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Process and efficacy of applying the TRIZ methodology to medical device innovations

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I declare that the work in this thesis was carried out in accordance with the regulations of the University of Gloucestershire and is original except where indicated by specific reference in the text. No part of the thesis has been submitted as part of any other academic award. The thesis has not been presented to any other education institution in the United Kingdom or overseas.
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ABSTRACT

The pharmaceutical business is driven by innovation and new technologies. In order to improve the overall efficiency, the modern R&D organisations nowadays have integrated problem-solving techniques in their innovation process. This thesis aims to explore and analyse the application of TRIZ technique in the problem-solving process in the medical device sector of the pharmaceutical industry.

The findings of the literature review indicate that TRIZ can effectively guide the problem-finding process with a tool kit that can recognise patterns and regularities based on the past solutions in a knowledgebase. The results suggest that such systematic approach is more effective than the conventional methods of trial-and-error.

This study conducted a survey amongst the innovative medical device departments of various pharmaceutical companies in the Rhine-Main region in Germany and provided contemporary data on the application of problem-solving tools, especially TRIZ, in those institutions. As a result, the survey data also delivered some possible criteria for technical solutions of medical devices which were subsequently discussed and finalised with a group of experienced experts (expert panel). The next step of the study was organised as a 2x2 experiment. During the experiments, two groups of experienced practitioners were asked to improve the design of two sample medical devices, alternatively using TRIZ and brainstorming. The efficacy of TRIZ application was analysed both in terms of the quality of the technical solutions and that of the group work. The SYMLOG Adjective Rating Form method initiated by Bales was used for the assessment of the group work.

The results of the experiment indicate that the impact of the problem-solving tools is influenced by the type of innovation problem. For the analysis of such influences, this research makes a contribution to knowledge by proposing a 2-dimensional framework to capture the problem types. In addition, a TRIZ procedure for the technical innovations of medical devices was developed based on the model of Su et al.

Due to the sensitive protection of intellectual property in the pharmaceutical industry, field studies of R&D processes in large pharmaceutical firms are limited in the public literature. This work provides valuable insights into this business sector, especially in respect of application of problem-solving tools and how those tools may potentially improve the outcomes of the R&D activities in the pharmaceutical industry.

Keywords: TRIZ, pharmaceutical industry, innovation, medical device, group work, SYMLOG

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ABREVIATIONS

AAI	Adrenaline Auto-Injector
API	Active pharmaceutical ingredient
ARIZ	алгоритм решения изобретательских задач [Russian: algorithm of inventive problems solving]
B	Backward (dimension in SYMLOG Adjective Rating Form)
BECM	Being, Engaging, Contextualizing and Managing
BLA	Biologics License Application
bn	Billion
BSRI	Bem Sex Role Inventory
C	Control
CAD	Computer-Aided Design
CEO	Chief Executive Officer
COCB	Company-Sponsored Online Co-Creation Brainstorming
D	Downward (dimension in SYMLOG Adjective Rating Form)
DMAIC	Define Measure Analyse Improve Control
EMA	European Medicines Agency
ER	External Rater
F	Forward (dimension in SYMLOG Adjective Rating Form)
FDA	Food and Drug Administration
GCMS	Gas Chromatography Mass Spectrometry
IP	Intellectual Property
IR	Internal Rater
LCMS	Liquid Chromatography Mass Spectrometry
MBA	Master of Business Administration
N	Negative (dimension in SYMLOG Adjective Rating Form)
N.A.	Not Applicable

NFC	Near Field Communication
OTC	Over the counter
PX	Participant X
P	Positive (dimension in SYMLOG Adjective Rating Form)
QR	Quick Response
R	Rater
R&D	Research and Development
RQ	Research Question
SME	Small and Medium-sized Enterprises
SYMLOG	System for the Multiple Level Observation of Groups
T	Test
TRIZ	теория решения изобретательских задач [Russian: Theory of inventive problem solving]
U	Upward (dimension in SYMLOG Adjective Rating Form)

FIGURES AND TABLES

1. Introduction

1.1 Research background

In late 1990s and early 2000s, the trend in the pharmaceutical market was the shift from small molecules to biological drugs with the development of erythropoietin and monoclonal antibodies. Monoclonal antibodies were a new class of biological medicines, manufactured from living organisms. These liquids monoclonal antibodies are often designed to be self-administered by the patients (Fox, 2010).

A new type of products, the combination of a drug and a single-use disposable medical device "*auto-injector*" supported the development of a new market for the pharmaceutical industry (Datamonitor, 2010). One of the best sold auto-injectors in the world with Humira (Adalimumab) monoclonal antibody as combination products made a turnover of US$9.3 bn. in 2012 (King, 2013). In early 2000s, the market researchers found the new drug Lantus (insulin glargine) for the treatment of diabetes Types I and II less promising. After the drug was launched as a combination product with the new Solostar injection system, the added patient convenience facilitates the steady sales growth of Lantus year by year. Richter estimated that more than 30% of all submissions to the FDA in the next years would be self-injected drugs via needle system (Richter, 2011).

The development of auto-injectors is a complex task and depends on the knowledge of biochemistry and pre-filled syringes or cartridges with mechanical engineering-driven plastic components (Datamonitor, 2010). In addition, the successful design of an auto-injector also requires a good understanding of patient psychology. Hamilton highlighted that 10% of all US patients had a congenital needle phobia. To bypass this phobia, needle-safe or needle-protected devices were developed for administration of monoclonal antibodies (Hamilton, 1995). A further challenge is that the patients' preference for the combination products is difficult to predict. In the case of Amgen, a pioneer for combination products, the patients' reactions towards the following products were totally different, although the same auto-injector design with comparable drugs was utilized for those devices (Amgen, 2013):

- Enbrel Sureclick [1998]: still on the market
- Aransep Sureclick [2001]: withdrawn in US [2011], in EU still available
- Neulasta Sureclick [2002]: withdrawn worldwide [2006]

The physicochemical behaviours of the fluid drug with interaction of primary (cartridges and pre-filled syringes) and secondary packages (auto-injector systems) are only one example of the challenges for the technical innovation. In addition, it needs intensive investigation of the combination of formulated drug substance, pre-filled syringe/ cartridge and plastic component-based auto-injectors.

The mechanical injection makes up only a fraction of the costs of the overall drug development programme which is obliged to elaborate biocompatibility tests, clinical trials with thousands of participants, marketing approvals and toxicology tests. However, a malfunction of the injection may cause an under-dosing of the patient and therefore jeopardise the patient's health outcome. This work intends to contribute to the development process of auto-injectors.

1.2 Research focus

The pharmaceutical business is driven by innovation and new technologies. Although TRIZ is a well-known technique for innovative problem-solving, studies on TRIZ application for pharmaceutical research and development seem rare in the peer-reviewed publications. Thus, this thesis aims to explore and analyse the application of TRIZ techniques for the problem-solving process in R&D of medical devices in the pharmaceutical industry.

TRIZ is the Russian abbreviation for теория решения изобретательских задач - *theory of innovative problem solving* (Ilevbare, Probert & Phaal, 2013). It is a problem-solving approach developed during the Cold War by the Russian engineer Altshuller (Altshuller, 1999). The TRIZ techniques were designed to overcome the uncertainty of a solution by directing feasible ideas in an appropriate channel and identifying patterns of previous problems solutions of comparable technical issues (Altshuller, 1999).

Over time, TRIZ methodology evolved to be adapted in non-technological sectors (Su, Lin & Chiang, 2008). Nowadays, the application of TRIZ covers a wide range of fields including e-commerce, service quality, healthcare and automotive engineering design, etc. (Su, Lin & Chiang, 2008; Altuntas & Yener, 2012; Gadd, 2011). Previous studies suggest

that the TRIZ problem-solving tools could also improve the innovation process for R&D in the pharmaceutical industry, e.g. for medical devices (Gadd, 2011).

This work is planned to explore and analyse, by means of a case study, the use of TRIZ for the development of a medical device: the auto-injector. The term "*auto-injector*" is used to describe the medical device for the self-administered application of a drug. The idea of auto-injector was developed during the Cold War by the US Armed Forces. The first auto-injectors were designed as devices to administer antidotes against chemical weapons, especially against nerve gas (Landauer, 1977).

During the case study, the participants made attempts to improve the design of two types of the well-known Epinephrine auto-injector (EpiPen) (Gallagher, Worth, Cunningham-Burley & Sheikh, 2011) which was commonly used for drug delivery to allergy patients. Both the outputs and the process of the group work were traced and subsequently analysed to assess the contribution of the problem-solving tools to the technical innovations.

1.3 Research aim

The research aim of this research may be transformed into the following research questions and research objectives:

Research questions

RQ1: Which problem-solving tools are currently used for R&D of medical devices in the pharmaceutical industry?

RQ2: How can TRIZ techniques be applied for medical device innovation?

RQ3: How and why do TRIZ techniques differentiate themselves from other problem-solving methods, from a theoretical perspective?

Research objectives

RO1: To capture the current status of the application of problem-solving tools used for R&D of medical devices in the pharmaceutical industry in the German Rhine-Main region.

RO2: To develop a TRIZ methodology for the practical use in the medical device innovation.

RO3: To develop a theoretical understanding of how and why TRIZ influences problem-solving in groups.

To achieve the research objectives involves the following steps.

- A survey of the current status of the application of problem-solving tools in the pharmaceutical medical device industry in the German Rhine-Main region;
- To develop a TRIZ methodology for the practical use in the medical device innovation based on the results of a literature review; and
- To conduct a field study on group work with problem-solving techniques including TRIZ.

The field study in this research concentrates on the innovative design improvements of auto-injectors. The researcher does not raise the claim of developing an overall methodology for the innovation of all medical devices in class I, II and III according to the FDA classification.

1.4 Organisation of the thesis

This thesis is structured into eight parts.

The first chapter consists of an introduction of the thesis, covering the research background and the research aim including the research questions and the research objectives.

The second chapter focuses on a systematic literature review on application of problem-solving techniques for innovative group work in the pharmaceutical industry, especially for the development of auto-injectors. The literature review delivers background information on the key concepts of this thesis, especially on how TRIZ may be tailored to guide the problem-finding process and how it can be applied to the present problems, as well as how group work and group behaviours are evaluated in the literature.

Chapter 3 is dedicated to the methodology and methods of this research. This includes the philosophical perspective considered in this research, the research methodology, the methods for data collection and data assessment, the quality of the research design, the role of researcher and the ethical considerations and finally, the research schedule.

Chapter 4 provides a documentation of the survey study on the application of problem-solving tools especially TRIZ for R&D of medical devices in the pharmaceutical industry in the German Rhine-Main region. The survey data also suggest assessment criteria for the technical solutions of medical devices. Subsequently, the proposed criteria are discussed and finalised with a group of experienced practitioners (expert panel).

Next, chapter 5 focuses on the group work experiment aiming at improvement of auto-injector design with problem-solving techniques. During the experiment, two groups of experienced practitioners are asked to improve the design of two sample medical devices, alternatively using TRIZ and a conventional problem-solving approach. Subsequently, the efficacy of TRIZ application is analysed both in terms of the quality of the technical solutions (the outputs) and that of the group work (the process). The SYMLOG Adjective Rating Form method initiated by Bales is used for the assessment of the group work.

Next, chapter 6 highlights the results of the experiments sessions, as well as the analysis and interpretation of the findings.

Subsequently, chapter 7 discusses the findings of the literature review, the survey study and the experiment in the previous chapters. It depicts the current usage of problem-solving tools and the influence of TRIZ techniques on R&D activities for medical devices in the pharmaceutical industry and the implications of this study.

Finally, conclusions for this research are drawn in chapter 8.

This research intends to make a contribution to knowledge by capturing the current status of the problem-solving process in R&D of medical devices in the pharmaceutical industry and developing a theoretical framework for the influence of problem-solving tools on technical innovations in group work. In addition, it proposes a new assessment approach of group work as a combination of technical solutions and group behaviours.

2. Literature Review

The literature review intends to provide background information on application of problem-solving techniques for innovations, especially for development of auto-injectors in the pharmaceutical environment. The review is divided in seven sections. Since the literature review in this chapter is organised as a systematic literature review, the characteristics of this type of literature review is introduced in some details in section 2.1. Next, section 2.2 explores previous researches on development and application of problem-solving techniques of TRIZ, followed by section 2.3 which is dedicated to auto-injector development and section 2.4, to the technical characteristics of EpiPen. While section 2.5 summarises the literature findings on concurrent studies on group work, section 2.6 highlights the assessment methods of group behaviours in the academic research. Finally, section 2.7 depicts the application of SYMLOG as an assessment method for group work.

2.1 Concept of systematic literature review

The systematic literature review is a result of the evidence-based movement in the 1990s. This style of literature review is intended to improve the quality of the literature review process by increasing its performance in transparency and selection of the appropriate literature (Wolf, Shea & Albanese, 2001; Cook, Mulrow & Haynes, 1997; Tranfield, Denyer & Smart, 2003).

Systematic reviews are often used for double-blinded clinical trials with the positivist research tradition in the pharmaceutical branch (Macdonald, 1999). According to Mulrow and Tranfield et al., healthcare authorities recommended systematic literature review for healthcare-related topics. This recommendation was also supported by the Cochrane Collaboration, as well as the National Institute for Clinical Excellence (Mulrow, 1994; Tranfield, Denyer & Smart, 2003).

Based on the research tradition in the field of research-based pharmaceutical industry, as well as the researcher's philosophical position, the literature review in this thesis was conducted in the manner of a systematic literature review.

Tranfield, Denyer and Smart conducted an in-depth analysis of literature reviews in which they compared the management-driven narrative with the evidence-driven systematic literature review (Tranfield, Denyer & Smart, 2003). Traditionally, management reviews are conducted in the narrative style. However, the narrative methodology is criticized for supporting indirect bias of the active researcher (Fink, 1998). The new path of a systematic literature review, on the other hand, enables relevant evidence with a clear synthesis of an existing summary of the investigated topic (Kitchenham, Brereton, Owen, Butcher & Jefferies, 2008).

The systematic approaches in literature reviews in the pharmaceutical industry are driven by evidence-based medicine. In the 1980s, researchers in healthcare and medical science recognised that misinterpretation of the research journals and papers were often the cause of wrong recommendation of medical therapies. Such findings had an impact on the whole pharmaceutical industry. From the 1990s – 2000s, researchers in the pharmaceutical industry and medical science improved the quality of review methods by creating transparent, reproducible and systematic research procedures. Such evidence-based processes were also essential, in order to provide best-in-class clinical trial reports by analysing the different population groups within API and placebo-armed studies. Since then, government-supported agencies like EMA and FDA demand to establish a more sophisticated systematic and scientific basis for literature reviews regarding clinical study evaluation. Nowadays, the systematic approach has become common practice in medical devices innovations (Wolf, Shea and Albanese, 2001; Becker Witkin, 1998; Tranfield, Denyer & Smart, 2003).

The systematic review tool developed by Tranfield and his colleagues Denyer and Smart in the 2000s' is a result of the evidence-based movement (Cook, Mulrow and Haynes, 1997, Tranfield, Denyer & Smart, 2003). The key features of their approach may be described in three stages of the procedure: development of the search strategy, inclusion and exclusion criteria of studies, and finally, quality and synthesis appraisals.

The systematic review in this thesis is conducted in the style as proposed by Tranfield, Denyer & Smart (2003). In order to increase the quality of the studies and outcomes, Tranfield, Denyer and Smart recommend a wider approach of management research which is similar as in biological medical science (Tranfield, Denyer & Smart, 2003). In

their opinion, this approach could help to minimize the biases of comments and reviews for sophisticated management research. The following is a comparison of the evidence-based process for the biological medicine to the traditions of management research according to Tranfield, Denyer & Smart (2003) (see table 2-1).

	Biological medicine	Management
Nature of study	Convergent	Divergent
Aims of study	Generally reducing illness and death; improving health	Multiple and competing, while the balance between the competing goals may change over time
Style of literature reviews	Systematic review and meta-analysis	Largely narrative reviews
Reporting and dissemination	Standardised reporting structures used. No explanatory style adopted. Short scripts are made widely available through internationally recognized institutions. Comprehensive to experts.	Non-standardised reporting structures. Interpretive long scripts. The explanatory power improved by using analogy, metaphor and homology. Process of knowledge generation omitted. Sometimes incomprehensive to experts due to lack of links between different literature sources.
Evidence into practice	Collaborative process and practice-oriented.	Implementation of evidence is often an afterthought.

Table 2-1: Biological medical research vs. management research (according to Tranfield et al., 2003)

By applying inclusion and exclusion criteria during data selection, Tranfield and his colleagues narrow down the available information to a feasible amount. However, this strategy also has weaknesses, as the applied inclusion /exclusion criteria have to be defined by the researcher as a subjective individual. To improve this, Kitchenham et al. proposed the use of structured abstracts (Kitchenham, Brereton, Owen, Butcher & Jefferies, 2008). However, the length of abstracts is limited at certain publication agencies, therefore the use of structured abstracts is not always possible. Another weakness of the systematic literature review is the synthesis and quality standard of heterogeneous findings, when cause-and-effect relationships are to be established based on the data

findings (Sandelowski, Docherty & Emden, 1997; Popay, Rogers & Williams, 1998). Popay et al. proposed a qualitative assessment of the systematic reviews (Popay, Rogers & Williams, 1998).

2.2 TRIZ

In my practical experience as a coordinator in the R&D of medical devices, nowadays problem-solving tools are finding increasingly applications in the development of medical devices in the pharmaceutical industry. Among such techniques for the solution of inventive problems, TRIZ appears to be a unique instrument. While the traditional problem-solving techniques follow the trial-and-error path and are rather products of accidental circumstances, TRIZ takes a systematic approach and searches for solutions for present problems in the solutions of past problems by analysing the patterns of those solutions (Savranksy, 2000; Eversheim, 2009).

The knowledge-based and systematic TRIZ methodology was reported to be effective in various business sectors in previous literature (Savranksy, 2000; Domb, Miller, MacGran & Slocum, 1998). However, literature on TRIZ application in the pharmaceutical industry still seems rare. Thus this thesis intends to explore how TRIZ influences the problem-solving process for design improvement of medical devices in the pharmaceutical industry and subsequently, analyse the effects in depth.

2.2.1 Research findings

In their study on TRIZ, Ilevbare, Probert & Phaal described in detail the benefits and challenges of TRIZ applications in practice (Ilevbare, Probert & Phaal, 2013). This journal provided a deep overview about TRIZ in terms of its general theory, as well as its instruments.

TRIZ is the Russian abbreviation for теория решения изобретательских задач - theory of innovative problem solving (Ilevbare, Probert & Phaal, 2013). In the 1940s, the Russian scientist and patent specialist Altshuller and his colleagues created TRIZ to speed up the development of solutions to technical problems. The idea behind TRIZ was to analyse and interpret 400.000 patents for technology issues, in order to identify patterns and regularities among those solutions and in a next step, so as to use this knowledge to

develop new ideas and innovations in a tighter timeframe than with brainstorming (Ilevbare, Probert & Phaal, 2013).

TRIZ is a methodology based on tools and techniques to mitigate problems. It is knowledge-based and systematic (Savranksy, 2000; Domb, Miller, MacGran & Slocum, 1998). While traditionally, inventive problems are solved based on the thoughts that inventions and technology development are products of accidental circumstances, Altshuller believes that there is a systematic approach to discover rules in solution-related thinking which may be utilized to solve contradictions and subsequently, to develop new ideas (Savranksy, 2000; Eversheim, 2009).

While the conventional problem solving methods e.g. brainstorming, meta plan techniques and mind maps concentrate on the problems, TRIZ focuses on the root cause of the problem instead of the problem itself (Gadd, 2011). A central point in the TRIZ concept is the conceptual solution finding under application of inventive principles and general solutions (also known as standard solutions). The basic idea of TRIZ is to transfer a specific problem into a general problem. The general problem is to be solved with TRIZ tools and techniques (e.g. Nine Windows, 76 standard solution and contradiction matrix, etc.), in order to develop a standard solution. The standard solution can then be subsequently transferred into the specific solution. The following graphic demonstrates the different approaches of conventional problem-solving tools (e.g. brainstorming) and TRIZ (see Figure 2-1).

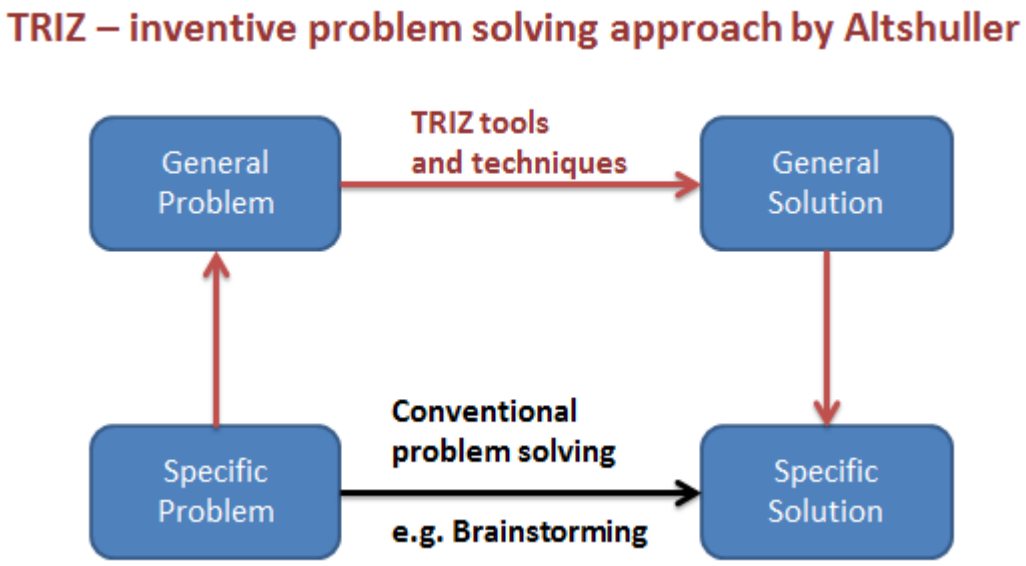

Figure 2-1 **Basic methodology of TRIZ (Ilevbare et al., 2013)**

With three concepts of parameters, Altshueller developed his TRIZ tools and techniques (Ilevbare, Probert & Phaal, 2013). Those concepts which distinguish TRIZ from other problem-solving tools are:

- Contradiction
- Ideality
- Patterns of evolution of systems

There are two different types of ***contradictions***: a) technical contradictions and b) physical contradictions.

A contradiction is related to the innovation process, when one system function which needs to be changed correlates with another. The following are some examples of such contradictions:

- a) Improvement of speed (bigger engine ⇔ higher weight)
- a) Sophisticated small device (more electronics ⇔ higher weight)
- b) Size of umbrella (large protection volume ⇔ pocket size)
- b) Handling of a small device (bigger device ⇔ pocket size)

(Ilevbare, Probert & Phaal, 2013)

Ideality derives from the term "the ideal machine" which is the target of the evolution steps (Altshuller, 1999). Altshuller defines ideality as the ideal final result if the system is guided into the direction which is considered ideal (Altshuller, 1999). Mathematically, ideality is described as:

$$Ideal\ final\ result = \frac{\sum Benefits}{\sum Costs + \sum Harms}$$

Benefit…..Useful system functions

Costs…….Input (e.g. design input requirements for medical devices)

Harms……Unwanted outputs, waste products (side products)

(Ilevbare, Probert & Phaal, 2013).

In Altshuller's opinion, all inventions follow certain rules and the majority of all solutions the mankind is looking for already exist as world knowledge (Altshuller, 1999). The rules

may be translated into ***patterns of evolution*** (Altshuller, 1999). Later on, Gadd defined 8 trends of development that were further divided into lines of evolution (Gadd, 2011).

Furthermore, Altshullers developed specific TRIZ tools and techniques for his 3 concepts. Among all tools and techniques developed between 1946 and 2008, Ilevbare et al. regard the following ones as the most useful:

- 40 Inventive principles
- 76 Standard solutions
- Separation Principles
- Nine windows
- Substance field analysis

(Ilevbare, Probert & Phaal, 2013).

However, some authors criticised Altshuller for not providing enough details for the TRIZ applications in practice, e.g. there was neither clear classification of the TRIZ tools, nor a specific sequence for the application of the tools (Eversheim, 2009). The explanations of the lists of improving and worsening features were too brief for a good understanding of the application of the contradiction matrix (Domb, Miller, MacGran & Slocum, 1998). To fill the above gaps, Zlotin et al. made efforts to categorise all TRIZ tools and subsequently divided them in 3 groups: analytical, knowledge-based and psychological tools (Zlotin et al., 2000). While analytical tools were used to describe the problem, knowledge-based tools could be selected for system transformation for the solution of the general problem. Psychological tools were defined as those which facilitate the overall process (Zlotin et al., 2000).

Alternatively, Moehrle classified the tools according to the five fields of application in the problem solving process. Those were: current state, intended state, goals, transformation, resource analysis (Moehrle, 2005a).

In spite of its popularity, TRIZ is not the only systematic problem solving methodology. In their essay, Kim & Cochran compared TRIZ with Axiomatic Design, another systematic problem solving approach developed by Suh and colleagues at Massachusetts Institute of Technology in the United States (Kim & Cochran, 2000). Although both concepts were developed independently from each other, Kim and Cochran discovered a

congruence relationship between some elements of both methodologies (Kim & Cochran, 2000).

In some business sectors, TRIZ application led to effective creation and improvement of new products in the past, successfully replacing the conventional trial-and-error method (Ishida, 2003; Su, Lin & Chiang, 2008). Below are some examples of such TRIZ implementations in the practice.

Skakun et al. described how TRIZ improved the design of chemical pumps at minimal operating costs for a petroleum company (Skakun, Martsinkovskaya & Skirdachenko, 2003).

Moehrle & Lessing (2004) used the classical TRIZ applications as a support for the strategic management. Focusing on the profiling of technological competencies, they developed a 5-step TRIZ process, combining a patent database with 40 inventive principles approach (Moehrle & Lessing, 2004). The application of their TRIZ process in a leading German company led to positive results (Moehrle & Lessing, 2004).

Sheu and Lee (2011) compared the systematic with the non-systematic approaches in innovation process. TRIZ was identified as a one of the leading systematic approaches. While the systematic approaches narrow down the path of solutions by using problem solving techniques and/or identifying opportunities, the conventional non-systematic tools (e.g. trial-and-error experiments or brainstorming) depend largely on coincidence (Sheu & Lee, 2011). Sheu & Lee described the advantages of TRIZ technique with practical examples and concluded that "…although innovation may be accidental, systematic innovation is destined" (Sheu & Lee, 2011). However, Sheu & Lee also pointed out that more efforts needed to be made for the application of systematic innovation tools like TRIZ, because the adaption required more training than brainstorming or other non-systematic approaches (Sheu & Lee, 2011).

Liu, Wu & Hong illustrated the specific process of applying the contradiction matrix for the development of a balanced sailboat patent (Liu, Wu & Hong, 2010).

Sun & Tan vividly described a further story of successful TRIZ application in the disruptive innovation process (Sun & Tan, 2012). The disruptive innovation with TRIZ tools helped the company Sony in the design of a new type of video games. Their final result was the evolution of Play Station 2 (with control sticks) to an easy-to-use (with movement detection devices) and cost efficient game console: the Play Station 3 (Sun & Tan, 2012).

Liou & Chen proposed a TRIZ approach for TeamSpirit, a web-based group decision supported tool (Liou & Chen, 2011). The authors found out that TRIZ had many advantages compared to the traditional creativity tools like brainstorming or mind maps (Liou & Chen, 2011). While the traditional techniques were restricted to the internal knowledge base of the company, the university or the internal think tank, TRIZ benefited additionally from the external knowledge base (Liou & Chen, 2011). That means, if a comparable problem to the described inventive problem was solved before, TRIZ would study the solution(s) to determine solution patterns (Liou & Chen, 2011). However, the translation process of the general or generic solution into the specific solution to the predefined problem still needed improvements (Liou & Chen, 2011). During the design process of TeamSpirit, TRIZ proved to be helpful in overcoming psychological barriers in the inventive product design (Liou & Chen, 2011).

Also the company Rolls-Royce achieved substantial improvement of design process with TRIZ methodology (Knott, 2001). Knott demonstrated how TRIZ reduced time and costs in the design process. In addition, TRIZ helped the company to reduce fuel consumption, which in turn increased business opportunities in the Aero Engine industry (Knott, 2001). For his case study, Knott used the method of semi-structured interviews which led to interesting insights of TRIZ applications in practice (Knott, 2001). Therefore, this method is integrated in the case study of this thesis.

Cascini & Rissone reported improved creativity and efficiency for plastic design by integrating TRIZ and semantic knowledge portals (Cascini & Rissone, 2004). However, they provided no measurements for the improvements.

Moehrle & Wenzke demonstrated how TRIZ could be especially helpful at problem analysis, the starting point for R&D processes that were often neglected in practice

(Moehrle & Wenzke, 2006). In the experiments, Moehrle & Wenzke considered the important aspect of team management. However, their study focused alone on the outcomes of the group work and did not address the process itself (Moehrle & Wenzke, 2006).

Mao et al. discussed the critical phase of creativity to enhance the value of engineering. In a case study, they compared the outcomes of problem-solving process with TRIZ and the alternative brainstorming method. Their findings suggested that TRIZ led to better results in a more efficient way (Mao, Zhang & Abourizk, 2009).

Hentschel found out, innovative ideas often did not lead to successful new products in the past, mainly due to the weak link between the new ideas and the practical requirements on new products. The systematic of TRIZ, on the contrary, helped the designers to become aware of the precise problem to solve and the available resources, therefore enhanced technical breakthroughs (Hentschel, 2009).
Based on a survey study, Belski found out that TRIZ improved the students' problem solving abilities (Belski, 2009). However, the survey study was based on self-assessment of the students. Such self-assessments are influenced by the subjective perceptions of the participants, causing biases in the statistics. This may be seen as a weakness of the study.

Birdi et al. explored the impact of TRIZ creativity training in a field study (Birdi, Leach & Magadley, 2012). The authors analysed the effect of TRIZ trainings by a survey study among the participated employees. Their findings indicated that the motivation and the creativity in generating new ideas were higher among the employees after the participation at the TRIZ training (Birdi, Leach & Magadley, 2012). Like Belski (2009), Birdi et al. constructed their survey study based on the self-assessment of the employees, thus their research contained a similar weakness of biases of the participants.

TRIZ methodology seems to be not only suitable for big-scale business, but also for small- and medium-sized enterprises (SMEs). Bianchi et al. illustrated how TRIZ methodology could be integrated in the innovation process of SMEs with limited resources (Bianchi, Campodall'Orto, Frattini & Paolo, 2010).

The previous literature suggests that each business sector has its specific requirements for TRIZ applications, e.g. the choice of TRIZ tools. As the pharmaceutical industry has already begun to focus on the combination production market, the improvement of engineering problem solving tools for such products is gaining more importance by the day. The design of the combination products involves the study of technical and biological influence parameters and the interplay of different forces. So far, the TRIZ applications for medical device design in the pharmaceutical industry have not yet been dealt with. Thus, one aim of this thesis is to develop a guideline for TRIZ application in this business sector.

Based on a cluster analysis on more than 40 reported applications of TRIZ in practice, Moehrle recognized that while the 39x39 contradiction matrix and the 40 inventive principles were often used, engineers and natural scientists were less familiar with the other TRIZ tools (Moehrle, 2005b). He concluded that the whole set of TRIZ tools were not always necessary to solve the individual inventive problems. Moehrle's recommendation to TRIZ users was to start with a basic TRIZ set and to move later on to the more complex resources and ideality-based or substance-based TRIZ tools after more experience was obtained (Moehrle, 2005b).

Ilevbare et al. conducted a web-based survey to explore practical insights of TRIZ techniques and tool kits (Ilevbare, Probert & Phaal, 2013). The questionnaire used by 40 participants focused on the specific fields of application, innovation drivers, technology and management of businesses. The main outcome of their study was the recommendation to reduce complexity, to increase awareness of communication and finally to create a more standard usage, so as to optimise the effect of TRIZ techniques (Ilevbare, Probert & Phaal, 2013).

Researchers also proposed further developments of the TRIZ techniques. For example, Wang et al. combined Althuller's tools with text mining to identify R&D trends from patent documents (Wang, Chang & Kao, 2010). Unlike the majority of the TRIZ researchers, Wang et al. did not focus on the contraction matrix. Their research indicated that the combination of the evolution patterns of TRIZ and text mining to extract technology trends was more efficient than TRIZ in its classic form (Wang, Chang & Kao, 2010). Vincent et al. proposed a standardised knowledgebase for applications in the

biological sector. For this purpose, the international research team provided a patent database of biological functions from cell organelle to other biological effects to facilitate the use of contradiction matrix (Vincent, Bogatyreva, Pahl, Bogatyrev & Bowyer, 2005). Mann discussed how generic matrices could be developed based on a systematic programme of patent- and science-based database (Mann, 2005). In order to deal with the perceived complexity of TRIZ, some researchers developed further variations of the classic form of this methodology. One of such solutions is Advanced Systematic Inventive Thinking (Reich, Hatchuel, Shai & Subrahmanian, 2012).

In time, TRIZ was further developed for broader application fields. Researchers adapted the TRIZ methodology to non-technological sectors, especially to the service sector (Su, Lin & Chiang, 2008; Zhang, Chai & Tan, 2005).

Su et al. developed a TRIZ approach to improve the service quality (Su, Lin & Chiang, 2008). In addition to the traditional TRIZ process, Su et al. proposed a parameter corresponding table which improved the application of contradiction matrix for solutions of service problems. Their approach was also adapted by Altuntas & Yener for the improvement of healthcare service (Altuntas & Yener, 2012) and by Akay et al. for the solution of human factors problems (Akay, Demiray & Kurt, 2008).

Su et al.'s concept was based on a decision tree with 8 stages, including definition of the scope of problem, extraction of relevant determinates, development of parameters to match the 39 TRIZ contradictions, generation of a feasible solution with support of the 40 inventive principles linked to the TRIZ parameters and the development of parameters criteria (Su, Lin & Chiang, 2008).

TRIZ methodology was adapted for technology forecasting (Slocum & Lundberg, 2001). Forecasting a new technology used to take an emotional path in the past. With help of the TRIZ methodology, the results based on empirical databases appear more reliable and efficient (Slocum & Lundberg, 2001).

Mueller comprehended TRIZ as a framework for the strategic management (Mueller, 2005). Her management framework was established based on the six categories of TRIZ resource tools (Mueller, 2005).

Researchers also proposed to improve ergonomics in the agricultural sector by means of TRIZ contradiction matrix (Tosetto & Camarotto, 2012).

Beyond the classical process flow, Glaser & Miecznik developed a reverse inventing flowchart based on TRIZ to overcome the classical lacks of market research. Their reverse inventing process based on TRIZ consists of the steps of situation analysis, abstraction of strengths, transformation into searchable queries, comparison with existing knowledge bases and evaluation of obtained results (Glaser & Miecznik, 2009). The process was successfully tested in a marketing case study for the medical facilities for limb prolongations (Glaser & Miecznik, 2009).

Another trend of TRIZ researches was the combination of TRIZ with other management tools, e.g. Six Sigma and Lean Manufacturing. Feo & Bar-El came up with an innovative design method for Six Sigma. Combining Six Sigma and TRIZ ideality, their solution was developed to ensure that new products were created efficiently and at the same time met Six Sigma and marketing requirements (De Feo & Bar-El, 2002).

Hipple argued that since the conventional management tools mainly dealt with the problem identification in the business process, the enterprises might benefit greatly from combining those tools with the problem-solving TRIZ tools. He suggested integrating TRIZ tests in the psychological assessment tools for the employee career development (Hipple, 2005).

Brad et al. applied the TRIZ tools in the improvement stage of the DMAIC cycle in a knowledge management software platform. The researchers used the terminology of enhanced sigma-TRIZ to describe the combination of the DMAIC and TRIZ methodology (Brad et al., 2009).

Although Six Sigma and TRIZ were both primarily methodologies used for technical optimisation in manufacturing sectors, Wang & Chen explored the integration of TRIZ methodology in a Lean Six Sigma solution to improve banking services (Wang & Chen, 2010). Lean Six Sigma was a popular methodology for improvements of business opportunities in the aspects of customer satisfaction, costs and process speed for

manufacturing (Wang & Chen, 2010). The authors first established a DMAIC Model (Define, Measure, Analyse, Improve, Control) for the service industry and subsequently, used TRIZ methodology to enhance the traditional Lean Six Sigma techniques (Wang & Chen, 2010). The results of their analysis indicated that TRIZ methodology improved the effectiveness of the Lean Six Sigma system (Wang & Chen, 2010).

Shirewalker and Okudan (2007) demonstrated the combination of TRIZ and Axiomatic Design in the engineering design process in a case study by embedding TRIZ in an Axiomatic Design framework (Shirewalker & Okudan, 2007).

2.2.2 Summary

TRIZ is a unique knowledge-based problem solving approach (Ilevbare, Probert & Phaal, 2013; Savranksy, 2000; Domb, Miller, MacGran & Slocum, 1998). While the conventional problem solving methods focus on specific solutions for the generic problems, TRIZ focuses on the root cause of the problem instead of the problem itself (Gadd, 2011). TRIZ transfers a specific problem into a general problem, solves the general problem with a set of tools and techniques and subsequently, transfer the general solution into a specific solution (Ilevbare, Probert & Phaal, 2013; Gadd, 2011; Savranksy, 2000).

Over time, TRIZ has evolved to become more effective and overcome some shortages in its classic form (Zlotin et al., 2000; Moehrle, 2005a). In the last decades, TRIZ has been successfully implemented in various business sectors and proved its advantages compared with the conventional trial-and-error methods (Ishida, 2003; Su, Lin & Chiang, 2008; Belski, 2009). Previous studies indicate that TRIZ helps to increase the innovation efficiency and cost deduction (Knott, 2001).

The current market development of the pharmaceutical industry shows that the combination products of liquid medication and injection device are gaining an increasing importance. Thus, more attention is paid to the engineering problems for such medical devices (auto-injectors). The design of the combination products involves the study of technical and biological influence parameters and the interplay of different forces. So far, it seems that the application of TRIZ for medical device design in the pharmaceutical industry has not yet been dealt with by the academics. Thus, this thesis aims to close this

research gap by developing a guideline for TRIZ application in pharmaceutical medical device business sector.

Su et al. developed a TRIZ approach to improve the service quality and provided a comprehensive description of their TRIZ process (Su, Lin & Chiang, 2008). Later on, their approach was adapted by other researchers and led to positive results in further application fields (Altuntas & Yener, 2012; Akay, Demiray & Kurt, 2008). Therefore, the TRIZ experiments in this thesis is designed based on the framework of Su et al.'s solution, with some modifications to meet the requirements for the design tasks of medical devices in the pharmaceutical industry. One challenge for the application of a modified Su et al.'s framework for the design improvement of auto-injectors is the adaption of the eight stages, especially the mapping of requirements on the new combination products, e.g. customer satisfaction of EpiPen or quality guidelines with the TRIZ parameters.

The literature review indicates that the majority of previous studies focused on the outcome of the applications when measuring the effect of TRIZ (Mao, Zhang & Abourizk, 2009; Birdi, Leach & Magadley, 2012). For the evaluation of the outcomes, they sometimes solely relied on self-assessment of the participants which was influenced by the participants' biases (Birdi, Leach & Magadley, 2012). One alternative method to capture the results of the problem solving process is the semi-structured interview as conducted by Knott for his study on a TRIZ project at the company Rolls-Roys (Knott, 2001). This thesis also integrates the method of semi-structured interviews in the case study.

However, in order to achieve the above advantages with TRIZ, elaborate prior trainings are necessary for a good command of the TRIZ instruments (Sheu & Lee, 2011).

Although Moehrle & Wenzke recognized the importance of team management for the problem solving process, like the other researchers, their study focused alone on the outcomes of the group work and did not address the process itself (Moehrle & Wenzke, 2006). This thesis intends to close this gap in research by exploring the group work during the problem solving process.

2.3 Auto-injector

2.3.1 Research findings

The term auto-injector is used to describe the application of a drug with a self-administering medical device as a drug/combination product. One of the well-known auto-injectors is the epinephrine auto-injector which is used against allergic reaction e.g. nuts, fish or insect stings (Gallagher, Worth, Cunningham-Burley & Sheikh, 2011). Gallagher et al. conduct a qualitative study to investigate the performance and the use of the auto-injector among teenagers in Scotland (Gallagher, Worth, Cunningham-Burley & Sheikh, 2011). In their in-depth interview and focus group study, 26 adolescents and 28 parents were interviewed for the investigation of under-use of auto-injectors in an anaphylactic case. Gallagher et al. found out through their field study, most of the female teenager carried the device, but did not use it due to a lack of training or re-training after a certain time. Boys did not carry the device with them due to the bulky size of the auto-injector and therefore would not be able to use the device in emergency cases.

Subsequently, Gallagher et al. proposed an improvement of the organisation of training (Gallagher, Worth, Cunningham-Burley & Sheikh, 2011). Till now, needle-free demonstration devices are mainly used for patient trainings. However, a clinical study indicated that using demonstration devices might compromise the results of patient training and that the real devices should be used instead (Gallagher, Worth, Cunningham-Burley & Sheikh, 2011).

Hawkins et al. proposed a multi-dose auto-injector, similar to those currently provided to e.g. diabetes patients, for anaphylactic patients (Hawkins, Weil, Baty, Fitzpatrick & Rowell, 2013). However, unlike the diabetes patients who inject up to five times on a daily basis, the anaphylactic patients are likely to suffer from an allergic reaction not more than a few times in their whole life. Therefore, the concept of Hawkins et al. might still need some rethinking to better fit the disease patterns (Hawkins, Weil, Baty, Fitzpatrick & Rowell, 2013).

Stecher et al. conducted a study on the needle length of the Epinephrine auto-injector. Auto-injectors are designed to administer the formulated drug substance subcutaneously (Stecher, Bulloch, Sales, Schaefer & Keahey, 2009). New studies implied that an intra-muscular injection was faster in reaching the peak in plasma concentration than via

subcutaneous injection (Stecher, Bulloch, Sales, Schaefer & Keahey, 2009). Stecher et al. conducted an empirical study with the participation of 256 children. The descriptive statistics and the regression analyses indicated that the needle length of current auto-injectors was not adequate to meet the requirements of recommended intra-muscular injections. Based on the empirical findings, Stecher et al. suggested extending the needle length of the auto-injectors for the administration of epinephrine (Stecher, Bulloch, Sales, Schaefer & Keahey, 2009).

Another investigation on auto-injectors for adults and children was conducted in Israel as preparation for a new gulf war (Bentur et al., 2006). Benture et al. (2006) investigated the atropine auto-injector which was replaced in 1992 with a new device containing both substances atropine sulfate and trimedoxime. The results showed, easy understanding and simple handling of the self-injecting device, as well as adequate patient trainings, had induced a higher self-injecting rate during the Gulf War in 2003.

According to Ramos et al.'s investigation (Ramos, Landy, Tepper, Wein & Schweizer, 2013) of Alsuma auto-injector by Meridian Medical Technologies, a pre-assembled single-use auto-injector was preferred by 95% of the patients. The self-developed instruction for use was even preferred by 100% of the 63 recruited patients. According to the results of their study, the most essential features of an auto-injector were: ease of use, safety and efficacy (Ramos, Landy, Tepper, Wein & Schweizer, 2013). Such requirements could only be met with adequate design of the auto-injector and precise and simple instruction for use, so as to convince the patients and healthcare professionals to use an auto-injector in case of emergency or on a routine basis. In addition, a good solution for storage and disposal of the used items was thought to further improve the acceptance in the society (Ramos, Landy, Tepper, Wein & Schweizer, 2013).

Despite a well-developed instruction of use, use errors take place from time to time. Greenberg and Rivello described in a toxicological journal the EpiPen's use errors, especially injection into hands (Greenberg & Riviello, 2010). They concluded that demo devices could be helpful for nurses and medical staff (Greenberg & Riviello, 2010). However, trainings with real devices instead of a non-needle demonstration device might produce even more positive effects (Gallagher, Worth, Cunningham-Burley & Sheikh, 2011).

Whyte pointed out in his article about the growing utilisation of auto-injectors the advantages of auto-injectors compared with pre-filled syringes: there were reportedly more than 1 million needle sticks of the syringes every year in the U.S., endorsing the request for a new needle protection device like the auto-injectors for routine injections (Whyte, 2010). The needle protection system of auto-injectors was designed to have hidden needle(s). Furthermore, a survey among patients who received injections on a regular basis showed the patients' preference for injection at home alone instead of having to go to the hospital for each routine injection. The home injections could also reduce healthcare costs dramatically. In addition, an EU initiative with directive 89/391/EEC and 2000/54/EC supported the change to a needle protecting medical device system. Currently, 2/3 of all Biologicals in clinical developments were highly viscous drugs which needed a high mechanical force like designed for the auto-injectors to pass through the small needle. However, time and design improvements for a precise injection were still needed in order to convince the patients (Whyte, 2010). In his final conclusion, Whyte emphasized that auto-injectors would be chosen by healthcare professionals as new state of the art in the near future (Whyte, 2010).

In spite of the widely accepted design of the EpiPen auto-injector, there were reports on random cases of accidental self-injections by the physicians during an allergic attack of the patients (Silverberg & Manoach, 2007). Therefore, reducing mechanically caused needle sticks was one of the tasks of design improvement of those devices.

To reduce use errors, Sheikh et al. recommended improvements in the following aspects:

- Healthcare professionals to be trained intensively as the connection between industrial manufacturers and patients;
- Patients to be trained and coached on a regular basis to reduce knowledge gaps in extreme physiological situations like anaphylaxis;
- To enlarge the public awareness of first aid activities with auto-injector treatments.

(Sheikh, Simons, Barbour & Worth, 2012).

Morris et al. conducted a study on measuring training potential and epinephrine stocking programme for school nurses in California (Morris, Baker, Belot & Ewards, 2011).

California's law required schools to store EpiPens or equals at school offices and to train school nurses to handle the devices. Altogether, 173 school nurses participated at the survey designed to investigate the training level of auto-injector usage. The survey results showed an inadequate training level of the school nurses. Besides, 73% of the students were equipped with epinephrine devices other than EpiPen or no device at all by their parents. In case of emergency, those students might need to receive an injection from the nurses with an auto-injector they were not familiar with. In such cases, use errors were likely to increase (Morris, Baker, Belot & Ewards, 2011).

Brandes et al. investigated bioequivalence of the needle-free systems Sumavel™ DosePro™ (needle-free) and the Imitrex STAT dose System (with needle) in a field study (Brandes et al., 2009). The results proved bioequivalence of injection in the thigh and the abdomen, but no bioequivalence of injection into the arm (Branders et al., 2009). This example indicated that pre-filled syringes, safety syringes, auto-injectors and needle-free application systems were not exchangeable without clinical trials. Changing method of action e.g. rectal gel application vs. an intra-muscular auto-injector would require additional clinical trials as well (Lamson et al., 2011). Currently, the research-based pharmaceutical industry is in preparation of new guidelines of the FDA which will strengthen the demand of usability studies.

To mitigate patients' different understandings of the auto-injector instruction, Smith suggested that a plain language be used to reduce use errors (Smith & Wallace, 2013). However, Smith & Wallace's experiment was conducted in the laboratory, therefore yet needed further validation under real-world conditions.

An investigation on practical use of auto-injectors was conducted by Moshiri et al. By analysing the effects of various types of auto-injectors, Moshiri et al. found Mark I to be the most effective device among all tested auto-injectors. Mark I was deployed as antidote against nerve gas agent, e.g. sarin, while a quick injection was considered critical for the survival of the patient in case of emergency (Moshiri, Darchini-Maragheh & Balali-Mood, 2012).

The first auto-injectors were developed by the US Army as antidotes for biological weapons (atropine and oximes). The US army arranged trainings on the use of auto-

injectors for each military member. However, they soon recognised the necessity of trainings also for civilians, since incorrect use of medical devices with needles could lead to transmission of infectious deceases, e.g. hepatitis B etc. (Ekwueme, Weniger & Chen, 2002).

Besides the risks of contraction of hepatitis B and human immunodeficiency virus, Ekwueme et al. also explored the economic aspect of seven different injection devices in the mid-Africa (Ekwueme, Weniger & Chen, 2002). Although from an ethical standpoint, every possible step should be taken to prevent any avoidable infections, in order to protect the life of the patients and the healthcare workers, financial limitation often constitutes a confinement in the developing countries (Ekwueme, Weniger & Chen, 2002). Similarly, cost-saving was identified as the key reason that children in Turkey sometimes did not receive epinephrine auto-injector or the training which was supposed to facilitate the use of the device (Orhan et al., 2011). Orhan et al. (2011) analysed in a case study 10 years' data of epinephrine application and they came to the conclusion, training and understanding the handling of auto-injectors was the critical point next to the financial costs of those devices for the developing countries.

To enhance better understanding and conscience of auto-injector trainings and the training methodology, Litarowsky et al. conducted a training session with inexperienced healthcare professionals by measuring their learning curves with self-prepared questionnaires (Litarowsky, Murphy & Canham, 2004). The researchers detected a positive correlation between the training material and an increased user performance. Their findings suggested that video material and the presentation used during the training program could reduce the misuse of the EpiPen auto-injector. However, like other similar studies, Litarowsky et al. did not provide any follow-up data on the participants' performance after a certain period of time to show the effects of trainings under real-world conditions and the sustainability of such trainings.

In the current literature, most of the clinical trials with auto-injectors are hidden, probably due to concerns of the IP security of the researching business organisations (Oude Elberink, van der Heide, Guyatt & Dubois, 2009; Drent, Jakobsdottir, van Wijk, Oostdijk & Wit, 2002). Yet sharing findings of the empirical user studies like Drent's group did would be very helpful in mitigating usability errors, so as to benefit the patients (Drent,

Jakobsdottir, van Wijk, Oostdijk & Wit, 2002). One useful finding Oude Elberink et al. shared with other researchers was that the patients performed better with the auto-injectors if they were given the choice of the device (Oude Elberink, van der Heide, Guyatt & Dubois, 2009). From a practical point of view, it might be more efficient to analyse the patients' needs by means of market researches prior to developing and testing the solutions in the clinical studies.

Improved design of medical devices seems to be a key factor for better training results or better use of the devices. During an interview, Rylander, CEO of a new start-up company for medical devices, revealed his secret of success as understanding the needs of the patients by listening to them. Many patients requested the manufacturers to develop new glucagon emergency kits which were currently constructed as pre-filled syringes (Rylander, 2009). According to Rylander, it was also important to analyse the complaint rate of use errors and the errors on the device. In order to meet the patients' requirements, Rylander's new company combined the old-fashioned drugs in primary packs with newly designed secondary packaging (auto-injector) (Rylander, 2009). Also another author Renstorm took a similar approach and discussed the option to change primary package from glass to co-polymer based syringes (Renstrom, 2008).

On the current market, only a few auto-injectors are easy to use thanks to their well-developed simple design (Renstrom, 2008). Design improvements are necessary for the majority of the devices. A useful instrument for the generation of new ideas for the device design might be the problem-solving tool TRIZ.

2.3.2 Summary

The previous field studies indicated that auto-injectors were widely accepted by the patients and the pharmaceutical industry (Gallagher, Worth, Cunningham-Burley & Sheikh, 2011; Hawkins, Weil, Baty, Fitzpatrick & Rowell, 2013; Whyte, 2010). Compared with pre-filled syringes, the needle protection of auto-injectors was proven to be a great advantage in the practice (Whyte, 2010). However, the manufacturers understood that the application of such medical devices needed to be further improved (Rylander, 2009; Renstrom, 2008).

First, the empirical studies showed that certain features of the auto-injectors could cause the patients' psychological declination of the devices (Gallagher, Worth, Cunningham-Burley & Sheikh, 2011; Stecher, Bulloch, Sales, Schaefer & Keahey, 2009; Hawkins, Weil, Baty, Fitzpatrick & Rowell, 2013; Ramos, Landy, Tepper, Wein & Schweizer, 2013). Therefore, the researchers proposed a number of improvements to the design of the existing auto-injectors, in order to encourage the patients to constantly carry the devices and to use them in case of emergency. For example, to reduce the bulky size of some existing models (Gallagher, Worth, Cunningham-Burley & Sheikh, 2011), to modify the needle length (Stecher, Bulloch, Sales, Schaefer & Keahey, 2009), or to design the auto-injectors to accommodate multi-doses (Hawkins, Weil, Baty, Fitzpatrick & Rowell, 2013). A survey study also showed that the majority of the patients preferred single-use auto-injectors to multiple-use devices (Ramos, Landy, Tepper, Wein & Schweizer, 2013).

Second, there seems to be a consensus among the researchers that also the social acceptance of the auto-injectors greatly depends on the adequate device design, including simple instruction for use (Ramos, Landy, Tepper, Wein & Schweizer, 2013). Previous field studies clearly indicated that a device design which enabled easy handling of self-injection could improve patient usage in the practice (Brandes et al., 2009). The assertion by Smith & Wallace based on laboratory experiments that plain language would reduce use errors of the auto-injectors (Smith & Wallace, 2013) yet needs to be validated in the practice.

Third, the researchers related a great number of use errors to a deficiency in the patient training. The academics discovered the necessity for such trainings long ago, especially for the sake of prevention of contagious diseases (Ekwueme Weniger & Chen, 2002). Greenberg & Riviello proposed the use of demo devices for the training of the medical staff (Greenberg & Riviello, 2010). Other researchers claimed that the use of real devices would produce better training results (Gallagher, Worth, Cunningham-Burley & Sheikh, 2011). Some empirical studies showed that professionally prepared trainings clearly improved the user performance (Litarowsky, Murphy & Canham, 2004). However, none of the researchers provided any follow-up information on the participants' mid-term performance after the training, although the sustainable effect of the trainings would be of great interest in the practice.

Finally, cost level was identified as a key factor for the success of the auto-injectors at the market, especially in the developing countries (Orhan et al., 2011). Unfortunately, the profit concerns also hindered the device developers and manufacturers from exchanging their valuable experiences, so that they could retain their competitive advantages (Oude Elberink, van der Heide, Guyatt & Dubois, 2009; Drent, Jakobsdottir, van Wijk, Oostdijk & Wit, 2002).

Satisfying the above competing objectives is a complex task. Currently, the researching firms of auto-injectors invest large spending on such tasks. In this work, the research shall test how problem-solving techniques may affect the results of such undertakings at the example of one specific problem-solving technique: TRIZ.

The limited number of pertinent disseminations on auto-injectors indicates that there is a demand in this research field. This thesis therefore intends to make a contribution with an empirical study.

2.4 EpiPen

One example of auto-injectors is the Adrenaline Auto-Injector (AAI) for the emergency treatment of anaphylaxis. Anaphylaxis is an acute allergic reaction caused by the release of pro-inflammatory mediators from mast cells and basophils in response to an allergen that may cause death within very short time (Schwirtz & Seeger, 2012).

EpiPen is one of the most popular AAIs at the global market (Hodges, Clack & Hodges, 2005; Nguyen Luu et al., 2012). This implies that EpiPen designs are representative for this type of medical devices. Contrary to other alternative AAIs, there are numerous studies on EpiPens, probably due to its popularity and its long history in the market. In consideration of the above, this thesis chose two models of EpiPen for the experiment of design improvement with aid of the problem-solving techniques.

2.4.1 Research findings

Currently, the medical emergencies of anaphylaxis are commonly treated by adrenaline auto-injectors, e.g. the cartridge-based EpiPen (Schwirtz & Seeger, 2012). A longitudinal study in the UK indicated that such treatments substantially reduced the frequency and severity of further reactions (Ewan & Clark, 2005).

Sicherer et al. concluded based on a survey study that many patients were not able to administer the life-saving EpiPen correctly. Even some paediatricians were not familiar with the functions of the device. Therefore, Sicherer et al. recommended improvement of education for the parents and paediatricians on auto-injector use (Sicherer, Forman & Noone, 2000).

After being contacted by three schools seeking advice on allergy management, a paediatric respiratory service in South Wales carried out an intensive investigation at the local schools. The study identified a deficiency in both diagnosis and treatment of severe allergy among the school children. In short term, the findings of this study promoted the collaborative working between healthcare professionals, school staff, children and their parents, including EpiPen training for the school children and their families (Hodges, Clack & Hodges, 2005).

In Australia, 20% of the young school children who suffered from anaphylaxis – mainly food allergy – were treated with EpiPen (Sanagavarapu, 2012). Sanagavarapu highlighted the importance to offer face-to-face trainings to the parents of the young school children, as well as to the educators to achieve satisfactory effect in case of emergency treatment (Sanagavarapu, 2012).

In Canada, two types of adrenaline auto-injectors were introduced to the market: Twinject and EpiPen (Nguyen Luu et al., 2012). Due to the limited uptake and the restrictions on applications by school personnel for Twinject, however, EpiPen was clearly favoured by the public (Nguyen Luu et al., 2012). During the field study, Nguyen Luu et al. asked the school personnel to demonstrate their ability to use the new generation of EpiPen in case of anaphylaxis. Their findings of a deficit in EpiPen usage among the school personnel suggested that user training and product instruction were the crucial points for the therapy success (Nguyen Luu et al., 2012).

Oude Elberink et al. (2009) traced the opinions of insect venom allergic patients with reactions limited to the skin on alternative treatments. They found out that although the majority of the patients chose the EpiPen therapy, a large number of the patients chose the alternative treatment method venom immunotherapy (VIT) because of a higher level

of perceived health-related quality of life (HRQL). The main complaint about the EpiPen therapy was the cumbersome size of the device, although the treatment itself was perceived as comfortable by the patients. A further demand of the patients was to have a bigger variety of devices (Oude Elberink, van der Heide, Guyattw & Duboisz, 2009). However, according to the current regulations for medical devices, each variant of combination product needs its own BLA submission with a lot of regulatory inputs. Therefore, a big variety of auto-injectors would probably lead to high expenses which the market is not ready to refund.

