Enhanced training devices for laparoscopic surgeons

Developping a laparoscopic simulator for the future

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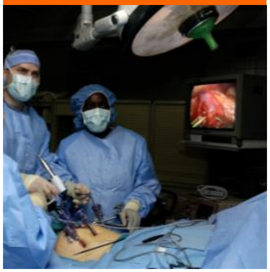

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Enhanced Training Devices for Laparoscopic Surgeons

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Foreword

This thesis is the result of an intensive and fruitful cooperation between the writer and the development team. The idea of a fusion between a medical simulator and a computer game was born three years ago as a result of an unexpected and frustrating observation that very attractive looking surgical simulators did not have the anticipated impact on surgical training. From a single persons hobby the project evolved to a multidisciplinary project with the professional participation of the computer gaming world. Both the medical world and the game developer's world are quite often characterized by an intuitive development approach. What was lacking was an analysis of the underlying assumptions, a structured approach of identifying the customer needs of a new simulator and an analysis of commercial opportunities. Mark Pieter helped us with the first two gaps with this thesis and in this way helped the team tremendously. He would have loved to tackle the commercial opportunities and market strategy but within the available time frame he had to restrict himself to the first two tasks. His work brought structure to the idea and has seriously contribute to, what we hope, unavoidable success of the simulator. On behalf of the whole development team I would like to thank him for his dedication, enthusiasm and painstaking research.

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Preface

This thesis is written as a final deliverable for the master thesis research of the MBA: Business Development at the University of Groningen. In this master the student learns how to study market, product, technology and organizational developments in an integrated way. During this research an integrated way of looking at these four elements was used to perform a master thesis research at the University Medical Hospital Groningen (UMCG).
The research in this thesis has focused on new product development in medical device technologies. A medical device technology development process was created to build an attractive and immersive laparoscopic simulator for the Skills Center at the UMCG. Furthermore the first steps of this process were performed to identify the functional design parameters for a laparoscopic simulator.

This thesis is written for the Skills Center to advise them on how to develop this simulator in a systematic way and how to involve users during this process. The thesis also contributes to the world of sciences. It shows the practical implementation of a theoretical framework for a medical device technology development process and gives recommendations for further scientific research in the field of medical device technology development and serious gaming.

Reading this thesis will help to understand the importance of new product development processes for medical devices. The thesis also highlights the importance of user involvement during the development process. Furthermore it gives a summary of scientific literature about the relationship of computer gaming and basic surgical skills.

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Summary

Since the beginning of the 90's minimal invasive surgery (laparoscopic surgery) has more and more replaced traditional 'open' methods of surgery. This form of surgery is different and more complex from the traditional 'open' methods, and requires different skills from surgeons than the traditional 'open' methods. Some major advantages of laparoscopic surgery are: shorter hospital stays for patients; less scar tissue; and patients return to full activity faster than patients undergoing traditional methods of surgery. The growing use of laparoscopic surgery however increased the number of incidents. The number of incidents for laparoscopic surgery far exceeded the incidents for 'open' surgery. This was also noticed by the Dutch Inspectorate for Healthcare. They performed a study on the quality of minimal invasive surgery in the Netherlands. One of the main causes of the problem was the lack of laparoscopic surgery training for surgeons and residents.
The Skills Center of the University Medical Center Groningen is a training facility for surgeons and residents. It offers multiple simulators which can be used to train laparoscopic skills. Despite of the free availability of high tech simulators and even after the report of the inspectorate was published the simulators in the Skills Center are hardly used by surgeons and residents. During preliminary research it became clear there were a few reasons for why these simulators were underutilized. Surgeons and residents said: that they do not have enough time to visit the center and use the simulators; simulators are not appealing enough; simulators are not realistic enough; simulators are not attractive enough to use; and not always readily available. For this reason the Skills Center made the simulators 24 hours a day available in an attempt to increase use. Still this did not resulted in increased use of the simulators. Consequently the Skills Center came up with the idea to build a entertaining and immersive simulator based on a commercially available game console Which intrinsically motivates the user to keep using it. This simulator is going to be based on computer game technology.

This research had two main objectives. Firstly it focused on creating a product development process which included the involvement of users. Secondly it focused on creating a list of functional design parameters for this new simulator. Before this research started a literature study was performed to check whether this product could theoretically work. In the literature plenty of evidence was found on a positive relationship between improved surgical skills and computer game experience. Multiple scientific articles proved that computer video game experience has a positive effect on basis surgery skills.

For this simulator a tailored new product development process was made. This model included five stages: idea generation and concept development; device design and concept development; prototype testing in-house and trials in real field; production; and device deployment in the market and user feedback. For every stage the user involvement methods were determined. Furthermore the process was iterative meaning the design team goes back and forth through the New Product Development stages. By consistently involving users throughout the process it could be checked whether the results comply with the user needs.

The first step of the design process was to come up with a list of functional design parameters. The two activities that were performed during this first stage were: identifying customer needs and translating these customer needs into functional design parameters. By means of unstructured interviews with fourteen medical professionals a list of hundred twenty raw user needs were made. The needs needed to be prioritized to be able to make trade-offs during the design process. These needs were categorized and prioritized by means of a focus group of medical professionals. The next step was for the researcher to translate these needs into functional design parameters for the simulator.

This process resulted in a list of twenty-four functional parameters with a relative importance for every parameter. Two main conclusions could be drawn from this list. Firstly the basic function of the simulator should be training basic surgical skills with replica laparoscopic instruments. This function was on top of the list of functional parameters and differed significantly from the rest of the list. Secondly there were five other parameters which were seen as most important for the simulator. These five parameters are: limited movement area for controllers; high enjoyment of play; freedom of choices during the game (sandbox style game); multiple players; and competition elements. These parameters must be used in the next step of the design process to develop concepts for the simulator. Furthermore these parameters can be used when trade-offs have to be made during the design process.

1 Introduction

The first chapter of this thesis will give an introduction to the setting that the research is executed in. It will also explain some terminology that is not common in the world of business studies.

1.1 Laparoscopic surgery

Since the 1990's minimal invasive surgery (MIS) or laparoscopic surgery has become a part of almost all surgical disciplines (Rosenberg et al., 2005). This form of surgery is different and more complex from the traditional 'open' methods, and requires different skills from surgeons than the traditional 'open' methods (Rosenberg et al., 2005; Inspectie voor Volksgezondheid, 2007).
The word laparoscopy comes from the Greek word *laparo* which means 'flank' and refers to the abdominal wall, and *scope* which means 'an instrument for observations' (Spanner and Warnock, 1997). Laparoscopy is a form of surgery where a surgeon uses two or three instruments (figure 1.1) and a camera to perform the operation. The abdominal cavity is distended with carbon dioxide. The camera is connected to an endoscope which is inserted with a trocar into the umbilicus. The instruments are inserted with a trocar through the abdominal flank so the surgeon can work with the instrument inside the abdominal cavity. The camera, which is often controlled by an assistant surgeon or an OR nurse, is connected to a video screen in front of the surgeon. The screen shows what happens inside the abdominal cavity of the patient (figure 1.2).

The instruments which are used during laparoscopic surgery can perform different tasks, for example cutting, burning, holding, and knotting. Laparoscopic surgery can be used for different surgical procedures. Some well known procedures are: gallbladder removal; appendix removal; and hernia surgery. Major advantages of laparoscopic surgery are: shorter hospital stay for patients; less scar tissue;

Figure 1.1 laparoscopic instrument

Figure 1.2 Laparoscopic stomach surgery

and patients return to full activity faster than patients undergoing traditional methods of surgery (Spanner and Warnock, 1997). Laparoscopic surgery asks for much more complex operating skills than traditional surgery does. Due to: inverse hand movement; rigid instruments; 2D video display instead of 3D vision; fixed camera positions in the umbilicus; limited tactile feedback; and dependent on clear view by others, laparoscopic surgery is much more complex than open surgery (Breedveld et al., 1999).

1.2 Risk research of MIS procedures by the healthcare inspectorate

In 2007 the Dutch healthcare inspectorate published a study on the quality of minimal invasive surgery in the Netherlands. The inspectorate received incident reports on laparoscopic surgery which far exceeded the incidents of 'open' procedures. Based on these reports and warnings offered by scientific literature, the inspectorate decided to execute a formal research of the risks presented by MIS procedures.

The inspectorate concluded that: "A broad arsenal of laparoscopic surgical techniques has been implemented within a relatively short period, and the level of experience with these techniques is extremely varied. In terms of training, policy, quality assurance and instrument safety, the Inspectorate reaches largely negative conclusions. There is as yet no (national) quality system covering laparoscopic procedures." (Inspectorate for Healthcare, 2007: 58-59).

This thesis is aimed at possibilities of training surgeons and residents in their MIS skills by means of computer gaming technology. The inspectorate concludes that there is no clear standard for laparoscopic surgical skills. This has resulted in inexperienced surgeons or residents who perform difficult and complex MIS procedures, without the proper training. The consequence of this lack in training is not just that this is dangerous for the patients' health but it can even result in death. The inspectorate discovered numerous examples of patients dying due to a lack of experience and training by the surgeon or resident (Inspectorate for Healthcare, 2007). One of the recommendations of the report is enhanced training facilities for surgeons and residents. By training on simulators surgeons and residents will improve their laparoscopic skills which will lead to less risk for the patient during laparoscopic procedures (Enochsson et al., 2004 and Inspectorate for Healthcare, 2007).

1.3 Laparoscopic simulators and skills center

In open surgery, learning by doing seems to be the way to improve technical skills (Anders Ericsson, 2004). In MIS this is much more difficult. Since the surgeon cannot directly see what he or she is doing, different ways of training have been developed. One of the most suitable ways of training MIS technical skills is by using a simulator. There are currently three different types of simulators: mechanical, hybrid or virtual reality (Halvorson et al., 2005). Mechanical simulators (boxtrainers) are boxes in which organs are placed; a laparoscope is connected to the box so that a video display can show the movement of the instruments within the box. A hybrid simulator is a mechanical simulator with a computer attached to it to give feedback and guidance of the training. Virtual reality simulators use computer-generated images of objects or organs allowing the trainee to manipulate these images by using instruments as controllers (Halvorson et al., 2005).

