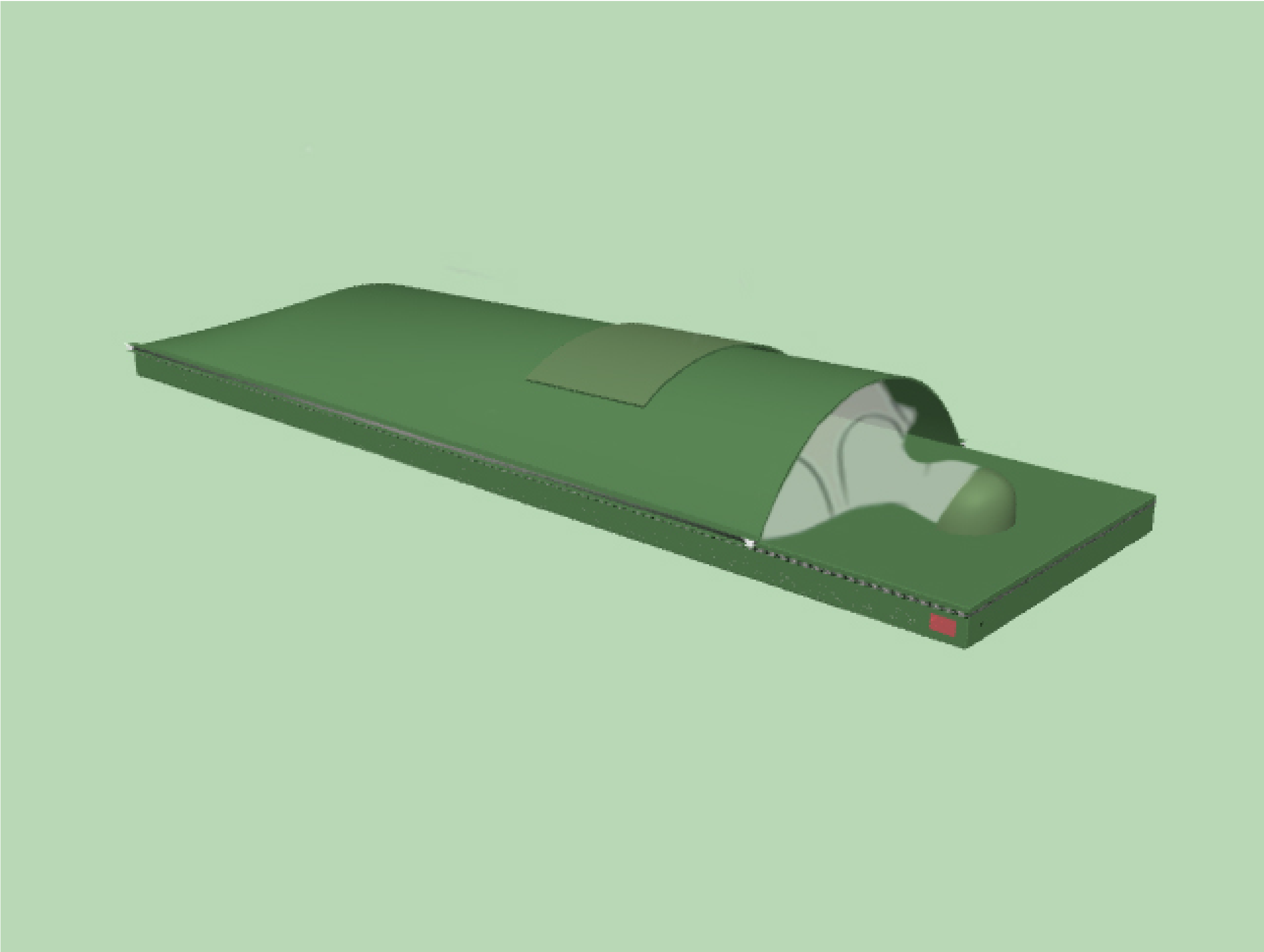

Keep the Temperature

Product Development of a Patient Warming system

Master's Thesis - IMSX30

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Keep the Temperature - Product Development of a Patient Warming System Development

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Abstract

In this thesis, the product development of a medical product is done. The product is to solve the problem of low body temperature in patients. Current products lack active heating to rewarm patients while others cause burn injuries due to a high heating rate. The developed product should provide safe but efficient active heating. While also be comfortable for patients and paramedics to use. Lastly, it should also do it at a lower cost.

The thesis began with a problem investigation and market analysis. Interviews with experts and literature studies were done to find and extract information about the problem. Analysis of the information brought the identification of two key markets. A requirement list was done by interpreting gathered statements and information. A function-means tree was also done, to identify relevant functions that were desired for the developed product. A top-down generation and screening of concepts according to function-means tree, were followed throughout the thesis. Through three loops an extensive exploration of the design space had been done and three concepts remained of the initial 15. After further evaluation, the final concept was chosen. As the final concept was chosen further detailing could be done, such as investigation of materials and heating method. To be able to determine the appropriate heating effect physical test were performed. The tests showed that the proposed materials for the layers worked as intended. However, calculations based on the tests revealed the lack of performance in terms of heating rate. But it still provided heating to the patient. An investigation of battery culminated in a decision to use laptop batteries. Cost estimation was done to evaluate the value of the product, it highlighted a costly layer which was subsequently removed. Finally, the final product had unique features to set it apart from competitor products. Such as passive and active warming in combination. While the let down of the product was its heating rate, often inferior to competitors. But unlike competitors, major body parts were easily accessible by a zip structure.

In summary, this thesis developed a product with a sample heating rate to heat patients suffering from low body temperature. A combination of active and passive warming provided safe and reliable heating. The developed product does this while providing comfort for both patients and paramedics. The material cost of the product ensured that it would be able to be used without much thought.

Key words low body temperature, active rewarming, pre-hospital, operation theater, burn injuries, safe, efficient, comfortable, low cost

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1
Introduction

This chapter aims to present the topic of this thesis. It highlights the aim, objectives, scope and delimitation of this thesis. A reading guide is also at the end of the chapter to guide the reader throughout the thesis.

1.1 Background

Normally, at the scenes of accidents, abdominal and thoracic cavity operation, patients temperature will decrease quickly so that physical functions may stop working, which can lead to serious injuries and even death. Among them, hypothermia significantly affects the rescue success rate. Research data provides evidence to this conclusion: hypothermia which can occur for accidental trauma patients is an independent predictor for a higher mortality (Rösli, Schüriger, Candinas, & Haltmeier, 2020). Also, statistics from Scotland show that low temperature is not the cause of death, but an important predictor of death, which confirms that low temperature can lead to higher mortality. (records of Scotland, 2020)

The problem of low body temperature has been tried to be solved through different methods such as warming blankets, warm oxygen, and extracorporeal circulation (Schilling, 2020). These heating methods can be divided into 2 types: passive rewarming and active rewarming. Active rewarming is to provide an external heating source to recover the patient's temperature. While passive rewarming is used to prevent further heat loss which could be caused by external factors such as cold temperatures. Generally, no method can solve this problem by itself. For example, a combination of active and passive heating methods for the patients can in a hospital be able to heat the patient. Compared with the treatment available inside the hospital, there are more limited rewarming options for pre-hospital care. This in turn makes it hard to recover temperature patients with low body temperature, which according to Rösli et al. (2020) is the stage where the rescue success rate can be affected the most. Usually, there is a passive blanket available in the pre-hospital treatment, this means that the low body temperature can only be maintained at a maximum rather than increasing unless the patients arrive at the hospitals. Due to this issue, an electric blanket and a chemical pad are also supplementary for some trauma teams. However, the design of these products increases the risk of skin burns so that these active products would not be used in pre-hospital care unless under extreme circumstances. From this perspective, there is still no active rewarming device for pre-hospital care. Therefore, it is urgent to develop an innovative device to solve the problem, especially for pre-hospital care. In short, the primary purpose of this project is to develop a medical product to keep or raise the temperature of patients in the scenes of accidents or operations without causing skin burns.

1.2 Aim

Low body temperature, especially hypothermia, is a serious condition for any patient. At first glance, the consequences caused by low body temperature will not result in death for patients, but it can seriously impair important functions of the human body, which results in a higher mortality and recovery time (Lundgren, 2012). It can also result in lifelong sequela to patients. Surgery-related hypothermia has been recognized for a long time and therefore recover the patient's temperature in surgery has been investigated for many years. It cannot be denied that a combination of heating methods can solve low body temperature which in turn makes it a solvable problem in surgery. However, there is still not a method that excels due to the risk of burn injuries. It is still a common issue for active heating devices which have relatively high heating efficiency. Compared with the operational theater, the pre-hospital care of low body temperature is still a problem that has to be recognized. With medical research and development, the effect of low body temperature during pre-hospital care has gradually been understood by an increasing number of practitioners. The active heating devices for pre-hospital care, therefore, have great market potential. Resulting in that this thesis aims to develop an active heating device that can be used in both emergency situations and operation theater to warm and maintain body temperature. Furthermore, this active heating device should have a high heating efficiency while not causing skin burns.

1.3 Objectives

To fulfil the aim of this thesis a number of objectives has to be fulfilled. These are visible below.

- Equivalent warming rate as established products
- Ensure that no skin burns occur
- Increase comfort for patients
- Decreased cost compared to established products

1.4 Scope

The purpose of this thesis is to develop an efficient external heating product that can maintain or raise the patients' body temperature to a normal range without causing additional harm. As stated in Section 1.2, a normal body temperature is desired due to the complications related to low body temperature such as loss of important physical functions of the human body (Lundgren, 2012). When applying the external heating, it should be noted that the temperature of the heating system should not burn the patients' skins. Gordon et al. (2019) listed several burn examples in field tests of active heating, these examples demonstrated that sometimes the heat energy left on the skin can lead to high skin temperatures and thus burn the skin. Thus the maximum safe skin temperature is in need of investigation and how to keep the heating temperature below the limit.

Rectifying the low body temperature is an important task, but standard treatment should also be possible to be done in parallel to save patients' lives. The concept should ensure that the presence of equipment must not increase the difficulty and complexity of the standard treatment. For example, minimal heat should be transferred to the environment, thus not affecting the comfort and performance of paramedics. The standard treatment might be done in the different areas of the body, indicating that this device should be area adjustable. This means that this device can exposure certain parts of the human body corresponding to the needs. This required feature is called compatibility in the latter part of this report.

1.5 Delimitation

To achieve the scope and aim of the thesis, a delimitation also has to be defined. The delimitation allows for a greater focus on the objectives. Further, the delimitation also prevents new areas of focus to be added later in the development process. Thus keeping the focus small and precise. The delimitation mentioned below has been established and complied with during this thesis.

- Only use of commercially available technologies
- The device will be developed to be used in the Scandinavian countries
- The device aims to be fully developed in the sense of functionality but not ready for production
- The device will not be able to address other classifications of hypothermia than Accidental and Iatrogenic hypothermia.
- Serious hypothermia is not in focus for this thesis
- The direction of exploration lies in medical devices rather than drug treatment
- Concepts that is generated will only regard external use
- Only hardware solutions will be included in the final product

1.6 Reading Guideline

The report is divided into several stages. The following chapter, Chapter 2, describes in detail what is the target of each stage and how to achieve it. Here, the description of each stage is brief, which is aimed to provide readers a walk-through.

1. Problem investigation and market analysis, where information about the causes, consequences and redemption's of the problem are investigated
2. Customer needs and requirement, where the information is converted into customer needs and subsequently into a requirement list. Functions are also identified with the use of information.
3. Concept generation and selection, generation of concepts for the identified functions. Each loop creates new concepts for next level of functions. Before each new generation loop a screening occurs. The final concept is chosen at the end.
4. Concept detailing, detailing the final concept through theoretical and practical investigation. Determining materials and dimensions.
5. Business plan, a canvas is made to highlight important aspects of selling the product.

6. Final product, shows the features, choices and rendering of the developed product. Also how well the product fulfills the requirements.
7. Discussion and conclusion, discusses choice of method and achieved results. A conclusion is made whether the established objectives are fulfilled.
8. Recommendations, brings information about what should be done in order to develop the product further.

2
Methodology

The methodology chapter provides the methods that are present in this thesis and how the methods are implemented. Each step of the development process has different methods that are described in detail and why it was chosen. Further, the method implementation is described. The structure associated with the development process is visible below in Figure 1.

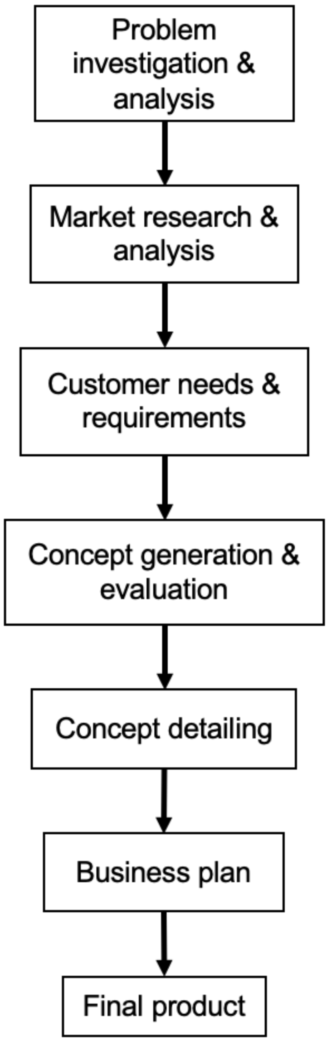

Figure 1: The structure of the process

2.1 Method of Problem Investigation & Analysis

Problem investigation and analysis is the first step to take place, this is to study the existing knowledge of the defined problem. But also to analyze the knowledge in order to understand the problem. There are different methods to find this existing knowledge and to analyze it.

2.1.1 Theoretical Method for Problem Investigation & Analysis

Common methods for gathering information are interviews, observations, literature study, the search of patents, general market research, internet searches, and questionnaires (Ulrich & Eppinger, 2008). The methods can be used as a combination to explore the knowledge that exists. The usage of different methods grants mixed information to be gathered. A mix of information is necessary to fully understand a problem. If all the angles of a product is not an uncovered issue can arise later in the development.

For this thesis, a literature study, interviews with relevant professionals, and general market research are performed. The mix of these methods supports the gathering of information and knowledge. A literature study finds relevant studies, papers, legislation, and literature within the subject. The interviews target professionals in different fields of the problem. The interviewees in focus are medical staff that has hands-on experience of the problem. Knowledge is collected for the authors to fully understand the problem from different perspectives. The knowledge is then interpreted, analyzed, and compiled for the next step in the development process, Customer needs, and requirements.

A literature study is always done early in a project to find out more about the problem to be solved, in this case, the problem of low body temperature. A study of the literature would give an insight into the academic world and how the problem is researched at the time of this thesis. The goal is to find the focus of research, the most prominent researchers, and what has been uncovered thus far. The prominent databases for this literature study are Scopus and PubMed. These two databases allow for a wide search for medicine-related articles that covers the problem.

2.1.2 Implementation of Method - Problem Investigation & Analysis

The initial search was performed by using Scopus and PubMed and the following search terms:

- "Body temperature changes"
- "Perioperative"
- "Hypothermia"+"Heating"+"Device"+"Surgery"
- "Rewarming"+"Hypothermia"+"Emergency"+"Intensive care"
- "Hypothermia"+"Rewarming"
- "Economy Hypothermia"

- "Heating"+"Accidental+"Hypothermia"
- "Inadvertent Hypothermia"
- "Hypothermia"+"Perioperative"

2.2 Method of Market Research & Analysis

The general market research aims to find target market groups, competitors, and trends to comprehend the market as a whole.

2.2.1 Theoretical Method for Market Research & Analysis

The market analysis uses a combination of the information gathered in the market research but also from the problem investigation. The collected information may not present characteristics of the market and therefore analysis is required. The information is analyzed to extract the necessary statements and facts about the market. This can be facts like the market size but also an analysis about the novelty of the technology acting in the market. An analysis is essential to understand how the developed product is to be fitted in the market. It is of no use if the product already covers a part of the market that is already well covered. Therefore the analysis is a part of the development.

2.2.2 Implementation of Method - Market Research & Analysis

The methods used to find relevant information about the market are a combination of previously mentioned methods, see Section 2.1. Information was found by using an Internet search engine to give width and depth to the research. A literature study also allowed for legislation information to be found.

2.3 Method of Customer Needs & Requirements

As the information about customer need is collected it is of importance to make it translatable to requirements. All requirements are collected in a list to be easy to access and read.

2.3.1 Theoretical Method for Customer Needs & Requirements

The first step is to sort and collect the information gathered in a structured way. The structure is created to fit the information to the development process. Often the information is formulated in statements that may require interpretation to be a need. The need is written as an imperative, using for example the word "must". This to express what needs to be fulfilled. In this form, the need can be used in the development of the product.

Further, a requirement list can be created to record the needs in an easy-to-read list. The list is an excellent way of recording the needs due to its continual development during the product development. It is often called that a requirement list "lives" since it is never finished. New needs will be added as the development progresses.

2.3.2 Implementation of Method - Customer Needs & Requirements

Thus, the requirement list must be used. As the development progresses it will also be more difficult to track the addition of needs. The list also provides a sense of a map for the development. It can be difficult to track where the development is heading sometimes.

2.4 Method of Concept Generation & Evaluation

Now that a requirement list is done, the generation of concept can be performed. The concept generation aims to explore the design space. While the concept evaluation screens the concepts to eliminate concepts that does not fulfill criterion often based on the requirement list.

2.4.1 Theoretical Method of Development Process

The product development process in this thesis is a combination of a traditional product development method and a lean product development method. The lean product development method uses a test-design-build cycle instead of the traditional design-build-test cycle (Ulrich & Eppinger, 2008), which is the primary reason to adopt a combination of product development methods. Figure 2 shows the influence on the design as time passes in the project, as can be observed the earlier more knowledge is gained about the design the better.

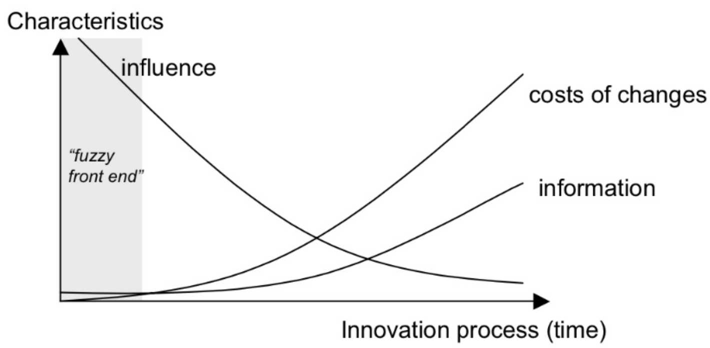

Figure 2: The figure shows how influence on design changes as time passes (Herstatt & Verworn, 2004)

2.4.2 Implementation of Method - Development Process

The test-design cycle was incorporated during the concept generation, concept evaluation, and concept elimination phases. The cycle allowed for knowledge to be created early in the development process and that the concepts iterative evolve. The cycle was done concurrently for the identified sub-functions in the previous chapter, Section 2.3. The cycle followed the structure in Figure 3.

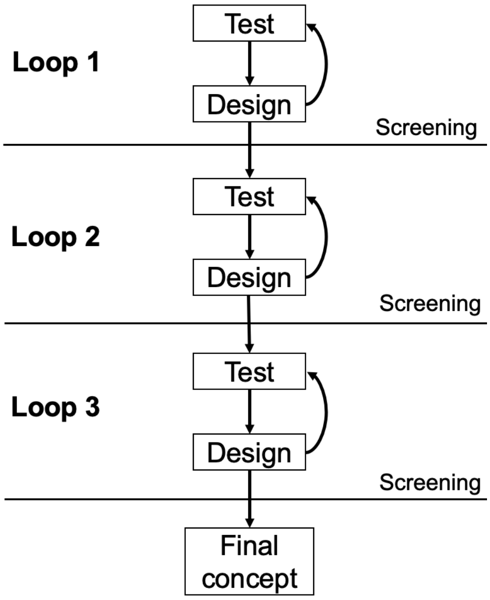

Figure 3: The structure of the Test-design cycle.

