injection*: http://www.dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=7560c201-9246-487c-a13b-6295db04274a. (2013-10-30)

Dekker, S. (2004). *To Engineer is to err. Human Factors of Engineers,* Sandom C., Harvey R. S. 137-150*.* London: The Institution of Electrical Engineers

Fass Allmänhet. (2014) *Jext*: http://www.fass.se/LIF/product?docType=&specId=&userType=&nplId=20091103000015&. (2014-02-15)

Hanin Y. L. (2004). Emotion in Sport: An Individualized Approach. *Encyclopaedia of applied Psychology*, *10*, 739-750.

Johannesson, H., Persson, J.-G., & Persson, D. (2004). *Produktutveckling effektiva metoder för konstruktion och design.* Stockholm: Liber.

Kletz, T. A. (2006). An engineer's view of human error. Rugby: Inst of Chemical Engineers.

Lazarus, S. (2000). How emotions influence performance in competitive sports. *The Sport Psychologist*, *14*, 229-252

Lazarus, R. S. (1999). *Stress and emotion*. Bristol: Springer publishing.

McGrath, J. E. (1970) *Social and psychological factors in stress*. Illinois: department of psychology.

Medicininstructioner.se. (2009) *Användarinstruktioner*: http://www.medicininstruktioner.se/Product.asp?ProductId=76. (2013-10-30)

Lineage Therapeutics. (2013) *How to use epinephrine injection, USP auto-injector*: http://www.epinephrineautoinject.com/how_to_use_epinephrine_injection_USP_auto_injector.ph. (2013-10-30)

Liu, Y. (2009). *Usability Evaluation of Medical Technology: Investigating the Effect of User Background and Users' Expertise.* Gothenburg: Department of Product and Production Development

Medeca Pharma AB (2014) *Om anafylaktisk shock*: http://www.medeca.se/anafylaxi/anafylaktisk-chock. (2014-06-02)

McGrath, J. E. (1984). *Groups: Interaction and Performance.* Inglewood: Prentice Hall, Inc.

Rasmussen, J. (1983). Skills, Rules and Knowledge; Signals, Signs and Symbol, and Other Distinctions on Human Performance Models. *IEEE transactions on systems, man, and cybernetic* , p. 257-266.

Livsmedelsverket (2014) *Allergi och överkänslighet*: http://www.slv.se/sv/grupp1/risker-med-mat/allergi-och-overkanslighet/. (2014-06-02)

Nötallergikernas vänner(2014) *Akuthjälp*: http://notallergi.se/fakta-om-notallergi/akuthjalp/. (2014-06-02)

Robinson-Riegler, G. a. R. (2008). *Cognitive Psychology – Applying the science of the mind*, 2nd Edition. Boston, MA: Allyn & Bacon.

Schmidt, A. R. & Wrisberg, C.A. (2000). Motorlearning and performance. Champaign: Human kinetics.

Thorelli, Eva leg. (2014-06-05) Expertintervju med leg. sjuksköterska inom astma och allergi

Twinject auto-injector (2008) *Instructions how to use*: http://www.twinject.ca/how.php?lang=en. (2013-10-30)

Ulrich, K. T., & Eppinger, S. D. (2012). *Product Design and Development.* 5th edition. New York: McGraw-Hill.

Waard, D. d. (1996). *The Measurement of Drivers' Mental Workload.* Haren: The Traffic Research Centre VSC, University of Groningen

West Pharmaceutical Services, Inc. (2012) *Self-Injection Technology*: http://www.westpharma.com/en/products/Pages/AdvancedInjectionSystems.aspx. (2013-10-30)

Wickens, C. D., & and Hollands, J. (2000). *Engineering Psychology and Human Performance.* 3rd Edition. Saddle River, New Jersey; Prentice Hall: Pearson.

Yerkes, R. M. & Dodson J. D. (1908). The relation of strength of stimulus to rapidity of habit-formation, *Journal of Comparative Neurology and Psychology*, *18*, 459-482.

Young, M. S., & Stanton, N. A. (2002). *Attention and Automation: new perspective on mental underload and performance*. London: Taylor & Francis.

Appendix 1

Design Principles and Guidelines for HMI

Requirements	Lower L	Specific	Upper L	Unit	Req.	Guidl.
Over all reqiurements						
Important objects should be emphasised						x
Enhance info that is the opposite to what's expected						x
Information on the screent may visualy represent the the variable that are described						
Group similar objects/ that belong together						x
Groups of objects at the same time in the display		5	7	st	x	
Shortcuts for reaching items that are deeper in the navigation or are used often (ex battery level)						x
Use the same terminology as the user						x
No display of unnecessary information						x
Avoid multiple scales						x
Avoid long words, shortenings, unusual expressions						x
Symbols & icons						
Use same symbols as the represented by the users' Menatal Models						x
Use same icons as the represented by the users' Mental Models						x
Use graphical symbols for representative info						x
Use abstact symbols for bottom up info						x
Text & Digits						
Levels of text size		3	5	st	x	
Use font as supported by the users' MM:s						x
Use digits for the most accurate information						x
Use bars/indicators to supprt imporant digits						x

Size capital letters/digits		1/200 the size of distance		cm	x	
Size lower case letters/digits		2/3 the size of capital letters		cm	x	
Bar with		1/6 the size of letters			x	
Letter/digit width		2/3 the size of letters		cm	x	
Space between two letters		1/5 the size of letters		cm	x	
Space between word & digits		2/3 the size of letters		cm	x	
Space between word/digit and pic/icon		2/3 the size of letters		cm	x	
Color						
Not use mor the 5 colors in the system						
Not combine colors within the conflicting frequency						
Consistent color scheme						x
Use Red for stop, danger, warm, fire						x
Use yellow for warning, slow, testing						x
Use Green for Ok, go, continue, on						x
Use Blue for cold, water, calm						x
Not use Red & Gren in combo						x
Use common display gray scale						x
Distinguage between objects is crucial						x
Sound						
Number of sound in the system			4	st	x	
Sounds in distinctly different HZ areas				Hz	x	
Only use sound icons						x
Sound to be localized	<1500		>3000	Hz	x	
Directions						
Movment up for increased value						x
Movment down for decreased value						x
Clockwise for increased value						x
Counter clockwise for decreased value						x
Right for increased value						x
Left for decreased value						x

Appendix 2

Interview Guide

1. a) Hur länge har du haft sprutor?
   b) Vad var den avgörande faktorn (till att du fick sprutor)?
   c) Vad har du för spruta?
   d) Hur många bär du runt på?
   e) Hur många borde du bära runt på?
   f) Kan du berätta lite hur du lever med din spruta?
      i) Har du med den överallt? Någon gång du inte tar med den? Varför?
      ii) Hur förvarar du den?
      iii) Hur bär du med dig den?
      iiii) Vet dina vänner att du har sprutor?
2. Beskriv situationen då du behöver använda sprutorna?
   a) Har du varit med om en sådan situation?
      i) när hände detta?
         Hur länge sedan?
         Tid på dygnet?
      ii) var hände det?
         Beskriv omgivningen; inomhus, utomhus, på jobbet/ i skolan, på semester, i bilen, på tåget, var de varmt, kallt, mörkt, ljus etc.?

      iii) hur hände det? – orsaken och reaktionen

      iiii) Varför hände det? (Någon gjorde en missbedömning, är man liten kanske man äter ngt utan att veta vad man äter, ett getingstick, ny allergi uppdagades osv.)

   b) Hur ofta har det hänt?
   c) Har du behövt ge dig eller någon annan sprutan?
      i) Vad fick du för emotioner då?
      ii) Hut gjorde du före, under och efter injektionen?
   e) Kände du att du visste/vet hur du skulle göra första gången?

3. a) Hur ofta kontrollerar du datumen på dina sprutor?
   b) hur ofta kontrollerar du vätskan?

4. Har du någon gång instruerat någon annan hur sprutorna skall ges?
      i) Hur förklarade du det då? Kan du förklara för mig som du gjorde då?

5. a) Får du reda på ny information kring sprutor någonstans? Vart får du den? (Av läkare, vänner, internet, FB etc.?)
   b) Har du letat efter andra lösningar själv?
      i) Varför?
   c) Är det något du är obekväm med? Storlek, instruktioner, blickar från andra, att behöva bära med den etc.?
   d) Har du själv modifierat något med sprutan, kan vara sättet att bära runt den på eller att man lägger till eller drar ifrån features. (Kanske tar ut den ut sin förpackning eller lättar på säkerhetsåtgärder.)

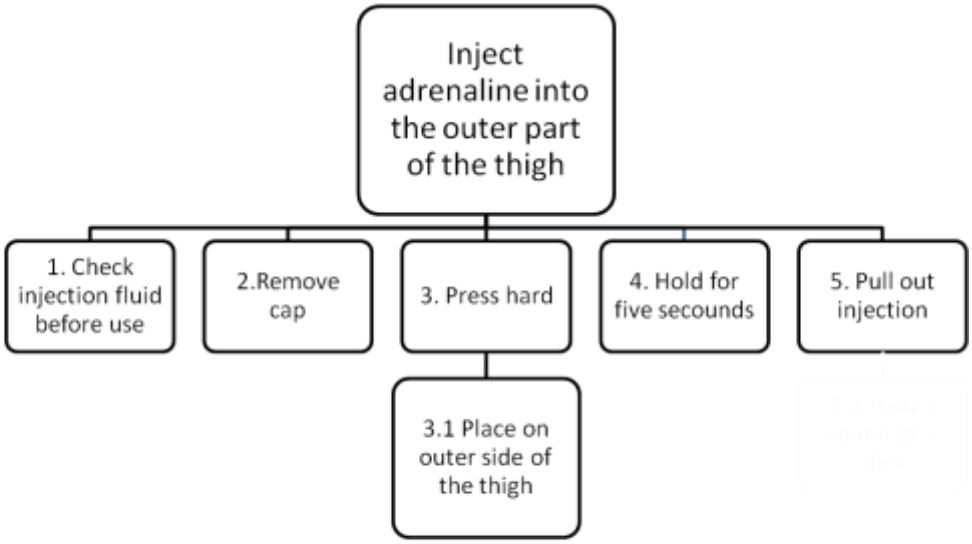
6. Om du nu får spåna fritt, vad tycker du om sprutan?
   a. Finns det något som är bra? – varför?
   b. Vad tycker du är dåligt? – varför?
   c. Hur skulle du vilja att den såg ut?
   d. Hur skulle du vilja att den fungerade?
   e. Tycker du att etiketten är förklarande nog? Vad kan ändras?
   f. Tror du att någon som är helt novis skulle kunna ge dig sprutan om du var avsvimmad? Varför?
   g. Tror du att någon förstår vad sprutan är till för om man inte har sett en sådan tidigare? – Har detta hänt? Varför?
   h. Skulle du tycka om att man hade ett mer transparent skal där man såg nålen och hur lösningen trycktes ner genom sprutan?