A Skills Center is a training facility for surgeons and residents to train their technical skills. In most cases Skills Centers are part of a hospital. Most Skill Centers have different kinds of simulators within their facilities. The University Medical Center in Groningen (UMCG) has both mechanical and virtual reality simulators. Since the Inspectorate has published their report on MIS, one might expect the Skills Centers to be full of surgeons and residents trying to improve their technical skills, but the contrary appears to be true. Occupancy figures of the simulators at the UMCG Skills Center are very low. With increased application of MIS this would suggest that simulation based competence enhancement does not keep up with the number of procedures.

During preliminary research for this study, it soon became clear that the simulators are seldomly used. This work aims to clarify the reasons why surgeons and residents not using the Skills Center. It will also aim at using computer gaming technologies to improve laparoscopic skills of surgeons and residents. In the end this will hopefully lead to reduced risks for patients during MIS procedures.

1.4 University Medical Center Groningen

The research of this thesis was performed at the University Medical Center Groningen (UMCG). The UMCG is one of the largest academic hospitals in the Netherlands. With its 10.000 employees and over 1300 beds, it is sometime seen as a city within a city. The research for this thesis was executed under the responsibility of the Skills Center of the UMCG.

2 Research approach

This chapter will firstly elaborate on the root causes why surgeons and residents do not use simulators. Secondly the problem statement of this research will be formulated.

2.1 Causes

It is very useful to perform preliminary research into the root causes that lead to the problems studied. By looking at these root causes it will be easier to create a problem statement as is done later on in this chapter (van Aken et al., 2009).

The Skills Center is a high-tech institute where nurses, doctors and other medical professionals can practice medical skills in situations without patients. By doing so surgeons can acquire medical skills and competences in a safe environment without putting a patient at risk. For that purpose a large range of simulators and training models are available. The simulators are used by medical professionals to train their surgical skills and to keep their skills up-to-date. However since the opening of the Skills Center the hospital has problems getting residents and surgeons to utilize the available equipement. The main reasons surgeons and residents give for this lack of use are: that they do not have enough time to go to the center and use the simulators; simulators are not appealing enough; simulators are not realistic enough; simulators are not fun to use; and not always readily available. These reasons are confirmed by research of Bokhari et al. (2010) and by questionnaires with employees of the Skills Center during preliminary research for this thesis. To deal with this problem leaders at the Skills Center decided they needed a new innovative simulator which was more accessible, and more fun to use. One of the solutions that was raised was to use the Nintendo Wii to create a simple, cheap, easy to use laparoscopic simulator to play a computer game which makes the simulator more attractive. The player controls the game with replica laparoscopic instruments. This means that while playing a computer game subconsciously the player learns to handle laparoscopic instruments. The Nintendo Wii can be used at the residents' lounge within the hospital or even at home. For a proof of concept and to invest preliminary reactions in the field, the Skills Center build a prototype in collaboration with software developer Grendel Games from Leeuwarden and hardware developer IMDS from Roden, see figure 2.1. The game was introduced at the Game Developers Conference in San Francisco (the largest computer game conference in the world) in March 2010. At this conference the idea behind the product appeared to be a big success and already many firms and governments showed interest in the product. Consequently the product has drawn considerable media attention (Appendix I). Therefore the Skills Center decided to invest in this product and develop it.

Figure 2.1 Prototype under further development

2.2 Problem statement

In this research there were five main items included into the problem statement: the objective of the research, the main research question, the sub questions, the theme of the research and the context.

2.2.1 Objective

The objective of this research will be to advise and help the Skills Center of the UMCG with using a systematic design process and getting users involved with the new simulator. Furthermore a list of functional design parameters will be created for this simualtor.

2.2.2 Research Question

The main question for this research will therefore be: "How should the Skills Center conduct a systematic design process that will lead to an immersive laparoscopic simulator based on current computer gaming technology?"

2.2.3 Sub questions

To answer the main research questions the following sub questions needs to be answered:

- How does playing a computer game help to improve laparoscopic/surgical skills?
- What does a new product development process look like for a medical device?
- What are the best methods to get users involved during the development process of a medical device and at what stage are they best utilized?
- What are the user requirements for a laparoscopic simulator?
- How are these needs translated into functional design parameters for the laparoscopic simulator?
- What are these functional design parameters for the laparoscopic simulator?

2.2.4 Context

The context of this research consists of four items: organization, department, research commissioner and stakeholders.

Organization:
University Medical Center Groningen (UMCG)
Department:
Wenckebach Institute (UMCG Skill Center)

Research Commissioner:
Skills Center and UMCG

Stakeholders:
UMCG – Organization
Skills Center (UMCG) – Main commissioner (design team)
Triade Groep (UMCG) – Financer of the project
Grendel Games – Software developer and Financer (design team)
LIMIS – Financier of the project (design team)

2.2.5 Theme

The theme of this research is *new product development (NPD)*. During the preliminary interviews at the UMCG it became clear there was very limited expertise within the institute about how to develop a new product. For example, during one of the intake interviews for this assignment the people working on the product were already drawing all kind of prototypes on a white board to show what the product should look like, whereas they had not answered the questions of what the simulator should do, and what the needs of the users are. This example illustrates there was a lack of knowledge on new product development process. If the Skills Center wants this product to succeed they need a new product development process that can be used for development of this product.

2.2.6 Scope

Van Aken et al. (2007) point out the importance of a well-defined research question. Due to limited time and resources a clear focus will guarantee higher quality research. In this research the focus is on two specific aspects: first the NPD process with involvement of users, secondly the first stage of the NPD process was used to define functional design parameters for the laparoscopic simulator. Further research needs to be performed after this thesis, to develop the simulator.

3 Theoretical framework

The first step in this research is to perform an extensive literature study to answer the first three sub questions. The first aspect that needs to be studied is; will playing video games help to improve technical skills as a surgeon. This determines whether it is useful to continue to develop the simulator. The second aspect that needs to be studied is; what will a new product development (NPD) process look like for a medical device. To guarantee that the simulator will be developed in a systematic way it is important to know how this needs to be done. The final aspect that needs to be studied is; what is the best ways to involve users in the development process of a medical device. Griffin and Hauser (1993) highlight the importance to implement “the voice of the customer” into the NPD process. They state that involving users in the NPD process is critical to develop a successful product (Griffin and Hauser, 1993). This research focuses on user involvement in the NPD process.

3.1 The influence of video gaming on surgical skills

In parallel with the introduction of modern laparoscopy about 20 years ago, the videogame industry also started to develop and grow rapidly (Rosser, 2007). Initially mostly children played video games, but those children who started to play video games in the 90’s are still playing games today. This means that the average gamer is now in his 30’s (Rosser, 2007). Therefore, many of today’s surgeons and residents grew up playing video games (Rosenberg et al., 2005). The skill of moving controls with your hands (joystick, mouse, etc.) which is translated on a 2D display (computer monitor, TV-screen, etc.) is very similar to the skills used during laparoscopic surgery. One would expect that playing video games is therefore a good training for eye-hand coordination and depth perception. But will playing a video game also improve surgical skills is the question.

In the last decade much research is done into the relationship between gaming and surgical skills (Badurdeen, 2009; Enochsson, 2004; Grantcharov et al., 2003; Kato, 2010; Lynch et al., 2010; Rosenberg et al., 2005; Rosser, 2007; and Shane et al., 2007). Although these studies differ in outcome most of them have positive evidence that gaming does improve surgical skills. The biggest difference in the outcome is connected to a difference in the complexity of skills. However some authors found that although basic surgery skills improves no evidence was found for improvement of more complex skills (Rosenberg et al. 2005 and Shane et al. 2007). No articles were found that opposed the positive results. In these studies there are two main methods used to prove the relationship between gaming and surgical skills. The first method is looking at the level of surgical skills of both experienced gamers and non experienced gamers. The general conclusion is that experienced gamers make fewer errors, complete tasks faster, and have better overall training scores than non-gamers (Bokhari et al., 2010; Enochsson et al., 2004; Rosser et al., 2007 and Shane et al. 2007). The second method uses two groups of non-gaming residents or surgeons. One group plays a video game for a certain amount of time every day over a certain period. The second (control) group does not play video games for that same period. At the end of the period both groups are tested on their surgical skills. Again the gamers group appears to have better results than the non gamers (Kolga Schlickum et al., 2009).
Most people think of video gaming as entertainment. But in the last few years the so-called serious games are gaining in popularity. Serious gaming is a term used to describe video games that have been designed specifically for training and education purposes (Annetta, 2010). Although a lot of serious games currently available are used for training and educational purposes, recently serious games also beginning to serve other purposes (Kato, 2010). In the context of healthcare, serious games have served several different purposes. For example: nausea in pediatric cancer; anxiety management; physical therapy and physical fitness; distrac-

tion of pain; and training surgical skills (Kato, 2010). What these games have in common is that they all seem to have an element of play. According to Rieber (1996) play consists of four attributes: "(a) it is usually voluntary; (b) it is intrinsically motivating, that is, it is pleasurable for its own sake and is not dependent on external rewards; (c) it involves some level of active, often physical, engagement; and (d) it is distinct from other behavior by having a make-believe quality" (Rieber, 1996: 44). Looking at children, they use play as a way to understand their social world. By playing "cops and robbers" for instance, they learn to understand their social world and understand feelings and viewpoints of other people (Kato, 2010). Kato (2010) poses that implementing the concept of play in training healthcare professionals would make practicing surgical skills on a simulator much more appealing. When you think of video games as a concept of play for healthcare professionals there are many opportunities to make training facilities much more appealing to them.