2.4.3 Theoretical Method of Determining Functions

An important aspect of the process is also how the generation of concepts is done. Often the generation of concepts is done for the desired functions of the concept. There are different methods to investigate what functions a concept should have. The most common methods are process-flow charts, function-means tree, and product breakdown structure. Another simple method is to make early sketches.

The process-flow chart details the input to the overall system of the concept. Where the input can be categorized as energy, information, or material. The major functions of the concept are identified and put into the system. For each function, there is an input and an output. The function is also meant to be divided into as small a sub-function as possible to make sure that each function is charted. The output of the system is also detailed at this point. The process flow chart is a systematic and appropriate approach for breaking down the main function of a concept.

The function-means tree is also a method for doing a functional decomposition of the main function. Since the method is a top to bottom level tree, the main function is identified first. Then a mean to achieve that function is identified. In the next step, functions are identified to achieve the mean. This process will go on until the functions are not decomposed anymore. When the decomposition is done the tree is created in order to visualize the sub-functions.

A product-break-down structure allows for the concept to be decomposed into the larger component. For each component, a smaller set of components are identified. The function of the smaller function will achieve the larger components function which in turn will fulfill the main function. The method is described as a hierarchical decomposition of a product. This to identify all the small components the product is to consist of.

The method of using early sketches of thought of concepts is a good way to visualize the concept. Thereby showing how the requirements can be converted to functions.

2.4.4 Implementation of Method - Determining Functions

For the development process chosen, a function-means tree has been used. The function-means tree suited the process with the loops since each level of functions could be identified and concepts could be generated for that specific level for each loop. The top to bottom level of the function-means tree also allowed for the loops to detail more about the concepts for each loop. This until the concepts were at a highly detailed level and that the tree had reached the bottom.

2.4.5 Theoretical Method of Loop 1

The first step of Loop 1 is the test step. The test step aims to explore the design space and to gain knowledge about the problem at an early stage. First of all, the knowledge from market analysis and customer needs are the solid foundation for the exploration. The methods used were chosen on the basis of the degree of possible knowledge gain. Here early sketches of possible concepts and looking at competitor solutions created new knowledge. As knowledge was collected the next step of the cycle can begin, the Design step.

The Design step is to generate concepts based on the knowledge gained in the previous step but also the sub-functions that are identified in the function-means tree. For the first loop, the focus is on the highest decomposition level of the function-means tree. The designed concepts include both a technical perspective and a design perspective. The technical aspect focuses on achieving the intended performance of the product whereas the design has a focus on functionality. It ensures that the concepts with both technical and design aspects are feasible. The Design and Technical steps use different methods which include methods such as brainstorming, quick sketching, and quick digital modeling. Each with a focus on the respective aspect. As the concepts are generated they are also refined in the test-design loop. The loop is designed so that the changes made to the concepts are tested until there is no change done to the concept. When the Design step does not make any changes the concept moves to the next step, the Screening.

The first Screening aims to prove the feasibility of each concept and allow for early feedback. Methods for screening of concepts can involve established methods such as an Elimination matrix. It can also be a session with stakeholders to get feedback before the screening.

The Elimination matrix is used to screen each concept according to the requirements that need to be fulfilled. Each concept is evaluated to each of the set requirements. If it fulfills the requirement it is awarded a plus sign. If it does not fulfill the requirement it is awarded a negative sign. As a concept get a negative sign it also means that the concept is rejected at this point. If the concept gets plus signs for all the requirements it means that it passed the screening and moves to further development. The rejection of concept is coupled with a comment on the right-hand side of the matrix where the explanation of the rejection is posted. It is also possible that there is not enough information to judge whether a concept fulfills or does not fulfill a requirement. Then a question mark is inserted instead. That means that the concept is not rejected but additional information about the concept is necessary in order to make a judgment. Which in turn means that the concept may be developed a bit more to gain the information needed. Another way of capturing the information is to get in touch with stakeholders that can provide this information.

2.4.6 Implementation of Method - Loop 1

For this process, the screening consisted of a session with stakeholders and an Elimination matrix to remove concepts that did not fulfill the target requirements. First, the session's aim was to provide feedback on the generated concepts. The feedback was then analyzed and appropriate measures could be done. The Elimination matrix was performed to allow for a structured elimination of concepts and to highlight the concepts that required additional development.

The Elimination matrix was modified in this process. Normally, an Elimination matrix only screens based on requirements. But for this process, additional criteria were identified and added to the matrix. These criterion reflected the realization of a concept. The criterion can be observed below.

- Solve main problem
- Fulfills all demands
- Realizable
- Reasonable cost
- Enough information
- Simplicity

2.4.7 Theoretical Method of Loop 2

Loop 2 is a loop consisting of a Test and a Design step, similar to the previous loop. For this loop, the test step involves the sketching of the product in a use scenario and user evaluation. These methods allow for the concepts to be further refined in the Design step. The concepts are detailed for each of the new sub-functions which is in the next level of the function-means tree. For each of the new sub-function, a brainstorming session is done to generate ideas for the concepts. But also to find new concepts that are not uncovered before. The new ideas are then incorporated into existing concepts or are fused into new concepts. As the concepts refine with new ideas eventually they reach a point of a higher detailed level, which makes them ready for screening.

The screening focus is on evaluating concepts from a business and performance perspective. The screening methods used in this screening are used to compare the concepts to each other. There are different methods for comparing concepts to each other. The two major product development methods are the Pugh matrix and the Kesselring matrix. The Pugh matrix allows for a general comparison of concepts while the Kesselring matrix allows for a more in-depth comparison.

The Pugh matrix is created to compare concepts. The comparison is done by first determining the criteria that are important to evaluate the concepts. The criteria reflect the requirements set but also the desired performance of the concept. As the criteria are set a concept has to be chosen for reference. This reference is set as the comparison concept. All other concepts will be compared with this concept about the criteria. If a concept performs better than the reference concept there is a plus sign, if it performs equally there is a zero and if it performs worse it is a minus sign. The result of each concept is summarized and a score can be obtained. A comparison in total score and score in certain criteria is possible. This is useful to understand each concept now only how it performs according to set requirements and wished performance but also for particular criteria. The Pugh matrix is used as a loop where the next matrix uses a different reference concept. This generates a new score since the reference is changed. No other aspects of the concepts can be visible. These iterations can continue as long as new knowledge is gained or that the results do not change. In other words, the result of the Pugh matrix is going to converge several times. As the matrices converge towards a result a decision is possible. Concepts can pass to further development but it is also possible that they may be removed. The screening only tells a score, it is up to the user to determine the outcome.

2.4.8 Implementation of Method - Loop 2

For this development process and step, the Pugh matrix was employed due to its ability to compare concepts on a lower detail level than the Kesselring matrix. Its wide range of ability to gain knowledge of the concepts was essential to drive the development further.

The Pugh matrix was mainly used to analyze the advantages and disadvantages of each concept. It also provided a platform for cross-pollination of concepts. Meaning that combining concepts can generate a different score in the Pugh matrix. It also highlighted important aspects of each concept. Lastly, the Pugh matrix was used to remove concepts that had inferior performance. The concepts that passed the Pugh matrix were further developed in the next loop.

2.4.9 Theoretical Method of Loop 3

Loop 3 aims to refine the concepts to a degree that they can be evaluated as complete concepts. The methods to refine the concepts further involve further analysis of the concepts in real environments, a User evaluation, and concept generation for the next tier of sub-functions in the function-means tree. In this loop, the design, shape, functionalities, and even performance are determined.

The analysis takes place at the site of the usage environment of the concept. Here an analysis of the environment in which the concept is to be used is done. This to highlight potential issues and to achieve a greater understanding of the environment. At the same time that the analysis of a real environment is done, an evaluation of concepts by the users is also of interest. The user can also provide input and feedback to the concepts and rule out a potential issue that may occur.

Since this is the last loop, the function-means tree is at the bottom. The sub-functions left are involved at a detailed level of the concepts. The detailing is done by finding new ideas through brainstorming, competitor products, and inspiration from the user environment.

The screening can take place when the concepts are detailed to such a high level that they can be determined as complete concepts. Like previous loops, the stakeholders provide feedback, and a method for comparing concepts is used. The method for this comparison is the Kesselring matrix. The Kesselring matrix includes all the aspects, which means that both performance and business are considered when doing the matrix.

To use the Kesselring matrix as an evaluation tool there is to be an identification of the criteria that compares the concepts. The criteria are chosen to represent the wanted functions and performance of the final concept. It also highlights the differences between the concepts. When the criteria are chosen the weighing of the criteria is performed. The criteria are compared to each other and ranked depending on the importance of each.

When the weighing is done each of the criteria has a weight attached to it. In this way, the criteria that are the most important would also get the most of the score. As the importance of each criterion is determined the next step would be to define parameters for all of the criteria. The parameter is thought to make the criteria measurable and quantified. It should also have a value and a unit to make each concept comparable. A scale is attached to each of the parameters. This to define what is a good value and a bad value, the scale ranges from one to five. Where the one is the worst score and the five is the best score.

The Kesselring matrix can now be performed and now each concept will be evaluated based on the value it is awarded from each parameter. The parameter value will determine the score depending on the set scale. Then the score will be multiplied with the weight of the criteria to receive the weighted score. The weighted score will be summarized for each concept. The concept with the highest weighted score will perform the best about the set criteria.

2.4.10 Implementation of Method - Loop 3

The Kesselring matrix was used in this process to be able to evaluate the concepts on a detailed level. The wide range of criteria and parameters that can be set allows for an adjustment to fit a particular product development process. The weighing of criteria also lifts the concepts that perform well in regards to the most important criteria. This in turn makes sure that the concept with the highest score is the concept that should perform the best. In turn, the highest-scoring concept would be the concept chosen for concept detailing.

2.5 Method of Concept Detailing

After determining the final concept, development of the concept is necessary. The development consists of several different methods to investigate and evaluate the final concept. The methods are categorized according to the purpose of the method. The categories are methods of theoretical approach and practical approach.

2.5.1 Method of Theoretical Detailing

The theoretical approach involves investigating the heating method, the battery pack, the mattress, and the blanket. For the heating method finding an appropriate way of heating to fulfill the requirement. Solutions for battery power and available outlets are investigated. The size, thickness, and materials of the mattress are also investigated. Lastly, the passive blanket also needs further detailing.

2.5.2 Theoretical Method of Physical Testing

The testing of the final concept is done to learn more about certain critical aspects that would affect the functionality. The primary function to test is the performance of the heating method, which is the main function to be performed of the concept. Other functionalities that are tested are the passive warming of the patient and the prevention of thermal burns. The tests are constructed so that the results would be reproducible while discovering if the function performed as intended. Methods for testing involve constructing smaller assemblies of the final concept to have a physical representation and to test practical functions. Verification of the design involves both looking at the actual dimensions in a 3D environment to find the optimal compromise between shape, weight, and size. By doing this in a 3D environment means that making adjustments a quick and easy process with instant changes.

Methods for physical testing involve creating tests that are replicable, involve scientific measurements and that can reject or approve design aspects. Each test inherits a certain purpose. The tests for this concept involve testing the active and passive warming. The active warming tests regard the heat transfer between body and heat source. The passive warming tests regard insulation and keeping of temperature.

As the testing is performed the last step of the concept detailing would be to make an actual product of the final concept. The digital rendering of the final concept is a good method for achieving that. An actual physical representation would be the best option but due to the ongoing pandemic, this would be difficult to do. Thus it is decided to make a 3D model of the product. The 3D model included all the functions of the product, the intended shape, and size. The model would be in an assembled view and in an exploded view to be able to interact with the different structures and layers of the product.

2.5.3 Implementation of Method - Physical Testing

The physical testing consisted of the following tests which were designed to evaluate practical functions. The testing involved the thermal paste, the layers of the mattress, the heat transfer, and the isolated layer of the mattress.

2.5.3.1 Testing Equipment & Procedure

The test equipment consisted of a warming pad, an Infrared thermometer, a piece of cotton fabric, a piece of fabric rubber, plastic bags, thermal pads, and foam used in cushions.

Procedures shared for the tests were that the amount of water in each plastic bag was 0.3 L. The temperature was always measured with the IR-thermometer.

2.5.3.2 Test 1

The first test was to evaluate the surface temperature that the warming pad could achieve. This was done by setting the heat level to the maximum setting and waiting ten minutes to achieve the maximum surface temperature. The surface temperature was then measured with the IR-thermometer.

2.5.3.3 Test 2

The second test aimed to investigate the heat transfer between body and heat source. The surface temperature of the warming pad and the water was measured. The water was placed on the pad for a time of ten minutes. When ten minutes had passed, the temperature of the water was measured again.

2.5.3.4 Test 3

The third test was done in a similar manner as the second test, the exception was the addition of the cotton and rubber fabric. The cotton fabric was placed first on the warming pad and then the rubber fabric was the top layer. The two layers mimic the layers of the concept. The layers were heated by placing them on the warming pad. After a certain time, the layers had reached a plateau in temperature. The surface temperature of the rubber layer and the water was measured. The plastic bag with water was placed on the rubber layer for ten minutes and then the water temperature was measured again.

2.5.3.5 Test 4

The fourth test added an insulation layer around the plastic bag. Otherwise, the test was done in the same manner as the third test. A surface temperature was measured on top of the rubber layer and the water temperature. The plastic bag was put on the layer and was wrapped in a three mm layer of cotton fabric. This mimics the passive warming achieved by the blanket on top of the mattress. The water temperature was then measured after ten minutes of heating.

2.5.3.6 Test 5

The fifth test was made to evaluate the potential of a thermal conductivity layer. The layer was represented by the thermal pad. A piece of cotton and the rubber fabric was cut to match the size of the thermal pad. The layers were the cotton fabric on the bottom, then the thermal pad, and on top of the rubber layer. The surface temperature was measured on the warming pad and then the layers were put on top of the pad. The temperature was after some time measured on top of the layers to evaluate the performance of the thermal conductivity layer.

2.5.3.7 Test 6

The sixth test investigated the effect of foam insulation. The foam was cut to the intended thickness of six cm. The surface temperature of the warming pad and the surface temperature on top of the foam were measured. The foam put on the pad and after 15 minutes the surface temperature of the foam was measured again.

2.6 Theoretical Method of Final Product

It was clear that the design solution had totally been determined after the testing, further little modification was no needed. Therefore, to help the readers quickly go through the report and better understand what features the product has a chapter called final product was showcased. Seen in Chapter 9. This chapter mainly explained how the product works to achieve the goal and fulfilled all the requirements. The details that can make the product unique and competitive were displayed. As stated in the delimitation, the final product may not be functional but built in order to be a showcase of the most important details. Therefore, the digital renderings were added as illustrations that can more directly express to readers.

2.7 Theoretical Method of Business Plan

Concurrent with the development of a product there also needs to be a viable business case of the product. There are different methods to create a business plan. Methods such as a promotion plan, financial plan, business model canvas, and achievement can provide the necessary structure for a business plan to be created.

In the Business model canvas, key partners, key activities, key resources, value proposition, customer relationship, channels, customer segment, cost structure, and revenue streams are discussed. These are aspects of the business plan that provide a structure for the business. Each aspect brings a consideration for the business to evaluate. A business always needs partners, income, and resources. While there are also costs and marketing to consider. Most important is to define the value proposition to be delivered to the customer. The business model canvas is a visual method for describing each of these aspects. Each box is dedicated to each of the headlines. As all the boxes are simple but yet efficient. An example of a Business model canvas can be observed in Figure **??**. (Insitute, 2021)

2.7.1 Implementation of Method - Business Plan

For this thesis, a Business model canvas was created. The canvas allowed for a visualization of the model and a tool to show potential customers and stakeholders.

2.8 Summary of Methodology

The methods stated in the implementation sections above was the process adopted in this thesis. The complete process can be seen in Figure 1, where all the steps associated with the development, can be seen. In the next chapter, Chapter 3, a literature study was performed to understand the defined problem and its background.

3
Result of Problem Investigation & Analysis

From the two literature searches, a broad and deep understanding of low body temperature has been acquired. The literature review allowed for a comprehension of the working principle of hypothermia, its consequences for humans and society, and the available devices that can help with rewarming.

3.1 Medicine Background

The issue of low body temperature was investigated to get the basic knowledge background. The background was mainly related to classifications of low body temperature and their consequences.

3.1.1 Low Body Temperature & Hypothermia

The description of low body temperature includes a normal but low body temperature and hypothermia. The low temperature is in the range of 35 °C to 37 °C while hypothermia is a condition that occurs when the core body temperature drops below 35 °C. This relatively large drop in core body temperature can occur from different circumstances. The circumstances can be divided into four different classifications depending on the cause of the drop in core body temperature. Descriptions of each classification are below.

Accidental

Accidental hypothermia occurs when the patient has been subjected to massive blood loss or/and environmental cooling. When the patients suffer the massive blood loss caused by serious accidents, it has a great possibility that their body temperature will decrease quickly and even lead to shock. Also, when the patient has been subjected to drowning/bathing, an accident when exercising in a winter climate, the trauma causes immobilization and intoxication. (Schilling, 2020)

Iatrogenic

Iatrogenic hypothermia occurs when the patient has been subjected to surgery. Often this is a bigger surgery where an anesthetic is needed. The anesthetic usually has an impact on the decreasing temperature. This since the normal body regulation is set shut down by the anesthetic. The long exposure time to the cold elements in operational theater can also make a drop in body temperature. (Schilling, 2020) Examples of the cold environment are the cold surgery table and the air surroundings. There is minimal clothing that can help with keeping the core body temperature.

Endogenous & Symptomatic

Endogenous hypothermia is classified when the patient has no primary temperature regulation with an unknown cause of the issue. Symptomatic hypothermia often occurs when the patient has Sepsis, a Neurodegeneration disease, or Endocrine disorders.(Schilling, 2020) These two types of hypothermia are quite complex so that hardly be rectified by the medical equipment alone. This is the reason that these two types of hypothermia are not planned to be solved in this project.

Temperature Classification

Additionally, hypothermia can be classified depending on the core body temperature. There exist three core body temperature intervals for classifying Hypothermia. These are mild, moderate, and severe hypothermia. Mild hypothermia is classified between 35 °C to 32 °C, moderate hypothermia between 32 °C and 28 °C, and severe hypothermia below 28 °C. Each class of Hypothermia has different effects on the circulation, breathing, neurological status, muscles, Gastrointestinal Tract, and Urinary tract. As the patient decreases in core body temperature the symptoms worsen and may result in cardiac arrest once core body temperature drop below 30 °C. (Schilling, 2020)

3.1.2 Burn Injuries

A burn injury can be defined as irreversible necrosis of the uppermost dermis. Burn injuries occur from contact with a hot source. The hot source can for example be dry heat, immersion heat, or a hot object. In this thesis, the main heat source will be a hot object. The hot object transfers heat to the skin of the body to raise the core body temperature. To achieve the transfer the hot object either needs a proximity contact or a skin contact. Thus, the risk of burns to occur is increased. The risk of burn to occur is tied to several parameters. These are: temperature of the hot object, time for exposure, pressure on the skin, and poor skin perfusion (Giesbrecht & Walpoth, 2019). The temperature of the heating object determines the time it takes to cause a burn injury. The temperature determined for causing a burn is when the dermo-epidermal junction reaches 44 °C(Martin & Falder, 2017). At this temperature, irreversible damage starts to happen at the dermis. Just below this temperature, at 43 °C, a feeling of pain starts to occur (Martin & Falder, 2017). Indicating that this is a limit of heating and should not be passed. Below the structure and layers of the human skin are visible in Figure 4.