Simons et al. raised the issue of the dosage of EpiPen auto-injector. When treating children weighting 15-30 kg, physicians only had the choice of the classic EpiPen for adults and EpiPen Jr for children, while neither of the dosages was optimal. Thus the EpiPen could be improved by providing a more flexible dosage (Simons, Gu, Silver & Simons, 2002).

The empirical data in Canada indicated that 35% of the adult patients needed more than a single shot of EpiPen in an acute situation (Ackaoui, 2011). Ackaoui suggested that such patients should always carry two auto-injectors or one with two doses (Twinject). However, there were not yet sufficient clinical studies to conclude if the second shot of Twinjet could be administered effectively. A further problem with auto-injectors was the short expiry date, causing wastes both in costs and pollution. Ackaoui also proposed multiple-use auto-injector designs for example with disposable needles to reduce pollution (Ackaoui, 2011).

Also Clegg & Richtie detected a lack of training on EpiPen use for the parents and teachers of school children in West Lothian (Clegg & Richtie, 2001). To improve this, they recommended to the local drug and therapeutics committee: to provide a standardised training package including a video demonstration, written material in the form of “frequently asked questions”, as well as contact addresses for additional advice; to educate the prescribing doctors on EpiPen background and use; to provide trainings to school staff on EpiPen use and to use survey study to identify the most prescribing areas for EpiPen, so as to organise more targeted training programmes (Clegg & Richtie, 2001).

In a recent comparison study of three adrenaline auto-injectors conducted by Schwirtz & Seeger, EpiPen showed a higher robustness in quickly and consistently delivering the correct dose of adrenaline to the correct tissue layer. However, a higher percentage of patients could use the syringe-based alternative auto-injectors correctly, implying that the instruction and user training of EpiPen could still be improved. A further weakness of EpiPen seemed to be in sustaining mechanical stress (e.g. slight bending of needles) (Schwirtz & Seeger, 2010).

In 2001, most families of children who were prescribed adrenaline auto-injectors in London were found unable to use the device properly. Three years later, most patient families were reported capable of using the device correctly. The improvement was mainly achieved by protocoled prescriptions and a follow-up patient training programme (Ratnaweera, Trilsbach, Rangasami, Green & Puliyel, 2006).

Based on a survey study conducted in different Canadian provinces, Cicutto et al. recommended that legislation be made to oblige schools to EpiPen trainings against anaphylaxis. Their findings indicated that in the provinces with legislated environment for EpiPen training, the schools made more efforts and the personnel mastered the techniques better (Cicutto et al., 2012).

Wong et al. surveyed the primary schools in the London area and found out, with the schools' policy in place, the majority of the staff with responsibility for medicine administration knew how to administer EpiPen properly (Wong, Awolowo, Gordon & Mo, 2004).

Sclar pointed out that besides the proper injection techniques, also the injection time of EpiPen was a critical parameter that might even decide life or death. His field study showed that EpiPen produced optimal delivery time of the medicine (Sclar, 2013).

An Australian survey study suggested that almost 10% of anaphylaxis patients were expected to experience recurrence. Still, very few patients carried adrenaline auto-injectors with them. According to the survey results, the main reasons for the patients' declination of the auto-injectors were: fear of needles; fear of adrenaline; preference of hospital treatment and the drug being out of date (Mullins, 2003). The preference of

hospital treatment might be interpreted as a result of the patients' perception of carrying EpiPen as a decrease of health-related life quality. In other words, the EpiPen design could be improved to counteract the patients' rejection in this aspect.

2.4.2 Summary

There seems to be a consensus among researchers that Adrenaline Auto-Injectors (AAIs) are one of the most effective therapies against life-threatening acute allergic reactions: anaphylaxis (Schwirtz & Seeger, 2012; Ewan & Clark, 2005).

Numerous survey studies were conducted in schools and hospitals among children suffering from anaphylaxis. The findings of the various regional studies often indicated a deficiency in understanding of the functions of EpiPen by the parents of the children and by the school staff (Hodges, Clack & Hodges, 2005; Sanagavarapu, 2012; Nguyen Luu et al., 2012; Clegg & Richtie, 2001). Similar deficiency was also observed among adult patients (Ackaoui, 2011; Oude Elberink, van der Heide, Guyattw & Duboisz, 2009; Ratnaweera, Trilsbach, Rangasami, Green & Puliyel, 2006; Mullins, 2003).

In some cases, the user knowledge was improved greatly by protocoled prescriptions and well-organised training programmes. However, follow-up trainings seem necessary, in order to achieve sustainable improvements (Ratnaweera, Trilsbach, Rangasami, Green & Puliyel, 2006). Also clearer product instructions were expected to improve AAI user skills (Nguyen Luu et al., 2012). In this aspect, Clegg & Richtie proposed to produce a standardised training package including a video demonstration and written material in the form of "frequently asked questions" (Clegg & Richtie, 2001).

A few authors suggest that well-placed school policies on medicine administration or even legislation may substantially improve the schools' performance (Cicutto et al., 2012; Wong, Awolowo, Gordon & Mo, 2004).

Although there was a relatively high risk of recurrence, many patients did not carry AAI with them (Mullins, 2003; Oude Elberink, van der Heide, Guyattw & Duboisz, 2009). The main reasons for the patients' rejection were thought to be the perceived reduced health-related life quality, e.g. due to the bulky size of the device (Oude Elberink, van der Heide, Guyattw & Duboisz, 2009), fear of needles or the medicine and the short shelf life so that sometimes the drug is found out of date when needed (Mullins, 2003).

2.5 Group work

2.5.1 Research findings

The term "group work" is used interchangeably with "teamwork" by some authors. In his essay, Cooter traced the history of the term "teamwork" and provided a description of the development of this concept (Cooter, 2004).

Researchers established different classifications of groups in the past. O'Donnell et al., for example, differentiated between "ad hoc groups" and "natural groups". In their opinion, ad hoc groups must go through a phase of entrainment to become natural groups (O'Donnell, Arnold & Sutton, 2000).

Group work was often studied in the context of psychodynamic or psychosocial functions in groups (Viney, Henry & Campbell, 2001). Cronin et al. pointed out that since groups were dynamic entities, it was important to focus on group dynamics instead of group statics (Cronin, Weingart & Todorova, 2011). By analysing the management science publications of three decades, Goyal et al. analysed the development of social distance among economists (Goyal, Van der Leij & Moraga-González, 2006).

Other researchers concentrated on the creation of cause-and-effect models for group work, with the aim of generating usable theories on group behaviour and performance (Hackman, 2012).

Marrone et al. analysed how boundary-spanning behaviour in groups was caused and how such behaviours affected the team work (Marrone, Tesluk & Carson, 2007).

Another prolific field in the terrain of group work research was the cooperative learning process (Mustafa, 2010; Bertucci, Conte, Johnson & Johnson, 2010). Mustafa analysed the cooperative learning process (Mustafa, 2010). The experiments of Bertucci et al. showed that cooperative learning seemed to be more effective than individual learning (Bertucci, Conte, Johnson & Johnson, 2010).

Many team work researches on learning process were conducted in the education sector, especially at the higher education institutions (Gaytan, 2010), but sometimes also in primary or secondary schools (Gillies & Robinson, 2012). Such studies often focused on the effect of specific education programmes on learning results (Lawrence, 2002).

A survey among college students indicated that although group works was well accepted, the majority of students preferred individual assignments to group works due to their concerns of certain disadvantages of group work, e.g. free riding of team members (Marks & O'Connor, 2013). Laverie et al. focused on how team-based active learning influenced the learning orientation of the individual students (Laverie, Madhavaram & McDonald, 2008).

Napier & Johnson found out that group work satisfaction of the college students were substantially influenced by ethical factors, as well as equal level of contributions of the group members (Napier & Johnson, 2007).

Group assessment became essential for higher education programme design in the modern time, so that meanwhile educators had developed a consensus that education needed to be organised in accordance with the students' skills (Gammie & Matson, 2007). Lavy & Yadin studied the effect of team-based peer-reviews on the students learning process (Lavy & Yadin, 2010). Furthermore, Ballantine & Larres analysed the link between the students' attitude towards group work and their academic abilities (Ballantine & Larres, 2007).

Taylor concludes based on his field study among college students that to promote the motivation of group work, group incentive seemed to be more effective than tournament or individual incentives (Taylor, 2006).

Group work in high education institutions was also understood as social skill trainings for the students – the future management members (Sathe, 2009). Umble et al. conducted survey studies among college students to test various hypotheses regarding project team processes with competition (Umble, Umble & Artz, 2008). Sathe's ethnographic study suggested that the cohort-based MBA programmes in the United States seemed to

improve the cooperative agenda of the students, however, the individualist and competitive tendencies remained unchanged (Sathe, 2009).

There were further aspects of group work research on learning process. Espey explored the influence of classroom design on the students' learning attitude and performance (Espey, 2008). Head proposed the establishment of a "shared history" to improve the team work (Head, 2006). Peek et al. observed the group work of university students from the United States and Canada on discussions of accounting ethics (Peek, Peek, Roxas, Robichaud & Blanco, 2007). Besides, although many students were aware of theories on group work techniques, they seemed to make seldom use of such techniques for their learning process (Tabatabaei & Lam, 2013).

In their investigations, Pil & Leana detected a strong link between the team leader and the performance of the team members (Pil & Leana, 2009).

Hu addressed the trend of "equal first authors" in the publications of the scientific journals. In his opinion, this could cause inefficient teamwork, because the individual research contribution was often not properly evaluated (Hu, 2009). Also Acedo et al. analysed the tendency of co-authorship, especially in the field of management science, and attempted to identify the major factors that caused this tendency (Acedo, Barroso, Casanueva & Galán, 2006).

The results of Walker et al.'s experiment could be applicable for the world outside the classrooms. During their experiment with team meetings as a tool for team projects, Walker et al. discovered an indifference point for the participants. The participants' perception towards team meetings were positive before and negative after the indifferent point was reached (Walker, Elson & O'callaghan, 2012).

In management science, group work was often studied in the context of project process. Some researchers studied the group work for creative projects. Harrison & Rouse concentrated on the dynamics of various internal forces that influenced the group coordination (Harrison & Rouse, 2014).

Researchers found out that based on the complexity of projects for product development, position-based, process-based or outcome-based rewards should be chosen in order to maximise the project outcomes (Sarin & Mahajan, 2001). Goby & Lewis emphasized the importance of communication in team work for the members of management (Goby & Lewis, 2000).

In their work, Kozlowski & Ilgen started with the analysis of cognitive, motivational and behavioural team processes and subsequently identified interventions that could align team processes, so as to improve team effectiveness (Kozlowski & Ilgen, 2006).

In the contemporary business world, group work was becoming ever more complex. For the development of new products, the firms nowadays increasingly set up project teams with participants from different disciplines (Sethi, 2000). Levy & Murname underlined the necessity of cross-disciplinary learning in group work on robot revolution among computer scientists and economist (Levy & Murname, 2014).

Based on their studies on teamwork processes among healthcare workers, Fay et al. argued that the multi-disciplinarity had a positive effect on the team performance only under restricted circumstances (Fay, Borrill, Amir, Haward & West, 2006).

Sethi proposed a test method to determine the effects of team characteristics and contextual influences (Sethi, 2000).

Different team works techniques seemed appropriate for different team styles to achieve the best outcome of business projects (Scarfino & Roever, 2009). One of the concepts was to classify project teams in the high-tech organisations in traditional, virtual and semi-virtual (or hybrid) teams (Webster & Wong, 2008).

Not only did groups often consist of multi-disciplinary members, but also the communications between the members sometimes had few opportunities for face-to-face contacts. To counteract this challenge, Majchrzak et al. proposed to develop know-how collaboration among group members by communicating not only content, but also context (Majchrzak, Malhotra & John, 2005).

As in today's world innovation is gaining more importance in most business sectors, companies begin to involve customers in their innovation process. One example is the on-line brainstorming sites termed "Company-Sponsored Online Co-Creation Brainstorming" by researchers. The researchers detected a group work process between the peers of the sponsoring companies and the involved customers. However, it seemed that the reviewing process of the submitted ideas by the sponsoring companies yet needed improvements (Chen, Marsden & Zhang, 2012).

The team transactive memory systems played an important role in group work focusing on leveraging the members' expertise. To measure the effectiveness of team transactive memory systems, Lewis developed a 15-item scale (Lewis, 2003).

2.5.2 Summary

Studies on group work (interchangeably with "teamwork") have a long history (Cooter, 2004). Researchers in the past developed various concepts for the classification of groups (O'Donnell, Arnold & Sutton, 2000).

Group work was often studied in the context of psychodynamic (Viney, Henry & Campbell, 2001; Cronin, Weingart & Todorova, 2011), or psychosocial functions in group work (Goyal, Van der Leij & Moraga-González, 2006). While some researchers were devoted in the analysis of how individual behaviours affected the team work (Marrone, Tesluk & Carson, 2007), others were more interested in the establishment of cause-and-effect relationships (Hackman, 2012).

Numerous researches were conducted in the education sector, especially in the higher education institutions, often to examine the success of educational programme (Lawrence, 2002; Sathe, 2009).

Group work also found wide applications in the business world, especially for creative projects (Harrison & Rouse, 2014). A central influence factor of such projects seemed to be communication in the group, which was essential in aligning group processes and improving group effectiveness (Goby & Lewis, 2000; Kozlowski & Ilgen, 2006).

To deal with the growing complexity of group work in the contemporary business world, the firms nowadays increasingly built up multi-disciplinary project teams (Sethi, 2000). However, some researchers claimed that the positive effect of the multi-disciplinarity on group performance could only be observed under restricted circumstances (Fay, Borrill, Amir, Haward & West, 2006). To counteract the complexity of group work, Majchrzak et al. proposed the communication of not only content, but also of context for the know-how collaboration among group members (Majchrzak, Malhotra & John, 2005).

With the growing importance of innovation in most business sectors, some companies involved not only internal personnel, but also customers in their innovation process (Chen, Marsden & Zhang, 2012).

Following the trend in the latest development of the business world, this study focuses on group work as an innovation process. Two problem-solving techniques are applied in the group work process. The group performance is measured in two dimensions: 1) The technical solutions as results of the innovation process; and 2) the group work process including the analysis of the behaviours of the individual group members and their perceptions for the group work.

2.6 Assessment methods of group behaviours

2.6.1 Research findings

In preparation of research design for the investigation on how TRIZ affects the group work of the innovation activities in terms of group behaviours (process), the assessment methods of group behaviour in previous literature are analysed in this part of the literature review.

Several studies explored behavioural changes in field of clinical institutions, often by means of observations by external researchers and interviews.

Reza et. al. focused on the impact of psycho-educational programme on behavioural changes among caregivers of individuals with schizophrenia and mood disorders. They findings on the positive effect of the educational programme on family dynamics in

favour of the patients were based on external observations using Solomon's experimental design (Reza, Shikha, Habibollah & Ali, 2004).

Through observations and perceptions of two external observers, Scherer, Scherer, & Campos evaluated the effects of coordinating general team meetings at a psychiatric day hospital. Their findings suggested that the intervention of an institutional supervisor could improve the efficacy of the meetings, in addition to analysis of the coordinator's performance, as well as the organisational dynamics and structure (Scherer, Scherer & Campos, 2007).
In a case study, De Casterlé et. al explored the leadership development in a clinical leadership promotion programme. Using mixed methods, they collected with individual interviews, focus groups and observation of participants. Based on the empirical findings, they developed a framework to describe the leadership development and its impacts on the stakeholders (De Casterlé, Willemse, Verschueren & Milisen, 2008).

In order to examine closely group work under pressure, Ren, Kiesler & Fussell conducted a case study of a hospital's operating room practices. By means of external observations and interviews, they analysed the coping mechanisms and their consequences in case of coordination disturbance in group work (Ren, Kiesler & Fussell, 2008).

In order to study team functions in high-risk environments, Kolbe et al. studied sequential patterns of the individual behaviours of several medical teams. Subsequently, the external observers established a relationship between certain behaviours and results of the group work by coding verbal and nonverbal behaviours of the participants and grouping the results in high-performing and low-performing. Their conclusion was that a number of interactions patterns were expected to lead to higher performance (Kolbe et al., 2014).

Other researchers dedicated their research interest to the complex effect of cognitive or coaching process.

With their Problem-Based Learning (PBL) approach for the complex holistic coaching process, Jones & Turner explored the colleague students' behaviours in group work under pressure. They collected data through external observations and semi-structured group interviews. The focus of their study was the influence of the coach's role in the outcome

of the group work and to establish PBL as a framework for academic research and practical application in this special field of coaching in group work (Jones & Turner, 2006).

The research interest of Larsen et al. was the development of top sport talents with focus on the overall environment for the athletes (Larsen, Alfermann, Henriksen & Christensen, 2013). They closely examined the talent development of some young male soccer players in a Danish soccer club in light of the relationship between players and a staff of coaches, assistants, and managers. Their means of data collection mainly included interviews, participant observations by external observers and analysis of documents. Based on their findings, they developed a holistic model with multiple influence factors for the success of young sport talents (Larsen, Alfermann, Henriksen, & Christensen, 2013).

Eidimtas' empirical study on the learning process of Lithuanian fire-fighters was organised as a survey study. He found out that the fire-fighters mainly learned from their colleagues and their own failures in extreme situations (Eidimtas, 2010).

Camara et al. investigate the relationship between the students' satisfaction, the individual performance and the type of student work groups (with homogeneous or heterogeneous performance levels). The group work compilation in their study was conducted by either self-selected or randomly selected. Both approaches have biases due to polarisation and variability of knowledge of the group members. The group compilation could be improved through control of cultural, gender, age or level of education of group participants. In practice, however, establishment of such homogeneous groups may not always be possible (Camara, Carr & Crota, 2007). The assessment of the group work was conducted by external observers. In addition, Camara et al. proposed peer review for the evaluation of individual performance of the students (Camara, Carr & Grota, 2007).

Praetorius and Lützhoft scrutinized user needs for dynamic risk management in Vessel Traffic Service (VTS). Their means of data collection were study visits and observations by external observers, as well as semi-structured interviews. However, the main focus of their study was the output, instead of the group dynamics (Praetorius & Lützhöft, 2012).

Compared with other studies, Perry Jr et al. took a relatively complex approach for the development of a model of team establishment by analysing group work among mid-career working professionals. The empirical study was constructed as an experiment with multiple teams working on similar tasks, with the results reported by the researchers through participant observation and interviews. Following this, a survey study was carried out with the participants after the above case reports were made available. Subsequently, the researchers conducted a qualitative analysis of the survey responses. With their research focus on team development, Perry Jr et al. did not follow up on the implications for individual performance, although the results suggested an interplay between the ongoing assessment and the participants' behaviours afterwards (Perry Jr, Karney & Spencer, 2013).

Bell and Morse (2013) investigated the advantages and disadvantages of the assessment approaches *inside out* which rely on group members' self-analysis of the individual behaviours and *outside in* which relies on the external observations. In a statistical analysis, they compared the quantitative SYMLOG method based on the group members' opinions and the BECM method based on the qualitative assessment by an external observer. Their findings confirmed the advantages of SYMLOG by allowing all group members to participate in the assessment. Furthermore, Bell and Morse proposed an improvement of the SYMLOG method by hybridising it with the BECM method by adding external observers to the rating process (Bell & Morse, 2013).

2.6.2 Summary

Group dynamics is relatively prolific research field, covering various professional fields ranging from medical institutions (Reza, Shikha, Habibollah & Ali, 2004; Scherer, Scherer & Campos, 2007; de Casterlé, Willemse, Verschueren & Milisen, 2008; Ren, Kiesler & Fussell, 2008; Kolbe et al., 2014) to vessel traffic service (Praetorius & Lützhöft, 2012).

Numerous works were organised as empirical studies with different research approaches, with participant observation as a frequently used research method (Reza, Shikha, Habibollah & Ali, 2004; Scherer, Scherer & Campos, 2007; De Casterlé, Willemse, Verschueren & Milisen, 2008; Ren, Kiesler & Fussell, 2008; Kolbe et al., 2014; Jones & Turner, 2006; Larsen, Alfermann, Henriksen & Christensen, 2013; Camara, Carr & Grota, 2007; Praetorius & Lützhöft, 2012; Perry Jr, Karney & Spencer, 2013).

Bell and Morse divided the observation methods into two groups according to the assessment approaches: *inside out* which relied on group members' self-analysis of the individual behaviours and *outside in* which relied on the external observations. In order to combine the advantages of both approaches, Bell & Morse proposed to hybridise the *inside out* SYMLOG method with the *outside in* approach by adding external assessment to the classic form of this method (Bell & Morse, 2013).

While most of the assessment methods for observations were developed individually to meet the special requirements of the research object, SYMLOG seemed to be universally applicable, since its criteria for the assessment of individual behaviours in group were independent of the situations. Therefore, this study chose SYMLOG for later assessment of the process of group work.

Another frequently used method was interviews, with the variety of individual interviews, group interviews, semi-structured interviews, etc. (De Casterlé, Willemse, Verschueren & Milisen, 2008; Ren, Kiesler & Fussell, 2008; Jones & Turner, 2006; Larsen, Alfermann, Henriksen & Christensen, 2013; Praetorius & Lützhöft, 2012).

Other research methods used in the analysed literature were survey (Eidimtas, 2010; Perry Jr, Karney, & Spencer, 2013) and experiment (Reza, Shikha, Habibollah & Ali, 2004; Camara, Carr & Grota, 2007). In order to combat the internal validity issues, Reza et al. applied Solomon's experimental design (Reza, Shikha, Habibollah & Ali, 2004).

2.7 SYMLOG

SYMLOG (System for the Multiple Level Observation of Groups) is a method for the study of group processes developed by Robert Freed Bales in the later 1970's (Bell & Morse, 2013). The study of the group work process in this thesis is guided by this method based on the considerations that: a) SYMLOG was positively evaluated by previous researchers especially in the study of social science and psychology; and b) abundant descriptions of the application of this method are available in the literature which facilitates a good understanding and command of this well-accepted method.

2.7.1 Research findings

One of the latest literature sources related to SYMLOG was Bell and Morse's discussion paper on a comparison study of SYMLOG and BECM (Bell & Morse, 2013). In the opinion of Bell and Morse, BECM (also known as "*Being, Engaging, Contextualizing* and *Managing*") focused on the external route in the assessment of group work. In the BECM method, the group work was rated by an external person. SYMLOG, on the other hand, was defined as an inside out methodology whereby group participants themselves were responsible for conducting an internal assessment of the group participants (Bell & Morse, 2013). However, to the understanding of some other researchers, the group work assessment in the SYMLOG methods also needed to be conducted by external persons (Marx, 2000).

Since the initiation by Bales, the SYMLOG methodology has been used in various contexts for the study of inter-personal relationships in small groups.

By measuring the SYMLOG leadership values instrument before and after skill trainings for the managers, the researchers determined the efficacy of the trainings in the three bipolar SYMLOG dimensions (Lawrence & Wiswell, 1993).

In the past, SYMLOG found wide applications in family observations. For the clinical social workers, Kutner and Kirsch developed a graphic system for the illustration of interpersonal relationships based on SYMLOG framework (Kutner & Kirsch, 1985). Similarly, Crespi adapted the SYMLOG methodology for the family of origin evaluation for family therapists (Crespi, 1993). The method of SYMLOG group observation was applied by Herzog and his medical colleagues for family observations on eating disorders (Herzog, Kronmüller, Hartmann, Bergmann & Kröger, 2000). Besides, Cashmann et al. used the SYMLOG approach to measure the interaction of healthcare professionals in interdisciplinary team in proving medical service (Cashman, Reidy, Cody & Lemay, 2004).

In the narratives of her life story after World War II, Chaitin used the SYMLOG framework to describe the family relationships, as well as the interpersonal values of the families in the first, second and third generation (Chaitin, 2000).

SYMLOG methodology was also used to analyse the gender differences in academic researches. Hare et al. used the SYMLOG techniques to compare the behaviours of female and male managers in a leadership program, analysing both the self-ratings of the managers and the ratings by the co-workers. Quite expectedly, they found out that the females managers were more dominant and positive and less task-oriented (Hare, Koenigs & Hare, 1997). Schneider et al. combined SYMLOG with Bem Sex Role Inventory (BSRI) which consisted of masculinity, femininity and social desirability scales (Schneider, Schneider-Düker & Becker-Beck, 2001) to identify the influence of gender on individual behaviours. They concluded that the SYMLOG reflected closely the level of individual behaviours in the group interaction (Schneider, Schneider-Düker & Becker-Beck, 2001).

Blumberg and Hare (1999) applied the classic form of SYMLOG techniques for their investigation of sociometry in organisations. They commented on the advantages and disadvantages of the rating process (Blumberg & Hare, 1999). Beyond real life data, Hare & Hare simulated group behaviours with SYMLOG under the use of survey data (Hare & Paul, 2001). Polley discussed the validation of the adjective rating tool set in the SYMLOG environment and offered improvements without clarification of the advantage and the application of the improvements (Polley, 1987).

The Scandinavian researcher Eisele compared the performance and decision-making process of individuals and in group, using the SYMLOG methodology (Eisele, 2003). Especially, he used the rating tools not only for the group investigation, but also for the research on individuals (Eisele, 2003).

Isenberg and Ennis compared multidimensional scaling with SYMLOG as a tool for personal perception investigations and detected a relatively high correlation of both approaches (Isenberg & Ennis, 1981).

In his experiment with 91 young adults using SYMLOG method, Hurley compared self-rating with group peers. His results showed that the public group peers shifted the individual self-estimation towards the average opinions of the other participants of the same group (Hurley, 1991).

In the words of Bell and Morse, SYMLOG has been a well-established quantitative group self-analysis tool for over 30 years. This method is often used for the analysis of group conflicting, gender work, family observation, face-to-face and computer facing communication and proves to be the state of art approach in those cases till this date (Bell & Morse, 2013)

2.7.2 Summary

SYMLOG is a well-recognized tool set with data of over 30 years (Bell & Morse, 2013). This method is often used for the analysis of interpersonal relationships in various contexts, e.g. management process (Eisele, 2003; Lawrence & Wiswell, 1993), family observations (Kutner & Kirsch, 1985; Crespi, 1993), patient observations by healthcare professionals (Herzog, Kronmüller, Hartmann, Bergmann & Kröger, 2000), analysis of gender differences (Hare, Koenigs & Hare, 1997; Schneider, Schneider-Düker & Becker-Beck, 2001), or even for narratives involving intensive personal interactions (Chaitin, 2000).

Some researchers compared SYMLOG with alternative assessment methodologies (Schneider, Schneider-Düker & Becker-Beck, 2001; Isenberg & Ennis, 1981). In some cases, the researchers detected a relatively strong association between SYMLOG and the alternative methods (Isenberg & Ennis, 1981). In other case, the researchers proposed the combination of SYMLOG with other methodologies (Schneider, Schneider-Düker & Becker-Beck, 2001).

Over time, the academics conducted numerous discussions on the advantages and disadvantages of SYMLOG and suggested improvements (Blumberg & Hare, 1999). Furthermore, although originally designed to measure interactions in small groups, SYMLOG was also applied for the research of individual behaviours (Eisele, 2003).

Although in the original form, SYMLOG is solely based on internal assessment by participants in the group consisting of self-rating and group-rating (Bell & Morse, 2013), some researchers suggested the inclusion of external assessment by external observers (Marx, 2000). One interesting method designed by Hurley was a combination of individual internal assessment and public group peers. This process seemed to mitigate the gap between self-estimation and external estimation (Hurley, 1991).

Altogether, SYMLOG is a well-established quantitative group self-analysis tool and still counts as one of the state of art approaches for researches on interpersonal relationships in small groups till this date (Bell & Morse, 2013).

Based on the results of the literature review, this thesis chose to apply the SYMLOG methodology for the assessment of the group work process, with the research design oriented on Hurley's method using both internal and external assessment.

3. Research Design

As described in Section 1.4, this section is dedicated to the research methodology and methods. This involves an introduction of the philosophical worldview, the research methodology, the methods for data collection and data assessment, followed by discussions on the quality of the research design, the role of researcher and the ethical considerations and finally, the research schedule.

3.1 Philosophical worldview

The individual philosophy of the researcher may crucially influence how he organises the research work, for example how to access the research topic and the research questions. Therefore, the philosophical position of the researcher is discussed in this section.

As a natural scientist, the researcher believes that the world with its real developments in and around living organism exists sovereignly from its observers. The truth about the real world can be best accessed through empirical observations and careful measurements. However, due to subjective perceptions, the observations will always be charged with biases. This position fits very well to the description of post-positivism by Creswell as one of the four main worldviews (Creswell, 2009, pp. 6-7). The post-positivistic position is also taken up for this study for the following reasons.

The findings of the literature review indicate that the post-positivist position is shared by the majority of the researchers in all pertinent fields for this study. A large part of the previous studies analysed in chapter 2 considered the innovation process in the pharmaceutical industry, problem-solving techniques and assessment of group work, etc. These are organised based on empirical data of observations and experiments.

Based on the above considerations, this research followed the research tradition and strongly relied on empirical data based on experiences and observations.

3.2 Research methodology and methods

The research methodology is an essential part of the study. According to Creswell, the research methodology describes the principles of the researcher's understanding of how the research is to be conducted (Creswell, 2009, pp. 11-12). Creswell distinguishes three categories of research methodologies:

- Quantitative approaches;

- Qualitative approaches; and
- Mixed approaches.

(Creswell, 2009, pp. 11-12).

In Creswell's opinion, the post-positivist researchers tend to take the **quantitative approaches**, which often involve collection and assessment of statistic data, experimental inquiries, etc. in access to a research topic (Creswell, 2009, pp. 14-15).

The **qualitative approaches** are described by Creswell as focusing on the qualitative feature of the data related to the participants' view. The researchers often take up a qualitative approach when they observe certain social groups, their development over time and their behaviour patterns. The qualitative approaches are suitable for explorative researches and are associated with a variety of philosophical positions (Creswell, 2009, pp. 14-15).

The third category of research methodologies, the **mixed methods approaches**, is a combination of the quantitative and the qualitative approaches (Creswell, 2009, pp. 14-15).

The research focus of this thesis involves both explorative studies and theory building based on descriptive statistics. Thus in Creswell's terms, the methodology of this thesis is organised with a mixed method approach.

The structure of the research design is illustrated in the following graphic (Figure 3-1).

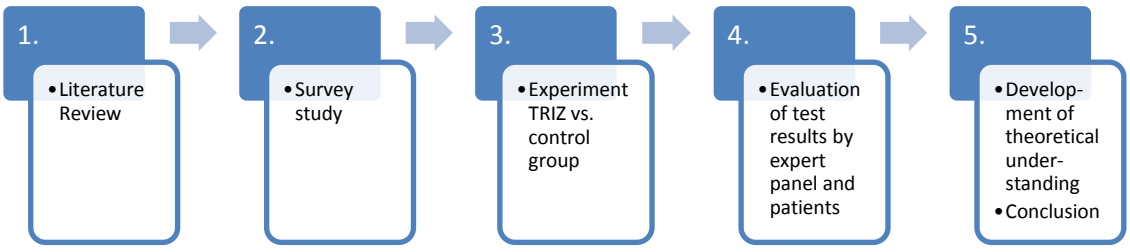

Figure 3-1 **Research design: mixed-method approach**

In a first step, the current literature on the key issues of this thesis (the problem-solving technique TRIZ, auto-injectors, EpiPen, group work and SYMLOG) is explored by means of a literature review. All parts of the literature review are organised as systematic

literature review in the style described by Tranfield et al. (see section 2.1). The findings of the literature review delivered indications for answers to RQ2 (“How can TRIZ techniques be applied for medical device innovation?”) and RQ3 (“How and why do TRIZ techniques differentiate themselves from other problem-solving methods, from a theoretical perspective?”). This led to the choice of research focus for the research design (see chapter 2).

Next, a survey study on the current status of the application of problem-solving tools for R&D of medical devices in the pharmaceutical industry is to be conducted in the German Rhine-Main region. The main aim of the survey study is to answer RQ1 “Which problem-solving tools are currently used for R&D of medical devices in the pharmaceutical industry?” The survey data shall depict the usage of problem-solving tools in the regional pharmaceutical medical device sector. Besides, the survey participants will be asked to propose assessment criteria for technical solutions of medical devices as combination products for pharmaceutical drug delivery. Subsequently, the proposed criteria will be discussed and finalised with a group of experienced experts (expert panel) for further rounds of this study (see chapter 4).

Next, a 2x2 experiment is to be carried out on group work for the improvement of auto-injector design, using problem-solving techniques TRIZ and the alternative technique identified by the survey study as the method currently used with the highest frequency. During the experiment, two groups of experienced practitioners will be asked to improve the design of two EpiPen models.

The efficacy of TRIZ application will be explored both in the aspect of the quality of the technical solutions (the outputs) and that of the group work (the process). The results shall provide further impulses in pursue of answers to RQ2 (“How can TRIZ techniques be applied for medical device innovation?”) and RQ3 (“How and why do TRIZ techniques differentiate themselves from other problem-solving methods, from a theoretical perspective?”).

The assessment of the technical solutions (the outputs) will be conducted in two steps: a) by evaluation of the expert panel based on the criteria determined after the survey study, and b) by evaluation of the pen-experienced patients. The assessment of the group work

(the process) will be conducted with the SYMLOG method initiated by Bales (see chapter 6).

Finally, the findings of the literature review, the survey study and the experiment will be analysed so that conclusions can be drawn on a theoretical level.

3.3 Systematic literature review: search plans

The literature review in this study aims to identify the current status of academic research, so as to gain background information and to detect research gaps in the fields of interest. The literature review in this thesis is conducted as systematic literature review in the style of Tranfield et al. (see section 2.1). The search plans for the key terms in this thesis are described in detail in the following sections.

3.3.1 Search plan: TRIZ

The focuses in this section of literature review are:

- To identify the current status of academic literature and research of TRIZ;
- To identify the current status of TRIZ application in the pharmaceutical industry;
- To create a search approach for the main review.

3.3.1.1 Literature scoping

The literature scoping was conducted on primary studies and previous literature reviews as proposed by Tranfield, Denyer & Smart (2003). The target of the scoping review was to identify the quantity of previous literature on TRIZ techniques and to develop a strategy for the main search. A scoping review was conducted with the electronic database EBSCO collection online database by the University of Gloucestershire on 15.12.2013.

During the scoping search, the search term "TRIZ" was chosen. By selecting only disseminations in the English language in academic journals, newspapers, periodical reviews and interviews for the timeframe from 1991 till 2013, this led initially to 264 retrievals.

3.3.1.2 Search outline

The EBSCO database was searched by using the following search plan. Subsequently, the search results were reduced to the data set considered relevant for this thesis by applying the inclusion and exclusion terms (see table 3-1).

Database: The EBSCO database collection including the following databases was accessed for the full review.

eBook Collection (EBSCOhost), Show all News (AP, UPI, etc.), Art & Architecture Complete, ATLA Religion Database with ATLASerials, Business Source Complete, CINAHL with Full Text, Education Research Complete, E-Journals, Environment Complete, ERIC, Film & Television Literature Index with Full Text, GreenFILE, Hospitality & Tourism Index, Humanities International Complete, Library, Information Science & Technology Abstracts, MEDLINE, PsycARTICLES, Psychology and Behavioral Sciences Collection, PsycINFO, Regional Business News, SocINDEX with Full Text, SPORTDiscus with Full Text and Teacher Reference Center

Search term: "TRIZ"

Language: English

Publication date: 1991 to 2013

Publication type: Academic journals

.

Parameters	Inclusion criteria	Exclusion criteria
Timeframe	Literature published from 1991 till 2013	Literature published before 1991
Business focus	Research and development	Irrelevant to research and development, e.g. banking and trading
Type of literature	Academic journals; literature reviews; clinical trial reviews	Advertisements, newsletters and opinion pieces by key opinion leaders
Language	English	Other languages

Table 3-1: Inclusion/exclusion criteria: TRIZ

To explain the choice of the inclusion and exclusion criteria, the single criteria are introduced in more details in the following.

Timeframe. The timeframe from 1991 till 2013 was selected for the literature search, in order to reflect the focus of current innovation methods for the pharmaceutical industry.

Business focus. The focus of the thesis is the application of TRIZ in the research activities of the pharmaceutical industry. Therefore, disseminations on application of TRIZ techniques for research activities in the pharmaceutical industry are considered pertinent to this study. On the contrary, disseminations with focus on special topics e.g. news and ad-hoc stock related information are considered non-related to this study and excluded from this search.

Type of literature. The academic journals are considered objective evidence and therefore included in the literature review. Advertisements and newsletters are considered subjective literature and therefore excluded.

Language. The main reason for the choice of language is the limited language knowledge of the researcher in German (native language) and English. A search for disseminations in German with the above search criteria resulted in no retreaval, therefore, this search concentrated on the English language. Since the majority of the pertinent disseminations are published in the English language, the focus on the data set in English is considered sufficient for this study.

The search plan yielded initially 264 articles in academic journals, news, periodical reviews and opinions published between 1991 and 2013. 120 findings were rejected because the abstract did not deliver adequate information and the full text was not available.

The abstracts of the articles were read for the inclusion/ exclusion decision. According to the inclusion and exclusion criteria for this search, 51 literature sources were rejected because they were non-academic journals. After reading the abstract of 219 sources, 182 were rejected, because they focused on special topics e.g. energy storage, banking and CAD design features etc., or because they were secondary literature. Altogether, 37 literature sources remained for the literature review.

By applying the inclusion/ exclusion criteria for a second time, the literature sources were further reduced from 37 to 36 academic journals. Two duplicates among the journal

publications were identified and subsequently excluded. Finally, 34 sources were considered pertinent to this part of literature review.

3.3.2 Search plan: Auto-injector

The focus of the literature review in this section is:

- To identify the current status of academic researches on auto-injectors, and
- To identify influence factors for the development of auto-injectors in the literature.

3.3.2.1 Literature scoping

The literature scoping was conducted on primary studies and previous literature reviews as proposed by Tranfield, Denyer & Smart (2003). The target of the scoping review was:

- To identify and estimate the volume of previous researches on auto-injector applications in the pharmaceutical industry
- To create a search approach for the main review of the auto-injector topics.

The scoping search was conducted at the electronic database EBSCO collection online database by the University of Gloucestershire on 17.11.2013. In the scoping review process, the EBSCO database search yielded in total 423 articles in academic journals, newspapers and periodical reviews in the English language, published between 1959 and 2013. The search terms "auto" and "injector" were chosen for the search, as the term auto-injector can be written alternatively as auto-injector, Auto-injector or Auto Injector. Due to the focus of this thesis on auto-injectors for drug device combination products, the timeframe 1991 till 2013 was selected to reflect this latest development in medical device research. This reduced the amount of literature of concern to 409 sources. Special topics e.g. news and ad-hoc stock related information were considered non-relevant, thus excluded from this search. Together with the focus on the academic journals, the number of disseminations was brought further down to 228.

The scoping search identified EpiPen as one of the most widely discussed subjects for academic discussions on auto-injectors. EpiPen is also named adrenalin pen or AAI. The medical substance in EpiPen is known as Epinephrine, (R)-4-(1-hydroxy-2-(methylamino) ethyl) benzene-1,2-diol, or adrenaline (Figure 3-2). A separate section of the literature review shall be dedicated to the discussions on EpiPen (see figure 3-2).

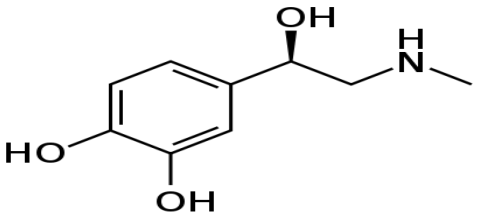

Figure 3-2 **(R)-4-(1-hydroxy-2-(methylamino) ethyl) benzene-1,2-diol.**

3.3.2.2 Search outline

The EBSCO eBook database was searched based on the keywords. According to the chosen inclusion and exclusion criteria, the search results were reduced to the data set relevant to this thesis.

Database: The EBSCO database collection including the following databases was accessed for the full review.

eBook Collection (EBSCOhost), Show all News (AP, UPI, etc.), Art & Architecture Complete, ATLA Religion Database with ATLASerials, Business Source Complete, CINAHL with Full Text, Education Research Complete, E-Journals, Environment Complete, ERIC, Film & Television Literature Index with Full Text, GreenFILE, Hospitality & Tourism Index, Humanities International Complete, Library, Information Science & Technology Abstracts, MEDLINE, PsycARTICLES, Psychology and Behavioral Sciences Collection, PsycINFO, Regional Business News, SocINDEX with Full Text, SPORTDiscus with Full Text and Teacher Reference Center

Search terms: “auto” AND “injector”

Language: English

Publication date: 1991 to 2013

Publication type: Academic journals

Inclusion/ exclusion criteria

The following exclusion and inclusion criteria were applied for the systematic literature review on auto-injectors (table 3-2).

Parameters	Inclusion criteria	Exclusion criteria
Medical device classification	Medical devices class II which defines auto-injectors for Biologicals (Monoclonal Antibodies) and Biosimilars (e.g. Erythropoietin)	Medical devices class I and III according to FDA
Timeframe	Literature published from 1991 – 2013	Literature till 1990
Products	New design strategies for auto-injectors as combination products for monoclonal antibodies; devices with injection volume not higher than 2 ml	Application devices with injection volume >2ml
Type of Literature	Academic journals and clinical trial reviews (primary literature)	Advertisements, newsletters and opinion pieces by key opinion leaders; literature reviews (secondary literature)
Focus on activities	Focus on development activities for innovative products regardless of the markets	Focus on sales & marketing activities
Business sector	Patent-protected drugs, Generics, OTC, Animal Health care, Biologics, Biosimilars	Non pharmaceutical sectors, e.g. chemical oil rig production, printing technology, insurances and food supply
Language	English	Other languages

Table 3-2: Inclusion/exclusion criteria: auto-injector

The choice of the inclusion and exclusion criteria is explained in detail in the following.

Medical device classification. The FDA, one of the world's most influential regulatory institutions for drugs, established three categories for medical devices. The three classes of the generic types of devices are defined based on the assessment of its safety, potential risks, as well as its influence on the daily routine of the patients. The auto-injectors are classified by FDA as Class II medical devices. The intended main application for auto-injectors is self-injection of Biologicals (patented-protected, e.g. Adalimumab) and Biosimilars (patented-free, e.g. Erythropoietin). Therefore, this literature review focuses on medical devices defined for Class II by FDA.

Timeframe. As discussed in the previous section, the literature search concentrates on the disseminations from 1991 to present, so as to focus on the new development of auto-injectors for drug device combination products e.g. monoclonal antibodies or adrenaline.

The FDA developed guidelines for self-administrating medical devices and combination products in the recent years. That means, older innovations may not fit the new rules, therefore cannot be in focus of this future-oriented research. In fact, auto-injectors are a relatively new segment in the pharmaceutical business. Therefore, the information on improvements of state-of-the-art auto-injectors has mainly become publically available after 1990. Therefore, the literature after 1990 was chosen to concentrate on the latest development in the pharmaceutical industry.

Products. This review focuses on new design innovations for auto-injectors as combination products. This includes the feedbacks from patients, as well as the new design and handling features of the products.

Large volume devices with more than 2 ml liquid to administrate are not in the focus of this review. In the current practice, 2 ml of administered liquid is the maximum for auto-injectors. Higher volumes are usually administered with other application systems, e.g. patch pumps.

Type of literature. The academic journals and clinical trial reviews are considered objective evidence and therefore included in the literature review. Advertisements and newsletters are considered subjective literature and therefore excluded.

Focus on activities. This search focuses on the research and development activities for innovative products. Disseminations with focus on sales and marketing activities are excluded, because the special research interests in this prolific research field do not concern the focus of this work.

Business sectors. The primary goal is the development of innovative combinations products in the pharmaceutical industry. Non-pharmaceutical business sections, e.g. chemical oil rig production, printing technology, insurances and food supply, are considered non-relevant to this review.

Language. The main reason for the choice of language is the limited language knowledge of the researcher in German (native language) and English. A search for disseminations in the German language with the above search criteria led to 3 retreavals, however the full text was not available in the chosen database.

Conventionally, clinical data of the pharmaceutical industry and academic literature on pharmaceutical researches are published in the English language. The reason behind this is that the two largest health care markets are under control of the US FDA and EU EMA, which both request clinical evaluation and the clinical literature review to be conducted in English. Also the majority of the pertinent disseminations in the chosen database are published in the English language. Therefore, the focus on the data set in English is considered sufficient for this study.

The above search plan yielded 228 citations. By employing the inclusion/ exclusion criteria, 176 were initially rejected because they focused on application devices with injection volume > 2 ml, sales & marketing activities, special business sectors like chemical oil rig production, insurance or food supply, or because they were secondary literature.

The remaining 52 studies were read for a second time. The full text was read for decision on inclusion or exclusion in case the abstract did not deliver sufficient information on the content of the disseminations. This led to the rejection of 30 citations due to their focus on special business sectors.

In addition, one duplicate was excluded. Finally, 21 sources were found pertinent to this literature review.

3.3.3 Search plan: EpiPen

The focus of the literature review in this section is:

- To identify the current status of academic researches on EpiPen, and
- To identify influence factors for the development of the EpiPen system in the literature.

3.3.3.1 Literature scoping

The literature scoping was conducted on primary studies as proposed by Tranfield, Denyer & Smart (2003). The targets of the scoping review were:

- To identify and estimate the volume of previous researches on the EpiPen auto-injector applications in the industry;
- To summarize subjects of existing literature on relevant issues regarding design features, handling and market information of the EpiPen;
- To create a search approach for the main review of the EpiPen application topics.

The scoping search was conducted with the EBSCO collection online database of the University of Gloucestershire on 08.04.2014. The search term "EpiPen" was chosen for the search. In the scoping review process, the EBSCO database search yielded initially 218 articles in academic journals, newspapers and periodical reviews in the English language, published between 1980 and 2014. The first literature was published in 1980 where the early generation of EpiPen was designed as a syringe without the auto-injector plastic components. Due to the focus of this thesis on EpiPen as auto-injector for adrenaline, the timeframe 2000 till 2014 was selected to reflect this latest development in medical device research. The reduced the amount of literature of concern to 205 sources.

Special topics e.g. news and ad-hoc stock related information were considered non-relevant thus excluded from the search. This brought down the numbers of disseminations further to 136.

3.3.3.2 Search outline

The EBSCO database was searched based on the keywords. According to the chosen inclusion and exclusion criteria, the search results were reduced to the data set considered relevant for this thesis.

Database: The EBSCO database collection including the following databases was accessed for the full review.

eBook Collection (EBSCOhost), Show all News (AP, UPI, etc.), Art & Architecture Complete, ATLA Religion Database with ATLASerials, Business Source Complete, CINAHL with Full Text, Education Research Complete, E-Journals, Environment

Complete, ERIC, Film & Television Literature Index with Full Text, GreenFILE, Hospitality & Tourism Index, Humanities International Complete, Library, Information Science & Technology Abstracts, MEDLINE, PsycARTICLES, Psychology and Behavioral Sciences Collection, PsycINFO, Regional Business News, SocINDEX with Full Text, SPORTDiscus with Full Text and Teacher Reference Center

Search term: "EpiPen"

Publication date: 2000 to 2014

Publication type: Academic journals

Inclusion/ exclusion criteria

The following inclusion and exclusion criteria were applied for the systematic literature review on EpiPen auto-injectors (see table 3-3).

Parameters	Inclusion criteria	Exclusion criteria
Timeframe	Literature published from 2000 – 2014	Literature till 1999
Type of literature	Academic journals and clinical trial reviews	Literature reviews; advertisements, newsletters and opinion pieces by key opinion leaders
Products	EpiPen as auto-injector	Non-branded EpiPens, auto-injectors of other brands and EpiPen syringes
Focus on activities	Development activities for innovative products	Sales & marketing activities
Language	English	Other languages

Table 3-3: Inclusion/exclusion criteria: EpiPen

The choice of the inclusion and exclusion criteria is explained in detail in the following.

Timeframe. As discussed in the previous section, the literature search shall concentrate on the EpiPen generations as adrenaline auto-injectors (instead of e.g. syringes in the

previous generations). The timeframe from 2000 to present was chosen to reflect this concurrent technological stage.

Type of literature. The academic journals and clinical trial reviews are considered objective evidence and therefore included in the literature review. Advertisements and newsletters are considered subjective literature and therefore excluded.

Products. The subject of this thesis is the EpiPen auto-injectors. The medical devices from the earlier generations e.g. the syringes are considered irrelevant to this search and therefore excluded.

Focus on activities. This search focuses on the development activities for the innovative EpiPen products. Such information serves as foundation for the experiment on technical innovation in group work in this study.
By employing the inclusion/ exclusion criteria, 65 out of 136 sources were rejected, because they were not clinical trial reviews, or they were secondary literature reviews or did not focus on the EpiPen products. The full text of the remaining 71 journals was read for exploration of the content. As a result, 53 citations were rejected because the studies did not focus on research and development of EpiPen. The reduced amount of literature of concern was 18 sources.

Language. The main reason for the choice of language is the limited language knowledge of the researcher in German (native language) and English. A search for disseminations in the German language with the above search criteria led to one single retreaval, however the full text was not available in the chosen database.

Conventionally, clinical data of the pharmaceutical industry and academic literature on pharmaceutical researches are published in the English language. The reason behind this is that the two largest health care markets are under control of the US FDA and EU EMA, which both request clinical evaluation and the clinical literature review to be conducted in English. Also the majority of the pertinent disseminations in the chosen database are published in the English language. Therefore, the focus on the data set in English is considered sufficient for this study.

3.3.4 Search plan: Group work

The focus of the literature review in this section is:

- To identify the current status of academic researches on the group work under the aspect of problem-solving, and
- To identify influence factors for the development of group work and problem-solving in the literature.

3.3.4.1 Literature scoping

The literature scoping was conducted on primary studies as proposed by Tranfield et al. (Tranfield, Denyer & Smart, 2003). The target of the scoping review was:

- To identify and estimate the volume of previous researches which focused on group work under the aspect of problem-solving process in the current existing literature;
- To summarize research design of previous studies on technical innovation in group work.

The scoping search was conducted at the EBSCO business source online database by the University of Gloucestershire on 16.11.2014. In the scoping review process with the search terms "group work" and "research", the search yielded 269 articles published between 1929 till 2014. Due to the focus of this thesis on the current research findings on group work, the timeframe 2000 till 2014 was selected to reflect the latest development in the academic studies. This reduced the dataset to 187 sources. The restriction of type of literature to academic journals led to the remaining 143 articles.

3.3.4.2 Search outline

The EBSCO online database was searched based on the keywords. According to the chosen inclusion and exclusion criteria, the search results were reduced to the dataset relevant for this thesis.

Database:	EBSCO business source
Search terms:	"group work" and "research"
Language:	English
Publication date:	2000 to 2014

Publication type: Academic journals

Among the 143 located literature sources (see section 3.3.4.1), 91 were rejected because the abstract did not deliver adequate information and the full text was not available. As a result, the remaining 52 articles were used for this part of the literature review.

Inclusion/ exclusion criteria

Timeframe. The literature search aims to concentrate on the current approaches and findings of investigations on group work. The timeframe from 2000 to present was considered adequate for this purpose.

Type of literature. The academic journals and clinical trial reviews are considered objective evidence and therefore included in the literature review. Advertisements and newsletters are considered subjective literature and therefore excluded.

Language. The main reason for the choice of language is the limited language knowledge of the researcher in German (native language) and English. A search for disseminations in German with the above search criteria resulted in no retreaval, therefore, this search concentrated on the English language. Since literature in this research field is mainly published in the English language, the focus on the data set in English is considered sufficient for this study.

No further inclusion and exclusion criteria were applied for this systematic literature review.

3.3.5 Search plan: Assessment methods of group behaviours

The focus of the literature review in this section is to explore assessment methods of group behaviours in the current literature.

3.3.5.1 Literature scoping

The literature scoping was conducted on primary studies as proposed by Tranfield, Denyer & Smart (2003). The targets of the scoping review were:

- To identify and estimate the volume of existing researches on assessment methods of group behaviours in the current literature;

- To summarize subjects of existing literature on assessment methods of group behaviours in the current literature.

The scoping search was conducted at the electronic database EBSCO collection online database by the University of Gloucestershire on 15.04.2014. The search terms “group dynamics”, “group work performance”, “observations”, “research method” were chosen for the search. In the scoping review process, the EBSCO database search yielded initially 52 articles in academic journals, newspapers and periodical reviews in the English language, published between 1952 and 2014. Due to the focus of this thesis on EpiPen as auto-injector for adrenaline, the timeframe 2000 till 2014 was selected to reflect this latest development. The reduced the amount of literature of concern to 42 sources.

Special topics e.g. news and ad-hoc stock related information were considered non-relevant thus excluded from this search which brought down the numbers of disseminations further to 21.

3.3.5.2 Search outline

The EBSCO database was searched based on the keywords. With the chosen inclusion and exclusion criteria, the search results were reduced to the data set considered relevant to this thesis.

Database: The EBSCO database collection including the following databases was accessed for the full review.

eBook Collection (EBSCOhost), Show all News (AP, UPI, etc.), Art & Architecture Complete, ATLA Religion Database with ATLASerials, Business Source Complete, CINAHL with Full Text, Education Research Complete, E-Journals, Environment Complete, ERIC, Film & Television Literature Index with Full Text, GreenFILE, Hospitality & Tourism Index, Humanities International Complete, Library, Information Science & Technology Abstracts, MEDLINE, PsycARTICLES, Psychology and Behavioral Sciences Collection, PsycINFO, Regional Business News, SocINDEX with Full Text, SPORTDiscus with Full Text and Teacher Reference Center

Search terms: "group dynamics" AND "group work performance" AND "observations" AND "research method"

Publication date: 2000 to 2014

Publication type: Academic journals

Inclusion/ exclusion criteria

The following inclusion and exclusion criteria were applied to the systematic literature review (see table 3-4).

Parameters	Inclusion criteria	Exclusion criteria
Timeframe	Literature published from 2000 – 2014	Literature till 1999
Type of literature	Academic journals and clinical trial reviews	Literature reviews; advertisements, newsletters and opinion pieces by key opinion leaders
Focus on activities	Group behaviours	Special medical issues; other technical issues that are non-relevant to group behaviours
Language	English	Other languages

Table 3-4: Inclusion/exclusion criteria: group behaviours

The choice of the inclusion and exclusion criteria is explained in detail in the following.

Timeframe. The timeframe from 2000 to present was chosen to reflect the concurrent status of knowledge.

Type of literature. The academic journals and clinical trial reviews are considered objective evidence and therefore included in the literature review. Advertisements and newsletters are considered subjective literature and therefore excluded.

Focus on activities. This search focuses on group behaviours, thus non-relevant issues e.g. special medical issues or other technical issues are excluded.

By employing the inclusion/ exclusion criteria, 3 out of 21 sources were rejected, because they did not focus on group behaviours. The full text of the remaining 18 journals was read for exploration of the content. As a result, 6 citations were rejected for the same reason. The literature of concern thus consists of 12 sources.

Language. The main reason for the choice of language is the limited language knowledge of the researcher in German (native language) and English. A search for disseminations in German with the above search criteria resulted in no retreaval, therefore, this search concentrated on the English language. Since literature in this research field is mainly published in the English language, the focus on the data set in English is considered sufficient for this study.

3.3.6 Search plan: SYMLOG

The focus of the literature review in this section is:

- To identify the current status of academic researches on the SYMLOG concept first published by Bales, and
- To identify influence factors for the development of SYMLOG in the literature.

3.3.6.1 Literature scoping

The literature scoping was conducted on primary studies as proposed by Tranfield et al. (Tranfield, Denyer & Smart, 2003). The target of the scoping review was:

- To identify and estimate the volume of previous researches on the SYMLOG after Bales' initiation of this investigation method for group work;
- To summarize subjects of existing literature on relevant issues;
- To create a search approach for the main review.

The scoping search was conducted at the electronic database EBSCO collection online database by the University of Gloucestershire on 28.06.2014. In the scoping review process with the search term "SYMLOG" initially yielded 266 articles in academic journals, newspapers and periodical reviews in the English language, published between 1974 and 2013. Only academic journals were further investigated. This reduced the amount of literature of concern to 172 sources. Furthermore, 137 sources were rejected

because the abstract suggested that the focus of the studies was not research on group work.

3.3.6.2 Search outline

The EBSCO database was searched based on the keywords. According to the chosen inclusion and exclusion specifications, the search results were reduced to the data set that was relevant for this thesis.

Database:	EBSCO database
	eBook Collection (EBSCOhost) and Business Source Complete
Search terms:	"SYMLOG"
Publication type:	Academic journals

Inclusion/ exclusion criteria

Language. The main reason for the choice of language is the limited language knowledge of the researcher in German (native language) and English. A search for disseminations in the German language with the above search criteria led to 12 retreavals, however the full text was not available in the chosen database. Since literature in this research field is mainly published in the English language, the focus on the data set in English is considered sufficient for this study.

No further inclusion and exclusion criteria were applied for this systematic literature review. As a result, 35 disseminations were considered pertinent to this study.

3.4 The survey

The survey study aims mainly at answering RQ1 ("Which problem-solving tools are currently used for R&D of medical devices in the pharmaceutical industry?").

The current status of the application of problem-solving tools in the medical device sector will be captured by a survey study among practitioners in the Rhine-Main region in Germany. The survey is to be contributed by e-mail and paper printouts.

The participants will be asked to describe their experience with problem-solving techniques, especially with TRIZ tools, as well as to make proposals for assessment criteria of the developed solutions. The questions will be organised as multiple choice questions, with the exception of proposals for the quality criteria of the developed solutions which will be organised as a qualitative open-end question.