Although there seems to be a lot of evidence that gaming has a positive influence on surgical skills and motivates surgeons and residents to practice more, there is not really one study that demonstrates the direct causal relationship between playing video games and improved surgical skills (Kato, 2010). Nevertheless one could conclude from reading the literature that gaming most likely will improve ones skills. Rosser et al. (2007) even make the following statement: "Theoretically, game controllers could be designed so that they resemble laparoscopic instruments and other medical appliances. In addition to over-the-counter video games being used in surgical education, video games in the future could be created with specific game forms and mechanics, content, and playtime constructs that coordinate directly with the development of medically related fine motor skills, eyehand coordination, visual attention, depth perception, and computer competency" (Rosser et al., 2007: 184).

So to conclude, there appears to be a positive relationship between gaming and improved surgical skills. Furthermore games seem to intrinsically motivate people to use games frequently. Both these arguments supported by the work of Rosser et al. (2007) makes that the design team for this project believes that there is sufficient merit in the idea of developing a laparoscopic simulator based on current computer gaming technology, software and hardware.

3.2 New Product Development process

This part of the chapter will focus on the history of NPD processes and specifically on NPD processes in the medical device industry.

3.2.1 History of New Product Development

In the early 1980's Booz, Allan and Hamilton (1982) published their book on new product development. They discovered that half of product development resources are wasted on products that fail. One of their solutions to this problem was to create a formal new product development process. In 1986 Cooper and Kleinschmidt published their article about a step by step NPD process. During their research they studied 252 new product histories at 123 firms. They distinguished 13 main activities in every process. Cooper and Kleinschmidt (1986) focused on the NPD process as a key to a successful new product program. They show that firms that have a disciplined step by step NPD process are more successful than firms that do not do so in a systematic way. Furthermore, a well implemented NPD process will lead to higher quality products. Together with the book of Booz, Allen and Hamilton (1982) these publications are still used today as the basic theory for many customized NPD processes. Many industries base their NPD processes on these stages; the medical device industry is no exception (Shah & Robinson, 2009; Rochford & Rudelius, 1997 and World Health Organization, 2003). The first NPD models of Cooper and Kleinschmidt (1986) and Booz, Allan and Hamilton (1982) were more formal processes which also had their downsides. For example, they were rigid, inflexible, and time consuming. About a decade after his first article (1986), Cooper (1994) published a renewed article about a third generation NPD process. This NPD process was more focused on today's market place where: flexibility; time-to-market; user needs; and efficiency are much more important. The biggest changes in his third-generation NPD process were: more fluidity; more fuzzy gates; more focus; and more flexibility (Cooper 1994). Due to a highly competitive medical device market and demand of high quality products with increased value (Dixon et al., 2006) this type of NPD process is currently used as a basic for medical device technology development processes (Dixon et al., 2005). The coming section will describe how medical devices can be developed within this process.

3.2.2 NPD process for Medical Devices

The basics of Cooper & Kleinschmidt (1986), Cooper (1994) and Booz, Allen & Hamilton (1982) were modified by Rochford and Rudelius (1997) into 12 stages for a medical device technology development process (MDTDP): idea generation; screening; preliminary market analysis; preliminary technical analysis; preliminary production analysis; preliminary financial analysis; market study; product development; in-house product testing; customer product testing; market testing; precommercial financial analysis. The World Health Organization (2003) extended this process over a broader product life cycle into seven stages: concept and development; manufacture; packaging and labeling; advertising; sale; use; disposal. In 2006 Shah and Robinson performed a literature review on the development of medical devices and the involvement of users. They modified the previous stages of Cooper & Kleinschmidt (1986), Rochford & Rudelius (1997) and the World Health Organization (2003) into five stages: concept; design; testing and trials; production; deployment. Table 3.1 shows in detail what these stages entail. It is notable no study has made a distinction based on complexity of the product. Medical devices cover a broad range of products, from bandages, to monitors, to simulators (Bridgelal Ram et al., 2007) and according to the literature all these products can be developed with an NPD process.
Shah et al. (2009) created an MDTDP model (appendix II) based on these five stages. The model describes multiple important issues for an MTDTP. User involvement is one of the most important aspects of this model. This research focuses on user involvement in the development process and will be discussed in the next section of this chapter.

Stage	Details
Concept	Starts with idea generation and includes technical financial and commercial assessment
Design	Involves product development process from (re)design to prototype development
Testing and trials	Starts with prototype testing in house and includes trails in the real field
Production	Includes production on large scale supported by business and commercial rationale
Deployment - marketing, launch and use	Includes product marketing, launch and use in the real field

Table 3.1 MDTDP by Shah & Robinson (2006:503)

3.3 User involvement in MDTDP

In the beginning of the 90's Griffin and Hauser (1993) published their article about "the voice of the customer". They stated that (product) quality was getting more and more important in gaining competitive advantage. One of the most important elements of quality is implementing "the voice of the customer" into the NPD process. Griffin and Hauser (1993) defined "the voice of the customer" as: "a hierarchical set of "customer needs" where each need (or set of needs) has assigned to it a priority which indicates its importance to the customer" (Griffin & Hauser, 1993: 2). New products based on customer needs are of high importance for many companies (Enkel et al., 2005; Shah and Ro-

binson, 2007). For many quality awards one of the key criteria is that quality is based on what customers want; the famous Baldrige Awards are evidence of that (National Institute of Standards and Excellence, 2010).
Consequently involving users into the MDTDP is also crucial for companies that develop medical devices (Biemans, 1991; Bridgelal Ram et al., 2007; Shah et al., 2009). Apart from product quality, a second important reason for user input during MDTDP is safety. Medical devices that meet the needs of users enhance safety (Shah & Robinson, 2006). In the medical device industry basically two types of users exist: professional users (healthcare professionals, professional carers) and end-users (lay carers, patients, people with disabilities and elderly people) (Grocott et al., 2007 and Shah et al., 2009). It is important to keep this distinction in mind since it shows that both groups of users of medical devices have different needs (Shah et al., 2009). A small example to illustrate the different needs of the two groups is a hospital bed. A professional user would like the bed to steer and drive light and smooth, whereas an end-user would like it to be comfortable. Achieving a culture where knowledge is exchanged and co-operation exists with both professional users and end-users is therefore vital to produce quality and safe products (Grocott et al., 2007). Scientific literature describes many ways of involving users into the development process: brainstorming sessions; interviews; observation; focus groups etc. The next section will focus on user involvement methods and at which stage of the MDTDP they are used. Bridgelal Ram et al. (2005) performed a literature study on how user needs are represented in the MDTDP. Important outcomes of their study were that end-users were mainly located within the testing/trials phase and post market surveillance. In the concept and design phases of the MDTDP there was a lack of user involvement (Bridgelal Ram et al., 2005). Shah et al. (2009) discovered there was no universal and formal framework for involvement of both professionals and end users into the MDTDP. Not having and using such a framework could have negative repercussions for firms that develop medical devices such as continuous abandonment of the devices by users (Batavia & Hammer, 1990). This also seems to be the problem with the current medical simulators at the UMCG. Therefore Shah et al. (2009) developed a theoretical framework for a MDTDP (Appendix II). A simplified version of their framework is displayed in figure 3.1. The framework makes a clear distinction between professional users and end-users. It also includes user involvement methods within the stages of new product development process (Table 3.1). Furthermore they distinguish three scenarios: (a) device new to the market, (b) major upgrading of existing device and (c) redesigning of device prototype. By making this distinction time and effort of the development process can be reduced, since not every product has to be developed entirely from scratch. The framework of Shah et al. (2009) has been used as a basis to perform the research at the UMCG.

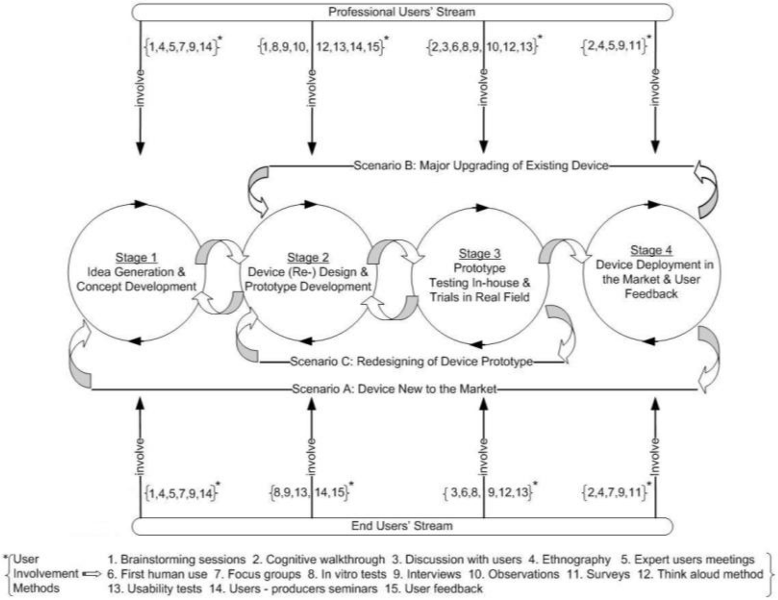

Figure 3.1 simplified framework (Shah et al., 2009)

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4 Research methodology

Based on the theoretical framework of the previous chapter it is now clear that a systematic development approach is essential for this project to succeed. The following aspects are central in this methodology chapter: the best MDTDP which fits this research; the best tools used during the different stages of the process; and the best user involvement methods for the process.

4.1 Research design

In the previous chapter it became clear that having an MDTDP has many benefits. Furthermore it highlighted the importance of involving users into MDTDP. The scientific literature describes multiple models which can be used to develop a product (Booz, Allen & Hamilton; Cooper, 1994; Cooper & Kleinschmidt, 1986 and Rochford & Rudelius, 1997). Shah et al. (2009) modified these models into a theoretical framework (appendix II) for developing medical devices and involving users in the process. The framework serves as the basis for this research. Firstly the framework is modified into a tailored MDTDP for this research (figure 4.1). Secondly a specific research model is created for this research (figure 4.2).