7. Har du ngt mer att tillägga?

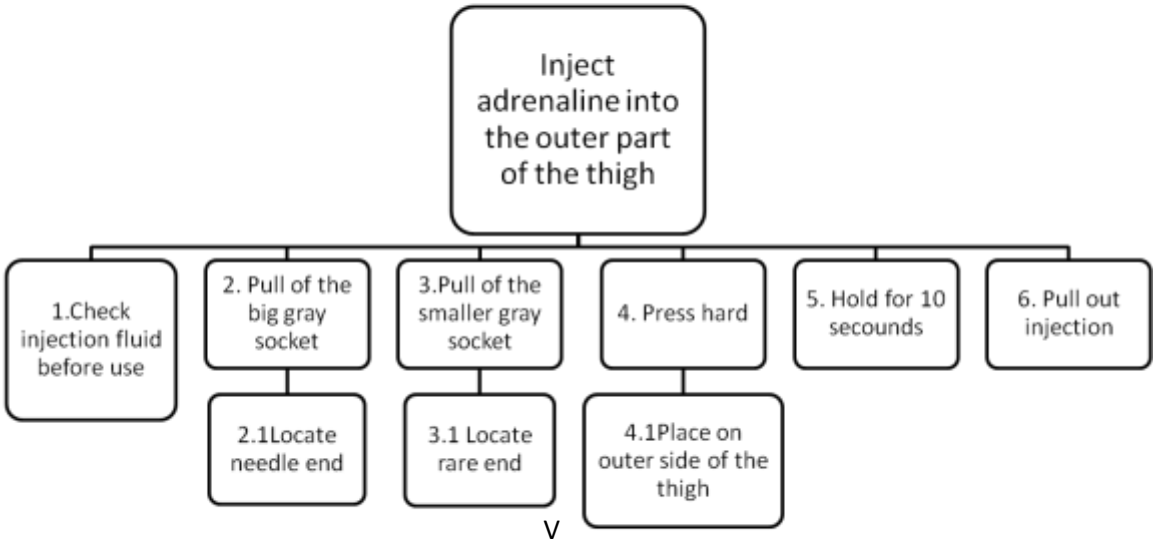
Appendix 3

HTA

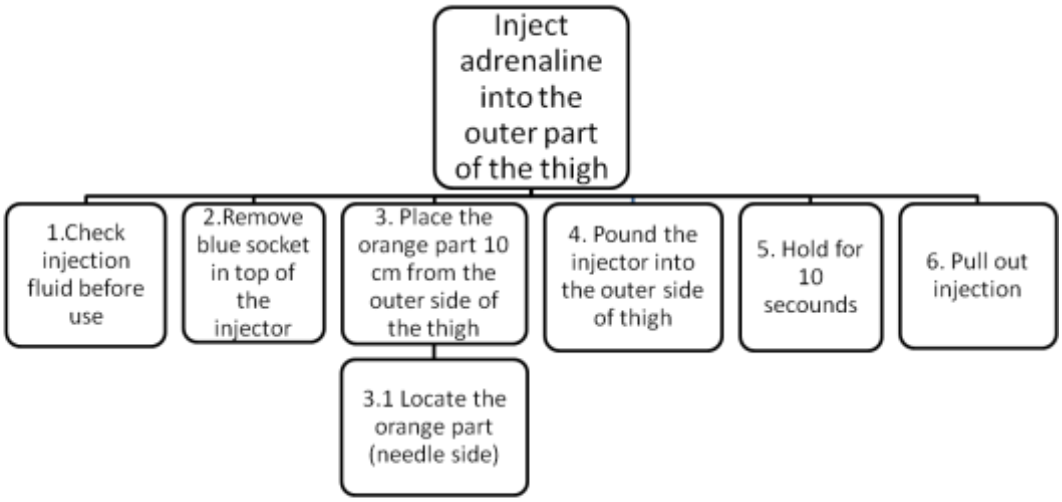
Emerade



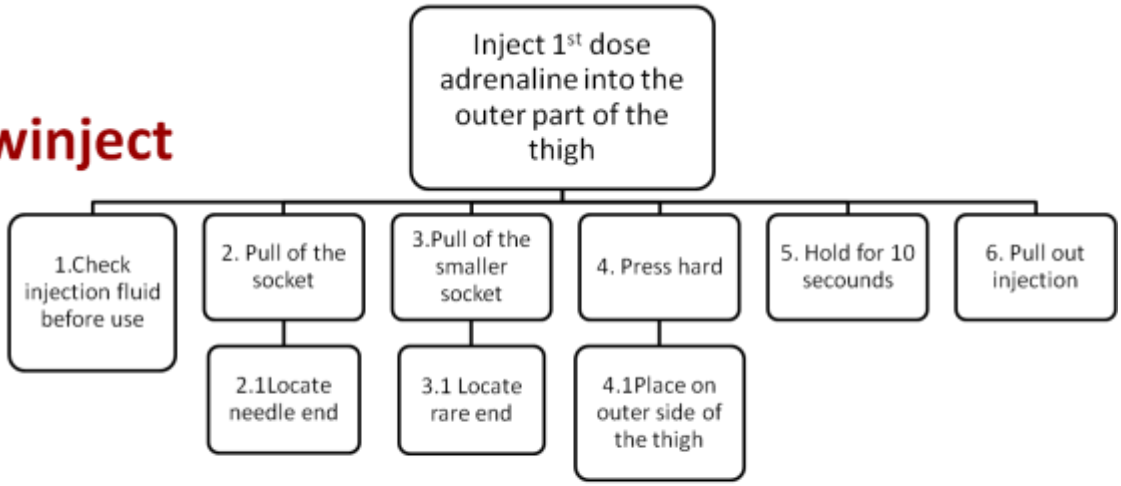
Adrenaline click

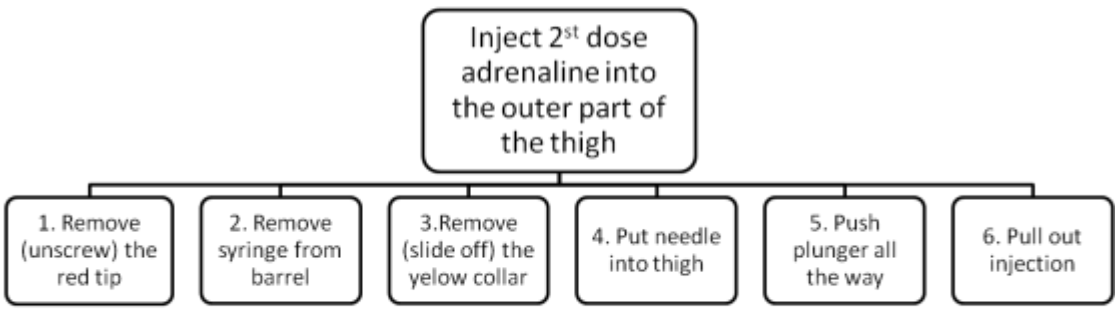


EpiPen

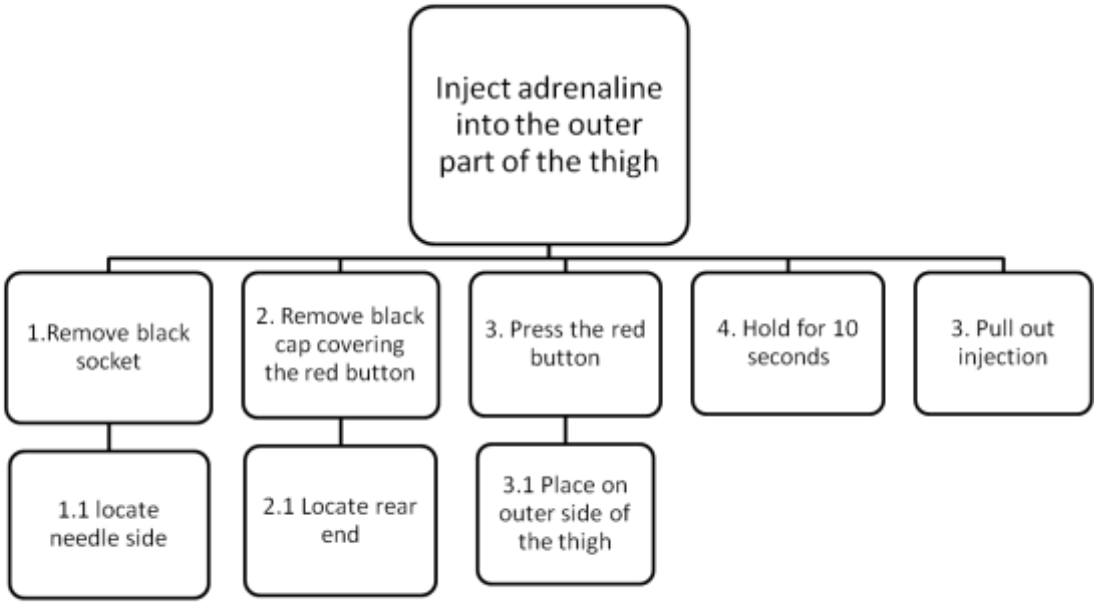


Twinject

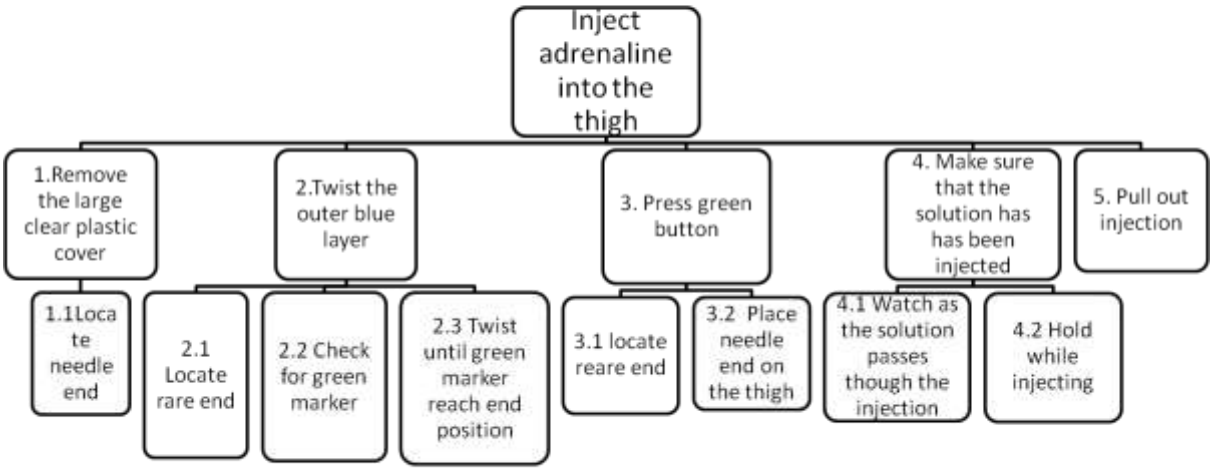




Anapen



ConfiDose



Appendix 4

Enhanced Cognitive Walkthrough

Anapen

Level 1 – Analysis of tasks/functions – Inject adrenaline into outer part of the thigh

1a	Will the user know that the evaluated function is available?	4. Yes, but less chance if not familiar with allergies, the label does not say it is for allergy use
1b	*Does the user expect, on the basis of previously given indications that the function exists in the machine?*	4. Yes probably, there is a label, but does not say it is for allergy use
2a	Will the user be able to notice that the function is available?	3. Do not know, stressful situation, label do not say what it is for
2b	*Does the machine give clues that show that the function exists?*	4. Yes probably, labels with instructions
3a	Will the user associate the clues with the function?	4. Yes probably, with successful generic knowledge but may be uncertain about where the adrenaline should be injected
3b	*Can the user's expectations and the machine's indications coincide?*	3. Do not know, depend on what expectations the user has – some think that the injection should go in the heart
4a	Will the user get sufficient feedback when using the function?	2. No uncertain, feedback is given if the injection is still ongoing nor when the injection has finished
4b	*Does the machine give information that the function has been chosen and the position the user is at in the interaction?*	4. Yes probably , there is a sound of a click that appears right after pushing the button
5a	Will the user get sufficient feedback to understand that the function has been fully performed?	1.No, no feedback is given when the injection has finished
5b	*Does the user understand, after the performed sequence of actions, that the right function has been performed?*	4. Yes probably, if the needle is not squirting fluid, (when pulled out) it provide feedback about whether or not the injection has been given

Level2 – Analysis of operations – 1. Remove black socket (covering needle)

1a	Will the user try to achieve the right goals of the operation?	4. Yes probably, information on the label
1b	*Does the user expect, on the basis of previously given indications, what is to be performed?*	3. Impossible to decide, Nothing but the label is given before to the un trained user so he/she might think that the needle will come out without removing anything
2a	Will the user be able to notice that the action of the operation is available?	4. Yes probably, information on label, a small label however
2b	*Does the machine give clues that show that the action is available and how to perform it?*	5. Yes – label
3a	Will the user associate the action of the operation with the right goal of the operation?	5. yes, the socked is successfully removed
3b	*Can the user's assumed operation and the machine's indications coincide?*	5. Yes
4a	Will the user be able to perform the correct action?	5. Yes, very easy action
4b	*Do the abilities of the user match the demands by the machine?*	4. Yes probably, very little force is needed to perform it
5a	Will the user get sufficient feedback to understand that the action has been performed and the goal has been achieved?	4. Yes probably, the label clearly illustrate that the socket should be removed
5b	*Does the user understand, after the performed operation, that he/she has done it correctly?*	4. Yes probably, it could be compared to the picture on the label

