CHALMERS
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Needs mapping with Systems Engineering

The future mobile x-ray

Master's thesis in Product development

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Department of Product & Production Development
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Daniel Weidenmark

Abstract

This master thesis project has been carried out at Solutions for Tomorrow AB (SFT) and the department of Product and Production Development at Chalmers University of Technology.

The purpose of the project has been to investigate needs for development of a mobile x-ray unit. Todays x-ray unit developed by STF was created for use in hospitals. This model should now be base for a new project aimed to take the mobile x-ray out of the hospital and carry out x-ray investigations at remote places as health care centers and nursing homes.

To perform this requirements research, a method has been set up inspired by the theory of systems engineering. Generally systems engineering is described for new product development. A challenge in this project has therefore been to adapt this theory for a refinement project. To facilitate long term success and use of the findings also in future it has been important to create a structure to capture knowledge gained in the research.

Research of requirements was carried out among a selection of stakeholders and contexts that was considered important for the new product version. The workplace was investigated for accessibility and radiation protection. Different transport solutions were investigated to determine how these affected the system. User requirements were captured during two user observation sessions and one use simulation. The investigation and analysis of needs captured was compiled into a requirements list and a summary of the key issues for the upcoming product development.

Capturing of knowledge related to the investigation was satisfied by applying a *thin slicing* method to the requirements specification. The essence of *thin slicing* is that only the most important information should be captured and stated in a very concise way to not overload the user with information. The aspect of how to reuse the knowledge is central in this method.

In a new product development project systems engineering suggest a research of what is mentioned as stakeholder requirements; needs that is totally independent of the solution to fulfill them. Since the preconditions for a refinement project is that there already is a product concept these solution independent needs were found hard to elicit and somehow also irrelevant. What was found thought is that some of the proposed tools to use for stakeholder requirements capturing aimed to visualize the life cycle of the system. These were still very valuable to use for system specific requirements and to stress the life cycle thinking in later stages.

Table of content

1. Background

In todays fast pace and competitive environment customers are becoming more and more demanding, product life cycles are generally shortened and there is a broad trend towards customization of products. Systems engineering (SE) is a product development method created to make companies survive in this challenging environment. (Burge Hughes Walsh, 2016) SE described in theory usually considers new product development but how can SE approach be applied in development of an already existing product, is there any difference? To investigate this, SE has in this project been used during the requirements identification process for development of a new type of mobile x-ray.

1.1 Mobile x-ray

During the last decade mobile x-ray have increased in popularity in the health care industry. The main use of mobile x-ray has been carried out at hospitals to bring the x-ray invention out of the fixed x-ray rooms. By moving the x-ray operations instead of the patient, higher level of patient comfort, time savings for personnel and shorter waiting time for patients could be achieved.

An upcoming concept for x-ray is to take the mobility one step further and provide x-ray also outside the hospital at places like health care centers, nursing homes and prisons. Such mobile x-ray machines are on the market today but most of them were developed for military use and have drawbacks in low performance and usability. Figure 1 shows two typical designs of todays mobile x-ray units.

Figure 1: The left machine is provided by Atomed and developed for x-ray outside the hospital. The right image shows a machine developed by Carestream for use at hospitals.

The benefits with mobile x-ray service at remote places as retirement homes and health care centers have been investigated on several places, among them at *Skånes universitetssjukhus, Lund* and *Akershus sykehus, Lørenskog, Norway*. The results from Lund showed that only 12 of 154 patients investigated at their homes needed further treatment at hospital, thus unnecessary patient transports were avoided and the need for keeping personnel to follow the patient to hospital was decreased. By providing the x-ray service remotely the patient security and comfort could also be improved. (Nordh, 2011) Studies carried out in Norway showed that the total societal cost for x-ray could, in the very most cases, be lowered with the use of mobile x-ray. Cost for transportation and the need for keepers to follow to hospital were the most significant saving factors. The economical benefit therefore increase with the distance between the hospital and nursing home. (Randers, 2005, p.154-156).

1.2 Research company

Solutions for tomorrow (SFT) is, since 2011, a startup company in the medical technology business with an idea of providing mobile x-ray units. By developing the x-ray unit and process with the user in focus they should, according to themselves, SFT (2015), set the new standard for mobile x-ray. Early in 2016 SFT launched their first version of mobile x-ray system to be used in hospitals. With this platform as a base they are now heading forward to start the development of the second version, which should take the x-ray activity out of the hospital. To be able to develop a product that sustains in the new environment and meets the market needs, the requirement capturing and specification is crucial. Therefor SFT invites for a student contribute in the pre-study and preparation of the requirement specification.

1.2.1 SFT model one

SFT model one is a mobile x-ray unit developed for use at hospitals. It is built with a modular design where battery, generator and electrical hardware is mounted on a frame structure and covered by the body panels. The telescopic pillar is rotatable and makes it possible for the operator to work 360 degrees around the machine and adjust it in height to cover the whole length of a standing grown up, also the horizontal arm is telescopic. Electrical engines mounted to the rear wheels drive the machine. The battery provides power for both the engines and for the x-ray investigation and no connection to the electric grid is needed for other than charging. Figure 2 shows approximate size of the machine in standby conditions.

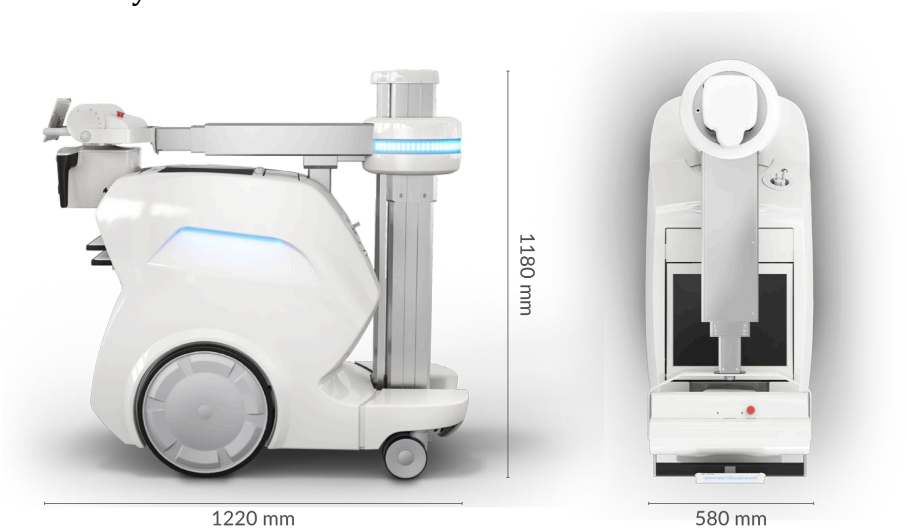


Figure 2: Concept picture of SFT version one in standby/driving position. (SFT, 2015)

1.3 Research goal

The industrial goal for this project is to provide a pre-study with needs for development of the second version of mobile x-ray. To do so, systems engineering will be applied in the research process. By using a systems engineering approach for development of an already existing product one should be able to answer the academic research question below.

Industrial research question

- How should SFT model one be developed to succeed according to the vision for SFT model two?

Academic research questions

- How can systems engineering be applied on the requirements specification process for development of an existing product?
- How could knowledge captured in the requirement generation phase be reusable and transferred to future development projects?

1.4 Objective

In order to answer the research questions the work will be carried out according to the following steps.

- Perform a theoretical research and set up a method for requirements capturing based on systems engineering.
- Identify the product vision and stakeholders throughout the product's lifetime
- Identify contexts and stakeholders of interest for investigation of needs
- Collect needs from stakeholders and contextual areas of interest
- Analyze needs and generate requirements list
- Analyze the method and execution of tools; evaluate the actual outcome in relation to the theory

1.5 Scope

The scope of this project includes the early phase of product development. The master thesis project is to help SFT in their work of creating a specification of needs for the second version of mobile x-ray unit. By creating a structured method for capturing and presenting needs and requirements, SFT should also be able to use the knowledge and processes for future work.

The benefits to gain with mobile x-ray have earlier been investigated in Sweden and Norway, therefore the research in this project will be with these markets in focus. However the final product may still be relevant to other markets as well.

The research will include a selection of stakeholders and contexts that are considered to have valuable input for development of the technical systems. This includes the workplace, the means for transportation and the use experience. Due to time constraints and the availability of research objects, the investigations have been limited to the primary market and nursing homes in focus. Requirements will be defined for the first system level.

2. Theoretical framework

The theoretical framework presented in this chapter has been used as knowledge base when setting up the research method for the project. The main topics described are *Systems engineering, Research methodology* and the *Requirements specification* including *Knowledge management.*

2.1 The general development process

There are many theories about the optimal product development process. The classical model is a set of activities carried out in series, Figure 3. It starts with the planning phase in which the product opportunity is explored according to the corporate strategy and a predicted market need. This initial phase typically results in a project plan or idea statement including target market, business goals, key assumptions and constraints to bring into the upcoming product development project. (Ulrich & Eppinger, 2012, p.12-15)

With a defined project plan the actual product development starts with concept development. Needs among the stakeholders are identified and from these needs concepts is generated. The concepts is then evaluated and tested to verify that the needs are met. Further refinements are done and the final concept solution is decided. The design and testing is usually an iterative process in the development phase, which ends up in the final product design and specification. With the final design decided production can be started and the product is launched on the market. (Ulrich & Eppinger, 2012, p.12-15)

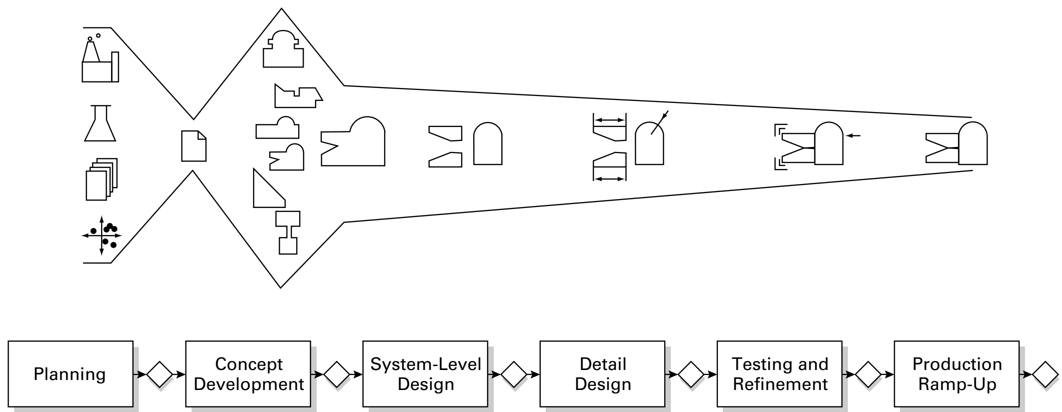


Figure 3: Sketch of the classical product development process. Tasks are carried out in sequence and separated by decision gates. (Ulrich & Eppinger, 2012)