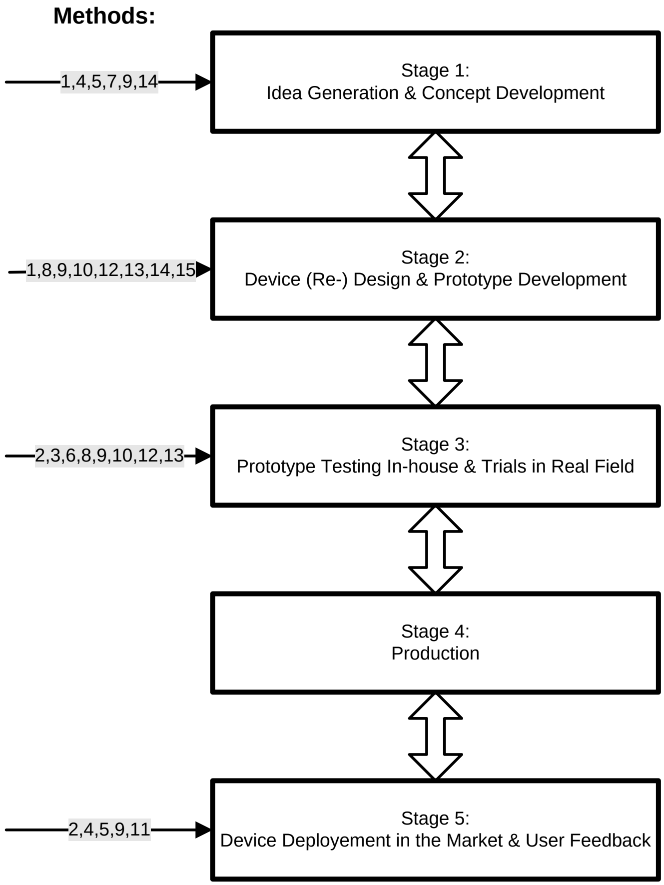
4.1.1MDTDP

The modified MDTDP (figure 4.1) for the laparoscopic simulator has two important modifications with respect to the model of Shah et al. (2009). The first modification is that one scenario is selected upfront. Of the three scenarios mentioned in section 3.3 for this project scenario (a), device new to the market, is most suitable. In the preliminary research it already became clear that the UMCG does not normally use an MDTDP. For this project it is essential to include all the stages of an MDTDP to create a structured design method, because there is an overall lack of experience within the UMCG with product development. The fact that the simulator is new to the market, is even more reason to include all the stages of the MDTDP The second modification is that in this case the end-user group is not relevant. Shah et al. (2009) make a distinction between professional users and end-users. The laparoscopic simulator is solely used by medical professionals to train their skills and is not used on patients, disabled people or elderly people. The focus in the research model is therefore exclusively on the professional user.

When looking at the modified MDTDP three aspects are important. Firstly the five stages of the NPD process form the core of the model. They are based on Shah and Robinson (2006). Shah et al. (2009) omitted stage four (production) from their framework (appendix II) since they focus solely on user involvement. The NPD process for this project is not solely focused on user involvement, thus the production stage is included. Secondly, the methods for involving the users are implemented into this model. It states which method is best used at what moment in the process. This is based on a literature study performed by Shah et al. (2009). Thirdly the NPD process is an iterative process meaning the design team goes back and forth through the NPD stages (Bridgelal Ram et al., 2007). By consistently involving users throughout the process the design team can check whether they are complying with what the user wants; hence the two way arrows in the research model (figure 4.1).

4.1.2 Research model

This research is limited to the first set of activities in stage 1 of figure 4.1. A specific, yet more elaborate research model is created which represents these activities see figure 4.2. The model is derived from the MDTDP as described in the previous section of this chapter.



User Involvement Methods:

1. Brainstorming sessions 2. Cognitive walkthrough 3. Discussion with users 4. Ethnography 5. Expert users meetings 6. First human use 7. Focus groups 8. In vitro tests 9. Interviews 10. Observations 11. Surveys 12. Think aloud method 13. Usability tests 14. Users - producers seminars 15. User feedback

Figure 4.1 Medical Device Technology Development Process

To execute stage 1 for the development of the laparoscopic simulator in a systematic way the design methods of Cross (2004) and Ulrich & Eppinger (2008) were combined. Both methods describe a step by step method about how customer needs can be identified. Furthermore quality function deployment (QFD) will be used to translate the customer needs into functional design parameters. For QFD the methodology of Cohen (1995) and Ramaswamy (1996) was used. In the next section a more elaborate explanation will be given about the design process activities. Finally some additional minor modifications are made to the model for our research, in which user involvement methods are limited to three methods: interviews, focus groups and observation. This will be further explained in section 4.2. In the center of the model (figure 4.2) the two arrows (feedback loops) show that systematic design is still an iterative process. On the right side of the model the final output for this research is given. This consists of: list of customer needs, affinity diagram (categorized customer needs) and a list of functional design parameters.

4.1.3 Systematic design activities

This research focuses on the front-end activities of the design process. There are many ways to draw models or maps for activities during the design process (Cross, 2004). For this research the model of front-end activities by Ulrich and Eppinger (2008) will be used, because they formulated a specialized sequence of activities performed in the front-end of the design process. The front-end of the process generally contains the following activities: identifying customer needs; establish target specifications; generate product concepts; select product concepts; test product concepts; set final specifications; and plan downstream development (Ulrich & Eppinger, 2008: 16). The research is aimed at finding the functional design parameters for the laparoscopic simulator. Therefore the process is modified into two activities: identifying customer needs and translating customer needs in functional design parameters (Table 4.1).

The first activity, identifying customer needs, exists of a five step method from Ulrich and Eppinger (2008). These steps will be used to identify the customer needs (Table 4.1). For the second activity: translating customer needs, quality function deployment (QFD) will be used. QFD is defined by Chan and Wu (2002) as: “an overall concept that provides a means of translating customer requirements into the appropriate technical requirements for each stage of product development and production (i.e., marketing strategies, planning, product design and engineering, prototype evaluation, production process development, production, sales)” (Chan and Wu, 2002: 463). QFD is a product development process based on interfunctional teams. This process is interesting because different functions bring different demands and needs to the design table. It also uses a visual data-presentation format that is easy to understand for both engineers and marketeers (Griffin & Hauser, 1993).
The QFD process involves the construction of multiple matrices on different design levels. On the left side of the matrices the customer wants and needs (the voice of the customer or the “whats”) are displayed while on the top of the matrices the development team gives their ideas for meeting those needs (the “hows”). Every matrix makes the “hows” more detailed. The last matrix will have the specifications for the product as “hows” on top of the matrix. A simplified example of a QFD matrix for a vacuum cleaner is shown in figure 4.3. QFD is a sequential mode where the attributes (“hows”) on top of the previous matrix serve as input on the left side (“whats”) for the next matrix. The customer needs are prioritized by the customer themselves, so that later on it is possible for the design team to determine the relative importance of every need. By building multiple matrices on different levels, the response of the design team gets more specific and detailed (Cohen, 1995 and Ramaswamy, 1996).
QFD is a methodology that originally was used to create tangible products (Griffin & Hauser, 1993). There is a disadvantage to this focus; a product has more than just tangible aspects. The traditional division between products

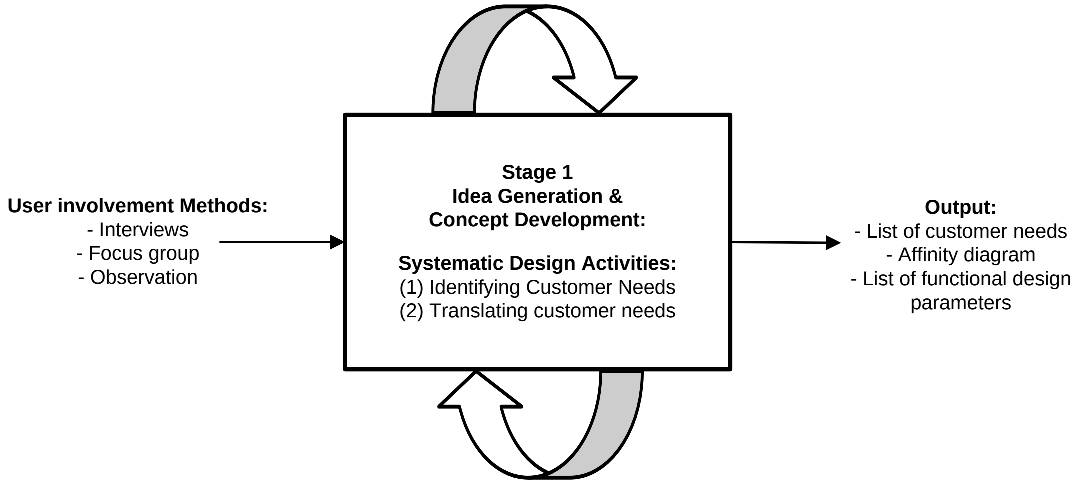


Figure 4.2 Research Model

Hows / Whats	customer importance	surface of nozzle	power	size of vacum cleaner	weight of vacum cleaner	filter bag volume
Low weight						
Easy handling/cleaning						
Quiet operation						
Saving energy						
Good dirt pickup						
Fast cleaning						
Small size						
Reliable product						
Multi-functionality						

Figure 4.3 QFD matrix example for a vacuum cleaner

(tangible) and services (intangibles) is long outdated. The focus today is much more on offerings (both tangible as intangible aspects), where products or tangibles are seen more as a tool to serve an offer (Vargo and Lusch, 2004). A small example to illustrate this statement. A laptop serves as a portable personal computer. It should therefore be portable and it should work as a computer (tangible aspects), but nowadays a laptop is much more. When looking at the successful Apple MacBook it focuses on the stylish design and the user-friendliness of the laptop (intangible aspects) making it much more than just a laptop. QFD lacks a focus on intangible aspects. Therefore implementing methods of service development in the development process of a tangible product creates a product which has the best of both worlds (Kuijpers, 2010). In this research SERVQUAL is used to determine whether the list of customer needs (the “whats” in the matrix) also covers the intangible aspects of the simulator. SERVQUAL is an instrument which comes from the world of services and is used to measure perception of service quality. SERVQUAL defines five dimensions by which quality can be measured: tangibles,

Activity	What	How	Who
(1) Identifying customer needs	Gather raw data from customers	Interviews	Surgeons
	Interpret raw data in terms of customer needs	Focus group	Surgeons and design team
	Organize the needs into a hierarchy	Focus group	Surgeons and design team
	Establish the relative importance of the needs	Focus group	Surgeons
	Reflect on the results and the process	Focus group / Design team*	Surgeons and design team
(2) Translating customer needs	Formulate list of dominant needs	Design team*	Design team
	Translate dominant needs into design issues	Design team*	Design team
	Translate design issued into functional design parameters	Design team*	Design team
	Reflect on the results and the process	Observation / Focus group/ Design team*	Surgeons and design team

Table 4.1 Systematic design activities * Is executed without involvement of users

reliability, responsiveness, assurance, and empathy (Parasuraman et al., 1988). In this research these dimensions, minus the tangible dimension, were used to categorize the customer needs. Thus it was possible to check whether intangible aspects of every dimension were included in the "whats" side of the matrix. In doing so a simulator is created with the focus on both tangible as intangible aspects.
Table 4.1 displays in detail which actions were performed during every activity. Furthermore it shows how it was done, and by whom it was done. The next section of this chapter will elaborate on the methods of user involvement.