The participants' answers will be entered in an electronic database. Based on the participants' indications of their previous experience with problem-solving techniques, the survey results will be used to identify the most common tools currently applied in the medical device sector. The entries made for proposed assessment criteria for the quality of medical device solutions will be evaluated for subsequent discussions with the acknowledged 'experts' ("expert panel"). Finally, the expert panel will determine the criteria for the assessment of the experiment in this thesis.

3.5 The experiment

3.5.1 Experiment design

The experiment is constructed to answer RQ2 ("How can TRIZ techniques be applied for medical device innovation?") and RQ3 ("How and why do TRIZ techniques differentiate themselves from other problem-solving methods, from a theoretical perspective?"

The experiment design applied in this study is a two group design with one repetition (2 x 2 experiment) (see figure 3-3).

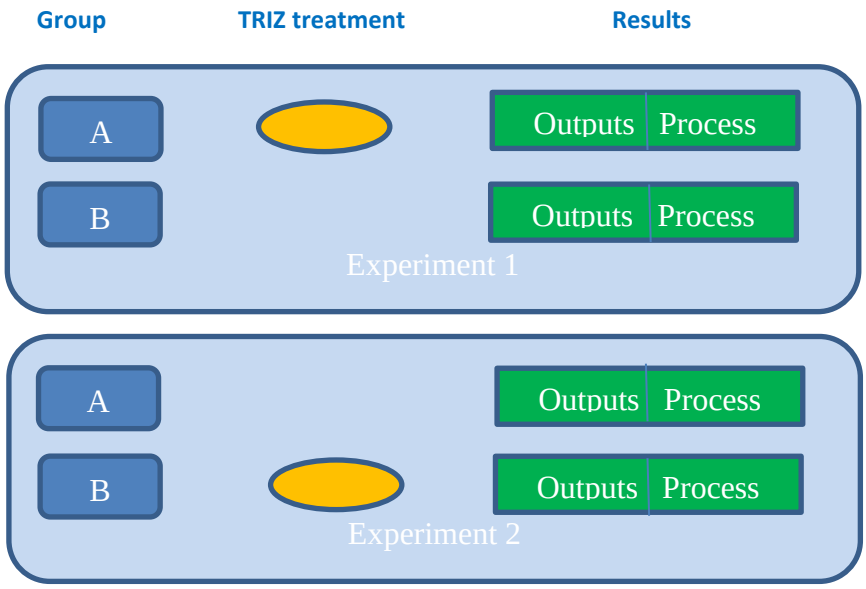

Figure 3-3 Experiment design

The 6 participants (P1, P2, …, P6), all volunteers with 5-10 years of practical experiences in medical devices design, as well as comparable academic background and experience with problem-solving techniques, will be divided into two groups. The allocation of the participants aims to control for a similar level of individual professional experience including experience with problem-solving tools, academic background, age and gender, etc. to ensure comparable groups.

Each group will conduct two experiments, each to improve the design of a different test device (auto-injector 1/ auto-injector 2). The test devices used for the experiment will be two models of EpiPen auto-injectors. The choice of test devices is explained in chapter 2. Since the selection of a group to run exclusively with TRIZ may bias the test results, the switched group experimental design is chosen. That means, in course of the experiment, each group will act as the test group for one product and the control group for the other. While the test group will be asked to fulfil their task by applying the TRIZ techniques, the control group will be asked to do the same with the alternative problem-solving approach defined by the results of the previous survey study (see test plan in table 3-5). This design is expected to reduce the bias caused by the differences between the groups in terms of experience and capacities.

Test devices	**TRIZ group**	**Control group**
Auto-injector 1	P1, P2, P3	P4, P5, P6

Auto-injector 2	P4, P5, P6	P1, P2, P3

P…Participant

Table 3-5 Experiment: test plan

At the beginning of each session of the experiment, the author will give the participating group instructions of the experiment steps. This includes an introduction of the test device, the problem-solving technique to be used, the background information, and the time limit, etc. After this, the researcher will stay in an adjacent room and will not be present for the rest of the experiment. All involvement of the author during the experiment will be recorded. At the end of each experiment session, the participants will submit the results of their group work in writing. The experiment will be video recorded in full length.

3.5.2 TRIZ procedure

The literature review in chapter 2 suggests that with some modifications, Su et al.'s approach for the improvement of service quality is the most suitable TRIZ procedure for the experiment in this study (Su, Lin & Chiang, 2008). In consideration of the features of research & development processes for medical devices, the initial 8-stage approach by Su et al. was modified to a 5-stage TRIZ innovation procedure with the following structure (see figure 3-4).

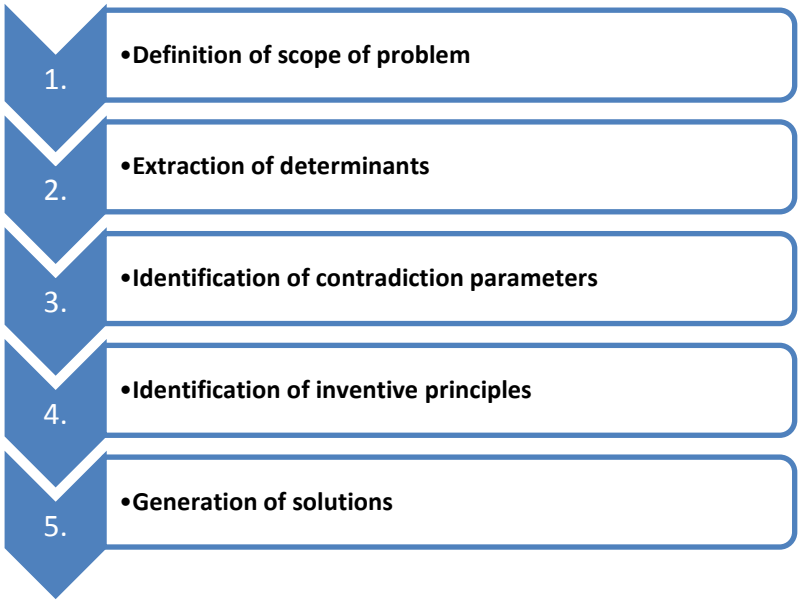

Figure 3-4 Research design: 5-stage TRIZ approach

Stage 1: Definition of scope of problem

This step of the experiment aims at the definition of the scope of problem for further procedures.

Stage 2: Extraction of determinants

The aim of this step is to extract determinants for the scope of problem based on the findings of the previous studies. For this purpose, the findings of literature reviews will be analysed, in order to extract the determinants that are considered relevant to design and use of the test subjects.

Next, some pen-experienced patients will be involved by means of semi-structured interviews. After an extensive introduction of the determinants extracted from the literature and the test devices, the patients will be asked to give their opinions on which of the determinants derived from the literature need to be improved for each test device and which of the determinants they consider essential for auto-injector design in general. They will also be given the opportunity to add further determinants for the improvement of the test devices. Their inputs will be recorded for further rounds of this research and subsequently, made available to both the test and the control groups.

Stage 3: Identification of contradiction parameters

At this stage, the appropriate TRIZ inventive principles shall derive from the determinants identified in stage 2. This shall be done by means of a parameter-corresponding table as proposed by Domb, Miller, MacGran & Slocum (1998) which involves the following steps in this research:

1. To finalise determinants for auto-injector design based on findings of stage 2;
2. To allocate the determinants to the parameters in the TRIZ 39x39 contradiction matrix;
3. To define each parameter as an improving or worsening parameter.

First, a group of six chosen TRIZ/medical device practitioners will be asked to verify the determinants detected in stage 2. They will be given the opportunity to add further determinants if they feel necessary.

With the help of the practitioners, each determinant will be mapped with a parameter in the TRIZ 39x39 contradiction matrix. To start this, the author will prepare an initial mapping for all verified determinants. The practitioners will be asked to examine the proposed mapping results and if they feel necessary, suggest alternative mappings.

Likewise, the author will also propose the specifications if each contradiction parameter is an improving or worsening parameter. Similar as in the previous step, the practitioners will examine the proposed specifications by analysing the conflict points which prevent the ideality from being achieved and if they feel necessary, make corrections.

The choice will be considered valid, if more than 50% of the practitioners consider the mapping and specification of a determinant correct. Otherwise, the choice will be considered invalid and the determinant(s) will be eliminated from further steps of the procedure.

Besides, for each test device, only those determinants related to future improvements in opinion of the patients (stage 2) are considered relevant to the further steps of the procedure. This implies, for each test device, only the determinants identified by the patients for whom a valid mapping and a valid specification is generated will enter the further steps of the procedure. In the end, a list of improving and worsening parameters will be generated for each test device.

Stage 4: Identification of inventive principles

The findings of stage 3 will be applied to the TRIZ 39x39 contradiction matrix in order to identify the corresponding inventive principles for the improvement of the test devices. This is organised as follows.

In the contradiction matrix, each combination of an improving and a worsening parameter is mapped with a number of inventive principles which were developed from a previous knowledge base. Therefore, the application of the contradiction matrix to the results of stage 2, the improving and the worsening parameters for the development of each test device, leads to a number of inventive principles.

Due to time limitation of the experiment, three inventive principles with the highest frequency will be selected for each test device to guide the further TRIZ process. The reason for this decision is that a higher frequency implies a higher potential that the principles will lead to solutions in the specific cases.

In case fewer than three inventive principles can be identified, or more than three of those will have the same highest frequency, the expert panel will be consulted for adding or eliminating certain principle(s), in order to keep the number of inventive principles constant for the further procedure of the experiment.

Stage 5: Generation of solutions

The inventive principles identified in stage 4 will be provided in the TRIZ experiment sessions. The participants will be asked to generate solutions for device improvements based on those principles.

3.5.3

3.5.4 The group work

Immediately after the groups have submitted their solutions at the end of the experiment sessions, each group member will receive copies of the SYMLOG Adjective Rating Form and be asked to fill out one form for each member (including him-/herself) as evaluation of the individual behaviours during the group work (see Appendix XI and XII).

The SYMLOG method was developed in 1960s by Robert Freed Bales based on the interaction analysis by Bales in the 1950s (Marx, 2000). The SYMLOG Adjective Rating Form describes the behaviour of the participants in a short-term evaluation (Marx, 2000). The evaluation of each individual is conducted with a separate rating form. The purpose of this instrument is to evaluate the personal attitude and characteristics during the experiment. Five choices were possible for the answer of each item: never, seldom, sometimes, often and always.

After the forms have been completed, the author will ask the participants to exchange the filled out rating forms, so that everyone can review the rating he/she receives from the others. The author will also moderate a group discussion for the group members to bring

up their opinions on group work. The group discussion will be guided by the following questions:

- How do you feel about working in a group?
- Do you prefer to work in a group or on your own?
- Did you feel comfortable during the solution-seeking process in the experiment?
- How would you describe the status of the solution-seeking process in the beginning, in the middle and at the end of the session?
- When was the most innovative moment?
- Would a moderator, facilitator or a group leader be helpful for the group work?
- Did you need more time or guidance?

After the discussion, the group members will be requested to fill out the Adjective Rating Forms for a second time. Subsequently, the results of two rounds of rating will be assessed in respect of personal attitude and characteristics of the participants of the experiment. Also the group discussions will be recorded and subsequently assessed for theory building on group work. Besides, two independent raters will also fill out the SYMLOG Adjective Rating Form for each experiment participant based on the video recordings.

3.5.5 Assessment of experiment results

In order to explore the influence of TRIZ tools on problem-solving process in group work, the results of the experiment will be analysed in terms of both the outputs and the process:

The outputs. The quality of the technical solutions will be evaluated based on the judgment of the expert panel and the patients. The same assessment methods will be applied to the test group following TRIZ procedure and the control group using the alternative problem-solving method. The following graphic illustrates the experiment procedure in terms of the outputs (see figure 3-5).

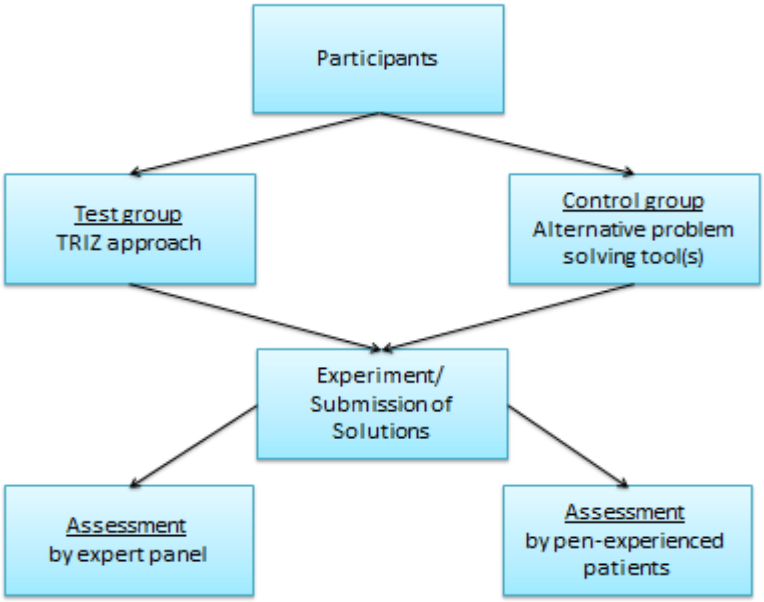

Figure 3-5 **Experiment procedure: the outputs**

The process. In terms of the process, the interactions among the group members will be analysed and interpreted, so as to develop a theoretical understanding of how and why TRIZ changes problem-solving processes in group work. The global assessment of interactions between the group members is conducted both internally by the group members of the experiment and externally, by two independent raters. The following graphic illustrates the experiment procedure in terms of the process (see figure 3-6).

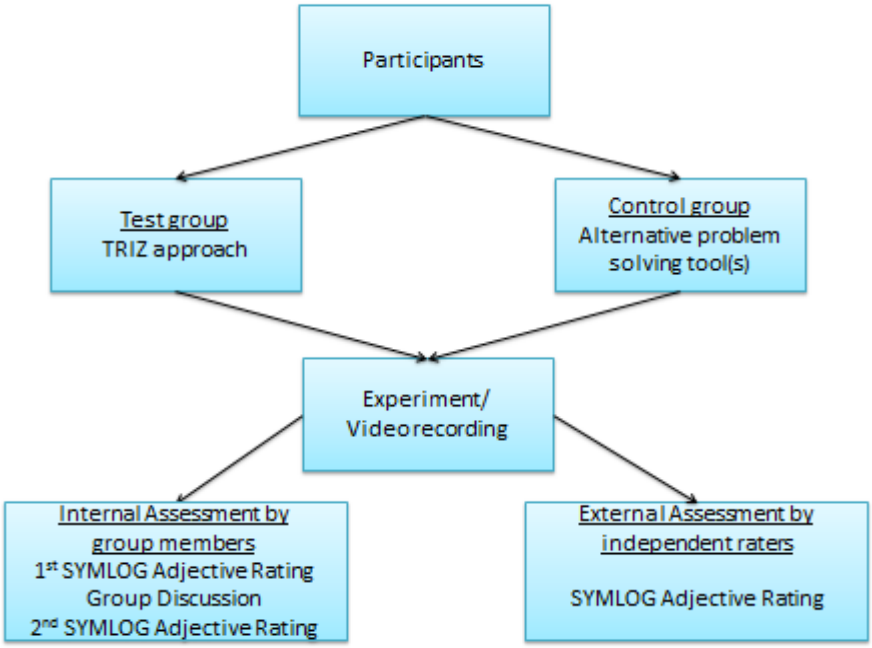

Figure 3-6 **Experiment procedure: the process**

3.5.6 Research hypotheses

There are many possible ways to describe the distinctive characteristics of the TRIZ techniques in comparison to other problem-solving tools. In order to answer RQ3 ("How and why do TRIZ techniques differentiate themselves from other problem-solving methods, from a theoretical perspective?"), three hypotheses were developed to be tested through the experiment based on the following considerations.

The findings of the literature review in section 2.2 suggest that the most unique characteristic of the TRIZ method is its knowledge-based problem-solving approach (Ilevbare, Probert & Phaal, 2013; Savranksy, 2000; Domb et al., 1998). This allows the assumption that TRIZ is more efficient than the conventional trial-and-error approach when dealing with well-defined technology-driven problems. On the other hand, its advantages may diminish when dealing fuzzy problems, e.g. if the problem focuses on subjective opinions.

Hypothesis 1: TRIZ is more effective than the conventional problems-solving approach when dealing with clearly defined technology-driven problems.

The previous study of Birdi et al. suggests a further difference between TRIZ and the conventional problem-solving techniques. According to Birdi et al., the participation in TRIZ training leads to higher motivation of the engineers in the technical renovations (Birdi, Leach & Magadley, 2012). However, their investigation took the path of self-assessment of the engineers which was affected by the individual biases of the participants.

This work intends to test Birdi et al.'s assumption by means of SYMLOG Adjective Rating Form method, in order to reduce the individual biases in the research process.

Hypothesis 2: TRIZ improves the motivation of the individual participants in the group work.

Due to the complexity of its techniques, TRIZ requires elaborate prior trainings and special knowledge of the relevant technical issues. Potentially, this could enable the individual participants to take greater influence in their special fields and the group might

then “automatically” allocate the leadership to the best knowledgeable during the group decision-making process. Thus, a final assumption in respect of instinctive features of TRIZ was made that TRIZ would promote a clear leadership structure in the group work.

Hypothesis 3: TRIZ promotes a clear leadership structure in the group work.

Altogether, the influence of TRIZ on the outputs and the process of group work may be captured with the following 2-dimentional coordinate system (see figure 3-7) for the classification of problem solving situations. The dimension “problem definition” illustrates if the problem description is clear or fuzzy. The dimension “demand on special knowledge” describes the level of special knowledge involved in the problem-solving approach and can be relatively high e.g. in case of TRIZ which requires elaborate prior knowledge, or relatively low in case of some conventional problem-solving techniques e.g. brainstorming (see figure 3-7).

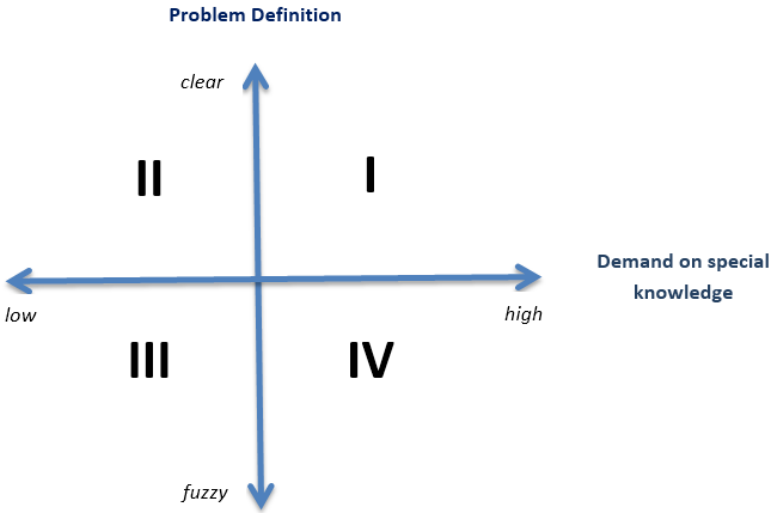

Figure 3-7 **2-dimensional system for classification of problem-solving situations**

The research hypotheses 1 & 2 may be described in the above coordinate system as follows.

Hypothesis 1: TRIZ is more effective than the conventional problems-solving approach when dealing with clearly defined technology-driven problems.

In comparison to the conventional problem-solving techniques, TRIZ requires higher level of special knowledge of the participants, both in terms of the relevant technologies and the TRIZ instruments. Therefore, innovations for clearly defined technology-driven problems by TRIZ are problem-solving situations in quadrant I and solution finding by conventional problem-solving techniques are situations in quadrant II. Thus Hypothesis 1 may be interpreted as "TRIZ is more effective for the problem type in quadrant I than the alternative problem-solving technique for the problem type in quadrant II".

Hypothesis 2: TRIZ improves the motivation of the individual participants in the group work.

Due to the higher requirements on the participants' special knowledge, innovations with TRIZ should be referred to as problem-solving situations in quadrant I (if problem is clearly defined) or quadrant IV (if problem is fuzzy). Similarly, innovations with the alternative conventional problem-solving technique should be referred to as situations in quadrant II (if problem is clearly defined) or quadrant III (if problem is fuzzy). Thus Hypothesis 2 may be interpreted as "TRIZ leads to higher motivation of the individual participants in group work in problem-solving situations of quadrant I (or IV) than the alternative problem-solving technique in situations of quadrant II (or III)".

Hypothesis 3: TRIZ promotes a clearer leadership structure in the group work.

As discussed above, innovations with TRIZ may be described as problem-solving situations in quadrant I (if problem is clearly defined) or quadrant IV (if problem is fuzzy). Likewise, problem-solving with the alternative technique are situations in quadrant II (if problem is clearly defined) or quadrant III (if problem is fuzzy). Thus Hypothesis 3 may be interpreted as "TRIZ leads to a clearer leadership structure in the group work in problem-solving situations of quadrants I (or IV) than the alternative problem-solving technique in situations of quadrants II (or III)".

3.6 Research design quality

In his book on the research methods for social science, Yin highlighted his major concerns of the researcher's biases and errors in research process, so as to misdirect the research findings. To counteract those biases, Yin recommended the following tests: construct

validity, internal validity, external validity and reliability to be applied during the case study research (Yin, 2009, pp. 141-144).

Construct validity:

Yin recommends three actions in the data collection stage to identify correct operational measures, i.e. use of multiple sources of evidence, establish chain of evidence and the review of research report by a third person (Yin, 2009, p. 41).

The evidence used for this study comes from multiple sources: the literature review, the survey study, the experiments, the expert interviews, the patient interviews, the individual evaluation and the public group peers, as well as the group discussions.

In addition, a chain of evidence is developed as follows throughout this study.

a) The literature review delivered the background information on the key terms of this research: TRIZ, auto-injector, EpiPen, group work and SYMLOG.

b) The survey study captures the contemporary status of the application of problem-solving tools, especially of TRIZ, in the R&D of medical devices in the pharmaceutical industry in the Rhine-Main region in Germany. Based on the survey results, the popular problem-solving tool in alternative to TRIZ is identified for the experiment. Besides, suggestions are made by the survey participants for the assessment criteria of created solutions for medical devices.

c) The proposed assessment criteria for the experiment outputs are verified by the medical device expert group. This is described as key informants review approach by Yin (2009).

d) The experiment is designed based on the findings of a), including internal and external ratings, as well as the group discussions between the two rounds of internal ratings.

e) The assessment of the experiment outputs is conducted based on the results of a), b) and c), as well as the patient interviews.

f) The assessment of the experiment process is conducted based on the findings of a) and d).

Internal validity:

Internal validity means to establish a causal relationship and to avoid a misinterpretation of the investigator's conclusion on the relationship between different variables (Yin, 2009, pp. 141-144). Steps are taken in the research design of this study to increase the internal validity.

The causal relationships in the experiment will be cross-examined by independent instances. First, the experiment outputs are reviewed by both the expert group and the pen-experienced patients. Second, the group work process will be reviewed by the individual participants, both before and after the public group peer discussions, as well as by two independent raters. Both steps are taken to reduce the biases and misinterpretations of one single investigator. In Yin's terms, the research design addresses rival explanations. Another principle advised by Yin in terms of strengthening the internal validity of a research program, Pattern matching, is also considered in the research design. This includes for example the assessment of the experiment process based on the participants' feedbacks in the Bales' Adjective Rating Forms.

External validity:

External validity deals with the generalisation issue of a specific case investigation (Yin, 2009, pp. 141-144). The generalisation of the results needs can only be verified by sufficient repetition of experiments of this study. Due to the limited capacity of this thesis, there is a limitation to the external validity of this study.

Reliability:

The goal is to enable a follow-up research that provides the same results as the previous study (Yin, 2009, pp. 141-144). Detailed documentation of the experiment comparable with an FDA audit of a medical device development is to be undertaken to record each single step.

Following Yin's recommendation, a research protocol will be written to facilitate the follow-up researches in the future. The reason for the protocol is that even the researchers

who are not familiar with the research topic will be able to reproduce the experiment following the detailed descriptions.

3.7 Researcher's role and ethical considerations

The research will comply with the University of Gloucestershire's Handbook of Research Ethics. To specify the most important aspects, the researcher will explain the nature and objectives of the study and how the results will be disseminated in advance in a brief statement. Free and informed consent will be obtained from all participants on a voluntary basis. In addition, the participants are given the opportunity to withdraw their consent at any time.

The data obtained will be stored with precaution and used exclusively for research purposes. In addition, the data will be released without any identifying information of the participants.

3.8 Research schedule

(see table 3-7).

Temporal plan is based on 48 months thesis program	
5 months	DBA501: Research methodology and methods
4 months	DBA502: Action and case research
5 months	DBA503: Systematic literature review
4 months	DBA504: Reflective professional development
6 months	**RD-1 draft, rework and submission**
9 months	**Preparation for research**
	Literature review
	Preparation of experiment and survey study
	Pilot study
	Identification of determinants and inventive principles for TRIZ procedure
3 months	**Improvement of research methods**
2 months	**Data collection and verification**
	Distribution and collection of questionnaires; verification by experts and patients
	Carrying out 2x2 experiment including internal rating and group discussions
	External rating and Experiment assessment by experts and patients
10 months	Data analysis, interpretation, writing up and final submission

Table 3-6 Research schedule

4. Survey study

4.1 Survey development

A survey instrument was developed with the aim to answer RQ1 ("Which problem-solving tools are currently used for R&D of medical devices in the pharmaceutical industry?") In other words, the survey aimed to capture the use of problem-solving techniques in various organisation fields and to identify the techniques that are most frequently used for R&D of medical devices in the pharmaceutical industry. In addition, the participants were intended to be asked to propose assessment criteria of technical solutions for medical device design.

In early June 2014, an initial survey was developed and from June to July tested by the expert panel for comprehension and completeness. Based on their opinions, some redundant questions were eliminated, a few additional questions of interest added and the structure of the questionnaire tightened. Besides, a few questions were rephrased for better understanding. The improved questionnaire was again distributed to the same recipients. The survey design was finalised upon positive feedbacks of the expert panel. The final version of the survey has three sections.

The first section of the survey consists of some general information on background of the participants, including gender, current position (department) and number of years of practical experience in the pharmaceutical industry.

The second section focuses on the participants' experience with problem-solving techniques, including training(s) on problem-solving techniques taken in the past three years, frequency of use of problem-solving techniques on the job, the types of problem-solving tools used on the job and proposals for quality criteria for problem solutions for medical devices.

The third section concentrates on the participants' knowledge of TRIZ, with special reference to Ilvebare et al.'s investigation on general benefits of TRIZ in the practice (Ilevbare, Probert & Phaal, 2013). This involves TRIZ training(s) taken in the past three years, frequency of use of TRIZ as problem-solving techniques on the job, the types of TRIZ tools that are known to the participants, as well as the individual opinions on

benefits of TRIZ (including the choice that TRIZ applications have “no special benefits in problem-solving process”).

The survey was first designed in English and subsequently translated by the author into German. Both the English and the German text were validated by the medical device expert panel involved in the piloting process. Whenever there were deviations between those two texts, the content was closely discussed with the expert panel till a consensus was reached that both texts were equal in content. The final version of the survey can be found in appendices I and II.

4.2 Survey distribution

In early winter 2014, the survey was distributed to staff members in three pharmaceutical companies in the Rhine-Main region in Germany.

The questionnaires were handed out as printouts by a supporter (contact person) in each participating company who was knowledgeable of the organisation structure. In some companies, the medical device business was handled by a stand-alone organisation unit; in other cases, such business was treated by a project team with members from various business units based on a matrix organisation structure. Only staff members with practical R&D experience of medical devices were invited to the survey study. School practicants, students and trainees were excluded. Altogether, 125 questionnaires were distributed to the above institutions by e-mail or printouts.

The survey was distributed with an accompanying letter which explained the voluntary basis of the study and guaranteed the data safety and discretion. The participants were asked to submit the questionnaires to the contact person in the company after filling them out in their private time. Both the companies and the participants were kept anonymous in the responses. The anonymity of participant’s employer to the researcher was constructed with reference to the separation between the sponsor and the patients in double-blinded clinical studies in the field of pharmaceutical research.

The responses were collected in the succeeding four weeks after the distribution. Subsequently, the supporters (contact persons) returned the collected responses to the author.

4.3 Survey findings

With 52 returned responses, the return rate of the survey study was 41.6 %. Among the participants, 35 were male and 17 female (see table 4-1).

			Gender		Total
			Male	Female	
Profession	R&D	Count	4	0	4
		% within profession	100.0%	0.0%	100.0%
		% within gender	11.4%	0.0%	7.7%
		% of Total	7.7%	0.0%	7.7%
	Marketing & sales	Count	1	0	1
		% within profession	100.0%	0.0%	100.0%
		% within gender	2.9%	0.0%	1.9%
		% of Total	1.9%	0.0%	1.9%
	Production Biotech & Chemistry	Count	0	1	1
		% within profession	0.0%	100.0%	100.0%
		% within gender	0.0%	5.9%	1.9%
		% of Total	0.0%	1.9%	1.9%
	Medical device development	Count	28	13	41
		% within profession	68.3%	31.7%	100.0%
		% within gender	80.0%	76.5%	78.8%
		% of Total	53.8%	25.0%	78.8%
	Medical device production	Count	0	2	2
		% within profession	0.0%	100.0%	100.0%
		% within gender	0.0%	11.8%	3.8%
		% of Total	0.0%	3.8%	3.8%
	Others	Count	2	1	3
		% within profession	66.7%	33.3%	100.0%
		% within gender	5.7%	5.9%	5.8%
		% of Total	3.8%	1.9%	5.8%
Total		Count	35	17	52
		% within profession	67.3%	32.7%	100.0%
		% within gender	100.0%	100.0%	100.0%
		% of Total	67.3%	32.7%	100.0%

Table 4-1 Descriptive statistics of survey study: participants

The current medical device departments were established only recently, due to the change from small molecules to biologicals drugs in the research-based pharmaceutical business. Most of the employees are men, due to the male domination in mechanical and technical working fields (many of them coming from the automobile industry). On the other hand, the laboratories of the pharmaceutical R&D remain a female domain, as a tradition of the pharmaceutical industry with biological-chemical roots (Smith-Doerr, 2004). The gender split in this survey study appears to be typical for the medical device development departments of the pharmaceutical industry.

Also, 4 of the participants indicated that they worked in R&D, 1 in marketing & sales, 1 in production Biotech & Chemistry, 41 in medical device development, 2 in medical device production and 3 in other professions in the organisation (see table 4-1).

The results of the survey study suggested that the participants had at an average 8 years of practical experience in the pharmaceutical industry and 6 years with R&D and/or production of medical devices. Out of the 52 participants, 26 took part in trainings on problem-solving tools in the last three years, among those 16 had at least 4 days of training in total during this period of time.

Among the participants of the survey study, the most frequently used problem-solving technique seemed to be brainstorming (making up 96.2% of all participants and 97.6% of the participants in the group "medical device development"), followed by mind-mapping (63.5% of all participants and 73.2% of the participants in the group "medical device development") and TRIZ (30.8% of all participants and 34.1% of the participants in the group "medical device development"). The problem-solving techniques comprised in the group "others" were: root cause analysis, DMAIC, strengthening sessions, risk analysis, Ishikawa diagram, meta-plan, card sorting/ brain writing and the 5-Why method.

Due to the high frequency of use by the practitioners, brainstorming was chosen to be the alternative problem-solving approach for the comparison study in the experiment sessions (see table 4-2).

			Methods						Total
			1	2	3	4	5	6	
Profession	R&D	Count	4	2	0	0	0	0	4
		% of Total	100.0%	50.0%	0.0%	0.0%	0.0%	0.0%	100.0%
	Marketing & sales	Count	1	0	1	0	1	0	1
		% of Total	100.0%	0.0%	100.0%	0.0%	100.0%	0.0%	100.0%
	Production Biotech & Chemistry	Count	1	0	0	0	0	0	1
		% of Total	100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	100.0%
	Medical device development	Count	40	30	7	2	14	11	41
		% of Total	97.6%	73.2%	17.1%	4.9%	34.1%	26.8%	100.0%
	Medical device production	Count	2	0	0	1	1	0	2
		% of Total	100.0%	0.0%	0.0%	50.0%	50.0%	0.0%	100.0%
	Others	Count	2	1	1	1	0	0	3
		% of Total	66.7%	33.3%	33.3%	33.3%	0.0%	0.0%	100.0%
Total		Count	50	33	9	4	16	11	52
		% of Total	96,2%	63.5%	17.3%	7.7%	30.8%	21.2%	100.0%

Method 1 = Brainstorming
Method 2 = Mind-mapping
Method 3 = Trial error experiments
Method 4 = Lateral thinking
Method 5 = TRIZ
Method 6 = Others

Table 4-2 Frequency of use of problem-solving tools

While 84.6% of the survey participants at least occasionally use some kind of problem-solving techniques, only 25% of them reported to use TRIZ at a similar frequency (see table 4-3).

	Use of problem-solving tools					Use of TRIZ				
	never	seldom	occasionally	frequently	always	never	seldom	occasionally	frequently	no reply
Count	2	6	20	18	6	22	9	10	3	8
% of Total	**3.8%**	**11.5%**	**38.5%**	**34.6%**	**11.5%**	**42.3%**	**17.3%**	**19.2%**	**5.8%**	**15.4%**

Table 4-3 Use of problem-solving tools vs. use of TRIZ

Altogether, 11 out of 52 participants took part in TRIZ trainings in the last three years with a total training duration of 1-3 days. Probably due to the high complexity of the methods, only 25% of the participants claimed to be knowledgeable of some concept(s) of the TRIZ toolkits (see table 4-4). Besides, only 7 out of 52 participants were familiar with more than two TRIZ tools. The participants seemed to be the most acquainted with the TRIZ concepts of "39 x 39 contradiction matrix" and "40 inventive principles". Those

two concepts are also the main foundation of the TRIZ approach used in the experiment sessions of this research (see table 4-4).

	TRIZ concepts*												
	0	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**
Count	39	8	8	4	3	7	2	3	0	2	1	1	1
% of Total	**75.0%**	**15.4%**	**15.4%**	**7.7%**	**5.8%**	**13.5%**	**3.8%**	**5.8%**	**0.0%**	**3.8%**	**1.9%**	**1.9%**	**1.9%**

* TRIZ concepts:
0= none
1 = 39 x 39 contradiction matrix
2= 40 inventive principles
3= 76 standard solutions
4= Ideality
5= Function analysis
6= Patterns of evolution
7= Nine windows
8= Su field analysis
9= Effects database
10= Smart little people
11= ARIZ
12= S-Curve analysis

Table 4-4 Participants' knowledge of TRIZ concepts

The participants provided the following reasons for their favour of the TRIZ methodology in their practical work:

- Methodological approach to innovative problem solving (20)
- Useful for generating new ideas (12)
- Applying principles and trends to find creative solutions (7)
- Rapidity and focus in solution finding (4)
- Promote team and group work (5)
- Shrinking systems size without decreasing performance (2)
- Provides solutions to put the organisation in a competitive position (1).

There were also three participants who claimed that TRIZ had no special benefits in the problem-solving process.

The participants proposed the following criteria for the evaluation of technical solutions for medical devices.

- Patient benefits;
- Costs (including costs of manpower, development time and production, also if the medical insurance will reimburse the costs);
- Level of innovation (differentiation from existing products);

- Feasibility (how well the proposed solution solves the problem; if the development and production of the proposed can be implemented without great difficulty) and
- Risks (if the solution will affect user safety).

4.4 Criteria for assessment of experiment outputs

In order to determine the criteria for the assessment of experiment outputs, the proposals made by the survey participants (see previous section) were discussed with the medical device expert panel. As a result, the evaluation of the technical solutions in this research was planned to be carried out in two sections:

i. Expert assessment (to be conducted by the expert panel) and
ii. Patient assessment (to be conducted by the pen-experienced patients).

The expert assessment consisted of the following three criteria.

- Feasibility. This criterion assesses if the development and production of the proposed solution can be implemented without great difficulty, as well as if the solution will raise critical issues e.g. user safety. Obviously, the criteria for feasibility of different solutions may vary strongly from each other, therefore cannot be completely defined prior to the development of the solutions. The assessment of feasibility of the solutions also depends on the previous knowledge and experience of the evaluating experts. During the experiment, the participants will not be aware of the exact content of this criterion. In other words, the requirements of this criterion are fuzzy problems to the participants.
- Novelty. This aspect describes the level of innovation of the technical solutions. The level of novelty is defined as how far the solution differs from the existing solutions. As the current solutions are predetermined for the participants, the content of this criterion is clearly defined to the participants of the experiment.
- Costs. This includes the costs for manpower, development time and production. The experts' anticipation of the costs of the developed solutions depends largely on their previous knowledge and experience. However, especially when dealing with innovative solutions that are not comparable with any existing products, the cost anticipation may be rather subjective. Also, which level of costs shall be considered appropriate depends largely on the type of solutions, therefore cannot be predetermined for the experiment procedure. Thus, the cost requirements on the technical solutions are fuzzy problems to the participants.

The patient assessment reflects the patient perceptions. The chosen patients will be asked to give their opinions on their perceived level of improvement of the technical solutions developed in the experiment sessions. The patient assessment is based mainly on the patients' subjective opinions if they like the individual solutions. Obviously, the patients' perceptions are substantially influenced by their experience in the past which are unknown to the participants of the experiments. Thus, the requirements of the patients' perceptions are fuzzy problems.

The possible scores range from "0" to "5" for each assessment dimension ("feasibility", "novelty" and "costs" for expert assessment and "patient perception" for patient assessment). The content of each score in the assessment dimensions is specified as in the following table (see table 4-5).

Assessment	**Expert Assessment**			**Patient Assessment**
Criteria	**Feasibility**	**Novelty**	**Costs**	**Patient perception**
Possible scores	0 not feasible 1 feasible with great difficulty 2 feasible with difficulty 3 feasible with efforts 4 feasible with slight efforts 5 feasible without efforts	0 old 1 improvement 2 modification 3 solution transfer 4 new idea 5 new technology	0 unfeasible 1 very expensive 2 expensive 3 acceptable 4 affordable 5 inexpensive	0 no improvement at all 1 unnoticeable improvement 2 minor improvement 3 some improvement 4 noticeable improvement 5 essential improvement

Table 4-5 Criteria for assessment of experiment outputs

5. Experiment procedure

5.1 General test procedure

In winter 2014/2015, six volunteers took part in the experiment as described in section 3.5. All six persons had 5-10 years of practical experience in medical devices research and development, similar academic background and experience with problem-solving techniques. The participants were divided into two groups by the author, with the consideration that each group should contain a similar level of "total balance" of capacity in terms of the group members' experience with product development and problem-solving tools, as well as their academic background, age and gender, etc.

During the experiment, both groups were asked to improve the test subjects chosen for the experiment. The test devices were two different models of EpiPen auto-injectors. To facilitate the technical development process, trainer devices of the test devices were provided to the participants.

Test device 1: EpiPen trainer device 1 (auto-injector 1)

(see figure 5-1).

Figure 5-1 **Test device 1: EpiPen trainer device 1**

Test device 2: EpiPen trainer device 2 (auto-injector 2)

(see figure 5-2).

Figure 5-2 **Test device 2: EpiPen trainer device 2**

Each group was asked to generate ideas for design improvement of the test device in two difference sessions. At the beginning of each session, the author gave instructions to the group on the problem-solving technique to apply. While the test group was asked to apply test procedure 1 (TRIZ techniques as described in 5.2), the control group was asked to work with test procedure 2 (brainstorming technique) throughout the session. The test plan is demonstrated in the following table (P1, P2, …, P6 stand for the participants 1-6) (see table 5-1).

Test devices	Test group	Control group
Auto-injector 1	P1, P2, P3	P4, P5, P6
Auto-injector 2	P4, P5, P6	P1, P2, P3

Table 5-1 **Experiment: test plan**

Apart from the test instructions, the participants also received further background information (the test procedures and the background information will be addressed with more details in section 5.2). At the end of each experiment session with the duration of

60 minutes, the group submitted their solutions in writing in accordance with the test instructions.

After the instruction, the author retreated to an adjacent room and stayed there till the end of the experiment session.

Immediately after the submission, the author entered the experiment room and distributed to each participant three copies of the SYMLOG Adjective Rating Form. The participants were asked to fill out one form for each group member including him-/herself as evaluation of the individual behaviours during the group work (see appendices X and XI). After completion of the forms, the participants were asked to show their ratings to the group mates, so that each participant could find out how she/he was rated by the others.

Subsequently, the author moderated a group discussion and asked the participants to bring up their opinions on the group work. After this, each participant was again given three copies of the Adjective Rating Form and asked to assess the behaviours of the group members during the experiment for a second time.

A video recorder was set up before hand, so that the complete experiment sessions including the behaviour ratings and the group discussions, as well as all involvement of the author, were recorded in full length.

Two independent raters who were knowledgeable of SYMLOG procedures were shown the video material afterwards and asked to assess the behaviour of each participant at each experiment session by filling out the SYMLOG Adjective Rating Form.

The German language was used for all procedures of the experiment.

5.2 Test procedure 1: the 5-stage TRIZ process

As introduced in section 3.5, the test procedure for the test group was designed as a 5-stage TRIZ process. This process derives from Su et al.'s approach (Su, Lin & Chiang, 2008) (see figure 5-3).

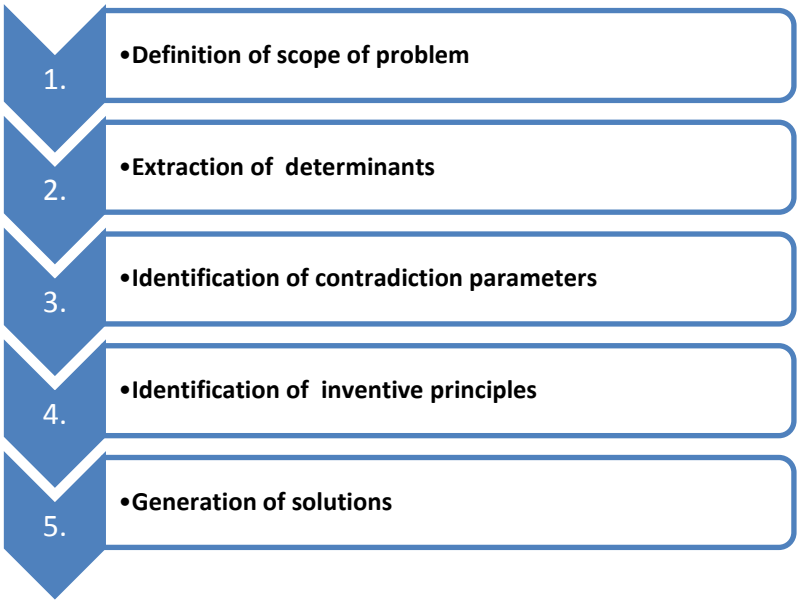

Figure 5-3 Experiment: 5-stage TRIZ approach

The intension of this procedure is to generate new ideas for medical device innovations (drug-device combination products) by applying pre-defined TRIZ techniques. The content of the five stages is described in more details in the following.

5.2.1 Stage 1: Definition of scope of problem

As mentioned in section 5.1, two models of EpiPen auto-injectors were chosen to be the test subjects. The EpiPen products were chosen for this study, because they were among the oldest marketed drug device combination products and therefore sufficient previous studies were made available in academic journals and other publically accessible databases. Besides, the author deliberately chose the experiment subjects which were not products of his employer to avoid potential conflicts of interest.

The scope of problem for the experiment (ideality in the TRIZ procedure) was thus defined as "*optimising design of medical devices by finding solutions for problems identified by previous studies on example of the test subject*".

5.2.2 Stage 2: Extraction of determinants

The findings of literature reviews on "auto-injectors" and "EpiPen" were analysed. The influence factors considered relevant to design and use of the test subjects were identified as determinants for this TRIZ procedure. The results are shown in the following table (see table 5-2).

No.	Description	Authors	Citations
1	Device identification	(Sicherer, Forman & Noone, 2000); (Nguyen Luu et al., 2012)	(Use assessment of self-administered Epinephrine among food-allergic children and pediatricians); (Management of anaphylaxis in schools:Evaluation of an epinephrine auto-injector (EpiPen) use by school personnel and comparison of two approaches of soliciting participation)
2	Comprehensive instruction of use	(Bentur et al., 2006); (Ramos, Landy, Tepper, Wein & Schweizer, 2013); (Smith & Wallace, 2013); (Nguyen Luu et al., 2012)	(Civilian Adult Self Injections of Atropine – Trimedoxime (TMB4) Auto-Injectors); (An Open-Label Trial of a Sumatriptan Auto-Injector for Migraine in Patients Currently Treated With Subcutaneous Sumatriptan An Open-Label Trial of a Sumatriptan Auto-Injector for Migraine in Patients Currently Treated With Subcutaneous Sumatriptan); (Reducing drug self-injection errors: a randomized trial comparing a "standard" versus "plain language" version of Patient Instructions for Use); (Management of anaphylaxis in schools:Evaluation of an epinephrine auto-injector (EpiPen) use by school personnel and comparison of two approaches of soliciting participation)
3	Ease of use	(Bentur et al., 2006); (Hawkins, Weil, Baty, Fitzpatrick & Rowell, 2013); (Ramos, Landy, Tepper, Wein & Schweizer, 2013); (Rylander, 2009); (Renstrom, 2008); (Brandes et al., 2009)	(Civilian Adult Self Injections of Atropine – Trimedoxime (TMB4) Auto-Injectors); (Epinephrine autoinjector warning); (An Open-Label Trial of a Sumatriptan Auto-Injector for Migraine in Patients Currently Treated With Subcutaneous Sumatriptan An Open-Label Trial of a Sumatriptan Auto-Injector for Migraine in Patients Currently Treated With Subcutaneous Sumatriptan); (Enject Inc.: Company Interview); (Finding right site for drug device); (Needle-free subcutaneous sumatriptan (SUMAVEL DOSEPRO): bioequivalence and ease of use)
4	Size of device	(Gallagher, Worth, Cunningham-Burley & Sheikh, 2011); (Nguyen Luu et al., 2012)	(Epinephrine auto-injector use in adolescents at risk of anaphylaxis:a qualitative study in Scotland, UK); (Management of anaphylaxis in schools:Evaluation of an epinephrine auto-injector (EpiPen) use by school personnel and comparison of two approaches of soliciting participation)
5	Customization for target groups	(Oude Elberink, van der Heide, Guyatt & Dubois, 2009); (Rylander, 2009); (Renstrom, 2008); (Hawkins, Weil, Baty, Fitzpatrick & Rowell, 2013)	(Immunotherapy improves health-related quality of life of adult patients with dermal reactions following yellow jacket stings); (Enject Inc.: Company Interview); (Finding right site for drug device); (Epinephrine autoinjector warning)
6	Needle length	(Stecher, Bulloch, Sales, Schaefer & Keahey, 2009); (Sclar, 2013)	(Epinephrine Auto-injectors: Is Needle Length Adequate for Delivery of Epinephrine Intramuscularly?); (Bioequivalence evaluation of epinephrine autoinjectors with attention to rapid delivery)

No.	Description	Authors	Citations
7	Needle protection	(Greenberg & Riviello, 2010); (Whyte, 2010); (Silverberg & Manoach, 2007); (Nguyen Luu et al., 2012); (Brandes et al., 2009)	(Local effects after inadvertent digital injection with an epinephrine auto-injector); (The growing need for auto-injectors); (Accidental self-administration of epinephrine with an auto-injector); (Management of anaphylaxis in schools:Evaluation of an epinephrine auto-injector (EpiPen) use by school personnel and comparison of two approaches of soliciting participation); (Needle-free subcutaneous sumatriptan (SUMAVEL DOSEPRO): bioequivalence and ease of use)
8	Flexibility of dose	(Simons, Gu, Silver & Simons, 2002); (Ackaoui, 2011)	(EpiPEN Jr Versus EpiPEN in young children weighing 15 to 30 kg at risk for anaphylaxis); (Treatment of anaphylaxis EpiPen, Twinject, or another autoinjector?)
9	Injection time	(Stecher, Bulloch, Sales, Schaefer & Keahey, 2009)	(Epinephrine Auto-injectors: Is Needle Length Adequate for Delivery of Epinephrine Intramuscularly?)
10	Marking of injection end	(Schwirtz & Seeger, 2010); (Schwirtz & Seeger, 2012); (Nguyen Luu et al., 2012)	(Are adrenaline autoinjectors fit for purpose?A pilot study of the mechanical and injection performance characteristics of a cartridge versus a syringe-based autoinjector); (Comparison of the robustness and functionality of three adrenaline auto-injectors); (Management of anaphylaxis in schools:Evaluation of an epinephrine auto-injector (EpiPen) use by school personnel and comparison of two approaches of soliciting participation)
11	Patient's fear of device	(Gallagher, Worth, Cunningham-Burley & Sheikh, 2011); (Stecher, Bulloch, Sales, Schaefer & Keahey, 2009); (Hawkins, Weil, Baty, Fitzpatrick & Rowell, 2013); (Ramos, Landy, Tepper, Wein & Schweizer, 2013); (Mullins, 2003)	(Epinephrine auto-injector use in adolescents at risk of anaphylaxis:a qualitative study in Scotland, UK); (Epinephrine Auto-injectors: Is Needle Length Adequate for Delivery of Epinephrine Intramuscularly?); (Epinephrine autoinjector warning); (An Open-Label Trial of a Sumatriptan Auto-Injector for Migraine in Patients Currently Treated With Subcutaneous Sumatriptan An Open-Label Trial of a Sumatriptan Auto-Injector for Migraine in Patients Currently Treated With Subcutaneous Sumatriptan); (Anaphylaxis: risk factors for recurrence)
12	Adequate training - trainer, participants, frequency, training device etc.	(Gallagher, Worth, Cunningham-Burley & Sheikh, 2011); (Bentur et al., 2006); (Greenberg & Riviello, 2010); (Sheikh, Simons, Barbour & Worth, 2012); (Morris, Baker, Belot & Ewards, 2011); (Ekwueme, Weniger & Chen, 2002); (Litarowsky, Murphy & Canham, 2004); (Sicherer, Forman & Noone, 2000); (Hodges, Clack, & Hodges, 2005); (Sanagavarapu, 2012); (Clegg & Richtie, 2001); (Ratnaweera, Trilsbach, Rangasami, Green & Puliyel, 2006)	(Epinephrine auto-injector use in adolescents at risk of anaphylaxis:a qualitative study in Scotland, UK); (Civilian Adult Self Injections of Atropine – Trimedoxime (TMB4) Auto-Injectors); (Local effects after inadvertent digital injection with an epinephrine auto-injector); (Adrenaline auto-injectors for the treatment of anaphylaxis with and without cardiovascular collapse in the community); (Preparedness for Students and Staff With Anaphylaxis); (Model-based estimates of risks of disease transmission and economic costs of seven injection devices in sub-Saharan Africa); (Evaluation of an Anaphylaxis Training Program for Unlicensed Assistive Personnel); (Use assessment of self-administered Epinephrine among food-allergic children and pediatricians); (Severe allergy: an audit and service review); (Don´t forget to pack my EpiPen® please: What issues does food allergy present for children's starting school?); ("EpiPen" training: a survey of the provision for parents and teachers in West Lothian); (Audit of nurse-led-training for epipen in a District General Hospital)
13	Shelf life	(Ackaoui, 2011); (Mullins, 2003.)	(Treatment of anaphylaxis EpiPen, Twinject, or another autoinjector?); (Anaphylaxis: risk factors for recurrence)

Table 5-2 TRIZ procedure: determinants from literature

In the next step, the determinants were verified by three pen-experienced patients. All patients had used delivery devices on themselves for more than ten years. Two of the patients were female, one male.

First, all 13 determinants from the literature were explained in plain language with examples. The patients were given the opportunity to ask questions for comprehension. Subsequently, the test devices used for the experiment were verbally introduced, followed by demonstration video clips for EpiPen user training in the internet (www.youtube.com). The trainer devices were handed out to the patients so that they could test the functions and the handling procedure of the devices.

Next, the patients were interviewed in the style of semi-structured interviews (see appendix VII).

The results of the patient interviews are summarised in the following.

General essential aspects for auto-injector design

The patients' opinions on the determinants from the literature are summarised in the following table 5-3.

No.	Description	Patient 1	Patient 2	Patient 3	Total
1	Device identification	1	1	1	3
2	Comprehensive instruction of use	1	1	1	3
3	Ease of use	1	1	1	3
4	Size of device	1	1	1	3
5	Customization for target groups	1	1	1	3
6	Needle length	1	1	1	3
7	Needle protection	1	1	1	3
8	Flexibility of dose	1	1	1	3
9	Injection time	1	1	1	3
10	Marking of injection end	1	1	1	3
11	Patient's fear of device	1	1	1	3
12	Adequate training	1	1	1	3
13	Shelf life	1	1	1	3

0 = The patient(s) consider(s) this aspect not essential for auto-injector design

1 = The patient(s) consider(s) this aspect essential for auto-injector design

Table 5-3 TRIZ procedure: determinants in patient opinion (general)

Since the above determinants were considered by all patients as relevant for the development of medical devices, they were chosen for further steps of the TRIZ procedure.

Further remarks of the patients were recorded in the following.

1. ***Device identification***

The device needed to be easily identifiable. Especially in some cases when the patient was not in position anymore to apply the device by him-/herself, a helper who was not familiar with the device should be able to identify it quickly.

2. ***Comprehensive instruction of use***

Comprehensive instruction of use was considered important especially for devices with relatively frequent updates. Graphics were believed to be more effective than text.
A senior patient claimed that she expected to receive assistance from medical professionals therefore intended to rely on the comprehension of those persons.

3. ***Ease of use***

Fast reaction time was considered essential for the administration of the medication, since this under circumstances could decide life or death. Therefore, the device must be easy to operate.

4. ***Size of device***

While the senior patients tended to be in favour of bigger size of the device, younger, especially male patients seemed to prefer more compact designs. The explanation for it was that while women had the possibility to carry a larger device in the lady' handbag, men usually had to carry the device in a pocket thus large-sized devices were considered bulky.

5. ***Customization for target groups***

The patients proposed customization for different age groups (for example, larger size for the senior, more colourful devices with popping and rocking function for children) and gender, etc. One patient proposed different designs for day use and night use.

6. Needle length

The female patients were in favour of longer needles, because they might need the needle to pierce through the relatively thick support tights. In their opinion, however, the needles should also not be too long, since the length of the needle was associated with patient's fear of device.

The interviewed male patient preferred shorter needles, mainly because shorter (also thinner) needles were supposed to cause less pain during the injection.

Also the female patients preferred thinner needles due to pain sensitiveness.

7. Needle protection

All patients considered needle protection as an important function of the auto-injector. Especially needle protection designs with hidden needles were preferred, because the invisible needle would reduce the patient's fear of device.

8. Flexibility of dose

Flexibility of dose was considered by all patients as an advantage.

9. Injection time

To all the patients, ideally, the injection time should not exceed 10 seconds. The male patient would even like to reduce the injection time to 5 seconds.

10. Marking of injection end

All patients reported that it was difficult to estimate the time used during the injection, thus it was always a challenge to judge when the injection was complete and the patient could release the device. A signal (acoustic signal or vibrations) at the end of the injection was considered an advantage.

11. Patient's fear of device

Patients often had to overcome their fear before the use of auto-injector. The fear was mainly associated with the visible needle, but also with the thoughts that foreign substances would enter the body.

12. Adequate training - trainer, participants, frequency, training device etc.

Adequate trainings were considered essential by all interviewed patients. In particular, they underlined the importance of training material in their native language, follow-up trainings and consideration of the physical conditions of the patient in the training programme (e.g. for those who suffer on hearing problems).

13. Shelf life

Since the type of devices could be expected to be used no more than a few times in the patients' life, all patients believed the shelf life of the device of currently one year needed to be extended to 5-10 years.

In addition, one patient mentioned that the device should be robust enough for a daily carriage (e.g. in the handbags) over longer period of time. Some improvement proposals were made, e.g. plastic rather than glass cartridges be used, or a stronger fitting for the cap of the device.

Summarizing the above, all the 13 aspects from the literature were perceived by the patients as essential for auto-injector design. Furthermore, they proposed the following additional aspects: *material of cartridge* (plastic instead of glass) and *strong fittings* (for exterior design).

Test device 1

The results of the interview indicate that all three pen-experienced patients found the design of test device 1 adequate in the four aspects *device identification, comprehensive instruction of use, ease of use* and *needle protection*. All patients perceived the exterior design with bright colours adequate for the identification of the device for emergency uses. The instruction of use including the illustrations was perceived as comprehensive. However, one of the patients suggested that instruction of use for injection by a third person be comprised, since in case of emergency the patient might not be in position to inject him-/herself, so that a third person had to take over. Also the operation of the device was considered easy by all interviewed patients. The needle protection design of the test device seemed adequate to all patients, although one of them would like to slightly enlarge the safety cap.

The patients unanimously agreed that the device needed further improvement in the aspects s*ize of device* and *shelf life of medication*. While one patient would like to increase the size of the device for the senior, the other two patients proposed to reduce the size. One of the patients would like to cut down the size by at least a half. Since any patients were most likely to have to use an EpiPen for no more than a few times in their life, all patients believed the shelf life of the device needed to be substantially extended. One patient proposed changeable interior syringe to extend the lifetime of the secondary package. With a standardised secondary package, patients who needed more than one type of medical devices, e. g. diabetes patients, only had to carry one large secondary package instead of a complete device for each type of medication.