2.2 Systems engineering

Systems engineering is a development approach that put emphasize on considering the "System" as a whole, to look at the system from a top-down perspective and include the whole lifecycle of the system of interest. (Blanchard & Fabrycky, 2006, p.18-19) The important philosophy that characterizes systems engineering from the generic development process is that tasks should not be seen as separate stages and executed in sequence. Instead one should execute them in a parallel and iterative manner to include feedback loops in the process, Figure 4. (INCOSE, 2016)

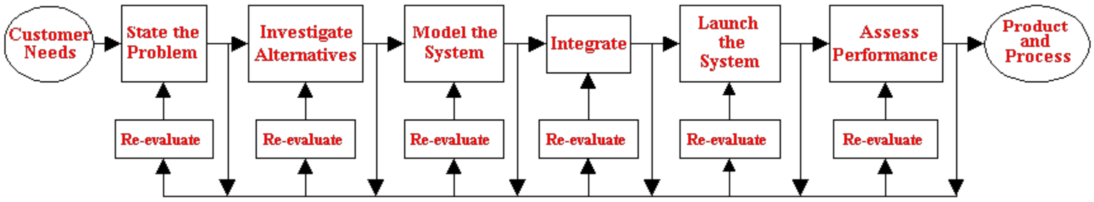


Figure 4: The systems engineering process. (INCOSE, 2016)

Another way to visually model the systems engineering development process is the Vee-model. In Figure 5 the systems engineering theory have been applied specifically on requirements engineering. The purpose of the model is to show that requirements play a vital role during the whole development process. The Vee-model also clarifies the idea of a top down perspective on the whole life cycle, already in the beginning of the development where stakeholder requirements are elicited one should consider the end stage of how these requirements should be tested. (Hull et al., 2005, p.16) By including all stakeholders, external as well as internal, from the beginning of development the goal is to provide products with a higher quality and better conformance to the user needs. (INCOSE, 2016)

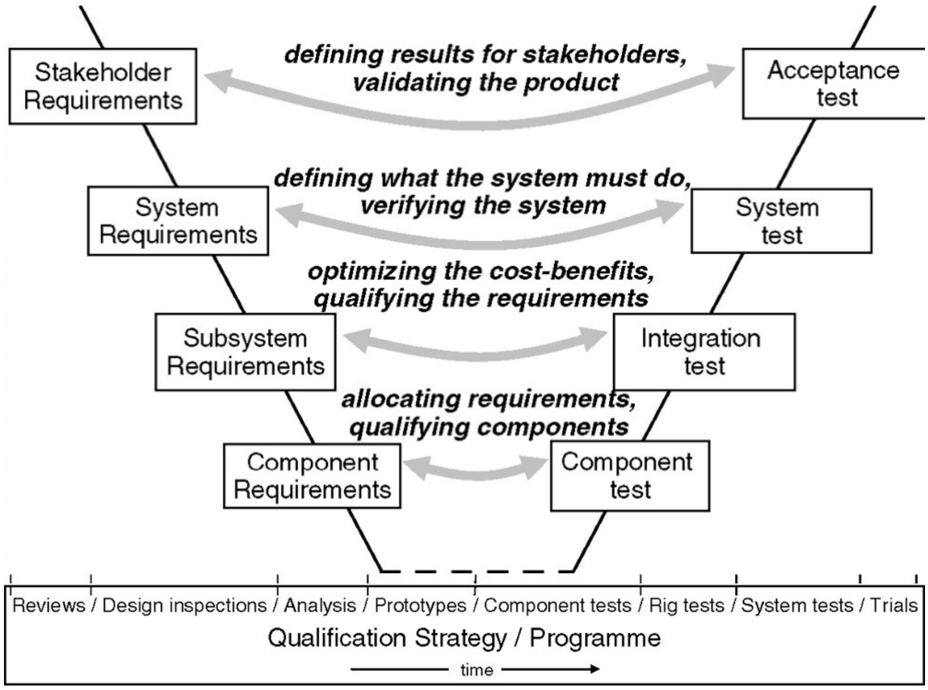


Figure 5: The Vee-model in requirements engineering. Image is modified from source. (Hull et al., 2005)

The scope of this project includes the early phase in the requirements specification process. In *Requirements engineering,* Hull et al. (2005) describes the requirement phase as shown in Figure 6. The first stage of requirements engineering is defined as the problem domain, here the problem is analyzed independently of the solution to solve it. The later stages are defined as the solutions domain. These phases aims to capture requirements on the solution to solve the problem.

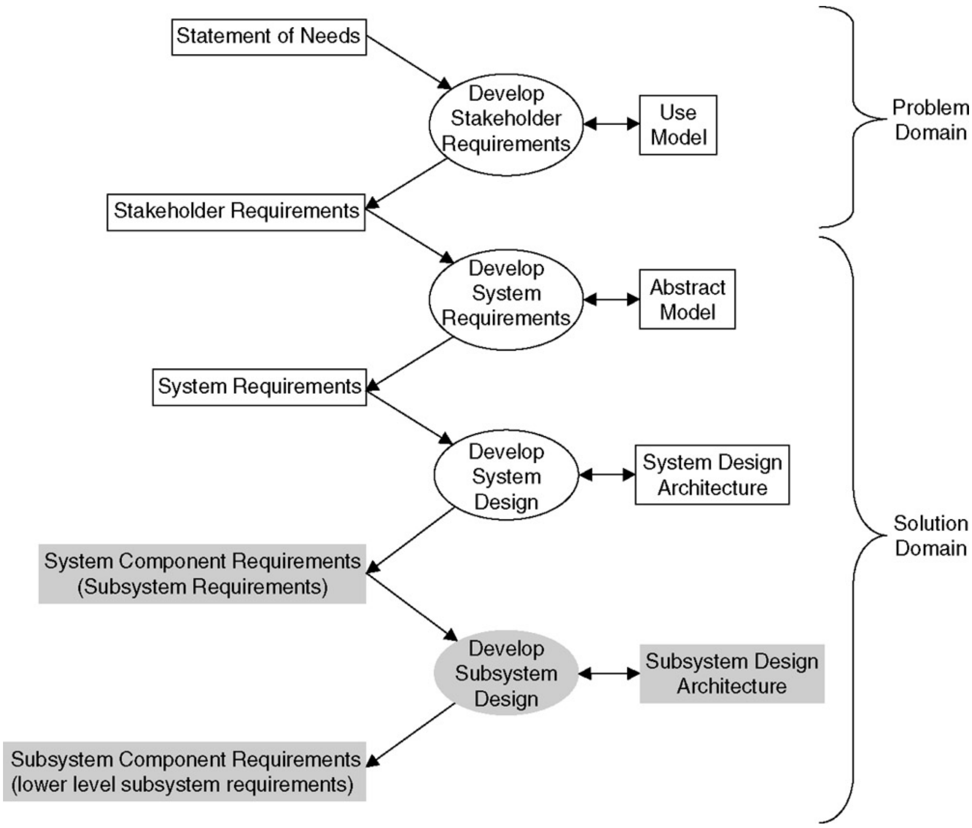


Figure 6: The system development process. (Hull et al., 2005)

2.2.1 Stakeholder requirements - The problem domain

In the problem domain solution independent requirements are captured. The problem domain refers to the environment in which the product is to be used. Stakeholders that may have requirements on the product are not only users, it can also be persons as investors, operational environment experts, government or service staff. The input for this requirements capturing process is a description of the needs, which can include just a rough business idea, a concept of operations or a complete pre study of market and possible options. Important is that the initial need or idea is understood so that stakeholders can be identified. With stakeholders listed one should determine which of them that is relevant for the particular project. (Hull et al., 2005, p.87-92)

2.2.1.1 Use scenarios

According to Hull et al. (2005, p.88) it has been found that use scenarios is a good way to understand a system and get what people do or want to do. A use scenario is a sequence of results or tasks produced and it is directly related to the actual job that is carried out. Preferably the use scenario is set up together with the customer and then used as base for discussions. To understand and capture the best way to carry out an activity one should focus on the goal of the activity rather than how it is done, Figure 7.

By thinking through the use scenario and elaborating on the activities, the requirements should be understood and elicited. On this level requirements can be phrased quite informal to then be refined in a later stage. (Hull et al., 2005, p.101)

To capture the whole life cycle, the use scenario can be set up from the very high perspective. By doing so requirements is captured also in development and at the end of product life, not only in the phase of operation. (Hull et al., 2005, p.97)

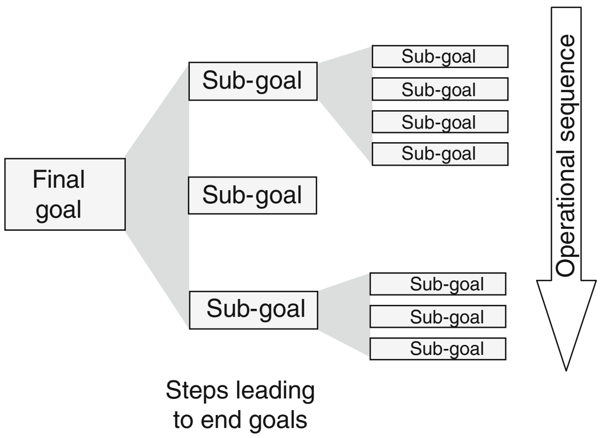


Figure 7: Use scenario stated as goal in a sequence of tasks. (Hull et al., 2005)

2.2.1.2 Derive requirements

The process of deriving the actual requirements from the different stakeholder can be done in numerous ways depending on e.g. the type of product and accessibility to the customers and market. The following list shows a few examples stated by Hull et al. (2005, p.99)

- Interviews
- Scenario exploration
- Descriptive documentation
- Problem and change suggestions
- Theory studies

For an engineer to be able to extract requirements from the user it is important to set oneself in the user's perspective. One should remember that the user usually does not think in the technical terms but from a human perspective; how things are done in daily use, how functions and attributes feel and are perceived is what the requirement engineer wants to extract. It is also important to fully take in what the user says and shows during an interview or study. The engineer should not be judgmental or overlook specific actions. Instead he should show interest and further explore an unexpected action to capture the purpose behind the behavior. (Hull et al., 2005, p.99-100)

2.2.2 System Requirements - The solutions domain

From the problem domain one goes into the solutions domain. This is where the development engineers use their technical skills to solve the problems the stakeholders have experienced. Requirements and needs that the stakeholders have expressed are now transformed into requirements on the solution and different systems. The work in the systems domain are typically carried out from a high system level and then narrowed down into sub-systems and finally component requirements. (Hull et al., 2005, p.109-110)

2.2.2.1 System breakdown

To support the system requirements generation the system can be decomposed and modeled visually in numerous ways. For example the system can be broken down into functions, physical modules, behaviors or interactions etc. The result of making a visual decomposition of the product is to increase the understanding and specification quality, the design characteristics and to improve communication in the development group. (Friedenthal et al., 2015, p.17 & 31-32)

2.2.3 Systems engineering to decrease cost and time

Systems engineering emphasize on a deeper understanding of the system in total throughout the whole life-cycle. Blanchard & Fabrycky (2006, p.45-48) describes the potential benefits to achieve from this.