4.2 Methods of user involvement

This part of the thesis will elaborate on user involvement methods as used during this research. It consists of: interviews, focus groups and observation. Interviews were used to identify the customer needs. Focus groups were used to sort and prioritize these needs. Observation was used to identify unstated needs and to reflect on the outcomes and results of the first activities of the process.

4.2.1 Interviews

Interviews are a common method to identify customer needs (Cohen, 1995; Cross 2004; Shah et al. 2009; Ramaswamy, 1996; and Ulrich & Eppinger, 2008). Cohen (1995) suggests using unstructured interviews with open-end questions. Cohen (1995) states that structured surveys with predetermined questions are of no use, since this does not generate important customer information. By using open-end questions customers come up with a mixture of true needs, most favorite and least favorite product features, complaints, suggestions and other types of comments (Cohen, 1995). Therefore in this research we used Cohen's (1995) suggestions. Although unstructured interviews were used, not every surgeon will express him/herself as clearly as others. Therefore some questions were prepared in advance (appendix III). The questions were used as a fall back during the interviews. All interviews were audio recorded, so no time and attention was lost on making notes during the interviews.
Another important issue is the number of interviews to gather a significant amount of needs. Literature does not provide one clear answer to this issue (Cohen, 1995 and Guest et al., 2006). Some authors say 90 percent of the customers' needs will be revealed after 30 interviews. Others

say 25 hours of interviews are needed. Others state no less than 10 and no more than 50 interviews (Ulrich & Eppinger, 2008). It is important to realize that the first interview will probably contain more new information than the second interview and so on. This means that after a number of interviews almost no new information is collected. This is called saturation (Guest et al., 2006) the interviewer should have some idea of when this point of saturation is reached (Cohen, 1995). Since there is no rule of thumb for the number of interviews, and because for this research more sources of data collection were used, ten one hour interviews were set as the minimal limit.

4.2.2 Focus groups

The second method of involving users were focus groups. In this research two focus groups were used to help categorize and prioritize customer needs. According to Ramaswamy (1996) it is not uncommon that two or three hundred needs are extracted from the interviews. Therefore it is important that the needs get sorted, categorized and prioritized. The list of needs should be reduced into a hierarchy so it can be used as input for the correlation matrices of QFD. This was done by means of the SERVQUAL dimensions and an affinity diagram. An affinity diagram is a powerful tool for organizing qualitative data. It can be used for structuring ideas in a hierarchical way. The diagram is built bottom up, and is based on the intuition of the focus group (Cohen, 1995). The affinity diagram was created by a focus group existing of a first year resident, a fifth year resident, an experienced surgeon, and a medical educationalist. These group members were chosen since they all represent a part of the customer group. Using a focus group for this process was very effective. Since the customer is the expert on how needs go together and how they are grouped, it is strongly advised to use customers for this process too (Cohen, 1995). The focus group was also used as a feedback mechanism. The entire group of residents and surgeons with laparoscopic surgery experience was gathered for this session. They were once again asked about their ideas. This time to confirm whether their needs matched the results of the study. Video recording was used to document this focus group meeting. Video recording is a very common and convenient method to document focus groups sessions (Ulrich and Eppinger, 2008). After the focus group meeting the video was studied by the researcher. The categorized and prioritized list of needs was checked on completion and prioritization by comparing the outcomes of the video with the list previously made in the research.

4.2.3 Observation

Observation is a powerful feedback tool. There are two important reasons to use observation. Firstly it is possible to misunderstand the significance of what the user stated during the interviews. Secondly it is possible that the user has unintentionally misled the interviewer. This could be either by exaggeration or use of unfamiliar vocabulary (Cohen, 1995). In the research residents and surgeons were asked to react and try some concepts and simple early prototypes. While they were experimenting with and talking about the prototypes, they were recorded by a camera. According to Ulrich and Eppinger (2008) video recording is a useful method for observation. The footage was used to find unstated needs and served as feedback for the outcome of the research.

5 Results

The methodology described in the previous chapter was used to perform the research. This chapter will describe the outcomes of the research.

5.1 Identifying customer needs

The first step of the research was to identify the needs of the surgeons and residents. Customer needs were gathered by means of unstructured interviews. In table 5.1 the interviewees are listed by function. The interviewees remained anonymous for this thesis. All the interviewees worked at the UMCG and had experience with laparoscopic surgery, the Skills Center, and laparoscopic simulators. A total of thirteen surgeons, residents and OR nurses were interviewed. One medical educational researcher was interviewed; he is specialized in teaching surgeons and residents. In total fourteen interviewees were used for this research.
The interviews were all digitally recorded. After each interview the customer needs were extracted from

the interview answers. The final list of customer needs consisted of one hundred twenty needs. Note that the first list may contain some duplicates and can appear a bit unspecific. It is important that needs are not excluded too early in the process. Some customer needs can contain important information which initially may not seem that obvious (Ramaswamy, 1996). The full list of needs is displayed in figure 5.1.

5.2 Categorize and prioritize customer needs

The next step in the process was to categorize and prioritize the customer needs. This was done by a focus group existing of a first year resident, a fifth year resident, an experienced surgeon, and a medical educationalist. The first list of customer needs contained needs at various levels of detail, duplicates, and incomplete statements. These needs were filtered and categorized by means of an affinity diagram (figure 5.2).
The focus group identified the following (sub)categories: instruments (controller, visuals, console, marketing), feedback, skills (basic, procedural, knowledge), and game (addiction, attraction, game elements).
After organizing the needs the focus group was asked to rate all the needs of the affinity diagram on absolute importance. A scale of 1 to 5 was used, the scale can be defined as: (1) not at all important to the customer; (2) of minor importance to the customer; (3) of moderate importance to the customer; (4) very important to the customer; (5) of highest importance to the customer (Cohen, 1995). The absolute importance will be used in the correlation matrices to calculate the relative importance of the different needs.

Number	Function
1	Surgeon
2	Surgeon
3	Resident (fifth year)
4	Surgeon
5	Surgeon
6	OR nurse
7	OR nurse
8	Resident (fifth year)
9	Surgeon
10	Resident (fifth year)
11	Resident (third year)
12	Resident (first year)
13	Surgeon
14	Medical educationalist

Table 5.1 Interviewees and function

The game is attractive for surgeons
The game is attractive for residents
The machine is easy accessible
Quick set-up of device
Attractive for experienced laparoscopic surgeons
Attractive for surgeons' with less laparoscopic surgery experience
Portable device
Use at home
3D movement for control
2D display for visuals
Mirror movement
Motivates users imagination and creativity
Affordable machine/game
Able to perform multiple tasks/functions
Tactile feedback of controllers
Game includes sudden changes in environment
Game includes sudden changes in situation
Thrill experience during play
Uncomfortable work positions practice
Distractions during game
Different view/camera angles during the game
Include teamwork
Dependency on other persons (communication)
Controllers are similar instruments as in laparoscopic surgery
Challenging time after time
Limited movement area of controllers
Stitching movement practice
Dynamic display of environment
Simulate movement of objectives in a 2d display
Searching something you know is there but you cannot see it yet
Controller is universal for multiple games
Fun to play
Social competitive element
Game is different every time you play
Stays attractive
Stimulate motivation to get better skills
Visual attractive
Ranking system of players
Train eye-hand coordination
Train precise hand movement
Controller is pressure sensitive
Resident/surgeons community with scores
Noticeable improvement by frequent playing
Unclear view of camera
Clearing view of cameras
Difficult decision making
Acute change of situation
Use fine and gross motor skills simultaneously
Work with both right and left hand
Choose training skills and levels
Is not be a bad simulation of an operation
Friendly or accessible image of console/game
Use of object exploration in a 3D environment
Dependent on good view by others
Traction of objects
Possible to play short sessions
Working together/ dependent on others
Get feedback on skills used during the game
High score system is dangerous
Different type of games for different people
Graphics are realistic
Learn to be more relaxed, ergonomic
Display is bright, environment is dark
Display is shaking
Trains basic skills
Movement scores feedback
Fake simulators don't work
Intrinsic motivation
Motivates to keep training basic surgery skills
Do not simulate skills which are not realistic
Easy accessible
In hospital use
Practice basis surgery skills in a completely different context
All direction movements (3D) of objects
Realistic movement and positioning
No calibration of controllers
No log-in function
High score for competition
No shaking or dirty display simulation
Teamwork element
Simple game whit basic skill training
Easy to understand
Unconscious training of skills
Notice improvement during play
Use fine motor skills
Locate positions of objects

Figure 5.1a List of customer needs

Learn to work with 'wrong' hand
Multiplayer
Hand objects over with instruments
Exciting to play
Short training sessions
Update or new games for simulator
Simulator also usable as a normal console
Obvious learning feedback
Compare results with other doctors
Try to make as less movement to finish the game
Effective movement of instruments
It has to keep challenge the player
Comparison with other scores
Step by step improvement
Game gets more and more complex as you play
Time element
Learn to be more efficient in movements
Perform steps in the right order
Minimizing errors
Compatible with the console
Awareness of improved surgery skills
Recover errors in game
Consequences for wrong movements
Feedback to operating skills
When changing a situation objects move to other positions
On/off functions for extra difficulty
Accurate movement sensor of controllers
Efficient movement
No necessary movement of objects

Figure 5.1b List of customer needs

5.3 QFD correlation matrices

In this stage of the process we start with an affinity diagram with customer importance for every dominant need. The next step is to use the affinity diagram as input for a correlation matrix. The correlation matrix is used to translate the customer needs into functional design parameters for the simulator. In this research two matrices were built. The first level matrix translates the dominant needs into dominant design issues. The second level matrix translates dominant design issues of the first matrix into functional design parameters.