Two out of the three patients felt that the device needed further improvement in the aspects *customization for target groups*, *sufficient needle length*, *flexibility of dose*, *marking of injection end*, and *adequate training*. Especially needs of the senior should be taken into account seriously, since the vital functions of their body differed greatly from those of other adults. Also the requirements of other age and gender groups should be attended to. One patient proposed a device version with a car key chain for men and a larger version for ladies' handbag. One of the patients suggested a longer needle so that the needle could pierce through thick cloths like support tights, while another preferred a shorter and thinner needle to reduce the pain of the intramuscular injection. To the patients, it was necessary that the dose of auto-injectors should become more flexible to suit patients in different body weight classes. The patients found it helpful if the injection end would be marked with acoustic or visual (e.g. colouration) signals. Two patients requested better training opportunities, e.g. training with real devices under supervision of medical professionals.

Only one patient considered it necessary to change the device in the aspects *injection time* and *patient's fear of device*. The patient would like to reduce the injection time from approximately 10 seconds to 5 seconds. However, the other two patients did not consider this necessary. Two out of three interviewed patients did not associate the test device with patient's fear thanks to the needle protection design with the hidden needle. However, one patient believed alone the thoughts that foreign substance was entering the body through the needle – even though an invisible needle – would still cause unease of the patients.

The results of the patient assessment were summarized in the following table 5-4.

No.	Description	Patient 1	Patient 2	Patient 3
1	Device identification	0	0	0
2	Comprehensive instruction of use	0	0	0
3	Ease of use	0	0	0
4	Size of device	1 (-)	1 (+)	1 (-)
5	Customization for target groups	1 (+)	1 (+)	1 (+)
6	Needle length	1 (+)	0	1 (-)
7	Needle protection	0	0	0
8	Flexibility of dose	1 (+)	1 (+)	0
9	Injection time	0	0	1 (-)
10	Marking of injection end	1 (+)	1 (+)	0
11	Patient's fear of device	1 (-)	1 (-)	0
12	Adequate training	1 (+)	1 (+)	0
13	Shelf life	1 (+)	1 (+)	1 (+)

0 = The patient(s) consider(s) device improvement in the particular aspect as not necessary

1 = The patient(s) consider(s) device improvement in the particular aspect necessary

(+) = The patient(s) want(s) the determinant to increase

(-) = The patient(s) want(s) the determinant to decrease

(+/-) = The patients hold different opinions if the determinant should increase or decrease

Table 5-4 TRIZ procedure: determinants in patient opinion (test device 1)

The determinants were considered relevant for the development of the test device if at least 1 patient declared improvements to be necessary. As a result, the following determinants were chosen as relevant for further steps of the TRIZ procedure (see table 5-5).

No.	Description	Patients' opinion
4	Size of device	3 (+/-)
5	Customization for target groups	3 (+)
6	Needle length	2 (+/-)
8	Flexibility of dose	2 (+)
9	Injection time	1 (-)
10	Marking of injection end	2 (+)
11	Patient's fear of device	2 (-)
12	Adequate training	2 (+)
13	Shelf life	3 (+)

(+) = All patients want the determinant to increase

(-) = All patients want the determinant to decrease

(+/-) = The patients hold different opinions if the determinant should increase or decrease

Table 5-5 TRIZ procedure: relevant determinants for test device 1

In addition, one patient asserted that the device ought to be more robust for a daily carriage over longer period of time.

Test device 2

All three patients found improvement necessary for test device 2 in the aspects *device identification*, *sufficient needle length, needle protection, patient's fear of device, adequate training* and *shelf life of medication*. All patients suggested a more intensive colour scheme for the exterior design. One of the patients proposed in addition a larger fond size to visualize the test device as emergency medicinal product. While two patients stated that the needle length should be increased so that the needle could pierce through thick cloths like support tights, the other patient preferred a shorter and thinner needle so that the intramuscular injections could be less painful. To all three patients, the patients' fear of device was mostly associated with the visible needle. Therefore, they proposed designs with hidden needles which at the same time could serve as needle protection. All patients were native German speakers and suggested that video and training material in the German language be provided. Since any patients were likely to use an EpiPen for no more than a few times in their life, it was considered a great advantage if its shelf life could be extended to 5-10 years.

Two out of the three patients felt that the device needed further improvement in the aspects *comprehensive instruction of use*, *size of device*, *customization for target groups*, *flexibility of dose* and *marking of injection end*. According to the patients, the instruction of use should be developed for different age groups to achieve better comprehension of the patients. Also the illustration needed to be improved to enable the patient or a third person to grasp the device procedure quickly in case of emergency. The size of the auto-injector should be smaller for younger people and bigger for the senior. Besides, men needed smaller pens for the daily carriage, while women could accept larger devices because they could easily find a place in a lady's handbag. Therefore, the patients recommended a variety of device designs, e.g. special designs for the senior, the minor or the teenagers. Especially devices for the senior could largely reduce the healthcare expenses, as currently, the senior were normally obliged to assistance by healthcare services, either at home or in a hospital. The dose of the auto-injectors should be more flexible to be optimal for patients in different body weight classes. One recommendation by the patients was the implementation of multi-use devices in favour of environmental

protection which should help to reduce the medication reserve in the device which was wasted after the injection, as well as cost reduction. The patients also found it difficult to estimate the ongoing injection time, therefore would appreciate a mark for the injection end, either as acoustic or visual (e.g. colouration) signals.

Only one patient considered it necessary to change the device in the aspects *injection time*. While the other two patients considered the current injection time adequate, one patient would like to have it reduced from approximately 10 seconds to 5 seconds. None of the patients thought further improvement necessary in the aspect of *ease of use*.

The results of the patient verification were shown in the following table 5-6.

No.	Description	Patient 1	Patient 2	Patient 3
1	Device identification	1 (+)	1 (+)	1 (+)
2	Comprehensive instruction of use	0	1 (+)	1 (+)
3	Ease of use	0	0	0
4	Size of device	0	1 (+)	1 (-)
5	Customization for target groups	1 (+)	1 (+)	0
6	Needle length	1 (+)	1 (+)	1 (-)
7	Needle protection	1 (+)	1 (+)	1 (+)
8	Flexibility of dose	1 (+)	1 (+)	0
9	Injection time	0	0	1 (-)
10	Marking of injection end	1 (+)	1 (+)	0
11	Patient's fear of device	1 (-)	1 (-)	1 (-)
12	Adequate training	1 (+)	1 (+)	1 (+)
13	Shelf life	1 (+)	1 (+)	1 (+)

0 = The patient(s) consider(s) device improvement in the particular aspect as not necessary

1 = The patient(s) consider(s) device improvement in the particular aspect necessary

(+) = The patient(s) want(s) the determinant to increase

(-) = The patient(s) want(s) the determinant to decrease

(+/-) = The patients hold different opinions if the determinant should increase or decrease

Table 5-6 TRIZ procedure: determinants in patient opinion (test device 2)

One patient proposed additional design improvements e.g. to use plastic rather than glass for the cartridge, or a stronger fitting for the cap to make the device more robust for a daily carriage over longer period of time.

The determinants were considered relevant for the development of the test device if at least 1 patient declared improvements to be necessary. As a result, the following

determinants were identified as relevant for further steps of the TRIZ procedure (see table 5-7).

No.	Description	Total
1	Device identification	3 (+)
2	Comprehensive instruction of use	2 (+)
4	Size of device	2 (+/-)
5	Customization for target groups	2 (+)
6	Needle length	3 (+/-)
7	Needle protection	3 (+)
8	Flexibility of dose	2 (+)
9	Injection time	1 (-)
10	Marking of injection end	2 (+)
11	Patient's fear of device	3 (-)
12	Adequate training - trainer, participants, frequency, training device etc.	3 (+)
13	Shelf life	3 (+)

(+) = All patients want the determinant to increase

(-) = All patients want the determinant to decrease

(+/-) = The patients hold different opinions if the determinant should increase or decrease

Table 5-7 TRIZ procedure: relevant determinants for test device 2

The finding of stage 2 were further analysed in stage 3 (see section 5.2.3).

5.2.3 Stage 3: Identification of contradiction parameters

The aim of this stage is to find the suitable TRIZ contradiction parameters for the later generation of the pursued solutions with inventive principles. This was done by means of a parameter-corresponding table as proposed by Domb, Miller, MacGran & Slocum (1998). This involves the following steps in this research:

1. To finalise determinants for auto-injector design based on findings of stage 2;
2. To allocate each determinant to a parameters in the TRIZ 39x39 contradiction matrix;
3. To define each parameter as an improving or worsening parameter.

In early November 2014, six medical device practitioners with TRIZ experience were presented with the findings of stage 2. They were asked to scrutinize the 13 determinants from the literature, as well as the additional essential aspects for auto-injector development *material of cartridge* (plastic instead of glass), *strong fittings* (for exterior design) proposed by the patients in stage 2. As a result, the practitioners all agreed that

the 13 determinants extracted from the literature were important aspects for the development of medical devices and should be treated as distinctive determinants for the further steps of the TRIZ procedure. Furthermore, the expert panel recommended adding a new determinant *device robustness* to reflect the patient proposals. No further determinants were considered necessary by the practitioners.

Next, each of the 14 determinants was to be allocated to a parameter in the TRIZ 39x39 contradiction matrix. For this purpose, the author produced an initial mapping table (see appendix VIII) and handed it out to the practitioners who were subsequently asked the following questions:

1. Do you agree with the proposed mapping (decisions 1)?
2. In case you agree with the proposal, do you consider the parameter as an improving or a worsening parameter (decision 2a)?
3. In case you disagree with the proposal, with which TRIZ contradiction parameter would you map the EpiPen determinant (decision 2b)?

The feedbacks of the six practitioners are summarised in the table 5-8.

Determinants for EpiPen use		**TRIZ contradiction parameter**		**Decision 1**		**Decision 2a**		**Decision 2b**
No.	**Description**	**No.**	**Description**	**A**	**D**	**I**	**W**	**Alternative**
1	Device identification	**12**	Shape	**6 x**	**0**	**6 x**	**0**	
2	Comprehensive instruction of use	**33**	Ease of operation	**6 x**	**0**	**5 x**	**1 x**	
3	Ease of use	**33**	Ease of operation	**6 x**	**0**	**6 x**	**0**	
4	Size of device	**8**	Volume of stationary object	**5 x**	**1 x**	**1 x**	**4 x**	**1x ease of operation (33; I); ***1x shape (12; I)**
5	Customization for target groups	**35**	Adaptability or versatility	**5 x**	**1 x**	**4 x**	**1 x**	**1 x shape (12) or ease of operation (33; I)**
6	Needle length	**3**	Length of moving object	**4 x**	**2 x**	**2 x**	**2 x**	**1 x measurement accuracy (28; I); 1 x device complexity (36; I) or shape (12; I)**
7	Needle protection	**12**	Shape	**6 x**	**0**	**5 x + 1 x?**	**0**	***1 x device complexity (36; I); *** 1 x ease of use (33; I)**
8	Flexibility of dose	**7**	Volume of moving object	**5 x**	**1 x**	**5 x**	**0**	**1 x device complexity (36; I); ***1 x ease of operation (33; I) or adaptability or versatility (35; I)**
Determinants for EpiPen use		**TRIZ contradiction parameter**		**Decision 1**		**Decision 2a**		**Decision 2b**

No.	Description	No.	Description	A	D	I	W	Alternative
9	Injection time	**25**	Loss of time	**5 x**	**1 x**	**2 x**	**3 x**	**1 x quantity of the substance/ the matter (26; I)**
10	Marking of injection end	**15**	Duration of action by a moving object	**4 x**	**1 x + 1 x?**	**4 x + 1 x?**	**0**	**1 x loss of information (24; W) or ease of operation (33; I); ***1 x device complexity (36; I)**
11	Patient's fear of device	**12**	Shape	**5 x**	**1 x**	**4 x + 1 x?**	**0**	**1 x ease of operation (33; I); ***1 x adaptability or versatility (35; I);**
12	Adequate training - trainer, participants, frequency, training device etc.	**24**	Loss of information	**3 x**	**3 x**	**2 x**	**1 x**	**1 x device complexity (36; I); 1 x ease of operation (33; I); 1 x ease of operation (33; I) or adaptability or versatility (35; I) or device complexity (36; I)**
13	Shelf life	**24**	Loss of information	**1 x**	**5 x**	**0**	**1 x**	**4 x stability of the object´s composition (13; I); 1 x loss of time (25; W)**
14	Device robustness	**11**	Stress and pressure	**6 x**	**0**	**0**	**6 x**	

A= agree; D = disagree; I = improving parameter; W = worsening parameter; alternative = alternative TRIZ contradiction parameter

***	Practitioners agrees with the proposed mapping, however proposes further alternative(s)
(XX; I/W)	XX= number of parameter in the TRIZ contradiction matrix; I = improving parameter; W = worsening parameter
?	Practitioners is not sure about the choice

Table 5-8 TRIZ procedure: parameter mapping by practitioners

In some cases, the practitioners proposed additional parameters to the TRIZ contradiction matrix to cover special demands of medical device research and development. In their opinion, some of those parameters were irrelevant to the development of medical devices thus ought to be eliminated, so that the total number of parameters could be reduced. Consequently, also the inventive principles should be modified to better accommodate the requirements of medical device development. However, the extension/modification of the TRIZ tools would involve extensive background research, including the search of pertinent knowledge bases. Due to the limitation of data access and resources of this study, such tasks are left to future researchers.

Furthermore, the practitioners suggested that a detailed written guidance for the application of TRIZ techniques to medical device development be compiled to specify each TRIZ instrument for this special use. This study took the first step for the compilation of the guidance by mapping the medical device relevant determinants with

the 39 TRIZ parameters in the 39x39 contradiction matrix and consequently with the TRIZ inventive principles.

Upon feedbacks of the practitioners, the researcher modified the initial parameter mapping according to the following principles.

1. The mapping (decision 1/ decision 2b) was considered valid, when at least 4 out of the 6 practitioners agreed with the choice. Otherwise, the mapping was considered invalid.
2. The decision of the parameter as an improving or a worsening parameter (decision 2a/ decision 2b) was considered valid, when at least 4 out of the 6 practitioners agreed with the choice. Otherwise, the mapping was considered invalid.

The results are shown in the table 5-9.

Determinants for EpiPen use		TRIZ contradiction parameter		Mapping	I / W
No.	Description	No.	Description		
1	Device identification	12	Shape	Valid	*I*
2	Comprehensive instruction of use	33	Ease of operation	Valid	*I*
3	Ease of use	33	Ease of operation	Valid	*I*
4	Size of device	8	Volume of stationary object	Valid	*W*
5	Customization for target groups	35	Adaptability or versatility	Valid	*I*
6	Needle length	3	Length of moving object	Invalid	
7	Needle protection	12	Shape	Valid	*I*
8	Flexibility of dose	7	Volume of moving object	Valid	*I*
9	Injection time	25	Loss of time	Invalid	
10	Marking of injection end	15	Duration of action by a moving object	Valid	*I*
11	Patient's fear of device	12	Shape	Valid	*I*
12	Adequate training - trainer, participants, frequency, training device etc.	24	Loss of information	Invalid	
13	Shelf life	13	Stability of the object's composition	Valid	*I*
14	Device robustness*	11	Stress and pressure	Valid	*W*

I = improving parameter; W = worsening parameter
*Determinant 14 was added based on the patient's proposal

Table 5-9 TRIZ procedure: parameter mapping by practitioners (results)

Thus the relevant parameters for the improvement of the test devices were mapped as follows (see table 5-10 and table 5-11).

Test device 1

Determinants for device improvement		TRIZ contradiction parameters		W / I
No.	Description	No.	Description	
4	Size of device	8	Volume of stationary object	*W*
5	Customization for target groups	35	Adaptability or versatility	*I*
6	Needle length	3	Invalid	
8	Flexibility of dose	7	Volume of moving object	*I*
9	Injection time	25	Invalid	
10	Marking of injection end	15	Duration of action by a moving object	*I*
11	Patient's fear of device	12	Shape	*I*
12	Adequate training - trainer, participants, frequency, training device etc.	24	Invalid	
13	Shelf life	13	Stability of the object's composition	*I*
14	Device robustness*	11	Stress and pressure	*W*

I = improving parameter; W = worsening parameter
*Determinant 14 was added based on the patient's proposal

Table 5-10 TRIZ procedure: parameter mapping for test device 1

Test device 2

Determinants for device improvement		TRIZ contradiction parameters		W / I
No.	Description	No.	Description	
1	Device identification	12	Shape	*I*
2	Comprehensive instruction of use	33	Ease of operation	*I*
4	Size of device	8	Volume of stationary object	*W*
5	Customization for target groups	35	Adaptability or versatility	*I*
6	Needle length	3	Invalid	
7	Needle protection	12	Shape	*I*
8	Flexibility of dose	7	Volume of moving object	*I*
9	Injection time	25	Invalid	
10	Marking of injection end	15	Duration of action by a moving object	*I*
11	Patient's fear of device	12	Shape	*I*
12	Adequate training - trainer, participants, frequency, training device etc.	24	Invalid	
13	Shelf life	13	Stability of the object's composition	*I*
14	Device robustness*	11	Stress and pressure	*W*

I = improving parameter; W = worsening parameter
*Determinant 14 was added based on the patient's proposal.

Table 5-11 TRIZ procedure: parameter mapping for test device 2

The relevant contradiction parameters for the improvement of the test devices are summarized in the following table (in case several determinants are mapped with the same contradiction parameter, the parameter appears more than one time in this table. This is because the frequency of the parameters is a part of the solution finding process) (see table 5-12).

Test device 1	Test device 2

Improving parameters		Worsening parameters		Improving parameters		Worsening parameters	
No.	**Description**	**No.**	**Description**	**No.**	**Description**	**No.**	**Description**
35	Adaptability or versatility	**8**	Volume of stationary object	**12**	Shape	**8**	Volume of stationary object
7	Volume of moving object	**11**	Stress and pressure	**33**	Ease of operation	**11**	Stress and pressure
15	Duration of action by a moving object			**35**	Adaptability or versatility		
12	Shape			**12**	Shape		
13	Stability of the object's composition			**7**	Volume of moving object		
				15	Duration of action by a moving object		
				12	Shape		
				13	Stability of the object's composition		

Table 5-12 TRIZ procedure: contradiction parameters for test devices

The content of the parameters is briefly introduced in the following. The description of the parameters is oriented on Gadd's book on TRIZ application for engineers (Gadd, 2011, pp. 468-470).

Parameter 7. Volume of a moving object

This means the space occupied by the object, measured by its length x width x height. In the context of medical device design, this can be related for example to the moving plunger and the stopper of a cartridge or pre-filled syringe-based system.

Parameter 8. Volume of a stationary object

Same as parameter 7, this parameter stands for the space occupied by a stationary object, measured by its length x width x height.

Parameter 11. Stress and pressure

Tension or force per unit area, e.g. such induced on a device by daily carriage of the patient.

Parameter 12. Shape

Shape stands for the external appearance of the object and concerns especially the exterior design of the auto-injector. Currently, ergonomic aspects play an increasingly important role in the device design.

Parameter 13. Stability of the object´s compositions

The stability of object's compositions describes its wholeness or integrity. The natural aging process of formulated drug substances and polymers components, for example, is considered decreases in stability.

Parameter 15. Duration of action by a moving object

This means the time, the object performs the action and can therefore be associated with e.g. the injection time of an auto-injector, which is an important technical requirement and aspect in the design development, as well as an essential criterion for the product release.

Parameter 33. Ease of operation

Simplicity, e.g. the device operation does not require assistance of a third person; a small number of steps in the operation, no need for special tools or accessories etc.

***Parameter 35.* Adaptability and versatility**

The variety of the device that can be used in multiple ways under different circumstances. In other words, specific devices with specific substances (different drugs or formulations) with focus on specific patient groups, e.g. suitable ergonomic features.

In the next stage, the contradiction matrix was applied with the above contradiction parameters to identify the matching TRIZ inventive principles for the generation of solutions.

5.2.4 Stage 4: Identification of inventive principles

The scope of problem for the experiment of this study was defined as "*optimising design of medical devices by finding solutions for problems identified by previous studies on example of the test subject*" (stage 1). Thus the ideality for the TRIZ procedure in this study was defined as design optimisation of the test subject.

The optimisation of auto-injector design usually involves a number of parameters which sometimes contradict each other. For example, the patient prefers a sensible mechanic construction so that the injection function can be triggered with little force. This can be enabled e.g. by a spring with a sufficient volume, so that its stretch and release of power in the inner system may lead to the sensible operations as desired. On the other hand,

many patients wish the device to be as small as possible, so that the maximum size of the spring must be restricted. The original 39x39 TRIZ contradiction matrix with the resulting 40 inventive principle provides indications for possible optimal solutions in such conflict situations. The inventive principles were developed based on a previous knowledge base (Gadd, 2011, p. 472).

The findings in stage 3 led to the following constellation of contradiction matrix for test device 1 (see table 5-13).

		Worsening parameter	
		8	**11**
Improving parameter	**35**	n. a.	35 16
	7	n. a.	6 35 36 37
	15	n. a.	19 3 27
	12	7 2 35	34 15 10 14
	13	34 28 35 40	2 35 40

Table 5-13 TRIZ procedure: extracted contradiction matrix for test device 1

Each combination of an improving and a worsening parameter was mapped with a number of inventive principles which were developed from a previous knowledge base (see table 5-14). The combinations (8; 35), (8; 7) and (8; 15) delivered no solutions since no such solution patterns could be extracted from the knowledge base. Other combinations led to 2-4 inventive principles, e. g. (11; 35) were related to the inventive principles 35 and 16; (8; 12) was mapped with the inventive principles 7, 2 and 35.

The following table is a summary of the inventive principles identified through the applications of TRIZ 39x39 contraction matrix, as well as their frequencies for device 1 (see table 5-14).

Inventive principles		Frequency
No.	Description	
2	**Taking out**	**2**
3	Local quality	1
6	Universality	1
7	Nested Doll	1
10	Prior action	1
14	Spheroidality – curvature	1
15	Dynamics	1
16	Partial or excessive action	1
19	Periodic action	1
27	Cheap short living objects	1
28	Replace mechanical system	1
34	Discarding and recovering	2
35	**Parameter change**	**5**
36	Phase transition	1
37	Thermal expansion	1
40	**Composite material**	**2**

Table 5-14 TRIZ procedure: inventive principles for test device 1

Due to the time limit of the experiment, only the three inventive principles with the highest frequency were chosen to guide the application of TRIZ approach in the experiment, since the higher frequency implied a higher potential that those principles could lead to solutions in the specific case. Since the inventive principles 2, 34 and 40 led to the same second highest frequency in this step of the TRIZ procedure, after consulting the expert panel, the inventive principle 2 *taking out* and 40 *composite material* were chosen. Thus out of 16 inventive principles, the following 3 were chosen for further TRIZ procedure in the experiment: *No. 35 parameter change* with 5 hits, *No. 2 taking out* with 2 hits and *No. 40 composite material* with 2 hits.

The content of the above inventive principles is introduced briefly in the following. The explanation is guided by Gadd's book on TRIZ application for engineers (Gadd, 2011, pp. 140-174).

- ***No. 2 Taking out***

Taking out may be applied in two forms: to extract the disturbing part and property from, e.g. to eliminate or minimize pain during the injection with a medical device; or to extract the only necessary part of property of an object, for example to reduce the auto-injector to the most necessary parts, e.g. the syringe and the liquid medication.

- ***No. 35 Parameter change***

Parameter change has many different forms, including change of physical state (e.g. to gas, liquid or solid), change of concentration or density, change of the degree of flexibility, change of the temperature or volume and change of pressure etc.

- ***No. 40 Composite materials***

This inventive principle stands for the change from uniform material to a composite/ multiple-layered structure. This could be, for example, to use different plastic material for the internal and the external surface, in order to implement ergonometric features like stronger grip for the patient on the outside and to decrease or increase the friction on the inside for the injection operations.

Similarly, the findings in stage 3 also delivered the following constellation of contradiction matrix for test device 2 (see table 5-15).

		Worsening parameter	
		8	**11**
Improving parameter	**12**	7 2 35	34 15 10 14
	33	4 18 39 31	2 32 12
	35	n. a.	35 16
	12	7 2 35	34 15 10 14
	7	n. a.	6 35 36 37
	15	n. a.	19 3 27
	12	7 2 35	34 15 10 14
	13	34 28 35 40	2 35 40

Table 5-15 TRIZ procedure: extracted contradiction matrix for test device 2

The following table is a summary of the inventive principles identified by the applications of TRIZ 39x39 contraction matrix, as well as their frequencies for device 2 (see table 5-16).

Inventive principles		Frequency
No.	**Description**	
2	**Taking out**	**5**
3	Local quality	1
4	Asymmetry	1
6	Universality	1
7	Nested Doll	3
10	Prior action	3
12	Equipotentiality	1
14	Spheroidality - curvature	3
15	Dynamics	3
16	Partial or excessive action	1
18	Mechanical vibration	1
19	Periodic action	1
27	Cheap short living objects	1
28	Replace mechanical system	1
31	Porous materials	1
32	Colour change	1
34	**Discarding and recovering**	**4**
35	**Parameter change**	**7**
36	Phase transition	1
37	Thermal expansion	1
39	Accelerated oxidation	1
40	Composite material	2

Table 5-16 TRIZ procedure: inventive principles for test device 2

Again the inventive principles with the three highest frequencies were chosen for the TRIZ procedure for test device 2. They were: *No. 35 parameter change* with 7 hits, *No. 2 taking out* with 5 hits and *No. 34 discarding and recovering* with 4 hits (see table 5-17).

Test device 1		Test device 2	
No.	**Description**	**No.**	**Description**
35	Parameter change	35	Parameter change
2	Taking out	2	Taking out
40	Composite material	34	Discarding and recovering

Table 5-17 TRIZ procedure: inventive principles for experiment

The inventive principles 2 and 35 are already introduced above. In the following, the inventive principle 34 is described based on Gadd's book (Gadd, 2011, pp. 140-174).

- ***No. 34 discarding and recovering***

Discarding means that objects or parts of objects disappear or change their physical form after the completion of their useful function, e.g. bio-needles are absorbed by the body after the injection. *Recovering* stands for restoration of consumable parts of an objection during the operation, e.g. self-sharping knifes.

5.2.5 Stage 5: Generation of solutions

In this final stage, the participants of the test group were provided with the inventive principles identified in stage 4. Based on the introduction and the list of the inventive principles, the participants were asked to generate solutions for device improvements. This stage is organised as experiment sessions with the following steps.

The group was instructed to act as a self-directing working group. Each participant was given a pencil and three sheets of paper. No further tools and instrument were allowed.

The first phase of this stage was focused on generation of new ideas based on the chosen inventive principles. At the beginning, the participants were give 15 minutes time to note down the individual initial ideas. Subsequently, they were given 60 minutes for discussions in the group. The participants received a signal 10 minute before the end of this phase so that they could take the time to produce a complete written list of their ideas.

5.3 Test procedure 2: brainstorming

The results of the survey study identified brainstorming as the problem-solving technique used with the highest frequency in the pharmaceutical industry (see section 4.3). Thus this method was chosen as the experiment procedure for the control group.

Brainstorming as a method for idea generation was first published by Osborn in 1953. Meanwhile, it has become a popular method with a variety of forms for technical innovation in different fields (Gobble, 2014).

The brainstorming procedure in this research is organised as follows.

Similar as the test group, the control group was given instructions on EpiPen and scope of problem for the experiment. However, unlike the test group, they did not receive the introduction on the TRIZ inventive principles.

The group was instructed to act as a self-directing working group. Each participant was given a pencil and three sheets of paper. No further tools and instrument were allowed.

Initially, the participants were give 15 minutes time to note down his/her initial ideas. Subsequently, they were given 60 minutes for discussions in the group. The participants received a signal 10 minute before the end of this phase, so that they could produce a complete written list of the ideas generated.
Altogether, the experiment session was organised in a similar style for both groups. The only difference was that only the test group received the additional introduction on TRIZ inventive principles to be used.

5.4 Test instructions

Prior to the experiment sessions, the participants were given the following background information.

5.4.1 EpiPen introduction

The EpiPen test device to be used in the experiment session was introduced verbally by the author, followed by a demonstration video clip for EpiPen user training from the internet (www.youtube.com). The trainer device was handed out to the participants so that they could test the function and the handling procedure of the device.

5.4.2 Introduction on scope of problem

The following literature findings on the patient requirements for device improvement were made available to all participants as printouts. This information was comprised by the author based on the literature review on “auto-injectors” and “EpiPen” and verified by the expert panel prior to the start of the experiment (see section 5.2.2).

The participants were given 10 minutes to go through the handouts and to ask questions for comprehension.

Scope of problem for improvement of EpiPen auto-injectors

The literature findings are divided in 13 categories. Besides, one additional point was added based on the results of patient interviews. Some of the categories have several aspects. The problem solutions recommended by the literature are given in brackets [*recommendation*]

- Device identification [*differentiation of EpiPen from other devices for use of the right device*]

1. Comprehensive instruction of use

- Clear instruction for use [*update of instruction for use with additional steps to reduce misuse*]
- Instruction of when to apply an EpiPen in the medical guide (anaphylaxis case)

2. Ease of use

- Convenience for use, carriage and storage in daily Life
- Backup solution in case of use error (e.g. failure of first injection) [*2nd dose regimen for 2nd shot, multi-injection delivery devices similar to diabetes pens*]

3. Bulky size

- Device design perceived by patients as bulky and cumbersome [*outer shape needs to suit into a pocket*; *new mechanism to activate the device to reduce inner mechanical items*]

4. Customization for target groups

- Development of device updates according to customers' needs on a regular basis [*new outer shape design and colours for target population*]
- Customisation for gender groups (previous studies indicate that men often only carry the EpiPen in risky situations like schools and restaurants, while women usually carry their device all the time)
- Customisation for age groups (e.g. currently EpiPen is not designed for self-injection by children)

5. Sufficient needle length (for intra-muscular injection)

- Needle protection (against accidental sticks) [*needle stick prevention*]

6. Flexibility of dose
- E.g. there are EpiPen and EpiPen Jr., however no device suitable for children weighting 15-30 kg

7. Injection time
- Unclear with the current devices, the user has to decide based on his/ her feelings

8. Marking of injection end
- Currently no indication of administration completion [*to develop features to reduce delay of indication*; *support by signs*]

9. Patient's fear of device
- Needle phobia [*oral drugs: e.g. antihistamines easier to use; alternative to subcutaneous: e.g. sublingual*]
- Psychological barrier associated with the device design
- Inadequate self-discipline for use and carriage of EpiPen (current design associated with fear and panic; fear of using an medical device)

10. Adequate training
- Training material [*new training material: social media, presentation, hand in hand practice, trainer device; diabetes based needle and syringe, and storage features to be considered*]
- Follow-up trainings [*follow-up trainings after initial training; improvement of skills by verbal and audio training*]
- Professional trainers [*professional training by experts increase confidence for transition from care-giver to self-medication management*]

11. Short shelf life of medication (70% of all device are destroyed without usage)

12. Device robustness (e.g. for daily carriage, shock resistance)

The task for the experiment was defined as "*optimising design of medical devices by finding solutions for problems identified by previous studies on example of the test subject*". Furthermore, the fields of improvements were defined as in the following table. This was the result of stage 2 of the 5-stage TRIZ procedure in this study (see table 5-18).

No.	Description
1	Device identification
2	Comprehensive instruction of use
3	Ease of use
4	Bulky size
5	Customization for target groups
6	Needle length
7	Needle protection
8	Flexibility of dose
9	Injection time
10	Marking of injection end
11	Patient's fear of device
12	Adequate training
13	Short shelf life of medication
14	Device robustness

Table 5-18 Experiment tasks

5.4.3 Problem-solving techniques

For the experiment sessions, the test group was asked to use the TRIZ procedure and the control group, the brainstorming procedure.

In addition to the EpiPen introduction and the introduction on the scope of problem, the test group received a briefing on the TRIZ procedure to be used for the experiment. This consisted of an introduction of the three inventive principles to be applied in the session (see section 5.2.4).

The control group received the same introduction on the test devices (EpiPen) and the scope of problem. Besides, the control group received an introduction on the brainstorming procedure for the experiment in this study (see section 5.3).

5.5 Group work and group discussions

Immediately after the group work was finished, the group was given an introduction on the SYMLOG Adjective Rating Form method. The author went through the form with the participants for comprehension.

The SYMLOG Adjective Rating Form was handed out to the participants as printouts. Each participant was asked to evaluate the behaviour of each group member by filling out a form for each person including him-/herself.

Next, the participants were asked to exchange the filled out rating forms with the author. The author and the participants reviewed the rating forms altogether. After this, the author initiated a group discussion for the group members to bring up their opinions on group work guided by the following questions:

- How do you feel about working in a group?
- Do you prefer to work in a group or on your own?
- Did you feel comfortable during the solution-seeking process in the experiment?
- How would you describe the status of the solution-seeking process in the beginning, in the middle and at the end of the session?
- When was the most innovative moment?
- Would a moderator, facilitator or a group leader be helpful for the group work?
- Did you need more time or guidance?

Subsequently, the group members filled out the Adjective Rating Forms for each group member for a second time. The group discussion was video recorded for later assessment.

In addition, two independent raters evaluated the behaviours of the participants based on the video recordings. Each rater filled out the SYMLOG Adjective Rating Form for the individual participants in each single experiment session.

6. Experiment findings

6.1 Outputs

6.1.1 Control group/ test device 1

The discussion using brainstorming technique was guided by the introduction on the scope of problem (see section 5.4.2). Using the background information handout as a checklist, the participants proposed the following improvements to the test device with reference to all of the 14 technical issues of auto-injectors.

1. Device identification

Solution: Improvement of secondary package, including:

- To highlight the emergency use (to emphasize the text ALLERGY and EMERGENCY PEN in striking colours and bigger size to differentiate the device from other pens for patients and third party users);
- To increase the colour contrast of the use instruction (instead of the current black/grey printing);
- To use consistent frame for the illustration of all use steps (currently steps 1 & 3 are framed and step 2 is unframed);
- To add production information including name and model type of device (this will facilitate the patient's choice of device and reduce the chance of misuse by users, especially in light of continuous lifecycle management of the products);
- To implement electronic audible instruction for use (so that the users can playback the instruction at any time and place of their choice).

1. Comprehensive instruction of use

Solutions:

- To implement clear introduction of symptoms for anaphylaxis in instruction for use;
- To implement diagnostic device to identify if patient has an anaphylaxis conditions e.g. electronic temperature sensors or blood test stripes.

2. Ease of use

Solutions:

- Mechanical or electronic dosage (with 2-3 levels of dosage, similar to the flame adjustment lever on a lighter);
- To integrate the interlock of the device in the dosage adjustment (this could also help to reduce the patient's fear of device);
- Additional needles (interchangeable similar to a three-coloured pen) that facilitate multiple injections;
- To implement a monitoring window (with marks of dosage to monitor the level of available medication in the syringe);
- New actuator design, e.g. sideways or electronic instead of mechanical actuator to reduce the necessary activation force (the force is perceived as too high, especially for the patient under physical distress);
- To implement more ergonomic designs e.g. handhold with nobs (like pencils for young pupils);
- To implement signals (flashing colours, vibrations or screen text) to indicate the status of the device (e.g. unlock, unlocked, dosage adjusted, injection proceeding, injection completed);
- Electronic search function (if device misplaced).

3. Size of device

Solution:

- To bring down the size of the device with a new actuator design.

4. Customization for target groups

Solution:

- Design customization based on gender, age group, body weight and body fat layer. The exterior design to be oriented on fashion articles e. g. as key ring for men and as necklace for women (similar to emergency necklace).

5. Needle length

Solution:

- To implement a lever for the needle length adjustment.

6. Needle protection

Solution:

- To reduced size of needle protection with a new actuator design.

7. Flexibility of dose

   Solution:

- To implement electronic dosage function.

8. Injection time

When under physical distress and with injection of adrenaline, the patient's feeling for time may be distorted, therefore an integrated timer was recommended.

Solution:

- To implement a timer which signals the end of injection time;
- To monitor the progress of the injection through an enlarged monitoring window.

9. Marking of injection end

Solution:

- To implement signals at the end of injection (flashy colours, vibrations or screen text).

10. Patient's fear of device

Solutions:

- To reduce the size of device by reducing the size of actuator;
- To reduce the activation force;
- To implement friendly and fashionable exterior design.

11. Adequate training

Solutions:

- Regular training programmes;
- Multimedia training material in the native language;
- Support groups (for patients and family members to exchange practical experience).

12. Shelf life

Solutions:

- To use refillable cartridge;

- To implement exchangeable cartridge and needles;
- To implement thermal insulation.

13. Device robustness

Solutions:

- To use more robust material especially for the cartridge;
- To implement thermal insulation.

The outputs of the control group with test device 1 are summarized in the following table (see table 6-1).

No.	Device features		Improvement ideas
1	Device identification		Improvement of secondary package, including:
		1	To highlight the emergency use
		2	To increase the colour contrast of the use instruction
		3	To use consistent frame for the illustration of all use steps
		4	To add production information including name and model type of device
		5	To implement electronic audible instruction for use
2	Comprehensive instruction of use	1	To implement clear introduction of symptoms for anaphylaxis in instruction for use
		2	To implement diagnostic device to identify if patient has an anaphylaxis conditions e.g. electronic temperature sensors or blood test stripes
3	Ease of use	1	Mechanical or electronic dosage (with 2-3 levels of dosage)
		2	To integrate the interlock of the device in the dosage adjustment
		3	Additional needles that facilitate multiple injections
		4	To implement a monitoring window
		5	New actuator design, e.g. sideways or electronic instead of mechanical actuator to reduce the necessary activation force
		6	To implement more ergonomic designs e.g. handhold with nobs
		7	To implement signals (flashing colours, vibrations or screen text) to indicate the status of the device
		8	Electronic search function
4	Size of device	1	The new actuator design could bring down the size of the device
5	Customization for target groups	1	Design customization based on gender, age group, body weight and body fat layer. The exterior design to be oriented towards fashion articles e. g. as key ring for men and as necklace for women.
6	Needle length	1	To implement a lever for the needle length adjustment
7	Needle protection	1	Reduced size of needle protection with a new actuator design
8	Flexibility of doses	1	Electronic dosage function
9	Injection time	1	To implement a timer which signals the end of injection time
		2	To monitor the progress of the injection through the monitoring window
10	Marking of injection end	1	To implement signals at the end of injection
11	Patient's fear of device	1	To reduce the size of device, e.g. with a new actuator design
		2	To reduce the activation force, e.g. with a new actuator design
		3	To implement friendly and fashionable exterior design
12	Adequate training	1	Regular training programmes
		2	Multimedia training material in the native language
		3	Support groups (for patients and family members to exchange practical experience)
13	Shelf life	1	To use refillable cartridge
		2	To implement exchangeable cartridge and needles
		3	To implement thermal isolation
14	Device robustness	1	To use more robust material especially for the cartridge
		2	To implement thermal isolation

Table 6-1 Outputs of control group (test device 1)

6.1.2 Test group/ test device 1

The group work of the test group using TRIZ techniques was primarily guided by the chosen inventive principles. Each found solution was guided by a single chosen inventive principle which sometimes aimed to solve more than one technical issue.

The following solutions were found during the group work. The treated technical issues of the test device are put in ( ) and the applied TRIZ inventive principles in [ ].

Solutions 1. [35 Parameter change - A. Physical state]

- Compressed gas drive {the injection to be triggered and driven by compressed gas instead of the spring force mechanism}. This solution may bring down the size of device (4 size of device), facilitate the application (3 ease of use) and reduce patient's fear (11 patient's fear of device);
- New delivery form: nasal to brain delivery via powder. This solution may greatly improve the convenience for use (3 ease of use) and reduces patient's fear of the application (11 patient's fear of device). With this solution, the injection device becomes obsolete (6 needle length; 7 needle protection; 9 injection time; 10 marking of injection end). New formulation as more stable (14 robustness) solid drug will lead to longer shelf time of the medication (13 shelf life) and a smaller device (4 size of device) that may operate with multiple dose/ cartridges (8 flexibility of dose);
- New delivery form: solid drug injection into muscle. This may reduce injection time (9 injection time). Solid drug is more stable (14 robustness) will lead to longer lifetime of the medication (13 shelf life) and a smaller device (4 size of device) that may operate with multiple dose/ cartridges (8 flexibility of dose). This may facilitate the daily carriage (3 ease of use).

Solutions 2. [35 Parameter change - B. Concentration and density]

- Micro needle {instead of one single needle, many tiny needles which cause much less pain} may reduce the pain of injection (3 ease of use) and reduces patient's fear at the application (11 patient's fear of device);
- Formulation change - increase drug concentration to build a smaller device (4 size of device) with a small syringe and primary package {possibly a stronger spring will be needed or a gas-driven instead of mechanical system shall be used}. This

will reduce the duration of injection (9 injection time), which in turn will reduce the discomfort of injection (3 ease of use) and reduces patient's fear (11 patient's fear of device);

- Formulation change - concentration/density/dosage adjustment depending on the target group e. g. gender, age etc. (5 customisation for target groups).

Solutions 3. [35 Parameter change - C. Degree of flexibility]

- Flip design {elements of the device may be folded in half size like a flip phone}. Such design will reduce the device size (4 size of device) and facilitate the daily carriage (3 ease of use);
- Softer plastic material for safety cap – the current cap can be easily removed and might loosen unwillingly (14 device robustness);
- Anti-slip grip {with more flexible material and anti-slip design} may improve the user comfort (3 ease of use) and robustness of the device (14 device robustness) at the same time;
- Waterproof material as label protection (14 robustness of device);
- Softer material for the tip which touches the body during the application may increase user comfort (3 ease of use) and reduces patient's fear (11 patient's fear of device).

Solutions 4. [35 Parameter change - D. Temperature and volume]

- Temperature detector for refrigeration of drug (13 shelf life) and warming up to body temperature before use (3 ease of use);
- Higher viscosity of drug shortens the injection time (9 injection time) and reduces the size of device (4 size of device) and the patient's tension (11 patient's fear of device);
- Cooling function with kinetic energy {to transform kinetic energy through movements of daily carriage into thermal energy and reduce temperature to enhance shelf life}. This prolongs the shelf time of the medication (13 shelf life);
- Warming up with a built-in chemical reaction to increase temperature before use in order to reduce pain by injection (3 ease of use) and to reduce the patient's tension (11 patient's fear of device).

Solutions 5. [35 Parameter change - E. Change of pressure]

- To reduce activation force with changed mechanism or compressed gas drive - the current necessary activation force is perceived as too strong and believed to cause patient's fear of device. This solution is thought to lead to more user comfort (3 ease of use), a smaller size of the device (4 size of device) and reduced tension of the patient's (11 patient's fear of device);
- To increase pull-off force of blue cap {the current cap can be removed easily thus arises concerns that the cap may loosen or fall off unwillingly}. This should make the device more robust for the daily transport (14 device robustness).

Solutions 6. [35 Parameter change - F. Change other parameters]

- Diverse pen designs to match patients' taste, e.g. toys in form of a giraffe for children (3 ease of use; 5 customisation for target groups) and put the patient at ease (11 patient's fear of device);
- Additional signals {e.g. acoustic function at the end of injection to mark the injection end} (10 marking of injection end);
- Change primary container material from glass to plastic (14 device robustness).

Solutions 7. [40 Composite materials]

- Additional plastic layer for grip as anti-slip grip to increase user comfort (3 ease of use) and robustness for daily transport (14 device robustness);
- Plastic windows {to monitor injection progress, especially to identify the end of injection} (10 marking of injection end);
- NFC chip for device information (1 device identification; 2 comprehensive instruction of use);
- Audio introduction for device use (1 device identification; 2 comprehensive instruction of use);
- APP for identification of anaphylaxis shock (1 device identification; 2 comprehensive instruction of use);
- Muscular tissue detection which adjusts needle length for accurate injection (3 ease of use; 6 needle length);
- Different springs in one device for different body weight classes {e.g. one for children and one for adults as a possibility for production customisation} (5 customization for target groups; 8 flexibility of dose);

- Other material for device body e.g. alloy to be stronger (14 device robustness) and more fashionable designs which match the patient's taste (5 customisation for target group; 11 patent's fear of device);
- More robust plastic case (14 device robustness).

Solutions 8. [2 Taking out]

- Electronic introduction of use, device tells patient what to do which should make the introduction for use more comprehensive (1 device identification; 2 comprehensive instruction of use).

The outputs of the test group with test device 1 are summarized in the table 6-2.

No.	Device features	Solution	Improvement ideas	
1	Device identification	7c	1	NFC chip for device information
		7d	2	Audio introduction for device use
		7e	3	APP for identification of anaphylaxis shock
		8	4	Electronic introduction of use
2	Comprehensive instruction of use	7c	1	NFC chip for device information
		7d	2	Audio introduction for device use
		7e	3	APP for identification of anaphylaxis shock
		8	4	Electronic introduction of use
3	Ease of use	1a; 5a	1	Compressed gas drive to trigger injection
		1b	2	New delivery form: nasal to brain as powder
		1c	3	New delivery form: solid drug injection into muscle
		2a	4	Micro needle
		2b; 4b	5	Increased drug concentration
		3a	6	Flip design
		3c; 7a	7	Anti-slip grip
		3e	8	Softer material for device tip
		4a	9	Temperature detector
		4d	10	Built-in chemical reaction to warm up drug
		6a	11	Diversification of pen design
		7f	12	Muscular tissue
4	Size of device	1a; 5a	1	Compressed gas drive to trigger injection
		1b	2	New delivery form: nasal to brain as powder
		1c	3	New delivery form: solid drug injection into muscle
		2b; 4b	4	Increased drug concentration
		3a	5	Flip design
5	Customization for target groups	2c	1	Diversification of concentration/density/dosage
		6a	2	Diversification of pen design
		7g	3	Different springs for each body weight class
		7h	4	Fashionable/robust exterior material
6	Needle length	1b	1	New delivery form: nasal to brain as powder
		7f	2	Muscular tissue

No.	Device features	Solution	Improvement ideas	No.
7	Needle protection	1b	1	New delivery form: nasal to brain as powder
8	Flexibility of doses	1b	1	New delivery form: nasal to brain as powder
		1c	2	New delivery form: solid drug injection into muscle
		7g	3	Different springs for each body weight class
9	Injection time	1b	1	New delivery form: nasal to brain as powder
		1c	2	New delivery form: solid drug injection into muscle
		2b; 4b	3	Increased drug concentration
10	Marking of injection end	1b	1	New delivery form: nasal to brain as powder
		6b	2	Acoustic signal at end of injection
		7b	3	Plastic window
11	Patient's fear of device	1a; 5a	1	Compressed gas drive to trigger injection
		1b	2	New delivery form: nasal to brain as powder
		2a	3	Micro needle
		2b; 4b	4	Increased drug concentration
		3e	5	Softer material for device tip
		4d	6	Built-in chemical reaction to warm up drug
		6a	7	Diversification of pen design
		7h	8	Fashionable/robust exterior material
12	Adequate training			
13	Shelf life	1b	1	New delivery form: nasal to brain as powder
		1c	2	New delivery form: solid drug injection into muscle
		4a	3	Temperature detector
		4c	4	Cooling function with kinetic energy
14	Device robustness	1b	1	New delivery form: nasal to brain as powder
		1c	2	New delivery form: solid drug injection into muscle
		3b	3	Soft plastic material for safety cap
		3c; 7a	4	Anti-slip grip
		3d	5	Waterproof material as label protection
		5b	6	To increase pull-off force of blue cap
		6c	7	More robust material for primary container
		7h	8	Fashionable/robust exterior material
		7i	9	Robust plastic case

Table 6-2 Outputs of test group (test device 1)

6.1.3 Control group/ test device 2

Like the control group for test device 1, this group also used the introduction on the scope of problem (see section 5.4.2) to lead their discussion. As a result, the following improvements with reference to the 14 technical issues of auto-injectors were proposed for test device 2.

1. Device identification

Solutions:

- To implement colourful ergonomic designs (e.g. with a handle) to distinguish this device from other devices;
- To implement the text "EPIPEN = ALLERGY//EMERGENCY USE" in noticeable letters (especially for external helpers who might not be familiar with the device);
- To make the plastic case, the cap and the needle tip with brand colour/design;
- To implement a distinctive new design (a cap to cover needle on top of the needle tip).

2. Comprehensive instruction of use

Solutions:

- To implement QR code* (in addition to instruction for use as 5 sec video for third persons as quick reference guide);
- To implement instruction for use with anaphylaxis third person decision tree on the plastic case and QR Code video (for third persons to find out if it is a case of anaphylaxis);
- To demonstrate how to hold the auto-injector during the application (add as the first point in the instruction for use);
- To use an arrow to indicate the direction of injection tip.

*QR-codes on the tertiary packaging are used by some companies for promotion of their products. For biopharmaceutical products, QR-code is nowadays commonly used for safety instructions.

3. Ease of use

Solutions:

- Eyeglasses case (which can be used for transport of device, so that others will not immediately recognize that the user carries the device);

- Reset button for 2nd dose (in case the first injection is misused under distress).

4. Size of device

Solution:

- Handle for portability (so that the device can be carried as a pen in the pocket of a shirt);
- To reduce the size with a new design of actuator.

5. Customization for target groups

Solution:

- Age group specific cap design (current design too small for elderly people);
- Adjustable dosage (based on body weight/muscle structure etc.);
- Instruction for use for children (e.g. supported by colourful cartoons, electronic friends etc.);
- QR-code video for children;
- Design/size for children (e.g. small parts big enough not to be swallowed for safety reasons);
- Gender specific device sizes (smaller for men, larger for women and distinguishable from other devices e.g. asthma devices);
- Weight and muscle mass specific needle length.

6. Needle length

Solution:

- Weight and muscle mass specific needle length.

7. Needle protection

The existing needle protection feature was a robust and reliable system to the participants. An improvement was proposed with a new actuator which requires less force for the activation.

Solution:

- Needle cover shield (which hides the needle before and after use);
- Retractable needle (needle retreats automatically into the inner system of the device after use);
- Bio-needle (needle consist of biological material and dissolves in the body after use, similar to biological surgical suture).

8. Flexibility of dose

Solution:

- Multiple dosages (implementation of multiple doses in the device).

9. Injection time

When under physical distress and with injection of adrenaline, the patient's feeling for time may be distorted. Therefore, an integrated timer was recommended.

Solution:

- Digital timer (which counts the injection time);
- Audible signal (1st click for the start and 2nd click for the end of injection);
- Sensorial feedback (e.g. vibration at injection end).

10. Marking of injection end

Solution:

- Implement of a window (large enough to monitor the drug/plunger);
- Discolouration of package (after completion of injection, the package changes colour).

11. Patient's fear of device

Solutions:

- Needle cover shield;
- Retractable needle;
- Bio-needle;
- Follow-up training;
- Training with real device;
- Training by medical professionals;
- Training in school;
- Training for canteen/restaurant/hotel.

12. Adequate training

Solutions:

- Follow-up training (once a year);
- Training with real device (to be filled with sucrose and injected into pad under assistance of doctor, not training device without needle);
- Training by medical professionals;
- Training in school;
- Training for canteen/restaurant/hotel (device to be stored in such locations).

13. Shelf life

Solutions:

- Exchangeable syringe (so that the drug which is the most responsible for the limited shelf life of the device can be renewed);
- Bring back device (manufacturer helps to exchange the syringe after expiry date).

14. Device robustness

- No solution was found in this aspect.

The outputs of the control group with test device 2 are summarized in the table 6-3.

No.	Device features	Improvement ideas	
1	Device identification	1	To implement colourful ergonomic designs
		2	To implement identifying text in noticeable letters
		3	To use brand colour/design
		4	To implement a distinguishable new design
2	Comprehensive instruction of use	1	To implement QR code
		2	To implement full instruction for use with anaphylaxis third person decision tree on the plastic case and QR Code video
		3	To picture how to hold the auto-injector during the application
		4	To use an arrow to show the direction of injection tip
3	Ease of use	1	Eyeglasses case
		2	Reset button for 2nd dose
4	Size of device	1	Handle for portability
		2	Eyeglasses case
5	Customization for target groups	1	Age group specific cap design
		2	Adjustable dosage
		3	Instruction for use for children
		4	QR-code video for children
		5	Design/size for children
		6	Gender specific device sizes
		7	Weight and muscle mass specific needle length
6	Needle length	1	Weight and muscle mass specific needle length
7	Needle protection	1	Needle cover shield
		2	Retractable needle
		3	Bio-needle
8	Flexibility of doses	1	Multiple dosages
9	Injection time	1	Digital timer
		2	Audible signal
		3	Sensorial feedback
10	Marking of injection end	1	Implement of a window
		2	Discolouration of package
11	Patient's fear of device	1	Needle cover shield
		2	Retractable needle
		3	Bio-needle
		4	Follow-up training
		5	Training with real device
		6	Training by medical professionals
		7	Training in school
		8	Training for canteen/restaurant/hotel
12	Adequate training	1	Follow-up training
		2	Training with real device
		3	Training by medical professionals
		4	Training in school
		5	Training for canteen/restaurant/hotel
13	Shelf life	1	Exchangeable syringe
		2	Bring back device
14	Device robustness		

Table 6-3 Outputs of control group (test device 2)

6.1.4 Test group/ test device 2

The problem-solving process of this group was guided by the chosen TRIZ inventive principles. In some cases, the group combined various inventive principles to develop more complex solutions.

The following ideas were generated by the test group for test device 2. The treated technical issues of the test device are put in ( ) and the applied TRIZ inventive principles in [ ].

Solution 1.

- To use more intensive colours for labels, instead of black and grey for easier identification of the device. [35 Parameter change - F. Other parameters] (1 device identification).

Solution 2.

- To use compressed air to replace the spring in the device [35 Parameter change - A. Physical state/ F. Other parameters], in order to reduce the activation force. This will on the one hand make the device easier to operate (3 ease of use), on the other hand, reduce the size of the device (4 size of device) and in turn the patient's fear (11 patient's fear of device);
- In the current design, the relatively big size of the spring due to necessary activation force confines the device to a minimum size. By replacing it with a compact compressed air system [2 Taking out or extraction - A. Extract disturbing objects], the device shall have more freedom in taking on smaller shapes (4 size of device) that are more comfortable or convenient to the patients (3 ease of use);
- The compressed air shall be refillable [34 Discarding and recovering - B. Restore consumable parts] which contribute to longer lifetime of the device (13 shelf life).

Solution 3.

- To implement exchangeable needles [34 Discarding and recovering - B. Restore consumable parts]. This will help to extend the useful time of the device (13 shelf life);
- To make the surface of the device, including the fixture e.g. holder for key ring or clip, exchangeable accessories of the device [34 Discarding and recovering - B. Restore consumable parts] to meet the ergonomic requirements of different

patients (3 ease of use; 5 customisation of target groups; 13 shelf life; 14 device robustness);

- To use softer material for the device surface [35 Parameter change - C. Degree of flexibility] in order to improve the user comfort (3 ease of use).

Solution 4.

- To implant the medication under the skin and release the necessary dose with an activation device based on magnet, electric impulse etc. [2 Taking out or extraction - B. Extract necessary objects]. This will simplify the use of device (3 ease of use) and reduce the patient's fear (11 patient's fear of device). With this solution, the needle will become obsolete (6 needle length; 7 needle protection) and the injection time and dose will be controlled by the electronic (8 flexibility of dose; 9 injection time, 10 marking of injection end). With this design, the device is well protected under the skin (14 device robustness);
- The medication implant should be refillable or exchangeable [34 Discarding and recovering - B. Restore consumable parts]. This does not only increase user comfort (3 ease of use), but also helps to avoid the patient's fear (11 patient's fear of device) and extend the lifetime of the device (13 shelf life);
- Also the batteries for the above systems should be rechargeable or exchangeable [34 Discarding and recovering - B. Restore consumable parts] (13 shelf life).

Solution 5.

- Exchangeable design for the consumable parts - the cartridge and the needle - [34. Discarding and recovering - B. Restore consumable parts]. With such designs, the life time of the device may be substantially extended (13 shelf life);
- Refillable cartridges [34 Discarding and recovering - B. Restore consumable parts] (13 shelf life);
- Threaded-coupling to be implemented to facilitate the replacement of the consumable parts [2 Taking out or extraction - B. Extract necessary objects] (3 ease of use; 13 shelf life).

Solution 6.

- To integrate multiple needles in the device [34 Discarding and recovering - B. Restore consumable parts]. This will provide the opportunity for backup

injections (3 ease of use) and extend the useful time of the device (13 shelf life). Different needle length may be implemented (6 needle length).

Solution 7.

- To replace the conventional needle with a biological needle which dissolves after use [2 Taking out or extraction - A. Extract disturbing objects]. This may reduce patient's fear (11 patient's fear of device).

Solution 8.

- To use solid instead of liquid medication [35 Parameter change - A. Physical state]. This will largely reduce the injection time (9 injection time) and the pain during the injection (3 ease of use), and bring down the size of device (4 size of device). Besides, needle or needle protection is no longer needed for this solution (6 needle length; 7 needle protection; 10 marking of injection end). Potentially, all the above may reduce the patient's fear (11 patient's fear of device).

Solution 9.

- The activation force is perceived as too high. A changed mechanism triggered by a sideways button should reduce the activation force [2 Taking out or extraction - A. Extract disturbing objects]. This should improve the use comfort (3 ease of use), bring down the size of device (4 size of device) and reduce the patient's fear (11 patient's fear of device).

Solution 10.

- To implement a lever to deliver different levels of dosage - similar as the design of some lighters [2 Taking out or extraction - B. Extract necessary objects] (8 flexibility of dose);
- The safety cap can be eliminated. The function can be maintained as a level of the above lever [2 Taking out or extraction - B. Extract necessary objects] (3 ease of use; 4 size of device).

The outputs of the test group with test device 2 are summarized in the table 6-4.