A reduction of the life cycle cost should be achieved. By adding effort in the early planning and requirements phase one have the opportunity to determine problems in an early phase when changes in the design is still easily and cheap implemented. The intention is to reduce the need for design changes in the later phases during detailed design and development, Figure 8. When more time investments is done in the early investigation phases experiences is also gained, which will be usable throughout the project and thereby improve the total cost of changes.

Reduction in time is another related achievement resulting from a front-loaded work process. A problem defined in detailed design or testing may imply a big design change and a step back to the beginning. By putting extra effort early more of these problems should be determined and solved in the beginning.

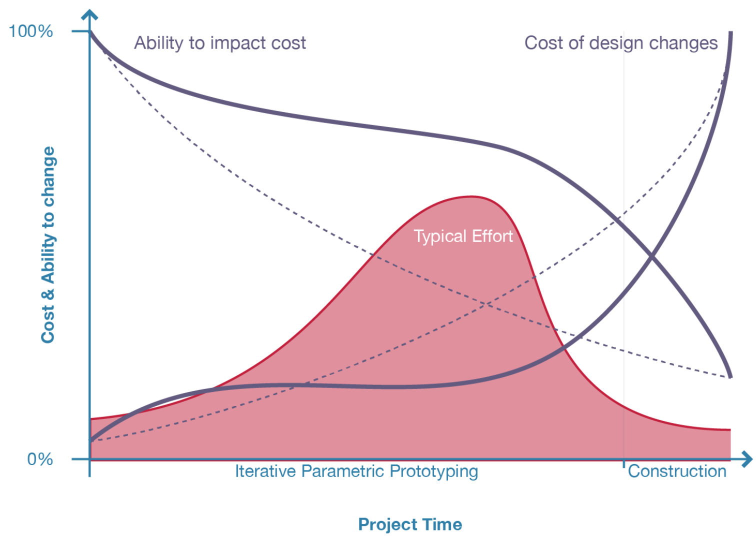


Figure 8: The engineers influence on design are very high early in the process when the cost of changes are low.

2.2.4 Systems engineering to reduce technical debt

Technical debt is a term that refers to the bag of unconsidered and half-hearted short cut solutions a company may build up during a product development process. Imagine facing a problem with two possible solutions, one is easy and fast to implement but maybe hard to adapt and configure for other circumstances in future. The other solution requires more initial planning and research, it is relatively demanding to implement and takes more time, but at the same time this solution is valid for a range of similar problems and can easily be configured for new situations. In an ongoing development process the first way to solve the problem could be quite attractive. A quick solution should mean faster progress directly and less planning and long-term thinking is needed. (Dvas, 2015)

Developers and companies that have a tendency to go for the quick-fix solutions will soon have a big burden of technical debt. One may have a lot of engineering hours spent on developing a product that work for now but is impossible to upgrade or customize. For such company to generate the next product version the majority of time spent in initial development is non reusable, engineers have to start over again. (Dvas, 2015)

By applying the mindset of systems engineering; to have a holistic view and consider the whole life cycle from the very beginning, this phenomenon of technical debt should be minimized. To have a thorough plan for the entire product life, and also a good understanding of the future vision for the product, should help in making the decisions that could result in technical debt or not.

2.3 Data collection methods

There are two basic types of research and data collection methods; quantitative and qualitative research. Quantitative research refers to the classical scientific way where data is quantified and measured as numbers. One uses statistical analysis and search for precision and accuracy of data. In a qualitative research method findings are instead presented as verbal expressions and in a non-numerical form. This type focus on the meanings of what is expressed and results have to be interpreted and understood in relation to its context. (Robson, 2011, p.17-18)

2.3.1 Semi-structured interviews

Semi-structured interviews are very common in design of a qualitative data collection method. The researcher has a prepared set of topics that should be answered during the interview but the exact wording, sequence and time for questions is flexible. Some parts or questions of the interview can also be more structured to get exact answers while some parts is more open like a discussion. Even if the approach is flexible it is recommended to set up the interview with an introduction where the interviewee is informed about the context, preconditions and topics. The interview is preferably also closed with a question if there is anything that the interviewee wants to add that could be valuable to know. (Robson, 2011, p.285-287)

2.3.2 Telephone interviews

Telephone interviews can sometimes replace face-to-face interviews and has the big advantage of being quicker and cheaper. It can also reduce eventual bias of the answers that can emerge when the interviewer and respondent sees each other. On the other hand since there are no visual connection non-verbal observations such as body language is hard to capture. (Robson, 2011, p.290)

2.3.3 Observations in research

To listen what people says they want or does is one thing, but to actually go and see the behavior in reality can give another or at least complementary answer. When observing a user or customer one get in direct contact with the actions in the real world of service. As a researcher one may not just find a conscious discrepancy between the words and real action, one may also find behaviors of which the user is not even aware. Even if there are many advantages, carrying out observations is very time and probably cost consuming. The fact that a respondent is under observation may also affect the behavior; this is a factor that the researcher has to be aware of. (Robson, 2011, p.315-317)

Observations can be carried out in different ways. One way is the typical "pure observation" where the researcher follows the activity from the side, trying to identify all actions. The user then carries out all tasks just as in the daily work. (Robson, 2011, p.329) Another way is the participatory observation where the researcher takes part of activates as a user; the observer becomes a part of the group to observe. This can improve the understanding of habits and the social interaction of participants. Being a part of the observation group can also improve the trustworthiness and openness between researcher and research objects, thereby more and deeper answers can be captured. (Robson, 2011, p.319-320)

2.4 The requirement specification document

For a complex technical product the number of requirements could be huge. To manage and structure the requirements is therefore a very important part of requirements engineering. If the requirements cannot be found easy, read and understood by the engineers it is likely that some of them will be overseen. A good structure of the requirements can also help to minimize the number of them, to detect duplications and conflicts or to make them reusable.

The requirements document is usually built on a hierarchy in a number of levels. What system the hierarchy shows can differ depending on the type of requirement. For stakeholder requirements it is common to use a high level of use scenario as structure to show when a certain need is experienced. On a system level, requirements may be decomposed in systems and sub-systems. (Hull et al., 2005, p.75)

Not only the structure but also what type of information to present in the requirements specification has to be considered. What information and how it is written will strongly affect the usability and interpretation of the requirements. Too much information will probably overload the reader and the important content may be missed, while too less information may give the reader too much freedom to interpret the requirements.

2.4.1 Capture the knowledge

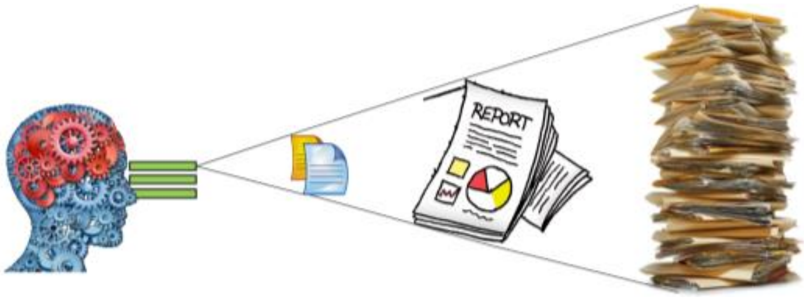
Knowledge management can be considered to consist of two parts; it is the capturing phase and the reuse phase. If both of these work efficiently together one can as a company look forward to higher quality, shorter lead times and lower costs etc. That's at least what the knowledge management usually promises. (Catic, 2015a)

At first the capturing phase could be seen as quite easy, just document the new findings and store them. But to just build piles of documented knowledge does not facilitate the efficiency in reuse. The flow of knowledge from capturing to reuse has to be streamlined; that is how one gets return on the investment. The capturing phase imply spent recourses in terms of time, its first in the reuse phase one get a payback on that investment. Catic (2015a) states two major reasons why the reuse of knowledge usually fails:

1. The captured knowledge is irrelevant for reuse
2. The captured knowledge is at wrong level, either too general or too specific.

2.4.1.1 Thin slicing

Thin slicing is a method that has been developed from the reuse perspective. By limiting the amount of information that our brains are exposed to the risk of mental overload, which is the result of too much content, should be eliminated. Basically the shin slicing method aims to provide enough knowledge to perform a task but not more. This is done by providing very concentrated "thin slices" of only the most relevant information. Usually it is not obvious what information that could be usable in the future and the decision of what information that is important is subjective. The capturing technique does therefore suggest to gradually building up the knowledge bank. In a first stage only the basics are stored and then the knowledge bank is updated and refined over time. Some information may be un-captured but at the same time it is more likely to be reused, and one have not made a big unnecessary investment in capturing everything. This should also improve the motivation to store knowledge when it does not require a big time investment and when one knows that it is likely to be reused. (Catic, 2015b) Figure 9 visualizes the idea of thin slicing. The original figure is complemented to relate to the specific requirements project.



- Requirements list
- Key Issues
- Use case
- Research report
- Captured raw data
- Videos & Photos

Figure 9: The thin slicing method highlights the most important content. (Catic, 2015b)

The concept of thin slicing does not specify exactly where knowledge could be stored. It rather handles how the knowledge should be stored. In the phase of requirements engineering the thin slicing concept can be applied on the requirements specification by including the what, why and how. (Catic, 2015b)

- What – States the actual requirement; what the system should do or what the user needs.
- Why – Describes why a specific requirement is needed. This is the information and knowledge the researcher has captured and want's to bring for the future. The why should support understanding of the "what".
- How – Can describe how the "what" could be achieved, or in the context of requirements, how the "what" should be verified.

This model does not handle any alternatives like "if" or "but" these could though be implemented in a later stage if needed.

The intended result of using thin slicing methodology applied on requirements specification should be that knowledge gained by the researcher during the research of requirements should be transferred and reusable during development. The requirements should also be reusable for the future as they are complemented with the background information of "why".

3. Research method

The research method used for requirements capturing in this project have been set up with inspiration from the systems engineering approach as it is described in theory.

3.1 Procedure

The list below describes the steps carried out in the project to go from the product vision to requirements defined for the product systems. In Figure 10 the procedure is shown visually and linked to the theoretical procedure of systems engineering.