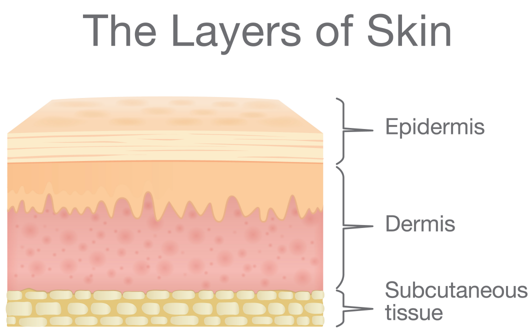

Figure 4: The different layers of human skin (Dermatology & Centers, 2020)

3.2 Existing Solutions

To rectify the medical issue of low body temperature, passive rewarming, active external rewarming, active core rewarming, and extra-corporeal blood rewarming are used today. Passive rewarming is the case in which the interventions are applied to promote heat retention (Shaw, Steelman, DeBerg, & Schweizer, 2017). For example, removing the wet clothes on the patients, moving patients to a dry and warm place, protecting from the cold surface with blankets are the most widely used passive rewarming methods. Since these methods can only prevent further heat loss, they can only avoid the further drop of the body temperature or create a very slow increase in patients' body temperature. For patients with hypothermia or massive blood loss, these passive methods make little sense because patients' metabolic heat production system is impaired. (Mccullough & Arora, 2004)

To improve the efficiency of treatment and thus reduce the mortality rate, active external rewarming is necessary. Active reheating refers to adding heat from an external source to the patient to quickly recover their core body temperature to the accepted level. (Mccullough & Arora, 2004) The most common active external rewarming method is forced-air heating. Currently, most hospitals have installed forced-air active rewarming devices. The Bair Hugger by 3M is such a device, it is used in operation theaters and is a well-known device. But none of these medical devices have been applied in the ambulance due to the issues of portability. Besides, when applying the active external heating to the patients whose body temperature is above 28 °C, the heating rate could be as high as possible. Normally, the rate of existing systems is an approximate 1 °C/h to 2.5 °C/h (Burns & McAuley, 2018). However, the rewarming rate to the patients with serious hypothermia will be quite different and critical since the same heating rate is too high and thus cause a cardiac arrest. Medically, rewarming the patients with serious hypothermia is more complicated, and more aspects need to be considered.

Active core rewarming is the method of using intravenous fluids or warm oxygen to warm patients. Among them, intravenous fluid is a method that uses drugs to quickly warm the patient. Before infusion, the fluids would usually be heated to 44 °C so that the body temperature will not be negative impacted by the sudden infusion of the cold fluids. Intravenous fluids are allowed to be used in both scenes. As for warm oxygen heating, it is a method to create a warm oxygen inhalation to make the patient feel warm from the inside out. To achieve this goal, special equipment is required to heat the normal oxygen to 44 °C. Although many studies have demonstrated that this method is one of the most efficient ways to heat patients, the complexity and in-portability make it infeasible in emergency scenes. There is some active core rewarming measures to make the patients' temperature recovery quickly, such as cavity (gastric, bladder, peritoneal, pleural) lavage using warm fluids. But these methods are quite invasive and complicated so that they only be used in special operation cases. (Burns & McAuley, 2018)

The last independent heating method is extra-corporeal blood heating, which warms the patient's blood to raise the patients' temperature. This is the fastest way of heating a person. This direct and invasive method works greatest the serious hypothermia patients who might refractory to all other methods of rewarming (Burns & McAuley, 2018). The disadvantage of this method is also obvious: this machine can only be used inside the hospitals and strict operations are needed.

3.3 Potential Risk of Existing Solutions

As stated previously, currently, only passive rewarming methods will be applied in the scenes of accidents. These methods would not bring potential risks to patients despite the very limited benefits gotten. In the remaining three types of heating methods, active core warming and extra-corporeal blood warming do not place any requirements on the patients. In other words, these medical machines can apply to all patients with different body temperatures any wound incisions. However, it should be mentioned that these two types of methods have high requirements on the skills of the operators. Gorden et al. (2019) listed one example of skin burn due to the operation that does not strictly comply with the requirements.

Active external rewarming is increasingly common but a bit complex. Since active external rewarming is to place the heating source directly on the skin surface to provide the heat energy, this heating method has a high demand on the heating points. It is suggested to place the heating device on the thermal resistive skin such as the upper torso, feet, neck, and head for more energy absorption (Lundgren, 2012). However, the incisions can easily occur on the torso in the scenes of accidents and big operations. This means that it is more difficult to heat the upper torso with a fixed device. This is why heating on the arms, legs, and heads is the most common. Therefore, the cover of the skin is usually not so large. To increase the temperature recovering rate, some paramedics might increase the heating rate and temperature which has a great possibility to burn patients' skins. It is quite tricky to find a balance between heating area and heating rate (Lundgren, 2012).

3.4 Analysis

Through further investigation of this problem, it is found that there are limited devices to heat patients in pre-hospital care. This due to the inherent properties of the devices, such as in-portability and complexity, so there is a market potential to develop such medical devices. To make this device feasible in pre-hospital care, the device should not be so large and heavy. Besides, it should be easy to install and operate. From the perspective of function, it is better to combine active rewarming and passive rewarming to optimize by complementary their functions. When applying the heat, it would be nice if the device could be modular and are adjustable so that the coverage of skin can be as large as possible. Under this premise, the balance of the heating area and heating rate can seldom make the skin burnt. Just to be on the safe side, a safety fixed heating system or a feedback loop can be added, the safe temperature or the automatic temperature advisability can avoid harm to the greatest extent (Martin & Falder, 2017). The extracted customer needs from the problem investigation & analysis are defined in the list below.

- Great market potential on the pre-hospital heating device
- Make the device portable, easy to install and operate
- Try to make the device modular and area adjustable to cover a larger heating area.
- Achieve a balance between the heating rate and heating area
- Safety fixed heating system or a feedback loop
- Determine the target group as soon as possible for the criteria set

4

Result of Market Research & Analysis

This chapter introduced the target markets through an analysis of market demand and industry trends. Relevant medical regulations were also referred to. An important section was the analysis of the advantages and disadvantages of existing competitors in the market.

4.1 Market Demand

The number of people subjected to low body temperature largely depends on the seasonal changes and age groups. As the temperature drop and the autumn begins the number of cases related to accidental low body temperature rises. Also, the risk of low body temperature increased among children and especially the elderly (Lundgren, 2012). For the Northern European countries which the aging situation getting more and more serious, winter can be harsh and present below freezing temperatures all over the countries, so low body temperature is a medical problem that cannot be ignored.

According to (Brändström, Johansson, & Giesbrecht, 2014) a study performed in the four most northern counties in Sweden, the incidence of Accidental Hypothermia was 244 cases over 8 years, which is the equivalent of 3.4 cases per 100000 inhabitants. The cases were primarily tied to the autumn, winter, and spring season as 80 % of the cases occurred between October and April. The study also highlighted intoxication as a major factor for Accidental Hypothermia, in 34 % of the cases Ethanol was a co-factor. According to the study, a 6 % in-hospital mortality exists for Accidental Hypothermia. The report stated that the number of cases has increased year by year in eight years. This highlights that this is a problem that needs to be resolved.

The issue of low body temperature can occur both in the scenes of accidents and big operations, such as thoracic operations: the hypothermia frequently happened in the big operations may increase the risk of infections and blood loss, so that more medicine will be consumed and the recovery time will be prolonged (Ruetzler & Kurz, 2018). To lower the negative impact of hypothermia, some methods and equipment have been applied in those scenes.

4.2 Swedish Regulations

To make sure that the product design could be sold in the Scandinavian countries, the product should meet the regulations of Europe. In this project, the Swedish regulations "SS-EN 1789:2020" (2020), "SS-EN 1865-1:2010+A1:2015" (2015), and "SS-EN 13718-1:2014+A1:2020" (2020) were referred to. The relative points have been synthesized and listed below. These regulations can be converted to requirements and detailed design in this thesis.

- The total load of the stretcher which includes the patient and even the device should not be more than 150kg. If the product would attach with the stretcher, the weight should be controlled
- The maximum sound level insides the ambulance should less than 77dB. Normally, the running of the car motor can also cause noise. Considering the effect of other noise, the heating device can not be louder than 30dB. Otherwise, the noise level insides the ambulance would not be accepted
- If the heating device will attach to the stretcher, the displacement caused by the vehicle running cannot larger than 150mm. This means that the device attached with the stretcher should be able to safely and stable stowed
- The length of the stretcher should be between 1900-1970mm, while the width should be between 530-570mm
- The normal medical mattress should be able to bend a maximum of 75 degrees to lift the upper part of the human body
- If the product is defined as "portable", it should fulfilled three requirements:
  It should have an active battery
  The product can be taken and used outsides the ambulance
  It can be taken and operated by one person
- The buttons, switches, indicators, and controls need to be easily accessible and visible
- The surface of the medical equipment should be sealed or in a similar way to make sure that the fluid of patients will not infiltrate
- The material of the equipment surface should be able to clean, disinfect, and sterile
- The material shell should unaffected by disinfectants
- The active battery of the product should be easy to take out for the maintains without be departed fiercely from the fixed device

4.3 Competitors

The competitors included the existing methods for both operational theater and emergencies. In this section, the advantages and disadvantages were also elaborated.

4.3.1 Competitors In the Operational Theater

In this thesis, actual medical treatment was not in focus, so medical solutions for heating were not be investigated. In this case, the investigation of competitors only focused on heating equipment. The existing equipment can be divided into two sections: one is mainly used inside the hospital and the other is for pre-hospital care. Inside the hospital, the options for active heating are more diverse. Among them, thermal oxygen devices, blood warming devices, and forced-air warmers are the most common in operations. (Burns & McAuley, 2018) The hospitals with surgical capabilities are often equipped with the three pieces of equipment.

It is known that hot oxygen devices are used in almost all operations. The hot oxygen passing through the heating circuit will be pumped directly into the patient's mouth. An example of the hot oxygen machine is visible in Figure 5. This method can directly heat the core body temperature by heat energy into the body so that the heat energy losses are minimal to the surrounding environment. Besides, the distance between the most heat-resistant area, the torso, and the mouth is short. The humid hot oxygen and energy can flow to the desired area quickly. As can be imagined, the shorter the transmission distance, the less heat loss, the higher the efficiency of reheating. The most important thing is this device should only need to cover the snout and mouth of the trauma patient. Hence it will not block normal surgery. In summary, the hot oxygen device is quite useful in rewarming trauma patients with low body temperature. Although this device is good at rewarming, the maximum heating temperature is still limited: the oxygen can only be heated to 43 °C, otherwise, a burn injury would occur. The limited heat energy input that this device can perform is not usually enough to restore the patient's body temperature in larger operations (Burns & McAuley, 2018).

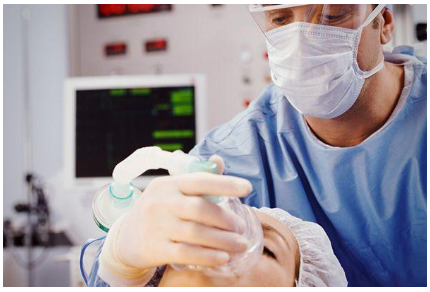

Figure 5: The figure shows an hot oxygen machine.
(wen7, 2021)

Due to a long time of exposure to the cold environment and the effect of anesthetic, the heat energy provided from the external heat sources should be as high as possible in large operations. To make up for the limitations of the hot oxygen device, an extracorporeal circulation heating machine in combination can give good results. An example of the extracorporeal machine is visible in Figure 6. The device is a way to directly heat the core body temperature. This by heating the blood, the blood close to the heart and lungs will put through the machine. Which acts like dialysis which heats the blood. The warm blood returning to the body will quickly warm the internal organs. Among the currently existing medical equipment, an extra-corporeal circulation heating machine is the fastest way of raising the core body temperature. The disadvantage of this device is also obvious: the device is not easy to operate due to its invasive and complexity, so skilled paramedic is the basis of this method (Burns & McAuley, 2018).

Figure 6: The figure shows an extracorporeal warming machine (Getinge, 2021)

As for the forced-air warmers, the Bair Hugger by 3M is the most common. It has the feature of easy to use as well as high heating efficiency. The paramedic only needs to connect the hose between the forced-air bag and warm air pump and attach the forced-air bag to the trauma patients. The air is automatically circulated by the warming pump. The continuous heating of the air would transfer the heat to the skin surface that contacts the bag. Normally, the forced-air bag cover as large a skin area as possible in order to increase the rewarming efficiency. To adapt to different operations, 3M company have developed force-air bags with different shapes. This means the Bair Hugger is compatible with different situations, one of these bags is visible in Figure 7. These prominent advantages make the Bair Hugger famous all around the world. But there are some things that Bair Hugger needs to improve. For example, the current Bair Hugger is a one-time-use product, so it is not sustainable and environmentally friendly. In addition, the expensive price of the Bair Hugger less attractive. (3M, 2021a)

Figure 7: The forced-air bag of the Bair Hugger (3M, 2021b)

4.3.2 Competitors In the Pre-hospital Care

Compared with the active heating inside in operational theaters, passive rewarming plays the dominant role in the pre-hospital treatment. The isolated blanket is the most common product. According to the interview, the paramedic pointed out that they use the blanket almost every time to maintain the temperature or prevent further temperature dropping. A version of a passive blanket can be viewed in Figure 8. But there is also agreement that the isolated passive is not enough for the patients with low body temperature. It is mentioned that a new active device that can work in combination with a passive blanket would make them satisfied. The re-usability and portability might be the reasons why the passive blanket is still not replaced by other devices.

Figure 8: Passive blanket
(Medical, 2021)

In reality, there is active heating equipment used in the pre-hospital treatment, namely the electric blanket. The electric blanket is visible in Figure 9. According to the feedback from the paramedic, the negative effects of this product are greater than the benefits, so the device is rarely used. The biggest issue of this product is the high risk of burn injuries. Once using it, the temperature could reach between 65 °C and 75 °C, which is too high (Martin & Falder, 2017). Therefore, to avoid burn injuries, it needs to be used intermittently. In this case, the operation of the blanket is complicated and the heating efficiency is not so high.

Figure 9: Medical eclectic blanket
(Medistore, 2021)

The same issue appears in another active device for the pre-hospital treatment, the chemical pad. Which is visible in Figure 10. To make the case worse for the pad, it is priced at 350 SEK with a one-time use. The pad only lasts 8 hours once opened, after that period it will no longer produce any heat. (Medkit, 2021) For usage in pre-hospital care where the time to hospital should be as short as possible, it poses some questions whether it is reasonable to use for this application.

Figure 10: Chemical pad
(Tree, 2021)

4.4 Industry Analysis

With the advancement of technology, some passive heating devices, and active heating devices, like the ones described in Section 4.3.2 and 4.3.1, have been developed. This to maintain or raise the core body temperature for different scenes. Most of these devices are only used inside the hospitals. For instance, the extra-corporeal circulation machines can only be seen in the operational theaters due to their complexity and large size. Therefore, the options of rewarming inside the hospitals are diverse, and rectifying the problem of low body temperature is not difficult. In contrast, the devices for pre-hospital heating are in shortage. Moreover, there is a great shortage of active heating devices for pre-hospital treatment. The only available devices were the electric blanket and the chemical pad which are not common in an ambulance. This since both methods have inherent design flaws. In this case, a pre-hospital active heating device would have great market potential. Therefore, the pre-hospital was chosen as the main target market in this thesis. To make this product more attractive, the operation theaters can be added as the secondary target market. In other words, the product designed could be used in both scenes of accidents as well as the operational theaters.

4.5 Business Opportunity

Through the market research, it is found that there is a gap in the market for an active heating device. A reason for this is a shortage of devices for pre-hospital treatment. But a more attractive product would be to develop a device that combines passive and active warming as a whole. Since the development shall make the device to be active heating, it can also be extended to make the device suitable for operations. The mapping of a business opportunity can be seen below in Figure 11.

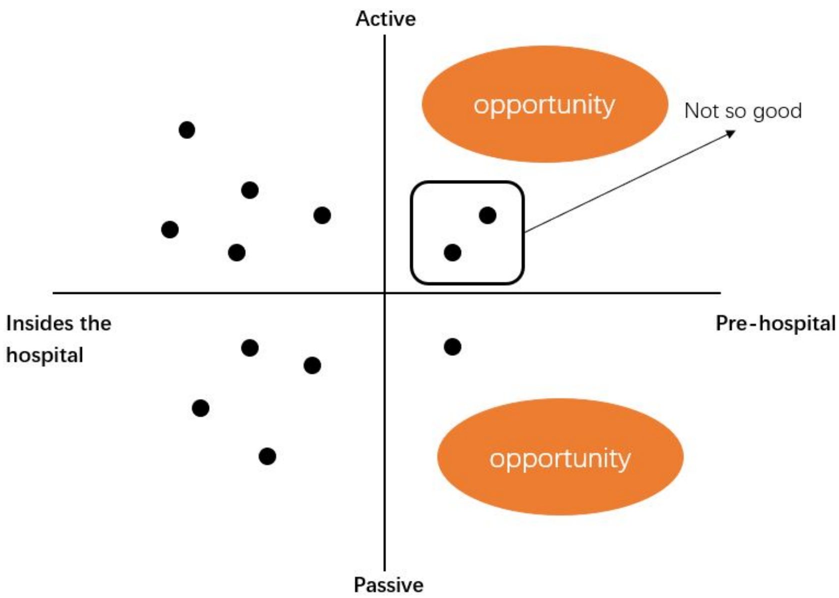

Figure 11: Placement of competitors with regards to form of warming and the environment which it operates in.

Because there are some competitors in the market, to win the business game, the designed product should better than the competitors. The product should combine some prominent features of competitors and its specific advantages to form a unique charm. Through the investigation and analysis of the advantages and disadvantages of competing products, safety, high heating efficiency, portability, re-usability, cost-efficiency, simplicity, compatibility for different situations should be the most important requirement in the list. Table 1 below are the detailed explanation of these requirements.

Table 1: Extracted requirements from the market analysis

Requirements	**Explanations**
Safety	This device can be used as long as the paramedic want without harming patients. Preventing burns is the top priority
High heating efficiency	The device can transfer most heat to the patients, few heat loss to the surrounding environment
Portability	It should not take up too much space of ambulance. The device might also need to be movable with the stretcher by one person, so the weight is a key point. It should also be easy to storage.
Re-usability	No one-time use product, could be washable.
Cost-efficiency	The average price for a single use is not too expensive, at least need to cheaper than the Bair Hugger and chemical pad
Simplicity	Simple to operate, ease to use. No need of highly skilled paramedic
Compatibility	It can heating different area according to the different situations but not block the normal treatment

As the most prominent requirements have been extracted from the market analysis, it is now possible to collect and sort among the collected requirements. This will be done in the next chapter where the customer needs and requirements will be converted and collected in a target requirements sheet.

5

Result of Customer Needs & Requirements

Through Chapter 4, the primary and secondary target market were initially determined. Along with some requirements extracted from the market analysis. It is important to deeply understand the customer's needs for each market segment. To investigate the customer needs for the product that is to be developed a data collection method was first chosen. As the method was chosen the appropriate stakeholders and customers were interviewed. The collected statements and quotes were then subjected to an examination. This was to confirm that the statements adhere to the literature but also to solve the contradictory statements.

5.1 Data Collection

The data collection was used to collect more data about the problems and potential market for the developed product. Here the task was to identify suitable and potential market segments that would benefit from a heating device for patients. But also information on the prevalent problems that belonged to each segment. It was also of interest to find solutions that exist on the market and mainly focus on whether the users of these solutions are satisfied with the performance. As the collection was done, statements from each segment could be interpreted and turned into customer needs. The need in turn could then be converted to a requirement.

5.1.1 Statements of the Pre-hospital Device From Customer Interview

To gather information about pre-hospital care of patients, two primary subjects were interviewed. One interview subject was a team at the SU ambulances who showed more practical and at hand problem-solving. Then a more theoretical interview together with a professor was made, an associate to the supervisor. The professor brought more theoretical knowledge but also a deeper understanding of the low body temperature problem.

Table 2: Statements from subjects related to the Pre-hospital care, the interpreted needs from statements and the data attached.