No.	Device features	Solution	Improvement ideas	
1	**Device identification**	**1**	1	Intensive colours for label
2	**Comprehensive instruction of use**			
3	**Ease of use**	**2a; 2b**	1	To replace spring by compressed air
		3b	2	Exterior design as exchangeable accessories
		3c	3	Soft exterior material

		4a	4	Drug implant
		4b	5	Refillable drug implant
		5c	6	Threaded-coupling in pen
		6	7	Multiple needles
		8	8	Solid drug
		9	9	Sideway trigger
		10b	10	Integrated safety catch
4	**Size of device**	**2a; 2b**	1	To replace spring by compressed air
		8	2	Solid drug
		9	3	Sideway trigger
		10b	4	Integrated safety catch
5	**Customization for target groups**	**3b**	1	Exterior design as exchangeable accessories
6	**Needle length**	**4a**	1	Drug implant
		6	2	Multiple needles
		8	3	Solid drug
7	**Needle protection**	**4a**	1	Drug implant
		8	2	Solid drug
8	**Flexibility of doses**	**4a**	1	Drug implant
		10a	2	Dosage lever
9	**Injection time**	**4a**	1	Drug implant
		8	2	Solid drug
10	**Marking of injection end**	**4a**	1	Drug implant
		8	2	Solid drug
11	**Patient's fear of device**	**2a; 2b**	1	To replace spring by compressed air
		4a	2	Drug implant
		4b	3	Refillable drug implant
		7	4	Biological needle
		8	5	Solid drug
		9	6	Sideway trigger
12	**Adequate training**			
13	**Shelf life**	**2c**	1	Refillable compressed air cartridge
		3a	2	Exchangeable needles
		3b	3	Exterior design as exchangeable accessories
		4b	4	Refillable drug implant
		4c	5	Rechargeable or exchangeable battery
		5a	6	Exchangeable consumable parts
		5b	7	Refillable cartridge
		5c	8	Threaded-coupling in pen
		6	9	Multiple needles
14	**Device robustness**	**3b**	1	Exterior design as exchangeable accessories

Table 6-4 Outputs of test group (test device 2)

6.1.5 Assessment of outputs

Sessions 1 and 3 were experiment sessions with brainstorming and sessions 2 and 4 with TRIZ techniques.

The outputs of each experiment session were reviewed by the expert panel. The following criteria were applied to the assessment of the individual solutions created during the experiment sessions (see section 4.4):

- Feasibility (possible scores: 0 = not feasible; 1 = feasible with great difficulty; 2 = feasible with difficulty; 3 = feasible with efforts; 4 = feasible with slight efforts; 5 = feasible without efforts);

- Novelty (possible scores: 0 = old; 1 = improvement; 2 = modification; 3 = solution transfer; 4 = new idea; 5 = new technology);

- Costs (possible scores: 0 = unfeasible; 1 = very expensive; 2 = expensive; 3 = acceptable; 4 = affordable; 5 = inexpensive).

In all experiment sessions, numerous ideas were generated as solution to the predefined technical problems (see section 5.4.2). During the expert assessment, the members of the expert panel evaluated each solution according to the above rating system. The results were summarised in detail in appendix XIII.

Parallel to the expert assessment, three 'pen-experienced' patients were invited to give their opinions on the solutions developed during the experiment sessions. The patients were asked to evaluate the improvement ideas generated in the experiment by applying a 5-point Likert scale defined as follows (see section 4.4).

- 0 = no improvement at all;
- 1 = unnoticeable improvement;
- 2 = minor improvement;
- 3 = some improvement;
- 4 = noticeable improvement;
- 5 = essential improvement

The results of the patient assessment are summarised in detail in appendix XIII.

While session 1 delivered solutions to all technical issues, session 3 delivered no solution in one case. Session 2 failed to deliver solutions to 1 case and session 4 failed in 2 out of

the totally 14 technical cases. Thus sessions 2 and 4 using TRIZ exhibit a slightly higher rate of missing solutions than sessions 1 and 3 using brainstorming.

The reason of the higher rate of missing solutions of the TRIZ sessions may lie in the TRIZ procedure. On one hand, the TRIZ procedure not only predicted the solutions to the technical problems, but also eliminated possible solutions which could contradict the solutions to other technical issues, therefore reduced the quantity of solutions. On the other hand, only the inventive principles with the highest likelihood of achieving successful solutions were introduced in the experiment sessions. Although the chosen inventive principles for the experiment were likely to be helpful in solving most of the problems, they were not necessarily matched to each single problem. In case the chosen principles did not match certain technical problems, there was a higher likelihood that TRIZ procedure would fail to deliver any solutions.

In the following, the outputs of session 1 are compared with those of session 2 and session 3 compared with session 4, as each of the session pairs dealt with the improvement of the same test device. The experiment sessions of each session pair is compared in terms of total number of generated solutions, as well as the numbers of "top solutions" (see tables 6-5 and 6-6).

The top solutions are defined as the number of rank 1 and rank 2 solutions to each problem. Rank 1 solutions are those with the highest average score of the two sessions in the expert or the patient assessment. Similarly, rank 2 solutions are those with the second highest score.

In order to restrict the influence of the extremely good performance in some single cases in the total evaluation, in each dimension of the assessment, each session is limited to two rank 1 & rank 2 solutions in total. That means, in case there are more than two rank 1 solutions, there will be several rank 1 solutions but no rank 2 solution. In addition, if more than two rank 1 solutions are found in the same session, the session will be evaluated with two rank 1 solutions. Similarly, if there is one rank 1 solution and several rank 2 solutions, the number of rank 2 solutions will be capped so that each session will be evaluated at a maximum of one rank 1 solution and one rank 2 solution or two rank 2 solutions.

The results of the assessment of the outputs are shown in the table 6-5 and table 6-6.

test device 1					Average experts				Average patients
No.	**Device features**	**Session**	**Solution**	**No. of solutions**	**Feasibility**	**Novelty**	**Costs**	**sum**	**Patient perception**
1	**Device identification**	**1**	Rank 1	**5**	1	0	1	**1**	**1**
			Rank 2		1	0	1	**0**	**1**
			Rank 1&2		**2**	**0**	**2**	**1**	**2**
		2	Rank 1	**4**	0	1	0	**2**	**0**
			Rank 2		0	1	0	**0**	**0**
			Rank 1&2		**0**	**2**	**0**	**2**	**0**
2	**Comprehensive instruction of use**	**1**	Rank 1	**2**	1	1	1	**0**	**1**
			Rank 2		0	0	0	**0**	**1**
			Rank 1&2		**1**	**1**	**1**	**0**	**2**
		2	Rank 1	**4**	2	1	0	**2**	**0**
			Rank 2		0	0	1	**0**	**1**
			Rank 1&2		**2**	**1**	**1**	**2**	**1**
3	**Ease of use**	**1**	Rank 1	**8**	0	0	0	**0**	**0**
			Rank 2		0	0	0	**0**	**0**
			Rank 1&2		**0**	**0**	**0**	**0**	**0**
		2	Rank 1	**12**	1	2	2	**1**	**2**
			Rank 2		1	0	0	**1**	**0**
			Rank 1&2		**2**	**2**	**2**	**2**	**2**
4	**Size of device**	**1**	Rank 1	**1**	1	0	0	**0**	**0**
			Rank 2		0	0	0	**0**	**0**
			Rank 1&2		**1**	**0**	**0**	**0**	**0**
		2	Rank 1	**5**	1	2	1	**2**	**1**
			Rank 2		0	0	1	**0**	**1**
			Rank 1&2		**1**	**2**	**2**	**2**	**2**
5	**Customization for target groups**	**1**	Rank 1	**1**	0	0	0	**0**	**1**
			Rank 2		0	0	0	**0**	**0**
			Rank 1&2		**0**	**0**	**0**	**0**	**1**
		2	Rank 1	**4**	2	1	1	**2**	**1**
			Rank 2		0	1	1	**0**	**0**
			Rank 1&2		**2**	**2**	**2**	**2**	**1**
test device 1					**Average experts**				**Average patients**
No.	**Device features**	**Session**	**Solution**	**No. of solutions**	**Feasibility**	**Novelty**	**Costs**	**sum**	**Patient perception**
6	**Needle length**	**1**	Rank 1	**1**	1	0	1	**1**	**0**
			Rank 2		0	1	0	**0**	**0**

			Rank 1&2		**1**	**1**	**1**	**1**	**0**
		2	Rank 1	**2**	0	1	0	**1**	**1**
			Rank 2		1	0	1	**0**	**1**
			Rank 1&2		**1**	**1**	**1**	**1**	**2**
7	**Needle protection**	**1**	Rank 1	**1**	1	0	1	**1**	**1**
			Rank 2		0	1	0	**0**	**0**
			Rank 1&2		**1**	**1**	**1**	**1**	**1**
		2	Rank 1	**1**	0	1	0	**0**	**0**
			Rank 2		1	0	1	**1**	**1**
			Rank 1&2		**1**	**1**	**1**	**1**	**1**
8	**Flexibility of doses**	**1**	Rank 1	**1**	1	0	1	**0**	**0**
			Rank 2		0	1	0	**1**	**1**
			Rank 1&2		**1**	**1**	**1**	**1**	**1**
		2	Rank 1	**3**	1	1	2	**1**	**1**
			Rank 2		0	1	0	**0**	**0**
			Rank 1&2		**1**	**2**	**2**	**1**	**1**
9	**Injection time**	**1**	Rank 1	**2**	1	0	1	**1**	**0**
			Rank 2		1	0	1	**1**	**2**
			Rank 1&2		**2**	**0**	**2**	**2**	**2**
		2	Rank 1	**3**	0	1	0	**0**	**1**
			Rank 2		0	1	0	**0**	**1**
			Rank 1&2		**0**	**2**	**0**	**0**	**2**
10	**Marking of injection end**	**1**	Rank 1	**1**	0	0	0	**0**	**1**
			Rank 2		0	1	1	**1**	**0**
			Rank 1&2		**0**	**1**	**1**	**1**	**1**
		2	Rank 1	**3**	1	1	1	**1**	**0**
			Rank 2		1	0	1	**0**	**2**
			Rank 1&2		**2**	**1**	**2**	**1**	**2**
11	**Patient's fear of device**	**1**	Rank 1	**3**	1	0	0	**0**	**2**
			Rank 2		0	0	1	**0**	**0**
			Rank 1&2		**1**	**0**	**1**	**0**	**2**
		2	Rank 1	**8**	0	1	1	**1**	**1**
			Rank 2		1	1	1	**1**	**0**
			Rank 1&2		**1**	**2**	**2**	**2**	**1**
12	**Adequate training**	**1**	**Rank 1&2**	**3**					
		2							
test device 1					**Average experts**				**Average patients**
No.	**Device features**	**Session**	**Solution**	**No. of solutions**	**Feasibility**	**Novelty**	**Costs**	**sum**	**Patient perception**
13	**Shelf life**	**1**	Rank 1	**3**	1	0	0	0	0
			Rank 2		1	0	1	1	1

			Rank 1&2		**2**	**0**	**1**	**1**	**1**
		2	Rank 1	**4**	0	1	1	1	1
			Rank 2		0	1	0	0	0
			Rank 1&2		**0**	**2**	**1**	**1**	**1**
14	**Device robustness**	**1**	Rank 1	**3**	0	0	2	0	0
			Rank 2		1	0	0	0	1
			Rank 1&2		**1**	**0**	**2**	**0**	**1**
		2	Rank 1	**9**	1	1	1	1	1
			Rank 2		1	1	1	1	1
			Rank 1&2		**2**	**2**	**2**	**2**	**2**
	Total	**1**	Rank 1	**32**	9	1	8	4	7
			Rank 2		4	4	5	4	7
			Rank 1&2		**13**	**5**	**13**	**8**	**14**
		2	Rank 1	**62**	9	15	10	15	10
			Rank 2		6	7	8	4	8
			Rank 1&2		**15**	**22**	**18**	**19**	**18**

Table 6-5 Comparison of outputs: top scores in sessions 1&2

test device 2					**Average experts**				**Average patients**
No.	**Device features**	**Session**	**Solution**	**No. of solutions**	**Feasibility**	**Novelty**	**Costs**	**sum**	**Patient perception**
1	**Device identification**	**3**	Rank 1	**4**	1	1	1	1	1
			Rank 2		0	1	1	0	1
			Rank 1&2		**1**	**2**	**2**	**1**	**2**
		4	Rank 1	**1**	1	0	0	1	0
			Rank 2		0	1	1	0	0
			Rank 1&2		**1**	**1**	**1**	**1**	**0**
2	**Comprehensive instruction of use**	**3**	**Rank 1&2**	**4**					
		4							
3	**Ease of use**	**3**	Rank 1	**2**	0	0	1	1	2
			Rank 2		1	0	0	0	0
			Rank 1&2		**1**	**0**	**1**	**1**	**2**
		4	Rank 1	**10**	1	1	0	0	0
			Rank 2		0	1	1	1	0
			Rank 1&2		**1**	**2**	**1**	**1**	**0**
test device 2					**Average experts**				**Average patients**
No.	**Device features**	**Session**	**Solution**	**No. of solutions**	**Feasibility**	**Novelty**	**Costs**	**sum**	**Patient perception**
4	**Size of device**	**3**	Rank 1	**2**	1	0	1	1	1
			Rank 2		1	0	1	1	0
			Rank 1&2		**2**	**0**	**2**	**2**	**1**

			Rank 1		1	1	0	0	1
		4	Rank 2	**4**	1	1	0	0	0
			Rank 1&2		**2**	**2**	**0**	**0**	**1**
5	**Customization for target groups**		Rank 1		2	1	2	1	1
		3	Rank 2	**7**	0	0	0	1	0
			Rank 1&2		**2**	**1**	**2**	**2**	**1**
			Rank 1		0	1	0	1	1
			Rank 2	**1**	0	0	1	0	0
		4	**Rank 1&2**		**0**	**1**	**1**	**1**	**1**
6	**Needle length**		Rank 1		0	1	0	1	1
		3	Rank 2	**1**	0	0	1	0	0
			Rank 1&2		**0**	**1**	**1**	**1**	**1**
			Rank 1		2	0	1	0	0
		4	Rank 2	**3**	0	1	0	1	1
			Rank 1&2		**2**	**1**	**1**	**1**	**1**
7	**Needle protection**		Rank 1		1	1	1	2	1
		3	Rank 2	**3**	1	0	0	0	0
			Rank 1&2		**2**	**1**	**1**	**2**	**1**
			Rank 1		0	0	0	0	1
		4	Rank 2	**2**	0	1	1	0	0
			Rank 1&2		**0**	**1**	**1**	**0**	**1**
8	**Flexibility of doses**		Rank 1		1	0	0	0	1
		3	Rank 2	**1**	0	1	1	1	0
			Rank 1&2		**1**	**1**	**1**	**1**	**1**
			Rank 1		1	1	1	1	0
		4	Rank 2	**2**	0	1	0	0	1
			Rank 1&2		**1**	**2**	**1**	**1**	**1**
9	**Injection time**		Rank 1		2	0	1	1	1
		3	Rank 2	**3**	0	1	0	1	0
			Rank 1&2		**2**	**1**	**1**	**2**	**1**
			Rank 1		0	1	1	0	1
		4	Rank 2	**2**	0	0	0	0	0
			Rank 1&2		**0**	**1**	**1**	**0**	**1**
10	**Marking of injection end**		Rank 1		1	0	2	1	1
		3	Rank 2	**2**	1	1	0	1	0
			Rank 1&2		**2**	**1**	**2**	**2**	**1**
			Rank 1		0	1	0	0	0
		4	Rank 2	**2**	0	1	0	0	1
			Rank 1&2		**0**	**2**	**0**	**0**	**1**
11	**Patient's fear of device**		Rank 1		2	1	2	1	1
		3	Rank 2	**8**	0	0	0	1	1
			Rank 1&2		**2**	**1**	**2**	**2**	**2**
			Rank 1		0	0	0	0	0
		4	Rank 2	**6**	0	1	0	0	0
			Rank 1&2		**0**	**1**	**0**	**0**	**0**
12	**Adequate training**	**3**	**Rank 1&2**	**5**					
		4							
test device 2					**Average experts**				**Average patients**
No.	**Device features**	**Session**	**Solution**	**No. of solutions**	**Feasibility**	**Novelty**	**Costs**	**sum**	**Patient perception**
			Rank 1		1	0	1	1	1
13	**Shelf life**	**3**	Rank 2	**2**	0	0	0	0	0
			Rank 1&2		**1**	**0**	**1**	**1**	**1**

		4	Rank 1	9	0	1	0	0	0
			Rank 2		2	1	1	2	1
			Rank 1&2		**2**	**2**	**1**	**2**	**1**
14	Device robustness	3							
		4	**Rank 1&2**	1					
	Total	3	Rank 1	35	12	5	12	11	12
			Rank 2		4	4	4	6	2
			Rank 1&2		**16**	**9**	**16**	**17**	**14**
	Total	4	Rank 1	42	6	7	4	3	4
			Rank 2		3	10	5	5	5
			Rank 1&2		**9**	**16**	**8**	**7**	**8**

Table 6-6 Comparison of outputs: top of scores sessions 3&4

Comparing the experiment sessions 1 & 2, the test group using TRIZ delivered no solution to the problem number 12 “adequate training”. For the remaining 13 problems, the test group delivered a higher number of solutions than the control group in 11 cases. Both groups delivered the same number of solutions in one case. In the other case, the control group delivered a higher number of solutions.

Comparing the experiment sessions 3 & 4, the test group using TRIZ delivered no solution to the problem number 2 “comprehensive instruction of use” and number 12 “adequate training”, while the control group using brainstorming technique brought no solution to problem number 14 “device robustness”. Out of the remaining 11 problems, the test group achieved a higher number of solutions in 5 cases, the control group in another 5 cases and both groups delivered the same number of solutions in one case.

In both experiment session pairs, the test group achieved a clearly higher number of solutions in total than the control group. In the experiment sessions with test device 1, 32 solutions were developed with brainstorming and 62 solutions with TRIZ techniques. For the improvement of test device 2, 35 solutions were developed with brainstorming and 42 solutions with TRIZ.

The above suggests that potentially, TRIZ generates more solutions to the predefined problems than brainstorming. However, there seems to be a weakness in the TRIZ procedure when dealing with problems rooted in the patients’ psychology, e.g. “comprehensive instruction of use” or “adequate training”, so that the test group failed to deliver a solution to the problem “adequate training” in both cases and only in one of both sessions solutions to the problem “comprehensive instruction of use”. Such problems may

be described as fuzzy problems, since it is difficult to parameterise those problems. In case of the problem "adequate training", the TRIZ expert held different opinions on the classification of this problem so that the allocation of the problem to the contradiction parameter stayed invalid (see section 5.2.3).

In the following, the performance of the control group and the test group in the session pairs are analysed in the dimensions "*feasibility*", "*novelty*", "*costs*" and "*patient perception*". A session was considered to outperform the comparison session if it achieved a higher number of rank 1 & rank 2 solutions and an equal number of rank 1 solutions or higher, or the equal number of rank 1 & rank 2 solutions and a higher number of rank 1 solutions. The performances were considered equal, if both sessions achieved the same numbers of both rank 1 and rank 2 solutions, or if one session achieved one rank 1 solution and the other two rank 2 solutions. The performance was not taken into account if the comparison session failed to deliver any solution to the specific problem.

In the dimension "*feasibility*", out of totally 13 cases, session 1 (control group) achieved better results than session 2 (test group) in 6 cases and equal performance in 2 cases. Session 2 performed better in the other 5 cases. In the comparison pair with session 3 (control group) and session 4 (test group), session 3 outperformed session 4 in 5 out of 11 cases, the results were equal in 4 cases. Session 4 performed better in the other 2 cases.

In the dimension "*novelty*", session 2 (test group) outperformed session 1 in 12 out of 13 cases. In the other case, the performance of both sessions was equal. Also session 4 (test group) reached better results than session 3 (control group) in 6 out of 11 cases and equal performance in 1 case. Session 3 (control group) performed better in the other 4 cases.

In the dimension "*costs*", session 2 (test group) performed better results in 7 out of 13 cases and in 2 cases equally to session 1 (control group). However, session 3 (control group) outperformed session 4 (test group) in 7 out of 11 cases and the performance of session 3 (control group) and session 4 (test group) was equal in the other 4 cases.

In the total score, session 2 (test group) outperformed session 1 (control group) in all the above assessment dimensions, while session 4 (test group) did clearly better in the dimension "*novelty*" and worse in the other dimensions.

The substantial difference between the two experiment procedures in this study was that only the test group received the additional indication of TRIZ inventive principles.

The above findings suggest that both brainstorming and TRIZ may lead to good results in technical innovation. Measured by the total scores, the experiment sessions using brainstorming and TRIZ techniques delivered a similar quality of outputs. However, TRIZ seems to have a clear advantage in the dimension "*novelty*", while the trend is not clear in the other dimensions of expert assessment.

The assessment criterion "*novelty*" describes the level of innovation of the solutions to the predetermined technical problems. Based on the determinants of those clearly defined problems, TRIZ inventive principles were selected and provided to the test groups during the experiment. The advantage of TRIZ in this dimension indicates that the TRIZ inventive principles successfully directed the innovation process into the "shortcuts" to the solutions.

Traditionally, the TRIZ inventive principles were developed to solve technology-driven problems. The results of the experiment suggest that the positive effect of TRIZ is weaker in dealing with soft targets e.g. "adequate training".

However, the advantage of TRIZ disappeared in the dimensions "feasibility" and "costs" of the expert assessment. This criterion "feasibility" describes to what extend the proposed solutions can be implemented without great difficulty and the criterion "costs" refers to the costs for manpower, development time and production of the proposed solutions etc. The assessment criteria in both dimensions could not be fixed prior to the determination of the solutions and depend largely on the previous knowledge and experience of the evaluating experts (see section 4.4). Therefore, the additional information received by the test group on TRIZ inventive principles did not reflect the requirements on problems solutions in the above two dimensions, thus it appears only logical that TRIZ did not lead to better results.

The patient assessment was conducted based on the patients' perceptions which were strongly influenced by their relevant experience in the past. Since such experiences were

largely unknown to others, the requirements of the patients' perceptions are fuzzy problems which were not taken into consideration in the selection of the TRIZ inventive principles. This could explain the experiment findings that TRIZ appeared not more advantageous than brainstorming in the patient assessment.

In summary, the TRIZ inventive principles improve the opportunity of finding solutions to problems with sophisticated technological background by canalising the search in certain directions. While brainstorming focuses on the specific problems, TRIZ extracts general problems out of the specific problems, or in other words detaches the problems from the immediate environment. The inventive principles are proven good solutions in the past to the general problems which should be transformed into specific solutions in the last stage of the TRIZ procedure (Altshuller, 1999).

The findings of the experiment indicate that the TRIZ inventive principles lead to improved innovation results in the clearly defined technology-driven problems. In addition, the general solutions can often be "translated" into multiple specific solutions. Therefore, TRIZ appears to be especially effective in solving clearly defined technical problems which enables distinctive determination of the applicable inventive principles. On the other hand, TRIZ seems to have no advantage over brainstorming when dealing with fuzzy or non-technical problems. This suggests that TRIZ might not be the appropriate instrument for fuzzy problems which cannot be adequately predefined or are subject to changing criteria.

6.2 Process

6.2.1 Rating method

In accordance with the experiment plan, the following experiment sessions were conducted as group work (see table 6-7).

Experiment session	Participants	Problem-solving technique	Test devices
1	P4, P5, P6	Brainstorming	1
2	P1, P2, P3	TRIZ	1
3	P1, P2, P3	Brainstorming	2
4	P4, P5, P6	TRIZ	2

Table 6-7 Organisation of experiment sessions

The group P1, P2 and P3 consists of two men and one woman. The group P4, P5 and P6 consists of one man and two women. The age of the participants are similar with the average age of each group being between 40-50 years.

During the experiment, all participants sat around a table with similar distance to each other. The seats were chosen by the participants themselves and each participant kept the same seat in both sessions.

Immediately after the group work for the following experiment sessions, the participants were asked to evaluate the behaviours of all group members, including themselves, by filling out the SYMLOG Adjective Rating Form.

After reviewing the ratings of the other participants and a subsequent group discussion, the participants filled out the forms for a second time. In addition, two independent raters filled out the forms for each participant at each session based on the video recording. The assessment of the above ratings was conducted in accordance with Bales' instructions (Bales & Cohen, 1979).

The adjectives in the SYMLOG Adjective Rating Form were developed to describe behaviours in three dimensions: U-D, P-N and F-B. Each dimension had two ends which were qualitatively the opposite of each other (e.g. U is the opposite of D).

Dimension U-D (= Upward – Downward) demonstrated how actively the observed person exerted influence on the observed event, ranging from dominant (U) to submissive (D).

Dimension P-N (= Positive – Negative) described if the observed person was friendly (P) or unfriendly (N).

Dimension F-B (= Forward – Backward) showed if the observed person was instrumentally controlled, in other words, task-oriented (F) or emotionally expressive, in other words, oriented by emotions and feelings (B).

Each item in the rating form was allocated to a code for a certain type of behaviour in the 3-dimensional space (see appendices XI and XII). The code was sometimes a single direction in the space (U, D, P, N, F and B) and in the other cases a combination of those (e.g. UP, UPF).

In the first step, the total score of each direction was calculated. To do this, the scores of all relevant items were summed up (for example, in dimension U, the relevant items were U, UP, UPF, UF, UNF, UN, UNB, UB and UPB). In other words, the combination items counted for each direction in their codes. The result of this step was a total score for each direction (U, D, P, N, F and B).

In the next step, the scores of the two opposite directions of each dimension were calculated against each other. For example, if U = 7 and F = 20, the result of dimension U-F would be 20-7 = 13F (Marx, 2000).

For further analysis of the results, average scores for each individual participant were calculated for the ratings before and after the group discussions. Those were then compared with the ratings by the independent external raters.

6.2.2 Control group/ test device 1

6.2.2.1 Internal ratings: first round

In the first round rating by the participants, all three participants rated each item, however in two cases, the participant P5 did not deliver an answer for P6 (see table 6-8).

Code	P4 by P4	P4 by P5	P4 by P6	P4 Average P	P5 by P4	P5 by P5	P5 by P6	P5 Average P	P6 by P4	P6 by P5	P6 by P6	P6 Average P
U	3	3	3	3.00	4	2	3	3.00	4	4	4	4.00
UP	4	4	3	3.67	4	3	4	3.67	4	4	3	3.67
UPF	4	3	3	3.33	4	2	2	2.67	4	4	3	3.67
UF	1	2	0	1.00	0	2	1	1.00	0	3	2	1.67
UNF	0	0	0	0.00	0	1	0	0.33	0	1	1	0.67
UN	2	1	0	1.00	3	0	0	1.00	4	2	0	2.00
UNB	0	1	0	0.33	0	0	0	0.00	0	1	0	0.33

UB	3	3	2	2.67	3	2	3	2.67	4	3	1	2.67
UPB	4	4	3	3.67	4	3	4	3.67	4	4	2	3.33
P	4	4	4	4.00	4	3	4	3.67	4	4	3	3.67
PF	3	3	4	3.33	4	3	4	3.67	4		3	3.50
F	3	3	3	3.00	4	3	4	3.67	4	3	4	3.67
NF	4	3	2	3.00	3	3	2	2.67	4	3	2	3.00
N	0	0	0	0.00	0	0	0	0.00	0	0	0	0.00
NB	0	0	0	0.00	0	0	0	0.00	0	0	0	0.00
B	0	0	0	0.00	1	1	0	0.67	0	0	0	0.00
PB	4	3	3	3.33	4	2	3	3.00	4	3	2	3.00
DP	4	3	4	3.67	4	3	4	3.67	4	3	3	3.33
DPF	4	3	4	3.67	4	3	4	3.67	4	3	2	3.00
DF	2	3	2	2.33	3	3	2	2.67	4	4	2	3.33
DNF	2	2	0	1.33	2	2	0	1.33	3		0	1.50
DN	1	1	0	0.67	1	1	0	0.67	0	1	0	0.33
DNB	1	2	0	1.00	0	1	0	0.33	0	1	0	0.33
DB	1	2	0	1.00	1	2	0	1.00	0	1	0	0.33
DPB	4	3	2	3.00	3	2	2	2.33	4	2	2	2.67
D	1	2	0	1.00	1	2	0	1.00	0	1	0	0.33

Table 6-8 Internal rating 1: experiment session 1

After completion of the rating, the participants exchanged the rating forms to view the results by the other group members, followed by the group discussion.

6.2.2.2 Group discussion

The group discussion was guided by some predefined questions.

Q1 How do you feel about working in a group?

All participants perceived the experience of group work as positive. Two participants stated that in the group work, solutions could be developed through discussions based on the ideas of all individual members. The other member of the group added that group work provided the opportunity for the participants to exchange ideas and to be inspired by the others.

Q2 Do you prefer to work in a group or on your own?

All participants preferred group work, because of the pleasant cooperative atmosphere and the opportunity to be inspired by others through exchange of thoughts.

Q3 Did you feel comfortable during the solution-seeking process in the experiment?

All three participants perceived the group work as pleasant.

Q4 How would you describe the status of the solution-seeking process in the beginning, in the middle and at the end of the session?

At the beginning, the group work concentrated on a common understanding of the task and the problem-solving approach. In the end, more attention was paid to the time limit and the focus was a consensus for the summary of found solutions. In the middle, the group work seemed to be more productive, since the tasks were clarified and the time pressure was not clearly noticeable.

Q5 When was the most innovative moment?

There were several innovative moments. In those moments, the new ideas were confirmed and/or further developed by the other two group members.

Q6 Would a moderator, facilitator or a group leader be helpful for the group work?

The group felt that a "democratic" structure without a leader was the best, because each member then had the equal opportunity to make a contribution. A moderator was not needed, because the participant found that the group members could get to know each other better and work more freely without moderation. It was asserted that a similar level of capabilities and experience among the participants promoted the group work without leadership.

Q7 Did you need more time or guidance?

To the participants, the time and guidance for the experiment were sufficient.

The participants did not make further assertions.

6.2.2.3 Internal ratings: second round

After the group discussion, the participants filled out the SYMLOG Adjective Rating Form for a second time. The results are summarised in the following table. All three participants rated each item, however in one cases, the participant P5 did not deliver an answer for P6 (see table 6-9).

Code	P4 by P4	P4 by P5	P4 by P6	P4 Average P	P5 by P4	P5 by P5	P5 by P6	P5 Average P	P6 by P4	P6 by P5	P6 by P6	P6 Average P
U	3	3	4	3.33	3	2	2	2.33	4	4	3	3.67
UP	4	4	4	4.00	4	3	4	3.67	4	4	4	4.00

UPF	4	4	2	3.33	4	2	3	3.00	4	4	3	3.67
UF	0	1	1	0.67	0	1	1	0.67	0	4	2	2.00
UNF	0	0	0	0.00	0	1	0	0.33	0	0	0	0.00
UN	2	2	0	1.33	1	1	0	0.67	4	1	0	1.67
UNB	0	0	0	0.00	0	0	0	0.00	0		0	0.00
UB	4	3	2	3.00	3	3	3	3.00	3	3	2	2.67
UPB	3	4	3	3.33	3	3	4	3.33	4	3	3	3.33
P	4	4	4	4.00	3	3	4	3.33	4	3	4	3.67
PF	4	4	4	4.00	3	3	4	3.33	3	3	4	3.33
F	3	3	3	3.00	4	3	3	3.33	4	3	4	3.67
NF	4	3	2	3.00	4	3	2	3.00	4	4	2	3.33
N	0	1	0	0.33	0	0	0	0.00	0	0	0	0.00
NB	0	0	0	0.00	0	0	0	0.00	0	0	0	0.00
B	1	0	0	0.33	1	0	0	0.33	1	0	0	0.33
PB	4	3	3	3.33	4	2	3	3.00	4	3	3	3.33
DP	3	3	4	3.33	4	3	4	3.67	4	3	4	3.67
DPF	3	3	3	3.00	4	3	4	3.67	4	3	3	3.33
DF	3	3	3	3.00	4	3	2	3.00	4	3	2	3.00
DNF	2	1	0	1.00	2	2	0	1.33	3	1	0	1.33
DN	1	0	0	0.33	0	1	0	0.33	0	0	0	0.00
DNB	1	1	0	0.67	0	1	0	0.33	0	0	0	0.00
DB	2	1	0	1.00	0	1	0	0.33	0	1	0	0.33
DPB	3	3	3	3.00	3	3	3	3.00	3	3	3	3.00
D	1	1	0	0.67	0	1	0	0.33	0	0	0	0.00

Table 6-9 Internal rating 1: experiment session 2

Compared to the first round of rating, although the participants made the same ratings in most of the cases, some corrections were made by rating the item with 1 score higher or lower. In two cases, the correction was more than 1 score. P5 did not provide a score for P6 in item PF in the first round and rated this item in the second round with "3", therefore the difference between the two rounds of ratings for this item was "3". P4 changed the rating for P5 by reducing the score by 2 and cause the change of "-2" of this item.

The change of scores in the second round compared to the first round is shown in the table 6-10.

Code	P4 by P4	P4 by P5	P4 by P6	P5 by P4	P5 by P5	P5 by P6	P6 by P4	P6 by P5	P6 by P6
U	0	0	1	-1	0	-1	0	0	-1
UP	0	0	1	0	0	0	0	0	1
UPF	0	1	-1	0	0	1	0	0	0
UF	-1	-1	1	0	-1	0	0	1	0

UNF	0	0	0	0	0	0	0	-1	-1
UN	0	1	0	-2	1	0	0	-1	0
UNB	0	-1	0	0	0	0	0	-1	0
UB	1	0	0	0	1	0	-1	0	1
UPB	-1	0	0	-1	0	0	0	-1	1
P	0	0	0	-1	0	0	0	-1	1
PF	1	1	0	-1	0	0	-1	3	1
F	0	0	0	0	0	-1	0	0	0
NF	0	0	0	1	0	0	0	1	0
N	0	1	0	0	0	0	0	0	0
NB	0	0	0	0	0	0	0	0	0
B	1	0	0	0	-1	0	1	0	0
PB	0	0	0	0	0	0	0	0	1
DP	-1	0	0	0	0	0	0	0	1
DPF	-1	0	-1	0	0	0	0	0	1
DF	1	0	1	1	0	0	0	-1	0
DNF	0	-1	0	0	0	0	0	1	0
DN	0	-1	0	-1	0	0	0	-1	0
DNB	0	-1	0	0	0	0	0	-1	0
DB	1	-1	0	-1	-1	0	0	0	0
DPB	-1	0	1	0	1	1	-1	1	1
D	0	-1	0	-1	-1	0	0	-1	0

Table 6-10 **Internal ratings 1 vs. 2: experiment session 1**

6.2.3 Test group/ test device 1

6.2.3.1 Internal ratings: first round

In the first round rating by the participants, all three participants rated each item, however in two cases, the participant P3 did not deliver an answer for P1 (see table 6-11).

Code	P1 by P1	P1 by P2	P1 by P3	P1 Average P	P2 by P1	P2 by P2	P2 by P3	P2 Average P	P3 by P1	P3 by P2	P3 by P3	P3 Average P
U	3	2		2.50	3	3	3	3.00	3	3	2	2.67
UP	3	3		3.00	3	3	3	3.00	3	3	3	3.00
UPF	4	2	3	3.00	3	3	3	3.00	3	3	2	2.67
UF	2	1	2	1.67	2	2	1	1.67	2	2	1	1.67
UNF	0	0	1	0.33	1	2	1	1.33	0	1	1	0.67
UN	0	0	1	0.33	0	0	1	0.33	0	0	1	0.33
UNB	0	1	1	0.67	1	1	1	1.00	0	1	1	0.67
UB	3	3	3	3.00	3	2	2	2.33	3	3	2	2.67
UPB	3	2	3	2.67	4	3	3	3.33	3	2	2	2.33
P	3	4	3	3.33	3	3	3	3.00	3	4	3	3.33
PF	3	2	3	2.67	4	3	3	3.33	3	3	2	2.67

F	3	3	2	2.67	3	4	3	3.33	3	4	2	3.00
NF	3	3	2	2.67	2	2	2	2.00	3	2	2	2.33
N	0	0	1	0.33	0	0	0	0.00	0	0	1	0.33
NB	0	0	1	0.33	0	0	0	0.00	0	0	0	0.00
B	0	1	1	0.67	1	1	0	0.67	0	1	1	0.67
PB	3	3	3	3.00	3	2	3	2.67	4	3	2	3.00
DP	3	2	2	2.33	3	3	2	2.67	3	2	2	2.33
DPF	3	3	2	2.67	3	3	3	3.00	3	3	2	2.67
DF	3	1	2	2.00	3	1	2	2.00	2	1	2	1.67
DNF	1	0	0	0.33	1	0	0	0.33	1	0	0	0.33
DN	0	0	0	0.00	0	0	0	0.00	0	0	1	0.33
DNB	0	0	0	0.00	0	0	0	0.00	0	0	1	0.33
DB	3	0	0	1.00	3	0	0	1.00	3	1	1	1.67
DPB	3	2	3	2.67	3	3	3	3.00	4	3	2	3.00
D	0	1	1	0.67	0	1	1	0.67	0	2	1	1.00

Table 6-11 Internal ratings 1: experiment session 2

After completion of the rating, the participants exchanged the rating forms to view the results by the other group members, followed by the group discussion.

6.2.3.2 Group discussion

The group discussion was guided by the following questions.

Q1 How do you feel about working in a group?

All participants perceived group work as positive if the atmosphere in the group was good.

Q2 Do you prefer to work in groups or on your own?

Group work seemed to be effective for the application of TRIZ. Since every participant had different interpretations for the inventive principles, the group work was very helpful not only for cross-examination of their own ideas, but also for inspiration by the interpretations and ideas by the others.

Q3 Did you feel comfortable during the solution-seeking process in the experiment?

All three participants experience the session as positive and pleasant.

Q4 How would you describe the status of the solution-seeking process in the beginning, in the middle and at the end of the session?

Due to the clear structure of the inventive principles, no "warming up" was necessary. Innovative ideas were generated right from the very beginning of the session.

Q5 When was the most innovative moment?

There were many moments where innovative ideas were generated, e.g. the giraffe design for children. Or as TRIZ led to the specific technical solutions of compressed gas system and changed formulation. TRIZ seemed to solve problems not only in short-term, but helped in finding out directions for long-term development.

Q6 Would a moderator, facilitator or a group leader be helpful for the group work?

No leadership or moderation was considered necessary by the group, since TRIZ was thought to provide very clear instructions.

Q7 Did you need more time or guidance?

The time was considered sufficient and no further guidance was needed.

The participants did not make further assertions.

6.2.3.3 Internal ratings: second round

After the group discussion, the participants filled out the SYMLOG Adjective Rating Form for a second time. The results are summarised in table 6-12.

Code	P1 by P1	P1 by P2	P1 by P3	P1 Average P	P2 by P1	P2 by P2	P2 by P3	P2 Average P	P3 by P1	P3 by P2	P3 by P3	P3 Average P
U	3	2	2	2.33	3	3	3	3.00	3	3	2	2.67
UP	3	3	3	3.00	3	3	3	3.00	3	3	3	3.00
UPF	3	3	3	3.00	3	2	3	2.67	3	3	3	3.00
UF	1	2	1	1.33	1	3	1	1.67	1	3	1	1.67
UNF	0	1	1	0.67	0	2	2	1.33	0	1	1	0.67
UN	1	1	1	1.00	1	1	2	1.33	1	1	1	1.00
UNB	0	1	1	0.67	0	1	1	0.67	1	0	1	0.67
UB	3	2	3	2.67	3	2	2	2.33	3	3	2	2.67
UPB	3	2	3	2.67	3	3	3	3.00	3	3	2	2.67
P	2	3	3	2.67	3	3	3	3.00	3	3	3	3.00

PF	3	2	2	2.33	3	3	3	3.00	3	3	2	2.67
F	3	2	2	2.33	3	3	3	3.00	2	4	2	2.67
NF	3	3	2	2.67	3	3	2	2.67	1	3	2	2.00
N	0	0	0	0.00	0	1	0	0.33	0	1	1	0.67
NB	0	0	0	0.00	1	0	0	0.33	0	0	0	0.00
B	1	2	0	1.00	2	1	0	1.00	1	1	1	1.00
PB	3	3	3	3.00	3	2	3	2.67	3	3	2	2.67
DP	3	2	3	2.67	3	3	2	2.67	3	3	2	2.67
DPF	3	3	3	3.00	3	3	3	3.00	3	3	2	2.67
DF	3	1	2	2.00	2	1	3	2.00	3	1	2	2.00
DNF	1	0	0	0.33	1	0	0	0.33	1	0	1	0.67
DN	0	0	0	0.00	0	0	0	0.00	0	1	1	0.67
DNB	0	0	0	0.00	0	0	1	0.33	0	0	1	0.33
DB	3	0	0	1.00	3	0	1	1.33	3	1	1	1.67
DPB	3	3	3	3.00	3	3	2	2.67	3	3	3	3.00
D	0	2	1	1.00	0	1	0	0.33	0	1	1	0.67

Table 6-12 Internal ratings 2: experiment session 2

Compared to the first round of rating, the participants made some corrections by rating the items with 1 score higher or lower. In two cases, the correction was more than 1 score. In both cases, P3 did not provide a score for P1 in the first round, however rated those items in the second round.

The change of scores in the second round compared to the first round is shown in the table 6-13.

Code	P1 by P1	P1 by P2	P1 by P3	P2 by P1	P2 by P2	P2 by P3	P3 by P1	P3 by P2	P3 by P3
U	0	0	2	0	0	0	0	0	0
UP	0	0	3	0	0	0	0	0	0
UPF	-1	1	0	0	-1	0	0	0	1
UF	-1	1	-1	-1	1	0	-1	1	0
UNF	0	1	0	-1	0	1	0	0	0
UN	1	1	0	1	1	1	1	1	0
UNB	0	0	0	-1	0	0	1	-1	0
UB	0	-1	0	0	0	0	0	0	0
UPB	0	0	0	-1	0	0	0	1	0
P	-1	-1	0	0	0	0	0	-1	0
PF	0	0	-1	-1	0	0	0	0	0
F	0	-1	0	0	-1	0	-1	0	0
NF	0	0	0	1	1	0	-2	1	0
N	0	0	-1	0	1	0	0	1	0

NB	0	0	-1	1	0	0	0	0	0
B	1	1	-1	1	0	0	1	0	0
PB	0	0	0	0	0	0	-1	0	0
DP	0	0	1	0	0	0	0	1	0
DPF	0	0	1	0	0	0	0	0	0
DF	0	0	0	-1	0	1	1	0	0
DNF	0	0	0	0	0	0	0	0	1
DN	0	0	0	0	0	0	0	1	0
DNB	0	0	0	0	0	1	0	0	0
DB	0	0	0	0	0	1	0	0	0
DPB	0	1	0	0	0	-1	-1	0	1
D	0	1	0	0	0	-1	0	-1	0

Table 6-13 Internal rating 1 vs. 2: experiment session 2

6.2.4 Control group/ test device 2

6.2.4.1 Internal ratings: first round

Details of the first round rating by the participants are summarized in table 6-14.

Code	P1 by P1	P1 by P2	P1 by P3	P1 Average P	P2 by P1	P2 by P2	P2 by P3	P2 Average P	P3 by P1	P3 by P2	P3 by P3	P3 Average P
U	3	3	3	3.00	4	3	3	3.33	2	3	3	2.67
UP	3	4	4	3.67	4	3	4	3.67	4	4	3	3.67
UPF	4	3	2	3.00	4	2	3	3.00	3	3	2	2.67
UF	1	2	1	1.33	2	2	2	2.00	3	3	2	2.67
UNF	0	1	1	0.67	0	1	2	1.00	0	0	2	0.67
UN	2	1	1	1.33	1	1	1	1.00	1	1	2	1.33
UNB	1	1	0	0.67	0	1	0	0.33	1	0	1	0.67
UB	4	2	2	2.67	3	2	3	2.67	4	3	1	2.67
UPB	4	2	3	3.00	3	2	4	3.00	4	3	3	3.33
P	4	3	4	3.67	4	3	4	3.67	4	3	3	3.33
PF	3	3	3	3.00	4	3	3	3.33	4	3	2	3.00
F	3	2	3	2.67	3	3	3	3.00	3	3	2	2.67
NF	4	2	2	2.67	2	3	3	2.67	2	4	3	3.00
N	0	0	0	0.00	0	0	0	0.00	0	0	1	0.33
NB	0	0	0	0.00	0	1	0	0.33	0	0	1	0.33
B	1	2	0	1.00	0	1	0	0.33	3	1	2	2.00

PB	3	3	4	3.33	4	2	4	3.33	4	3	3	3.33
DP	3	3	4	3.33	3	3	3	3.00	4	3	2	3.00
DPF	3	4	4	3.67	4	3	3	3.33	4	3	3	3.33
DF	3	1	3	2.33	3	1	3	2.33	3	2	2	2.33
DNF	3	0	0	1.00	1	1	0	0.67	1	1	0	0.67
DN	0	0	0	0.00	0	0	0	0.00	0	0	1	0.33
DNB	0	0	0	0.00	0	1	0	0.33	0	1	0	0.33
DB	4	0	0	1.33	4	0	0	1.33	3	1	1	1.67
DPB	4	4	3	3.67	4	4	3	3.67	4	4	2	3.33
D	0	1	1	0.67	0	2	0	0.67	0	1	1	0.67

Table 6-14 Internal ratings 1: experiment session 3

After completion of the first round of rating, the participants exchanged the rating forms to view the results by the other group members, followed by the group discussion.

6.2.4.2 Group discussion

During the group discussion, the following questions were answered by the participants.

Q1 How do you feel about working in a group?

All participants found the group work positive, especially with the pleasant relationship among the group members. It was also perceived as a benefit that each group member could contribute with his own expertise.

Q2 Do you prefer to work in a group or on your own?

None of the participants seemed to have a clear preference. Two participants found a combination of both good, so that each individual could develop his/her own solutions first, then cross-examine and combine those ideas in the subsequent group work.

Q3 Did you feel comfortable during the solution-seeking process in the experiment?

All participants perceived the experiment as pleasant.

Q4 How would you describe the status of the solution-seeking process in the beginning, in the middle and at the end of the session?

In the beginning, it took time to reach a common understanding of the technical issues. The discussion was repeated in the middle and at the end of the session, because one

participant felt it was necessary to clarify the interconnections of identified solutions. The focus on solution finding was stronger in the middle and at the end of the session.

Q5 When was the most innovative moment?

To all participants the use of QR-code was the most innovative idea. Till this idea came across, all proposals were experience-driven as modifications to the existing solutions. QR-code suggested the application of a new technology that had not been used in the observed field of research and development.

Q6 Would a moderator, facilitator or a group leader be helpful for the group work?

No hierarchy was considered necessary. At times, some group member appeared more dominant, therefore a moderator could be helpful in giving each member the equal opportunity to contribute to the group work.

Q7 Did you need more time or guidance?

More time would be helpful, more guidance was not considered necessary.

The participants did not make further assertions.

6.2.4.3 Internal ratings: second round

After the group discussion, the participants filled out the SYMLOG Adjective Rating Form for a second time. The results are summarised in table 6-15.

Code	P1 by P1	P1 by P2	P1 by P3	P1 Average P	P2 by P1	P2 by P2	P2 by P3	P2 Average P	P3 by P1	P3 by P2	P3 by P3	P3 Average P
U	3	3	3	3.00	3	3	3	3.00	3	3	3	3.00
UP	4	3	3	3.33	3	3	3	3.00	4	4	3	3.67
UPF	3	3	3	3.00	4	3	3	3.33	3	3	2	2.67
UF	0	1	1	0.67	2	2	2	2.00	1	2	1	1.33
UNF	0	0	1	0.33	0	1	1	0.67	0	0	1	0.33
UN	1	0	1	0.67	0	1	1	0.67	1	1	1	1.00
UNB	0	1	1	0.67	1	1	0	0.67	0	1	1	0.67
UB	4	2	3	3.00	3	3	3	3.00	4	3	2	3.00
UPB	3	3	3	3.00	3	2	3	2.67	3	3	2	2.67
P	3	3	3	3.00	3	3	3	3.00	3	4	2	3.00
PF	3	2	3	2.67	3	3	3	3.00	3	3	3	3.00
F	4	2	2	2.67	3	3	3	3.00	3	4	3	3.33
NF	3	3	2	2.67	2	3	3	2.67	3	3	2	2.67
N	0	0	0	0.00	0	1	0	0.33	0	0	1	0.33

NB	0	0	0	0.00	0	0	0	0.00	0	0	1	0.33
B	0	1	0	0.33	0	1	0	0.33	1	1	2	1.33
PB	4	3	3	3.33	4	2	3	3.00	4	3	2	3.00
DP	3	3	3	3.00	3	3	3	3.00	3	3	2	2.67
DPF	3	3	3	3.00	4	3	3	3.33	3	3	3	3.00
DF	3	2	2	2.33	3	1	3	2.33	3	2	2	2.33
DNF	2	0	0	0.67	2	0	0	0.67	1	0	1	0.67
DN	0	0	0	0.00	0	0	0	0.00	0	0	1	0.33
DNB	0	0	0	0.00	0	0	0	0.00	0	0	1	0.33
DB	3	0	0	1.00	3	0	0	1.00	3	0	1	1.33
DPB	3	4	3	3.33	3	3	3	3.00	3	4	2	3.00
D	0	2	1	1.00	0	1	0	0.33	0	2	1	1.00

Table 6-15 Internal ratings 2: experiment session 3

Compared to the first round of rating, the participants made some corrections by rating the items with 1 score higher or lower. In two cases, the correction was more than 1 score. In both cases, P1 reduced the rating for P3 by 2 scores.

The changes of scores in the second round compared to the first round are shown in the table 6-16.

Code	P1 by P1	P1 by P2	P1 by P3	P2 by P1	P2 by P2	P2 by P3	P3 by P1	P3 by P2	P3 by P3
U	0	0	0	-1	0	0	1	0	0
UP	1	-1	-1	-1	0	-1	0	0	0
UPF	-1	0	1	0	1	0	0	0	0
UF	-1	-1	0	0	0	0	-2	-1	-1
UNF	0	-1	0	0	0	-1	0	0	-1
UN	-1	-1	0	-1	0	0	0	0	-1
UNB	-1	0	1	1	0	0	-1	1	0
UB	0	0	1	0	1	0	0	0	1
UPB	-1	1	0	0	0	-1	-1	0	-1
P	-1	0	-1	-1	0	-1	-1	1	-1
PF	0	-1	0	-1	0	0	-1	0	1
F	1	0	-1	0	0	0	0	1	1
NF	-1	1	0	0	0	0	1	-1	-1
N	0	0	0	0	1	0	0	0	0
NB	0	0	0	0	-1	0	0	0	0
B	-1	-1	0	0	0	0	-2	0	0
PB	1	0	-1	0	0	-1	0	0	-1
DP	0	0	-1	0	0	0	-1	0	0
DPF	0	-1	-1	0	0	0	-1	0	0

DF	0	1	-1	0	0	0	0	0	0
DNF	-1	0	0	1	-1	0	0	-1	1
DN	0	0	0	0	0	0	0	0	0
DNB	0	0	0	0	-1	0	0	-1	1
DB	-1	0	0	-1	0	0	0	-1	0
DPB	-1	0	0	-1	-1	0	-1	0	0
D	0	1	0	0	-1	0	0	1	0

Table 6-16 Internal ratings 1 vs. 2: experiment session 3

6.2.5 Test group/ test device 2

6.2.5.1 Internal ratings: first round

In the first round rating by the participants, all three participants rated each item, however in three cases, the participant P5 did not deliver an answer for P4, P5 did not rate himself and P5 did not delivered a rating for P6 (see table 6-17).

Code	P4 by P4	P4 by P5	P4 by P6	P4 Average P	P5 by P4	P5 by P5	P5 by P6	P5 Average P	P6 by P4	P6 by P5	P6 by P6	P6 Average P
U	3	3	3	3.00	4	3	3	3.33	4	4	4	4.00
UP	3	3	4	3.33	3	3	4	3.33	4	4	4	4.00
UPF	3	3	2	2.67	3	1	2	2.00	4	4	3	3.67
UF	1	0	1	0.67	0	1	1	0.67	1		2	1.50
UNF	0	1	0	0.33	0	0	0	0.00	0	0	0	0.00
UN	2	2	0	1.33	1	1	0	0.67	3	4	0	2.33
UNB	0		0	0.00	0	1	0	0.33	0	0	0	0.00
UB	3	3	3	3.00	3	2	4	3.00	4	3	2	3.00
UPB	4	4	4	4.00	3	3	4	3.33	4	4	4	4.00
P	4	3	4	3.67	3	3	4	3.33	4	4	4	4.00
PF	3	3	4	3.33	3	4	4	3.67	4	4	3	3.67
F	3	3	3	3.00	4	3	3	3.33	4	4	4	4.00
NF	3	3	2	2.67	4	3	2	3.00	4	4	2	3.33
N	0	0	0	0.00	0	1	0	0.33	0	0	0	0.00
NB	0	0	0	0.00	0	1	0	0.33	0	0	0	0.00
B	1	1	0	0.67	1		0	0.50	0	0	0	0.00
PB	3	4	3	3.33	3	2	4	3.00	3	3	2	2.67
DP	2	3	4	3.00	3	2	4	3.00	4	3	4	3.67
DPF	3	3	3	3.00	3	2	4	3.00	4	4	3	3.67
DF	2	3	2	2.33	4	3	3	3.33	4	4	2	3.33
DNF	2	2	0	1.33	1	2	0	1.00	1	2	0	1.00
DN	1	0	0	0.33	0	1	0	0.33	0	0	0	0.00

DNB	1	1	0	0.67	0	2	0	0.67	0	1	0	0.33
DB	1	1	0	0.67	0	2	0	0.67	0	1	0	0.33
DPB	2	1	3	2.00	3	3	3	3.00	4	1	4	3.00
D	1	0	0	0.33	0	2	0	0.67	0	0	0	0.00

Table 6-17 Internal rating 1: experiment session 4

After completion of the rating, the participants exchanged the rating forms to view the results by the other group members, followed by the group discussion.

6.2.5.2 Group discussion

The group discussion was guided by the following questions.

Q1 How do you feel about working in a group?

Group work was described as positive and pleasant by all participants. Especially for the application of TRIZ, group work was considered more effective, as this gave the members the opportunity to combine their own ideas with those from the others, or further develop the new ideas using the guidance of the TRIZ inventive principles.

Q2 Do you prefer to work in a group or on your own?

All participants preferred group work than working alone. The main benefits of group work were thought to be the mutual supports in terms of supportive inspirations, as well as approving and further development of the individual ideas.

Q3 Did you feel comfortable during the solution-seeking process in the experiment?

The process was perceived by the participants as pleasant. However, the beginning of the session involved some difficulties in reaching a common understanding of the content of the TRIZ inventive principles.

Q4 How would you describe the status of the solution-seeking process in the beginning, in the middle and at the end of the session?

After the tentative beginning where the participants spent some time on achieving a consensus for the content of the inventive principles, new ideas emerged. Most of the ideas were generated in the middle of the session. As it approached the end of the session, the group focused mainly on finalising the ideas and put the results in writing.

Q5 When was the most innovative moment?

The middle part of the group work seemed to be the most innovative during the session.

Q6 Would a moderator, facilitator or a group leader be helpful for the group work?

Free discussions without formal leadership were stated by the participants to be especially helpful. There was no need for a moderator.

Q7 Did you need more time or guidance?

The participants raised concerns of time during the lengthy discussions on the TRIZ techniques at the beginning. However, in the end the time seemed to be sufficient. A prior TRIZ refresher training was considered beneficial.

In addition, the participants asserted that compared with their previous experience with brainstorming, TRIZ seemed to be more effective for the solution of "hard" technical problems. However, brainstorming seemed to be more appropriate for the solution of "soft" issues, e.g. instruction for use or training programmes. Besides, in order to produce good results, at least one of the group members should have a thorough understanding of each relevant technology.

6.2.5.3 Internal ratings: second round

After the group discussion, the participants filled out the SYMLOG Adjective Rating Form for a second time. The results are summarised in table 6-18.

Code	P4 by P4	P4 by P5	P4 by P6	P4 Average P	P5 by P4	P5 by P5	P5 by P6	P5 Average P	P6 by P4	P6 by P5	P6 by P6	P6 Average P
U	3	2	3	2.67	3	1	3	2.33	4	3	4	3.67
UP	3	4	4	3.67	3	4	4	3.67	4	4	4	4.00
UPF	3	2	2	2.33	3	2	2	2.33	4	4	4	4.00
UF	1	1	1	1.00	0	1	1	0.67	1	3	1	1.67
UNF	0	0	0	0.00	0	1	0	0.33	0	1	0	0.33
UN	2	1	0	1.00	3	1	0	1.33	4	3	0	2.33
UNB	0	0	0	0.00	0	1	0	0.33	0	0	0	0.00
UB	3	3	2	2.67	3	2	3	2.67	3	2	3	2.67
UPB	4	4	4	4.00	4	3	4	3.67	4	4	3	3.67
P	4	4	4	4.00	4	3	4	3.67	4	4	4	4.00
PF	4	4	4	4.00	4	3	4	3.67	4	4	4	4.00
F	3	4	2	3.00	4	3	3	3.33	4	4	3	3.67
NF	3	3	2	2.67	4	3	2	3.00	4	3	2	3.00
N	0	0	0	0.00	0	1	0	0.33	0	1	0	0.33
NB	0	0	0	0.00	1	0	0	0.33	1	1	0	0.67

B	1	1	0	0.67	1	0	0	0.33	1	1	0	0.67
PB	4	3	3	3.33	4	2	3	3.00	4	3	3	3.33
DP	3	3	4	3.33	3	2	4	3.00	3	3	3	3.00
DPF	3	3	3	3.00	3	2	4	3.00	4	4	4	4.00
DF	3	3	2	2.67	3	3	2	2.67	3	4	2	3.00
DNF	2	2	1	1.67	2	2	0	1.33	2	2	0	1.33
DN	0	1	0	0.33	0	0	0	0.00	0	1	0	0.33
DNB	0	1	0	0.33	0	1	0	0.33	0	0	0	0.00
DB	0	2	0	0.67	1	2	0	1.00	0	0	0	0.00
DPB	2	2	3	2.33	3	1	3	2.33	4	2	3	3.00
D	1	2	0	1.00	0	2	0	0.67	0	0	0	0.00

Table 6-18 Internal rating 2: experiment session 4

Compared to the first round of rating, the participants made some corrections by rating the items with 1 score higher or lower. In four cases, the correction was made by 2 scores. In a further case, the deviate was "3" because the rating was only given in the second round.