Level2 – Analysis of operations – 1.1 Locate needle end

1a	Will the user try to achieve the right goals of the operation?	5. Yes, it is crucial
1b	*Does the user expect, on the basis of previously given indications, what is to be performed?*	4. Yes probably
2a	Will the user be able to notice that the action of the operation is available?	4. Yes probably, it is crucial
2b	*Does the machine give clues that show that the action is available and how to perform it?*	4. Yes probably – an arrow is pointing in the direction of the needle at the bottom of the needle end
3a	Will the user associate the action of the operation with the right goal of the operation?	5. yes, the user want to find the needle end
3b	*Can the user's assumed operation and the machine's indications coincide?*	4. Yes probably, but it can be mistaken for being the rear end since there is just an arrow and nothing saying that it is the needle end
4a	Will the user be able to perform the correct action?	4. Yes probably, depend on how the user interprets the instructions and clues on the injection
4b	*Do the abilities of the user match the demands by the machine?*	3. Impossible to say, depend on the experience of the user
5a	Will the user get sufficient feedback to understand that the action has been performed and the goal has been achieved?	1. No, not until the user tries to inject
5b	*Does the user understand, after the performed operation, that he/she has done it correctly?*	1. No,

Level2 – Analysis of operations – 2. Remove black cap covering red button

1a	Will the user try to achieve the right goals of the operation?	3. Do not know, it depend on how well the user reads the instruction label
1b	*Does the user expect, on the basis of previously given indications, what is to be performed?*	3. Do not know, depend on the pre knowledge of the user
2a	Will the user be able to notice that the action of the operation is available?	4. Yes probably, instructing label
2b	*Does the machine give clues that show that the action is available and how to perform it?*	4. Yes probably, instruction label, and the appearance of the cap on the red button
3a	Will the user associate the action of the operation with the right goal of the operation?	5. Yes, cap successfully removed
3b	*Can the user's assumed operation and the machine's indications coincide?*	5. Yes,
4a	Will the user be able to perform the correct action?	5. Yes, very easy action
4b	*Do the abilities of the user match the demands by the machine?*	4. Yes probably, very little force is needed to perform it
5a	Will the user get sufficient feedback to understand that the action has been performed and the goal has been achieved?	4. Yes probably, the label clearly illustrate that the socket should be removed
5b	*Does the user understand, after the performed operation, that he/she has done it correctly?*	4. Yes probably, it could be compared to the picture on the label

Level2 – Analysis of operations – 2.1 locate rear end

1a	Will the user try to achieve the right goals of the operation?	3. Do not know, might not know the importance of the rear end
1b	*Does the user expect, on the basis of previously given indications, what is to be performed?*	3. Do not know,
2a	Will the user be able to notice that the action of the operation is available?	3. Do not know,
2b	*Does the machine give clues that show that the action is available and how to perform it?*	3. Do not know, depend on how the user interpret the arrow indicating the needle end
3a	Will the user associate the action of the operation with the right goal of the operation?	3. Do not know,
3b	*Can the user's assumed operation and the machine's indications coincide?*	4. Yes probably, but it can be mistaken for being the needle end since there is just an arrow indicating the needle end without saying that it is
4a	Will the user be able to perform the correct action?	3. Do not know, depend on how the user interprets the instructions and clues on the injection
4b	*Do the abilities of the user match the demands by the machine?*	3. Do not know, depend on the experience of the user
5a	Will the user get sufficient feedback to understand that the action has been performed and the goal has been achieved?	1. No, not until the user tries to inject
5b	*Does the user understand, after the performed operation, that he/she has done it correctly?*	1. No,

Level2 – Analysis of operations – 3. Press the red button

1a	Will the user try to achieve the right goals of the operation?	4. Yes probably, it looks like a button with its shape and color
1b	*Does the user expect, on the basis of previously given indications, what is to be performed?*	3. impossible to say,
2a	Will the user be able to notice that the action of the operation is available?	4. Yes probably, instructing label
2b	*Does the machine give clues that show that the action is available and how to perform it?*	5. Yes probably, by shape color and instructions
3a	Will the user associate the action of the operation with the right goal of the operation?	4. Yes probably, the user might not be certain of the goal (should he/she press button for needle to come out and then penetrate the skin or should it be used when to penetrate the skin)
3b	*Can the user's assumed operation and the machine's indications coincide?*	4. Yes probably – instructing label
4a	Will the user be able to perform the correct action?	5. Yes, very easy action
4b	*Do the abilities of the user match the demands by the machine?*	4. Yes probably, very little force is needed
5a	Will the user get sufficient feedback to understand that the action has been performed and the goal has been achieved?	5. Yes, there is a sound of a click when the needle comes out. If the patient is awake it could also provide feedback. If the user is the patio net, he/she will feel the needle when after pushing.
5b	*Does the user understand, after the performed operation, that he/she has done it correctly?*	5. Yes, the needle has popped out

Level2 – Analysis of operations – 3.1 place on outer side of thigh, 90^{o}

1a	Will the user try to achieve the right goals of the operation?	5. Yes, very crucial
1b	*Does the user expect, on the basis of previously given indications, what is to be performed?*	4. Yes probably, but some might expect it to be somewhere other than thigh and some may not expect the 90^{o} angle
2a	Will the user be able to notice that the action of the operation is available?	4. Yes probably, label with instructions
2b	*Does the machine give clues that show that the action is available and how to perform it?*	4. Yes probably, instructing label
3a	Will the user associate the action of the operation with the right goal of the operation?	4. Yes probably,
3b	*Can the user's assumed operation and the machine's indications coincide?*	4. Yes probably, comparison with instruction label
4a	Will the user be able to perform the correct action?	4. Yes probably, the 90^{o} angle might be the slightly hard when in a stressful situation
4b	*Do the abilities of the user match the demands by the machine?*	5. Yes,
5a	Will the user get sufficient feedback to understand that the action has been performed and the goal has been achieved?	4. Yes probably, the user will feel (haptic feedback) when touching the thigh but only eye measure (visual feedback) determine if the position and angle is correct
5b	*Does the user understand, after the performed operation, that he/she has done it correctly?*	4. Yes probably, comparison with the mental image of the instruction label (since the hand is now covering it)

Level2 – Analysis of operations – 4. Hold for 10 seconds

1a	Will the user try to achieve the right goals of the operation?	3. impossible to say, information suppressed in the information label
1b	*Does the user expect, on the basis of previously given indications, what is to be performed?*	2. No, uncertain
2a	Will the user be able to notice that the action of the operation is available?	4. Yes probably, since there is instructions on the information label, however small
2b	*Does the machine give clues that show that the action is available and how to perform it?*	4. Yes probably, since the information is available on the information label but the machine itself does not give any clues
3a	Will the user associate the action of the operation with the right goal of the operation?	2. No, uncertain
3b	*Can the user's assumed operation and the machine's indications coincide?*	4. Yes probably, comparison with instruction label
4a	Will the user be able to perform the correct action?	5. Yes,
4b	*Do the abilities of the user match the demands by the machine?*	4. Yes probably, time can however be perceived as going faster when in a stressful situation
5a	Will the user get sufficient feedback to understand that the action has been performed and the goal has been achieved?	1. No, no feedback is given after 10 seconds
5b	*Does the user understand, after the performed operation, that he/she has done it correctly?*	4.Yes probably, no injection fluid is still running when the needle has been pulled out

Level2 – Analysis of operations – 5. Pull out injection

1a	Will the user try to achieve the right goals of the operation?	5. Yes
1b	*Does the user expect, on the basis of previously given indications, what is to be performed?*	5. Yes,
2a	Will the user be able to notice that the action of the operation is available?	5. Yes,
2b	*Does the machine give clues that show that the action is available and how to perform it?*	3. Impossible to decide - the machine itself does not give any clues but generic knowledge about injections does
3a	Will the user associate the action of the operation with the right goal of the operation?	5. Yes,
3b	*Can the user's assumed operation and the machine's indications coincide?*	5. Yes,
4a	Will the user be able to perform the correct action?	5. Yes,
4b	*Do the abilities of the user match the demands by the machine?*	5. yes,
5a	Will the user get sufficient feedback to understand that the action has been performed and the goal has been achieved?	5. Yes, the will see (visual feedback) that the needle is no longer in the thigh
5b	*Does the user understand, after the performed operation, that he/she has done it correctly?*	5. Yes,

EpiPen

Level 1 – Analysis of tasks/functions – inject adrenaline in to the outer part of the thigh

1a	Will the user know that the evaluated function is available?	4. Yes probably, but less chance if not familiar with allergies, the label does not say it is for allergy use
1b	*Does the user expect, on the basis of previously given indications that the function exists in the machine?*	4. Yes probably, there is a label, but does not say it is for allergy use
2a	Will the user be able to notice that the function is available?	3. Do not know, stressful situation, label do not say what it is for
2b	*Does the machine give clues that show that the function exists?*	4. Yes probably, label with instructions
3a	Will the user associate the clues with the function?	4. Yes probably, with successful generic knowledge but may be uncertain about where the adrenaline should be injected
3b	*Can the user's expectations and the machine's indications coincide?*	3. Do not know, depend on what expectations the user has – some think that the injection should go in the heart
4a	Will the user get sufficient feedback when using the function?	2. Uncertain, no feedback is given if the injection is still ongoing nor when the injection has finished
4b	*Does the machine give information that the function has been chosen and the position the user is at in the interaction?*	4. Yes probably, there is a sound of a click that appears right after trigger action of the injection
5a	Will the user get sufficient feedback to understand that the function has been fully performed?	1. No, no feedback is given when the injection has finished
5b	*Does the user understand, after the performed sequence of actions, that the right function has been performed?*	4. Yes probably, if the needle is not squirting fluid, (when pulled out) it provide feedback about whether or not the injection has been given

Level2 – Analysis of operations – 1. Check injection fluid before use

1a	Will the user try to achieve the right goals of the operation?	2. No uncertain, there is a small window to watch the fluid and insufficient clues about what to do with it
1b	*Does the user expect, on the basis of previously given indications, what is to be performed?*	1. No,
2a	Will the user be able to notice that the action of the operation is available?	3. Do not know, very hard to notice the instructions but there is a chance since there are instructions on the label
2b	*Does the machine give clues that show that the action is available and how to perform it?*	3. Do not know. The label gives poor clues but the machine itself does not.
3a	Will the user associate the action of the operation with the right goal of the operation?	3. Do not know. It might be hard to understand what to look for since the explanation on the label is vague and only says replace if discolored
3b	*Can the user's assumed operation and the machine's indications coincide?*	3. Do not know.
4a	Will the user be able to perform the correct action?	3. Do not know. It depend of what is perceived as discolored
4b	*Do the abilities of the user match the demands by the machine?*	2. No uncertain, since there is room for misunderstandings
5a	Will the user get sufficient feedback to understand that the action has been performed and the goal has been achieved?	2. No uncertain, no feedback but subjective visual feedback is provided
5b	*Does the user understand, after the performed operation, that he/she has done it correctly?*	2. No uncertain, since there is a subjective judgment regarding the color of the fluid

Level 2 – Analysis of operations – Remove blue socket on top of the injector

1a	Will the user try to achieve the right goals of the operation?	4. Yes probably, instructing label
1b	*Does the user expect, on the basis of previously given indications, what is to be performed?*	1. No,
2a	Will the user be able to notice that the action of the operation is available?	4. Yes probably, instructing label
2b	*Does the machine give clues that show that the action is available and how to perform it?*	4. Yes, instructing label and the design, both color & shape (harder to understand)
3a	Will the user associate the action of the operation with the right goal of the operation?	4. Yes, the instructing label for comparison
3b	*Can the user's assumed operation and the machine's indications coincide?*	3. Do not know
4a	Will the user be able to perform the correct action?	5. Yes,
4b	*Do the abilities of the user match the demands by the machine?*	4. Yes probably, very little force and technique is required.
5a	Will the user get sufficient feedback to understand that the action has been performed and the goal has been achieved?	4. Yes probably, by to instruction label for comparison
5b	*Does the user understand, after the performed operation, that he/she has done it correctly?*	4. Yes probably, by to instruction label for comparison