Expression of product vision, context and stakeholders

- Creation of concept of operations that express the intended use cycle for the mobile x-ray unit.
- Creation of list of primary and secondary working areas
- Creation of stakeholder list

Needs investigation

- Research of the work site in terms of accessibility and radiation protection
- Use studies conducted at *Skånes universitetssjukhus, Lund* and *Akershus universitetssjukhus, Lørenskog*
- Complementary interviews
- Creation of use case and use scenario
- Research of transportation solution
- Use cycle simulation

Creation of requirements list

Since the requirements specification process is about learning the behavior, thoughts and context for the stakeholders the sequence above has been carried out in an iterative manner. Main gates for summing up and process control did though take place. First stage was to understand the vision for the product from an inventor point of view, second gate was when external requirements were determined and the third stage was to agree on the system requirements.

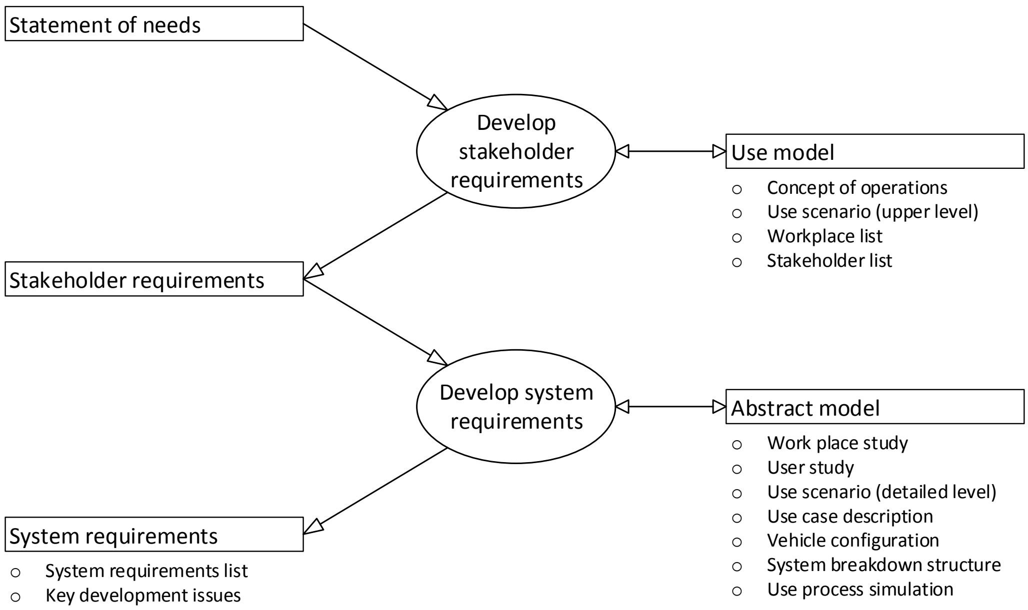


Figure 10: The research method related to the theoretical method of systems engineering.

3.2 Identifying the scope, context and stakeholders

The purpose of this product development project was to develop an existing product to fit in new working environment. In order to explore the vision and the intended use scenario for the product a semi-structured meeting was conducted with the CEO, COO and CTO of SFT present. During the meeting the vision was communicated by elaborating on the intended working process and working areas for the product.

With the scope and vision for the product agreed the requirement identification process started by formally structure a product use cycle, also called concept of operations. The operations include the working process related to the mobile x-ray system from the initial start to end. In parallel to the creation of the operations cycle, stakeholders were identified. By doing it iteratively stakeholders in each phase could easier be identified. The stakeholders included all persons and organizations that may have requirements or wishes on the product. Later in the process user studies were conducted and the list of identified stakeholders where concurrently updated.

Having the concept of operations and stakeholders well defined a meeting was set up with SFT to agree on the stakeholder map and identify which stakeholders and contextual environments to investigate for requirements. Since the product to develop is a derivative of an existing product platform not all stakeholders and contextual environments had to be investigated, only the ones considered new or changed for this new product. Focus was put on investigating working areas, transportation possibilities and stakeholders that should affect the usage and technical systems of the x-ray machine.

3.3 Identification of needs – external research

The initial activities of exploring the vision and identifying context and stakeholders for the product resulted in a list of investigation areas for capturing of stakeholder needs and requirements. The following sections will describe the method used to understand the stakeholder and capture their needs.

3.3.1 Work site study

The working areas for the mobile x-ray were investigated from two points of view; accessibility and radiation protection.

3.3.1.1 Accessibility

To gather information about the accessibility issue of the facilities one semi-structured interview was conducted with a construction engineer having experience from preparing building projects of public buildings and hospitals. In addition to the interview, secondary research was done to gather exact guidelines and regulations for accessibility in public buildings and areas. In the research related to accessibility the mobile x-ray unit was treated as an electric wheel chair. Rules issued to enable accessibility for an electric wheel chair will therefore be used as reference during the development of mobile x-ray. Also three site visits was conducted in connection to use studies and use simulation to get a reference from the situation in reality.

3.3.1.2 Radiation protection

In the research of radiation protection two semi-structured phone interviews were held with medical physicists to get information about laws and regulations regarding radiation protection related to x-ray activities. The investigation also included secondary research of laws and regulations issued by the Swedish Radiation Safety Authority. In addition user studies was conducted for comparison and as a reference from use of regulations in reality.

3.3.2 User study

To elicit needs from user behavior user studies were conducted. The first user study was carried out at *Skånes universitetssjukhus, Lund* and and was focused on passive observations to capture the whole working process. At *Akershus universitetssykehus, Lørenskog* a second user study was conducted. This was used to confirm or reject activities and behavior from the first user study as well as adding new findings. It also included a semi-structured interview about the working process, problems and advantages with the existing solution.

The raw data captured from the first study at *Skånes universitetssjukhus* was used as a base for setting up a use case for the x-ray activity. The purpose of logging every activity and context as a use case was to stress thinking of problems and possible unexpressed wants in the job as x-ray operator. By logging the use case as a sequence of tasks, knowledge and observations could also be shared and stored for later review by other persons not present during the visit. The list below shows how the use case were structured.

- Overview — Showing an overview of the use case
- Transfer in hospital — Include all tasks carried out from where the machine is parked in the hospital until it is placed by the transport vehicle
- Transportation — The transportation phase include all activities

from loading, transporting in vehicle and unloading the machine

- Transfer — In the transfer phase, all actions from unloading until the machine were placed in the right position for x-ray investigation were collected
- X-ray operation — The x-ray phase included the tasks carried out from the positioning of the machine until the investigation was finished and the operator were ready to transfer back to the car. In this slot the actual x-ray activity were carried out

For every phase in the use case the actual tasks were stated as a sequence and also the context for the activity. The purpose of the context description was to capture the environmental conditions and observations of how task were carried out. Identified needs were stated for each step in the use case and later transferred to the requirements list.

After both user studies were carried out and analyzed a complementary semi-structured interview was conducted. Main focus for this was to get a deeper understanding about the file transfer activity. The interviewee was Frode Lærum, doctor and professor in radiology; a person with relevant knowledge from the work site in Norway.

3.3.2.1 Use scenario

In parallel to the use case creation a use scenario, which summarizes the user process in a more concise way, was written. It was formulated to express the goals for each of the activities, which makes the use process more independent of the actual product solution. (Hull et al., 2005, p.101) The use scenario was later used when writing the requirement list.

3.3.3 Transportation

The x-ray unit should be transported to and back from the work site in a suitable transportation vehicle. A secondary research was conducted to find possible advisors and collaborators for customization of a vehicle. Main functions investigated related to transportation were the loading and unloading of the system into the vehicle, a way to secure the load during transports, how to possibly charge the machine in the vehicle and what kind of vehicle that could be used for the purpose of transportation.

To get knowledge about the customization alternatives a visit was made at Autoadapt, a firm customizing cars. They were chosen since they are one of the biggest actors also had a geographically convenient location for a physical meeting. In a later stage also Holmgrens bil and Bilanpassarna Växjö was included.

The final configuration of the vehicle should put requirements on the x-ray unit that had to be taken into consideration for development. To define requirements on the x-ray machine related to transportation a proposed configuration was determined. This was done in collaboration with SFT. A semi-structured meeting was set up where different alternatives of vehicle, loading solution, cargo securing and charging system were discussed. The meeting resulted in a preliminary configuration of the vehicle, which lay as a base for further requirements research.

3.4 Identification of needs - Internal research

The work carried out in this phase of the project was to make the engineers at SFT aware of the external stakeholder needs and complement them with needs experienced by the internal staff. This is where the engineers got involved and the needs were applied directly on the SFT x-ray unit.

3.4.1 Use simulation

As an alternative way of applying participatory observation, a practical use simulation was conducted to elicit system requirements in a realistic environment. For the simulation the SFT model one, the existing x-ray unit, was used. The assessment was carried out at *Ekbacka sjukhem*, *Urshult*, a nursing home for mentally disabled people. This place was chosen for simulation since they had a good geographical location in relation to SFT office and could offer a demanding environment for accessibility.

The use simulation was set up as a real x-ray investigation, starting with transportation of the x-ray unit to the nursing home. Upon arrival the x-ray unit was unloaded and driven into the building via a ramp, into a lift and further into an apartment. In the apartment an x-ray investigation was simulated and images were sent for analysis. After finished investigation the unit was driven back to the transport vehicle.

During the simulation a moderator facilitated the discussion by bringing up selected need statements from external stakeholders. The purpose was to keep the discussion on track to elicit issues and requirements for the systems. As a mediating tool the moderator used a system breakdown structure. When facing a certain situation or task the engineers could elaborate on the different sub-systems in a structured way.

Participants for the use simulation were six engineers from SFT, one person responsible for taking photos during the assessment and one person moderating and documenting during the research. The group of engineers had different kinds of experience, knowledge and responsibilities. Together their knowledge covered all sub-systems in the system breakdown structure and thereby they could capture needs and requirements for the entire system.

The discussions and findings during the use simulation were collected by video recording, photos and by taking notes.

3.5 Requirements list

In parallel to the research of needs two requirement specification documents was created; one for the x-ray system and one for the transportation system. Each requirement was defined with a unique id number. The first digit in the id number is based on the use scenario and shows where in the use cycle the requirement appeared. The second digit represents the class for the requirement. The third digit gives the requirement its unique number. A fourth digit in the id is given to requirements that could be considered as sub-requirements. Table 1 shows the requirement specification structure and Table 2 & clarifies the id structure.

The requirements that are sub requirements, id containing four digits, should be covered by the upper level requirement. Still the sub-requirements are important since it gives further explanation and ideas of the stakeholder need.

Table 1: Stakeholder requirement specification structure.