The changes of scores in the second round compared to the first round are shown in the table 6- 19.

Code	P4 by P4	P4 by P5	P4 by P6	P4 Average P	P5 by P4	P5 by P5	P5 by P6	P5 Average P	P6 by P4	P6 by P5	P6 by P6
U	0	-1	0	0	-1	-2	0	-1	0	-1	0
UP	0	1	0	0	0	1	0	0	0	0	0
UPF	0	-1	0	0	0	1	0	0	0	0	1
UF	0	1	0	0	0	0	0	0	0	3	-1
UNF	0	-1	0	0	0	1	0	0	0	1	0
UN	0	-1	0	0	2	0	0	1	1	-1	0
UNB	0	0	0	0	0	0	0	0	0	0	0
UB	0	0	-1	0	0	0	-1	0	-1	-1	1
UPB	0	0	0	0	1	0	0	0	0	0	-1
P	0	1	0	0	1	0	0	0	0	0	0
PF	1	1	0	1	1	-1	0	0	0	0	1
F	0	1	-1	0	0	0	0	0	0	0	-1
NF	0	0	0	0	0	0	0	0	0	-1	0
N	0	0	0	0	0	0	0	0	0	1	0
NB	0	0	0	0	1	-1	0	0	1	1	0
B	0	0	0	0	0	0	0	0	1	1	0
PB	1	-1	0	0	1	0	-1	0	1	0	1
DP	1	0	0	0	0	0	0	0	-1	0	-1
DPF	0	0	0	0	0	0	0	0	0	0	1
DF	1	0	0	0	-1	0	-1	-1	-1	0	0
DNF	0	0	1	0	1	0	0	0	1	0	0
DN	-1	1	0	0	0	-1	0	0	0	1	0
DNB	-1	0	0	0	0	-1	0	0	0	-1	0
DB	-1	1	0	0	1	0	0	0	0	-1	0

DPB	0	1	0	0	0	-2	0	-1	0	1	-1
D	0	2	0	1	0	0	0	0	0	0	0

Table 6-19 Internal rating 1 vs. 2: experiment session 4

6.2.6 External rating

The experiment sessions were also evaluated by two raters based on the video recordings, using the SYMLOG Adjective Rating Form.

Prior to the evaluation, the raters reached a consensus on how scores should be given by discussing on the standards for different levels of each item in the form. They tested the standard with two sample sessions. Subsequently, they conducted the rating independently from each other.

The results of the external rating are listed in the table 6-20, table 6-21, table 6-22 and table 6-23.

Session 1: Control group/ test device 1

Code	P4 by Rater 1	P4 by Rater 2	P4 Average R	P5 by Rater 1	P5 by Rater 2	P5 Average R	P6 by Rater 1	P6 by Rater 2	P6 Average R
U	3	3	3.00	2	3	2.50	4	3	3.50
UP	4	4	4.00	2	4	3.00	4	3	3.50
UPF	3	2	2.50	1	2	1.50	4	3	3.50
UF	1	0	0.50	1	2	1.50	1	2	1.50
UNF	2	0	1.00	1	0	0.50	1	0	0.50
UN	2	0	1.00	2	0	1.00	2	0	1.00
UNB	1	0	0.50	0	0	0.00	0	0	0.00
UB	3	1	2.00	3	2	2.50	3	2	2.50
UPB	4	3	3.50	4	3	3.50	4	3	3.50
P	4	3	3.50	4	3	3.50	4	3	3.50
PF	3	3	3.00	3	3	3.00	3	3	3.00
F	2	2	2.00	2	3	2.50	4	3	3.50
NF	3	2	2.50	4	2	3.00	4	2	3.00
N	0	0	0.00	1	0	0.50	1	0	0.50
NB	0	0	0.00	2	0	1.00	0	0	0.00
B	2	0	1.00	1	0	0.50	0	0	0.00
PB	4	2	3.00	2	2	2.00	3	2	2.50
DP	3	2	2.50	4	3	3.50	4	3	3.50
DPF	4	2	3.00	2	3	2.50	3	3	3.00
DF	2	2	2.00	1	2	1.50	3	2	2.50
DNF	1	0	0.50	2	0	1.00	2	0	1.00
DN	2	0	1.00	1	0	0.50	1	0	0.50
DNB	1	0	0.50	3	0	1.50	1	0	0.50
DB	0	0	0.00	2	0	1.00	0	0	0.00
DPB	3	2	2.50	3	2	2.50	3	3	3.00

D	1	0	0.50	3	0	1.50	1	0	0.50

Table 6-20 External rating: experiment session 1

Session 2: Test group/ test device 1

Code	P1 by Rater 1	P1 by Rater 2	P1 Average R	P2 by Rater 1	P2 by Rater 2	P2 Average R	P3 by Rater 1	P3 by Rater 2	P3 Average R
U	1	2	1.50	3	3	3.00	3	3	3.00
UP	2	3	2.50	4	4	4.00	4	4	4.00
UPF	2	2	2.00	3	3	3.00	4	3	3.50
UF	1	0	0.50	2	1	1.50	1	1	1.00
UNF	0	0	0.00	1	0	0.50	1	0	0.50
UN	0	0	0.00	0	0	0.00	2	0	1.00
UNB	0	0	0.00	0	0	0.00	0	0	0.00
UB	3	2	2.50	2	2	2.00	4	2	3.00
UPB	2	3	2.50	3	4	3.50	4	3	3.50
P	3	3	3.00	3	4	3.50	4	4	4.00
PF	1	3	2.00	4	4	4.00	3	3	3.00
F	3	2	2.5	2	3	2.5	4	3	3.50
NF	2	1	1.50	3	2	2.50	3	2	2.50
N	0	0	0.00	1	0	0.50	1	0	0.50
NB	0	0	0.00	0	0	0.00	0	0	0.00
B	0	0	0.00	0	0	0.00	0	0	0.00
PB	4	2	3.00	2	0	1.00	4	3	3.50
DP	3	2	2.50	3	4	3.50	3	3	3.00
DPF	2	2	2.00	4	3	3.50	3	3	3.00
DF	1	1	1.00	2	2	2.00	2	2	2.00
DNF	0	0	0.00	0	0	0.00	0	0	0.00
DN	1	0	0.50	1	0	0.50	1	0	0.50
DNB	1	0	0.50	0	0	0.00	0	0	0.00
DB	1	0	0.50	1	0	0.50	0	0	0.00
DPB	3	2	2.50	3	3	3.00	4	3	3.50
D	2	0	1.00	0	0	0.00	1	0	0.50

Table 6-21 External rating: experiment session 2

Session 3: Control group/ test device 2

Code	P1 by Rater 1	P1 by Rater 2	P1 Average R	P2 by Rater 1	P2 by Rater 2	P2 Average R	P3 by Rater 1	P3 byRater 2	P3 Average R
U	2	2	2.00	3	3	3.00	4	3	3.50
UP	4	3	3.50	2	4	3.00	4	3	3.50
UPF	1	1	1.00	1	2	1.50	4	3	3.50
UF	1	0	0.50	2	1	1.50	1	1	1.00
UNF	0	0	0.00	0	0	0.00	0	0	0.00
UN	0	0	0.00	0	0	0.00	3	0	1.50
UNB	0	0	0.00	0	0	0.00	0	0	0.00
UB	4	2	3.00	2	2	2.00	4	1	2.50
UPB	4	2	3.00	3	3	3.00	4	2	3.00
P	4	3	3.50	4	4	4.00	3	4	3.50
PF	3	2	2.50	2	4	3.00	3	2	2.50
F	4	2	3.00	3	3	3.00	4	3	3.50
NF	3	1	2.00	3	2	2.50	3	3	3.00
N	1	0	0.50	1	0	0.50	0	0	0.00
NB	0	0	0.00	0	0	0.00	0	0	0.00
B	0	0	0.00	0	0	0.00	0	0	0.00
PB	4	0	2.00	2	2	2.00	4	2	3.00
DP	3	3	3.00	3	3	3.00	4	2	3.00
DPF	3	3	3.00	2	4	3.00	3	2	2.50
DF	2	2	2.00	1	2	1.50	2	2	2.00
DNF	0	0	0.00	0	0	0.00	1	0	0.50
DN	0	0	0.00	1	0	0.50	0	0	0.00
DNB	1	0	0.50	1	0	0.50	0	0	0.00
DB	1	0	0.50	0	0	0.00	1	0	0.50
DPB	4	2	3.00	3	2	2.50	4	2	3.00
D	2	0	1.00	0	0	0.00	1	0	0.50

Table 6-22 External rating: experiment session 3

Session 4: Test group/ test device 2

Code	P4 by Rater 1	P4 by Rater 2	P4 Average R	P5 by Rater 1	P5 by Rater 2	P5 Average R	P6 by Rater 1	P6 by Rater 2	P6 Average R
U	3	3	3.00	1	3	2.00	4	3	3.50
UP	2	3	2.50	1	3	2.00	4	4	4.00
UPF	3	2	2.50	2	2	2.00	4	3	3.50
UF	2	1	1.50	2	2	2.00	4	2	3.00
UNF	1	0	0.50	1	0	0.50	3	0	1.50
UN	1	0	0.50	1	0	0.50	4	0	2.00
UNB	2	0	1.00	0	0	0.00	1	0	0.50
UB	3	2	2.50	2	2	2.00	3	2	2.50
UPB	4	3	3.50	3	3	3.00	4	3	3.50
P	4	3	3.50	4	3	3.50	3	4	3.50
PF	2	3	2.50	2	3	2.50	2	3	2.50
F	3	2	2.50	4	2	3.00	4	3	3.50
NF	4	2	3.00	3	2	2.50	4	3	3.50
N	0	0	0.00	0	0	0.00	1	0	0.50
NB	1	0	0.50	1	0	0.50	2	0	1.00
B	1	0	0.50	0	0	0.00	1	0	0.50
PB	4	3	3.50	3	2	2.50	4	2	3.00
DP	1	3	2.00	4	3	3.50	4	3	3.50
DPF	2	3	2.50	4	3	3.50	3	3	3.00
DF	1	2	1.50	2	2	2.00	1	2	1.50
DNF	0	0	0.00	1	0	0.50	1	0	0.50
DN	1	0	0.50	0	0	0.00	0	0	0.00
DNB	2	0	1.00	1	0	0.50	0	0	0.00
DB	1	0	0.50	2	0	1.00	0	0	0.00
DPB	3	2	2.50	3	2	2.50	3	3	3.00
D	1	0	0.50	1	0	0.50	0	0	0.00

Table 6-23 External rating: experiment session 4

6.2.7 Assessment of process

6.2.7.1 External rating vs. internal rating

The results of the external ratings are compared with the internal ratings in the following graphics.

The x-axis illustrates the dimension P-N (= Positive – Negative) in the SYMLOG Adjective Rating method and describes if the observed person is friendly (P) or unfriendly (N). The y-axis demonstrates dimension F-B (= Forward – Backward) and shows if the observed person is instrumentally controlled (F) or emotionally expressive (B). The size of the bubbles represent dimension U-D (= Upward – Downward) and depicts how actively the observed person exerts influence on the observed event, ranging from dominant (U) to submissive (D).

Session 1 (test device 1/ brainstorming)

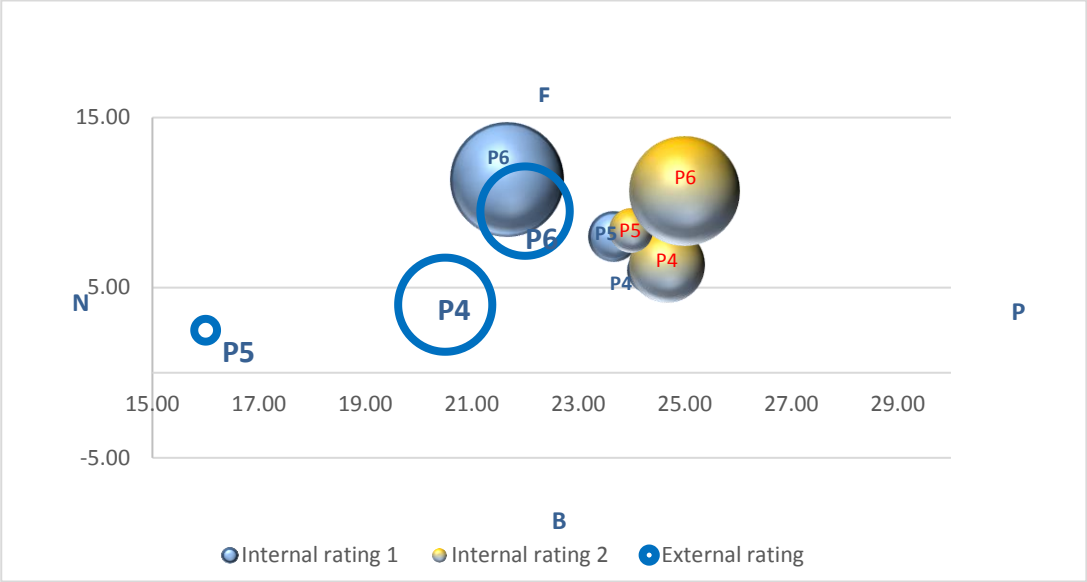

Figure 6-1 **Ratings in session 1 (test device 1/ brainstorming)**

The behaviour of all participants during this session was perceived as positive (dimension P-N), instrumentally controlled (dimension F-B) and active (dimension U-D) by both internal and external ratings.

In the second round of internal rating, P6 appeared to be more positive than in the first round and was perceived as the friendliest person (highest value in dimension P-N) in the group. This opinion was also shared by the external raters. According to the external raters, the behaviour of P5 was less positive than the others. However, the group members did not seem to have noticed such essential difference in each other's behaviour in this aspect.

P6 was also perceived as the most task-oriented (dimension F-B) participant of the session in all internal and external ratings. Furthermore, while P6 was judged by the group members as the leading person (the highest value in dimension U-D), while the external raters evaluated P4 as almost as dominant as P6.

(See figure 6-1).

Session 2 (test device 1/ TRIZ)

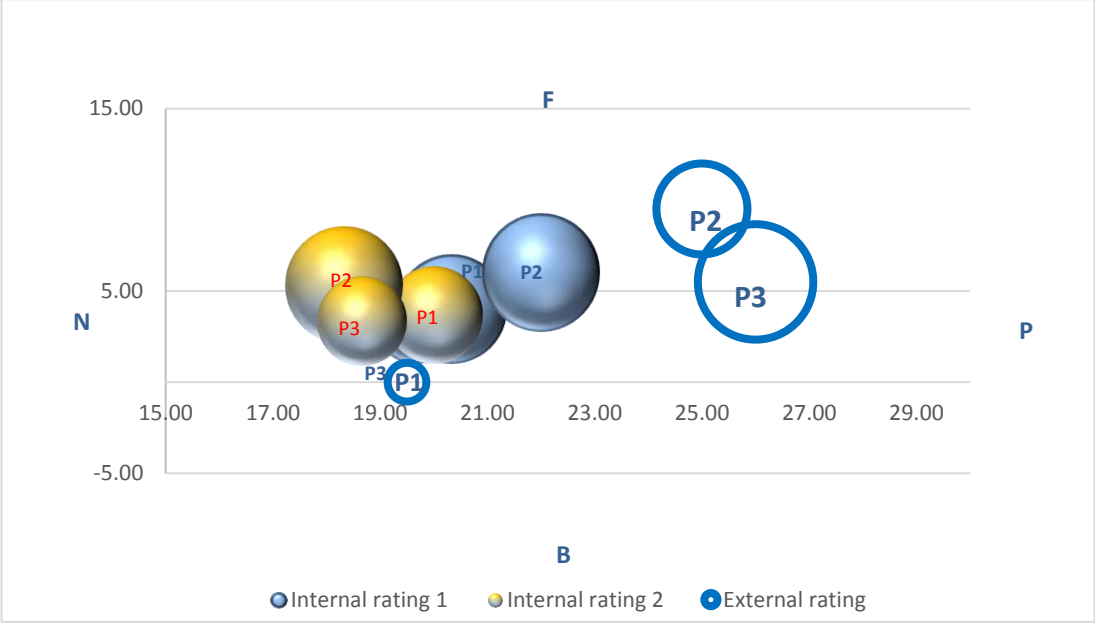

Figure 6-2 **Ratings in session 2 (test device 1/ TRIZ)**

Like in session 1, the behaviours of all participants during this session were perceived as positive (dimension P-N), instrumentally controlled (dimension F-B) and active (dimension U-D) by both internal and external ratings.

In all ratings, all participants illustrated a similar level of friendliness (dimension P-N), task-orientation (dimension F-B) and active participation (dimension U-D). Exceptionally, according to the external rating, P1 was less positive, less instrumentally controlled and less active than the others.

(See figure 6-2).

Session 3 (test device 2/ brainstorming)

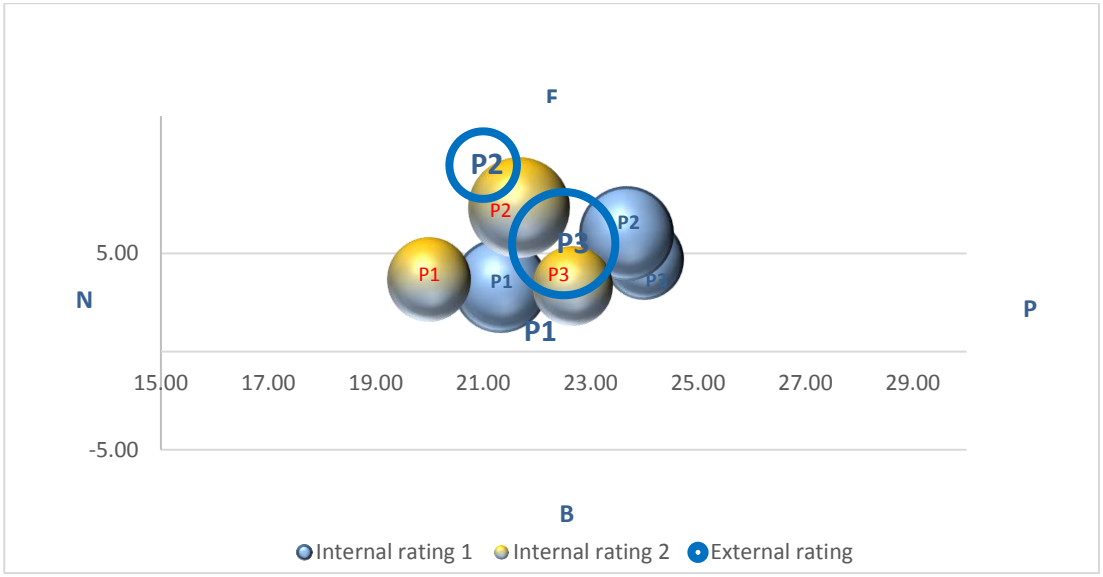

Figure 6-3 **Ratings in session 3 (test device 2/ brainstorming)**

The participation of all members seemed to have been positive (dimension P-N), instrumentally controlled (dimension F-B) and active (dimension U-D) according to the internal and external ratings.

In both internal and external rating, P3 was seen as the friendliest (dimension P-N) and P2 the most task-oriented (dimension F-B) among all participants. Although to the group members, each individual played a similarly active role in the group work, the external raters recognised a difference. To them, P3 was clearly more dominant than the others, while P1 was hardly active at all.

(See figure 6-3).

Session 4 (test device 2/ TRIZ)

Also in the last session, the behaviour of all participants during this session was perceived as positive (dimension P-N), instrumentally controlled (dimension F-B) and active (dimension U-D) by both internal and external ratings

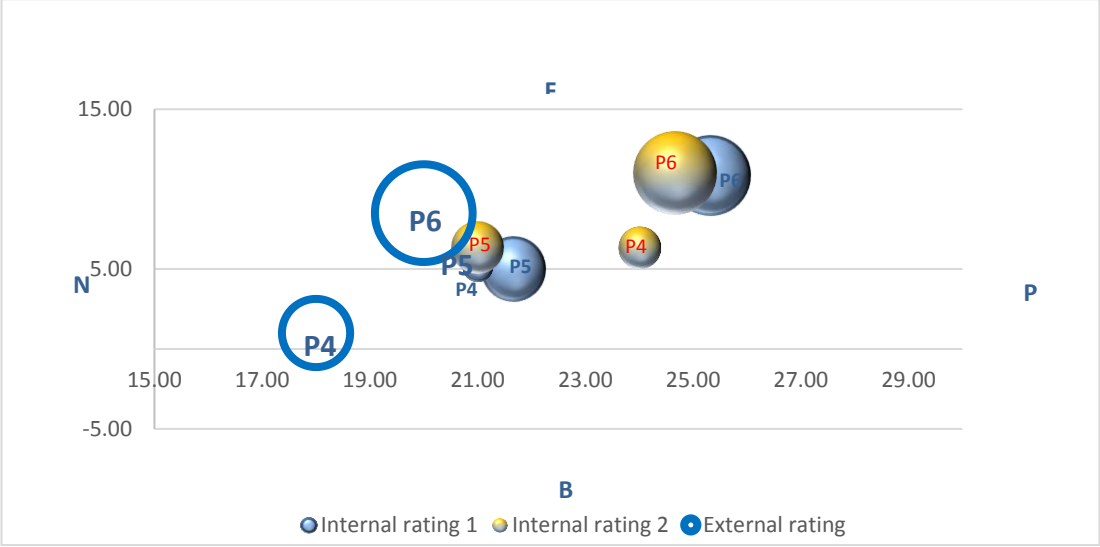

Figure 6-4 **Ratings in session 4 (test device 2/ TRIZ)**

In both internal and external ratings, P6 was essentially more positive (dimension P-N), more task-oriented (dimension F-B) and more dominant (dimension U-D) than the others.

(See figure 6-4).

For each session in each dimension, the participants' scores were put into ranks. The results are shown in table 6-24.

No.	Session	Dimension	Participant	Rank IR1	Rank IR2	Rank ER	Rank IR1 vs. IR2	Rank IR1 vs. ER	Rank IR2 vs. ER
1	1	F-B	P4	3	3	2	0	1	1
2	1	F-B	P5	2	2	3	0	1	1
3	1	F-B	P6	1	1	1	0	0	0
4	1	P-N	P4	1	1	2	0	1	1
5	1	P-N	P5	3	2	3	1	0	1
6	1	P-N	P6	2	3	1	1	1	2
7	1	U-D	P4	2	2	1	0	1	1
8	1	U-D	P5	3	3	3	0	0	0
9	1	U-D	P6	1	1	2	0	1	1
10	2	F-B	P1	2	3	3	1	1	0
11	2	F-B	P2	1	2	1	1	0	1
12	2	F-B	P3	3	1	2	2	1	1

13	2	P-N	P1	2	2	3	0	1	1
14	2	P-N	P2	1	3	2	2	1	1
15	2	P-N	P3	3	1	1	2	2	0
16	2	U-D	P1	2	3	3	1	1	0
17	2	U-D	P2	1	2	2	1	1	0
18	2	U-D	P3	3	1	1	2	2	0
19	3	F-B	P1	2	3	3	1	1	0
20	3	F-B	P2	1	1	2	0	1	1
21	3	F-B	P3	3	2	1	1	2	1
22	3	P-N	P1	1	1	2	0	1	1
23	3	P-N	P2	3	3	3	0	0	0
24	3	P-N	P3	2	2	1	0	1	1
25	3	U-D	P1	2	3	3	1	1	0
26	3	U-D	P2	3	2	2	1	1	0
27	3	U-D	P3	1	1	1	0	0	0
28	4	F-B	P4	2	2	3	0	1	1
29	4	F-B	P5	3	2	2	1	1	0
30	4	F-B	P6	1	1	1	0	0	0
31	4	P-N	P4	2	1	3	1	1	2
32	4	P-N	P5	3	2	2	1	1	0
33	4	P-N	P6	1	3	2	2	1	1
34	4	U-D	P4	2	2	2	0	0	0
35	4	U-D	P5	3	3	3	0	0	0
36	4	U-D	P6	1	1	1	0	0	0

Table 6-24 External rating vs. internal rating in ranks

Comparing with the first round, in 18 out of 36 cases, the ranks remained unchanged, 13 were modified by one rank and 5 by two ranks in the second round of internal rating. Thus it may be said that the participants made moderate corrections to their perceptions after the group discussion which disclosed the results of the first round of rating.

In 10 out of 36 cases, the external rating rank was identical with the first round of internal rating. Compared with the first round of internal rating, the rank in the external rating was different by 1 rank in 23 cases and by 2 ranks in 3 cases.

In 18 out of 36 cases, the external rating rank was identical with the second round of internal rating. Compared with the second round of internal rating, the rank in the external rating was different by 1 rank in 16 cases and by 2 ranks in 2 cases.

The results of the comparisons between the external rating and the two rounds of internal rating indicated that the deviations between the perception of the participants and the independent raters were reduced in the second round of internal rating. A possible explanation for this effect is that the participants' perceptions became more objective after

publicly viewing the results of the first round of rating. Thus the results of the second round of internal rating became closer to the potentially more objective external rating.

No.	Session	Participant	Rank IR1	Rank IR2	Rank ER	Rank IR1 vs. IR2	Rank IR1 vs. ER	Rank IR2 vs. ER
1	1	P4	3	3	2	0	1	1
2	1	P5	2	2	3	0	1	1
3	1	P6	1	1	1	0	0	0
4	3	P1	2	3	3	1	1	0
5	3	P2	1	1	2	0	1	1
6	3	P3	3	2	1	1	2	1
7	2	P1	2	3	3	1	1	0
8	2	P2	1	2	1	1	0	1
9	2	P3	3	1	2	2	1	1
10	4	P4	2	2	3	0	1	1
11	4	P5	3	2	2	1	1	0
12	4	P6	1	1	1	0	0	0

Table 6-25 External rating vs. internal rating in ranks: dimension F-B

No.	Session	Participant	Rank IR1	Rank IR2	Rank ER	Rank IR1 vs. IR2	Rank IR1 vs. ER	Rank IR2 vs. ER
1	1	P4	1	1	2	0	1	1
2	1	P5	3	2	3	1	0	1
3	1	P6	2	3	1	1	1	2
4	3	P1	1	1	2	0	1	1
5	3	P2	3	3	3	0	0	0
6	3	P3	2	2	1	0	1	1
7	2	P1	2	2	3	0	1	1
8	2	P2	1	3	2	2	1	1
9	2	P3	3	1	1	2	2	0
10	4	P4	2	1	3	1	1	2
11	4	P5	3	2	2	1	1	0
12	4	P6	1	3	2	2	1	1

Table 6-26 External rating vs. internal rating in ranks: dimension P-N

No.	Session	Participant	Rank IR1	Rank IR2	Rank ER	Rank IR1 vs. IR2	Rank IR1 vs. ER	Rank IR2 vs. ER
1	1	P4	2	2	1	0	1	1
2	1	P5	3	3	3	0	0	0
3	1	P6	1	1	2	0	1	1
4	3	P1	2	3	3	1	1	0
5	3	P2	3	2	2	1	1	0
6	3	P3	1	1	1	0	0	0
7	2	P1	2	3	3	1	1	0
8	2	P2	1	2	2	1	1	0
9	2	P3	3	1	1	2	2	0
10	4	P4	2	2	2	0	0	0
11	4	P5	3	3	3	0	0	0
12	4	P6	1	1	1	0	0	0

Table 6-27 External rating vs. internal rating in ranks: dimension U-D

In the dimension F-B, the first round of internal rating led to the identical ranks as the external rating in 3 cases, different by 1 rank in 8 cases and by 2 ranks in 1 out of 12 cases in total. Compared with the external rating, the second round of internal rating resulted in the identical rank in 5 cases, different by 1 rank in 7 cases and in none of the cases different by 2 ranks (see table 6-25).

In the dimension P-N, the first round of internal rating led to the identical ranks as the external rating in 2 cases, different by 1 rank in 9 cases and by 2 ranks in 1 out of totally 12 cases. Compared with the external rating, the second round of internal rating resulted in the identical rank in 3 cases, different by 1 rank in 7 cases and different by 2 ranks in 2 cases (see table 6-26).

In the dimension U-D, the first round of internal rating resulted in the identical ranks as the external rating in 5 cases, different by 1 rank in 6 cases and by 2 ranks in 1 out of totally 12 cases. Compared with the external rating, the second round of internal rating resulted in the identical rank in 10 cases, different by 1 rank in 2 cases and in none of the cases different by 2 ranks (see table 6-27).

Dimension	Identical	Difference by "1"	Difference by "2"
F-B (IR 1 vs. ER)	3	8	1
F-B (IR 2 vs. ER)	5	7	0
P-N (IR 1 vs. ER)	2	9	1
P-N (IR 2 vs. ER)	3	7	2
U-D (IR 1 vs. ER)	5	6	1
U-D (IR 2 vs. ER)	10	2	0

Table 6-28 External rating vs. internal rating in ranks: summary

Summarizing the above, the results of the second round of internal rating lay closer to the external rating in all three dimensions in comparison to the first round of rating. Furthermore, this development was the strongest in the dimension U-D, moderate in the dimension F-B and slight in the dimension P-N (see table 6-28). This suggested that it was relatively easy for the participants to adjust their views on the individual contribution, however more difficult to change their impression of how friendly each person had been to the others during the experiment sessions. It seemed that with some reservation, the participants were also ready to modify their opinions on how instrumentally controlled the individuals had worked.

6.2.7.2 Test group vs. control group

This section sets out to explore the behaviour of each individual participant at different experiment sessions.

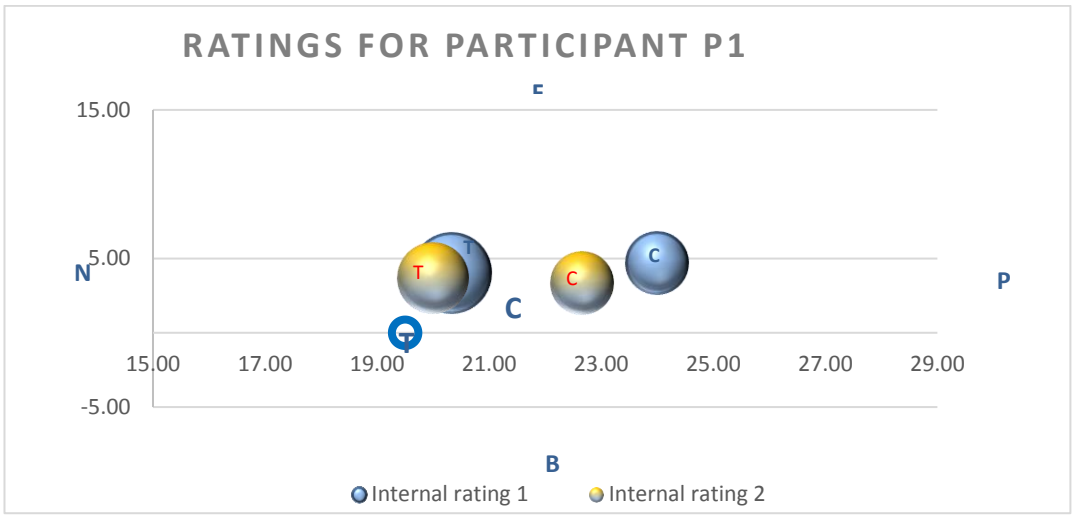

Figure 6-5 Ratings for participant P1

In all internal and external ratings, Participant P1 seemed to have been more dominant during the group work (dimension U-D) in the test session than in the control session. However, P1 was observed to be less pleasant to the other group members in the test session than in the control session (dimension P-N). In perception the fellow group members, the level of task orientation (dimension F-B) in both sessions was almost the same, while to the external raters, it was slightly higher in the control session (see figure 6-5).

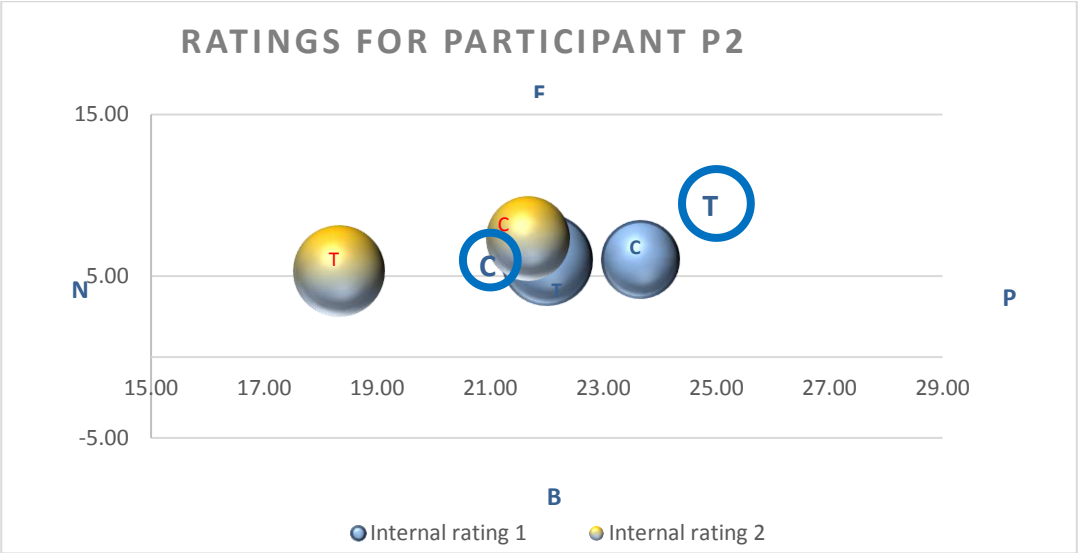

Figure 6-6 **Ratings for participant P2**

Also participant P2 appeared to have inserted more active influence on the group work (dimension U-D) in the test session than in the control session according to both internal and external rating. Although in the observation of the external raters P2 was more positive in the test session than in the control session, the group members perceived P2 as more pleasant in the control session (dimension P-N). The level of task orientation (dimension F-B) in both sessions was similar in the internal rating, however the score was higher in the test session according the external rating (see figure 6-6).

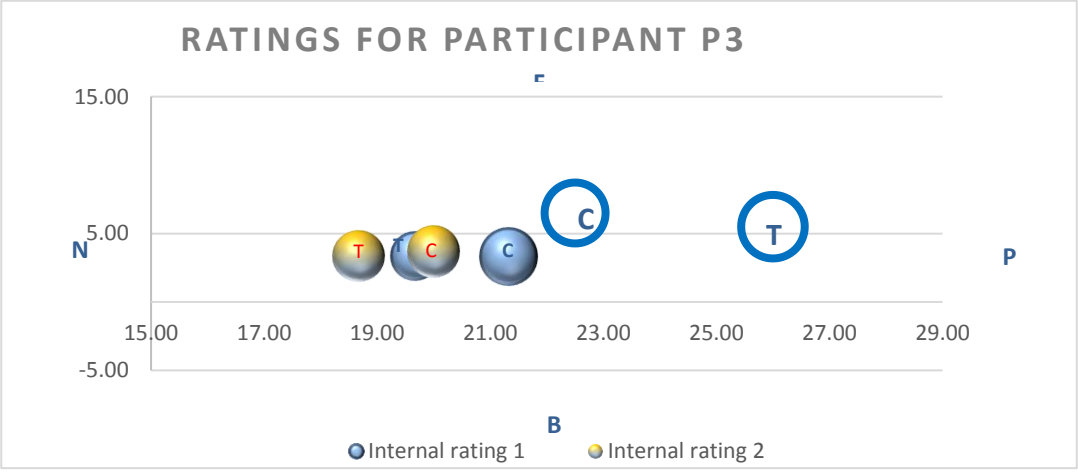

Figure 6-7 **Ratings for participant P3**

In all internal and external ratings, P3 demonstrated a moderate level of active participation at the group work (dimension U-D). According to the external raters, P3 had acted more positively in the test session than in the control session (dimension P-N). However, only a moderate difference in the behaviour of P3 was observed by the group

members in this aspect. Both the internal and the external rating indicated that the level of task orientation (dimension F-B) of P3 was similar in both sessions (see figure 6-7).

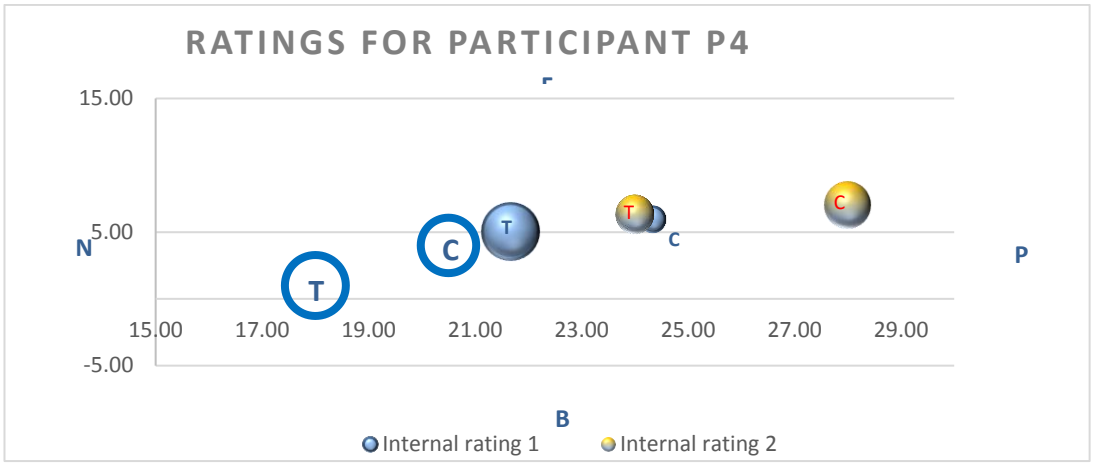

Figure 6-8 **Ratings for participant P4**

The first round of the internal rating suggested that P4 inserted more influence on the group work in the test session (dimension U-D). In the second round of internal rating and also in the external rating, P4 was observed with a similar level of active participation in both sessions. In both internal and external ratings, P4 appeared to be friendlier in the control session than in the test session (dimension P-N). The task orientation (dimension F-B) of P4 was perceived as similar in both sessions in the internal ratings and slightly higher in the control session according to the external rating (see figure 6-8).

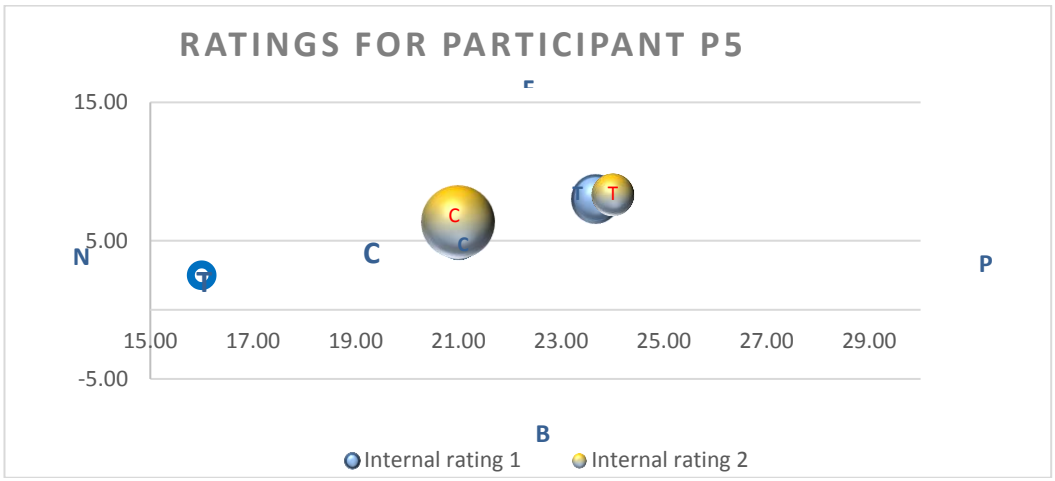

Figure 6-9 **Ratings for participant P5**

The first round of the internal rating suggested that P5 inserted more influence on the group work (dimension U-D) in the test session; however this relation was reversed in the

second round of the internal rating. In the external rating, P5 did not demonstrate any dominance in the process. In the external ratings, P5 appeared to be friendlier in the control session than in the test session (dimension P-N). However, the group members perceived P5 as more positive in the test session than in the control session. The task orientation (dimension F-B) of P5 was observed to be similar in both sessions in the internal ratings and slightly higher in the control session according to the external rating (see figure 6-9).

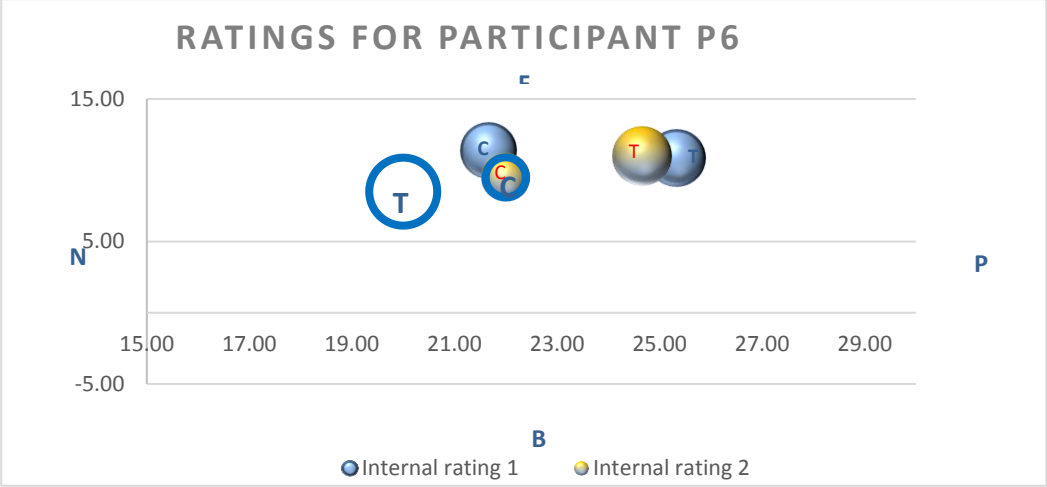

Figure 6-10 **Ratings for participant P6**

Both rounds of internal rating suggested that P6 inserted moderate influence on the group work (dimension U-D) in both sessions. In the external rating, however, P6 was observed to be much more dominant in the test session than in the control session. According to the external ratings, P6 was friendlier in the control session than in the test session (dimension P-N). However, the group members perceived P6 as more positive in the test session than in the control session. The task orientation (dimension F-B) of P6 was observed to be similar in both sessions in both the internal and the external rating (see figure 6-10).

The group behaviours in TRIZ and brainstorming sessions during the experiment are summarized in the following table (see table 6-29).

Participant	TRIZ	Brainstorming
P1	internal rating: -stronger domination -less friendliness -similar level of task orientation external rating: -stronger domination -less friendliness -lower task orientation	internal rating: -weaker domination -more friendliness - similar level of task orientation external rating: -weaker domination -more friendliness -higher task orientation
P2	internal rating: -stronger domination -less friendliness -lower task orientation external rating: -stronger domination -more friendliness -higher task orientation	internal rating: -weaker domination -more friendliness -higher task orientation external rating: -weaker domination -less friendliness -lower task orientation
P3	internal rating: -stronger domination -more friendliness -lower task orientation external rating: -stronger domination -more friendliness - lower task orientation	internal rating: -weaker domination -less friendliness -higher task orientation external rating: - weaker domination -less friendliness -higher task orientation
P4	internal rating: -stronger domination -less friendliness -similar level of task orientation external rating: -stronger domination -more friendliness -higher task orientation	internal rating: -weaker domination -more friendliness -similar level of task orientation external rating: -weaker domination -less friendliness -lower task orientation
P5	internal rating: -stronger domination - more friendliness -lower task orientation external rating: -stronger domination -more friendliness -lower task orientation	internal rating: -weaker domination - less friendliness -higher task orientation external rating: -less friendliness -less friendliness -higher task orientation
P6	internal rating: -weaker domination -less friendliness -lower task orientation external rating: -weaker domination -less friendliness -lower task orientation	internal rating: -stronger domination -more friendliness -higher task orientation external rating: -stronger domination -more friendliness -higher task orientation

Table 6-29 Comparison of process: individual behaviours

Altogether, in the dimension F-B, the majority of the participants achieved a lower score in the test session than in the control session. In the first round of internal rating, with 4 out of 6 participants achieved a lower and only one participant a higher score, the average score was reduced by 2.1 in the test session. In the second round, with 4 participants receiving a clearly lower score (<-1.0) and 2 participants a slightly higher score (<0.4), the average was lowered by 1.3. In the external rating, 4 out of 6 participants scored lower

and 2 scored higher in the test session compared to the control session. The average score decreased by 0.3 (see table 6-30).

Participant	Internal rating 1 (control)	Internal rating 1 (test)	test vs. control	Internal rating 2 (control)	Internal rating 2 (test)	test vs. control	External rating (control)	External rating (test)	test vs. control
P1	4.7	4.0	*-0.7*	3.3	3.7	*0.4*	2.0	0.0	*-2.0*
P2	5.0	8.0	*3.0*	7.3	5.3	*-2.0*	6.0	9.5	*3.5*
P3	3.3	3.3	*0.0*	6.5	5.5	*-1.0*	6.5	5.5	*-1.0*
P4	6.0	3.3	*-2.7*	6.3	6.5	*0.2*	4.0	6.5	*2.5*
P5	9.0	5.0	*-4.0*	8.3	6.3	*-2.0*	2.5	1.0	*-1.5*
P6	11.3	3.0	*-8.3*	9.5	6.3	*-3.2*	9.5	6.5	*-3.0*
average	**6.6**	**4.4**	**-2.1**	**6.9**	**5.6**	**-1.3**	**5.1**	**4.8**	**-0.3**

Table 6-30 Ratings for participants: dimension F-B

A possible interpretation of the above findings is that the individual behaviour at the group work appeared more emotionally expressive with the TRIZ procedure in the subjective perception of the participants. However, this tendency seemed much milder in the relatively objective observation represented by the external rating.

Also in the dimension P-N, most of the participants achieved a lower score in the test session than in the control session. In the first round of internal rating, with 4 out of 6 participants achieved a lower and 2 participants a higher score, the average score in the test session was lower by 1.4. In the second round, with 4 participants receiving a lower and only one participant a higher score, the average was lowered by 1.0. In the external rating, however, 4 out of 6 participants scored higher in the test session and 2 scored lower. The average score increased by 1.3 (see table 6-31).

Participant	Internal rating 1 (control)	Internal rating 1 (test)	test vs, control	Internal rating 2 (control)	Internal rating 2 (test)	test vs, control	External rating (control)	External rating (test)	test vs, control
P1	24.0	20.3	*-3.7*	22.7	20.0	*-2.7*	21.5	19.5	*-2.0*
P2	16.0	21.0	*5.0*	21.7	18.3	*-3.4*	21.0	25.0	*4.0*
P3	21.3	19.7	*-1.6*	22.5	26.0	*3.5*	22.5	26.0	*3.5*
P4	24.3	21.3	*-3.0*	24.7	22.5	*-2.2*	20.5	22.5	*2.0*
P5	16.0	21.7	*5.7*	24.0	24.0	*0.0*	16.0	18.0	*2.0*
P6	21.7	11.0	*-10.7*	22.0	21.0	*-1.0*	22.0	20.0	*-2.0*
average	**20.6**	**19.2**	**-1.4**	**22.9**	**22.0**	**-1.0**	**20.6**	**21.8**	**1.3**

Table 6-31 Ratings for participants: dimension P-N

A possible interpretation of the above findings is that the participants using the TRIZ techniques acted friendlier to their group mates in the relatively objective observation of the external raters. However, in the subjective perception of the group members, the participants seemed friendlier in the brainstorming session. One reason for this effect could be, since the TRIZ procedure delivered well defined paths, the discussion during the test session was more "straightforward" thus leaving such subjective impression.

In the dimension U-D, contrary to the results in the other two dimensions, most of the participants achieved a higher score in the test session than in the control session. In the first round of internal rating, with 4 out of 6 participants achieved a higher and 2 participants a lower score, the average score in the test session was higher by 1.4. In the second round, with 5 participants receiving a higher and only one participant a lower score, the average was higher by 0.8 in the test session. Similarly in the external rating, 5 out of 6 participants scored higher in the test session leaving the average score of the test session surpassing the control session by 0.8 (see table 6-32).

Participant	**Internal rating 1 (control)**	**Internal rating 1 (test)**	test vs, control	**Internal rating 2 (control)**	**Internal rating 2 (test)**	test vs, control	**External rating (control)**	**External rating (test)**	test vs, control
P1	3.3	5.5	*2.2*	3.3	4.3	*1.0*	0.0	1.0	*1.0*
P2	2.0	8.0	*6.0*	5.3	6.3	*1.0*	3.0	4.5	*1.5*
P3	4.7	3.3	*-1.4*	6.5	7.0	*0.5*	6.5	7.0	*0.5*
P4	1.0	4.7	*3.7*	3.0	6.5	*3.5*	5.5	6.5	*1.0*
P5	-4.0	4.7	*8.7*	1.0	2.0	*1.0*	0.5	6.5	*6.0*
P6	6.8	-4.0	*-10.8*	5.0	3.0	*-2.0*	5.0	0.0	*-5.0*
average	**2.3**	**3.7**	**1.4**	**4.0**	**4.9**	**0.8**	**3.4**	**4.3**	**0.8**

Table 6-32 Ratings for participants: dimension U-D

The above findings suggested that the participants exerted more active influence on the process of development and research when using the TRIZ techniques. This activeness was confirmed both by the subjective perceptions of the group members in the internal rating and by the relatively objective assessment of the external rating.

The findings on group behaviours of totally 6 participants in TRIZ and brainstorming sessions during the experiment are summarized in the table 6-33.

Dimension	TRIZ	Brainstorming
F-B	1st round internal rating: 1participant with a higher score 2nd round internal rating: 2 participants with a slightly higher score External rating: 2 participants with a higher score Interpretation: • Group work more emotionally expressive in subjection perception of group members; • Tendency much milder in objective external rating	1st round internal rating: 4 participants with a higher score 2nd round internal rating: 4 participants with a higher score External rating: 4 participants with a higher score Interpretation: • Group work less emotionally expressive in subjection perception of group members; Tendency much milder in objective external rating
P-N	1st round internal rating: 2participants with a higher score 2nd round internal rating: 1 participant with a higher score External rating: 4 participants with a higher score Interpretation: • Participants friendlier to group mates in objective external rating • Participants less friendly to group mates in subjective perception of group members	1st round internal rating: 4 participants with a higher score 2nd round internal rating: 4 participants with a higher score External rating: 2 participants with a higher score Interpretation: • Participants less friendly to group mates in objective external rating • Participants friendlier to group mates in subjective perception of group members
U-D	1st round internal rating: 4 participants with a higher score 2nd round internal rating: 5 participants with a higher score External rating: 5 participants with a higher score Interpretation: Participants exerted more active influence in objective external rating and subjective perception of group members	1st round internal rating: 2 participants with a higher score 2nd round internal rating: 1 participant with a higher score External rating: 1 participant with a higher score Interpretation: Participants exerted less active influence in objective external rating and subjective perception of group members

Table 6-33 Comparison of process: summary

6.2.7.3 Group discussion

During the experiment sessions, a group discussion was conducted between the two internal rating rounds (see sections 6.2.2.2, 6.2.3.2, 6.2.4.2 and 6.2.5.2). The discussions were guided by the predefined questions. The findings of those are summarised in the table 3-34.

Question	**Session 1 (control group/ test device 1)**	**Session 2 (test group/ test device 1)**	**Session 3 (control group/ test device 2)**	**Session 4 (test group/ test device 2)**
Q1. How do you feel about working in a group?	Positive. Reasons: Exchange of ideas; inspiration by each other; combination of more ideas to develop solution.	Positive if the atmosphere in the group was good.	Positive, especially if relationship among group members is pleasant; members possess individual expertise.	Positive and pleasant, effective for TRIZ application. Reasons: Opportunity for group members to combine ideas, or further develop the new ideas.
Q2. Do you prefer to work in a group or on your own?	Preference for group work. Reasons: Pleasant cooperative atmosphere; opportunity to be inspired by others through exchange of thoughts.	Preference for group work. Reasons: Cross-examination of individual ideas, inspiration by the interpretations and ideas by the others.	Preference for combination of both. Reasons: Development of individual and subsequent cross-examination and combination of the ideas in group work.	Preference for group work. Reasons: Mutual supports in terms of supportive inspirations; approving and further development of the individual ideas.
Q3. Did you feel comfortable during the solution-seeking process in the experiment?	Pleasant.	Pleasant.	Pleasant.	Pleasant, in spite of difficulties in reaching a common understanding of the content of the TRIZ inventive principles at the beginning.
Q4. How would you describe the status of the solution-seeking process in the beginning, in the middle and at the end of the session?	Beginning: Concentration on a common understanding of the task and the approach to the solutions. Middle: Productive (the tasks were clarified and the time pressure was not clearly noticeable). End: Attention to time and consensus for summary of found solutions.	Beginning: No "warming up" was necessary (clear structure of the inventive principles. Innovative ideas generated right from the very beginning of the session.	Beginning: Focus on common understanding of the technical issues. Middle & end: Focus on solution finding.	Beginning: Focus on consensus for the content of the inventive principles. Middle: Most innovative ideas generated. End: Focus on finalising the ideas and put the results in writing.
Q5. When was the most innovative moment?	Several innovative moments were experienced. New ideas were confirmed and/or further developed by the other two group members.	As the idea for the giraffe design for children device was generated.	As the idea of QR-code came across. Till then the solutions were experience-driven as modifications to the existing solutions.	The middle of group work.

Question	Session 1 (control group/ test device 1)	Session 2 (test group/ test device 1)	Session 3 (control group/ test device 2)	Session 4 (test group/ test device 2)
Q6. Would a moderator, facilitator or a group leader be helpful for the group work?	No. Reason: The group was "democratic", thus each member had the equal opportunity to make a contribution.	No. Reason: TRIZ provides very clear instructions.	Not in general, however a moderator could have been helpful in giving each member the equal opportunity to contribute to the group work as one group member appeared dominant.	No.
Q7. Did you need more time or guidance?	No.	No.	More time but no more guidance.	No more time needed. Prior TRIZ refresher training recommended.

Table 6-34 Summary of group discussions

As a whole, group work was experienced as pleasant by the participants in all four experiment sessions. The reasons were given as the exchange of ideas with others, inspiration by each other and the opportunity to combine ideas from different individuals in order to develop better solutions.

Group work was preferred in 3 out of the 4 experiment sessions. In the third session guided by brainstorming techniques, a combination of individual work and group work was preferred, as the group members asserted that individual work was more efficient in generating the initial ideas. After that stage, Group work was thought to be more effective in cross-examination and combination of the ideas.

In all experiment sessions, the group work was described as a pleasant experience by all participants. This could be a result of the initial good interpersonal relationship previously confirmed by the group members.

While the brainstorming sessions seemed to have focused on achieving a common understanding of the technical issues, one TRIZ session started with a brief discussion on the content of the inventive principles, while the other TRIZ session set out straightforward to the innovative development without "warming up". This indicated that TRIZ gave clearer guidance in comparison to brainstorming, however the concept of TRIZ was more complicated thus required more prior knowledge and experience.

The middle part of the group work was reported to be the most innovative during both test and control sessions. The members of a test group and a control group described the moments as the most innovative as new ideas that were not experience driven were generated. All groups reported that the middle and the end of the sessions were more productive, with one brainstorming and one TRIZ team claiming that they paid more attention to synthesising the ideas towards the end of the sessions due to the time factor.

According to the participants, a formally defined leadership was not necessary. While the members in one brainstorming session stated that the group achieved good results being democratic, the participants in the other brainstorming session wished to have a moderator because one of the members acted occasionally dominantly and a moderator was expected to be able to provide each member an equal opportunity to make a contribution. A TRIZ group stated that since TRIZ provided clearly instructions, no leadership or moderation would be necessary.

The time for the experiment sessions was sufficient for most of the groups. Only one out of the 4 groups wished to have more time. One group in the test session proposed prior refresher training for the TRIZ techniques.

It seems that in the experience of the participants, TRIZ led to solutions in shorter time thanks to the clear guidance. With the TRIZ techniques, little discussion was necessary for the clarification of the technical aims. Adequate prior knowledge of the TRIZ procedure was necessary, in order to reach good results. However, compared to brainstorming, a good command of the TRIZ procedure took much more efforts due to its complexity.

In addition, the participants asserted that TRIZ seemed to be more effective for the solution to “hard” technical problems. However, brainstorming might be more appropriate for the solution of “soft” issues, e.g. instruction for use or training programmes.

6.2.7.4 Summary

The two rounds of internal ratings delivered similar results. Also the external ratings showed a similar trend in the assessment of the individual behaviours during the experiment sessions.

In dimension Upward – Downward, in both internal and external ratings, the participants seemed to exert more active influence on the process of development and research when using the TRIZ techniques.

While dominant behaviours of some group members could affect the participation of others in the brainstorming sessions, the technical guidance of TRIZ seemed to lead to a clearer leadership structure. This was probably because the role allocation in the TRIZ group work was related to the special knowledge of the participants.

In general, since it is unlikely that a single member in the group can be the leader in all fields of special knowledge that are relevant to the problem solutions, TRIZ practically improves the equal chance for each participant to make a contribution.

The participants also reported that although TRIZ seemed to be more effective for the solution of "hard" technical problems, little advantage of this approach was detected compared to brainstorming when dealing with "soft" issues, e.g. instruction for use or training programmes.