Level2 – Analysis of operations – 3 Place the orange part 10 cm from the outer side of the thigh

1a	Will the user try to achieve the right goals of the operation?	3. Do not know. The instructing label says so but the label has very much text in an a small size
1b	*Does the user expect, on the basis of previously given indications, what is to be performed?*	3. Do not know, depend on the experience of the user, the exact measurement of 10 cm might not be expected
2a	Will the user be able to notice that the action of the operation is available?	3. Do not know. The instructing label has very much text in an a small size
2b	*Does the machine give clues that show that the action is available and how to perform it?*	3. Do not know. The machine does not but the fuzzy label does.
3a	Will the user associate the action of the operation with the right goal of the operation?	3. Do not know
3b	*Can the user's assumed operation and the machine's indications coincide?*	4. Yes probably, instructing label
4a	Will the user be able to perform the correct action?	4. Yes probably, might be hard to measure 10 cm by estimation the distance
4b	*Do the abilities of the user match the demands by the machine?*	2. No uncertain, might be hard to measure 10 cm by estimation the distance
5a	Will the user get sufficient feedback to understand that the action has been performed and the goal has been achieved?	1. No
5b	*Does the user understand, after the performed operation, that he/she has done it correctly?*	2. Do not know, depend on the experience of the user

Level2 – Analysis of operations – 3.1 Locate the orange part (needle end)

1a	Will the user try to achieve the right goals of the operation?	5. Yes, it is crucial
1b	*Does the user expect, on the basis of previously given indications, what is to be performed?*	4. Yes probably
2a	Will the user be able to notice that the action of the operation is available?	5. Yes, very well indicated
2b	*Does the machine give clues that show that the action is available and how to perform it?*	5. Yes, well indicated with orange color, arrow in the direction of the needle by the needle end and a marking saying “needle end”
3a	Will the user associate the action of the operation with the right goal of the operation?	5. yes, the user want to find the needle end
3b	*Can the user's assumed operation and the machine's indications coincide?*	5. Yes
4a	Will the user be able to perform the correct action?	4. Yes probably,
4b	*Do the abilities of the user match the demands by the machine?*	4. Yes probably
5a	Will the user get sufficient feedback to understand that the action has been performed and the goal has been achieved?	5. Yes, by the orange color, arrow in the direction of the needle by the needle end and a marking saying “needle end”
5b	*Does the user understand, after the performed operation, that he/she has done it correctly?*	4. Yes probably,

Level2 – Analysis of operations – 4. Pound the injector into the outer side of the thigh

1a	Will the user try to achieve the right goals of the operation?	3. Do not know, depend on if the user understand the instructions on the label and the level of experience.
1b	*Does the user expect, on the basis of previously given indications, what is to be performed?*	3. Do not know,
2a	Will the user be able to notice that the action of the operation is available?	4. Yes probably, instructing label
2b	*Does the machine give clues that show that the action is available and how to perform it?*	3. Do not know. The machine itself does not but instructions on it does
3a	Will the user associate the action of the operation with the right goal of the operation?	4. Yes probably,
3b	*Can the user's assumed operation and the machine's indications coincide?*	4. Yes probably,
4a	Will the user be able to perform the correct action?	5. Yes, only a little force is needed
4b	*Do the abilities of the user match the demands by the machine?*	4. Yes probably, if correct understanding of the instructions
5a	Will the user get sufficient feedback to understand that the action has been performed and the goal has been achieved?	5. Yes, the needle comes out and the user could feel it, (patient is the user) 4. Yes probably, sound of the needle and possibly vibrations in the pen, if patient awake it could give feedback that the needle has penetrated the skin, (other than patient is the user)
5b	*Does the user understand, after the performed operation, that he/she has done it correctly?*	4. Yes probably --||--

Level2 – Analysis of operations – 5. Hold for 10 seconds

1a	Will the user try to achieve the right goals of the operation?	3. impossible to say, depend on if the user understand the fuzzy label
1b	*Does the user expect, on the basis of previously given indications, what is to be performed?*	2. No, uncertain
2a	Will the user be able to notice that the action of the operation is available?	4. Yes probably, since there is instructions on the information label both in words and with an image of a clock.
2b	*Does the machine give clues that show that the action is available and how to perform it?*	4. Yes probably, since the information is available on the information label but the machine itself does not give any clues
3a	Will the user associate the action of the operation with the right goal of the operation?	2. No, uncertain
3b	*Can the user's assumed operation and the machine's indications coincide?*	4. Yes probably, comparison with instruction label
4a	Will the user be able to perform the correct action?	5. Yes,
4b	*Do the abilities of the user match the demands by the machine?*	4. Yes probably, time can however be perceived as going faster when in a stressful situation
5a	Will the user get sufficient feedback to understand that the action has been performed and the goal has been achieved?	1. No, no feedback is given after 10 seconds
5b	*Does the user understand, after the performed operation, that he/she has done it correctly?*	4.Yes probably, no injection fluid is still running when the needle has been pulled out

Level2 – Analysis of operations – 6. Pull out injection

1a	Will the user try to achieve the right goals of the operation?	5. Yes
1b	*Does the user expect, on the basis of previously given indications, what is to be performed?*	5. Yes,
2a	Will the user be able to notice that the action of the operation is available?	5. Yes,
2b	*Does the machine give clues that show that the action is available and how to perform it?*	3. Impossible to decide - the machine itself does not give any clues but generic knowledge about injections does
3a	Will the user associate the action of the operation with the right goal of the operation?	5. Yes,
3b	*Can the user's assumed operation and the machine's indications coincide?*	5. Yes,
4a	Will the user be able to perform the correct action?	5. Yes,
4b	*Do the abilities of the user match the demands by the machine?*	5. yes,
5a	Will the user get sufficient feedback to understand that the action has been performed and the goal has been achieved?	5. Yes, visual feedback can tell that the needle is no longer in the thigh
5b	*Does the user understand, after the performed operation, that he/she has done it correctly?*	5. Yes,

ConfiDose

Level 1 – Analysis of tasks/functions – inject adrenaline into thigh

1a	Will the user know that the evaluated function is available?	4. Yes probably, but less chance if not familiar with allergies, the label does not say it is for allergy use
1b	*Does the user expect, on the basis of previously given indications that the function exists in the machine?*	3. Impossible to say, no label on the device, might be a label on a possible cover, if any
2a	Will the user be able to notice that the function is available?	3. Do not know, stressful situation, may be lack of instructions
2b	*Does the machine give clues that show that the function exists?*	4. Yes probably, the injection fluid is exposed
3a	Will the user associate the clues with the function?	4. Yes probably, with successful generic knowledge but may be uncertain about where and the adrenaline should be injected
3b	*Can the user's expectations and the machine's indications coincide?*	3. Do not know, depend on what expectations the user has – some think that the injection should go in the heart
4a	Will the user get sufficient feedback when using the function?	5. Yes, a transparent part of the injection displays how the injection fluid is being pushed down and then plunger pulls right up when done injecting, there might even be a sound when done.
4b	*Does the machine give information that the function has been chosen and the position the user is at in the interaction?*	4. Yes probably, --||--
5a	Will the user get sufficient feedback to understand that the function has been fully performed?	5. The plunger pulls right up when done injecting, there might even be a sound when done.
5b	*Does the user understand, after the performed sequence of actions, that the right function has been performed?*	5. Yes.

Level2 – Analysis of operations – 1. Remove large plastic cover

1a	Will the user try to achieve the right goals of the operation?	4. Yes probably,
1b	*Does the user expect, on the basis of previously given indications, what is to be performed?*	4. Yes probably,
2a	Will the user be able to notice that the action of the operation is available?	4. Yes probably
2b	*Does the machine give clues that show that the action is available and how to perform it?*	4. Yes probably,
3a	Will the user associate the action of the operation with the right goal of the operation?	4. Yes probably,
3b	*Can the user's assumed operation and the machine's indications coincide?*	4. Yes probably, might not be instructions to compare with
4a	Will the user be able to perform the correct action?	5. Yes,
4b	*Do the abilities of the user match the demands by the machine?*	4. Yes probably, might be lack of instructions though
5a	Will the user get sufficient feedback to understand that the action has been performed and the goal has been achieved?	3. Impossible to say, depend on if there is instructions or not
5b	*Does the user understand, after the performed operation, that he/she has done it correctly?*	3. Impossible to say, might not be instructions to compare with

Level2 – Analysis of operations 1.1 Locate needle end

1a	Will the user try to achieve the right goals of the operation?	5. Yes, it is crucial
1b	*Does the user expect, on the basis of previously given indications, what is to be performed?*	4. Yes probably
2a	Will the user be able to notice that the action of the operation is available?	4. Yes probably, it is crucial
2b	*Does the machine give clues that show that the action is available and how to perform it?*	4. Impossible to say – no outer indications but design factors that plead to the interpretation and experience of the user
3a	Will the user associate the action of the operation with the right goal of the operation?	3. Impossible to say,
3b	*Can the user's assumed operation and the machine's indications coincide?*	3. Impossible to say, no indications
4a	Will the user be able to perform the correct action?	4. Yes, probably, depend on how the user interprets the design features since no indications
4b	*Do the abilities of the user match the demands by the machine?*	3. Impossible to say, depend on the experience of the user
5a	Will the user get sufficient feedback to understand that the action has been performed and the goal has been achieved?	1. No, not until the user tries to inject
5b	*Does the user understand, after the performed operation, that he/she has done it correctly?*	1. No,

Level2 – Analysis of operations – 1. twist the outer blue layer

1a	Will the user try to achieve the right goals of the operation?	2. No uncertain,
1b	*Does the user expect, on the basis of previously given indications, what is to be performed?*	2. No uncertain,
2a	Will the user be able to notice that the action of the operation is available?	3. do not know, depend on if there is instructions and if the user notice the markers and associates them with the action
2b	*Does the machine give clues that show that the action is available and how to perform it?*	4. Yes probably, there are markers
3a	Will the user associate the action of the operation with the right goal of the operation?	4. Yes probably, only two markers are given
3b	*Can the user's assumed operation and the machine's indications coincide?*	4. Yes probably,
4a	Will the user be able to perform the correct action?	4. Yes probably,
4b	*Do the abilities of the user match the demands by the machine?*	4. Yes probably,
5a	Will the user get sufficient feedback to understand that the action has been performed and the goal has been achieved?	5. Yes, The layer cannot be twisted more further as it reaches the second marker
5b	*Does the user understand, after the performed operation, that he/she has done it correctly?*	3. Do not know

Level2 – Analysis of operations – 1.1 Locate rare end

1a	Will the user try to achieve the right goals of the operation?	3. Impossible to say, might not know the importance of the rear end
1b	*Does the user expect, on the basis of previously given indications, what is to be performed?*	3. Impossible to say,
2a	Will the user be able to notice that the action of the operation is available?	3. Impossible to say,
2b	*Does the machine give clues that show that the action is available and how to perform it?*	3. Impossible to say, depend on how the user interpret the design of the needle end
3a	Will the user associate the action of the operation with the right goal of the operation?	3. impossible to say,
3b	*Can the user's assumed operation and the machine's indications coincide?*	4. Yes probably,
4a	Will the user be able to perform the correct action?	3. Impossible to say, depend on how the user interprets the design an possible instructions,
4b	*Do the abilities of the user match the demands by the machine?*	3. Impossible to say, depend on the experience of the user
5a	Will the user get sufficient feedback to understand that the action has been performed and the goal has been achieved?	1. No, not until the user tries to inject
5b	*Does the user understand, after the performed operation, that he/she has done it correctly?*	1. No,