5.3.1 First level matrix

Table 5.2 shows the first correlation matrix with only the dominant customer needs. The dominant needs were selected by means of an iterative process. Firstly the needs from the affinity diagram were categorized with the SERVQUAL dimensions, reliability, responsiveness, assurance, and empathy. This was done by taking the results of figure 5.1 and plotting them in an alternative SERVQUAL affinity diagram. Secondly the most dominant needs of every category were selected. This was based on the interviews and prioritization of the user. Thirdly the dominant needs of the affinity diagram were selected, again based on the interviews and customer importance. Finally the two lists of dominant needs from both the SERVQUAL and the affinity diagram categories were combined to create the final list of dominant needs for the matrix.

The next step was to define the dominant design issues that come with these dominant needs. This is a creative iterative process performed by the researcher of this thesis. The dominant design issues are placed on the top of the matrix.

The next step was to mark all the relationships and the strength of these relationships between dominant needs and dominant design issues in the matrix. This relationship is used to determine the relative importance for the next matrix.

The relationship strengths were determined by the researcher of this study. A square symbol means a strong link and has a numerical value of 9. The circle symbol means a moderate link and has a numerical value of 3. The triangle symbol means a possible link and has a numerical value of 1. An empty cell means not linked and has no numerical value. This is a common scale used for correlation matrices in QFD (Cohen, 1995 and Ramaswamy, 1996).

Instruments

Controller:
Tactile feedback of controllers
No calibration of controllers
Limited movement area of controllers
Accurate movement sensor of controllers
Controllers are similar instruments as in laparoscopic sugery
Portable device

Visuals
No shaking or dirty display simulation
Display is shaking
Unclear view of camera
Dependent display on good view by others
Dynamic display of environment
Visual attractive
Display is bright, environment is dark
Graphics are realistic
Different view/ camera angles during the game

Console:
No log-in function
Friendly or accessible image of console/game (usability)
Easy to play without too much instructions
Possible to play short sessions
Quick set-up
The machine is easy accessible
Use at home
In hospital use

Marketing:
Awareness of improved surgery skills
Simulator also usable as a normal console
Affordable machine/game
Update or new games for simulator
The game is attractive for surgeons
Controller is universal for multiple games
The game is attractive for residents
Attractive for experienced laparoscopic surgeons

Feedback

Feedback:
Movement scores feedback
Ranking system of players
Get feedback on skills used during the game
High score system is dangerous
Noticeable improvement by frequent playing
Obvious learning feedback
Unconscious training of skills

Skills

Basic Skills:
Train precise hand movement
Use fine motor skills
Learn to be more efficient in movements
Mirror movement
No necessary movement of objects
Locateposition of objects
Learn towork with "wrong hand"
Hand objects over with instruments
Train eye-hand coordination
Work with both right and left hand
Feeling with 3d movements in a 2d worlds
Traction of objects

Procedural skills:
Do not simulate skills which are not realistic
Perform steps in the right order. Minimizing errors
Consequences for wrong movements
Able to perform multiple tasks/ functions
Use fine and gross motor skills simultaneously
Stitching movement practice
Learn to be more relaxed, ergonimic
Time element

Knowledge skills:
Difficult decision making
Recover errors in game
Game includes sudden changes in situation

Game

Addiction:
Game gets more and more complex as you play
Game is different every time you play
Stays attractive
Fun to play
Motivates users imagination and creativity
Motivates to keep training basic surgery skills
Choose training skills and levels

Attraction:
Exciting to play
Thrill experience during pley
Possible to do short play sessions
Intrinsic motivation
Balans tussen "op rails" en volledige vrijheid (player agency)
Game includes sudden changes in environment
Game in a game
Should not be a bad simulation of an operation
Different type of games for different people

Game Elements:
Practice basic surgery skills in a completely different context
When changing a situation objects move to other position
Time elemens
Distraction during game
Teamwork element

Figure 5.2 Affinity diagram

The last step is to calculate the relative importance of every dominant design issue at the bottom of the matrix. This was done by multiplying the customer importance with the numerical value of every cell. These outcomes were added on the bottom of the matrix to calculate the absolute importance. The absolute importance was then used to calculate the relative importance for every dominant design issue

5.3.2 Second level matrix

The dominant design issues of the previous matrix are the input for the second matrix. QFD focuses on what the customer wants. Therefore to keep this focus the low importance design issues need to be left out in the second matrix since they are less important to customers. The final list of dominant design issues was determined based on three criteria: the opinion of the researcher which was based on the experiences during the interviews the relative importance of the first level matrix, and the number of relationship of each design issue (Cohen, 1995 and Ramaswamy, 1996). By including the opinion of the researcher the dominant design issues are not solely based on figures but also on his own professional background and thus the customer. The researcher has interviewed many customers en is therefore able to check whether the list of dominant design issues is representative for what is said during the interviews (Cohen, 1995). After the final list of dominant design issues was determined, the functional design parameters were defined and again the relationships were determined and the importance was calculated. The final results are displayed in table 5.3. These results were presented to a focus group and confirmed by the focus group. The next chapter will continue with the results of this chapter by giving the conclusions which can de drawn from this study.

Impact Symbols:	
□ Strongly linked	9
○ Moderately linked	3
Δ Possibly linked	1

				Dominant design issues															
				Hardware						Software							Skills		
			Customer importance	Simulates movements of a laparoscopic instrument	Controller is sturdy	Limited amount of instructions needed for use of controller	Console is easy accessible	Console is easy to operate	Console works with multiple games and controllers	Game enviroment should be dynamic	Limited amount of time needed to learn the basics of the game	Fun to play	Game motives player to keep playing	Game looks visually good	Gives feedback on basic movement skills	Clear added value for medical proffesionals	Teach basic surgery skills	Teach knowledge surgery skills	Teach procedural surgery skills
Domiant needs	Controller	Works similiar as as laparoscopic instrumer	**4**	□	○							Δ				□	○		
		Does not damage easily	**4**		□														
		Is easy to use	**3**			□					Δ								
	Console	Easy to start playing	**4**				□	□											
		Is easy to use	**4**					□											
		Is multifunctional	**4**						□										
	Game	Dynamic environment	**4**							□							□		
		Easy to operate	**4**			□					□		Δ						
		Attractive for medical professionals	**5**	○								□			□	□	□	○	○
		Challenging to play	**5**							Δ		□	□	○	○	○			
		Looks good	**5**							Δ		○		□					
		Provides useful feedback	**4**												□		○		
		Improves basic surgery skills	**5**														□		
		Improves knowledge surgery skills	**4**															□	
		Improves procedural surgery skills	**4**																□
		Absolute importance		51	48	63	36	72	36	46	39	109	49	60	96	96	150	51	51
		Relative importance		5%	5%	6%	3%	7%	3%	4%	4%	10%	5%	6%	9%	9%	14%	5%	5%

Table 5.2 First level matrix

Impact Symbols:	
□ Strongly linked	9
○ Moderately linked	3
Δ Possibly linked	1

				Functional design parameters																							
				Controller				Console					Game								Training						
			Importance 1st level matrix	Controller looks like a laparoscopic instrument	Consequent movement of controllers	Accurate motion sensing	Controller can handle reasonable forces	Can be used in multiple places	Quick set-up	Easy to transport	Based on consumer hardware	Game can be played with or without the extra instrument	Tutorial time	High enjoyment of play	High level of graphics	Different every time you play	Game gets more complex as you play	non-lineair Sandbox style game	Multible players	Competition element	Trains eye-hand coordination	Trains mirror movement of the hands	Trains both hands	Limited movement area for controllers	Trains difficult decision making	Trains to follow a procedure	Time element
Dominant design issues	Hardware	Simulates movements of a laparoscopic instrument	**5**	□	□	□	Δ																	○			
		Limited amount of instructions needed for use of controller	**6**	○					○				○														
		Simulator is easy to operate	**7**	○	○	Δ		Δ	□	○	○	□	○														
		Fun to play	**10**	○					Δ					□	○	○	○	□	□	□							
	Software	Game motives player to keep playing	**5**											□		□	□	□	□	□	○	○	○		○	○	○
		Game looks visually good	**6**											○	□												
		Gives feedback on basic movement skills	**9**											Δ			Δ				□	□	□				
		Clear added value for medical proffesionals	**9**	○		○															□	□	□	○	○	○	○
	Skills	Teach basic surgery skills	**14**	□																	□	□	□	□			
		Teach knowledge surgery skills	**5**																						□		
		Teach procedural surgery skills	**5**																							□	□
		Absolute importance		267	66	79	5	7	91	21	21	63	39	162	84	75	84	135	135	135	303	303	303	168	87	87	87
		Relative importance		10%	2%	3%	0%	0%	3%	1%	1%	2%	1%	6%	3%	3%	3%	5%	5%	5%	11%	11%	11%	6%	3%	3%	3%

Table 5.3 Second level matrix

6 Conclusion

This research had two important objectives, designing an MDTDP which include user involvement to build a new laparoscopic simulator, and using this MDTDP to formulate a list of functional design parameters for the simulator. To reach this objective a number of questions were formulated in the problem statement of the research. The next section will answer these questions.