Statement	**Interpreted Need**
Accessibility to different skin areas to the patient is restricted due to different trauma and different kind of transports	Allow access to different body parts
Local burns is caused by a temperature gradient between skin and heating device	Minimize the heating temperature gradient
Moving of patients is important in the medical field	Minimize movement of the patient when operating the device
A probe in the ear canal is used to measure the temperature of the patient	Access to the ear canal is prioritized
Local heating of the body area does not transfer enough heat, especially the heating alone in arms and lower limb	Maximize the surface area covered by the device, the upper torso should be the main focus to heat
Desire to have a device that is easy to use	Minimal calibration, minimize user input, and simply apply
The earlier the warming starts the better it is	Incorporate the device early in the treatment process
Paramedics often get warm when they work due to thick clothes, masks and air conditioning in the ambulance	The device should not heat paramedics in the vicinity of the device
Conversations with the patient are often disturbed by road noise and sirens	Operating noise level should be kept to a minimum level
Most of the normal treatment is applied to the left arm and head (mouth, ears, and nose)	Accessibility to the important parts of the head and left arm of the patient should be prioritized
The patient is often, but not always, transferred in different stretchers	The device should be able to be used for different stretchers
We often carry the medical equipment in a bag or place it on the stretcher	Device should be portable enough to be carried by one person
We always use a fabric blanket to keep the patient comfortable and warm	Device should be able to be used multiple times a day, and passive rewarming is still important

5.1.2 Statements of Operational Theater Device From Customer Interview

There have been two parties of interest for this thesis regarding this segment: the supervisor for this thesis and a professor. The supervisor has experience as a professor in Cardiovascular surgery and is capable of giving information about the environment in an operational theater. He also has information about the problem of heating patients during surgery. This gave an early insight into the problems occurring during surgery. The professor is more familiar with the problem of low body temperature and has been researching and tried several different methods for warming patients. This interview was arranged together with the supervisor which was the basis of these statements. Another source of statements and information reported from the IKOT-teams from previous years. The accessibility to these reports was given by the supervisor.

Table 3: Statements from person related to the Operational theater, their interpreted need and the data attached.

Statement	**Interpreted Need**
Every stage of surgery, from preparation to the closing up, should be as short as possible	the mounting time of the device should be minimized
Powerful currents and noise from equipment in combination with air-conditioning makes the operational theater a noisy environment	Minimize strong currents and noise
Heating devices that is used at the moment cannot be mounted after surgery has started	It would be good if the device could be mounted and used at any stage of the surgery
Short surgery don't often allow for the patient to be warmed	The heating device should be designed for the big operations
The surgeons can be affected by the heating device since they need to be in close contact with the patient	Heat loss to the surroundings shall be kept to a minimum level
Too much area of the body can be covered which makes the surgery more complicated	The body area to be covered should be adjustable to be compatible enough
The equipment used in the operational theater is often cleaned with surface disinfectant or thrown in the washer if washable	The device should either be washable or be resistant to surface disinfectant
Too soft a mattress underneath the patient will be an issue since it does not allow for CPR	A maximum thickness/softness of the mattress

5.2 Function-means Tree

A function-means tree was established concurrently with the data collection. The function-means tree is a structure used to visually and analytically define a product. It starts with the identification of the main function of the product. The next level in the tree is a mean level which is how the function would be achieved. After the mean level, a function level would return to identify the functions that would compose the mean. As these levels progress the product structure moves from an abstract level to a detailed level.

The tree is not only used for describing the functions of a product but also to serve as a road map when developing. For this thesis, the concept generation will start at the abstract level, with the first function, and move downwards along the tree as the loops, seen in Chapter 2, was finished. At the bottom of the tree, the concept would be detailed to a high level. Below was the function-means tree for the product, see Figure 12.

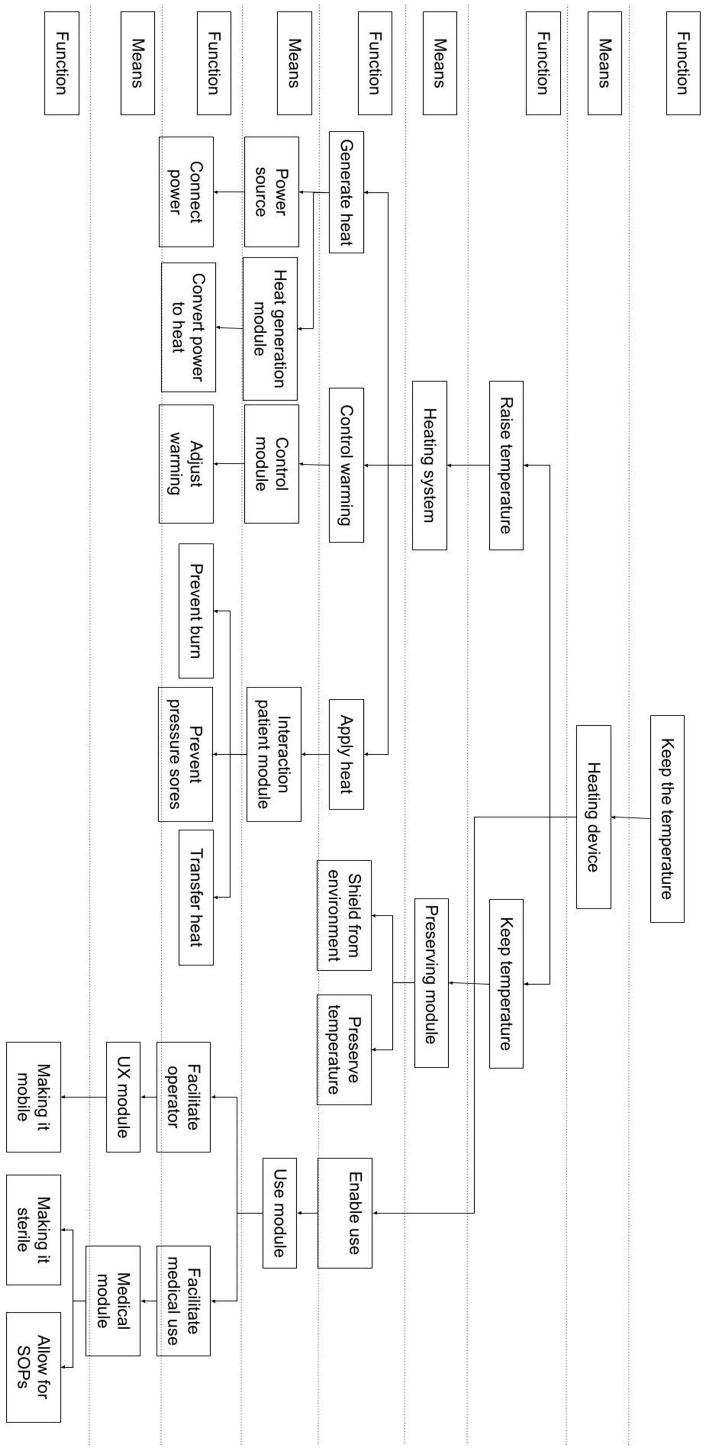

Figure 12: Function-means tree used to identify functions and modules of the product

As can be seen above in Figure 12, the main function can be divided into three main themes. These were the enabling use, keeping of temperature, and raising the temperature. Each theme had its particular functions and means of achieving. The themes allowed for concepts to be generated tailored to each of the themes. The functions had been identified by the information gathered from interviews, literature, and supervisor feedback.

5.3 Target Requirement List

As customer needs have been identified through the help of data collection, now it was time to turn these into requirements. Each requirement was classified as a demand or a wish. It was classified as a demand if the requirement must be fulfilled for the product whereas if it was classified as a wish, it would be good to fulfilled. Thus a ranking can be had for the requirements but also where the focus of development should be. Further, each requirement should have a measurable unit attached to it. This way each requirement could be tested to make sure that it fulfilled the set requirements. Below in Figure 13 were the target requirements set before the concept generation.

Requirement	Demand/Wish	Value	Metric
Applicability to different scenes	Wish	2	0- Ambulance stretcher 1- Ambulance strentcher + operation 2- Ambulance+stretcher+chair + operation
Applicability to different scenes	Demand	0	0- Ambulance stretcher 1- Ambulance strentcher + operation 2- Ambulance+stretcher+chair + operation
Automatic level	Demand	1	0 - User operated 1 - On/Off 2- Adjustable heating 3- Feedback loop
Maximum burn level	Demand	0,53	Thermal damage
Body parts not to cover	Demand	Head and left arm	Body parts
Level of complexity	Wish	Std.>unique	Nmb. of comp.
Minimum life time	Wish	5475	Uses
Minimum life time	Demand	3650	Uses
Maximum heat loss to patient	Demand	5	%
Minimal heat loss to the surrounding area	Demand	30	%
Maximum mounting time	Demand	90	seconds
Maximum mounting time	Wish	60	seconds
Must be able to be disassembled to the degree that the parts can be recycled	Demand	30	%
Maximum noise level	Wish	30	dB
Maximum noise level	Demand	50	dB
Maximum output temperature to patient	Demand	38	Celsius
Reusable when washed	Demand	40	degree wash
Reusable when cleaned with surface disinfectant w/tensid	Wish	Yes/no	Yes/no
Minimum shelf lifetime	Demand	5	years
Should be able to be dissambled in order to facilitate recycling of materials	Wish		
Minimum surface contact area	Demand	36	% of human body
Maximum time to cool	Demand	10	min
Maximum time to heat	Demand	3	min
Maximum total cost of product	Demand	2000	SEK
Maximum weight	Demand	2	kg
Maximum weight	Wish	<1	kg
Minimal working time outside of the ambulance	Demand	1	Hr

Figure 13: Target requirement list used for developing the product

The target requirements, seen above in Figure 13, reflect the interpreted needs shown in the previous section, see Section 5.1. The target requirements reflect the knowledge that was known at the start of the concept generation. As the development proceeds the requirements will be revised. Requirements regarding the heating performance should be revised since the shape and size of the device were unknown. Requirements regarding the portability of the device would also be affected by these parameters.

6

Result of Concept Generation & Selection

With the target requirements list created and functions defined in Chapter 5, the concept generation could be started. The top-to-down methodology was chosen to be applied in the concept generation. This means that the design progresses from an abstract level to a detail level. This process was divided into three loops. Loop 1 was to design the top established functions of the function-means tree. Loop 2 was to further investigate the concepts picked from Loop 1 to make the concepts more detailed and feasible through the next level of function in the functions-means tree. Once completing this loop, the rough appearance and the features for the functions had been determined. The last loop, Loop 3, was to perfect the chosen final solution and define the system such as the dimension, color, and structure. After the first two loops of concept generation, Elimination and Pugh matrix were used for screening. In Loop 3, the Kesselring matrix was used to evaluate the concepts.

6.1 Loop 1 - Design

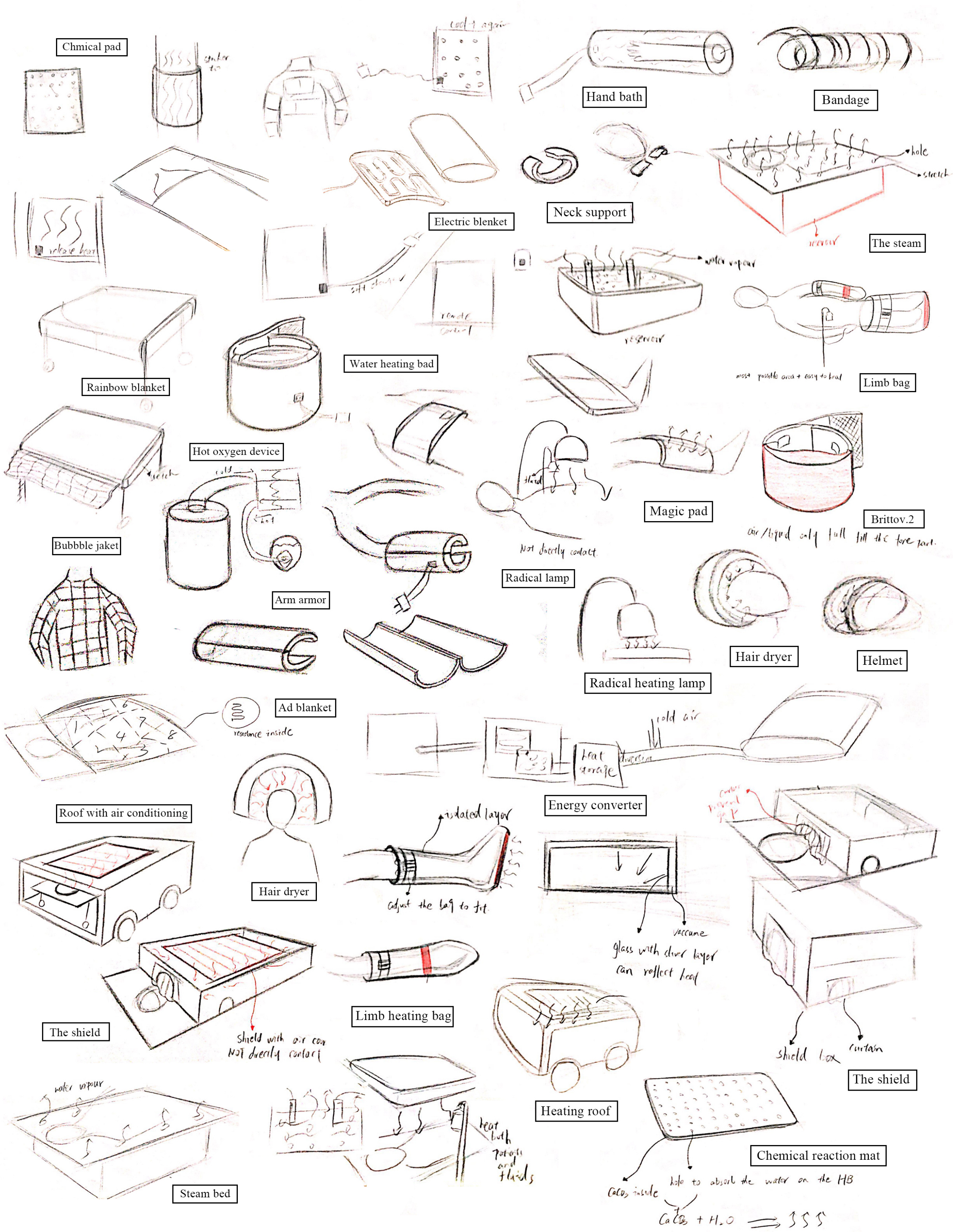

Figure 14: Loop 1 of design: Concepts generated for top functions

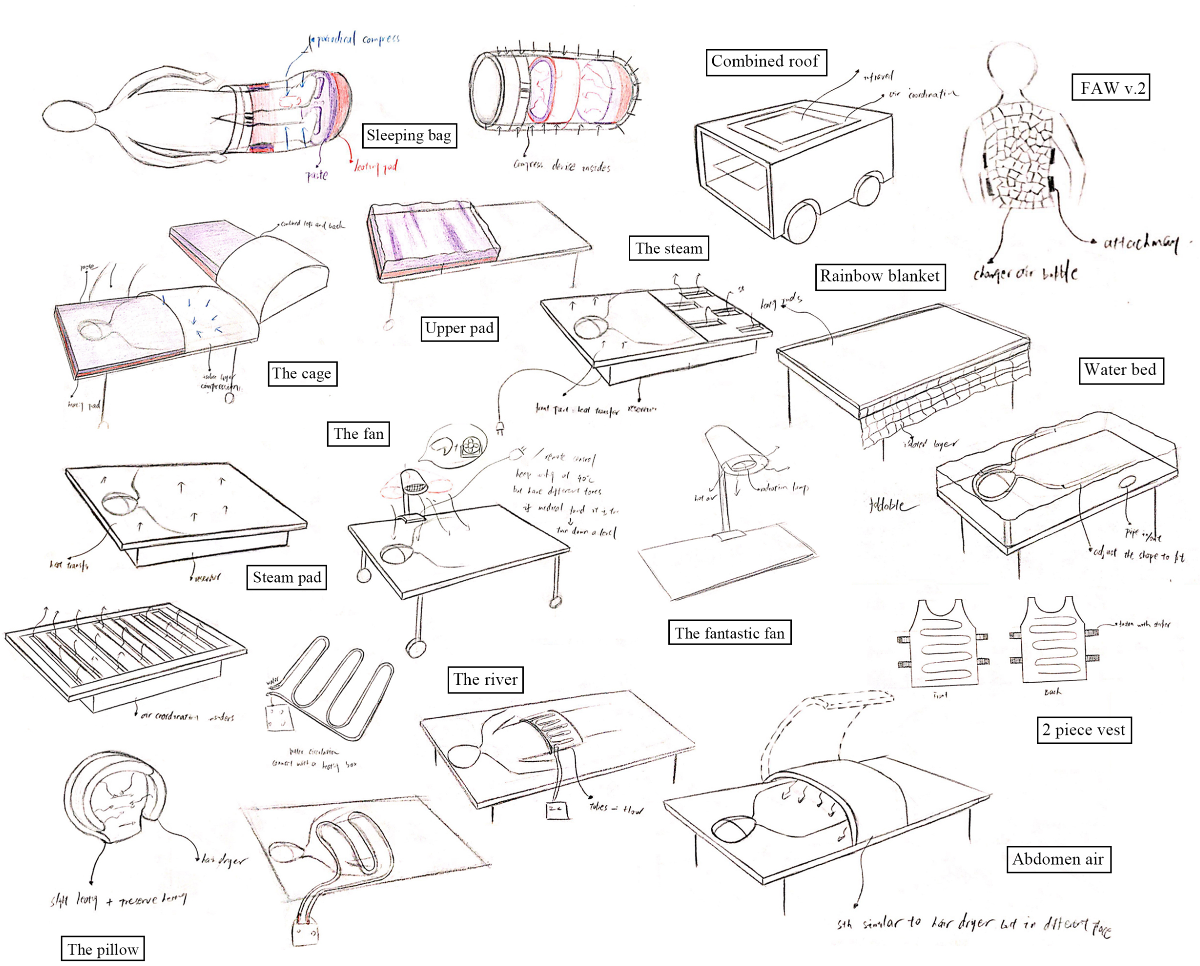

Figure 15: Loop 1 of design: Concepts generated for top functions

The requirement list seen in Section 13 were the basis through the customer tests and analysis. Based on these information, the first loop of design started, which can be called the test-loop design. As shown in Figure 12, the first level of concept generation was to achieve functions of raising the temperature and keeping the temperature for trauma patients. At this level, exploration of the heat working principle was the main task. Many different concepts have been explored and evaluated in this loop. The explored design space can be seen in Figure 14 and 15 above.

Concepts generated for this principle can be viewed in Figure 14 and 15. Concepts that had a similarity in design were combined in order to create new concepts. Through discussion and synthesis, only 15 different concepts were entered into the first screening due to their diversity and potential. The details of these 15 concepts are elaborated below.

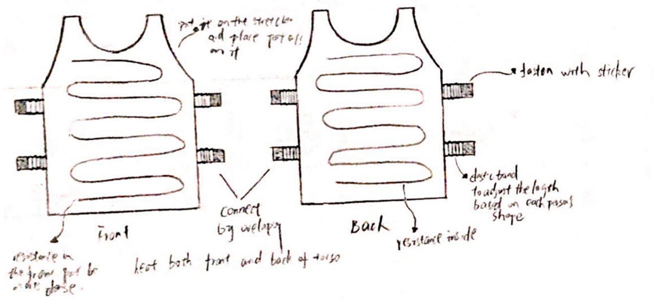

Figure 16: Loop 1 of design: 2 piece vest

2 Piece Vest

The first idea is called *2 piece vest*, which can directly heat patients by resistive heating. The concept can be seen in Figure 16. The vest is made of two separate pieces, each vest has elastic straps and Velcro on the side so that the two pieces can be assembled to work together. In this application, active heating can cover the upper torso of patients.