Level2 – Analysis of operations – 2.2 Check for green marker

1a	Will the user try to achieve the right goals of the operation?	1. No
1b	*Does the user expect, on the basis of previously given indications, what is to be performed?*	1. No
2a	Will the user be able to notice that the action of the operation is available?	3. do not know, depend on if there is instructions and if the user notice the markers and associates them with the action
2b	*Does the machine give clues that show that the action is available and how to perform it?*	4. Yes probably, there are markers
3a	Will the user associate the action of the operation with the right goal of the operation?	4. Yes probably,
3b	*Can the user's assumed operation and the machine's indications coincide?*	4. Yes probably,
4a	Will the user be able to perform the correct action?	3. Do not know
4b	*Do the abilities of the user match the demands by the machine?*	3. Do not know
5a	Will the user get sufficient feedback to understand that the action has been performed and the goal has been achieved?	4. Yes probably, if looking for marker, the user would probably find them
5b	*Does the user understand, after the performed operation, that he/she has done it correctly?*	4. Yes probably,

Level2 – Analysis of operations – 2.3 Twist until green marker reaches end position

1a	Will the user try to achieve the right goals of the operation?	3. Do not know,
1b	*Does the user expect, on the basis of previously given indications, what is to be performed?*	4. Yes probably,
2a	Will the user be able to notice that the action of the operation is available?	4. yes probably, there are two markers
2b	*Does the machine give clues that show that the action is available and how to perform it?*	4. Yes probably, there are two markers
3a	Will the user associate the action of the operation with the right goal of the operation?	4. Yes probably,
3b	*Can the user's assumed operation and the machine's indications coincide?*	5. Yes,
4a	Will the user be able to perform the correct action?	4. Yes probably,
4b	*Do the abilities of the user match the demands by the machine?*	4. Yes probably,
5a	Will the user get sufficient feedback to understand that the action has been performed and the goal has been achieved?	5. Yes, The layer cannot be twisted more further as it reaches the second marker
5b	*Does the user understand, after the performed operation, that he/she has done it correctly?*	4. Yes probably,

Level2 – Analysis of operations – 3. Press the green button

1a	Will the user try to achieve the right goals of the operation?	4. Yes probably, it looks like a button with its shape and color
1b	*Does the user expect, on the basis of previously given indications, what is to be performed?*	3. impossible to say,
2a	Will the user be able to notice that the action of the operation is available?	3. impossible to say, depend on how the design is interpreted and if there is instructions
2b	*Does the machine give clues that show that the action is available and how to perform it?*	4. Yes probably, by shape and color
3a	Will the user associate the action of the operation with the right goal of the operation?	4. Yes probably, the user might not be certain of the goal (should he/she press button for needle to come out and then penetrate the skin or should it be used when to penetrate the skin)
3b	*Can the user's assumed operation and the machine's indications coincide?*	4. Yes probably
4a	Will the user be able to perform the correct action?	5. Yes, very easy action
4b	*Do the abilities of the user match the demands by the machine?*	4. Yes probably, very little force is needed
5a	Will the user get sufficient feedback to understand that the action has been performed and the goal has been achieved?	4. Yes probably, if observing that the transparent part of the injection displays how the injection fluid is being pushed down and then plunger pulls right up when done injecting, there might even be a sound when done.
5b	*Does the user understand, after the performed operation, that he/she has done it correctly?*	5. Yes, the needle has popped out and the injection has started which can be visually noticed

Level2 – Analysis of operations – 3.1 Locate rare end

1a	Will the user try to achieve the right goals of the operation?	3. Impossible to say, might not know the importance of the rear end
1b	*Does the user expect, on the basis of previously given indications, what is to be performed?*	3. Impossible to say,
2a	Will the user be able to notice that the action of the operation is available?	3. Impossible to say,
2b	*Does the machine give clues that show that the action is available and how to perform it?*	3. Impossible to say,
3a	Will the user associate the action of the operation with the right goal of the operation?	3. impossible to say,
3b	*Can the user's assumed operation and the machine's indications coincide?*	4. Yes probably,
4a	Will the user be able to perform the correct action?	3. Impossible to say, depend on how the user interprets the design and possible instructions
4b	*Do the abilities of the user match the demands by the machine?*	3. Impossible to say, depend on the experience of the user
5a	Will the user get sufficient feedback to understand that the action has been performed and the goal has been achieved?	1. No, not until the user tries to inject
5b	*Does the user understand, after the performed operation, that he/she has done it correctly?*	1. No,

Level2 – Analysis of operations – 3.2 Place injection on thigh

1a	Will the user try to achieve the right goals of the operation?	5. Yes, very crucial
1b	*Does the user expect, on the basis of previously given indications, what is to be performed?*	3. Impossible to say, depend on if there are instructions, some think it should go in the heart
2a	Will the user be able to notice that the action of the operation is available?	3. Impossible to say, depend on if there are instructions
2b	*Does the machine give clues that show that the action is available and how to perform it?*	2. No uncertain, the machine does not, but possible instructions might do
3a	Will the user associate the action of the operation with the right goal of the operation?	2. No uncertain, possible instructions might help
3b	*Can the user's assumed operation and the machine's indications coincide?*	2. No uncertain, the machine does not, but possible instructions might do
4a	Will the user be able to perform the correct action?	4. Yes probably,
4b	*Do the abilities of the user match the demands by the machine?*	3. Impossible to say, depend on the user and if there are instructions
5a	Will the user get sufficient feedback to understand that the action has been performed and the goal has been achieved?	3. Impossible to say, depend on if the user knows it should be in the thigh
5b	*Does the user understand, after the performed operation, that he/she has done it correctly?*	3. Impossible to say

Level2 – Analysis of operations – 4. Make sure solution has been injected

1a	Will the user try to achieve the right goals of the operation?	3. impossible to say, depend on if the user understand the fuzzy label
1b	*Does the user expect, on the basis of previously given indications, what is to be performed?*	2. No, uncertain
2a	Will the user be able to notice that the action of the operation is available?	4. Yes probably, a transparent part of the injection displays how the injection fluid is being pushed down and then plunger pulls right up when done injecting, there might even be a sound when done.
2b	*Does the machine give clues that show that the action is available and how to perform it?*	4. Yes probably, the transparent part indicates this
3a	Will the user associate the action of the operation with the right goal of the operation?	5. Yes
3b	*Can the user's assumed operation and the machine's indications coincide?*	4. Yes probably,
4a	Will the user be able to perform the correct action?	4. Yes probably,
4b	*Do the abilities of the user match the demands by the machine?*	4. yes probably
5a	Will the user get sufficient feedback to understand that the action has been performed and the goal has been achieved?	5. Yes probably, a transparent part of the injection displays how the injection fluid is being pushed down and then plunger pulls right up when done injecting, there might even be a sound when done.
5b	*Does the user understand, after the performed operation, that he/she has done it correctly?*	5. Yes, --||--

Level2 – Analysis of operations – 4.1 Watch as solution passes though the injection

1a	Will the user try to achieve the right goals of the operation?	5. yes,
1b	*Does the user expect, on the basis of previously given indications, what is to be performed?*	4. Yes probably,
2a	Will the user be able to notice that the action of the operation is available?	4. Yes probably,
2b	*Does the machine give clues that show that the action is available and how to perform it?*	5. Yes probably
3a	Will the user associate the action of the operation with the right goal of the operation?	5. Yes,
3b	*Can the user's assumed operation and the machine's indications coincide?*	5. Yes,
4a	Will the user be able to perform the correct action?	5. Yes,
4b	*Do the abilities of the user match the demands by the machine?*	4. Yes probably,
5a	Will the user get sufficient feedback to understand that the action has been performed and the goal has been achieved?	5. Yes,
5b	*Does the user understand, after the performed operation, that he/she has done it correctly?*	4. Yes probably, might however think it will go down again

Level2 – Analysis of operations – 4.2 Hold while injecting

1a	Will the user try to achieve the right goals of the operation?	4. Yes probably,
1b	*Does the user expect, on the basis of previously given indications, what is to be performed?*	4. Yes probably,
2a	Will the user be able to notice that the action of the operation is available?	4. Yes probably,
2b	*Does the machine give clues that show that the action is available and how to perform it?*	5. Yes
3a	Will the user associate the action of the operation with the right goal of the operation?	4. Yes probably,
3b	*Can the user's assumed operation and the machine's indications coincide?*	4. Yes probably,
4a	Will the user be able to perform the correct action?	5. Yes
4b	*Do the abilities of the user match the demands by the machine?*	4. Yes probably,
5a	Will the user get sufficient feedback to understand that the action has been performed and the goal has been achieved?	5. Yes,
5b	*Does the user understand, after the performed operation, that he/she has done it correctly?*	4. Yes probably,

Level2 – Analysis of operations – 6. Remove injection

1a	Will the user try to achieve the right goals of the operation?	5. Yes
1b	*Does the user expect, on the basis of previously given indications, what is to be performed?*	5. Yes,
2a	Will the user be able to notice that the action of the operation is available?	5. Yes,
2b	5. Yes,	5. Yes, since the machine displays how the needle is being with drawn
3a	Will the user associate the action of the operation with the right goal of the operation?	5. Yes,
3b	*Can the user's assumed operation and the machine's indications coincide?*	5. Yes,
4a	Will the user be able to perform the correct action?	5. Yes,
4b	*Do the abilities of the user match the demands by the machine?*	5. yes,
5a	Will the user get sufficient feedback to understand that the action has been performed and the goal has been achieved?	5. Yes,
5b	*Does the user understand, after the performed operation, that he/she has done it correctly?*	5. Yes,

Adrenaline click and Twininject (dose 1)

Level 1 – Analysis of tasks/functions – inject adrenaline into outer part of the thigh

1a	Will the user know that the evaluated function is available?	4. Yes probably, but less chance if not familiar with allergies, the label does not say it is for allergy use
1b	*Does the user expect, on the basis of previously given indications that the function exists in the machine?*	4. Yes probably, there is a label, but does not say it is for allergy use
2a	Will the user be able to notice that the function is available?	3. Do not know, stressful situation, label do not say what it is for
2b	*Does the machine give clues that show that the function exists?*	4. Yes probably, label with instructions
3a	Will the user associate the clues with the function?	4. Yes probably, with successful generic knowledge but may be uncertain about where the adrenaline should be injected
3b	*Can the user's expectations and the machine's indications coincide?*	3. Do not know, depend on what expectations the user has – some think that the injection should go in the heart
4a	Will the user get sufficient feedback when using the function?	2. Uncertain, no feedback is given if the injection is still ongoing nor when the injection has finished
4b	*Does the machine give information that the function has been chosen and the position the user is at in the interaction?*	4. Yes probably, there is a sound of a click that appears right after trigger action of the injection
5a	Will the user get sufficient feedback to understand that the function has been fully performed?	1. No, no feedback is given when the injection has finished
5b	*Does the user understand, after the performed sequence of actions, that the right function has been performed?*	5. Yes, if the needle is exposed or not, and not still squirts fluid, (when pulled out) provide feedback about whether or not the injection has been given

Level2 – Analysis of operations – 1. Check injection fluid before use

1a	Will the user try to achieve the right goals of the operation?	2. No uncertain, there is a small window to watch the fluid and insufficient clues about what to do with it
1b	*Does the user expect, on the basis of previously given indications, what is to be performed?*	1. No,
2a	Will the user be able to notice that the action of the operation is available?	3. Do not know, very hard to notice the instructions but there is a chance as there are instructions under the window
2b	*Does the machine give clues that show that the action is available and how to perform it?*	4. Yes probably, there are instructions, however vague
3a	Will the user associate the action of the operation with the right goal of the operation?	4. Yes probably, it might be hard to understand what to look for since the explanation on the label is vague and only says replace if cloudy or discolored
3b	*Can the user's assumed operation and the machine's indications coincide?*	3. Do not know.
4a	Will the user be able to perform the correct action?	3. Do not know, it depend of what is perceived as cloudy or discolored
4b	*Do the abilities of the user match the demands by the machine?*	3. Do not know, since there is room for misunderstandings
5a	Will the user get sufficient feedback to understand that the action has been performed and the goal has been achieved?	2. No uncertain, no feedback but subjective visual feedback is provided
5b	*Does the user understand, after the performed operation, that he/she has done it correctly?*	2. No uncertain, since there is a subjective judgment regarding the color of the fluid