Nr. [Scenario]	Nr. [Class]	Nr. [Id]	Scenario	Class	Justification	Requirement/ Wish	Need/ Requirement	Evaluation	Extracted from:
1	1.1	1.1.1	Scenario 1	Class 1	Why?	Requirement	*What?*	*Assessment*	*Interview with X*
		1.1.1.1	Scenario 1	Class 1	Why?	Wish	*What?*	*CAD*	*Use study at H*
	1.2	1.2.1	Scenario 1	Class 2	Why?	Wish	*What?*	*CAD*	*Interview with L*

,

Table 2: Stakeholder requirement identification structure for the x-ray system.

1.X.X.X First number defines scenario 1= Administrate a job order 2= Relocate from hospital to nursing home 3= Relocate from vehicle to patient 4= Perform x-ray investigation 5= Get the image analyzed by doctor 6= Maintain or service the system	X.1.X.X Second number defines class 1= Maintenance 2= Process 3= Maneuverability 4= Ergonomics 5= System design - Structural system 6= System design - Electromechanical system 7= System design - Interaction design
	X.1.X.X Second number defines class 8= Transportation system - vehicle 9= Transportation system - ramp 10= Transportation system - cargo securing

3.5.1 Key development issues

To provide a quicker overview of what has to be developed *Key issues* were formulated. These Key issues does not include all details in the requirements specification but by stating these the engineers should be able to get a cognitive understanding of what has to be done.

4. Research results

This chapter includes the results from the research of needs that have been conducted according to the method.

4.1 Identifying the scope, context and stakeholders

The first step in the project was to explore and investigate the scope of the case, operations process and the stakeholders. The purpose was to gain understanding of the product and to secure that the vision of the product was uniformly understood.

4.1.1 Concept of operations

From the initial meeting a concept of operations was set up, Figure 11.

1. The process is triggered by a referral to radiology sent from the doctor at the nursing home to the hospital.
2. The x-ray service provider receives the order and plans the activity.
3. The operator travels to the works site with the x-ray unit
4. The operator unloads the x-ray machine and transfers to the assigned room.
5. The operator executes the x-ray investigation.
6. The operator sends the images to the hospital for image analysis.
7. The operator brings the machine back to the vehicle and loads it into the cargo compartment.
8. The operator drives back to base or to next place for investigation.

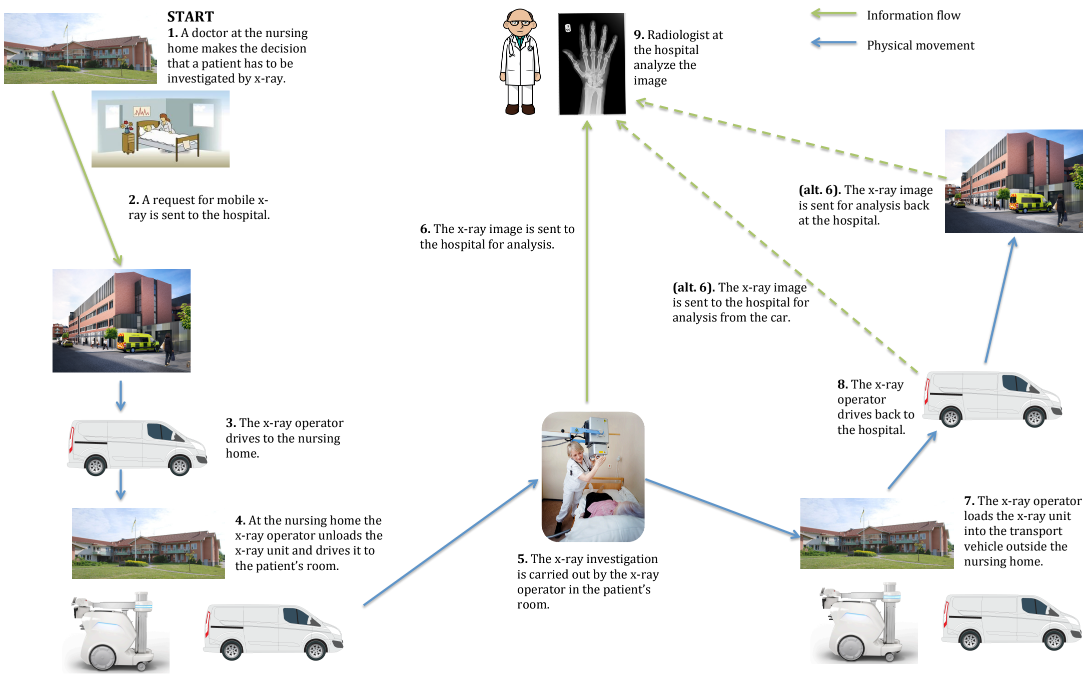


Figure 11: The concept of operations.

4.1.2 Stakeholders

A stakeholder identification session resulted in a list of stakeholders; Table 3 shows a segment of this. Each stakeholder have been identified with a role and classified in order to build up a structure and better overview. This stakeholder list was used to define which ones to investigate for requirements.

Table 3: Stakeholders related to the mobile x-ray activity.

Stakeholder Class	Stakeholder Sub-class		Stakeholder
SFT employees	Business		Business development manager Sales manager
	R&D		Mechanical system designer Electromechanical system designer Interaction designer Industrial designer
	Production & Assembly		Production manager Testing manager
	Service & aftersales		Service manager
	Logistics		Logistigs manager
Financial	Investor		SFT founder & owner Venture capitalist
	Loan provider		Bank
User (Consumer)	X-ray system user		Radiologist/X-ray operator Radiologist/Image analyzer Patient keeper
			Patient
Customer	Private customer		x-ray service providing firm
	Public customer		Landstinget (Politicians)
Authorities	Certifier		Certification company
	Law maker	National Law maker	Boverket Strålsäkerhetsmyndigheten
			EU

4.1.3 Working areas

The discussion and research of possible working areas for mobile x-ray resulted in a list of primary and secondary working areas, Table 4. The list was also updated during interviews with users.

Table 4: Possible working areas for the mobile x-ray unit.

Possible work areas	

Primaray	Health care centres
	Nursing homes
	    Retirement homes
	    Homes for mentally retarded people
	Prisons

Secondary	Shelters
	    For homeless
	    For refugees
	Peoples homes

4.2 Identification of needs

The following sections includes the outcome from interviews, user studies and use simulations carried out to elicit needs for development.

4.2.1 Accessibility

In the research of accessibility in common areas the mobile x-ray unit has been likened to an electric wheel chair. The dimensions of an electric wheel chair is standardized within EU and presented in EN12184:1999 and EN 12184:2009. Three classes of wheelchairs with different purposes and dimensions are described. (Svensson, 2012).

- Manual wheel chair built mainly for use indoors. Recommended dimensions: Length 1,2 meters, width 0,7 meters and turn around circle diameter of 1,3 meters.
- Electric wheel chair for limited outdoor use. Dimensions Length 1,3 meters, width 0,7 meters and turn around circle 1,5 meters. Figure 12
- Electric wheelchair for outdoor use. Dimensions Length 1,4 meters, width 0,8 meters and turn radius 2meters.

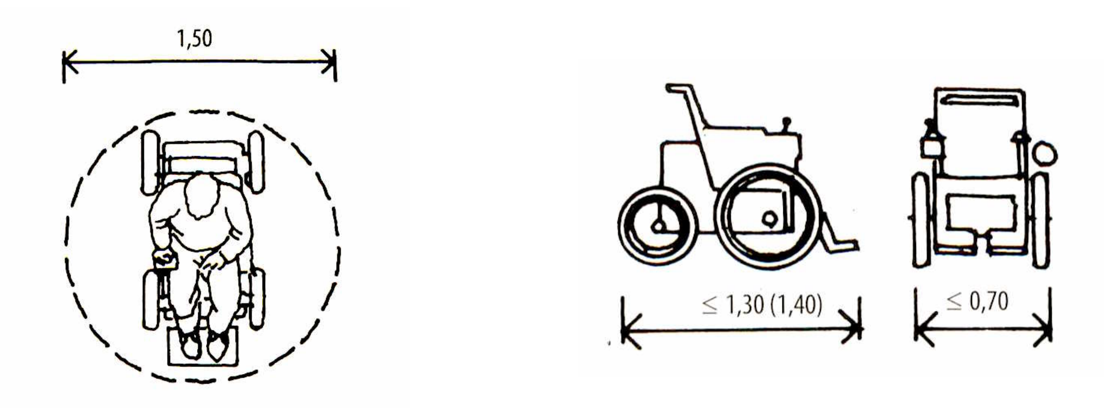


Figure 12: Length, width and turn around circle for electric wheel chair for limited outdoor use, type B. (Svensson, 2012)

Laws regarding design of common areas in Sweden are issued by the government. The laws are broken down to building regulations and recommendations by Boverket. The following section elaborates on the relevant regulations set to enable accessibility and freedom to move with an electric wheel chair of class B, intended for limited outdoor use.

Corridors and doors

Corridors should have a minimum width of 1,3 meters in general areas. In case of obstacles like pillars the width are allowed to be 0.8 meters. [BFS 2011:6 3:142]

Doors should have a minimum width of 0,8 meters when the door is opened in 90°. [BFS 2011:6 3:143]

Threshold

There is no maximum height of thresholds specified by Boverket. They advice to build without any height differences but if necessary keep the thresholds as low as possible. In *Bygg ikapp,* Svensson (2012) has stated guidelines for threshold to be of a maximum height of 15-20mm. Earlier the maximum height was 25mm.

Ramps

Ramps can have an elevation of maximum 1:12 and preferably not more than 1:20. The minimum free width is 1,3 meters. [BFS 2011:6 § 3:1422]

Elevators

Standards for accessibility in elevators are presented in SS-EN 81-70. For an electric wheel chair of class B the minimum elevator size is 1.1x1.4 meters, given that the door is placed at the shorter side.

4.2.2 Radiation screening

Laws and regulations governing the use of x-ray in Sweden are issued by the Swedish Radiation Safety Authority. The primary document stating rules for radiation screening is SSMFS 2008:11. The maximum dose of radiation that people outside the room can be exposed to is limited to 0,1mSv per year.

To limit the dose of radiation in rooms without built in screening material, a mobile radiation screen can be used. According to SSMFS 2008:11 §5.4 a mobile radiation screen should be used if the primary radiation can hit persons in the vicinity. Local rules issued by Region Skåne (2013) say that a mobile screen should always be used in public areas when conducting an x-ray investigation with a horizontal or angled radiation field. When conducting x-ray investigation with vertical radiation field no radiation screen is needed. According to Tingberg (2016) the local rules for Region Skåne were issued based on the national rules in SSMFS 2008:11.