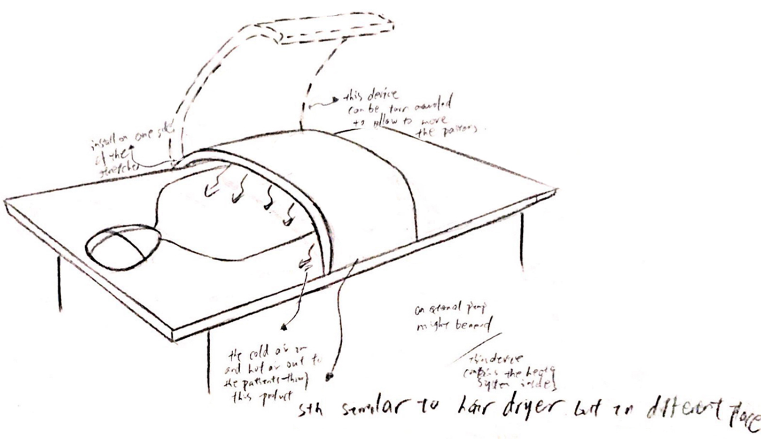

Figure 17: Loop 1 of design: Abdomen air

Abdomen Air

The working principle was to use hot air to heat the lower torso of the patients, hence the name *Abdomen air*. Visible in Figure 17, this device can be attached to a stretcher. The continuous hot air can then be forced to flow on the body.

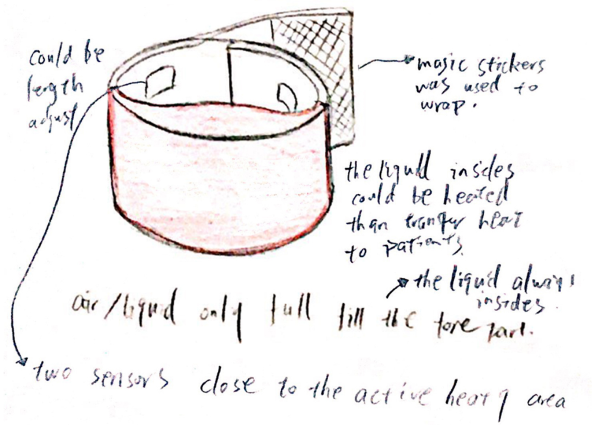

Figure 18: Loop 1 of design: Burrito v.2

Burrito v.2

The concept *Burrito v.2* made use of a liquid to heat patients. As shown in Figure 18, the red front part of this device was filled with a specific liquid: a mixture of water and sodium acetate. This mixture has features of fast heating and high heat absorption. When the resistive heating element heats this liquid heat can transfer quickly since the wrapper is in contact with the skin.

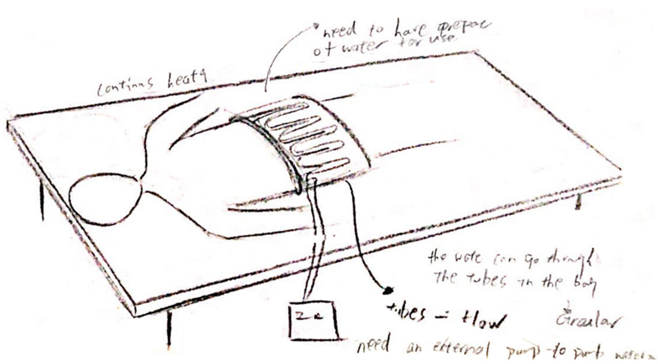

Figure 19: Loop 1 of design: The river

The River

The river, visible in Figure 19, also used liquid to transfer heat. But the difference was that *The river* consisted of two separated parts: a heating wrap that is in contact with the patients and a pump that can pump the water through the wrapper. Before usage, the water is contained in the external pump. Once using it, the water heats and pumps into the tube and recycles the cool water.

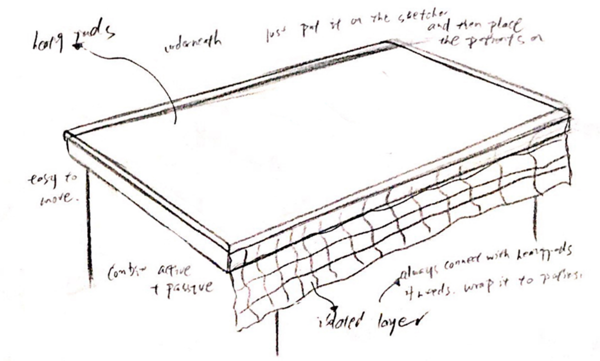

Figure 20: Loop 1 of design: Rainbow blanket

Rainbow Blanket

Rainbow blanket, which can be seen in Figure 20, combined passive rewarming and active rewarming in one. It has two connected parts: an underneath the electric heating mat and a blanket. The heating mat will be placed on the stretcher or operation table. Once the patient is lying on this mat, the connected passive blanket can be wrapped to cover the front of the body. The combination of active and passive rewarming makes this concept unique.

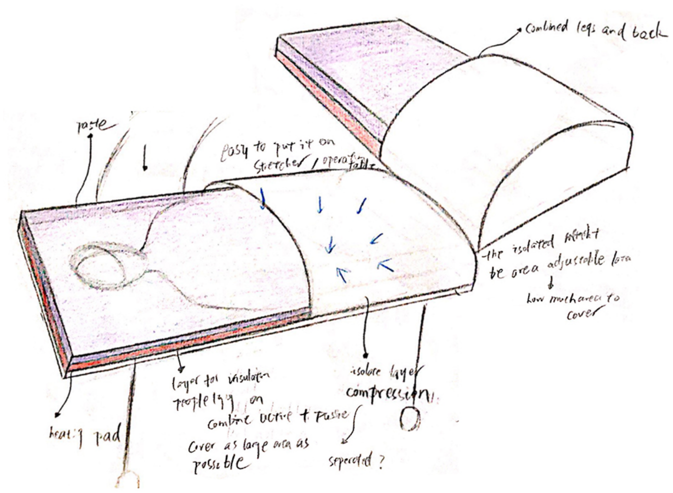

Figure 21: Loop 1 of design: The cage

The Cage

The cage concept was something similar to *Rainbow blanket*. It is visible in Figure 21. The concept includes an underneath the electric heating mat and an isolated blanket. However, compared with *Rainbow blanket*, the isolated blanket of *The cage* can be attached differently depending on the situation. A layer to improve heat transfer was also used in this mat. Another difference was that foam was included in the mat to create an effect of immersion. So that the body can be supported and the heating efficiency may be increased.

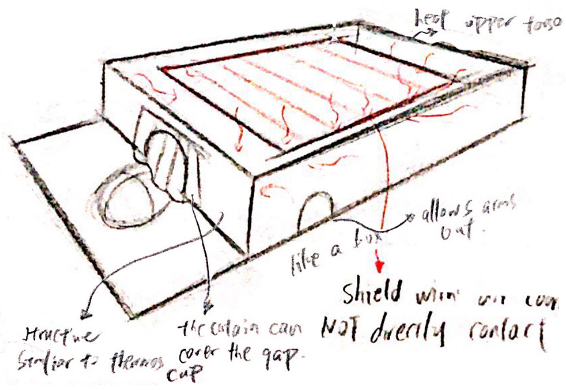

Figure 22: Loop 1 of design: The shield

The Shield

The shield, in Figure 22, will be mounted on a stretcher to cover the upper torso of the body. At the top of this device, an Infrared heating lamp was installed to provide active warming to heat. *The shield* also had an inner structure similar to that of a Thermos, which uses a vacuum to insulate and keeping heat. To further prevent heat loss, several isolated pieces of fabric were added in gaps between the legs, arms, and neck.

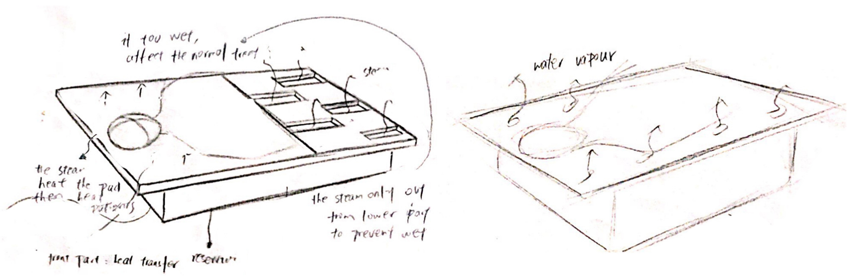

Figure 23: Loop 1 of design: The steam

The Steam

In this concept, *The steam*, hot steam was investigated as a source for heating patients. Visible in Figure 23. A reservoir was installed at the bottom of the stretcher. When connecting the cables, the electrodes inside the reservoir can heat the water to turn it into steam. Then, the steam was allowed to flow upwards to the patient to heat. A paramedic can add water as it is used. Direct contact with steam at 100 °C, the boiling temperature of the water, is dangerous. The steam also brings a humid environment and could affect normal treatment.

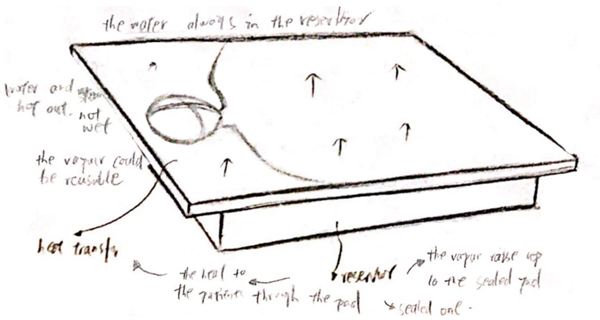

Figure 24: Loop 1 of design: Steam pad

Steam Pad

To further develop steam heating, a new concept named *Steam pad* was created. The concept can be seen in Figure 24. Here, steam generated can only heat the pad of the stretcher to transfer heat to patients. Therefore, the steam cannot cause any injury to patients. Since the reservoir of *Steam pad* was sealed, the steam return and then be cooled to change phase to liquid, thus no filling of liquid is necessary.

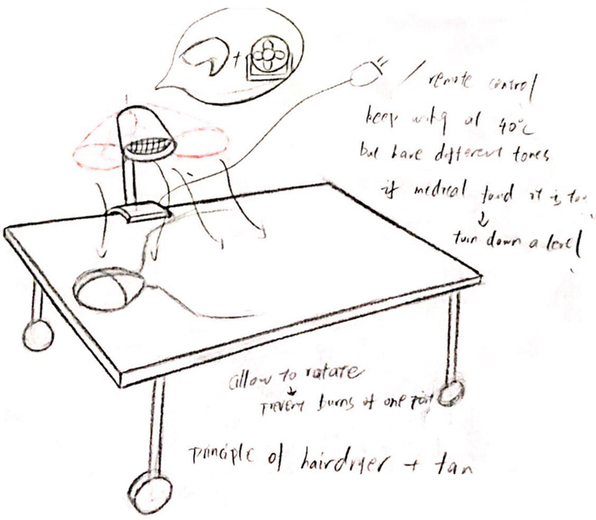

Figure 25: Loop 1 of design: The fan

The Fan

The fan was similar to the *The shield*: resistive heating can heat the surrounding air to rewarm patients. As can be seen in Figure 25, *The fan* can be attached with the stretcher by clamping. It can automatically swivel to heat different body parts.

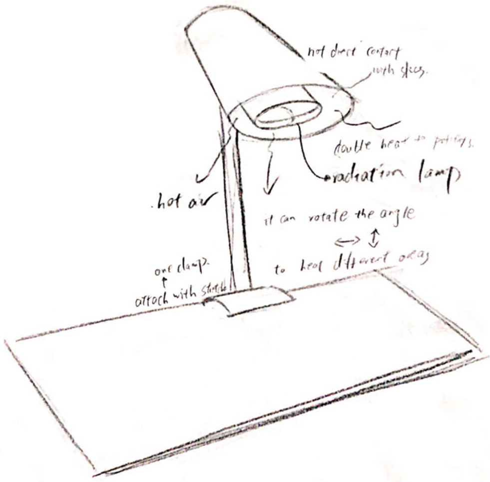

Figure 26: Loop 1 of design: The fantastic fan

The Fantastic Fan

The fantastic fan was an extension of *The fan*. In this concept, a heating lamp can be attached to a stretcher or an operating table to heat patients. The lamp uses infrared heating in contrast to resistive heating in *The fan*. The heating efficiency of infrared heating could be high due to less loss of heat in transfer. The concept is visible in Figure 26.

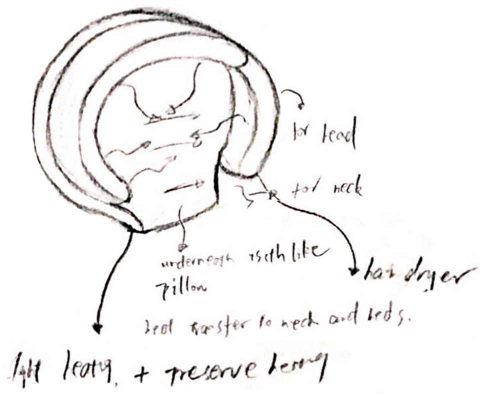

Figure 27: Loop 1 of design: The pillow

The Pillow

The aim of *The pillow*, which can be seen in Figure 27, was to heat patients' heads and necks to transfer heat. The device can be placed flatly on a stretcher or an operating table. The device intends to look like a helmet. The helmet can heat the head and neck of patients with hot air. It would work similarly to that of a hair styling machine in hair salons.

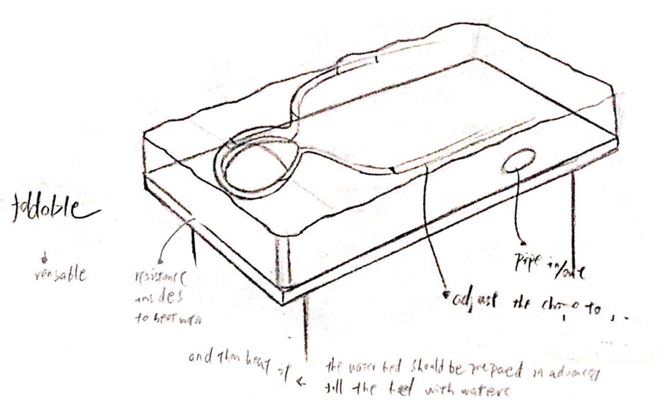

Figure 28: Loop 1 of design: Water bed

Water Bed

The key point of *Water bed* was immersion of patients, visible in Figure 28. It is an idea that patients' body weight allows for immersion into the device to a certain extent. Thus, it may increase heating surface area. In other words, the back and peripheral areas of patients can both be heated by water inside the bed. In addition, when patients are lying on the bed, the shape of the bed can be automatically adjusted due to the property of water. This means that *Water bed* can support patients well to increase comfort.

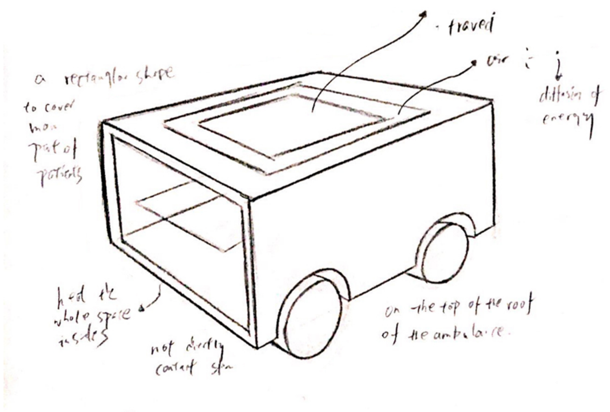

Figure 29: Loop 1 of design: Combined roof

Combined Roof

Combined roof is a device that will be installed in the ceiling of ambulances or operation theaters. The illustration, in Figure 29, displayed how to use this device. The reason why this device is called *Combined roof* was that it combined air conditioning and infrared heating methods. Thus, this concept will have two heating methods to heat the space inside the ambulance to rewarm patients.

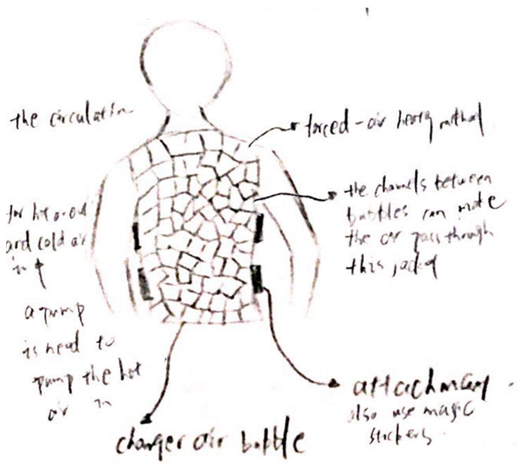

Figure 30: Loop 1 of design: FAW v.2

FAW v.2

FAW v.2 was a forced-air heating device, observed in Figure 30. This FAW jacket had a bubble structure, this allowed hot air to pass through each bubble. During treatment, paramedics can put this concept on patients. Once turning on this device, the external air pump can provide continuous hot air through the bubble structure to heat patients by direct skin contact.

The design loop generated concepts for the two functions identified in the function-means tree, visible in Figure 12. The concepts were now ready to be evaluated in the next step of Loop 1, the screening of the concept.

6.2 Loop 1 - Screening

After completing the first loop of design, the Elimination and the Pugh matrix were used to screen concepts. They were also used to analyze the advantages and disadvantages of each concept for the next loop of design.

6.2.1 Loop 1 - Elimination Matrix

In the Elimination matrix, six criteria were chosen for the screening: can it heat patients to raise or keep their body temperature; can it fulfill several elementary demands; can the concept be realizable; does it have a reasonable cost; is the operation of the device simple enough and is there enough information to support further design.

The elementary demands contain four aspects. First, the product should be easy to attach to patients without causing too much body movement. Second, the device should not bring additional harm to patients. Third, the device should have the possibility to generate enough heat. Lastly, the device needs to be portable enough to be used in an ambulance. Below in Figure 31 the result of the Elimination matrix can be seen.

Concept	Solves main problem	Fulfills all demands	Realizable	Reasonable cost	Enough info	Simplicity	Decision
2 piece vest	+	+	+	+	+	+	+
Abdomen air	+	?	+	+	+	?	?
The river	?	?	+	+	+	+	?
Burrito v.2	+	+	+	+	+	+	+
The cage	+	+	+	+	+	+	+
Rainbow blanket	+	+	+	+	+	+	+
The shield	+	?	?	?	?	+	?
The steam	+	-	-				-
Steam pad	+	+	+	+	+	+	+
The fan	+	+	+	+	+	+	+
The pillow	+	?	+	?	?	?	?
The fantastic fan	+	+	+	?	?	+	?
Water bed	+	?	+	+	+	+	+
Combined roof	+	-					-
FAW v.2	+	+	+	+	+	+	+

Figure 31: The Elimination matrix for screening in Loop 1

Through team discussion and performing the Elimination matrix, the concepts below passed the Elimination matrix.

- *2 piece vest*
- *Burrito v.2*
- *The cage*
- *Rainbow blanket*
- *Steam pad*
- *The fan*
- *Water bed*
- *FAW v.2*

While *The steam* and *Combined roof* were eliminated. Both of these concepts were eliminated due to their approaches of heat transfer which can bring additional harm to patients and affect the work environment for paramedics. Some concepts had uncertainties as highlighted by the question mark in the matrix. The concepts with uncertainties can be seen in the list below.

- *Abdomen air*
- *The river*
- *The shield*
- *The pillow*
- *The fantastic fan*

The *Abdomen air* had a size issue. The large size means that it may not fit in an ambulance. Moreover, a single paramedic may not be able to operate it alone. *The river* had uncertainty regarding the weight of the device. To provide enough heat, more liquid would be needed. However, increasing the amount of liquid also increases the weight of the device. A balance between heat and weight had to be solved, which needs to be further investigated. *The shield* and *The fantastic fan* used infrared heating as a heating method. Infrared heating is a powerful and efficient heating method. The uncertainty regards the ability to control and prevent further injury to a patient. Lastly, *The pillow* had uncertainty regarding heating of the head. Since injury can be brought to the patient by heating the head for a long time, an evaluation of the risks has to be done before either passing or eliminating the concept.

To further evaluate the uncertainties that exist, stakeholder discussion and literature study were done. For concepts *The shield* and *The fantastic fan*, it was decided that the infrared heating needed further investigation to determine the effects and consequences. *The pillow* was eliminated at this point, it was determined that the concept by itself would not generate enough heat. *The river* and *Abdomen air* uncertainties were determined to be solvable by further design. The amount of liquid for the former and the size of the latter might be altered depending on the design. Since they had not been eliminated yet, the concepts passed to the next design loop.