In dimension Forward – Backward, in both subjective perceptions of the participants and the more objective observation of the external raters, most of the participants appeared to act more emotionally expressive when using the TRIZ procedure.

The above findings may be interpreted as an evidence for the stronger emotional involvement of the participants in the TRIZ sessions, as well as a further evidence for the improved individual participation at the innovation activities. TRIZ delivered clear directions for the development of technical solutions. This seemed to facilitate the identification of the participants with the tasks thus they acted more emotionally expressive during the TRIZ sessions.

In dimension Positive – Negative, the test group members using the TRIZ techniques were observed to be friendlier to their group members in the relatively objective observation of the external raters. However, the contrary was the subjective perception of the group members. The reason behind this phenomenon could be that the group work with TRIZ focused more on the task than on the social interactions among the group members. Therefore, the friendliness of the participants was not perceived intensively by their fellow group members.

The above interpretation is also supported by the group discussions. The group discussions revealed that while the brainstorming sessions began with a "warming up" phase by searching for a common understanding of the technical issues, with the TRIZ techniques, little discussion was necessary for the clarification of the technical aims. However, due to the higher complexity of the TRIZ techniques, more preparatory trainings were necessary for this problem-solving approach.

Summarising the above, on one hand, the individual role in the group work seems to depend on the participant's pertinent knowledge rather than his/ her personality; on the other hand, the group work guided by TRIZ is more "straightforward" and the social interactions among group members are reduced while the behaviours among the group members remain friendly. Compared to brainstorming, the larger interpersonal distance when using TRIZ seems to be more promising for group work which requires strong focus on task orientation and less attention on social interactions among the group members, for the achievement of solutions to complex technical solutions.

In order to achieve good results, extensive prior trainings on TRIZ applications are necessary. Also, TRIZ may be more appropriate for the solution of "hard" technical problems than for the "soft" issues like instruction for use or training programmes.

7. Discussions of findings and implications

7.1 Problem-solving tools for R&D of medical devices

In order to explore the application of problem-solving tools in R&D of medical devices in the pharmaceutical industry, a survey study was conducted for this research. The participants of the survey study were employees in some big pharmaceutical companies in the German Rhine-Main region, with an average of 8 years of practical experience in the pharmaceutical industry and 6 years with the development and production of medical devices.

The findings suggested that currently, problem-solving techniques found wide application in the surveyed companies. Among those, brainstorming was reported to be the most frequently used problem-solving technique (96.2%), followed by mind-mapping (63.5%) and TRIZ (30.8%). Furthermore, the following problem-solving techniques were reported to be used occasionally: root cause analysis, DMAIC, strengthening sessions, risk analysis, Ishikawa diagram, Meta-plan, card sorting/ brain writing and the 5-Why method. While 84.6% of the survey participants at least occasionally used some kind of problem-solving techniques, only 25% of them reported to use TRIZ at a similar frequency.

In addition, the employers in the German pharmaceutical industry seemed to provide a moderate level of trainings on problem-solving tools to their employees. Out of the 52 returned answers, 26 reported to have taken part in trainings on problem-solving tools, among those 16 had at least totally 4 days of training in the last three years. TRIZ training seems to play an important role in such training programmes. The survey showed that 11 out of 52 participants took TRIZ trainings in the last three years with a total training duration of 1-3 days.

The main advantages of the TRIZ methodology were described by the survey participants as methodological approach to innovative problem solving, usefulness for generating new ideas, application of principles and trends to find creative solutions and promotion of team and group work.

The TRIZ methodology was known to most of the practitioners dealing with the development of medical device. The best known TRIZ concepts seemed to be “39 x 39

contradiction matrix" and "40 inventive principles". However, due to the complexity of the methods, only 25% of the participants claimed to be knowledgeable of some concept(s) of the TRIZ toolkits and 13.5% of the participants were familiar with more than 2 TRIZ tools.

The above findings of the survey study imply that in order to use TRIZ effectively in the technical innovation, the pharmaceutical industry needs yet to provide more TRIZ trainings on a more frequent basis.

7.2 Influence of TRIZ on outputs

The findings in section 6.1.5 indicate several differences in the results of the problem-solving approaches brainstorming and TRIZ.

First, TRIZ seems to be more effective than brainstorming in solving clearly defined technology-driven problems.

The benefits of the TRIZ procedure in this study are the inventive principles which improve the opportunity of finding solutions to sophisticated technological problems by restricting the search towards the more effective directions. In the TRIZ procedure, the specific problems are initially "translated" into a general problem. The solutions to the general problem can be extracted from the TRIZ knowledge base. In the final stage, the solutions to the general problems are "translated back" to the specific situations (Altshuller, 1999). Like several previous studies, the findings of this work supported the positive effect of connection to the external knowledge base in the above manner for clearly defined technology-driven problems.

The dimension "*novelty*" of expert assessment represents level of innovation of the generated solutions to the predetermined technical problems. With the additional information of TRIZ inventive principles, the test groups achieved clearly higher results in this dimension than the control groups. In other words, during the experiment, the TRIZ inventive principles directed the innovation process into the "shortcuts" to the technical solutions.

Second, TRIZ appears not more effective than brainstorming in solving fuzzy problems, including problems with soft targets.

A critical step of the TRIZ procedure is the extraction of determinants of contradiction parameters, or, the translation of the specific problem into a general problem. Obviously, biases in this step will lead to suboptimal solutions. By definition, the features of fuzzy problems make it difficult to precisely identify the determinants of the contradiction parameters. Therefore, the strength of TRIZ does not lie in the solution of such problems.

The above implications were supported by the experiment results. While the test groups achieved clearly better results in the dimension "*novelty*" for clearly defined requirements on technical innovations, the TRIZ techniques showed no advantage in solving fuzzy problems in the dimensions "feasibility" and "costs" of the expert assessment, as well as in the patient assessment.

Summarising the above, TRIZ is not a panacea or golden solution to all problems. It has clear strength when dealing with clearly defined technology-driven problems, however might not be the appropriate instrument for fuzzy problems which cannot be adequately predefined or are subject to changing criteria. Therefore, the problem-solving technique should be chosen based on the characteristics of the problems, so as to achieve the best results in the innovation process.

7.3 Influence of TRIZ on process

TRIZ is a complex problem-solving approach in comparison to brainstorming, therefore demands special knowledge of the users. This difference also has an impact on the process of group work.

Unlike the brainstorming techniques which rely largely on the accidental circumstances, the TRIZ inventive principles guide the search for the technical solutions specifically into the potentially prolific directions. While the personality and experience of the group members play an essential role in the group leadership structure for the brainstorming process, the complexity of the TRIZ techniques makes the leadership in the group work often dependent on special knowledge relevant to the problem solution. Consequently, the application of TRIZ leads to a clearer leadership.
Since it is most likely that each single member in the group is the most knowledgeable in some relevant fields, TRIZ practically promotes a more efficient participation of all group

members. As a result, the participants exert more active influence on the process of development and research when using the TRIZ techniques.

In addition, the guidance of TRIZ in the search process seems to reduce emotional reactions among the group members, thus potentially increases the interpersonal distance in the group. This suggests, in terms of the process, TRIZ is more appropriate if strong focus on the task is considered beneficial for the group work, e.g. when dealing with complex technical solutions, and less suitable if the target is highly related to interpersonal reactions, e.g. when dealing with psychological topics.

7.4 Limitations and future research directions

The limitations of this research as well as possible improvements and some directions for future researches are discussed in the following.

First, this work has been organised as a 2x2 experiment. In order to avoid a systematic bias caused by the difference between the groups in terms of their problem-solving capacity, the switched group experimental design was chosen, i.e., each group acted as the test group in one experiment session and the control group in the other. However, due to the rather limited repetitions of the experiment, there is a limitation to the generalisation of the study findings. This may be improved by sufficient repetition of the research procedure.

Second, the test and control groups were not perfectly homogenous. Due to the limited resources for this study, the groups could not be controlled for age, gender, academic background, etc. However, efforts were made to keep up a similar level of "total balance" of the group capacities in the above dimensions.

Third, there might be a learning effect in the second experiment session, since the participants might be inspired by their experience in the first session. However, this effect was limited due to the different features of the test devices for the comparison sessions. Efforts to counteract the bias were made by beginning the experiment with TRIZ in one group and with brainstorming with the other group of participants. The learning effect could be further reduced with more available resources, in order to increase the internal validity by e.g. organising the experiment with Solomon's four group design.

Fourth, the experimental conditions, especially the participants' awareness of the video recording, might have had an impact on their behaviours. This is a typical weakness for this kind of participant observation.

Fifth, the assessment of outputs was conducted with caution and several repetitions. However, due to the author's personal research interest, there might be a remaining bias in favour of TRIZ.

Sixth, the scope of problem in the test procedure was defined based on the findings of a systematic literature review. A more extensive scope of problem could be achieved by means of exploration of further databases.

Seventh, the TRIZ procedure in this research involves the standard 39x39 contradiction matrix and the standard TRIZ inventive principles. A modified contradiction matrix and specialised inventive principles could be developed to meet the specific demands of the research & development of medical devices in the pharmaceutical industry. However, this task would involve extensive exploration of the relevant knowledge bases and could not be accomplished within the frame of this work. This may be a direction for future research.

Eighth, this study investigates how the problem definition affects the outputs of the technical innovation and how the requirements on special knowledge influence the process of group work. A possible direction for future research may also be to investigate how the problem definition influences the process of group work.

Ninth, the literature review in this work concentrates on the English language. The main reason for the choice of language is the limited language knowledge of the researcher in German (native language) and English. A search for disseminations in the German language with the above search criteria led to few retreavals, however the full text was not available in the chosen database. Therefore, the disseminations in German are not included in the review.

Conventionally, clinical data of the pharmaceutical industry and academic literature on pharmaceutical researches are published in the English language. The reason behind this is that the largest health care markets are under control of the US FDA and EU EMA, which both request clinical evaluation and the clinical literature review to be conducted

in English. Also the majority of the pertinent disseminations in the chosen database are published in the English language. Therefore, the focus on the data set in English is considered sufficient for this study. However, the quality of the literature review may be improved by including disseminations in further languages.

8. Conclusions

8.1 Most relevant conclusions

Through the experiment in this thesis, conclusions are drawn in seeking answers to the research questions.

RQ1: Which problem-solving tools are currently used for R&D of medical devices in the pharmaceutical industry?

The findings of the survey study indicate that problem-solving tools are frequently used in the pharmaceutical industry in the current time. Among those, brainstorming seems to be the most frequently used technique, reportedly utilised by 96.2% of all survey participants. Another popular problem-solving tool appears to be mind-mapping, used by 63.5% of the survey participants. Also TRIZ finds applications by 30.8% of the survey participants. There are also further problem-solving techniques mentioned to be used by the participants in the pharmaceutical industry, however less often, e.g. root cause analysis, DMAIC, strengthening sessions, risk analysis, Ishikawa diagram, Meta-plan, card sorting/ brain writing and the 5-Why method.

RQ2: How can TRIZ techniques be applied for medical device innovation?

This work developed a 5-stage TRIZ procedure for the technical innovation for medical devices based on Su et al.'s approach, with some modifications to meet the requirements of medical device innovation (Su, Lin & Chiang, 2008).

The modifications made to Su et al's TRIZ procedure are are summarized in table 8-1.

Su et al.'s 8-stage model (Su, Lin & Chiang, 2008)	5-stage TRIZ procedure for medical device innovations
Stage 1: Define the scope of the problem - Based on company internal knowledgebase	*Stage 1: Definition of scope of problem* - Based on external knowledgebase through systematic literature review
Stage 2: Extract the determinants - Based on external literature review	*Stage 2: Extraction of determinants* - Based on multiple sources, including external literature review, patient interviews with option to add determinants, as well as expert panel review with option to add determinants
Stage 3: Develop a parameter corresponding table - Authors' proposal	*Stage 3: Identification of contradiction parameters* - Authors' proposal; - Verification and improvement by independent TRIZ experts; - Verifications by independent patients
Stage 4: Generate the feasible solutions through the TRIZ contradiction matrix - All inventive principles with more than two mappings are selected.	*Stage 4: Identification of inventive principles* - Frequency of inventive principles with scoring model is applied, in order to focus on the three most beneficial inventive principles.
Stage 5: Implement feasible solution - Prioritization by internal experts (management); - Fix criteria (time, money, resources).	*Stage 5: Generation of solutions* - Prioritization by external experts (expert panel) and independent patients; - Criteria defined by expert panel based on survey findings.
Stage 6: Are the results effective?	- Design loops after initial design; - Effective check (feasibility testing) after initial production or prototyping.
Stage 7: Identify the next problem	- Product technical complaint management
Stage 8: Is the new problem belong to the next sector	- Life cycle management for medical device and/or combination product

Table 8-1 Comparison of TRIZ procedure in this thesis with Su et al. (2008)

The TRIZ techniques 39x39 contradiction parameter and 40 inventive principles are applied in the above 5-stage procedure for the technical innovation of medical devices.

Initially, the specific problems are defined as a number of determinants. In order to abstract the general problems out of the specific problems, each determinant is subsequently mapped with a parameter (either as an improving or a worsening parameter) out of the 39x39 condradiction matrix.

Next, the general solutions to the general problems are identified by looking up the inventive principles for the combination of each improving and worsening parameter in the 39x39 condradiction matrix. To improve the efficiency of the procedure, only the inventive principles with the highest frequency are selected for the further steps as they are considered the most beneficial.

In order to transfer the general solutions into specific solutions, the chosen inventive principles are provided to the participants to guide their search for improvements. Finally, the generated ideas are to be prioritized for the implementation in specific device designs (see figure 8-1).

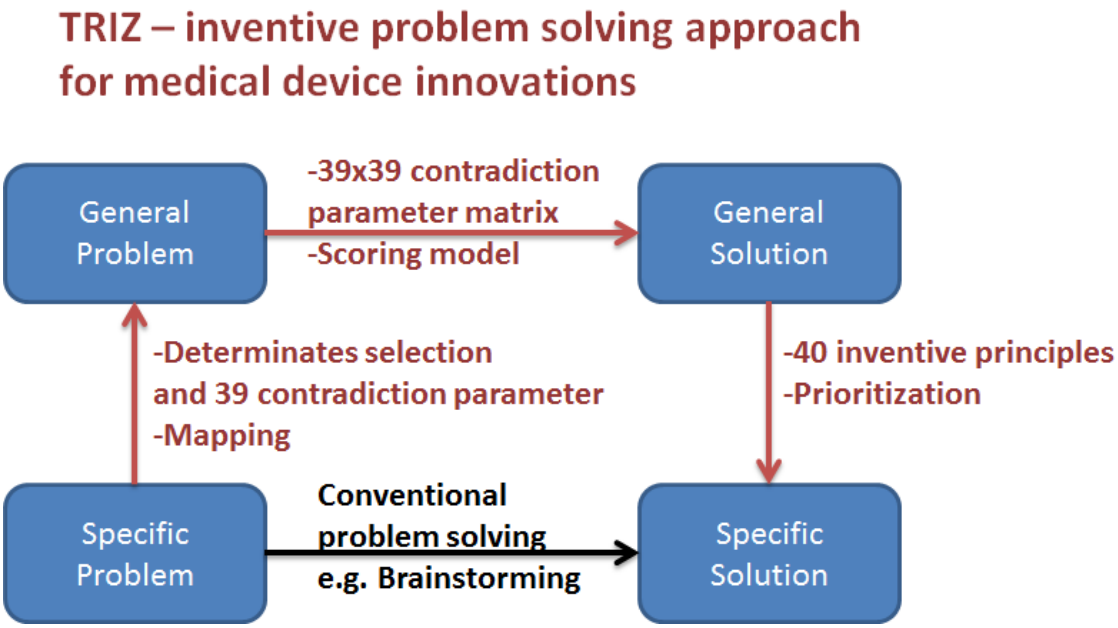

Figure 8-1 5-stage procedure with TRIZ framework

RQ3: How and why do TRIZ techniques differentiate themselves from other problem-solving methods, from a theoretical perspective?

The findings of this research suggest several differences between TRIZ techniques and the chosen alternative problem-solving method brainstorming.

The results of the experiment in chapter 6 indicate that the TRIZ procedure seeks effectively technical solutions after narrowing down the problem field with aid of the inventive principles. Aiming at improvement of several technical issues at the same time, TRIZ potentially leads to a higher number of solutions to the single problems. This suggests that the strength of TRIZ in solving complex technical problems, especially when there are trade-offs among the optimal solutions of different partial problems.
However, the above advantages are not observed for the solution of fuzzy problems. The reason behind it is that the fuzziness of the problems worsens the quality of the inventive principle so that their advantages diminish when seeking solutions. Hence it may be said that the outcomes of the group work with specific problem-solving tools are influenced by the type of problem definition.

Basically, no problem-solving approach seems to be a golden solution to all problems. In order to achieve the best results of the innovations activities, the problem-solving tools should be chosen based on the type of the problems.

Based on the findings in this study, the following 2-dimensional framework was developed for the classification of the problems. The dimension "*problem definition*" describes if the problems are clearly defined or fuzzy and the dimension "*demand on special knowledge*" illustrates the level of special knowledge necessary for the generation of solutions (see figure 8-3).

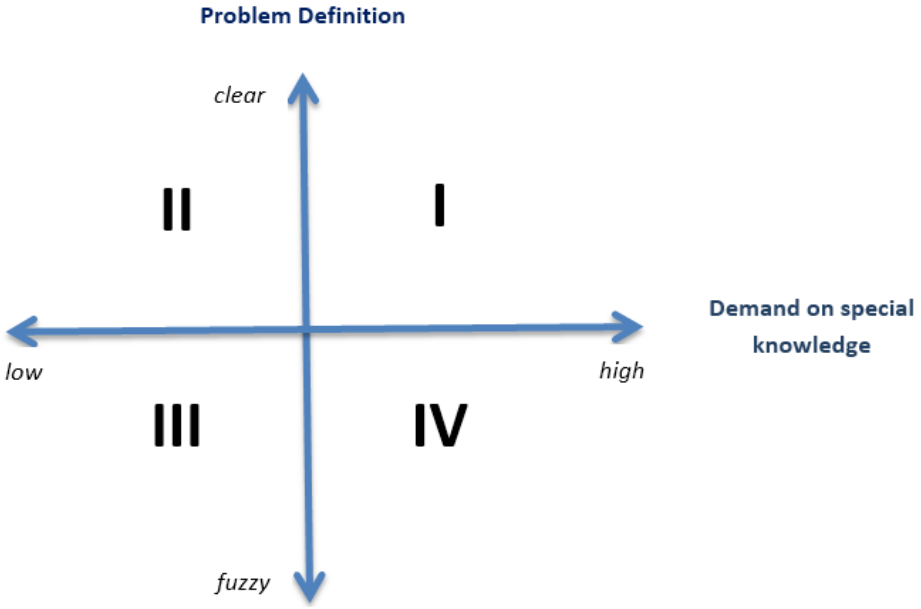

Figure 8-2 2-dimensional system for classification of problems

While TRIZ was found more effective with the predefined, technology-driven problems (TRIZ is more effective for the problem type in quadrant I than brainstorming for the problem type in quadrant II), brainstorming performed at a similar level or better with the fuzzy problems (the performance of brainstorming for problem type in quadrants III is comparable with that of TRIZ for problem type in quadrant IV). Thus research hypothesis 1 is positively supported by the findings of the experiment.

Hypothesis 1: TRIZ is more effective than the conventional problems-solving approach when dealing with clearly defined technology-driven problems.

During the group discussions, the participants reported that contrary to brainstorming, there was no "warming up" phase during the TRIZ sessions. This indicates that the innovation process with TRIZ has a strong focus on the task.

In general, the analysis of the process of group work leads to the conclusion that the participants exert more individual influence when applying TRIZ techniques. That means, the problem solving process with TRIZ in situations of quadrant I and IV leads to higher motivation of the individual participants in the group work than with brainstorming problem-solving tool in situations of quadrant II and III. The reason for this is probably that the higher requirements of TRIZ on special knowledge of the participants improve

the opportunity of the individual participants to make a contribution, especially those with a less dominant personality. Thus, hypothesis 2 is positively supported by the findings of the experiment.

Hypothesis 2: TRIZ improves the motivation of the individual participants in the group work.

The experimental findings on the process of the group work suggest that there is a clearer leadership structure when TRIZ is used for the innovation activities. With brainstorming techniques, the leadership in the group depends largely on the personality of the participants; hence sometimes the leadership structure is unclear. In group work with TRIZ, the leadership is mainly influenced by the special knowledge relevant to the problem solutions. The most knowledgeable participant in each pertinent field is the most likely to take over the leader role during the process. In short, the problem situations in quadrant I and IV when using TRIZ leads to a clearer leadership structure in the group work than those in quadrant II and III using brainstorming. Thus research hypothesis 3 is positively supported by the findings of the experiment.

Hypothesis 3: TRIZ promotes a clear leadership structure in the group work.

In addition, the larger interpersonal distance in group work with TRIZ allows the assumption that TRIZ is more suitable if a strong focus on the task and less on the social interactions among the group members are advantageous.

Summarising the above, no problem-solving approach seems to be a golden solution to all problems. In order to achieve the optimal results of the innovations activities, the problem-solving tools should be chosen based on the type of problems.

8.2 Contribution to knowledge

This thesis provided the following contributions to knowledge.

First, the effect of the problem-solving tools was explored not only from the perspective of the outputs as the majority of previous researchers did in the past, but also from a new perspective - the process of group work. The findings of this research provide valuable

insights into R&D activities in the pharmaceutical industry in terms of design improvement tools for medical devices.

Second, the results of the experiment suggest that the impact of problem-solving tools in the innovation activities is related to the type of problems to be solved. A 2-dimensional framework was developed for the classification of the problem types. Within this theoretical framework, TRIZ is found more suitable for the solution of clearly defined, technology-driven problems, especially when the complex task instead of social interactions is a necessary part of the group work.

Third, the application of problem-solving tools for R&D of medical devices in the pharmaceutical industry was explored. The survey study indicates that problem-solving tools are frequently used in the above business sector in the current time. Among those, the most frequently used tools are identified as brainstorming, mind-mapping and TRIZ. Further problem-solving techniques, e.g. root cause analysis, DMAIC, strengthening sessions, risk analysis, Ishikawa diagram, Meta-plan, card sorting/ brain writing and the 5-Why method also find applications in this field, however less frequently.

Fourth, a specific TRIZ procedure was developed for the research and development of medical device in the pharmaceutical industry based on a modified model by Su et al. (Su, Lin & Chiang, 2008). This procedure is tailored to meet the requirements of technical innovation for medical devices. The detailed description may guide future research in this field (see section 5.2).

Fifth, comparison studies on the effect of different problem-solving tools were rare in the past. This work proposed a method for the comparison of the different methods, both in the aspect of technical solutions and in terms of group behaviours.

Finally, due to the sensitive protection of intellectual property in the pharmaceutical industry, the results of field studies in the large pharmaceutical firms can be rarely found in the public literature. This study provides valuable insights of the application of problem-solving tools in some pharmaceutical firms, as well as how the TRIZ approach influences the outputs and the process of the development and research activities in the special field of medical devices of the pharmaceutical industry.

8.3 Closing note

This thesis explores the effect of the application of TRIZ approach to the technical innovations for R&D of medical devices in the pharmaceutical industry.

The pharmaceutical business is driven by innovation and new technologies. The results of the survey study in this research indicates that the modern R&D organisation units nowadays have integrated various problem-solving techniques in their innovation process in order to improve the overall efficiency. However, it seems that currently, TRIZ is not used as frequently as some conventional problem-solving tools e.g. brainstorming and mind-mapping.

The literature review identified TRIZ as a unique knowledge-based problem-solving approach (Ilevbare, Probert & Phaal, 2013; Savranksy, 2000; Domb, Miller, MacGran & Slocum, 1998) which, unlike the conventional problem solving methods, focuses on the root cause of the problem instead of the problem itself (Gadd, 2011). The previous implementation of TRIZ techniques in various business sectors clearly indicated the advantages of TRIZ compared with the conventional trial-and-error methods (Ishida, 2003; Su, Lin & Chiang, 2008; Belski, 2009).

In order to test the effect of TRIZ on the technical innovations for R&D of medical devices in the pharmaceutical industry, an experiment was carried out with two sample medical devices (auto-injectors). During the experiment, two groups of experienced practitioners were asked to improve the design of the test devices, alternatively using TRIZ and brainstorming. The TRIZ procedure for this study was based on the framework of Su et al.'s solution (Su, Lin & Chiang, 2008), with some modifications to meet the requirements for the design tasks of medical devices. Although previous researchers seemed to have solely concentrated on the technical solutions in their studies on problem-solving techniques, in this study, the efficacy of TRIZ application was analysed in two aspects: the outputs and the process.

Based on the findings of the literature review, the survey study and the subsequent expert and patient interviews, an assessment system was developed to measure the innovative group work both in outputs and in process. For the assessment of the group work process, behaviours of the individual group members and their perceptions for the group work were observed and analysed by using the SYMLOG Adjective rating form method with

two rounds of internal ratings and an external rating by two independent raters, supplemented by group discussions between the two rounds of internal ratings.

In addition, the results of the experiment indicate that the impact of the problem-solving tools is influenced by the type of innovation problems. For the analysis of such influences, this research makes a contribution to knowledge by developing a 2-dimensional framework to capture the problem types. This framework may be used to guide future studies in this field.

To close, continued efforts are still needed in this challenging research field. A few directions for future researches are pointed out by this thesis, including the development of a modified contraction matrix and specialised inventive principles, in order to meet the specific demands of the research & development for medical devices in the pharmaceutical industry.

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Appendix I SURVEY-English

A. General Information

1. My gender ☐ male ☐ female

2. My current position is in
   ☐ R&D ☐ marketing & sales
   ☐ Production Biotech & Chemistry ☐ general administration
   ☐ medical device development ☐ medical device production
   ☐ others, which is _____

3. Altogether, I have _____ years of practical experience in the pharmaceutical industry.

4. Altogether, I have _____ years of practical experience with the **development** of **medical devices**.

B. Experience with problem-solving techniques

1. Altogether, I have taken _____ days of training(s) on problem-solving techniques in the past three years.

2. My job in the pharmaceutical industry now and in the past involves problem-solving techniques e.g. brain-storming, mind-mapping etc….
   ☐ never ☐ seldom ☐ occasionally
   ☐ frequently ☐ always

3. My job in the pharmaceutical industry now and in the past involves the following problem-solving techniques:
   ☐ brainstorming ☐ mind-mapping
   ☐ trial error experiments ☐ lateral thinking
   ☐ TRIZ
   ☐ Others, which are _____

4. In my opinion, the quality of a problem solution for medical devices in an ongoing study shall be judged by its:
   ☐ _____
   ☐ _____
   ☐ _____
   ☐ _____
   ☐ _____

C. Experience with TRIZ

1. Altogether, I have taken _____ days of training(s) on the application of TRIZ in the past three years.

2. My job in the pharmaceutical industry now and in the past involves the application of TRIZ….
   ☐ never ☐ seldom ☐ occasionally
   ☐ frequently ☐ always

3. I am especially knowledgeable of the following TRIZ tools:
   ☐ 39 x 39 contradiction matrix ☐ 40 inventive principles
   ☐ 76 standard solutions ☐ ideality
   ☐ function analysis ☐ patterns of evolution
   ☐ nine windows ☐ Su field analysis
   ☐ effects database ☐ smart little people
   ☐ ARIZ ☐ others, namely_____

4. In my opinion, the TRIZ applications have the following benefits (multiple choice):

☐ A structure approach to innovative problem solving
☐ Useful for generating new ideas
☐ Applying principles and trends to find creative solutions
☐ Fast speed in solution finding
☐ Prediction the next big jump in problem solving using trends and nine windows
☐ Promotion teamwork
☐ Shrinking systems size without decreasing performance
☐ Others, namely _____
☐ No special benefits in problem-solving process.

Appendix II SURVEY-German

A. Allgemeine Information

1. Geschlecht ☐ männlich ☐ weiblich

2. Meine jetzige Position ist im Bereich…
   ☐ F&E ☐ Marketing & Vertrieb
   ☐ Produktion Biotech & Chemistry ☐ Allgemeine Verwaltung
   ☐ Medical Device Entwicklung ☐ Medical Device Produktion
   ☐ Sonstiges, nämlich _____

3. Insgesamt verfüge ich über _____ Jahre praktische Erfahrungen in der Pharmaindustrie.

4. Insgesamt verfüge ich über _____ Jahre praktische Erfahrungen mit der **Entwicklung von Medical Device**.

B. Erfahrungen mit Problemlösungstechniken

1. Insgesamt habe ich an _____ Tage an die Weiterbildungsmaßnahme(n) für Problemlösungstechniken in den letzten drei Tagen teilgenommen.

2. Auf meinem jetzigen bzw. frühere(n) Job(s) in der Pharmaindustrie werden Problemlösungstechniken wie z.B. Brainstorming, Mind-Mapping etc. eingesetzt….

☐ nie ☐ selten ☐ gelegentlich
☐ regelmäßig ☐ immer

3. Auf meinem jetzigen bzw. frühere(n) Job(s) in der Pharmaindustrie werden die folgenden Problemlösungstechniken eingesetzt:

☐ brainstorming ☐ mind-mapping
☐ trial error experiments ☐ lateral thinking
☐ TRIZ
☐ Sonstige, nämlich _____

4. Meiner Meinung nach, die Güte einer Problemlösung für die Verbesserung eines Medical Devices soll nach folgenden Kriterien beurteilt werden:

☐ _____
☐ _____
☐ _____
☐ _____
☐ _____

C. Erfahrungen mit TRIZ

1. Insgesamt habe ich an _____ Tage an die Weiterbildungsmaßnahme(n) für TRIZ Anwendungen in den letzten drei Tagen teilgenommen.

2. Auf meinem jetzigen bzw. frühere(n) Job(s) in der Pharmaindustrie werden TRIZ-Anwendungen eingesetzt….
   ☐ nie ☐ selten ☐ gelegentlich
   ☐ regelmäßig ☐ immer

3. Ich bin besonders erfahren im Umgang mit den folgenden TRIZ-Tools:
   ☐ 39 x 39 contradiction matrix ☐ 40 inventive principles
   ☐ 76 standard solutions ☐ ideality
   ☐ function analysis ☐ patterns of evolution
   ☐ nine windows ☐ Su field analysis
   ☐ effects database ☐ smart little people
   ☐ ARIZ ☐ others, namely _____

4. Meiner Meinung nach haben die TRIZ-Anwendungen die folgenden Vorteile (mehrfache Antworte möglich):

☐ Ein strukturierter Ansatz für die innovative Problemlösung
☐ Hilfreich für die Generierung neuer Ideen
☐ Kreative Lösungen generieren durch Anwendung von Prinzipien und Trends
☐ Schnelligkeit im Lösungsfindungsprozess
☐ Vorzeitige Erkennung vom nächsten großen Sprung in der Problemlösungsprozess unter Anwendung von Trends und nine windows
☐ Förderung vom Teamwork
☐ Einschränkung der Systemgröße ohne die Leistung zu beeinträchtigen
☐ Sonstige, nämlich _____
☐ Keine besonderen Vorteile im Problemlösungsprozess.

Appendix III SURVEY-ACCOMPANYING LETTER 1 English

Dear colleagues,

For the final thesis of my study of Doctor of Business Administration at the University of Gloucestershire (England), I would like to conduct a survey study on ***the application of TRIZ methodology in the pharmaceutical industry***. The aim of my survey study is to examine the status quo of the application of problem-solving techniques, especially the application of TRIZ techniques in the pharmaceutical industry.

I would like to ask you kindly to fill out the attached questionnaire and submit it my pigeon hole. In case of any further questions, please do not hesitate to contact me under the e-mail address: rene.dathe@hotmail.com

The participation on the survey is on a voluntary basis. *I herewith explicitly guarantee the **anonymity** of all data entries made and will use such for my intended doctorate study only. No data which might reveal the identity of the participants will be released to any third party.*

I would like to thank everybody in advance for your support and the timely response.

Yours sincerely,
René Dathe

Appendix IV SURVEY-ACCOMPANYING LETTER 1 German

Liebe Kolleginnen und Kollegen,

im Rahmen meiner Promotionsarbeit für das Studium "Doctor of Business Administration" an der University of Gloucestershire (England) möchte ich eine Umfrage über **die Anwendung der *TRIZ Methodologie in der Pharmaindustrie*** durchführen. Das Ziel dieser Umfrage ist es, den aktuellen Stand der Anwendung von Problemlösungstechniken, insbesondere der Anwendung von TRIZ-Techniken, festzustellen.

Ich möchte euch bitten, den beigefügten Fragebogen auszufüllen und anschließend in mein Postfach einzulegen. Bei Rückfragen bitte ich um Kontaktaufnahme per e-Mail unter: rene.dathe@hotmail.com

Die Teilnahme an diese Umfrage ist freiwillig. *Ich garantiere zudem explizit die **Anonymität** aller Datenangaben und werde diese ausschließlich für den Zweck meines Promotionsstudiums verwenden. Keine Daten werden an Dritte freigegeben, die den Rückschluss auf die Identität der Teilnehmer zulassen.*

Ich bedanke mich im Voraus für eure Unterstützung und zeitliche Antwort.

Viele Dank und viele Grüße
René Dathe

Appendix V SURVEY-ACCOMPANYING LETTER 2 English

Dear Sirs,

For the final thesis of my study of Doctor of Business Administration at the University of Gloucestershire (England), I would like to conduct a survey study on ***the application of TRIZ methodology in the pharmaceutical industry***. The aim of my survey study is to examine the status quo of the application of problem-solving techniques, especially the application of TRIZ techniques in the pharmaceutical industry.

For the above purpose, I would like to ask you kindly to fill out the attached questionnaire and submit it to my e-mail address my rene.dathe@hotmail.com. In case of any further questions, please do not hesitate to contact me.

The participation on the survey is on a voluntary basis. *I herewith explicitly guarantee the **anonymity** of all data entries made and will use such for my intended doctorate study only. No data which might reveal the identity of the participants will be released to any third party.*

I would like to thank everybody in advance for your support and the timely response.

Yours sincerely,

René Dathe

Appendix VI SURVEY-ACCOMPANYING LETTER 2 German

Sehr geehrte Damen und Herren,

im Rahmen meiner Promtionsarbeit für das Studium "Doctor of Business Administration" an der University of Gloucestershire (England) möchte ich eine Umfrage über **die Anwendung der *TRIZ Methodologie in der Pharmaindustrie*** durchführen. Das Ziel dieser Umfrage ist es, den aktuellen Stand der Anwendung von Problemlösungstechniken, insbesondere der Anwendung von TRIZ-Techniken, festzustellen.

Ich möchte Sie bitten, den beigefügten Fragebogen auszufüllen und anschließend mir zuzumailen (rene.dathe@hotmail.com). Bei Rückfragen selbstverständlich gerne jederzeit zur Verfügung.

Die Teilnahme an diese Umfrage ist freiwillig. *Ich garantiere zudem explizit die **Anonymität** aller Datenangaben und werde diese ausschließlich für den Zweck meines Promotionsstudiums verwenden. Keine Daten werden an Dritte freigegeben, die den Rückschluss auf die Identität der Teilnehmer zulassen.*

Ich bedanke mich im Voraus für Ihre Unterstützung bzw. Ihre zeitliche Antwort.

Mit freundlichen Grüßen
René Dathe

Appendix VII SEMI-STRUCTURED PATIENT INTERVIEW

The semi-structured interviews in section 5.2.2 were guided by the following standard questions.

1. Do you think any of the following 13 points in general essential for auto-injector design?

No.	Description	Yes (=1) / no (=0)	The needs to be increased (=”+”)/ decreased (=”-“)
1	Device identification		
2	Comprehensive instruction of use		
3	Ease of use		
4	Size of device		
5	Customization for target groups		
6	Needle length		
7	Needle protection		
8	Flexibility of dose		
9	Injection time		
10	Marking of injection end		
11	Patient's fear of device		
12	Adequate training - trainer, participants, frequency, training device etc.		
13	Shelf life		

2. Are there any further aspects which are in your opinion generally essential for the auto-injector design?

_____

_____

_____

_____

3. Do you think test device 1 need improvements in the following 13 points?

No.	Description	Yes (=1) / no (=0)	The needs to be increased (=”+”)/ decreased (=”-“)
1	Device identification		
2	Comprehensive instruction of use		
3	Ease of use		
4	Size of device		
5	Customization for target groups		
6	Needle length		
7	Needle protection		
8	Flexibility of dose (e.g. for children weighting 15-30 kg)		
9	Injection time		
10	Marking of injection end		
11	Patient's fear of device		

12	Adequate training - trainer, participants, frequency, training device etc.		
13	Shelf life		

4. Are there any further aspects you wish to change about test device 1?

_____

_____

_____

_____

5. Do you think test device 2 need improvements in the following 13 points?

No.	Description	Yes (=1) / no (=0)	The needs to be increased (=”+”)/ decreased (=”-“)
1	Device identification		
2	Comprehensive instruction of use		
3	Ease of use		
4	Size of device		
5	Customization for target groups		
6	Needle length		
7	Needle protection		
8	Flexibility of dose (e.g. for children weighting 15-30 kg)		
9	Injection time		
10	Marking of injection end		
11	Patient's fear of device		
12	Adequate training - trainer, participants, frequency, training device etc.		
13	Shelf life		

6. Are there any further aspects you wish to change about the test device 2?

_____

_____

_____

_____

Appendix VIII INITIAL MAPPING TABLE FOR TRIZ PROCEDURE

Determinants for EpiPen use		TRIZ contradiction parameter		Decision 1		Decision 2a		Decision 2b
No.	**Description**	**No.**	**Description**	**A**	**D**	**I**	**W**	**Alternative**
1	Device identification	**12**	Shape					
2	Comprehensive instruction of use	**33**	Ease of operation					
3	Ease of use	**33**	Ease of operation					
4	Size of device	**8**	Volume of stationary object					
5	Customization for target groups	**35**	Adaptability or versatility					
6	Sufficient needle length (for intra-muscular injection)	**3**	Length of moving object					
7	Needle protection (against accidental sticks)	**12**	Shape					
8	Flexibility of dose (e.g. for children weighting 15-30 kg)	**7**	Volume of moving object					
9	Injection time	**25**	Loss of time					
10	Marking of injection end	**15**	Duration of action by a moving object					
11	Patient's fear of device	**12**	Shape					
12	Adequate training - trainer, participants, frequency, training device etc.	**24**	Loss of information					
13	Shelf life	**24**	Loss of information					
14	Device robustness	**11**	Stress and pressure					

A= agree; D = disagree; I = improving parameter; W = worsening parameter; alternative = alternative TRIZ contradiction parameter

Appendix IX INFORMED CONSENT English

Dear participant,

I would like to invite you to take part in my research study at the University of Gloucestershire on the efficacy of problem-solving tools for the development of medical devices. The participation is on a voluntary basis and you will only be included if you provide your permission. **The purpose of this study is to examine the efficacy of problem-solving tools for the development of medical devices**.

I would like to invite you to participate at two experiment sessions for the improvement of auto-injector design. At the beginning of each session, you will be given clear instruction of the problem-solving techniques to be used. During the session you will be requested to generate ideas in group for the improvement of the example medical devices by using the described problem-solving tools. Subsequently, you will be requested to evaluate the behavior of the group members during the sessions.

The sessions will be video recorded for later assessment of your group work. I will keep all recording and the assessment private and secret in private premises. I will keep data for five years after the study has finished. After five years, I will destroy the data. For the assessment of the results, no participant will be identifiable by name.

By taking part in this study, you may help to find out the efficacy of problem-solving tools in the pharmaceutical industry. There are no known risks associated with taking part in this study.

If you would like to participate in this study, please read and sign the informed consent form and return it to me in person or by e-mail to rene.dathe@hotmail.com.

Many thanks

René Dathe

Informed consent form

Title of Project:

Application of problem-solving techniques to medical device innovations

Researcher:

René Dathe, University of Gloucestershire

	Yes	No
Do you understand that I have asked you to participate in a research study?		
Have you read and received a copy of the attached information letter?		
Do you understand the benefits and risks involved in taking part in this research study?		
Do you understand that you are free contact the researcher to take the opportunity to ask questions and discuss this study?		
Do you understand that you free to refuse participation, or to withdraw from the study at any time, without consequence, and that your information will be withdrawn at your request?		
Do you understand that I will keep your data confidential?		
Do you understand who will have access to your information?		

I wish to take part in this study.

Printed Name: _____

Signature: _____

Date: _____

Preferred Contact number: _____

Email: _____

Appendix X INFORMED CONSENT German

Liebe Teilnehmerinnen,
Liebe Teihnehmer,

Ich möchte euch zur Teilnahme an die Studie für mein Forschungsstudium an der University of Gloucestershire über die Auswirkung der Problemlösungstools in der Entwicklung der medical devices. Die Teilnahme ist freiwillig und setzt voraus, dass ihr die Zustimmung für eure Teilnahme ausdrücklich erteilt habt. **Das Ziel dieser Studie ist es, die Auswirkung der Problemlösungstools für die Entwicklung der medical devices festzustellen.**

Ich möchte dich zu zwei Experimenten für die Verbesserung des Autoinjektor-Designs einladen. Am Anfang jedes Experiments wirst du klare Anweisungen für die anzuwendenden Problemlösungstechniken erhalten. Während des Experiments wirst du aufgefordert, Ideen für die Verbesserungen der Beispiel-medical devices mit Hilfe der vorgegebenen Problemlösungstechniken in Gruppe zu generieren. Anschließend wirst du aufgefordert, das Verhalten anderer Gruppenmitglieder während des Experiments zu bewerten.

Die Experimente werden per Video aufgezeichnet zwecks späterer Auswertung der Gruppenarbeit. Ich werde alle Aufzeichnungen bzw. Auswertungen in meinen Privaträumlichkeiten vertraulich aufbewahren. Alle Daten werden für fünf Jahre nach dem Studienabschluss aufbewahrt. Alle Daten werden nach dieser Aufbewahrungsfrist vernichtet. Für die Auswertungen werden die Namen der Teilnehmer nicht erwähnt.

Deine Teilnahme an diese Studie wird dazu beitragen, die Auswirkung der Problemlösungstechniken für die Pharmaindustrie festzustellen. Es gibt keine bekannten Risiken, die mit der Teilnahme verbunden sind.

Falls du an die Teilnahme der Experimente interessiert bist, bitte lese das beigefügte Formular für informierte Zustimmung durch und diese unterschrieben an mich persönlich übergeben bzw. an meine e-Mail Adresse verwenden (rene.dathe@hotmail.com).

Besten Dank!

René Dathe

Formular für informierte Zustimmung

Projektthema:

Anwendung der Problemlösungstechniken für die Entwicklung der medical devices

Forscher:

René Dathe, University of Gloucestershire

	ja	nein
Hast du verstanden, dass ich dich um die Teilnahme an eine Forschungsstudie gebeten habe?		
Hast du das beigefügte Infoschreiben gelesen bzw. eine Kopie davon erhalten?		
Hast du die Vorteile sowie die Risiken, die mit der Teilnahme an die Studie verbunden sind, verstanden?		
Hast du verstanden dass es dir freisteht, den Forscher zu kontaktieren, um mit ihm die Fragen zu klären bzw. über die Studie zu diskutieren?		
Hast du verstanden dass es dir freisteht, die Teilnahme abzulehnen bzw. die Zustimmung an die Studie jederzeit folgenlos zu widerrufen und auf deinem Wunsch, all deiner Daten zurückgezogen werden können?		
Hast du verstanden dass ich deine Daten diskret behandeln werde?		
Hast du verstanden wer Zugang zu deinen Daten erhalten wird?		

Ich möchte gern an diese Studie teilnehmen.

Name in Druckschrift: _____

Unterschrift: _____

Datum: _____

Bevorzugte Telefonnummer: _____

Email: _____

Appendix XI THE SYMLOG ADJECTIVE RATING FORM IN ENGLISH

Your Name_____ Group _____

Name of person described_____ Circle the best choice for each item:

		(0)	(1)	(2)	(3)	(4)
U	active, dominant, talks a lot	never	rarely	sometimes	often	always
UP	Extroverted, outgoing, positive	never	rarely	sometimes	often	always
UPF	a purposeful democratic task leader	never	rarely	sometimes	often	always
UF	an assertive business-like manager	never	rarely	sometimes	often	always
UNF	authoritarian, controlling, disapproving	never	rarely	sometimes	often	always
UN	domineering, tough-minded, powerful	never	rarely	sometimes	often	always
UNB	provocative, egocentric, shows off	never	rarely	sometimes	often	always
UB	jokes around, expressive, dramatic	never	rarely	sometimes	often	always
UPB	entertaining, sociable, smiling, warm	never	rarely	sometimes	often	always
P	friendly, equalitarian	never	rarely	sometimes	often	always
PF	works cooperatively with others	never	rarely	sometimes	often	always
F	analytical, task-oriented, problem-solving	never	rarely	sometimes	often	always
NF	legalistic, has to be right	never	rarely	sometimes	often	always
N	unfriendly, negativistic	never	rarely	sometimes	often	always
NB	irritable, cynical, won't cooperate	never	rarely	sometimes	often	always
B	shows feelings and emotions	never	rarely	sometimes	often	always
PB	affectionate, likable, fun to be with	never	rarely	sometimes	often	always
DP	looks up to others, appreciative, trustful	never	rarely	sometimes	often	always
DPF	gentle, willing to accept responsibility	never	rarely	sometimes	often	always
DF	obedient, works submissively	never	rarely	sometimes	often	always
DNF	self-punishing, works too hard	never	rarely	sometimes	often	always
DN	depressed, sad, resentful	never	rarely	sometimes	often	always
DNB	alienated, quits, withdraws	never	rarely	sometimes	often	always
DB	afraid to try, doubts own ability	never	rarely	sometimes	often	always
DPB	quietly happy just to be with others	never	rarely	sometimes	often	always
D	passive, introverted, says little	never	rarely	sometimes	often	always

(Bales & Cohen, 1979, p. 393)

Appendix XII THE SYMLOG ADJECTIVE RATING FORM IN GERMAN

Name_____ Gruppe _____

Name der beschriebenen Person_____

Machen Sie bei jeder Position einen Kreis um die bestzutreffende Antwort:

		(0)	(1)	(2)	(3)	(4)
U	aktiv, dominant, spricht viel	nie	selten	manchmal	häufig	immer
UP	extravertiert, geht aus sich heraus, positiv	nie	selten	manchmal	häufig	immer
UPF	ein zielorientierter, demokratischer Leiter in der Aufgabenlösung	nie	selten	manchmal	häufig	immer
UF	ein durchsetzungsfreudiger, geschäftsorientierter Manager	nie	selten	manchmal	häufig	immer
UNF	autoritär, kontrollierend, ablehnend	nie	selten	manchmal	häufig	immer
UN	dominant, hartnäckig, stark	nie	selten	manchmal	häufig	immer
UNB	provozierend, eigensinnig, protzend	nie	selten	manchmal	häufig	immer
UB	witzelt, ausdrucksstark, dramatisch	nie	selten	manchmal	häufig	immer
UPB	unterhaltsam, kontaktfreudig, lächelnd, warm	nie	selten	manchmal	häufig	immer
P	freundlich, partnerschaftlich	nie	selten	manchmal	häufig	immer
PF	kooperativ in der Zusammenarbeit mit anderen	nie	selten	manchmal	häufig	immer
F	analytisch, aufgaben- bzw. lösungsorientiert	nie	selten	manchmal	häufig	immer
NF	gewissenhaft, rechthaberisch	nie	selten	manchmal	häufig	immer
N	unfreundlich, negativistisch	nie	selten	manchmal	häufig	immer
NB	reizbar, zynisch, unkooperativ	nie	selten	manchmal	häufig	immer
B	zeigt Gefühle und Emotionen	nie	selten	manchmal	häufig	immer
PB	liebevoll, sympathisch, lustig als Gesellschaft	nie	selten	manchmal	häufig	immer
DP	heraufschauend, anerkennend, vertrauensvoll	nie	selten	manchmal	häufig	immer
DPF	nett, verantwortungsbewusst	nie	selten	manchmal	häufig	immer
DF	gehorsam, unterwürfig in der Arbeit	nie	selten	manchmal	häufig	immer
DNF	selbstbestrafend, arbeitet zu hart	nie	selten	manchmal	häufig	immer
DN	depressiv, traurig, zurückweisend	nie	selten	manchmal	häufig	immer
DNB	entfremdet, resigniert, zurückziehend	nie	selten	manchmal	häufig	immer
DB	gehemmt vor dem Versucht, zweifelt an eigener Fähigkeit	nie	selten	manchmal	häufig	immer
DPB	in Stille glücklich darüber, mit anderen zusammen zu sein	nie	selten	manchmal	häufig	immer
D	passiv, introvertiert, spricht wenig	nie	selten	manchmal	häufig	immer

English original: (Bales & Cohen, 1979, p. 393)

Appendix XIII RESULTS OF OUTPUT ASSESSMENT

EXPERT ASSESSMENT

Experiment session 1

Control group/ test device 1			Expert 1				Expert 2			
No.	Device features	Solution	Feasibility	Novelty	Costs	sum	Feasibility	Novelty	Costs	sum
1	Device identification	1	4	1	4	9	3	3	4	10
		2	4	1	4	9	4	1	4	9
		3	5	0	4	9	4	0	3	7
		4	4	1	4	9	3	0	5	8
		5	3	4	2	9	5	4	2	11
2	Comprehensive instruction of use	1	4	2	3	9	3	4	4	11
		2	1	5	1	7	4	4	3	11
		1	2	3	2	7	5	5	2	12
		2	3	2	3	8	4	4	3	11
		3	3	3	3	9	5	4	3	12
		4	3	3	2	8	4	2	5	11
		5	2	4	2	8	3	3	2	8
		6	4	2	3	9	4	4	3	11
		7	2	4	2	8	5	4	2	11
		8	3	4	1	8	4	4	2	10
4	Size of device	1	3	2	2	7	3	2	2	7
5	Customization for target groups	1	5	2	1	8	3	4	3	10
6	Needle length	1	3	4	3	10	3	5	3	11
7	Needle protection	1	1	4	2	7	4	3	3	10
8	Flexibility of doses	1	2	3	2	7	5	4	3	12
9	Injection time	1	4	3	3	10	5	4	3	12
		1	5	2	3	10	5	3	4	12
10	Marking of injection end	1	2	3	2	7	5	4	3	12
11	Patient's fear of device	1	2	4	2	8	3	2	2	7
		2	3	3	3	9	5	2	3	10
		3	5	2	1	8	5	3	3	11
12	Adequate training	1	3	0	3	6	5	0	4	9
		2	4	1	3	8	5	0	4	9
		3	2	1	1	4	5	0	3	8
13	Shelf life	1	4	0	3	7	3	1	4	8
		2	3	2	4	9	5	2	4	11
		3	4	3	3	10	5	4	3	12
14	Device robustness	1	3	3	1	7	4	3	3	10
		2	4	3	3	10	5	4	3	12

Control group/ test device 1			Expert 3				Average experts			
No.	Device features	Solution	Feasibility	Novelty	Costs	sum	Feasibility	Novelty	Costs	sum
1	Device identification	1	4	1	4	9	3.7	1.7	4.0	**9.3**
		2	4	0	4	8	4.0	0.7	4.0	**8.7**
		3	4	0	4	8	4.3	0.0	3.7	**8.0**
		4	4	1	4	9	3.7	0.7	4.3	**8.7**
		5	2	1	3	6	3.3	3.0	2.3	**8.7**

2	Comprehensive instruction of use	1	3	1	3	7	3.3	2.3	3.3	**9.0**
		2	1	3	3	7	2.0	4.0	2.3	**8.3**
3	Ease of use	1	1	3	1	5	2.7	3.7	1.7	**8.0**
		2	1	2	1	4	2.7	2.7	2.3	**7.7**
		3	0	4	0	4	2.7	3.7	2.0	**8.3**
		4	2	2	2	6	3.0	2.3	3.0	**8.3**
		5	1	2	1	4	2.0	3.0	1.7	**6.7**
		6	2	2	2	6	3.3	2.7	2.7	**8.7**
		7	1	3	1	5	2.7	3.7	1.7	**8.0**
		8	1	3	1	5	2.7	3.7	1.3	**7.7**
4	Size of device	1	2	2	1	5	2.7	2.0	1.7	**6.3**
5	Customization for target groups	1	1	2	2	5	3.0	2.7	2.0	**7.7**
6	Needle length	1	1	2	1	4	2.3	3.7	2.3	**8.3**
7	Needle protection	1	1	2	1	4	2.0	3.0	2.0	**7.0**
8	Flexibility of doses	1	2	3	1	6	3.0	3.3	2.0	**8.3**
9	Injection time	1	2	1	2	5	3.7	2.7	2.7	**9.0**
		1	3	1	3	7	4.3	2.0	3.3	**9.7**
10	Marking of injection end	1	3	2	2	7	3.3	3.0	2.3	**8.7**
11	Patient's fear of device	1	2	2	1	5	2.3	2.7	1.7	**6.7**
		2	2	1	2	5	3.3	2.0	2.7	**8.0**
		3	3	1	2	6	4.3	2.0	2.0	**8.3**
12	Adequate training	1	4	0	4	8	4.0	0.0	3.7	**7.7**
		2	4	0	4	8	4.3	0.3	3.7	**8.3**
		3	4	1	4	9	3.7	0.7	2.7	**7.0**
13	Shelf life	1	1	3	1	5	2.7	1.3	2.7	**6.7**
		2	1	3	1	5	3.0	2.3	3.0	**8.3**
		3	2	1	1	4	3.7	2.7	2.3	**8.7**
14	Device robustness	1	2	2	2	6	3.0	2.7	2.0	**7.7**
		2	2	1	2	5	3.7	2.7	2.7	**9.0**

Experiment session 2

Test group/test device 1			**Expert 1**				**Expert 2**			
No.	Device features	Solution	Feasibility	Novelty	Costs	sum	Feasibility	Novelty	Costs	sum
1	Device identification	1	3	4	2	9	4	5	3	12
		2	3	4	2	9	4	5	3	12
		3	2	5	2	9	4	5	3	12
		4	3	3	4	10	5	5	2	12
2	Comprehensive instruction of use	1	3	4	2	9	4	5	3	12
		2	3	4	2	9	4	5	3	12
		3	2	5	2	9	4	5	3	12
		4	3	3	4	10	5	5	2	12
3	Ease of use	1	2	5	2	9	4	5	4	13
		2	2	3	1	6	1	5	2	8
		3	3	3	1	7	3	4	3	10
		4	3	4	2	9	3	5	2	10
		5	1	2	1	4	3	2	3	8
		6	3	5	2	10	4	4	3	11
		7	4	3	3	10	4	3	3	10

		8	5	3	3	11	4	5	3	12
		9	2	4	3	9	4	4	4	12
		10	3	3	2	8	4	4	3	11
		11	4	4	2	10	5	4	4	13
		12	1	5	1	7	4	4	3	11
4	Size of device	1	2	5	2	9	4	5	4	13
		2	2	3	1	6	1	5	2	8
		3	3	3	1	7	3	4	3	10
		4	1	2	1	4	3	2	3	8
		5	3	5	2	10	4	4	3	11
5	Customisation for target groups	1	1	3	1	5	0	4	1	5
		2	4	4	2	10	5	4	4	13
		3	3	4	3	10	5	4	2	11
		4	4	3	2	9	4	3	3	10
6	Needle length	1	2	3	1	6	1	5	2	8
		2	1	5	1	7	4	4	3	11
7	Needle protection	1	2	3	1	6	1	5	2	8
8	Flexibility of doses	1	2	3	1	6	1	5	2	8
		2	3	3	1	7	3	4	3	10
		3	3	4	3	10	5	4	2	11
9	Injection time	1	2	3	1	6	1	5	2	8
		2	3	3	1	7	3	4	3	10
		3	1	2	1	4	3	2	3	8
10	Marking of injection end	1	2	3	1	6	1	5	2	8
		2	3	2	3	8	5	4	2	11
		3	4	2	4	10	5	3	3	11
11	Patient's fear of device	1	2	5	2	9	4	5	4	13
		2	2	3	1	6	1	5	2	8
		3	3	4	2	9	3	5	2	10
		4	2	4	1	7	3	2	3	8
		5	5	3	3	11	4	5	3	12
		6	3	3	2	8	4	4	3	11
		7	4	4	2	10	5	4	4	13
		8	4	3	2	9	4	3	3	10
12	Adequate training									
13	Shelf life	1	2	3	1	6	1	5	2	8
		2	3	3	1	7	3	4	3	10
		3	2	4	3	9	4	4	4	12
		4	2	5	2	9	2	5	2	9
14	Device robustness	1	2	3	1	6	1	5	2	8
		2	3	3	1	7	3	4	3	10
		3	4	2	4	10	4	3	3	10
		4	4	3	3	10	4	3	3	10
		5	5	1	4	10	4	4	3	11
		6	4	3	2	9	4	3	3	10
		7	3	3	2	8	3	3	3	9
		8	4	3	2	9	4	3	3	10
		9	5	2	3	10	5	4	3	12

Test group/test device 1			**Expert 3**				**Average experts**			
No.	Device features	Solution	Feasibility	Novelty	Costs	sum	Feasibility	Novelty	Costs	sum
1	Device identification	1	3	1	2	6	3.3	3.3	2.3	**8.9**
		2	3	1	2	6	3.3	3.3	2.3	**8.9**
		3	3	2	2	7	3.0	4.0	2.3	**9.3**