The first question focused on whether the idea of a laparoscopic simulator based on computer gaming technology could theoretically work. This study has proven that most likely it can. Multiple authors confirm the positive relationship between computer gaming and improved surgical skills (Bokhari et al., 2010; Enochsson et al., 2004; Kolga Schlickum et al., 2009; Rosser et al., 2007 and Shane et al. 2007). This confirms that one can teach basic surgery skills by playing a game. Games also intrinsically motivate people, thus making it an ideal means to use for a simulator. Rosser et al. (2007) even state that a customized computer game console should be able to teach surgeons and residents basic surgical skills. The arguments found in these studies supported by the work of Rosser et al. (2007) makes that there is sufficient merit in the idea of developing a laparoscopic simulator based on current computer gaming technology, software and hardware.

The next two questions focused on designing an MDTDP for the laparoscopic simulator, and on determining how customers could be involved into this MDTDP. The importance of involving customer during the development process was proven by multiple authors (Biemans, 1991; Bridgelal Ram et al., 2007; Enkel et al., 2005; Griffin & Hauser, 1993; and Shah et al., 2009). A tailored process with user involvement methods was created (figure 4.1 NPD process: 17) based on basic models and processes for new product development (Booz, Allen & Hamilton; Cooper, 1994; Cooper & Kleinschmidt, 1986; Rochford & Rudelius, 1997; Shah et al. 2009; and Shah & Robinson, 2006). The process consists of five stages: idea generation and concept development; device design and concept development; prototype testing in-house and trials in real field; production; and device deployment in the market and user feedback. For every stage in the process the user involvement methods were given. The process is iterative, meaning that the design team goes back and forth through the MDTDP stages. By consistently involving users throughout the process, the design team can check whether they are complying with what the user wants.

The fourth question concerned creating a list of user needs. The MDTDP, which was created for this study, was used to perform the first steps of the design process i.e. gathering customer needs and translate them into functional design parameters. With unstructured interviews fourteen users (surgeons, residents, OR nurses and a medical educationalist) were interviewed to determine a broad list of customer needs. This resulted in a list of one hundred twenty needs (figure 5.1 List of customer needs: 25). The list was categorized by a focus group into an affinity diagram (tangible point of view) and with the SERVQUAL dimensions (intangible point of view). By combining these two points of view a simulator is created which combines the most important needs of both worlds. This was done to prevent solely focusing on either tangible or intangible aspects.

The fifth question concerned translating the customer needs into functional design parameters. This was achieved with two correlation matrices according to QFD method. The first matrix translated the user needs into dominant design issues. The results of this matrix are shown in table 6.1.

The first level matrix determines which design issues the design team needs to solve to build a simulator based on customer input. For every design issue a functional design parameter is created in the next matrix.

The process of translating these needs is performed by the researcher of this study. To keep this focus only the important dominant design issues are used in the second level matrix. Table 6.1 shows two columns the first column shows the dominant design issues, and the second column shows the relative importance of every issue. This matrix clearly shows that teaching basic surgery skills (orange row table 6.1) is the most important design issue. With a RI of 14% it is the only design issue which is significantly (difference of 5%) higher than the second design issue on the list. The objective of matrices in QFD is to create a focus on customer importance during the design process. For a design issue to be important, and move to the next level matrix, it must at least have a relative importance of 5% (yellow rows table 6.1). Therefore the last four dominant design issues were not used in the second level matrix. The results were validated and accepted by the focus groups. Also during subsequent contacts with the design team it appeared that the predominant design issues were found to be relevant and aligned with preliminary ideas of the concept they developed.

The final question was to list the functional design parameters for the simulator. This is shown in table 6.2. The functional design parameters are solutions to the dominant design issues set in the first level matrix. The functional design parameters were determined by the researcher of this study. The table consists of three columns: the first column shows the functional design parameters for the simulator; the second column shows the relative importance for every parameter; and the third column shows the cumulative relative importance. The total sum of relative importance is more than a hundred due to a small rounding difference. Two conclusions can be drawn from this table. Firstly the top four of the list (orange rows table 6.2) have a significant higher relative importance than the rest of the list (significant difference is about five percent). It can therefore be

Dominant design issues	RI %
Teach basic surgery skills	14
Fun to play	10
Clear added value for medical proffesionals	9
Gives feedback on basic movement skills	9
Console is easy to operate	7
Game looks visually good	6
Limited amount of instructions needed for use of controller	6
Controller is sturdy	5
Game motives player to keep playing	5
Simulates movements of a laparoscopic instrument	5
Teach knowledge surgery skills	5
Teach procedural surgery skills	5
Game enviroment should be dynamic	4
Limited amount of time needed to learn the basics of the game	4
Console is easy accessible	3
Console works with multiple games and controllers	3

significantly more important = (orange)
significanlty important = (yellow)
not significantly important =

Table 6.1 Dominant design issues

concluded that the first four parameters on the list are most important to the customer. This means the customer clearly wants to use the simulator for training basic surgery skills: eye-hand coordination; mirror movement of the hands; and use of both hands. The fourth parameter, the controller looks like a laparoscopic instrument, is noted as important by the customer. This indicates that the customer wants to use a laparoscopic like instrument to control the simulator. This is in line with the literature which also states that video games will improve basic skills (Bokhari et al., 2010; Enochsson et al., 2004; Rosser et al., 2007 and Shane et al. 2007). Secondly the first nine functional design parameters are based on 70% of the total relative importance. Furthermore all these parameters have a minimal relative importance of 5%. This means that these nine parameters are significantly important to the customer. The focus for the design team in the next matrix should therefore be on the top nine of the list. The top nine of the list consists besides training basic surgery skills and replica laparoscopic instruments of (yellow rows table 6.2): limited movement area for controllers; high enjoyment of play; freedom of choices during the game (sandbox style game); multiple players; and competition elements. This was confirmed by what was prioritized by the focus group and what was said in interviews during the research. The results were also presented to a focus group of surgeons and residents and confirmed.

The research project had two main objectives: creating a systematic design process to build an immersive laparoscopic simulator and finding the functional design parameters for this simulator. By creating a tailored MDTDP and executing the first activities of this process, this study has managed to reach its objectives.

A tailored MDTDP was created to build the simulator. Then the customer needs were translated into functional design parameters for the laparoscopic simulator by means of QFD. The next step should be to continue using the QFD method, thus building a third and fourth level matrix to create a list of specifications for the simulator. This was not performed during this study since it was outside of the scope of this study. Helped by the list of specifications, the design team should develop a number of concepts for the simulator. It is recommended to present these concepts to the users by means of expert users meetings, focus groups, or users - producers seminars. In doing so, the customer keeps being involved in the development project and the simulator remains in line with what the customer wants.

With the feedback of the user, a concept needs to be elaborated into a working prototype. This prototype should be tested by the design team and by the user. When the prototype is to the satisfaction of both the design team and the user, it can be prepared for production and market launch.

It is recommended to continue using the MDTDP and the user involvement methods of this study for stages 2 to 5.

Functional design parameter:	RI %	Cum. RI %
Trains eye-hand coordination	11	11
Trains mirror movement of the hands	11	22
Trains both hands	11	33
Controller looks like a laparoscopic instrument	10	43
Limited movement area for controllers	6	49
High enjoyment of play	6	55
Sandbox style game (non-linear)	5	60
Multiple players	5	65
Competition element	5	70
Quick set-up	3	73
Trains difficult decision making	3	76
Trains to follow a procedure	3	79
Time element	3	82
High level of graphics	3	85
Game gets more complex as you play	3	88
Accurate motion sensing	3	91
Different every time you play	3	94
Game can be played with or without the extra instrument	2	96
Consequent movement of controllers	2	98
Tutorial time	1	99
Easy to transport	1	100
Based on consumer hardware	1	101
Can be used in multiple places	0	101
Controller can handle reasonable forces	0	101

significantly more important = (orange)
significanlty important = (yellow)
not significantly important =

Table 6.2 Functional design parameters

7 Discussion and recommendations

This study has drawn a few strong conclusions which can be used for further research. This study has also drawn a few conclusions which may lead to criticism. In this chapter a discussion of the conclusions can be found. Based on this discussion recommendations are given for further scientific research.

7.1 Discussion

The study started by performing a literature study on the relationship between playing computer games and improved surgical skills. The idea of the simulator was based on the assumption that this relationship was positive. This study has proven it to be so. Basic surgery skills will improve by playing computer games. This gives great opportunities for new applications in medical simulators, and opens the door for developing a simulator based on computer gaming technology. By proving this relationship the possibilities to create a successful simulator that intrinsically motivates medical professionals to keep using it, has grown enormously. For medical devices to sell it is important that the product is validated and thus has clear added value for surgeon and residents. By proving this relationship a first step for the validation of this simulator is made, making this conclusion an essential element of the study.
To design the simulator in a systematic way, an MDTDP was created. This study has looked in scientific literature for design processes in the world of medical devices. Most MDTDP did not deviate much from standard NPD processes and therefore not much MDTDP processes were found in literature. The MDTDP for this study was based on a theoretical framework. Because it is a theoretical framework, there is no guarantee it will work in practice. However during this study it was found that the framework served as an excellent tool to systematically design the simulator and involve users throughout the process. Using interviews, focus groups and observation delivered relevant and useful results for this front end phase of the design process. It also appeared practical and not too lengthy and ambitious, thus making the framework suitable for this study. By means of an iterative process and extensive user involvement throughout the design process, a list of functional design parameters was made. This list is a good representation of the functional demands of the customer. The list is based on user need and confirmed by the user. It is possible that QFD focuses too much on tangible aspects of a product. By not solely using an affinity diagram but also the SERVQUAL dimensions, the list is not just focused on tangible aspects. A last point of attention for the list were the unstated needs of the user. By means of observation latent needs were extracted from the user. These methods turned out to be very succesful. The list is based on expressed needs and unstated needs with both tangible aspects and intangible aspects making it a complete list for the next step in the design process.
There are also elements in this research which the researcher thinks may lead to criticism. In this study the simulator is considered to be a medical device. Therefore the NPD process was based on MDTDP. It could be argued that the simulator is not a medical device, but a computer game and should therefore be developed as a computer game. In this study it is more suitable to consider the simulator to be a medical device for the following reasons. The simulator is not just a computer game. It also includes hardware for which a NPD process is needed, which also includes tangible aspects. A computer game development process lacks these elements (Stacey & Nandhakumar, 2007). Furthermore the simulator is solely developed for medical professionals. Consequently a medical point of view is more suitable. Since not much literature exists on process-oriented game development (Stacey & Nandhakumar, 2007). The NPD processes used in this study are based on two basic NPD processes in literature, including Booz, Allan & Hamilton (1982) and Cooper & Kleinschmidt (1986). Therefore they can be used for a broad range of products and are suitable for both simulators and computer games.