Finally, it is determined that 12 of 15 ideas passed the Elimination matrix. These concepts will be brought to the design loop. But before that, a Pugh matrix was also performed.

6.2.2 Loop 1 - Pugh Matrix Made for Analysis

The Pugh matrix was not used for screening but rather as a tool to cross-pollinate and to analyze in which aspects the concepts performed well. The criteria chosen for the Pugh matrix was the following:

- Safety: This criteria regard safety, if the concept is safe enough to prevent the skin burns and other harms to the patients. Here, the judgment was from an abstract level, which means inherent features of each concept was focused on. Therefore, safety level was measured based on the comparison of inherent features of each heating method.
- Automation level: This criteria was to judge whether the concept could be automated. The judgement was based on the usage steps that was designed. The higher automation level, the more attractive the concept was.
- Cost to produce: What are the cost to manufacture each concept. Here, cost of raw material for all known parts were taken into consideration. If a concept used more common materials the less manufacturing cost for all the parts.
- Operating costs: This criteria was linked with the automation level. A higher level, the less operations from the paramedic was needed. It also included ease of operation and time for manual operation. Difficult operation and more time needed, result in higher operation cost.
- Ease of use: Is the concept easy to use? How many steps are needed to prepare this product before it is ready to be used? Can these steps take a long time? How many persons are needed to operate the concept?
- Manufacturability: Here, number of parts, number of standard parts and special parts were taken into consideration. Fewer amount of parts and more standard parts results in a more realizable concept. Besides, it makes the concept easy to assemble.
- Modularity: The criteria evaluates the possibility of changing parts within the concepts. If more parts were easily accessible the higher the rating. Also, the ease of updating parts of the concept without replacing the complete unit.
- Crazy level: To what extent is each concept more imaginative? How different is it from existing products?
- Portable: Can one paramedic transport the concept? Can the concept be easily stored? Does the concept have a regular shape and a weight that make it easy to transport?
- Efficiency: The efficiency regarding time to heat and cool the concept. Less time to heat and cool means less heat waste. In addition, it also indicate the efficiency of heat transfer. The larger contacting area, the higher efficiency it has.

Among these 12 concepts, *The fan* and *The fantastic fan* were something similar, so at this point, they were combined into one concept with the name *The fan and fantastic fan. The river* were similar to *Burrito v.2*, they were combined and *Burrito v.2* was the new name of the concept. In this matrix, the *2 piece vest* was chosen as the reference due to its ability to combine portability with heating efficiency.

Criteria	2 piece vest	The fan and fasr	Burrito v.2	The cage	Rainbow blanket	Steam pad	Water bed	FAW v.2	Abdomen air	The shield
Safety	R	+	0	0	0	0	0	0	0	0
Automation level	E	0	0	0	0	-	0	0	0	0
Reuse level	F	+	0	0	0	0	0	-	0	+
Cost to produce (Buying, manufacture etc.)	E	+	0	0	0	-	-	0	-	-
Operating costs	R	0	-	0	0	-	-	0	0	0
Ease of use	E	+	0	0	0	+	+	0	+	0
Manufacturability - Number of unique parts	N	+	0	0	0	0	+	+	-	-
Modularity after installation	C	+	0	0	0	-	-	+	-	-
Crazy level	E	+	0	0	0	+	+	0	0	0
Portable	R	0	0	0	0	-	-	-	-	-
Efficiency (heat level, time to heat, time to cool)	E	0	0	0	0	0	0	0	0	0
Σ+	0	7	0	0	0	2	3	2	1	1
Σ-	0	0	1	0	0	5	4	2	4	4
ΣS	0	4	10	11	11	4	4	7	6	6
Total:	0	7	−1	0	0	−3	−1	0	−3	−3

Figure 32: Pugh matrix made for analysis

Result of the Pugh matrix is visible in Figure 32. The concepts *2 piece vest*, *The fan and fantastic fan*, *The cage*, *Rainbow blanket* and *FAW v.2* had a score of zero or above. The *Burrito v.2*, *Steam pad*, *Water bed*, *Abdomen air* and *The shield* had a score below zero.

The low score of some concepts can be related to different factors. The liquid of *Burrito v.2* suffers due to its weight. To make this concept portable, the amount of liquid should be kept to a minimum. However, might harm heating efficiency. Weight is also an issue for *Water bed*, this concept cannot be used in pre-hospital care due to the weight since it is not portable enough. The reason why *Abdomen air* had a low score was that this concept was not portable enough for pre-hospital care, albeit the issue was not weight but rather the shape and attachment for the concept. A similar problem existed for *The shield*. However, it was judged that these issues might be solved by design, so all four of them passed to Loop 2. As for the *Steam pad*, it had an inherent issue, it would be difficult to control the heat. The process of heating water to turn it into steam meant a long reaction time, both for heating and cooling. In this case, either the heating efficiency suffers or a higher risk for burn injuries. This inherent issue in combination with a short time to the hospital meant that the concept was removed. Therefore, the concept *Steam pad* was eliminated. After this screening, *2 piece vest*, *The fan and fantastic fan*, *The cage*, *Rainbow blanket*, *FAW v.2*, *Burrito v.2*, *Water bed*, *Abdomen air* and *The shield* would be further developed.

6.3 Loop 2 - Design

According to Section 6.2, nine abstract concepts passed to be further developed. In this design loop, the design will be more in detail. It needs to be thought of how the concept can provide sufficient heat to patients in a certain period without causing burn injuries, how the concepts can attach to patients without major movement, and how to make the concept easy to use for paramedics. The results from the analysis would also be the test phase for the second loop of concept generation, so this was the second test-loop design. The further detailing of concepts is visible in the figures below.

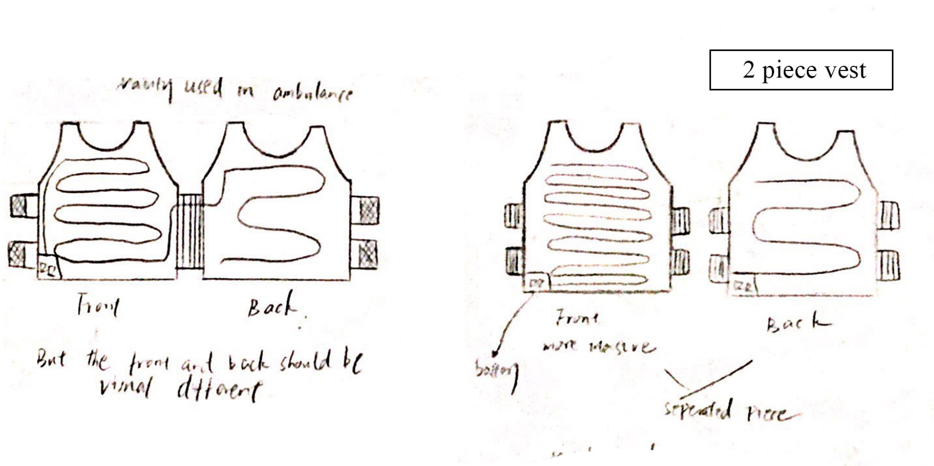

Figure 33: Loop 2 of Design: 2 piece of vest

2 Piece of Vest

The concept was further developed by attaching an elastic band between the two pieces. The concept is visible in Figure 33. Which in turn made the vest into one piece. Velcro is still present to be able to close the vest around the patient. The concept covers the torso of the patient. Hence it can only be used for pre-hospital care. First, the vest is placed on the stretcher and the patient will be moved to be placed on one half of the vest, the other half can then be wrapped around the patient. Then, velcro connects the two pieces and an elastic band will adjust the shape of the vest accordingly. When turned on, resistive heating in each of the pieces heats the patient. To reduce the risk of burn injury, in particular from the pressure generated from body weight, heating from beneath will be less than the front. In addition, integrated into the vest is a battery to allow for service at scenes. As the vest returns to the ambulance, a cable can be connected to the charge.

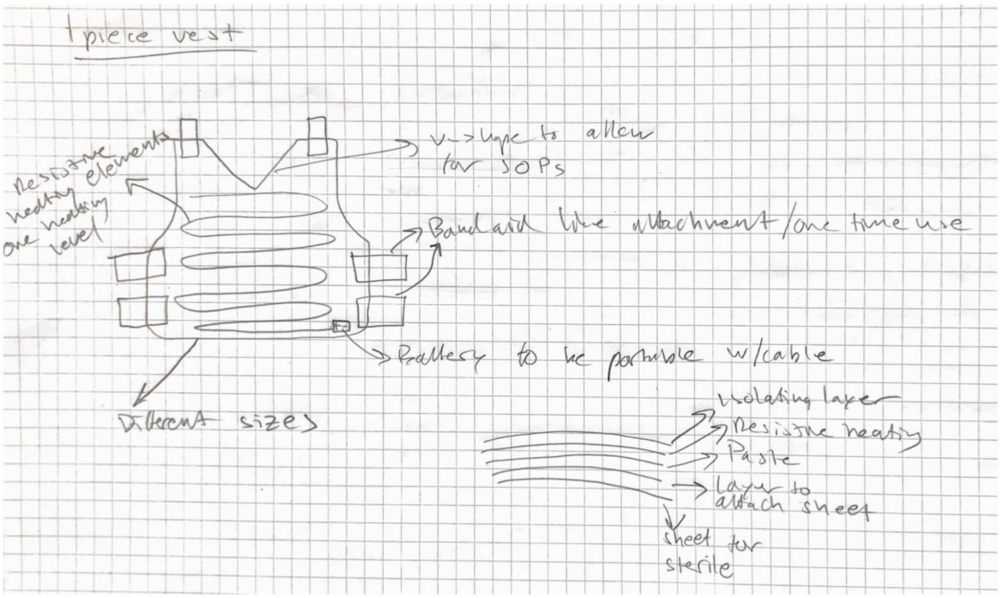

Figure 34: Loop 2 of Design: 1 piece vest

1 Piece Vest
Based on *2 piece of vest*, *1 piece vest* was developed. Observed in Figure 34. The concept keeps the front vest of *2 piece of vest* which covers the torso and uses resistive heating. As for attachment with patients, stickers similar to a band-aid keeps the vest attached to the torso. These stickers can be reused several times until the ability to attach is lost. This vest is intended for pre-hospital care.

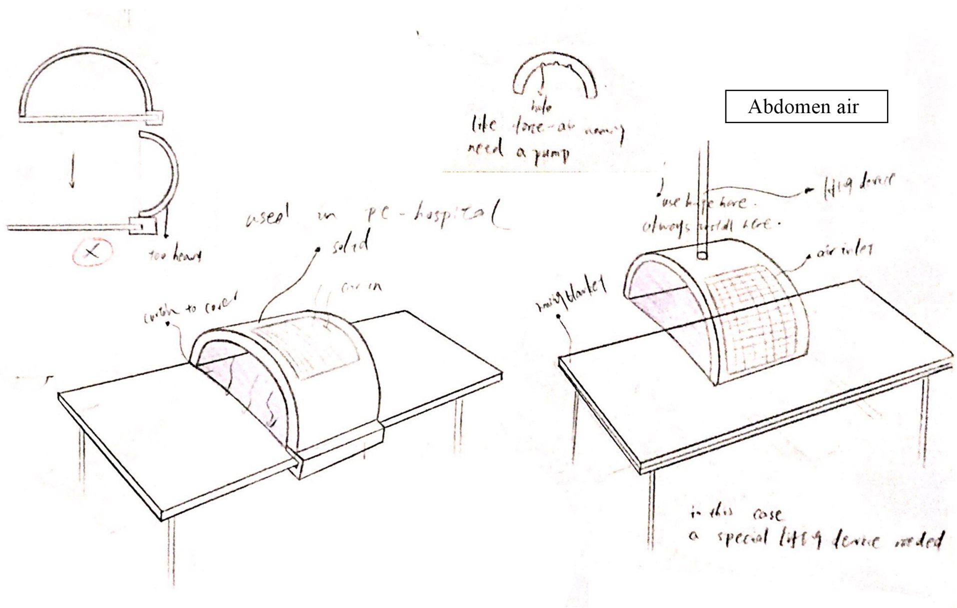

Figure 35: Loop 2 of Design: Abdomen air

Abdomen Air

Above in Figure 35 *Abdomen air* can be split into two parts, one on the left side and one on the right side.

The left side concept covers a part of the body to heat air so that patients can be re-warmed. Heating surroundings to heat patients is not an efficient heating method, to decrease the heat loss, two pieces of fabric were used for the open sections.

The right side concept is suitable for pre-hospital care since parts of the concept prevent normal surgery in an operational setting. Besides, this concept is large, and therefore attaching it to a stretcher would not be appropriate. Thus, it must be attached inside the ambulance and therefore treatment can start as soon as the patient is in. As the patient is inside, the paramedic can manually attach the concept by a hinge on the handles. This can be a labor-intensive process, one paramedic might not be able to handle it due to the weight and shape. Therefore, an improvement can be that the hinge is fixed to a rod which allows for the opening and closing. When the stretcher is placed at a designated location, the concept can be lower down to heat the patient.

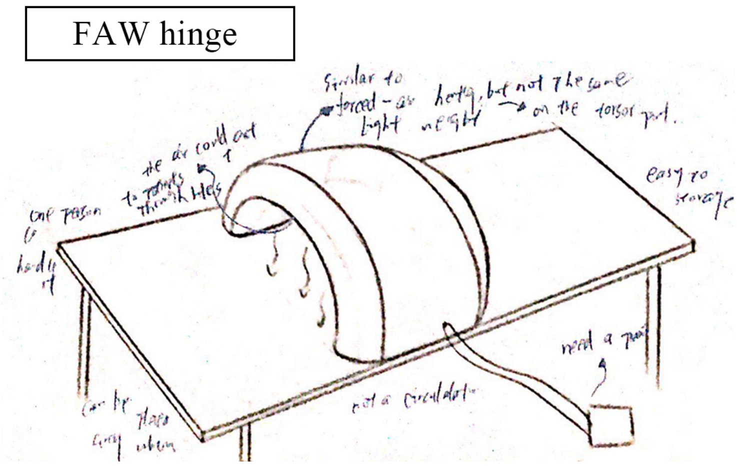

Figure 36: Loop 2 of Design: FAW hinge

FAW Hinge

As mentioned in the previous loop, *Abdomen air* is heavy. To reduce weight a new heating method was implemented. Thus creating a new concept, named *FAW hinge*, which can be seen in the Figure 36. Weight was reduced due to the implementation of forced-air heating. The concept consists of two major components, one is an air heating pump and the other is an airbag. The paramedic connects soft plastic pipes between the pump and the airbag so that it fills with hot air. Since the airbag has holes aimed towards the patient, the hot air will escape and heat.

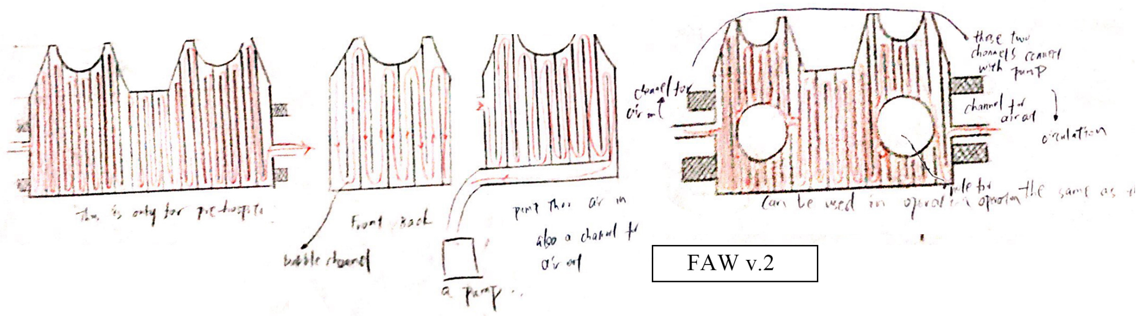

Figure 37: Loop 2 of Design: FAW v.2

FAW v.2

FAW v.2 was also a forced-air heating concept, can be seen in Figure 37. Compared with the *FAW hinge*, *FAW v.2* had a smaller size so it was more portable. Compared to *FAW hinge*, the hot air will not escape but continuously flow inside. Thus, two connectors on this jacket were needed to connect with the air pump. One was for hot air and one was for cold air.

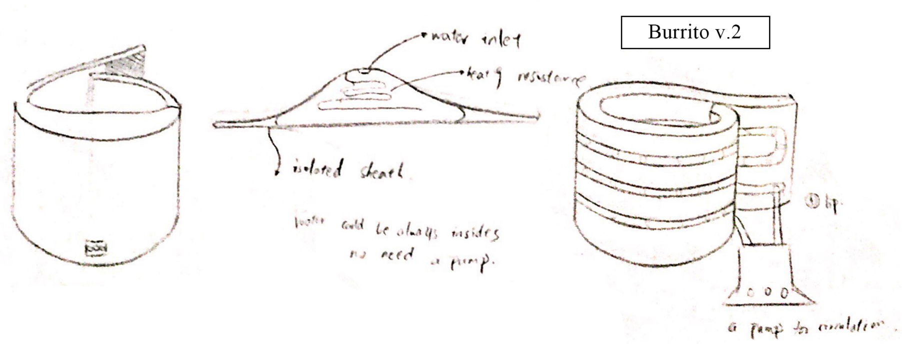

Figure 38: Loop 2 of Design: Burrito v.2

Burrito v.2

Burrito v.2 use liquid to heat patients. Visible in Figure 38. As stated, in Section 6.1, the liquid is heavy. Development intended to reduce the weight. This was tried to be solved by reducing the amount of liquid or finding a lighter substitution. However, through the detailing, no substitution was found. As for the amount of liquid, it was decided that at least 3.2 L of liquid was needed to heat the abdomen, which in turn means that this product was still too heavy to be portable. Also, the weight of the liquid causes pressure on patients resulting in discomfort.

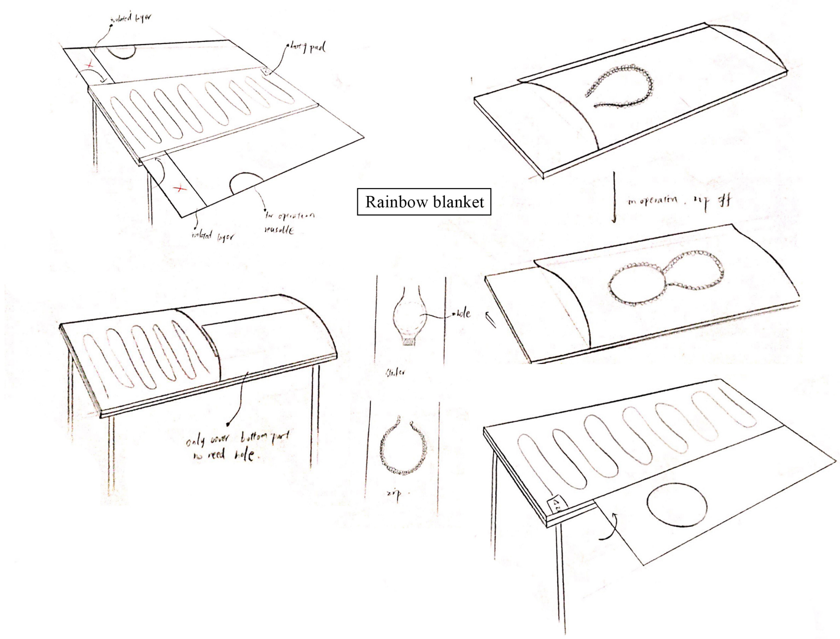

Figure 39: Loop 2 of Design: Rainbow blanket

Rainbow Blanket

Rainbow blanket combined an electric heating blanket and a passive blanket, in Figure 39. The two blankets are always connected. The heating blanket will be placed directly on the stretcher and then the passive blanket can be wrapped around the patient. To be usable in operational theaters, an access pocket can be added. However, a hole might cause unnecessary heat loss during pre-hospital care. Where no surgery is performed. In this case, zip can be used to access desired body parts when necessary. As can be seen in Figure 39, during the pre-hospital care, the zip can be closed. For operational theaters, the zip can be opened and folded back to expose desired body parts.