		4	2	1	3	6	3.3	3.0	3.0	**9.3**
2	Comprehensive instruction of use	1	3	1	2	6	3.3	3.3	2.3	**8.9**
		2	3	1	2	6	3.3	3.3	2.3	**8.9**
		3	3	2	2	7	3.0	4.0	2.3	**9.3**
		4	2	1	3	6	3.3	3.0	3.0	**9.3**
3	Ease of use	1	1	3	1	5	2.3	4.3	2.3	**8.9**
		2	1	2	1	4	1.3	3.3	1.3	**5.9**
		3	2	2	2	6	2.7	3.0	2.0	**7.7**
		4	1	3	1	5	2.3	4.0	1.7	**8.0**
		5	2	2	2	6	2.0	2.0	2.0	**6.0**
		6	1	4	1	6	2.7	4.3	2.0	**9.0**
		7	4	1	4	9	4.0	2.3	3.3	**9.6**
		8	2	2	3	7	3.7	3.3	3.0	**10.0**
		9	2	1	3	6	2.7	3.0	3.3	**9.0**
		10	1	3	1	5	2.7	3.3	2.0	**8.0**
		11	1	2	1	4	3.3	3.3	2.3	**8.9**
		12	1	4	2	7	2.0	4.3	2.0	**8.3**
4	Size of device	1	1	3	1	5	2.3	4.3	2.3	**8.9**
		2	1	2	1	4	1.3	3.3	1.3	**5.9**
		3	2	2	2	6	2.7	3.0	2.0	**7.7**
		4	2	2	2	6	2.0	2.0	2.0	**6.0**
		5	1	4	1	6	2.7	4.3	2.0	**9.0**
5	Customisation for target groups	1	2	2	2	6	1.0	3.0	1.3	**5.3**
		2	1	2	1	4	3.3	3.3	2.3	**8.9**
		3	1	4	1	6	3.0	4.0	2.0	**9.0**
		4	2	1	3	6	3.3	2.3	2.7	**8.3**
6	Needle length	1	1	2	1	4	1.3	3.3	1.3	**5.9**
		2	1	4	2	7	2.0	4.3	2.0	**8.3**
7	Needle protection	1	1	2	1	4	1.3	3.3	1.3	**5.9**
8	Flexibility of doses	1	1	2	1	4	1.3	3.3	1.3	**5.9**
		2	2	2	2	6	2.7	3.0	2.0	**7.7**
		3	1	4	1	6	3.0	4.0	2.0	**9.0**
9	Injection time	1	1	2	1	4	1.3	3.3	1.3	**5.9**
		2	2	2	2	6	2.7	3.0	2.0	**7.7**
		3	2	2	2	6	2.0	2.0	2.0	**6.0**
10	Marking of injection end	1	1	2	1	4	1.3	3.3	1.3	**5.9**
		2	3	2	2	7	3.7	2.7	2.3	**8.7**
		3	4	2	3	9	4.3	2.3	3.3	**9.9**
11	Patient's fear of device	1	1	3	1	5	2.3	4.3	2.3	**8.9**
		2	1	2	1	4	1.3	3.3	1.3	**5.9**
		3	1	3	1	5	2.3	4.0	1.7	**8.0**
		4	2	2	2	6	2.3	2.7	2.0	**7.0**
		5	2	2	3	7	3.7	3.3	3.0	**10.0**
		6	1	3	1	5	2.7	3.3	2.0	**8.0**
		7	1	2	1	4	3.3	3.3	2.3	**8.9**
		8	2	1	3	6	3.3	2.3	2.7	**8.3**
12	Adequate training									
13	Shelf life	1	1	2	1	4	1.3	3.3	1.3	**5.9**
		2	2	2	2	6	2.7	3.0	2.0	**7.7**
		3	2	1	3	6	2.7	3.0	3.3	**9.0**
		4	1	3	1	5	1.7	4.3	1.7	**7.7**
14	Device robustness	1	1	2	1	4	1.3	3.3	1.3	**5.9**
		2	2	2	2	6	2.7	3.0	2.0	**7.7**
		3	3	2	2	7	3.7	2.3	3.0	**9.0**

		4	4	1	4	9	4.0	2.3	3.3	**9.6**
		5	4	1	4	9	4.3	2.0	3.7	**10.0**
		6	3	1	3	7	3.7	2.3	2.7	**8.7**
		7	1	2	1	4	2.3	2.7	2.0	**7.0**
		8	2	1	3	6	3.3	2.3	2.7	**8.3**
		9	4	1	4	9	4.7	2.3	3.3	**10.3**

Experiment session 3

Control group/ test device 2			**Expert 1**				**Expert 2**			
No.	Device features	Solution	Feasibility	Novelty	Costs	sum	Feasibility	Novelty	Costs	sum
1	Device identification	1	3	2	3	8	3	3	4	10
		2	5	1	4	10	4	4	3	11
		3	4	3	4	11	4	3	3	10
		4	3	3	3	9	4	4	3	11
2	Comprehensive instruction of use	1	4	4	3	11	4	3	3	10
		2	3	5	2	10	3	3	2	8
		3	4	2	4	10	5	3	3	11
		4	4	2	3	9	5	4	3	12
3	Ease of use	1	3	3	4	10	3	4	4	11
		2	2	3	3	8	4	4	3	11
4	Size of device	1	3	2	4	9	5	4	3	12
		2	3	3	4	10	3	4	4	11
5	Customization for target groups	1	4	2	1	7	4	3	3	10
		2	2	3	2	7	4	3	3	10
		3	4	3	3	10	4	3	3	10
		4	4	4	3	11	4	3	3	10
		5	3	3	3	9	4	3	3	10
		6	3	3	3	9	4	3	3	10
		7	1	5	2	8	3	4	3	10
6	Needle length	1	1	5	2	8	3	4	3	10
7	Needle protection	1	4	1	3	8	4	3	3	10
		2	2	3	2	7	4	3	3	10
		3	2	5	1	8	4	4	4	12
8	Flexibility of doses	1	3	3	2	8	4	4	3	11
9	Injection time	1	4	3	2	9	4	4	3	11
		2	3	3	3	9	5	3	3	11
		3	2	4	1	7	5	4	3	12
10	Marking of injection end	1	4	2	3	9	4	3	3	10
		2	4	3	3	10	3	3	4	10
11	Patient's fear of device	1	4	1	3	8	4	3	3	10
		2	2	3	2	7	4	3	3	10
		3	2	5	1	8	4	4	4	12
		4	4	3	3	10	5	0	4	9
		5	4	4	2	10	5	0	3	8
		6	3	3	3	9	5	0	4	9
		7	4	3	2	9	5	4	2	11
		8	4	3	1	8	1	4	1	6
12	Adequate training	1	4	3	3	10	5	0	4	9
		2	4	4	2	10	5	0	3	8
		3	3	3	3	9	5	0	3	8
		4	4	3	2	9	5	1	2	8
		5	4	3	1	8	1	4	1	6

13	Shelf life	1	3	3	2	8	3	3	3	9
		2	4	1	4	9	4	3	4	11
14	Device robustness									
Control group/ test device 2			**Expert 3**				**Average experts**			
No.	Device features	Solution	Feasibility	Novelty	Costs	sum	Feasibility	Novelty	Costs	sum
1	Device identification	1	4	1	3	8	3.3	2.0	3.3	**8.6**
		2	4	1	4	9	4.3	2.0	3.7	**10.0**
		3	2	1	2	5	3.3	2.3	3.0	**8.6**
		4	2	1	2	5	3.0	2.7	2.7	**8.4**
2	Comprehensive instruction of use	1	3	1	2	6	3.7	2.7	2.7	**9.1**
		2	3	1	2	6	3.0	3.0	2.0	**8.0**
		3	3	1	4	8	4.0	2.0	3.7	**9.7**
		4	4	0	4	8	4.3	2.0	3.3	**9.6**
3	Ease of use	1	4	1	3	8	3.3	2.7	3.7	**9.7**
		2	1	3	2	6	2.3	3.3	2.7	**8.3**
4	Size of device	1	3	2	2	7	3.7	2.7	3.0	**9.4**
		2	4	1	3	8	3.3	2.7	3.7	**9.7**
5	Customization for target groups	1	3	1	2	6	3.7	2.0	2.0	**7.7**
		2	2	2	2	6	2.7	2.7	2.3	**7.7**
		3	4	1	4	9	4.0	2.3	3.3	**9.6**
		4	4	1	4	9	4.0	2.7	3.3	**10.0**
		5	1	2	2	5	2.7	2.7	2.7	**8.1**
		6	2	2	2	6	3.0	2.7	2.7	**8.4**
		7	2	4	2	8	2.0	4.3	2.3	**8.6**
6	Needle length	1	2	4	2	8	2.0	4.3	2.3	**8.6**
7	Needle protection	1	3	2	3	8	3.7	2.0	3.0	**8.7**
		2	2	3	1	6	2.7	3.0	2.0	**7.7**
		3	1	4	1	6	2.3	4.3	2.0	**8.6**
8	Flexibility of doses	1	1	3	1	5	2.7	3.3	2.0	**8.0**
9	Injection time	1	2	2	1	5	3.3	3.0	2.0	**8.3**
		2	2	2	2	6	3.3	2.7	2.7	**8.7**
		3	2	2	2	6	3.0	3.3	2.0	**8.3**
10	Marking of injection end	1	3	0	3	6	3.7	1.7	3.0	**8.4**
		2	1	3	2	6	2.7	3.0	3.0	**8.7**
11	Patient's fear of device	1	3	2	3	8	3.7	2.0	3.0	**8.7**
		2	2	3	1	6	2.7	3.0	2.0	**7.7**
		3	1	4	1	6	2.3	4.3	2.0	**8.6**
		4	4	1	4	9	4.3	1.3	3.7	**9.3**
		5	4	1	4	9	4.3	1.7	3.0	**9.0**
		6	4	1	4	9	4.0	1.3	3.7	**9.0**
		7	4	1	4	9	4.3	2.7	2.7	**9.7**
		8	4	1	3	8	3.0	2.7	1.7	**7.4**
12	Adequate training	1	4	1	4	9	4.3	1.3	3.7	**9.3**
		2	4	1	4	9	4.3	1.7	3.0	**9.0**
		3	4	1	4	9	4.0	1.3	3.3	**8.6**
		4	4	1	4	9	4.3	1.7	2.7	**8.7**
		5	4	1	3	8	3.0	2.7	1.7	**7.4**
13	Shelf life	1	1	3	2	6	2.3	3.0	2.3	**7.6**
		2	4	1	5	10	4.0	1.7	4.3	**10.0**
14	Device robustness									

Experiment session 4

Test group/test device 2			Expert 1				Expert 2			
No.	Device features	Solution	Feasibility	Novelty	Costs	sum	Feasibility	Novelty	Costs	sum
1	Device identification	1	4	3	3	10	5	3	4	12
2	Comprehensive instruction of use									
3	Ease of use	1	2	3	2	7	3	4	2	9
		2	3	4	3	10	2	4	2	8
		3	4	3	3	10	5	3	4	12
		4	2	5	1	8	2	4	1	7
		5	1	5	1	7	1	5	1	7
		6	4	3	3	10	3	4	2	9
		7	3	3	2	8	4	4	3	11
		8	1	3	2	6	5	3	4	12
		9	3	4	2	9	4	4	3	11
		10	3	3	2	8	4	4	2	10
4	Size of device	1	2	3	2	7	3	4	2	9
		2	1	3	2	6	5	3	4	12
		3	3	4	2	9	4	4	3	11
		4	3	3	2	8	4	4	2	10
5	Customisation for target groups	1	3	4	3	10	2	4	2	8
6	Needle length	1	2	5	1	8	2	4	1	7
		2	3	3	2	8	4	4	3	11
		3	1	3	2	6	5	3	4	12
7	Needle protection	1	2	5	1	8	2	4	1	7
		2	1	3	2	6	5	3	4	12
8	Flexibility of dose	1	2	5	1	8	2	4	1	7
		2	2	4	3	9	4	4	3	11
9	Injection time	1	2	5	1	8	2	4	1	7
		2	1	3	2	6	5	3	4	12
10	Marking of injection end	1	2	5	1	8	2	4	1	7
		2	1	3	2	6	5	3	4	12
11	Patient's fear of device	1	4	3	3	10	3	4	2	9
		2	2	5	1	8	2	4	1	7
		3	1	3	1	5	1	5	1	7
		4	2	4	2	8	3	4	2	9
		5	1	3	2	6	5	3	4	12
		6	3	4	2	9	4	4	3	11
12	Adequate training									
13	Shelf life	1	2	4	1	7	3	4	2	9
		2	3	3	2	8	5	3	4	12
		3	3	4	3	10	2	4	2	8
		4	2	5	1	8	2	4	1	7
		5	1	5	3	9	1	5	1	7
		6	3	3	1	7	4	3	4	11
		7	3	3	2	8	4	3	4	11

		8	4	3	3	10	3	4	2	9
		9	3	3	2	8	4	4	3	11
14	Device robustness	1	3	4	3	10	2	4	2	8
Test group/test device 2			**Expert 3**				**Average experts**			
No.	Device features	Solution	Feasibility	Novelty	Costs	sum	Feasibility	Novelty	Costs	**sum**
1	Device identification	1	4	1	3	8	4.3	2.3	3.3	**9.9**
2	Comprehensive instruction of use									
3	Ease of use	1	1	3	1	5	2.0	3.3	1.7	**7.0**
		2	2	2	2	6	2.3	3.3	2.3	**7.9**
		3	2	2	2	6	3.7	2.7	3.0	**9.4**
		4	1	3	1	5	1.7	4.0	1.0	**6.7**
		5	1	3	1	5	1.0	4.3	1.0	**6.3**
		6	1	3	2	6	2.7	3.3	2.3	**8.3**
		7	0	4	0	4	2.3	3.7	1.7	**7.7**
		8	1	3	2	6	2.3	3.0	2.7	**8.0**
		9	1	3	2	6	2.7	3.7	2.3	**8.7**
		10	1	3	2	6	2.7	3.3	2.0	**8.0**
4	Size of device	1	1	3	1	5	2.0	3.3	1.7	**7.0**
		2	1	3	2	6	2.3	3.0	2.7	**8.0**
		3	1	3	2	6	2.7	3.7	2.3	**8.7**
		4	1	3	2	6	2.7	3.3	2.0	**8.0**
5	Customisation for target groups	1	2	2	2	6	2.3	3.3	2.3	**7.9**
6	Needle length	1	1	3	1	5	1.7	4.0	1.0	**6.7**
		2	0	4	0	4	2.3	3.7	1.7	**7.7**
		3	1	3	2	6	2.3	3.0	2.7	**8.0**
7	Needle protection	1	1	3	1	5	1.7	4.0	1.0	**6.7**
		2	1	3	2	6	2.3	3.0	2.7	**8.0**
8	Flexibility of dose	1	1	3	1	5	1.7	4.0	1.0	**6.7**
		2	2	2	2	6	2.7	3.3	2.7	**8.7**
9	Injection time	1	1	3	1	5	1.7	4.0	1.0	**6.7**
		2	1	3	2	6	2.3	3.0	2.7	**8.0**
10	Marking of injection end	1	1	3	1	5	1.7	4.0	1.0	**6.7**
		2	1	3	2	6	2.3	3.0	2.7	**8.0**
11	Patient's fear of device	1	1	3	1	5	2.7	3.3	2.0	**8.0**
		2	1	3	1	5	1.7	4.0	1.0	**6.7**
		3	1	3	1	5	1.0	3.7	1.0	**5.7**
		4	1	3	1	5	2.0	3.7	1.7	**7.4**
		5	1	3	2	6	2.3	3.0	2.7	**8.0**
		6	1	3	2	6	2.7	3.7	2.3	**8.7**
12	Adequate training									
13	Shelf life	1	1	3	2	6	2.0	3.7	1.7	**7.4**
		2	1	3	2	6	3.0	3.0	2.7	**8.7**
		3	2	2	2	6	2.3	3.3	2.3	**7.9**
		4	1	3	1	5	1.7	4.0	1.0	**6.7**
		5	1	3	1	5	1.0	4.3	1.7	**7.0**
		6	1	3	2	6	2.7	3.0	2.3	**8.0**
		7	2	3	2	7	3.0	3.0	2.7	**8.7**
		8	1	3	2	6	2.7	3.3	2.3	**8.3**
		9	0	4	0	4	2.3	3.7	1.7	**7.7**
14	Device robustness	1	2	2	2	6	2.3	3.3	2.3	**7.9**

PATIENT ASSESSMENT

Experiment session 1

Control group/ test device 1			Patient 1	Patient 2	Patient 3	Average patients
No.	Device features	Solution	Patient perception	Patient perception	Patient perception	Patient perception
1	Device identification	1	4	5	3	**4.0**
		2	5	5	4	**4.7**
		3	3	3	1	**2.3**
		4	4	4	0	**2.7**
		5	4	1	5	**3.3**
2	Comprehensive instruction of use	1	5	5	3	**4.3**
		2	5	5	0	**3.3**
3	Ease of use	1	4	4	0	**2.7**
		2	3	0	0	**1.0**
		3	4	4	0	**2.7**
		4	4	1	4	**3.0**
		5	4	1	1	**2.0**
		6	4	4	2	**3.3**
		7	4	3	3	**3.3**
		8	4	4	0	**2.7**
4	Size of device	1	1	2	5	**2.7**
5	Customization for target groups	1	5	5	3	**4.3**
6	Needle length	1	2	3	1	**2.0**
7	Needle protection	1	4	3	3	**3.3**
8	Flexibility of doses	1	4	4	4	**4.0**
9	Injection time	1	5	5	2	**4.0**
		1	4	4	4	**4.0**
10	Marking of injection end	1	5	5	4	**4.7**
11	Patient's fear of device	1	4	1	1	**2.0**
		2	5	4	4	**4.3**
		3	5	5	3	**4.3**
12	Adequate training	1	5	3	4	**4.0**
		2	5	2	4	**3.7**
		3	4	1	5	**3.3**
13	Shelf life	1	5	1	0	**2.0**
		2	4	1	3	**2.7**
		3	5	5	1	**3.7**
14	Device robustness	1	4	3	3	**3.3**
		2	5	5	1	**3.7**

Experiment session 2

Test group/test device 1			Patient 1	Patient 2	Patient 3	Average patients
No.	Device features	Solution	Patient perception	Patient perception	Patient perception	Patient perception
1	Device identification	1	5	0	0	**1.7**
		2	5	0	0	**1.7**
		3	4	1	0	**1.7**
		4	5	1	4	**3.3**
2	Comprehensive instruction of use	1	5	0	0	**1.7**
		2	5	0	0	**1.7**
		3	4	1	0	**1.7**
		4	5	1	4	**3.3**
3	Ease of use	1	3	3	4	**3.3**
		2	1	1	5	**2.3**
		3	4	4	5	**4.3**
		4	4	2	4	**3.3**
		5	4	5	3	**4.0**
		6	3	1	2	**2.0**
		7	4	4	2	**3.3**
		8	5	4	1	**3.3**
		9	5	5	0	**3.3**
		10	3	2	0	**1.7**
		11	5	5	3	**4.3**
		12	5	4	0	**3.0**
4	Size of device	1	3	3	4	**3.3**
		2	1	1	5	**2.3**
		3	4	4	5	**4.3**
		4	4	5	3	**4.0**
		5	3	1	2	**2.0**
5	Customisation for target groups	1	4	5	1	**3.3**
		2	5	5	3	**4.3**
		3	5	5	1	**3.7**
		4	5	5	0	**3.3**
6	Needle length	1	1	1	5	**2.3**
		2	5	4	0	**3.0**
7	Needle protection	1	1	1	5	**2.3**
8	Flexibility of doses	1	1	1	5	**2.3**
		2	4	4	5	**4.3**
		3	5	5	1	**3.7**
9	Injection time	1	1	1	5	**2.3**
		2	4	4	5	**4.3**
		3	4	5	3	**4.0**
10	Marking of injection end	1	1	1	5	**2.3**
		2	4	5	3	**4.0**
		3	4	4	4	**4.0**
11	Patient's fear of device	1	3	3	4	**3.3**
		2	1	1	5	**2.3**
		3	4	2	2	**2.7**
		4	3	5	1	**3.0**
		5	5	4	1	**3.3**
		6	3	2	0	**1.7**

		7	5	5	3	**4.3**
		8	5	5	0	**3.3**
12	Adequate training					
13	Shelf life	1	1	1	5	**2.3**
		2	4	4	5	**4.3**
		3	5	5	0	**3.3**
		4	5	3	1	**3.0**
14	Device robustness	1	1	1	5	**2.3**
		2	4	4	5	**4.3**
		3	4	4	3	**3.7**
		4	4	4	2	**3.3**
		5	4	4	4	**4.0**
		6	4	2	3	**3.0**
		7	2	1	2	**1.7**
		8	5	5	0	**3.3**
		9	4	2	2	**2.7**

Experiment session 3

Control group/ test device 2			**Patient 1**	**Patient 2**	**Patient 3**	**Average patients**
No.	Device features	Solution	Patient perception	Patient perception	Patient perception	Patient perception
1	Device identification	1	5	5	4	**4.7**
		2	5	5	3	**4.3**
		3	5	1	3	**3.0**
		4	5	5	3	**4.3**
2	Comprehensive instruction of use	1	5	1	0	**2.0**
		2	5	5	0	**3.3**
		3	5	1	4	**3.3**
		4	4	1	5	**3.3**
3	Ease of use	1	4	4	3	**3.7**
		2	5	2	4	**3.7**
4	Size of device	1	5	3	1	**3.0**
		2	5	2	3	**3.3**
5	Customization for target groups	1	4	4	1	**3.0**
		2	4	2	0	**2.0**
		3	4	4	0	**2.7**
		4	4	4	0	**2.7**
		5	4	3	2	**3.0**
		6	4	3	0	**2.3**
		7	5	5	4	**4.7**
6	Needle length	1	5	5	4	**4.7**
7	Needle protection	1	4	4	2	**3.3**
		2	4	1	2	**2.3**
		3	0	0	2	**0.7**
8	Flexibility of doses	1	4	3	2	**3.0**
9	Injection time	1	4	1	0	**1.7**
		2	4	4	2	**3.3**
		3	4	1	2	**2.3**
10	Marking of injection end	1	4	1	4	**3.0**
		2	5	5	1	**3.7**
11	Patient's fear of device	1	4	4	1	**3.0**
		2	4	1	1	**2.0**
		3	0	0	1	**0.3**

		4	4	1	3	**2.7**
		5	4	4	3	**3.7**
		6	4	4	3	**3.7**
		7	4	4	3	**3.7**
		8	5	5	3	**4.3**
12	Adequate training	1	4	1	3	**2.7**
		2	4	4	2	**3.3**
		3	4	4	3	**3.7**
		4	4	4	3	**3.7**
		5	5	5	3	**4.3**
13	Shelf life	1	4	2	1	**2.3**
		2	5	5	3	**4.3**
14	Device robustness					

Experiment session 4

Test group/test device 2			**Patient 1**	**Patient 2**	**Patient 3**	**Average patients**
No.	Device features	Solution	Patient perception	Patient perception	Patient perception	Patient perception
1	Device identification	1	4	4	4	**4.0**
2	Comprehensive instruction of use					
3	Ease of use	1	2	1	1	**1.3**
		2	4	4	2	**3.3**
		3	3	3	1	**2.3**
		4	4	1	0	**1.7**
		5	4	0	0	**1.3**
		6	4	1	0	**1.7**
		7	4	4	0	**2.7**
		8	4	3	3	**3.3**
		9	4	2	3	**3.0**
		10	4	1	1	**2.0**
4	Size of device	1	2	1	1	**1.3**
		2	4	3	3	**3.3**
		3	4	2	3	**3.0**
		4	4	1	1	**2.0**
5	Customisation for target groups	1	4	4	2	**3.3**
6	Needle length	1	4	1	0	**1.7**
		2	4	4	0	**2.7**
		3	4	3	3	**3.3**
7	Needle protection	1	4	1	0	**1.7**
		2	4	3	3	**3.3**
8	Flexibility of dose	1	4	1	0	**1.7**
		2	4	3	1	**2.7**
9	Injection time	1	4	1	0	**1.7**
		2	4	3	3	**3.3**
10	Marking of injection end	1	4	1	0	**1.7**
		2	4	3	3	**3.3**
11	Patient's fear of device	1	2	1	3	**2.0**

		2	4	1	2	**2.3**
		3	4	0	0	**1.3**
		4	1	1	0	**0.7**
		5	4	3	3	**3.3**
		6	4	2	2	**2.7**
12	Adequate training					
13	Shelf life	1	4	2	0	**2.0**
		2	4	3	0	**2.3**
		3	4	4	2	**3.3**
		4	4	1	0	**1.7**
		5	4	1	0	**1.7**
		6	4	1	0	**1.7**
		7	4	2	0	**2.0**
		8	4	1	0	**1.7**
		9	4	4	0	**2.7**
14	Device robustness	1	4	4	2	**3.3**

Appendix IX TRIZ TOOLS AND METHODS

This section is intended to provide more details on the TRIZ tools and methods used in the 5-stage TRIZ procedure in this thesis.

A key concept in the above-mentioned procedure is “contradiction”. A contradiction in the innovation process arises when the attempt to improve one system function leads to the deterioration of another system function at the same time. The following are some examples of such contradictions:

- A bigger size of the ventilation fan is thought to increase the cooling effect. However, with the same electrical capacity, the heavier weight of the bigger fan will reduce the rotation force and in turn reduce the cooling benefit (bigger fan to increase cooling effect ⇔ higher weight that reduces cooling effect);
- Especially elderly female patients need longer needles to pierce through the tights they wear. However, bigger needle size increases the patients fear of the device (langer needle for practical application ⇔ small needle size to reduce patients’ fear);
- Medical device patients often prefer a small device for easier daily transport. At the same time, they also require a number of sophisticated device functions. However, sophisticated device funtions tend to take up more space, which sets a limit to the desired small size (bigger device size to accommodate sophisticated functions ⇔ small size for daily transport).

The basic idea of the contradiction matrix is to improve one system function wihout having to compromising the other apparently contradicting function. In order to do so, Althuller extracted information out of thousands of patents and identified the solutions to each pair of contradictions as inventive principles in the39 x 39 contradiction matrix (Ilevbare, Probert & Phaal, 2013).

Below is an overview of the 39 x 39 contradiction matrix.

Worsening parameter → / Improving parameter ↓		1 Weight of moving object	2 Weight of stationary object	3 Length of moving object	4 Length of stationary object	5 Area of moving object	6 Area of stationary object	7 Volume of moving object	8 Volume of stationary object	9 Speed	10 Force (Intensity)	11 Stress or pressure	12 Shape	13 Stability of the object´s composition	14 Strength	15 Duration of action by moving object	16 Duration of action by stationary object	17 Temperature	18 Illumination intensity	19 Use of energy by moving object	20 Use of energy by stationary object	21 Power	22 Loss of energy	23 Loss of substance	24 Loss of information	25 Loss of time	26 Quantity of substance	27 Reliability	28 Measurement Accuracy	29 Manufacturing precision	30 Object-affected harmful factors	31 Object-generated harmful factors	32 Ease of manufacture	33 Convenience of use	34 Ease of repair	35 Adaptability or versatility	36 Device complexity	37 Difficulty of detecting and measuring	38 Extent of automation	39 Productivity
1	Weight of moving object		-	15 8 29 34	-	29 2 40 28	-	29 2 40 28	-	2 8 15 38	8 10 18 37	10 36 37 40	10 14 35 40	1 35 19 39	28 27 18 40	5 34 31 35	-	6 29 4 38	19 1 32	35 12 34 31	-	12 36 18 31	6 2 34 19	5 35 20 28	10 24 35	10 35 20 28	3 26 18 31	3 11 1 27	28 27 35 26	28 35 26 18	22 21 18 27	22 35 31 39	27 28 1 36	35 3 2 24	2 27 28 11	29 5 15 8	26 30 36 34	28 29 26 32	26 35 18 19	35 3 24 37
2	Weight of stationary object	-		-	10 1 29 35	-	35 30 13 2	-	5 35 14 2	-	8 10 19 35	13 29 10 18	13 10 29 14	26 39 1 40	28 2 10 27	-	2 27 19 6	28 19 32 22	19 32 35	-	18 19 28 1	15 19 18	18 19 28 15	5 8 13 30	10 15 35	10 20 35 26	19 6 18 26	10 28 8 3	18 26 28	10 1 35 27	2 19 22 37	35 22 1 39	28 1 9	6 13 1 32	2 27 18 11	19 15 29	25 28 17 15	2 26 35	1 28 15 35
3	Length of moving object	8 15 29 34	-		-	15 17 4	-	7 17 4 35	-	13 4 8	17 10 4	1 8 35	1 8 10 29	1 8 15 34	8 35 29 34	19	-	10 15 19	32	8 35 24	-	1 35	7 2 35 39	4 29 23 10	1 24	15 2 29	29 35	10 14 29 40	28 32 4	10 28 29 37	1 15 17 24	17 15	1 29 17	15 29 35 4	1 28 10	14 15 1 16	1 19 26 24	35 1 26 24	17 24 26 16	14 4 28 29
4	Length of stationary object	-	35 28 40 29	-		-	17 7 10 40	-	35 8 2 14	-	28 10	1 14 35	13 14 15 7	39 37 35	15 14 28 26	-	1 40 35	3 35 39 18	3 25	-	-	12 8	6 28	10 28 24 35	24 26	30 29 14	-	15 29 28	32 28 3	2 32 10	1 18	-	15 17 27	2 25	3	1 35	1 26	26	-	30 14 7 26
5	Area of moving object	2 17 29 4	-	14 15 18 4	-		-	7 14 17 4	-	29 30 4 34	19 30 35 2	10 15 36 28	5 34 29 4	11 2 13 39	3 15 40 14	6 3	-	2 15 16	15 32 19 13	19 32	-	19 10 32 18	15 17 30 26	10 35 2 39	30 26	26 4	29 30 6 13	29 9	26 28 32 3	2 32	22 33 28 1	17 2 18 39	13 1 26 24	15 17 13 16	15 13 10 1	15 30	14 1 13	2 36 26 18	14 30 28 23	10 26 34 2
6	Area of stationary object	-	30 2 14 18	-	26 7 9 39	-		-	-	-	1 18 35 36	10 15 36 37	-	2 38	40	-	2 10 19 30	35 39 38	-	-	-	17 32	17 7 30	10 14 18 39	30 16	10 35 4 18	2 18 40 4	32 35 40 4	26 28 32 3	2 29 18 36	27 2 39 35	22 1 40	40 16	16 4	16	15 16	1 18 36	2 35 30 18	23	10 15 17 7
7	Volume of moving object	2 26 29 40	-	1 7 4 35	-	1 7 4 17	-		-	29 4 38 34	15 35 26 37	6 35 36 37	1 15 29 4	28 10 1 29	9 14 15 7	6 35 4	-	34 39 10 18	2 13 10	35	-	35 6 13 18	7 15 13 16	36 39 34 10	2 22	2 6 34 10	29 30 7	14 1 40 11	26 28	25 28 2 16	22 21 27 35	17 2 40 1	29 1 40	15 13 30 12	10	15 29	26 1	29 26 4	35 34 16 24	10 6 2 34
8	Volume of stationary object	-	35 10 19 14	19 14	35 8 2 14	-	-	-		-	2 18 37	24 35	7 2 35	34 28 35 40	9 14 17 15	-	35 34 38	35 6 4	-	-	-	30 6	-	10 39 35 34	-	35 16 32 18	35 3	2 35 16	-	35 10 25	34 39 19	30 18 35 4	35	-	1	-	1 31	2 17 26	-	35 37 10 2
9	Speed	8 28 13 38	-	13 14 8	-	29 30 34	-	7 29 9 34	-		13 28 15 19	6 18 38 40	35 15 18 34	28 33 1 18	8 3 26 14	3 19 35 5	-	28 30 36 2	10 13 19	8 15 35 38	-	19 35 38 2	14 20 19 35	10 13 28 38	13 26	-	10 19 29 38	11 35 27 28	28 32 1 24	10 28 32 25	1 28 35 23	2 24 35 21	35 13 8 1	32 28 13 12	34 2 28 27	15 10 26	10 28 4 34	3 34 27 16	10 18	-
10	Force (Intensity)	8 1 37 18	18 13 1 28	17 19 9 36	28 10	19 10 15	1 18 36 37	15 9 12 37	2 36 18 37	13 28 15 12		18 21 11	10 35 40 34	35 10 14 27	35 10 14 27	19 2	-	35 10 21	-	19 17 10	1 16 36 37	19 35 18 37	14 15	8 35 40 5	-	10 37 36	14 29 18 36	3 35 13 21	35 10 23 24	28 29 37 36	1 35 40 18	13 3 36 24	15 37 18 1	1 28 3 25	15 1 11	15 17 18 20	26 35 10 18	36 37 10 19	2 35	3 28 35 37
11	Stress or pressure	10 36 37 40	13 29 10 18	35 10 36	35 1 14 16	10 15 36 28	10 15 36 37	6 35 10	35 24	6 35 36	36 35 21		35 4 15 10	35 33 2 40	9 18 3 40	19 3 27	-	35 39 19 2	-	14 24 10 37	-	10 35 14	2 36 25	10 35 3 37	-	37 36 4	10 14 36	10 13 19 35	6 28 25	3 35	22 2 37	2 33 27 18	1 35 16	11	2	35	19 1 35	2 36 37	35 24	10 14 35 37
12	Shape	8 10 29 40	15 10 26 3	29 34 5 4	13 14 10 7	5 34 4 10	-	14 4 15 22	7 2 35	35 15 34 18	35 10 37 40	34 15 10 14		33 1 18 4	30 14 10 40	14 26 9 25	-	22 14 19 32	13 15 32	2 6 34 14	-	4 6 2	14	35 29 3 5	-	14 10 34 17	36 22	10 40 16	28 32 1	32 30 40	22 1 2 35	35 1	17 32 1 28	32 15 26	2 13 1	1 15 29	16 29 1 28	15 13 39	15 1 32	17 26 34 10
13	Stability of the object´s composition	21 35 2 39	26 39 1 40	13 15 1 28	37	2 11 13	39	28 10 19 39	34 28 35 40	33 15 28 18	10 35 21 16	2 35 40	22 1 18 4		17 9 15	13 27 10 35	39 3 35 23	35 1 32	32 3 27 15	13 19	27 4 29 18	32 35 27 31	14 2 39 6	2 14 30 40	-	35 27	15 32 35	-	13	18	35 24 30 18	35 40 27 39	35 19	32 35 30	2 35 10 16	35 30 34 2	2 35 22 26	35 22 39 23	1 8 35	23 35 40 3

Worsening parameter → / Improving parameter ↓		Weight of moving object	Weight of stationary object	Length of moving object	Length of stationary object	Area of moving object	Area of stationary object	Volume of moving object	Volume of stationary object	Speed	Force (Intensity)	Stress or pressure	Shape	Stability of the object´s composition	Strength	Duration of action by moving object	Duration of action by stationary object	Temperature	Illumination intensity	Use of energy by moving object	Use of energy by stationary object	Power	Loss of energy	Loss of substance	Loss of information	Loss of time	Quantity of substance	Reliability	Measurement Accuracy	Munufacturing precision	Object-affected harmful factors	Object-generated harmful factors	Ease of manufacture	Convenience of use	Ease of repair	Adaptability or versatility	Device complexity	Difficulty of detecting and measuring	Extent of automation	Productivity
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39
1 4	Strength	1 8 40 15	40 26 27 1	1 15 8 35	15 14 28 26	3 34 40 29	9 40 28	10 15 14 7	9 14 17 15	8 13 26 14	10 18 3 14	10 3 18 40	10 30 35 40	13 17 35		27 3 26	-	30 10 40	35 19	19 35 10	35	10 26 35 28	35	35 28 31 40	-	29 3 28 10	29 10 27	11 3	3 27 16	3 27	18 35 37 1	15 35 22 2	11 3 10 32	32 40 28 2	27 11 3	15 3 32	2 13 28	27 3 15 40	15	29 35 10 14
1 5	Duration of action by moving object	19 5 34 31	-	2 19 9	-	3 17 19	-	10 2 19 30	-	3 35 5	19 2 16	19 3 27	14 26 28 25	13 3 35	27 3 10		-	19 35 39	2 19 4 35	28 6 35 18	-	19 10 35 38	-	28 27 3 18	10	20 10 28 18	3 35 10 40	11 2 13	3	3 27 16 40	22 15 33 28	21 39 16 22	27 1 4	12 27	29 10 27	1 35 13	10 4 28 15	19 29 39 35	6 10	35 17 14 19
1 6	Duration of action by stationary object	-	6 27 19 16	-	1 40 35	-	-	-	35 34 38	-	-	-	-	39 35 3 23	-	-		19 18 36 40	-	-	-	16	-	27 16 18 38	10	28 20 10 16	3 35 31	34 27 6 40	10 26 24	-	17 1 40 33	22	35 10	1	1	2	-	25 34 6 35	1	20 10 16 38
1 7	Temperature	36 22 6 38	22 35 32	15 19 9	15 19 3	3 35 39 18	35 38	34 39 40 18	35 6 4	2 28 36 30	35 10 3 21	35 39 19 2	14 22 19 32	1 35 32	10 30 22 40	19 13 39	19 18 36 40		32 30 21 16	19 18 36 40	-	2 14 17 25	21 17 35 38	21 36 39 31	-	35 28 21 18	3 17 30 39	19 35 3 10	32 19 24	24	22 33 35 2	22 35 2 24	26 27	26 27	4 10 16	2 18 27	2 17 16	3 27 35 31	26 2 19 16	15 28 35
1 8	Illumination intensity	19 1 32	2 35 32	19 32 16	-	19 32 26	-	2 13 10	-	13 19 10	26 19 6	-	32 30	32 3 27	35 19	2 19 6	-	32 35 19		32 1 19	32 35 1 15	32	13 16 1 6	13 1	1 6	19 1 26 17	1 19	-	11 15 32	3 32	15 19	35 19 32 39	19 35 28 26	28 26 19	15 17 13 16	15 1 19	6 32 11 3	32 15	2 26 10	2 25 16
1 9	Use of energy by moving object	12 18 28 31	-	12 28	-	15 19 25	-	35 13 18	-	8 15 35	16 26 21 2	23 14 25	12 2 29	19 13 17 24	5 19 9 35	28 35 6 18	-	19 24 3 14	2 15 19		-	6 19 37 18	12 22 15 24	35 24 18 5	-	35 38 19 18	34 23 16 18	19 21 11 27	3 1 32	-	1 35 6 27	2 35 6	28 26 30	19 35	1 15 17 28	15 17 13 16	2 29 27 28	35 38	32 2	12 28 35
2 0	Use of energy by stationary object	-	19 9 6 27	-	-	-	-	-	-	-	36 37	-	-	27 4 29 18	35	-	-	-	19 2 35 32	-		-	-	28 27 18 31	-	-	3 35 31	10 36 23	-	-	10 2 22 37	19 22 18	1 4	-	-	-	-	19 35 16 25	-	1 6
2 1	Power	8 36 38 31	19 26 17 27	1 10 35 37	-	19 38	17 32 13 38	35 6 38	30 6 25	15 35 2	26 2 36 35	22 10 35	29 14 2 40	35 32 15 31	26 10 28	19 35 10 38	16	2 14 17 25	16 6 19	16 6 37	-		10 35 38	28 27 18 38	10 19	35 20 10 6	4 34 19	19 24 26 31	32 15 2	32 2	19 22 31 2	18 2 35	26 10 34	26 35 10	34 2 10 34	19 17 34	20 19 30 34	19 35 16	28 2 17	28 35 34
2 2	Loss of energy	15 6 19 28	19 6 18 9	7 2 6 13	6 38 7	15 26 17 30	17 7 30 18	7 18 23	7	16 35 38	36 38	-	-	14 2 39 6	26	-	-	19 38 7	1 13 32 15	-	-	3 38		35 27 2 27	19 10	10 18 32 7	7 18 25	11 10 35	32	-	21 22 35 2	21 35 2 22	-	35 32 1	2 19	-	7 23	35 3 15 23	2	28 35 34
2 3	Loss of substance	35 6 23 40	35 6 22 32	14 29 10 39	10 28 24	35 2 10 31	10 18 39 31	1 29 30 36	3 39 18 31	10 13 28 38	14 15 18 40	3 36 37 10	29 35 3 5	2 14 30 40	35 28 31 40	28 27 3 18	27 16 18 38	21 36 39 31	1 6 13	35 18 24 5	28 27 12 31	28 27 18 38	35 27 2 31		-	15 18 35 10	6 3 10 24	10 29 39 35	16 34 31 28	35 10 24 31	33 22 30 40	10 1 34 29	15 34 33	32 28 2 24	2 35 34 27	15 10 2	35 10 28 24	35 18 10 13	35 10 18	28 35 10 23
2 4	Loss of information	10 24 35	10 35 5	1 26	26	30 26	30 16	-	2 22	26 32	-	-	-	-	-	10	10	-	19	-	-	10 19	19 10	-		24 26 28 32	24 28 35	10 28 23	-	-	22 10 1	10 21 22	32	27 22	-	-	-	35 33	35	13 23 15
2 5	Loss of time	10 20 37 35	10 20 26 5	15 2 29	30 24 14 5	26 4 5 16	10 35 17 4	2 5 34 10	35 16 32 18	-	10 37 36 5	37 36 4	4 10 34 17	35 3 22 5	29 3 28 18	20 10 28 18	28 20 10 16	35 29 21 18	1 19 26 17	35 38 19 18	1	35 20 10 6	10 5 18 32	35 18 10 39	24 26 28 32		35 38 18 16	10 30 4	24 26 28 32	24 26 28 18	35 18 34	35 22 18 39	35 28 34 4	4 28 10 34	32 10 1	35 28	6 29	18 28 32 10	24 28 35 30	-
2 6	Quantity of substance	35 6 18 31	27 26 18 35	29 35 14 18	-	15 14 19	2 18 40 4	15 20 29	-	35 29 34 28	35 14 3	10 36 14 3	35 14	15 2 17 40	14 35 34 10	3 35 34 10	3 35 31	3 17 39	-	34 29 16 18	3 35 31	35	7 18 25	6 3 10 24	24 28 35	35 38 18 16		18 3 28 40	3 2 28	3 2 28	33 30	35 33 29 31	3 35 40 39	29 1 35 27	35 29 25 10	2 32 10 25	15 3 29	3 13 27 10	8 35	13 29 3 27
2 7	Reliability	3 8 10 40	3 10 8 28	15 9 14 4	15 29 28 11	17 10 14 16	32 35 40 4	3 10 14 24	2 35 24	21 35 11 28	8 28 10 3	10 24 35 19	35 1 16 11	-	11 28	2 35 3 25	34 27 6 40	3 35 10	11 32 13	21 11 27 19	36 23	21 11 26 31	10 11 35	10 35 29 39	10 28	10 30 4	21 28 40 3		32 3 11 23	11 32 1	27 35 2 40	35 2 40 26	-	27 17 40	1 11	13 35 8 24	13 35 1	27 40 28	11 13 27	1 35 38

Worsening parameter → / Improving parameter ↓		Weight of moving object	Weight of stationary object	Length of moving object	Length of stationary object	Area of moving object	Area of stationary object	Volume of moving object	Volume of stationary object	Speed	Force (Intensity)	Stress or pressure	Shape	Stability of the object's composition	Strength	Duration of action by moving object	Duration of action by stationary object	Temperature	Illumination intensity	Use of energy by moving object	Use of energy by stationary object	Power	Loss of energy	Loss of substance	Loss of information	Loss of time	Quantity of substance	Reliability	Measurement Accuracy	Munufacturing precision	Object-affected harmful factors	Object-generated harmful factors	Ease of manufacture	Convenience of use	Ease of repair	Adaptability or versatility	Device complexity	Difficulty of detecting and measuring	Extent of automation	Productivity
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39
28	Measurement Accuracy	32 35 26 28	28 35 25 26	28 26 5 16	32 28 3 16	26 28 32 3	26 28 32 3	32 13 6	-	28 13 32 24	32 2	6 28 32	6 28 32	32 35 13	28 6 32	28 6 32	10 26 24	6 19 28 24	6 1 32	3 6 32	-	3 6 32	26 32 27	10 16 31 28	-	24 32 28 32	2 6 32	5 11 1 23		-	28 24 22 26	3 33 39 10	6 35 25 18	1 13 17 34	1 32 13 11	13 35 2	27 35 10 34	26 24 32 28	28 2 10 34	10 34 28 32
29	Munufacturing precision	28 32 13 18	28 35 27 9	10 28 29 37	2 32 10	28 33 29 32	2 29 18 36	32 23 2	25 10 35	10 28 32	28 19 34 36	3 35	32 30 40	30 18	3 27	3 27 40	-	19 26	3 32	32 2	-	32 2	13 32 2	35 31 10 24	-	32 26 28 18	32 30	11 32 1	-		26 28 10 36	4 17 34 26	-	1 32 35 23	25 10	-	26 2 18	-	26 28 18 23	10 18 32 39
30	Object-affected harmful factors	22 21 27 39	2 22 13 24	17 1 39 4	1 18	22 1 33 28	27 2 39 35	22 23 37 35	34 39 19 27	21 22 35 28	13 35 39 18	22 2 37	22 1 3 35	35 24 30 18	18 35 37 1	22 15 33 28	17 1 40 33	22 33 35 2	1 19 32 13	1 24 6 27	10 2 22 37	19 22 31 2	21 22 35 2	33 22 19 40	22 10 2	35 18 34	35 33 29 31	27 24 2 40	28 33 23 26	26 28 10 18		-	24 35 2	2 25 28 39	35 10 2	35 11 22 31	22 19 29 40	22 19 29 40	33 3 34	22 35 13 24
31	Object-generated harmful factors	19 22 15 39	35 22 1 39	17 15 16 22	-	17 2 18 39	22 1 40	17 2 40	30 18 35 4	35 28 3 23	35 28 1 40	2 33 27 18	35 1	35 40 27 39	15 35 22 2	15 22 33 31	21 39 16 22	22 35 2 24	19 24 39 32	2 35 6	19 18 22	2 35 18	21 35 2 22	10 1 34	10 21 29	1 22	3 24 39 1	24 2 40 39	3 33 26	4 17 34 26	-		-	-	-	-	19 1 31	2 21 27 1	2	22 35 18 39
32	Ease of manufacture	28 29 15 16	1 27 36 13	1 29 13 17	15 17 27	13 1 26 12	16 40	13 29 1 40	35	35 13 8 1	35 12	35 19 13 7	1 28 13 27	1 13 11	1 3 10 32	27 1 4	35 16	27 26 18	28 24 27 1	28 26 27 1	1 4	27 1 12 24	19 35	15 34 33	32 34 18 16	35 28 34 4	35 23 1 24	-	1 35 12 18	-	24 2	-		2 5 13 16	35 1 11 9	2 13 15	27 26 1	6 28 11 1	8 28 1	35 10 28 1
33	Convenience of use	25 2 13 15	6 13 1 25	1 17 13 12	-	1 17 13 16	18 16 15 39	1 16 35 15	4 18 39 31	18 13 34	28 13 35	2 32 12	15 34 29 28	32 35 30	32 40 3 28	29 3 8 25	1 16 25	26 27 13	13 17 1 24	1 13 24	-	35 34 2 10	2 19 13	28 32 2 24	4 10 27 22	4 28 10 34	12 35	17 27 8 40	25 13 2 34	1 32 35 39	2 25 28 39	-	2 5 12		12 26 1 32	15 34 1 16	32 26 12 17	-	1 34 12 3	15 1 28
34	Ease of repair	2 27 35 11	2 27 35 11	1 28 10 25	3 18 31	15 13 32	16 25	25 2 35 11	1	34 9	1 11 10	13	1 13 2 4	2 35	11 1 2 9	11 29 28 27	1	4 10	15 1 13	15 1 28 6	-	15 10 32 2	15 1 32 19	2 35 34 27	-	32 1 10 25	2 28 10 25	11 10 1 16	10 2 13	25 10	35 10 2 16	-	1 35 11 10	1 12 26 15		7 1 4 16	35 1 13 11	-	34 35 7 13	1 32 10
35	Adaptability or versatility	1 6 15 8	19 15 29 16	35 1 29 2	1 35 16	35 30 29 7	15 16	15 35 29	-	35 10 14	15 17 20	35 16	15 37 1 8	35 30 14	35 3 32 6	2 16	13 1 35	27 2 3 35	6 22 26 1	19 35 29 13	-	19 1 29	18 15 1	15 10 2 13	-	35 28	3 35 15	35 13 8 24	35 5 1 10	-	35 11 32 31	-	1 13 31	15 34 1 16	1 16 7 4		15 29 37 28	1	27 34 35	35 28 6 37
36	Device complexity	26 30 34 36	2 26 35 39	1 19 26 24	26	14 1 13 16	6 36	34 26 6	1 16	34 10 28	26 16	19 1 35	29 13 28 15	2 22 17 19	2 13 28	10 4 28 15	-	2 17 13	24 17 13	27 2 28 29	-	20 19 30 34	10 35 13 2	35 10 28 29	-	6 29	13 3 27 10	2 26 10 34	2 26 10 34	26 24 32	22 19 29 40	19 1	27 26 1 13	27 9 26 24	1 13	29 15 28 37		15 10 37 28	15 1 24	12 17 28
37	Difficulty of detecting and measuring	27 26 28 13	6 13 28 1	16 17 26 24	26	2 13 18 17	2 39 30 16	29 1 4 16	2 18 26 31	3 4 16 35	36 28 40 19	35 36 37 32	27 13 1 39	11 22 39 30	27 3 15 28	19 29 39 25	25 34 6 35	3 27 35 16	2 24 26	35 38	19 35 16	19 1 16 10	35 3 15 19	1 18 10 24	35 33 27 22	18 28 32 9	3 27 29 18	27 40 28 8	26 24 32 28	-	22 19 29 28	2 21	5 28 11 29	2 5	12 26	1 15	15 10 37 28		34 21	35 18
38	Extent of automation	28 26 18 35	28 26 35 10	14 13 17 28	23	17 14 13	-	35 13 16	-	28 10	2 35	13 35	15 32 1 13	18 1	25 13	6 9	-	26 2 19	8 32 19	2 32 13	-	28 2 27	23 28	35 10 18 5	35 33	24 28 35 30	35 13	11 27 32	28 26 10 34	28 26 18 23	2 33	2	1 26 13	1 12 34 3	1 35 13	27 4 1 35	15 24 10	34 27 25		5 12 35 26
39	Productivity	35 26 24 37	28 27 15 3	18 4 28 38	30 7 14 26	10 26 34 31	10 26 34 31	2 6 34 10	35 37 10 2	-	28 15 10 36	10 37 14	14 10 34 40	35 3 22 39	29 28 10 18	35 10 2 18	20 10 16 38	35 21 28 10	26 17 19 1	35 10 38 19	1	35 20 10	28 10 29 35	28 10 35 23	13 15 23	-	35 38	1 35 10 38	1 10 34 28	18 10 32 1	22 35 13 24	35 22 18 39	35 28 2 24	1 28 7 19	1 32 10 25	1 35 28 37	12 17 28 24	35 18 27 2	5 12 35 26	

(Gadd, 2011, p. 472)

Altogether, there are 40 inventive principles which may be looked up in the 39x39 contradiction matrix as generic solutions to the generic problems described as standardised contradictions. The 40 inventive principles are listed in the following table.

1	Segmentation
2	Talking out
3	Local quality
4	Asymmetry
5	Merging
6	Universality
7	Nested doll
8	Anti-Weight
9	Prior counteraction
10	Prior action
11	Cushion in advance
12	Equipotentiality
13	The other way around
14	Spheroidality – curvature
15	Dynamics
16	Partial or excessive action
17	Another dimension
18	Mechanical vibration
19	Periodic action
20	Continuity of useful action
21	Rushing through
22	Blessing in disguise
23	Feedback
24	Intermediary
25	Self-Service
26	Copying
27	Cheap short-living objects
28	Replace mechanical system
29	Pneumatics and hydraulics
30	Flexible membranes / thin films
31	Porous materials
32	Colour change
33	Homogeneity
34	Discarding and recovering
35	Parameter change
36	Phase transition
37	Thermal expansion
38	Accelerate oxidation
39	Invert environment
40	Composite materials

(E.g. Gadd, 2011, p. 472)

In the example of the ventilation fan, the objective of increasing the size without increasing the weight of fan may be described in the terminology of the 39x39 contradiction matrix as “8 volume of stationary object” (improving parameter) and “2 weight of stationary object” (worsening parameter).

By consulting the 39x39 contradictio matrix, the combination of the above parameters leads to the inventive principles “5 merging/consolidation”, “35 parameter changes”, “14 spheroidality curvature” and “2 taking out or extraction”.

a. Inventive principle “5 merging/consolidation”

This principle stands for merging identical or similar objects or operations, or to produce parallel objects or operations. A possible application of this principle is e.g. to increase the number of fan blades of the ventilator.

b. Inventive principle “35 parameter changes”

There are several variations of this inventive principle, including:

- Change the physical state (e.g. to use cooling air in gas form instead of solid fans).
- Change the concentration or density (e.g. to decrease the density of the material and thus the weight of the fans).
- Change the degree of flexibility (e.g. to use flexible fan blades out of plastic instead of metal).
- Change the temperature or volume (e.g. to reduce the thickness of the fan blades).
- Change the pressure (e.g. to produce a vacuum environment to reduce the resistance).
- Change other parameters (e.g. to implement solar cells as additional energy source).

c. Inventive principle “14 spheroidality curvature”

Some example of this principle are, e.g. to implement linear instead of rotary motion of the fan blades; to use centrifugal forces in the blade design.

d. Inventive principle “2 taking out or extraction”

This principle requires that only the necessary parts shall remain in the fan structure (e.g. elimination of the decorative housing).

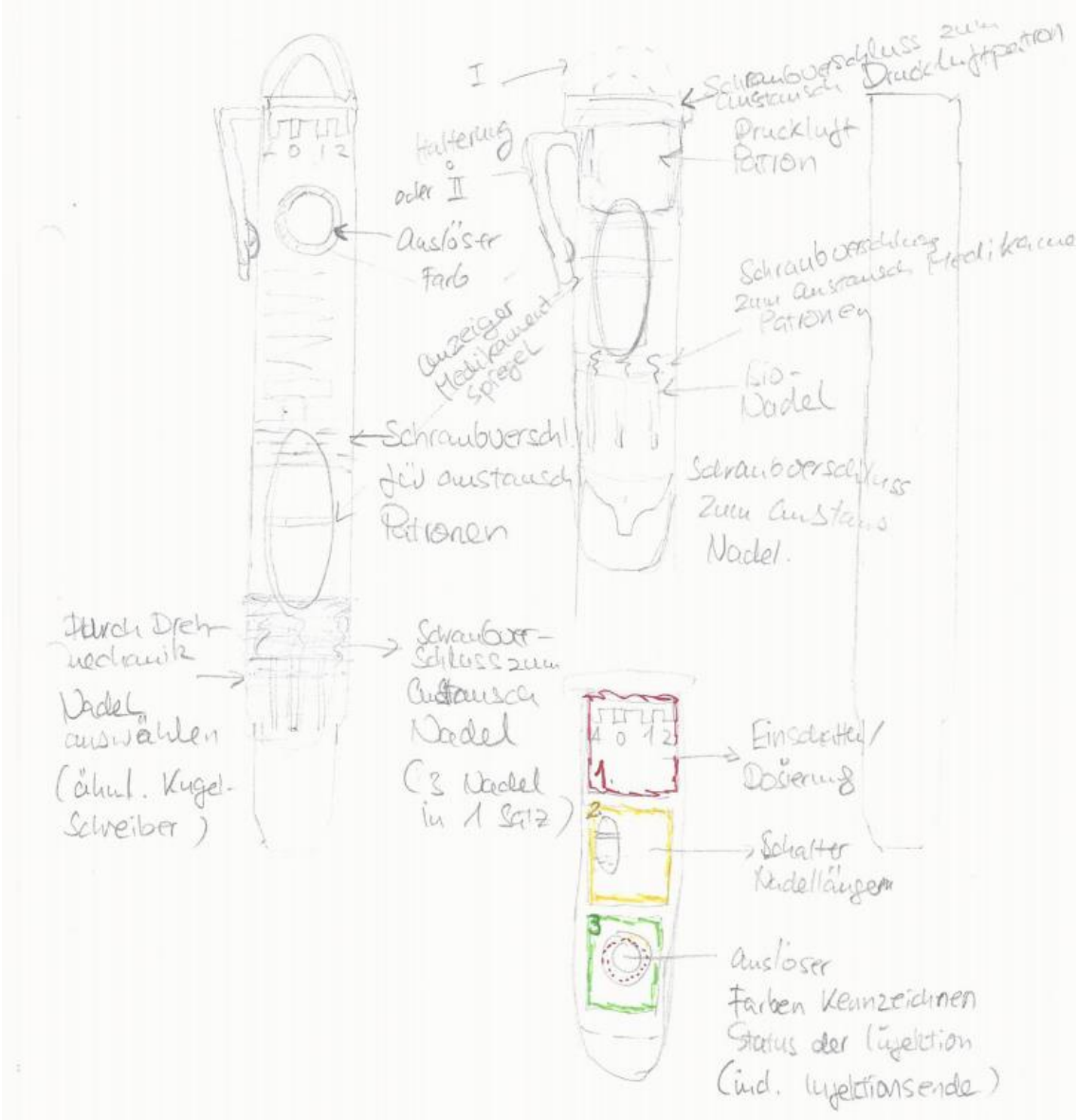
The above explanation of the inventive principle is orientated on Gadd’s interpretation (Gadd, 2011, pp. 140-174).

In practice, the determination of the improving and worsening parameters, the idea generation based on the identified inventive principles, as well as the subsequent priorization of the solutions require both experience in the relevant technical fields and TRIZ knowledge. This task is often a challenge especially when dealing with complex practical problems.

Appendix X DRAWINGS OF DESIGN DRAFTS

In some experiments sessions, the paticipants illustrated their innovation ideas in sketches of the improved device design. Those drawings are enclosed in the following.

I. TRIZ session - design a



II. TRIZ session - design b