4.2.3 Transportation

The main questions regarding transportation was what vehicle could be used, how loading and unloading could be done, how to secure the load during transport and possibly how to charge the machine during drive.

4.2.3.1 Loading & Unloading

The loading of the machine into the car could either be done by driving the unit up a ramp or by using a lift. Also a car with lowered floor could be used in combination with a ramp.

Lift

There are two kinds of lifts. Either the lift lifts machine from ground level up to the floor level of the car and stops there. The operator does then have to drive the machine from the lift platform into the car cargo space. This will require a lift that can carry the weight of the machine and the operator together. The other alternative is a lift that picks up the machine at ground level, lifts it up to the car floor level and then slides the lift platform into the car. This should require less work from the user since there is no second driving needed to get the machine into the car. Important to consider is the weight the lift can carry.

Autoadapt provides lifts of both types. The second, sliding version, has a weight limit of 150kg, which is to less to lift the x-ray machine. The first version, lifting up to floor level, can be configured to carry up to 500 kg. Thus the only alternative is to use the lift where the operator manually has to drive the machine into the car.

Ramp

Ramps are either fix mounted in the car or portable and they are typically split in two or three sections. A fixed ramp split in two section requires the operator to only do one movement folding out the ramp. For the three-section version the operator first has to fold out two sections and then the third. The length of the ramp affects the slope but also the height when folded up into the car. When choosing a ramp one therefore has to consider both the wanted slope, the height of the rear opening of the car and the number of movements required folding the ramp. To choose a ramp that is fully manual is the cheapest of the three possible alternatives for loading and unloading.

Car with lowered floor

A car with a lowered floor has a built in ramp on which the x-ray unit is loaded into the car. The lowered floor allows for a shorter ramp without increasing the elevation. With a shorter ramp the car can also be smaller since the ramp does not occupy space. Due to regulations and certification of cars, only cars registered as passenger car can be adapted with a lowered floor. Cars registered as transport vehicle are not suitable for this kind of adaption. To lower the floor of the car requires major change of the car and therefore this is a more expensive solution than using lift or ramp. (Asp, 2016)

4.2.3.2 Cargo securing

Mainly two ways of securing the cargo can be used. With a docking system that automatically fixates the cargo the operator only has to drive the machine into the car and dock it. This solution requires one piece of the snap system to be mounted under the machine and one docking station to be mounted on the car floor. The other way to secure the cargo is to use belts that tie the machine to the car floor. A belt solution requires the operator to manually fixate the belts onto the machine. Critical for both the docking system and the belt system is the weight they are certified for. The products provided by Autoadapt are developed to secure electric wheel chairs. Each fixation point is therefore typically certified for securing 200-250kg but they can be combined to secure higher weights.

4.2.3.3 Charging system
To charge the system during drive a transformer has to be used to transform the 12 volts power in the car battery to the wanted power for charging. Depending on the wanted output power the transformer in the car may have to be scaled up. If the x-ray machine should be charged also when the car engine is not running there is a risk of discharging the car battery. This risk has to be taken into consideration when building the systems.

4.2.3.4 Vehicle
There are two main classes of cars possible for transportation; transport vehicles and passenger cars. A passenger car is generally more expensive and has a smaller cargo space; it has windows all around and no fixed wall between cargo compartment and the driver. The transport vehicle does generally have a cargo compartment without windows and usually only the front row of seats. (Asp, 2016)

The car that should be used for transport of the x-ray system has to be compatible with the chosen adaption as well as the size and weight of the system. Another factor to consider when choosing the configuration is the usability. (Asp, 2016)

If using a ramp for loading the critical feature is the height from ground to the cargo compartment. The height will affect the slope of the ramp and thereby put requirement on the machine. The choice of ramp will also be limited by the height of the car rear opening.

4.2.3.5 Choice of vehicle-loading solution
To be able to set requirements for the x-ray system a meeting were set up with SFT to decide on a preliminary configuration of vehicle and adaption to investigate further.

Chosen loading solution
The pros and cons, Table 5, with each of the three alternatives for loading and unloading were discussed with SFT to agree upon a solution for further investigation. Cost and usability were considered as most important when making the decision. All alternatives were found to have sufficient usability but the ramp had a significant lower cost. Only the ramp has therefore been considered in the generation of requirements on the x-ray system.

Table 5: Evaluation of loading solutions.

Pros and cons with loading solutions		
Ramp	+ Lowest price + No major modification of the car	- Ramp is folded out by hand - The ramp requires a car with sufficient rear door height - The x-ray unit has to be driven backwards down the ramp - The ramp requires long space behind the car
Lift	+ Motorized, no lifting or bending movements required for the operator	- Requires two drive sequences by the operator - Requires the operator to step up on the lift platform - Electricity supply needed
Lowered floor	+ The short ramp allows for smaller parking lot + Allows for small car, smallest segment of transport vehicle	- Ramp is folded out by hand - The machine has to be driven backwards down the ramp - Highest price - May be harder to secure load in small car

Vehicle

The factor to consider when choosing vehicle, which will put requirements on the x-ray machine, is the elevation of the ramp. The typical rear height of a sufficient transport vehicle was about 55-58 cm. This height could though be lowered down to approximately 45 cm if the vehicle was configured with air suspension.

To set a requirement for ramp-driving abilities for the x-ray unit the elevation angle was calculated for a vehicle with 58cm rear height and a ramp with a length of 220cm. This resulted in a requirement that the x-ray unit should be able to drive up a ramp with an angle of 14,5 degrees.

See Appendix 1 for details about vehicles and ramps.

4.2.4 User studies

Two user studies were carried out in this project. The first one in Lund was mainly focus on pure observation of the working cycle. The second one in Norway was used to clarify uncertainties, get a second opinion of thoughts and to increase understanding about the work process.

During the visit at Lunds universitetsjukhus two x-ray operations were executed at two different retirement homes. Both investigations were thorax x-rays, lungs. The whole use cycle including all tasks was transcribed into a use case from which user needs could be defined. To give an overview and to support the needs structure in a later stage a use scenario was also set up based on the use case.

In Norway one x-ray operation was studied. Also this one was a thorax investigation carried out at a retirement home. During the visit a semi-structured interview was also conducted with the x-ray operator.

4.2.4.1 Use scenario

In the use scenario all activities carried out throughout the working life of the x-ray machine is stated. The activities are formulated as goals to leave the specific solution, of how the activities should be executed, undefined, Table 6.

Table 6: Use scenario for mobile x-ray.

Use scenario - Lifetime of the mobile x-ray What do you want to be able to do?							
The x-ray system life	1	Take the system to market	1.1	Design the system			
			1.2	Get the system certified			
			1.3	Sell the system			
	2	Get the system in operation	2.1	Perform x-ray where people are	2.1.1	Administrate a job order	
					2.1.2	Relocate from hospital to nursing home	
					2.1.3	Relocate from vehicle to patient	
					2.1.4	Perform x-ray investigation	
					2.1.5	Get the image analyzed by doctor	
					2.1.6	Be able to get back to base	
			2.2	Maintain or service the system			
	3	Take the system out of service	3.1	Upgrade the system			
			3.2	Scrap system			

4.2.4.2 Use case

The following section shows a segment of the use case, transcribed from user studies, including the summary and the first stage, *transfer in the hospital*.

Use Case scenario

The use case scenario is based on user studies during two x-ray investigations carried out in Lund. The two investigations were done within one day at two different retirement homes and the x-ray machine had to be transported in the car between these homes. In order to capture as many needs as possible critical parts from the investigations have been merged together, the use case scenario does thus not represent one investigation solely.

Use sequence overview

1. *The operator drives the x-ray unit from the x-ray department in the hospital via the elevator to the car in the garage*
2. *The operator loads the x-ray unit in the car.*
3. *The operator drives the car to the retirement home.*
4. *The operator unloads the x-ray unit, picks needed equipment from the car and drives the machine to the patient's room.*
5. *The operator set up the x-ray unit and makes two exposures.*
6. *The operator packs his stuff and drives the machine back to the car.*
7. *The operator loads the machine in the car and drives back to the hospital.*
8. *The operator unloads the machine from the car and drives it up to the x-ray department.*
9. *The operator connects the machine to the wall socket and to a network cable.*
10. *The operator sends the images to the image analyzer and the operation is thereby finished*

Transfer in the hospital

Start position: The machine is parked at the department office

1. *The operator unplugs the x-ray machine's power cable from the wall socket and winds it up on the hanger on the x-ray machine*
2. *The operator grabs the handles and pushes the machine in the corridor, passes the patient waiting room, into an elevator with sliding doors.*
3. *The operator goes down with the elevator to garage level.*
4. *The operator pulls the unit out the elevator and pushes it to a air station (One tire is almost flat)*
5. *The operator fills the tires with air*
6. *The operator pushes the machine to the garage and stops by the car.*

Context

- *The machine is parked in the department by the wall. No specific "garage".*
- *The operator cannot see freely over the machine so he has to lean to the side to see where to go.*
- *The operator has to drive the machine in the corridors where patients are sitting.*
- *The air station is located in the garage*

- *The machine is bumpy and hard to steer when there is not sufficient air pressure in the wheels*
- *There is a curb in the garage, approximately 30 mm, which the machine has to be pushed over.*
- *The operator forgets the referral papers at his office and have to go back to pick them*

Identified needs

- *The machine has a flat tire that makes it hard to drive and takes extra maintenance time.*
    - *Minimize risk for flat tire or related maintenance*
- *To reduce need for moving the machine it should be stored in the car, this would also reduce need for driving in the corridors*
    - *Store the machine in the car when not in use*
- *To reduce the risk of forgetting papers the solution should be totally paperless or prevent that risk in another way.*
    - *Minimize risk of loss or forgetting papers and other information.*
    - *Make a fully digital solution and provide information to the operator wherever he/she is.*
    - *Minimize the effort needed by the operator to get and handle needed information.*
- *The machine should be able to drive up and down low curbs, 30mm.*
    - *The machine should be able to drive up and down 30mm high curbs.*

4.2.4.3 Complementary interview

In connection to the user study at Akershus sykehus a semi-structured interview was conducted with the operator. A semi-structured interview was also conducted with Frode Lærum to explore the problems regarding file transfer. Below is a list of the most important statements and answers from the interviews.

- *Small size is important, usually there are furniture and stuff in the patient rooms.*
- *The weight is an important factor. The machine should be easy to handle and should be easy to drive over thresholds, up ramps and similar obstacles.*
- *Wireless transfer of images is wanted; it should save time and also to help the x-ray operator to make decisions at the nursing home.*
- *Service and support has to be quick, good communication is necessary.*
- *The machine should be easy to clean, sometimes patients with contagious deceases are visited and then the whole machine has to be disinfected.*
- *The machine has to be robust; it will be exposed to a tough environment.*
- *The machine has to be able to drive in some slushy snow and mud. The weather and ground is not always good.*
- *The reason why mobile file transfer is not used today is mainly organizational, the demand is too low for someone to get it work.*
- *Mobile network technology should be evaluated for speed and connectivity*

4.2.5 Use case simulation

A use case simulation was completed according to plan described in 3. Research method. The needs identified during the simulation were added to the requirements list under appropriate topic. To highlight some of the most important findings and discussion points the main needs statements was phrased also separate from the needs list. Some of these main statements are presented below.