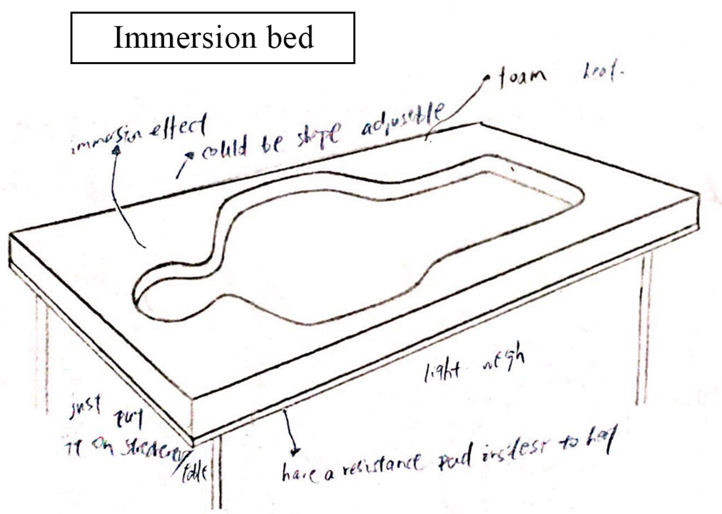

Figure 40: Loop 2 of Design: Immersion bed

Immersion Bed

The *Immersion bed* was an evolution of *Water bed*. In Section 6.2 there was a conviction that *Water bed* was too heavy to be used reliably. Through analysis, it was discovered that the most prominent and wanted feature of *Water bed* was its immersion ability. The immersion is thought to increase the surface contact area available for heating, desirable for any heating device. Therefore, in Loop 2, it was determined that the water could be replaced by a material that could achieve the immersion effect. A foam material would achieve a similar effect with a lower weight. Therefore it replaced the water. The detail can be seen in the Figure 40.

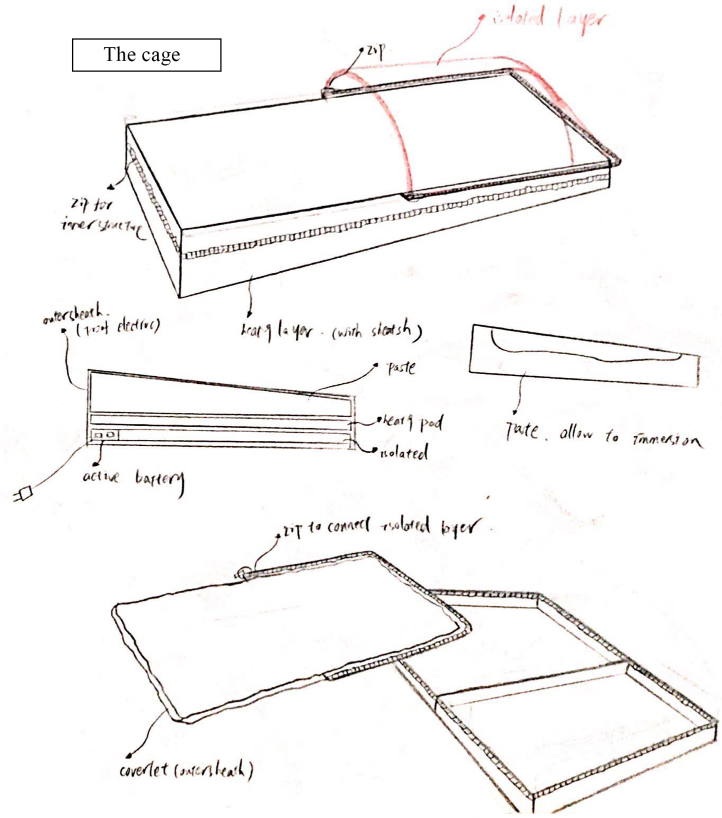

Figure 41: Loop 2 of Design: The cage

The Cage

The cage was a concept similar to the *Rainbow blanket* and *Immersion bed*, it combined their prominent features. It can be seen in Figure 41. Indifference to *Rainbow blanket*, the passive blanket of *The cage* can be assembled or disassembled at any time. Parts of the blanket can also be removed while the remaining parts are assembled with the heating pad. A thermally conductive layer was also added to the pad to increase heat efficiency and reduce heat loss. A foam layer was added to the pad to achieve an immersion effect. Immersion allows for patients to be immersed in the foam to support the body weight and increase surface area for heating. Adding foam to the pad created a shape similar to that of a mattress. In turn, it was determined that this concept would replace the existing medical mattresses.

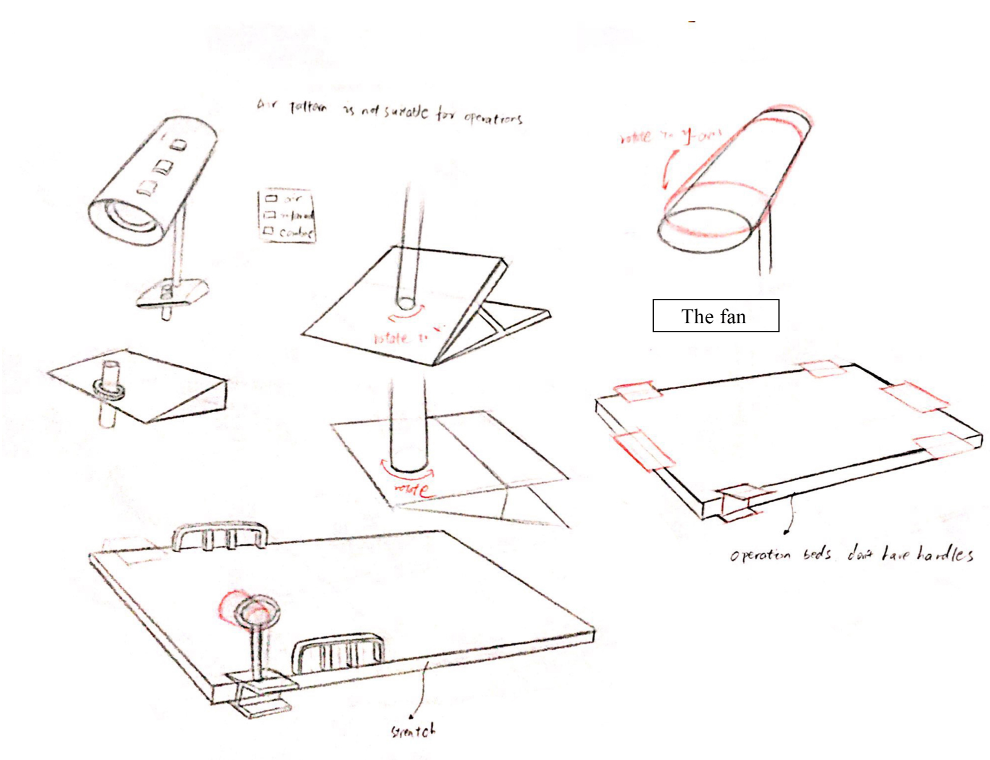

Figure 42: Loop 2 of Design: The fan

The Fan

The fan can heat patients through blowing hot air. *The fan* will be installed on the side of stretchers or near operation tables, which can be seen in the Figure 42. It does swivel continuously to avoid concentrated spots of heating to reduce the risk for burn injuries. It can also be set in a non-swivel mode to reduce the flow of air in operational theaters. For this mode, the heating power is also set lower.

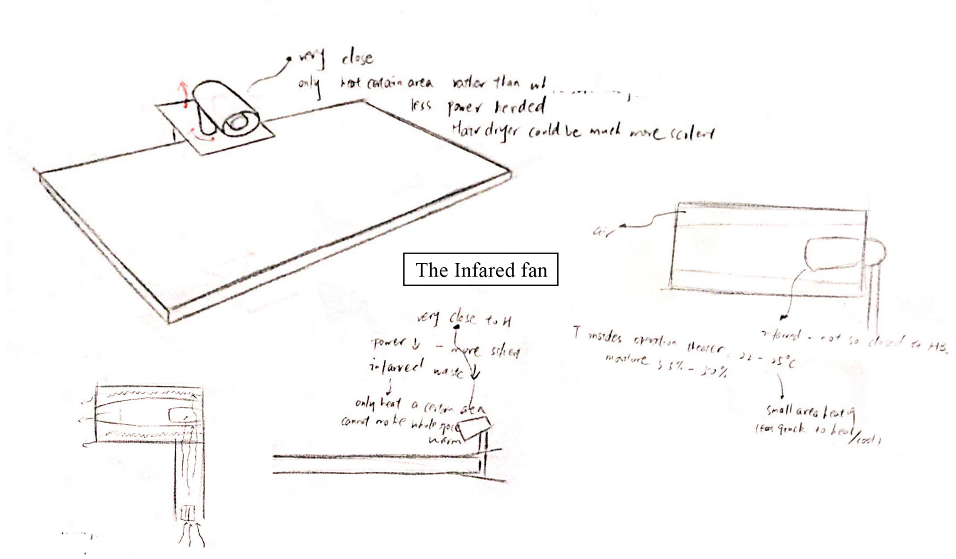

Figure 43: Loop 2 of Design: The Infrared fan

The Infrared Fan

The Infrared fan was previously called *The fantastic fan* in Loop 1. It has a similar shape as *The fan*, but the method for heating is infrared heating. The concept can be seen in Figure 43. *The Infrared fan* outlet for directing heat will be small, the smaller size would allow for less heat loss to the environment. A result of heat loss is a negative impact on paramedics. Therefore, to reduce the negative effect on paramedics heating should be concentrated on specific body parts. However, only heating a small spot means the heating efficiency will be lower. Therefore, several *Infrared fan* can be installed to heat different body parts to improve heat transfer.

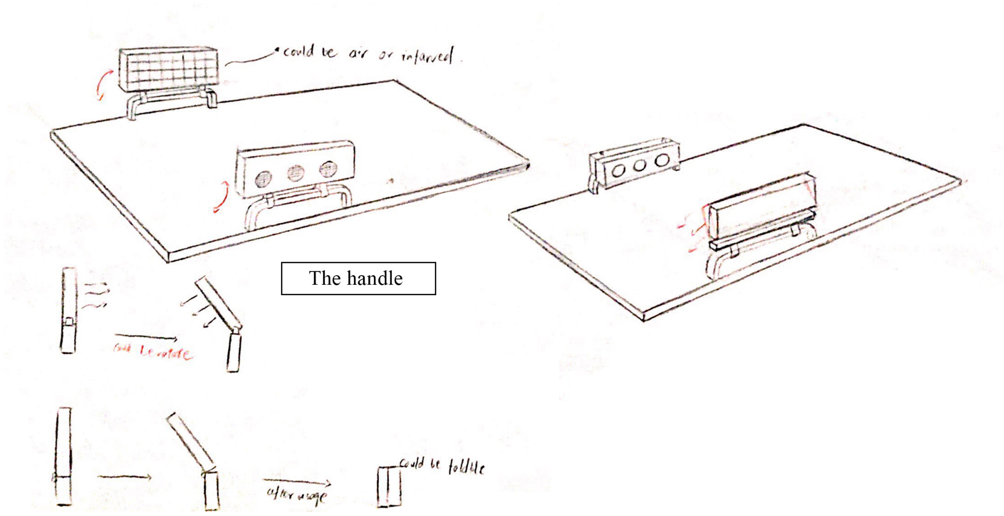

Figure 44: Loop 2 of Design: The handle

The Handle

The origin of *The handle* was from *Infrared fan* since the shape and heating method is identical. In contrast to *Infrared fan*, *The handle* will be mounted on the handles of a stretcher. The detail can be seen in the Figure 44. The concept will heat the torso of patients. The angle of heating can be adjusted to cater to different body types. After usage, it can be folded to be a part of the handle. Hence, it does not require any disassembly.

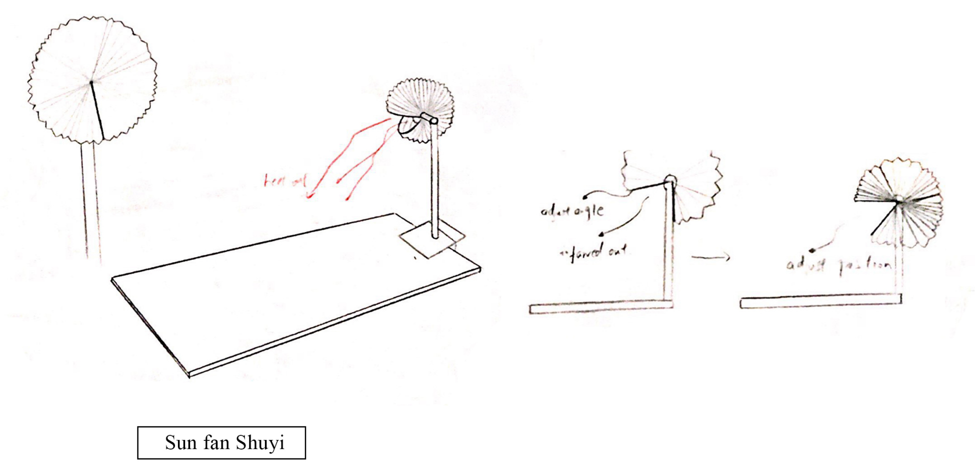

Figure 45: Loop 2 of Design: Sun fan Shuyi

Sun Fan Shuyi
This concept was also an extension of the *Infrared fan*. The concept is related to a Chinese traditional lantern, an infrared light bulb would be installed instead. The concept is visible in Figure 45. Due to the large size, it would only fit in operational theaters. As can be seen in Figure 45, the shell of the lantern can alter the angle of opening, so infrared heating can scatter and cover a large surface area. But a disadvantage could be that a large amount of heat does not reach the patient due to a 360 degree spread.

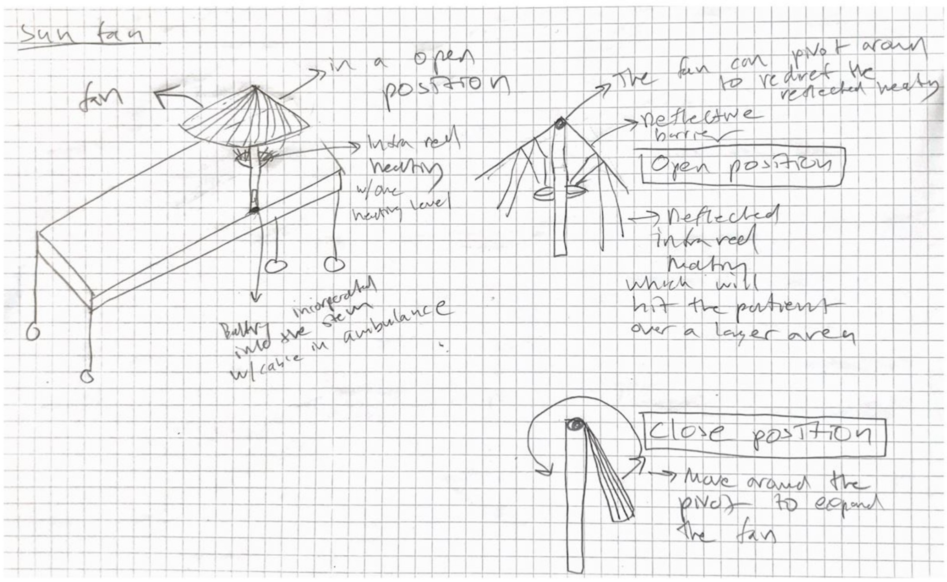

Figure 46: Loop 2 of Design: Sun fan Fabbe

Sun Fan Fabbe

This concept is identical to *Sun fan Shuyi*. The difference is in the addition of a reflective surface, which can be seen in Figure 46. Here, an infrared light bulb was installed under the sun fan which looked like an umbrella. Once turned on, heat is reflected on the inside of the umbrella to redirect it to patients. This was achieved by a reflective coating on the inside. Despite reflection, some heat will be lost. Especially since the refection can be unpredictable. Due to its sheer size, it would be difficult to use in an ambulance, therefore operational theaters would be an appropriate application.

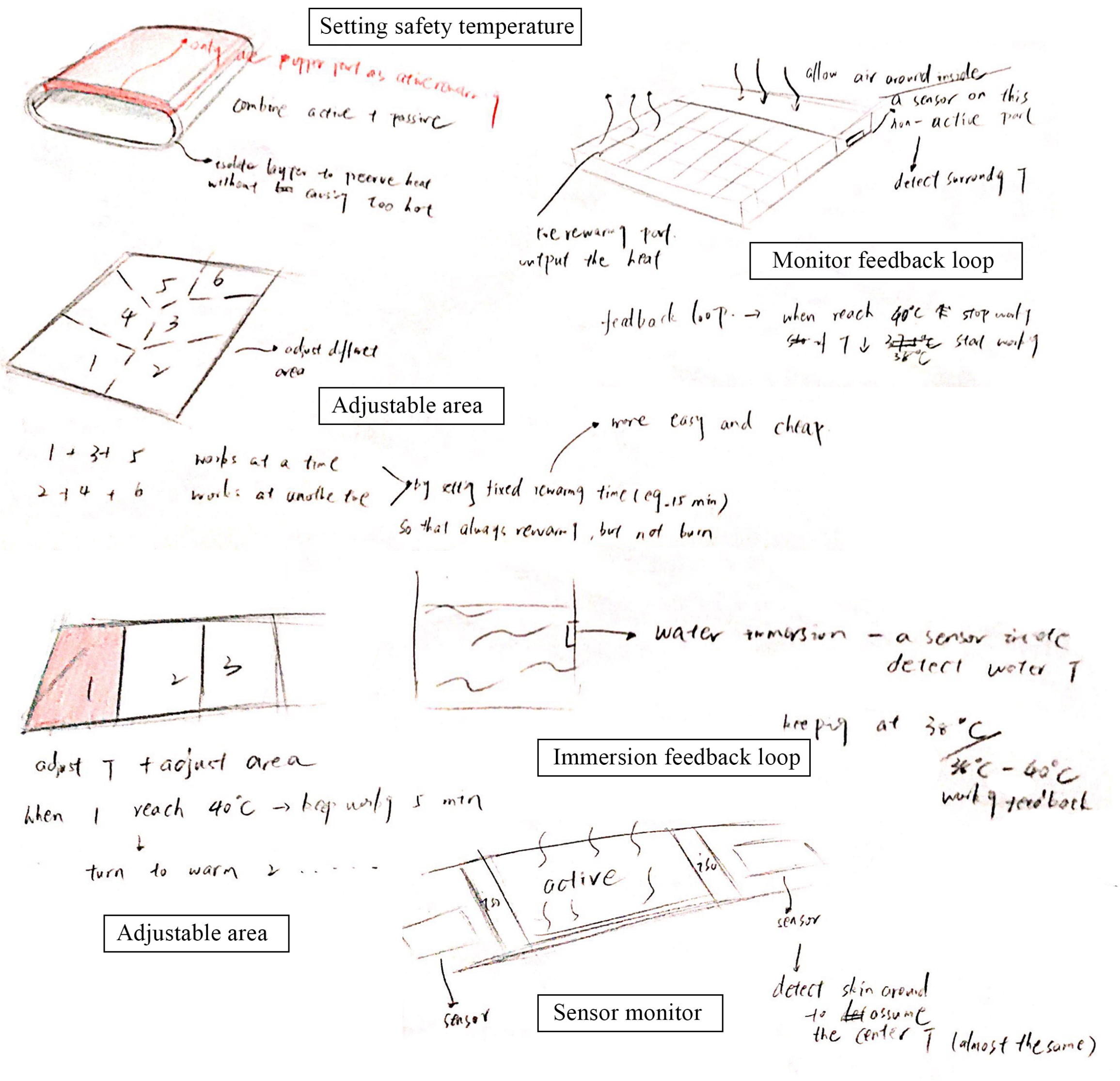

Figure 47: Loop 2 of Design: Control system

Temperature Control Systems

In Loop 2, different control systems were designed to prevent and minimize the risk of burn injuries, as can be observed in Figure 47. There were three methods developed to minimize the risk. The first idea was to set a fixed safe heating temperature. For example, the heating temperature can be set to 38 °C to prevent a burn injury from happening. While also allowing for some healing to occur. The actual heating temperature to be set has to be further evaluated. Secondly, a control system that would allow for adjustment of the heating area can be incorporated. This means that the system can automatically alter the area heated to prevent a high surface temperature. Lastly, an idea where the control system can integrate a feedback loop. Sensors have to be placed so that the heating temperature can be measured and give input to the feedback loop, which adjusts the heating temperature.