Level2 – Analysis of operations – 2. Pull of the big gray socket

1a	Will the user try to achieve the right goals of the operation?	5. Yes probably, it is marked ("1"), information on the label say to remove
1b	*Does the user expect, on the basis of previously given indications, what is to be performed?*	4. Yes probably, because of the marking ("1") & "PULL"
2a	Will the user be able to notice that the action of the operation is available?	5. Yes, information on label, marked ("1") & "PULL"
2b	*Does the machine give clues that show that the action is available and how to perform it?*	5. Yes – label and making ("1") & "PULL"
3a	Will the user associate the action of the operation with the right goal of the operation?	5. yes, the socked is successfully removed
3b	*Can the user's assumed operation and the machine's indications coincide?*	5. Yes
4a	Will the user be able to perform the correct action?	5. Yes, very easy action
4b	*Do the abilities of the user match the demands by the machine?*	5. Yes, very little force is needed to perform it
5a	Will the user get sufficient feedback to understand that the action has been performed and the goal has been achieved?	4. Yes probably, the label clearly illustrate that the socket should be removed
5b	*Does the user understand, after the performed operation, that he/she has done it correctly?*	4. Yes probably, it could be compared to the picture on the label

Level2 – Analysis of operations – 2.1. Locate needle end

1a	Will the user try to achieve the right goals of the operation?	5. Yes, it is crucial
1b	*Does the user expect, on the basis of previously given indications, what is to be performed?*	4. Yes probably
2a	Will the user be able to notice that the action of the operation is available?	5. Yes, it is crucial
2b	*Does the machine give clues that show that the action is available and how to perform it?*	4. Yes probably, design of gray socket, red end when socket is removed
3a	Will the user associate the action of the operation with the right goal of the operation?	5. yes, the user want to find the needle end
3b	*Can the user's assumed operation and the machine's indications coincide?*	4. Yes probably,
4a	Will the user be able to perform the correct action?	4. Yes probably, depend on how the user interprets the instructions and clues on the injection
4b	*Do the abilities of the user match the demands by the machine?*	3. Impossible to say, depend on the experience of the user
5a	Will the user get sufficient feedback to understand that the action has been performed and the goal has been achieved?	1. No, not until the user tries to inject
5b	*Does the user understand, after the performed operation, that he/she has done it correctly?*	1. No,

Level2 – 3. Pull of smaller gray socket

1a	Will the user try to achieve the right goals of the operation?	5. Yes probably, it is marked ("2"), information on the label say to remove
1b	*Does the user expect, on the basis of previously given indications, what is to be performed?*	4. Yes probably, because of the marking ("2")
2a	Will the user be able to notice that the action of the operation is available?	5. Yes, information on label, marked ("1")
2b	*Does the machine give clues that show that the action is available and how to perform it?*	5. Yes – label and making ("1")
3a	Will the user associate the action of the operation with the right goal of the operation?	5. yes, the socked is successfully removed
3b	*Can the user's assumed operation and the machine's indications coincide?*	5. Yes
4a	Will the user be able to perform the correct action?	5. Yes, very easy action
4b	*Do the abilities of the user match the demands by the machine?*	5. Yes, very little force is needed to perform it
5a	Will the user get sufficient feedback to understand that the action has been performed and the goal has been achieved?	4. Yes probably, the label clearly illustrate that the socket should be removed
5b	*Does the user understand, after the performed operation, that he/she has done it correctly?*	4. Yes probably, it could be compared to the picture on the label

Level2 – Analysis of operations – 3.1 locate rear end

1a	Will the user try to achieve the right goals of the operation?	3. Impossible to say,
1b	*Does the user expect, on the basis of previously given indications, what is to be performed?*	3. Impossible to say,
2a	Will the user be able to notice that the action of the operation is available?	3. Impossible to say,
2b	*Does the machine give clues that show that the action is available and how to perform it?*	3. Impossible to say, depend on how the user interpret the red tip indicating the needle end
3a	Will the user associate the action of the operation with the right goal of the operation?	3. impossible to say,
3b	*Can the user's assumed operation and the machine's indications coincide?*	4. Yes probably,
4a	Will the user be able to perform the correct action?	3. Impossible to say, depend on how the user interprets the instructions and clues on the injection
4b	*Do the abilities of the user match the demands by the machine?*	3. Impossible to say, depend on the experience of the user
5a	Will the user get sufficient feedback to understand that the action has been performed and the goal has been achieved?	1. No, not until the user tries to inject
5b	*Does the user understand, after the performed operation, that he/she has done it correctly?*	1. No,

Level2 – Analysis of operations 4. Press hard

1a	Will the user try to achieve the right goals of the operation?	4. Yes probably, depend on if the user understand the instructions on the label and the level of experience – good instructions with pictures and highlighted text saying to press hard
1b	*Does the user expect, on the basis of previously given indications, what is to be performed?*	3. Do not know,
2a	Will the user be able to notice that the action of the operation is available?	4. Yes probably, illustrative, instructing label
2b	*Does the machine give clues that show that the action is available and how to perform it?*	3. Do not know. The machine itself does not but instructions on it does
3a	Will the user associate the action of the operation with the right goal of the operation?	4. Yes probably,
3b	*Can the user's assumed operation and the machine's indications coincide?*	4. Yes probably,
4a	Will the user be able to perform the correct action?	5. Yes, only a little force is needed
4b	*Do the abilities of the user match the demands by the machine?*	4. Yes probably,
5a	Will the user get sufficient feedback to understand that the action has been performed and the goal has been achieved?	5. Yes, the needle comes out and the user could feel it, (patient is the user) 4. Yes probably, sound of the needle and possibly vibrations in the pen, if patient awake it could give feedback that the needle has penetrated the skin, (other than patient is the user)
5b	*Does the user understand, after the performed operation, that he/she has done it correctly?*	4. Yes probably --||--

Level2 – Analysis of operations – 4.1 place on outer side of thigh

1a	Will the user try to achieve the right goals of the operation?	5. Yes, very crucial
1b	*Does the user expect, on the basis of previously given indications, what is to be performed?*	4. Yes probably, but some might expect it to be somewhere other than thigh
2a	Will the user be able to notice that the action of the operation is available?	5. Yes, illustrating label with instructions
2b	*Does the machine give clues that show that the action is available and how to perform it?*	5. Yes, illustrating instructing label
3a	Will the user associate the action of the operation with the right goal of the operation?	4. Yes probably,
3b	*Can the user's assumed operation and the machine's indications coincide?*	4. Yes probably, comparison with instruction label
4a	Will the user be able to perform the correct action?	5. Yes,,
4b	*Do the abilities of the user match the demands by the machine?*	5. Yes,
5a	Will the user get sufficient feedback to understand that the action has been performed and the goal has been achieved?	4. Yes probably, the user will feel (haptic feedback) when touching the thigh
5b	*Does the user understand, after the performed operation, that he/she has done it correctly?*	4. Yes probably, comparison with the mental image of the instruction label (since the hand is now covering it)

Level2 – Analysis of operations – 5. Hold for 10

1a	Will the user try to achieve the right goals of the operation?	4. Yes probably, highlighted instructions on the information label,
1b	*Does the user expect, on the basis of previously given indications, what is to be performed?*	2. No, uncertain
2a	Will the user be able to notice that the action of the operation is available?	4. Yes probably, since there is highlighted instructions on the information label,
2b	*Does the machine give clues that show that the action is available and how to perform it?*	4. Yes probably, since the information is available on the information label but the machine itself does not give any clues
3a	Will the user associate the action of the operation with the right goal of the operation?	2. No, uncertain
3b	*Can the user's assumed operation and the machine's indications coincide?*	4. Yes probably, comparison with instruction label
4a	Will the user be able to perform the correct action?	5. Yes,
4b	*Do the abilities of the user match the demands by the machine?*	4. Yes probably, time can however be perceived as going faster when in a stressful situation
5a	Will the user get sufficient feedback to understand that the action has been performed and the goal has been achieved?	1. No, no feedback is given after 10 seconds
5b	*Does the user understand, after the performed operation, that he/she has done it correctly?*	4.Yes probably, no injection fluid is still running when the needle has been pulled out

Level2 – Analysis of operations – 6. Pull out injection

1a	Will the user try to achieve the right goals of the operation?	5. Yes
1b	*Does the user expect, on the basis of previously given indications, what is to be performed?*	5. Yes,
2a	Will the user be able to notice that the action of the operation is available?	5. Yes,
2b	*Does the machine give clues that show that the action is available and how to perform it?*	3. Do not know - the machine itself does not give any clues but generic knowledge about injections does
3a	Will the user associate the action of the operation with the right goal of the operation?	5. Yes,
3b	*Can the user's assumed operation and the machine's indications coincide?*	5. Yes,
4a	Will the user be able to perform the correct action?	5. Yes,
4b	*Do the abilities of the user match the demands by the machine?*	5. yes,
5a	Will the user get sufficient feedback to understand that the action has been performed and the goal has been achieved?	5. Yes, the will see (visual feedback) that the needle is no longer in the thigh
5b	*Does the user understand, after the performed operation, that he/she has done it correctly?*	5. Yes,

Twininject (dose 2)

Level 1 – Analysis of tasks/functions – inject 2nd dose adrenaline into the outer part of the thigh

1a	Will the user know that the evaluated function is available?	2. No uncertain, there are instruction but you have to remove the first instructions in order to find to the new once, there is a small label explaining this
1b	*Does the user expect, on the basis of previously given indications that the function exists in the machine?*	1. No
2a	Will the user be able to notice that the function is available?	3. Do not know, there is an instructing label but it might be hard to find and understand
2b	*Does the machine give clues that show that the function exists?*	4. Yes probably, small label exist
3a	Will the user associate the clues with the function?	3. Do not know,
3b	*Can the user's expectations and the machine's indications coincide?*	3. Do not know,
4a	Will the user get sufficient feedback when using the function?	5. Yes, what happens is very clear
4b	*Does the machine give information that the function has been chosen and the position the user is at in the interaction?*	5. Yes,
5a	Will the user get sufficient feedback to understand that the function has been fully performed?	5. Yes,
5b	*Does the user understand, after the performed sequence of actions, that the right function has been performed?*	4. Yes probably, as long as the user understand were the injection should go.

Level2 – Analysis of operations – 1. Remove (unscrew) the red tip

1a	Will the user try to achieve the right goals of the operation?	2. No uncertain, there are instruction but you have to remove the first instructions in order to find to the new once, there is a small label explaining this
1b	*Does the user expect, on the basis of previously given indications, what is to be performed?*	2. No uncertain,
2a	Will the user be able to notice that the action of the operation is available?	3. Do not know, there is an instructing label but it might be hard to find and understand
2b	*Does the machine give clues that show that the action is available and how to perform it?*	4. Yes probably, there are instructions but might be hard to find.
3a	Will the user associate the action of the operation with the right goal of the operation?	4. Yes probably,
3b	*Can the user's assumed operation and the machine's indications coincide?*	4. Yes probably,
4a	Will the user be able to perform the correct action?	4. Yes probably,
4b	*Do the abilities of the user match the demands by the machine?*	4. Yes probably,
5a	Will the user get sufficient feedback to understand that the action has been performed and the goal has been achieved?	4. Yes probably, the tip is removed
5b	*Does the user understand, after the performed operation, that he/she has done it correctly?*	4. Yes probably, comparison with instructing label

Level2 – Analysis of operations – 2 Remove syringe from barrel

1a	Will the user try to achieve the right goals of the operation?	4. Yes probably,
1b	*Does the user expect, on the basis of previously given indications, what is to be performed?*	3. Do not know
2a	Will the user be able to notice that the action of the operation is available?	3. Do not know,
2b	*Does the machine give clues that show that the action is available and how to perform it?*	2. No uncertain,
3a	Will the user associate the action of the operation with the right goal of the operation?	3. do not know,
3b	*Can the user's assumed operation and the machine's indications coincide?*	4. Yes probably,
4a	Will the user be able to perform the correct action?	4. Yes probably,
4b	*Do the abilities of the user match the demands by the machine?*	4. Yes Probably,
5a	Will the user get sufficient feedback to understand that the action has been performed and the goal has been achieved?	4. Yes Probably, when the syringe is out the generic knowledge tell it is an additional injection that looks even more like an injection than the auto injector
5b	*Does the user understand, after the performed operation, that he/she has done it correctly?*	4. Yes Probably, when the syringe is out the generic knowledge tell it is an additional injection that looks even more like an injection than the auto injector