Temperature – The unit will probably be exposed to high and low temperatures

- *During warm days the inside temperature of a car ban be very hot. Hot temperatures may damage the battery.*
- *During winter nights the temperature in the car can decrease very low. Low temperatures may cause damage on the x-ray tube.*
- *Quick temperature variations may cause condensation inside the system and damage the electromechanical components.*

Ground clearance – The system is sometimes too low.

- *The hooks for transport securing should be mounted to not limit the clearance when driving over thresholds.*
- *Problems may appear if there is snow on the ground. Snow may get into the transmission for the elevating column. This can cause corrosion and wear of components.*
- *If driving outdoors in snow the bottom plate may be wet, therefore keep the bottom plate free from water- and corrosion-sensitive parts*

Vibrations – The unit will be exposed to vibrations

- *Attachments in the unit should be secured for vibrations*
    - *Mating metal components may have rubber interface*
    - *Electric couplings should be secure for vibrations*

Driving – The unit driving system should be configured for the right environment

- *The driving system should be configured to improve driving on ramps and over thresholds where high power is needed.*

Loading & Unloading – Is ramp the right choice

- *Driving up and down a ramp is not very easy, maybe another loading solution should be considered.*
- *The unfolded ramp behind the vehicle occupies big space. It may be problematic to find a big enough space for loading & unloading.*

4.3 List of requirements

The needs captured throughout the investigation were compiled into a requirements document and structured according to description in 3.5 Requirements list. A section of the list is shown as an example in Table 7

Table 7: Selection of stakeholder requirements list.

Nr. [Scenario]	Nr. [Class]	Nr. [requirement	Scenario	Class	Justification		Need/Requirement	Evaluation method	Extracted from:
3	3.7	SR-3.7.1	2.1.3 Relocate from vehicle to patient	Ergonomics	General requirement contributing to high level of user satisfaction.	D	*The unit and related system shall contribute to good ergonomics*	*Assessment*	*User study/ interview Lunds sjukhus*
		SR-3.7.1.1	2.1.3 Relocate from vehicle to patient	Ergonomics	General requirement contributing to high level of user satisfaction.	D	*The number of lifting movements should be minimized*	*Engineering test*	*User study/ interview Lunds sjukhus*
		SR-3.7.1.2	2.1.3 Relocate from vehicle to patient	Ergonomics	General requirement contributing to high level of user satisfaction.	D	*The number of bending and kneeing movements should be minimized*	*Engineering test*	*User study/ interview Lunds sjukhus*
		SR-3.7.2	2.1.3 Relocate from vehicle to patient	Ergonomics	General requirement contributing to high level of user satisfaction.	D	*The number of movements and position changes for the operator should be minimized*	*Engineering test*	*User study/ interview Lunds sjukhus*
		SR-3.7.3	2.1.3 Relocate from vehicle to patient	Ergonomics	General requirement contributing to high level of user satisfaction.	D	*The need for carrying equiment in relation to movement should be minimized*	*Engineering test*	*User study/ interview Lunds sjukhus*
	3.8	SR-3.8.1	2.1.3 Relocate from vehicle to patient	Unit design - Structural system	The unit will be exposed to tough environemt. Bumpy roads, curbs, tresholds, weather and demanding use.	R	*The system shall be robust to sustain in tough environment*	*Engineering-/CAD assessment*	*User study/Interview Akershus sykehus*
		SR-3.8.2	2.1.3 Relocate from vehicle to patient	Unit design - Structural system	The unit will be exposed to weather when transferring between car and location for x-ray investigation.	D	*The unit shall be resistant to rain, snow and weather*	*Engineering test*	*User study/ interview Lunds sjukhus*
		SR-3.8.2.1	2.1.3 Relocate from vehicle to patient	Unit design - Structural system	The unit will be exposed to weather when transferring between car and location for x-ray investigation.	O	*The unit may be equipped with a rain cover*	*Design choice*	*User study/ interview Lunds sjukhus*
		SR-3.8.2.2	2.1.3 Relocate from vehicle to patient	Unit design - Structural system	Water may reach the bottom plate and wheels when driving in snow or rain	D	*The unit's uncovered parts should sustain some water and snow*	*Engineering test*	*Use simulation*
		SR-3.8.2.3	2.1.3 Relocate from vehicle to patient	Unit design - Structural system	Salt may reach uncovered parts when driving on salted roads	D	*The unit uncovered parts should sustain some road salt*	*Engineering test*	*User study/ interview Lunds sjukhus*
		SR-3.8.3	2.1.3 Relocate from vehicle to patient	Unit design - Structural system	The unit do sometimes scratch along the wall or door openings. Scratches should be avoided to maintain appearence.	D	*The unit should be protected against scratches caused by doors and collision*	*CAD assessment*	*Use simulation*
		SR-3.8.4	2.1.3 Relocate from vehicle to patient	Unit design - Structural system	The system may be exposed to single hard hits when driving down curbs and thresholds	D	*The system should sustain hits from driving down 25mm thresholds*	*Engineering test*	*Use simulation*
		SR-3.8.5	2.1.3 Relocate from vehicle to patient	Unit design - Structural system	Vibrations will affect the system when driving on rough asphalt and gravel	D	*The system should sustain vibrations from driving on rough asphalt and gravel*	*Engineering test*	*Use simulation*
		SR-3.8.6	2.1.3 Relocate from vehicle to patient	Unit design - Structural system	The unit will be driven outdoors and into the building for x-ray investigation. The wheels tend to bring dirt.	D	*The risk of bringing dirt inhouse should be reduced*	*Engineering test*	*User study/ interview Lunds sjukhus*
		SR-3.8.7	2.1.3 Relocate from vehicle to patient	Unit design - Structural system	During transportation the unit has to be secured in the car. Consider failure modes in design, should the unit or securing system break first.	R	*The unit shall be designed with a solution for securing during transport*	*CAD assessment*	*Vehicle customizer*

5. Analysis of product needs

Not all stakeholder needs identified during the research is relevant for the development of the mobile x-ray unit. There are also contradicting requirements and requirements that are inherited in others.

Maximum size is not a problem for accessibility if just looking at building regulations. The electrical wheel chair of type B, which is used bot indoors and outdoors like the machine, has dimensions larger than the existing x-ray unit. So if the next version is not made significantly bigger this is not an issue. Anyway user studies shows that size is an important factor since people's homes are sometimes crowded with furniture and other stuff. A small machine is also easier to handle for the operator; thereby small size can improve user satisfaction. In the research of transport vehicles it was also found that most transport vehicles is built to fit a standard sized pallet, so it the machine is built small enough to fit a pallet it may improve transportation and shipping.

Thresholds do not have a specific height restriction in law. The recommendations are though to not exceed 20mm and earlier the recommendation was 25mm. During user studies the thresholds were found to be within this limit in most cases even if a few exceptions could be identified. Often higher thresholds and changes in height were completed with a small ramp. These ramps could be quite short so even if the machine may get over it one should consider the height and make sure the machine have clearance enough to stand with one wheel pair on each side of the threshold.

Ramps are used both when entering building and entering the vehicle. According to the research the ramp to enter the vehicle will have a steeper elevation and therefore this elevation will be the critical one during development.

Radiation screen should be used during horizontal x-ray investigations according to the local regulations issued by Region Skåne (2013). On a national level there is no rule like that, instead a dose limit is set to 0,1mSv per year. During user studies it was found that radiation screen had never been used either in Lund or in Oslo. Therefore the requirement to bring radiation screen could be considered of less importance, one should though keep the regulations in mind if they are taken up for discussion in future.

Wheels are components that are affected by many needs and environmental challenges. They should have a structure rough enough to enable driving on snow and bad ground. At the same time they should bring as little dirt as possible and they should be able to be cleaned and disinfected after certain investigations. When driving over thresholds or down curbs the wheels will be subjected to an impact load, which they have to sustain. Preferably they should also be secured from puncture while an air-filled wheel would be to prefer to absorb vibrations

File transfer via wireless connection is an important function for efficiency in x-ray operations at remote places. This is not running efficiently either at *Akershus*

Sykehus or at *Skånes universitetssjukhus* but according to Lærum (2016) the problem is mainly in operations. The demand for wireless file transfer has been low and therefore the issue has not been prioritized by the hospitals. Regarding technical functionality of the machine it should be equipped with a mean for mobile file transfer.

Temperature is a factor that may cause problems to many of the sub-systems. The x-ray unit will probably be exposed to both very hot and cold temperatures when being stored in the car. Either the sub-systems themselves have to be developed to sustain these temperatures or the unit has to be kept away from the extremes by controlling the surrounding temperature.

Loading solution used for this research has been a ramp. Weather this is the best solution should be investigated further. The choice to go for a ramp solution was mainly because of cost but how the tradeoff between cost and usability should be interpreted is weakly investigated. To make a better informed decision the business case and purchaser of the product should be analyzed further.

5.1 Key Issues for development

The most important development focus points were concluded as Key issues. These were considered crucial for SFT model one to fit in the new working environment intended for model two.

To inspire and guide the workforce in the right direction during development three keywords describing the x-ray unit characteristics were also stated. These are based on a general interpretation of what are important characteristics for the product to succeed.

Maneuverability

Robustness

Ergonomics

6. Analysis of research method

In this section the method are analyzed in relation to the academic research questions.

6.1 Stakeholder and system requirements

In the theoretical framework of systems engineering a difference is made between stakeholder requirements and system requirements. Stakeholder requirements are defined as needs that are totally independent of the solution to solve the need, while system requirements are needs that are related to the solution. The precondition in this project has been that there is a product, which should be developed to fit in a new working environment. Since the product concept was already defined it has been hard to elicit the actual stakeholder needs during the investigation. When analyzing the needs captured during user studies and interviews it was found that the majority of them were directly related to the product solution. This applies to both the needs expressed verbally by the operator, as well as the needs captured from observations. Thereby the solution independent stakeholder needs were left out and considered irrelevant for research in the product refinement project.

One of the first steps in this project was to define a concept of operations showing the intended use process. Based on this, a use scenario was set up as a sequence of wanted results. By stating the use scenario as “what results the user wants to achieve” it was made solution independent. In a new product development project this use scenario could probably be created to express stakeholder requirements. By exploring the scenario the developers could then come up with different system concepts to meet the wanted results. For this project though, where the system concept was already defined the use scenario did not serve the purpose as base for concept generation. The use scenario was instead used only to get an overview of the working process and as a base for structuring system requirements.