Finally it must be noted that most tools and methods used for this research have a qualitative nature. An iterative process was used for this study. By constantly involving users in every step of the design process, the users were being used as a control mechanism to keep complying with what the customer wants. As a result the first list of user needs had to be adjusted. Furthermore the relative importance of the dominant design issues in the first level matrix and the relative importance of the functional design parameters in the second level matrix were presented to the user. They confirmed that these were the most important issues and parameters to them, making it an objective representation of the user needs, the dominant design issues, and the functional design parameters.

7.2 Recommendations

Based on this study two recommendations for further scientific research are given: establishing the causal relationship between playing video games and improved surgical skills; and validating the theoretical framework of Shah et al. (2009).
The literature used in this study has found a positive relationship between computer gaming and improved basic surgical skills. Although many studies show that video gaming positively influences surgical skills (Bokhari et al., 2010; Enochsson et al., 2004; Rosser et al., 2007 and Shane et al. 2007), so far the causal relationship that playing video games will lead to improved surgical skills is not demonstrated (Kato, 2010). Further research into this causal relationship is therefore recommended. Once this relationship is confirmed, more applications can be built based on this relationship. Eventually this can lead to more enhanced training facilities for laparoscopic surgery.
The theoretical framework of Shah et al. (2009) has incorporated many important aspects in MDTDP based on past scientific literature: NPD process; user involvement methods; different scenarios; distinction between end user and professional user. The model has the potential to become a leading MDTDP. The downside of the framework is that it still has to be validated in practice. Therefore validating the framework is recommended so that it can be used on a broad scale in practice.

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Appendix I Media publications

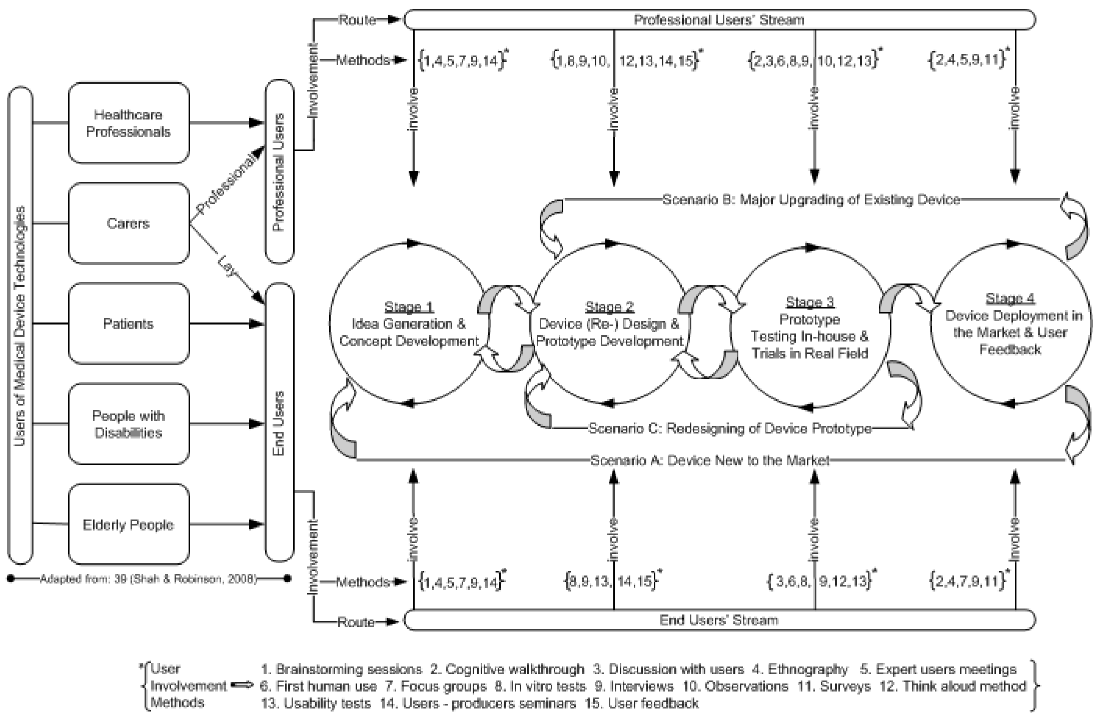
Forbes Magazine:
http://www.forbes.com/2010/05/04/farmville-minimonos-mangahigh-technology-videogames_slide_5.html

USA today:
http://content.usatoday.com/communities/gamehunters/post/2010/05/serious-games-deliberated-at-twin-conferences-this-week/1

Nu.nl:
http://www.nu.nl/games/2259108/grendel-komt-met-speciale-game-chirurgen.html

Medgadget:
http://www.medgadget.com/archives/2010/05/games_for_health_2010_disneyesque_laparoscopy_trainer_to_train_our_surgeons_of_tomorrow_today.html

Appendix II MDTDP Framework



Appendix III Interviews

Vragen over de persoon zelf
Geslacht:
Leeftijd:
Fase van opleiding/functie:

Vragen over gamegedrag
Speel je wel eens computer spelletjes?

Waar speel je dan spelletjes op?
Voorbeeld: pc, game console via internet.

In welke setting?
Voorbeeld: Alleen, met vrienden, bij vrienden thuis

Welke soort spelletjes speel je dan?
Voorbeeld: behendigheid, puzzel, platform, first/third person shooter, sport etc

Hoe lang speel je dan achter elkaar?

Hoeveel uur speel je dan per week?

Vragen over gebruik skills center
Maakt u momenteel gebruik van de simulators van het skills center?

Met welke frequentie gebruikt u deze simulators?

Wat is de reden voor het wel of niet gebruiken van deze simulators?

Wat kan er beter aan deze simulator en wat vindt je goede eigenschappen aan de simulator?

Console
Wat voor console/pc zou u het liefste willen gebruiken en waarom als simulator?
Voorbeeld: Achter de PC, een aparte console?

Als u op een PC zou spelen zou u dit dan op uw eigen werkkamer willen doen of liever in een aparte ruimte in het ziekenhuis (koffiekamer etc.) of thuis?

Welke console/computer die momenteel op de markt is spreekt u het meeste aan en waarom of waarom niet?
Voorbeeld: Nintendo Wii, playstation/xbox, toetsenbord en muis, speciaal gemaakt console

Soort game
Hoe zou de game er volgens u uit moeten komen te zien?
Voorbeeld: Realistische operatieve handelingen, of meer een fun game?

Als het een leuke game zou zijn wat voor game zou u dan willen spelen?
Voorbeeld: behendigheid, puzzel, platform, first/third person shooter, sport etc.

- vooral gebaseerd op actie/behendigheid/besturing?
- wat meer diepgang heeft (in verhaal, planning, strategie)
- wat realistisch is (iets wat lijkt op de echte wereld, een situatie, of actualiteit)
- wat verder weg ligt van de werkelijkheid (fantasy, science fiction, abstract)
- wat zou je zelf willen doen als je twee grijpers in je hand hebt

Duur van de game
- wat je gemakkelijk even kort kan spelen (sessies gemiddeld tot 5-15 minuut)?
- wat langer duurt (sessies gemiddeld langer dan 15 minuut)?

Met of tegen wie spelen
Zou u het spel meer gebruiken als u tegen andere mensen kon spelen?
of:

Zou u het leuker vinden als u het spel met meerdere mensen tegelijk kon spelen?

Zou u het spel via een netwerk tegen andere mensen/afdelingen willen spelen?

Met of tegen wie zou u het liefste willen spelen?

Zou u het spel willen kunnen uitspelen of zou u het zelfde spel eindeloos willen spelen?

Functionaliteit/vaardigheden:
Welke vaardigheden zouden volgens u getraind moeten worden op eens simulator?

Welke functionaliteit mag absoluut niet ontbreken op een simulator?

Wie worden de gebruikers
Wie zullen volgens u het meeste gebruik maken van de “game” simulator?

Omgeving
In welke omgeving zou u dit soort simulator het liefst gebruiken?
Voorbeeld: thuis, afdeling, skills center, achter het bureau.

Uiterlijk van de simulator

Hoe zou de simulator er uit moeten zien?
Voorbeeld: Design of praktische, klein of groot, draagbaar of vast?

Zou u liever losse controllers (één, twee of drie?) hebben of alles in één unit?

Moeten de controllers wireless zijn of mogen ze ook snoeren hebben?

Kosten
Wat zou een simulator die u net geschetst heeft mogen kosten?

Zou u overwegen om zelf een dergelijke simulator aan te schaffen?

Zou u dit dan doen om beter te leren operen of voor uw plezier?

Frequentie van gebruik
Zou u de door u zojuist geschetste simulator vaker gebruiken dan de huidige simulators in het skills center?

Doet u dit dan voor uw plezier of om uw chirurgische vaardigheden te verbeteren?

Wat zal voor u de reden zijn om deze simulator meer te gaan gebruiken?

Veiligheid
Wat voor gevaren ziet u aan dit soort simulators?
Voorbeeld: last van armen door teveel spelen, verslaving etc.

Overige tips of ideeën