Level2 – Analysis of operations – 3. Remove (slide off) the yellow collar

1a	Will the user try to achieve the right goals of the operation?	4. Yes probably, instructing label
1b	*Does the user expect, on the basis of previously given indications, what is to be performed?*	4. Yes probably, instructing label
2a	Will the user be able to notice that the action of the operation is available?	4. Yes probably, instructing label and the possibility to move it
2b	*Does the machine give clues that show that the action is available and how to perform it?*	4. Yes probably, instructing label, color coding
3a	Will the user associate the action of the operation with the right goal of the operation?	4. Yes probably,
3b	*Can the user's assumed operation and the machine's indications coincide?*	4. Yes probably,
4a	Will the user be able to perform the correct action?	5. Yes,
4b	*Do the abilities of the user match the demands by the machine?*	5. Yes,
5a	Will the user get sufficient feedback to understand that the action has been performed and the goal has been achieved?	5. Yes,
5b	*Does the user understand, after the performed operation, that he/she has done it correctly?*	5.Yes,

Level2 – Analysis of operations – 4. Put needle into thigh

1a	Will the user try to achieve the right goals of the operation?	5. Yes,
1b	*Does the user expect, on the basis of previously given indications, what is to be performed?*	4. Yes probably, might thing that the injection should be injected elsewhere even though there is an instructing label
2a	Will the user be able to notice that the action of the operation is available?	5. Yes,
2b	*Does the machine give clues that show that the action is available and how to perform it?*	5. Yes,
3a	Will the user associate the action of the operation with the right goal of the operation?	5. Yes,
3b	*Can the user's assumed operation and the machine's indications coincide?*	5. Yes,
4a	Will the user be able to perform the correct action?	5. Yes,
4b	*Do the abilities of the user match the demands by the machine?*	5. Yes,
5a	Will the user get sufficient feedback to understand that the action has been performed and the goal has been achieved?	5. Yes,
5b	*Does the user understand, after the performed operation, that he/she has done it correctly?*	5. Yes,

Level2 – Analysis of operations – 5. Push plunger all the way

1a	Will the user try to achieve the right goals of the operation?	5. Yes,
1b	*Does the user expect, on the basis of previously given indications, what is to be performed?*	5. Yes,
2a	Will the user be able to notice that the action of the operation is available?	5. Yes,
2b	*Does the machine give clues that show that the action is available and how to perform it?*	5. Yes,
3a	Will the user associate the action of the operation with the right goal of the operation?	5. Yes,
3b	*Can the user's assumed operation and the machine's indications coincide?*	5. Yes,
4a	Will the user be able to perform the correct action?	5. Yes,
4b	*Do the abilities of the user match the demands by the machine?*	5. Yes,
5a	Will the user get sufficient feedback to understand that the action has been performed and the goal has been achieved?	5. Yes,
5b	*Does the user understand, after the performed operation, that he/she has done it correctly?*	5. Yes,

Level2 – Analysis of operations – 6. Pull out injection

1a	Will the user try to achieve the right goals of the operation?	5. Yes,
1b	*Does the user expect, on the basis of previously given indications, what is to be performed?*	5. Yes,
2a	Will the user be able to notice that the action of the operation is available?	5. Yes,
2b	*Does the machine give clues that show that the action is available and how to perform it?*	5. Yes,
3a	Will the user associate the action of the operation with the right goal of the operation?	5. Yes,
3b	*Can the user's assumed operation and the machine's indications coincide?*	5. Yes,
4a	Will the user be able to perform the correct action?	5. Yes,
4b	*Do the abilities of the user match the demands by the machine?*	5. Yes,
5a	Will the user get sufficient feedback to understand that the action has been performed and the goal has been achieved?	5. Yes,
5b	*Does the user understand, after the performed operation, that he/she has done it correctly?*	5. Yes,

Emerade

Level 1 – Analysis of tasks/functions – 1. Inject adrenaline in to the outer part of the leg

1a	Will the user know that the evaluated function is available?	4. Yes probably, but less chance if not familiar with allergies, the label does not say it is for allergy use
1b	*Does the user expect, on the basis of previously given indications that the function exists in the machine?*	4. Yes probably, there is a label, but does not say it is for allergy use
2a	Will the user be able to notice that the function is available?	3. Do not know, stressful situation, label do not say what it is for
2b	*Does the machine give clues that show that the function exists?*	4. Yes probably, label with instructions
3a	Will the user associate the clues with the function?	4. Yes probably, with successful generic knowledge but may be uncertain about where the adrenaline should be injected, however clear picture shows this
3b	*Can the user's expectations and the machine's indications coincide?*	3. Do not know, depend on what expectations the user has – some think that the injection should go in the heart
4a	Will the user get sufficient feedback when using the function?	2. Uncertain, no feedback is given if the injection is still ongoing nor when the injection has finished
4b	*Does the machine give information that the function has been chosen and the position the user is at in the interaction?*	4. Yes probably, there is a sound of a click that appears right after trigger action of the injection
5a	Will the user get sufficient feedback to understand that the function has been fully performed?	1. No, no feedback is given when the injection has finished
5b	*Does the user understand, after the performed sequence of actions, that the right function has been performed?*	5. Yes, if the needle is exposed or not, and not still squirts fluid, (when pulled out) provide feedback about whether or not the injection has been given

Level2 – Analysis of operations – 1. Remove cap

1a	Will the user try to achieve the right goals of the operation?	5. Yes, sufficient instructions on label, and on the cap itself marked ("1") and design
1b	*Does the user expect, on the basis of previously given indications, what is to be performed?*	5. Yes,
2a	Will the user be able to notice that the action of the operation is available?	5. Yes,
2b	*Does the machine give clues that show that the action is available and how to perform it?*	5. Yes, both design of machine and instructing label
3a	Will the user associate the action of the operation with the right goal of the operation?	5. Yes,
3b	*Can the user's assumed operation and the machine's indications coincide?*	5. Yes,
4a	Will the user be able to perform the correct action?	5. Yes,
4b	*Do the abilities of the user match the demands by the machine?*	5. Yes,
5a	Will the user get sufficient feedback to understand that the action has been performed and the goal has been achieved?	4. Yes probably, the cap comes off
5b	*Does the user understand, after the performed operation, that he/she has done it correctly?*	4. Yes probably

Level2 – Analysis of operations – 3. Press hard

1a	Will the user try to achieve the right goals of the operation?	5. Yes,
1b	*Does the user expect, on the basis of previously given indications, what is to be performed?*	3. Do not know, the user might not understand how hard to press
2a	Will the user be able to notice that the action of the operation is available?	4. Yes probably,
2b	*Does the machine give clues that show that the action is available and how to perform it?*	4. Yes probably, not the machine itself but the instructing label
3a	Will the user associate the action of the operation with the right goal of the operation?	4. Yes probably,
3b	*Can the user's assumed operation and the machine's indications coincide?*	4. Yes probably,
4a	Will the user be able to perform the correct action?	5. Yes,
4b	*Do the abilities of the user match the demands by the machine?*	5. Yes,
5a	Will the user get sufficient feedback to understand that the action has been performed and the goal has been achieved?	5. Yes, the needle comes out, sound of a click
5b	*Does the user understand, after the performed operation, that he/she has done it correctly?*	5. Yes,

Level2 – Analysis of operations – 3.1 place on outer side of thigh

1a	Will the user try to achieve the right goals of the operation?	5. Yes, very crucial
1b	*Does the user expect, on the basis of previously given indications, what is to be performed?*	4. Yes probably, but some might expect it to be somewhere other than thigh
2a	Will the user be able to notice that the action of the operation is available?	5. Yes, illustrating label with instructions
2b	*Does the machine give clues that show that the action is available and how to perform it?*	5. Yes, illustrating instructing label
3a	Will the user associate the action of the operation with the right goal of the operation?	4. Yes probably,
3b	*Can the user's assumed operation and the machine's indications coincide?*	4. Yes probably, comparison with instruction label
4a	Will the user be able to perform the correct action?	5. Yes,
4b	*Do the abilities of the user match the demands by the machine?*	5. Yes,
5a	Will the user get sufficient feedback to understand that the action has been performed and the goal has been achieved?	4. Yes probably, the user will feel (haptic feedback) when touching the thigh
5b	*Does the user understand, after the performed operation, that he/she has done it correctly?*	4. Yes probably, comparison with the mental image of the instruction label (since the hand is now covering it)

Level2 – Analysis of operations – 4. Hold for 5 seconds

1a	Will the user try to achieve the right goals of the operation?	4. Yes probably, illustrating label
1b	*Does the user expect, on the basis of previously given indications, what is to be performed?*	2. No, uncertain
2a	Will the user be able to notice that the action of the operation is available?	4. Yes probably, since there is instructions on the information label both in words and with an image of a clock.
2b	*Does the machine give clues that show that the action is available and how to perform it?*	4. Yes probably, since the information is available on the information label but the machine itself does not give any clues
3a	Will the user associate the action of the operation with the right goal of the operation?	2. No, uncertain
3b	*Can the user's assumed operation and the machine's indications coincide?*	4. Yes probably, comparison with instruction label
4a	Will the user be able to perform the correct action?	5. Yes,
4b	*Do the abilities of the user match the demands by the machine?*	4. Yes probably, time can however be perceived as going faster when in a stressful situation
5a	Will the user get sufficient feedback to understand that the action has been performed and the goal has been achieved?	1. No, no feedback is given after 5 seconds
5b	*Does the user understand, after the performed operation, that he/she has done it correctly?*	4.Yes probably, no injection fluid is still running when the needle has been pulled out

Level2 – Analysis of operations – 5. Pull out injection

1a	Will the user try to achieve the right goals of the operation?	5. Yes
1b	*Does the user expect, on the basis of previously given indications, what is to be performed?*	5. Yes,
2a	Will the user be able to notice that the action of the operation is available?	5. Yes,
2b	*Does the machine give clues that show that the action is available and how to perform it?*	3. Do not know - the machine itself does not give any clues but generic knowledge about injections does
3a	Will the user associate the action of the operation with the right goal of the operation?	5. Yes,
3b	*Can the user's assumed operation and the machine's indications coincide?*	5. Yes,
4a	Will the user be able to perform the correct action?	5. Yes,
4b	*Do the abilities of the user match the demands by the machine?*	5. yes,
5a	Will the user get sufficient feedback to understand that the action has been performed and the goal has been achieved?	5. Yes, the will see (visual feedback) that the needle is no longer in the thigh
5b	*Does the user understand, after the performed operation, that he/she has done it correctly?*	5. Yes,

Appendix 5

Metric List

Customer/User need		
Nr of doses to carry	**Importance**	**Nr of expressed needs**
2	***	4
2 to 3	*	1
1	**	2
1 to 3	*	1
Properties		
Have longer expiration date than 1 year	*	1
Provide secure impression regarding safety catches	*	1
Not to be misstaken for something else	*	1
Cover	*	
Cover	*	1
Customized cover	*	1
Cover bag	*	1
Cover not make it larger	*	1
Discreet cover or cover bag	*	1
Routines for expiration date and fluid		
Routine for checking expiration date	***	5
Routine for checking injection fluid	*	1
Practise		
Opportunity to practise	***	4
Demonstration sessions	**	2
Convenience		
Place to store Betapred in conjunction with injection	**	2
Environment to ba able to use it	*	1
Noisy	*	1
Dirty	**	2
Dusty	*	1
In a whicle on a bumpy road	*	1
Outdoor	*	1
Abroad	**	3
In warm climate	*	1
Sunny weather	*	1
Home	**	3
Djungle	*	1
On a bus	*	1
Resturant	*	1