A risk by not stressing the solution independent thinking in requirements research could be that one assumes the concept developed to be what the stakeholders want. The precondition for a refinement project is though that a product is already developed, so one has to assume that a deeper stakeholder requirement research was done for the initial product.

6.2 Method choice to achieve systems engineering benefits

One of the major benefits that should be achieved by applying the systems engineering philosophy is to decrease the total development cost and time. The intension is that if one stress thinking of the system from a holistic view and consider the entire life cycle in the beginning, problems should be identified early when they can easily be solved. The mindset that should be applied is that the extra time and effort put early in research, before actual development, should decrease the total cost and time. To make well-founded decisions early should also lead to another benefit, to decrease the technical debt.

6.2.1 Visual tools

By using visual tools as concept of operations together with other overview tools as use scenario the entire work process and product life was highlighted early in the requirements generation process. These overview tools were also efficient for improving the understanding and identification of possible alternative scenarios. For example the concept of operations helped in defining possible ways to send images to hospital. The stakeholder list served the same purpose of giving a broad overview and stress thinking about the whole life cycle already from the beginning of the project.

6.2.2 Use simulation

The purpose of the use simulation carried out was to be able to identify system requirements by applying an alternative of participatory observation. By providing the engineers and internal stakeholders at SFT with an actual use experience an extra dimension of understanding should be achieved. Considering the life cycle of the product, the engineers could better relate to all the activities from the entire use process.

Since the research of needs in this project have been executed by an external researcher the use simulation was not only valuable to define new requirements; it also provided an efficient and reliable way for the researcher to explain how external users had expressed needs in the real context. As a part of knowledge transfer between researcher and engineer this factor was of big importance. This way to transfer knowledge does not directly secure storage of knowledge for future since only the participants of the use simulation receives the information. To improve the storage of knowledge the use simulation was filmed and the outcomes in form of needs were stored in the requirement specification. Filming is though not a very efficient way for reuse so it only supports one of the two important factors in knowledge management.

6.3 Requirement specification

As described above, the stakeholder requirements in this project was somehow defined already from the beginning since the product vision and concept were defined as preconditions. Therefore the analysis of captured needs resulted in needs almost only valid as systems requirements. The few solution independent expressions, stakeholder requirements, captured were also typically mentioned in relation to a system requirement and therefore they were all included in the system requirements specification. One example of an expression that can be considered solution independent was “The need for maintenance of the system should be minimized”. This was though put as system requirement since there was no freedom to completely change system solution anyway.

An advantage found by structuring the system requirements according to use scenario was that one could identify where more effort had been put and see which parts of the life cycle that lack completeness. In systems engineering the whole use scenario should be object for research and by having the requirements structured for all these life cycle stages, thinking of future activities such as how to take the product out of service were stressed.

6.3.1 Justification of requirements

The justification statement for each requirement expressed in the specification is a way of applying the thin slicing method for knowledge capturing. The raw stakeholder statements that were captured during interviews, user studies and use simulation have been recited in a concise way to not overload with information but still provide background information to the actual requirement. When having this background information it is also possible for the engineers to reuse or adjust requirements to alternative context and thereby the effort put in capturing needs for this product can be reused. An example of this is clarified below.

Requirement: *The unit shall be resistant to rain, snow and weather during transfer outdoors.*

Justification: *The unit will be exposed to weather when transferring between car and location for x-ray investigation.*

The justification of the requirement in this case clarifies that the situation where the system has to be resistant to weather is when it is transferred between the vehicle and the location for x-ray investigation. By including the justification the engineer knows the context. If this requirement cannot be met, the engineer is now given the possibility to eliminate the requirement by adding an alternative requirement like:

Alternative requirement: *The vehicle shall be parked so that the system cannot be exposed to weather when transferring between vehicle and the location for x-ray investigation*.

6.3.2 Evaluation

A direct application of the systems engineering theory has been to include evaluation method in the requirements specification document. Just by stressing the thinking of how to handle and evaluate a requirement in a later stage have increased the awareness of why a requirement is important and how to fulfill it. When clarifying the evaluation method in the beginning requirements can be evaluated in parallel to development instead of postponing all evaluation until the end. If a problem is found in the end it may not only affect that single system, but also relating systems. The intension is that such situations should be avoided by having the evaluation method defined early.

7. Conclusion of academic research

This thesis has been carried out with two parallel purposes. From an industrial point of view the purpose have been to investigate what to develop on the specific x-ray system to succeed in a new working environment. The final answer to this question is handled in 4.3 List of requirements & 5. Analysis of product needs. Seen from the academic side the project have been a test of how to use the theory of systems engineering and apply it during needs investigation for refinement of an existing product.

Whatever development method studied, one is likely to be presented with a number of tools to use along the project, and systems engineering is no exception. All these tools presented are developed from an underlying philosophy of how to carry out a research project. What has been found after performing this research project is that the tools may be helpful to push the workforce in the right direction but more important is to understand the underlying thinking.

To be able to successfully implement systems engineering the research group should therefore first of all be well introduced to the mindset of systems engineering. To get the promised advantages of decreased total development cost and time it is crucial for the management to encourage preparatory research and implement life-cycle thinking instead of reward quick outcome. This is probably more important than the actual tools used.

Regarding technical debt this is a result of badly investigated decisions taken foremost during the product design stage. A well defined requirements specification and life-cycle mindset should though guide in the right direction. Especially early discussions of different alternative use scenarios should improve the awareness of robustness in design.

More precise for development of an existing product the research of stakeholder needs is less relevant since these are somehow inherited in the prerequisites for the project. Still, overview tools as concept of operations and use scenarios, which is suggested for use when defining solution independent needs, are very powerful to communicate and investigate needs for the whole product life.

The second academic research question has been how to capture knowledge gained during requirements specification. In this project the concept of thin-slicing have been applied and included in the requirements specification. This has enabled an efficient way to store findings in a concise way together with the most important outcome, the requirement. The use simulation was also a good way to transfer knowledge in this particular project where the researcher is not a part of the development team. To store the actual use simulation in form of videos is though harder from a knowledge reuse perspective. There one should instead rely on the requirements specification.

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Appendix 1

Appendix 1 describes the detailed process of investigating possible car-ramp configurations.

Car

Table A1 1 shows a list of selected transport vehicles and the important parameters. The choice of cars included is based on the size. Transport vehicles relevant for this purpose can be divided into three segments; small- mid- and large compartment. Cars in the smallest segment of transport vehicles were found to have too low height of the rear doors to fit a ramp of sufficient length. Two of these smaller cars are the Renault Kangoo and Citroën Berlingo, which are shown in the table as a reference. There are also a segment of bigger cars that are more expensive and unnecessary big. Volkswagen Transporter and Renault Traffic is such cars, they are shown as reference from the bigger segment.

The important factor to consider when choosing vehicle, which will put requirements on the x-ray machine, is the elevation of the ramp. Price information is approximate list prices provided from the car manufacturers. In reality the car will be acquired with specific configuration and volumes, the price will therefore differ. Due to these variations the price in Table A1 1 should be considered only for rough comparison. Cars classified as passenger car, with windows and no separated cargo compartment, was excluded due to the higher price and unnecessary extra features.

Table A1 1: Vehicles possible for transport of mobile x-ray.

Brand	Model	Size segment	Engine	Reference price [SEK]	Comparment floor length [mm]	Rear door height [mm]	Ground to floor height [mm]
Peugeot	Expert	Mid size	1,6 HDI	195000	2254	1245	562
Renault	Kangoo Express Maxi	Small size	1.5 dCi	165000	2115	1129	575
Renault	Traffic	Large size	1.6 dCi	215000	3750	1320	552
Ford	Transit Connect	Mid size	1,6 TDCi	170000	1753	1228	599
Volkswagen	Transporter	Large size	2.0 TDI	265000	2572	1299	568
Citroen	Berlingo transport	Small size	HDI 100	155000	2050	1148	586
Citroen	Jumpy	Mid size	HDI 90	210000	2254	1272	562
Toyota	Proace L1H1	Mid size	1,6 D	185000	2254	1272	562
Nissan	NV200	Mid size	1.5 dCi	155000	2040	1228	524
Mercedes	Citan Long	Large size	1.6 CDI	235000	2586	1261	558

Ramp

The different ramps provided by Autoadapt, which could be used, are presented in Table A1 2. There are also other suppliers on the market with the same or similar offer. The maximum weight the ramp can carry is an important factor. Most ramps carry 400kg but can according to Autoadapt be made stronger upon request. Both x-ray machine and operator has to be counted for when dimensioning the ramp. The number of section is also important to consider since it will affect usability and the required parking space.

Table A1 2: Ramps possible for loading and unloading of x-ray unit.

Name	nr. of sections	Extended length	Height in car	Weight	Max load*
BGR 21	2	202	112	24	400
BGR 23	2	222	122	26	400
BGR 27	2	262	142	30	400
BGR 27-3	3	265	102	30	400
BGR 33-3	3	325	122	35	400
BGR 27-3	3	365	135	39	400
BGR 90-21P	2	202	112	28	600
BGR 90-25P	2	242	132	31	600

* Standard values, ramps can be strengthen upon request

Car-Ramp configuration

The elevation for each car-ramp combination was calculated and shown in Table A1 3. For each car the longest possible ramp, two and three sections, were calculated for. When choosing the final configuration one should consider the elevation and the number of sections. The elevation for the chosen configuration will be set as requirement for the mobile x-ray machine.

The two alternatives, which imply the lowest elevation are highlighted in green.

Table A1 3: Ramp elevation for different configurations.

Vehicle		Ramp 2 sections		Ramp 3 sections	
Brand	Name	Name	Elevation [deg]	Name	Elevation [deg]
Peugeot	Expert	BGR 23	14,7	BGR 33-3	10,0
Renault	Kangoo Express Maxi	BGR 21	16,5	BGR 27-3	12,5
Renault	Traffic	BGR 23	14,4	BGR 33-3	9,8
Ford	Transit Connect	BGR 23	15,7	BGR 33-3	10,6
Volkswagen	Transporter	BGR 23	14,8	BGR 33-3	10,1
Citroen	Berlingo transport	BGR 21	16,9	BGR 27-3	12,8
Citroen	Jumpy	BGR 23	14,7	BGR 33-3	10,0
Toyota	Proace L1H1	BGR 23	14,7	BGR 33-3	10,0
Nissan	NV200	BGR 23	13,7	BGR 33-3	9,3
Mercedes	Citan Long	BGR 23	14,6	BGR 33-3	9,9