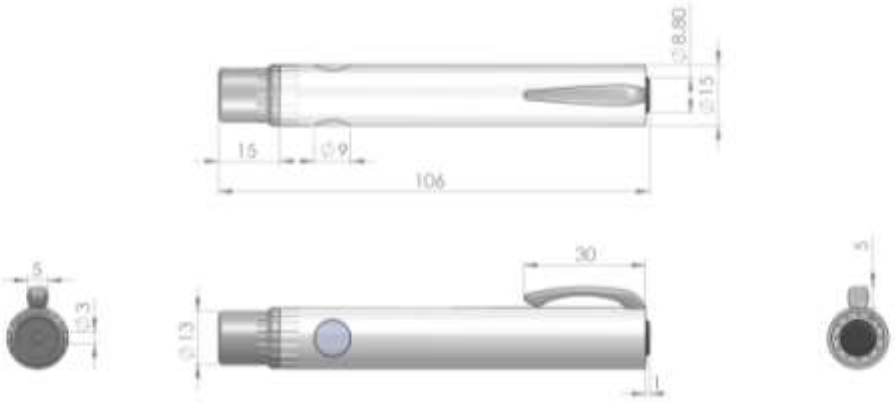
Fast vehicle	*	1
Hotel room	*	1
Carrying		
Convenient to carry at all times	***	8
without wearing special cloths	**	3
When wearing a dress	*	1
Without additional bag	**	2
Someting to carry in/with	*	1
Way to store in bag	**	2
Customized case	*	1
Consistent way & place	*	1
Fit average pocket	***	5
Fit small bag	*	1
Convenient to carry for childern	*	1
Fit average jacket pocket	**	2
Fit in school bag	*	1
All injections at the same place	*	1
Fit smaller pocket of bag	*	1
Convenient to carry in bar environment	*	1
Fit average back pocket of pants	*	1
Fit average font pocket of pants	*	1
Storage		
Consistent way to store	*	1
Able to store in office	*	1
Easy to store in a persons room	*	1
Able to stoe in kitchen	*	1
Able to store in bathroom	*	1
Able to store together with other medicine	*	1
Able to store in a pantry	*	1
Use functions		
Fast to use	*	1
Intuitive to use	***	5
Easy to use	*	1
Way to recognize when injection has been forgotten	*	1
Be able to be handled by a child	*	1
Child proof	*	1
Simple to explain to others	*	1
Can be injected through cloths	*	1
Little muscle foce to inject	*	1
Support mental model off current injection	***	8
Information on injection		
Clearly indicate when fluid is ok	*	1
Clearly indicate when fluid is not ok	***	4
Clearly inform about cecking injection fluid	**	3

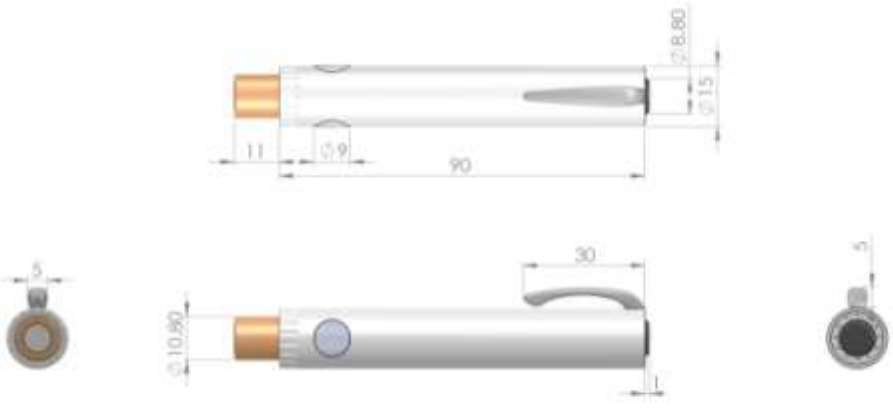
Clearly communicate whati it is for	***	5
Clearly display expiration date	*	1
Clearly communicate how many doses injection contains	*	1
Easy instructions to interpret	**	3
Sufficient & clear instructions	**	3
Communicate injection	*	1
Clear disposal instructions	*	1
Communicate that it is medicine	*	1
Font size suitable for reading on an average arm lenght distance	**	2
Clear instructing pictures	**	2
Instructions to be understood by young adoloescents	**	2
Communicate the severity of the allergy	**	2
Instructions that support memory functions	**	3
Instructions should be precieved by any one	**	3
Clearly emphezise that injection should be given in the thigh	**	2
Clear temperature handling instructions	*	1
Other information in conjuction with injection		
Sufficient information about the allergy reaction	*	1
Overall information	***	5
Pregnacy and inejction	*	1
Appearance		
Distract attention from the needle	**	3
Not scare other people	**	2
Not scare the user / victim	*	1
Not look to hospital like	*	1
Give serious impression	**	3
Discreet design	**	3
Give "cool" impression	***	4
Comforting design	*	1
Less seruios impression for childern	*	1
Design that distracs childern	**	3
Distract attention from inejction fluid movement (when using)	*	1
Gracefull	*	1
Deliver pride to the young owner	*	1
Other physical design		
Convenient shape for daily carrying	***	4
Small	***	7
Big enough for average hand to grasp	*	1
Few colors	*	1

Enable the user to sit comfortably with injection in average pocket in trowsers (front / back pocket)	*	1
Not slip or roll away if dropped	*	1
Fit movement patterns of young adolescents & children	**	3
When dancing, no hindrance	**	2
When playing, no hindrance	*	1
Functions and features		
Inject fast	*	1
Communicate how to use while start using	*	1
Communicate while still injecting	***	6
Communicate when done injecting	***	9
Communicate when injection has expired	***	5
Before / after injection		
Easy to find in case of emergancy	**	3
Safely carry used injection to disposal	*	1
Temperature		
Withstand heat	**	3
be able to be stored in room temperature	*	1
Withstand cold temperature	**	2
Withstand a moist environment	*	1
Withstand summer climate (heat)	*	1

Appendix 6

Elektra Fusion – Before testing

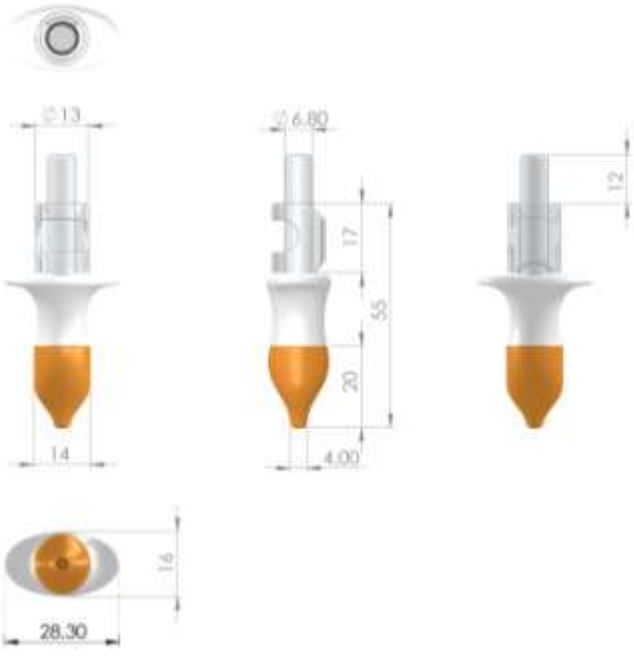




XL

Appendix 7

MicroJect Assembler – Before testing



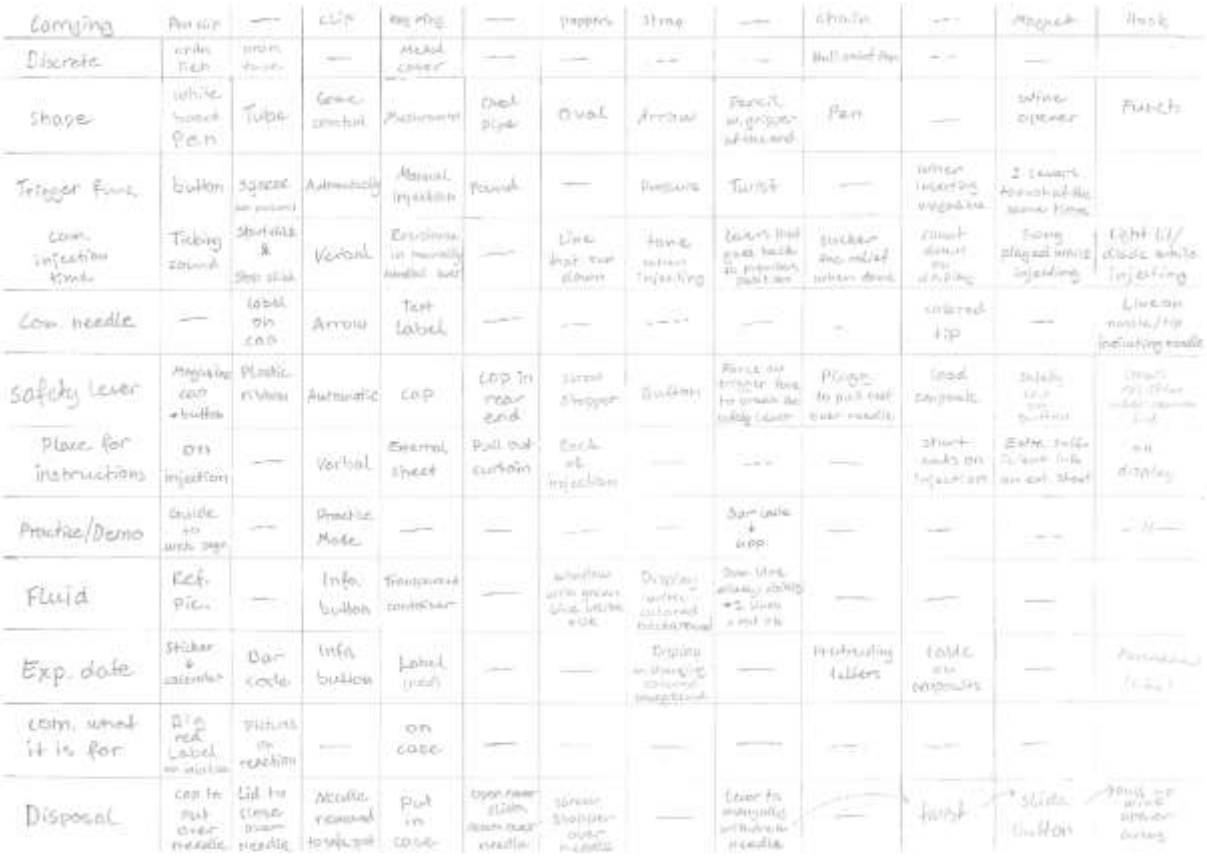
Appendix 8

Pugh Matrix

Rererence; EpiPen	Puzzlepen	Air Tube	The Player	MicroJect	O.W.G.	Oval R.D.	Robin Hood	Twister	BubblePen	Multi amp	Punch liner	Superman
Size & Shape	+	+	+	+	+	+	+	+	+	+	0	0
Place to store other medicine	0	0	+	0	0	0	+	+	0	+	-	0
Few steps as possible	-	-	-	+	0	-	0	0	-	0	-	0
Intuitive	0	+	+	+	0	-	+	0	+	0	+	0
Support mental models	+	+	+	0	0	-	+	-	+	0	-	0
Injecting status	+	+	+	+	0	+	+	+	+	+	+	0
Communicate needle	-	0	+	+	+	0	+	+	0	0	0	0
Safety levers	**+**	**+**	+	0	0	+	+	0	+	+	+	0
Place for Instructions	-	0	+	+	+	0	+	0	-	0	0	0
Over all information	-	+	+	+	+	0	+	0	-	0	0	0
Com. what it is for	+	-	+	+	+	+	+	0	+	+	+	0
Practice/Demo	+	+	+	+	+	+	+	+	+	+	+	0
Com. fluid status	+	+	+	+	0	+	+	+	+	+	+	0
Com. expiration date	+	+	+	+	+	+	+	+	+	+	+	0
Discret	+	+	+	+	0	+	0	0	+	+	+	0
Serious	+	-	-	+	0	0	-	-	0	+	0	-
Interesting	0	-	+	+	+	+	+	0	-	+	0	+
Distractig	+	+	+	-	0	+	+	0	0	0	+	+
Unfrightening	+	+	+	-	+	+	+	0	0	0	0	+
Carrying / storage	+	+	+	+	0	+	0	0	+	+	0	0
Disposal carry	+	+	+	+	0	+	0	-	-	+	-	0
Score	10	10	19	14	9	10	14	3	6	12	5	2
Max 21												

Appendix 9

Morphological Matrix



Appendix Morphological Matrix

Preferable sub solutions