Re-usability

Re-usability was kept in mind for all the concepts mentioned above. Some of them could be kept sterile due to the distance to the patient. While some have to incorporate a water-proof outer sheet to be able to be sterilized.

6.4 Loop 2 - Screening

The Elimination and Pugh matrix was used in this loop of screening. In this loop, a number of Pugh matrices were used to screen concepts and for the first time compare them to each other. The iteration of Pugh matrices achieves convergence of scores for the concepts.

6.4.1 Loop 2 - Elimination Matrix

The second loop of Elimination matrix performed was visible in Figure 48. This matrix assisted the designers to further understand the potential of each method.

Concept	Solve main problem	Fulfills all demands	Enough info	Simplicity	Decision
2 piece vest	+	?			+
Abdomen air	+	-			-
Burrito v.2	+	?			-
The cage	+	+	+	+	+
Rainbow blanket	+	+	+	+	+
FAW v.2	+	+	+	+	?
Immersion bed	+	+	+	+	+
1 piece vest	+	?			-
The handle	+	+	?	+	?
The Infared fan	+	+	+	+	+
Sun fan Shuyi	+	?			?
Sun fan Fabbe	+	?			?
FAW hinge	+	+	+	+	?
The fan	+	-			-

Figure 48: Elimination matrix in Loop 2 to screen new and old concepts

The result of the Elimination matrix can be observed above in Figure 48. Through an analysis of the results, the following results can be had. The issue of weight for *Abdomen air* cannot be solved, the lack of portability made it less attractive for pre-hospital care. As for *Burrito v.2*, the balance of weight and heating efficiency was difficult to achieve. To attain a low weight and portability, the size would have to be smaller. Which in turn means less liquid. It was determined that to achieve a desired level of portability the amount of liquid has to limit. To the point where the amount of liquid will not be enough to heat patients. As for *The fan*, high noise was its fundamental issue. Based on a comparison of products, the most silent hair dryer has a noise level of 65dB.(qqnews, 2021) It was assumed that *The fan* also has a noise level of 65 dB. According to Swedish regulations visible in Section 4.2, a noise level of 65 dB would be too high. The regulations state that 77 dB should not be exceeded. But since there are other noises created by the surrounding environment 65 dB of a fan would be too high. It would interrupt all verbal communication in an ambulance or operational theater which is essential when treating a patient or performing surgery. Besides interrupting verbal communication, there is a great heat loss to the environment. Not only do patients lose heat that is much needed but paramedics are also heated in the process. These issues were difficult to solve with existing technology since the fundamental issue arises from the specific technology used. *1 piece vest* has a limited heating area, restricted to be used on the torso. The limited area results in a heat transfer that is not enough to heat a patient. With this in mind, the concept *2 piece of vest* was more attractive. The concepts *Abdomen air*, *Burrito v.2*, *The fan* and *1 piece vest* were at this point eliminated due to reasons mentioned above.

6.4.2 Loop 2 - Pugh Matrix Iteration

After completing the Elimination matrix, 10 concepts continue to the Pugh matrices. The Pugh matrix was repeated three times to ensure the convergence of results. The criteria of the second loop of Pugh are explained below:

- Reuse level: Reuse level was about whether the concept can be easily reused. What level it can be reused: sterile, washable or non-reusable?
- Surface area to contact: This regarded how much surface skin can be heated. The higher contacting area, the higher heating efficiency it was.
- Usability in all situations: This criteria referred to the compatibility of each concept. Can the concepts be used inside an ambulance? Outside an ambulance? Used in operational theater? The more scenarios the concept can be used in, the better the concept was.
- Impact to environment: How the concept affect the surrounding environment? This criteria was mainly discussed from noise, heating loss to environment and electromagnetic field aspects.
- Installation: This criteria focused on the preparing of concept. Were many steps taken to install the concept as intended? How long time does it take to install? Can one paramedic handle this process?

With the criteria set, the reference had to be chosen. For the first iteration the concept *The cage* was chosen. This due its potential performance.

Criteria	The cage (paste	2 piece vest	The infrared fan	Rainbow blanket	Immersion bed	The handle	Sun fan Shuyi	Sun fan Fabbe	FAW v.2	The FAW hinge
Safety	**R**	0	0	0	0	-	+	0	0	0
Automation level	**E**	0	0	0	0	0	-	0	0	0
Reuse level	**F**	0	+	0	0	+	+	+	0	0
Cost to produce (Buying, manufacture etc.)	**E**	0	-	0	0	-	-	-	-	-
Operating costs	**R**	0	-	0	0	-	-	-	-	-
Ease of use	**E**	0	-	0	0	-	-	-	-	-
Manufacturability - Number of unique parts	**N**	-	-	0	0	-	-	-	-	-
Portable level	**C**	0	-	0	0	0	-	-	-	-
Crazy level	**E**	0	+	0	0	+	+	+	0	0
Efficiency (heat level, time to heat, time to cool)	**R**	-	-	0	0	0	-	-	0	0
Surface area contact	**E**	-	-	0	0	-	-	-	-	-
Useability in all situations	**F**	0	-	0	0	-	-	-	0	-
Impact to environment (noise, heating, current ...	**E**	0	-	0	0	-	-	-	-	-
Installation	**R**	-	-	0	0	-	-	-	-	-
Σ+	0	0	2	0	0	2	3	2	0	0
Σ-	0	4	10	0	0	9	11	10	8	9
ΣS	0	10	2	14	14	3	0	2	6	5
Total:	0	−4	−8	0	0	−7	−8	−8	−8	−9

Figure 49: First iteration of Pugh matrix

The result of the Pugh matrix is shown in Figure 49. From the result it can be observed that *The cage*, *Rainbow blanket* and *Immersion bed* had a similar score. While the rest of the concepts with either forced-air heating or infrared heating had a lower score. Through further analysis, it was reasoned that *The cage*, *Rainbow blanket* and *Immersion bed* are variants of each other. As stated previously, *The cage* combined prominent features of both *Rainbow blanket* and *Immersion bed*. Thus, the three concepts were combined under the name of *The cage*.

Criteria	2 piece vest	The infrared fan	The cage	The handle	Sun fan Shuyi	Sun fan Fabbe	FAW v.2	The FAW hinge
Safety	**R**	-	0	-	-	-	0	0
Automation level	**E**	0	0	0	0	0	0	0
Reuse level	**F**	+	0	+	+	+	0	0
Cost to produce (Buying, manufacture etc.)	**E**	-	0	-	-	-	0	-
Operating costs	**R**	-	0	-	-	-	-	-
Ease of use	**E**	-	0	-	-	-	-	-
Manufacturability - Number of unique parts	**N**	0	0	-	-	-	-	-
Portable level	**C**	-	0	-	-	-	-	-
Crazy level	**E**	+	+	+	+	+	+	+
Efficiency (heat level, time to heat, time to cool)	**R**	-	+	-	-	-	0	-
Surface area contact	**E**	-	+	-	-	-	0	-
Useability in all situations	**F**	-	+	-	-	-	0	-
Impact to environment (noise, heating, current ...	**E**	-	0	-	-	-	-	-
Installation	**R**	-	+	0	-	-	-	-
Σ+	0	2	5	2	2	2	1	1
Σ-	0	10	0	10	11	11	6	10
ΣS	0	2	9	2	1	1	7	3
Total:	0	–8	5	–8	–9	–9	–5	–9

Figure 50: Second iteration of Pugh matrix

In the second iteration, the reference was changed to *2 piece of vest*. This since it was the only concept remaining with resistive heating as a heating method. The results demonstrated that *The cage* performed the best with the highest score. The rest of the concepts performed worse than the reference. A discussion was made regarding *2 piece of vest* and *The cage*. The score of *The cage* indicated that it performs well compared to *2 piece of vest*. It uses the same heating method but still has a higher heating efficiency since *The cage* covers a larger surface area. No concept was eliminated at this iteration.

Criteria	FAW v.2	The infrared fan	The cage	The handle	Sun fan Shuyi	Sun fan Fabbe	2 piece vest	The FAW hinge
Safety	**R**	-	0	-	-	-	0	0
Automation level	**E**	0	0	0	0	0	0	0
Reuse level	**F**	+	+	+	+	+	+	0
Cost to produce (Buying, manufacture etc.)	**E**	-	0	-	-	-	0	-
Operating costs	**R**	-	+	-	-	-	+	0
Ease of use	**E**	-	+	-	-	-	0	-
Manufacturability - Number of unique parts	**N**	-	-	-	-	-	-	-
Portable level	**C**	-	+	-	-	-	0	-
Crazy level	**E**	+	0	+	+	+	0	+
Efficiency (heat level, time to heat, time to cool)	**R**	-	+	-	-	-	0	-
Surface area contact	**E**	-	+	-	-	-	0	-
Useability in all situations	**F**	-	+	0	-	-	+	-
Impact to environment (noise, heating, current ...	**E**	-	+	-	-	-	+	0
Installation	**R**	-	+	-	-	-	0	-
Σ+	0	2	9	2	2	2	4	1
Σ-	0	11	1	10	11	11	1	8
ΣS	0	1	4	2	1	1	9	5
Total:	0	–9	8	–8	–9	–9	3	–7

Figure 51: Third iteration of Pugh matrix

The reference chosen for the third iteration was *FAW v.2* since it was interesting to compare the performance of a forced-air heating concept to the rest. The result of the third and last iteration of the Pugh matrix is visible above in Figure 51. The results show that *The cage* performed with the highest score, with *2 piece of vest* in second. The other concepts have a lower score, indicating a worse performance with regards to criteria. The concepts are still in development. Therefore, one for each of the heating methods was chosen to be further developed. *Infrared fan* for the infrared heating and *FAW v.2* for the forced-air heating. These two concepts perform admirably and would be passed to the next loop. Lastly, *2 piece vest* was eliminated due to its similarities to *The cage* but performed worse.

The concepts moved to next loop, Loop 3, will be *Infrared fan*, *FAW v.2* and *The cage*.

6.5 Loop 3 - Design

Concepts chosen to be further developed were detailed in this design loop. They were *The cage*, *Infrared fan* and*FAW v.2*. In this design loop, heating method, appearance, control system and other detail aspects should be improved or decided.

Selection of the Control System

According to the experts and paramedics, it was argued that a simple control system is preferred. Especially for pre-hospital care. It was also mentioned that it was better to set a fixed but safe heating temperature. Therefore, it was determined that the concepts would only have one heating temperature. The heating temperature set will be determined further on. But the temperature should be set above normal body temperature is desired while not exceeding a safe temperature. An interval between 38 °C and 40 °C is desirable.

Detailing of Concepts

The results of the second loop of selection was the indicators for the further concept detailing, which was the starting of third test-loop design. The detailing of concepts continued in this loop. Sketches of the concepts after detailing is visible below in Figure 52, 54, 55 and 56.

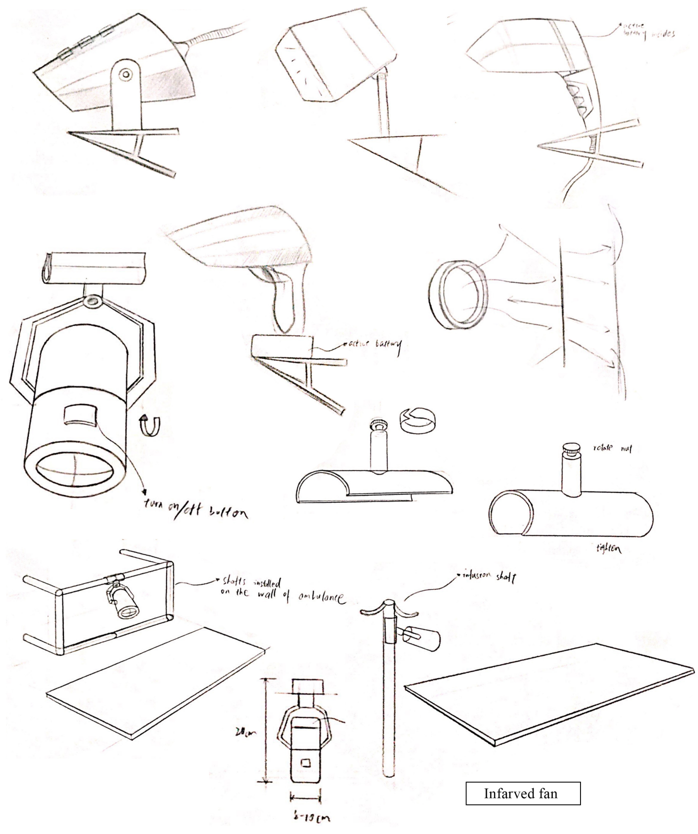

Figure 52: Loop 3 of design: The infrared fan

Figure 53: Loop 3 of design: The space of ambulance

The Infrared Fan It was initially planned that *The infrared fan* would attach to the side of stretchers by a clamp. However, according to paramedics, it might be impossible to attach it on the side of stretchers due to regulation. It was suggested that this concept could be attached to rails placed on the wall of the ambulance, the rails are visible in Figure 53. Therefore, this attachment method is only possible in an ambulance. This concept was detailed so that it looked like a spotlight. A grab bar was added so it can grasp the rails tightly. As can be seen in Figure 52, a screw on the grab bar controls the tightness to the rails. The screw ensures stability for the concept. The structure holding the infrared lamp allows for angle adjustment due to two arms on both sides. As can be imagined, heating will be done in spots. Due to usage limitations, there was no need for an active battery therefore a cable powers the concept. When defining dimensions, small size is preferred in the cramped space of an ambulance. Dimensions of 10*10*20 cm might be suitable to be able to fit. Due to the fundamental issue with spot heating, a limited heating area would mean that several pieces of the concepts are necessary. The number of devices would occupy space and indicate a long mounting time. Besides mounting, paramedics also need to pay attention to where the aim of the device should be. Both with regards to angle and distance to patient.

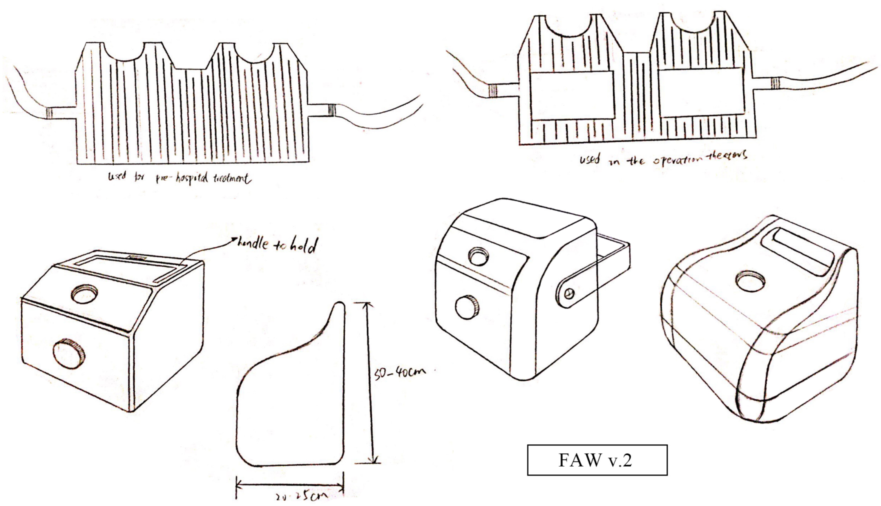

Figure 54: Loop 3 of design: FAW v.2

The FAW v.2 Two variants of *FAW v.2* have been designed, one variant was for pre-hospital care and another was for operational theater. The pre-hospital variant can cover the torso of patients while the operational variant covers the whole front side. Except for the size of the bag, the rest of the components are identical. To make the concept portable, a handle was designed and added to the pump. The pump would include a heating composite, one motor for the air circulation, a noise reduction composite, and one soft pipe. Referring to the size of Bairhugger, which uses the similar heating method of *FAW v.2*, the dimensions were defined as 25*25*40cm for the concept. The detail can be seen in the Figure 54.

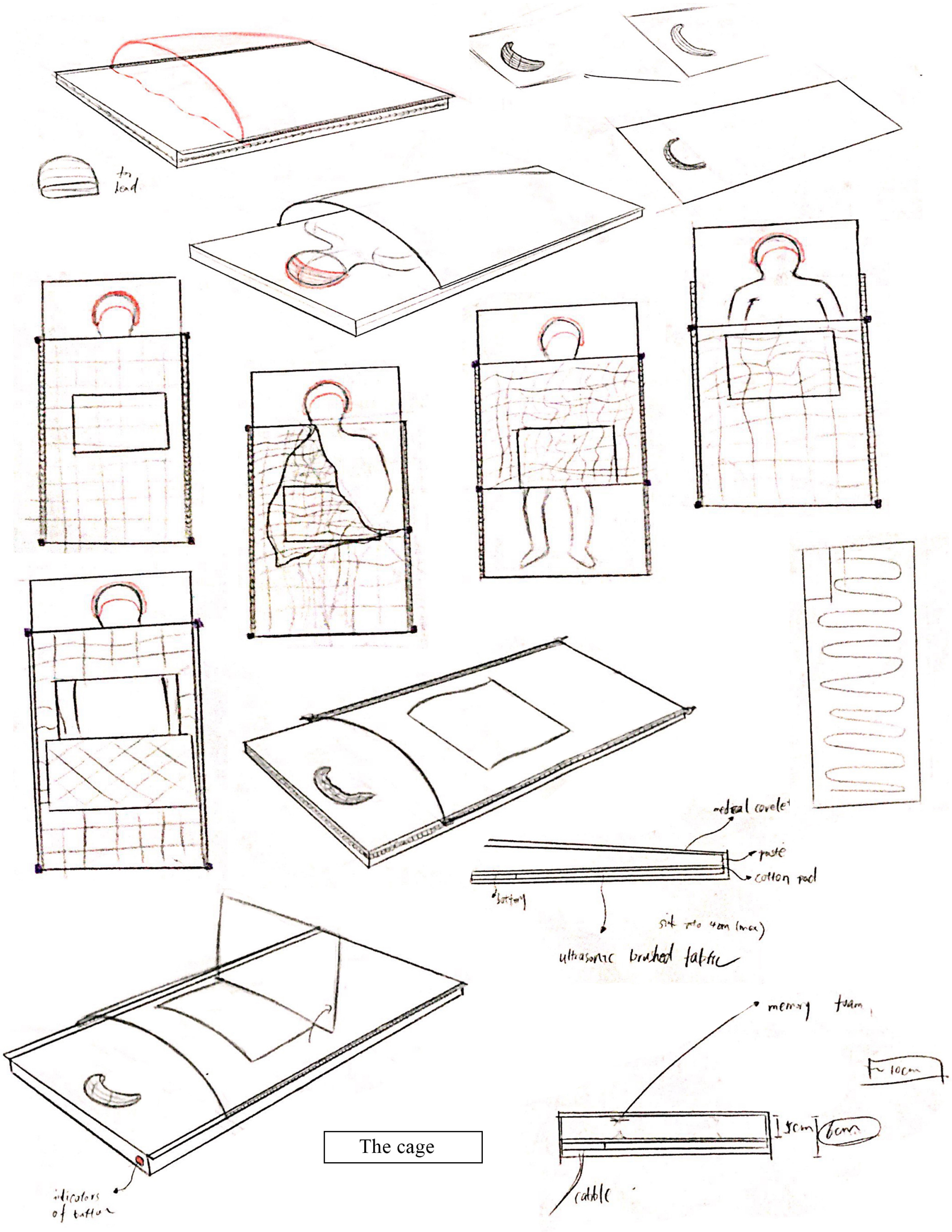

Figure 55: Loop 3 of design: The cage

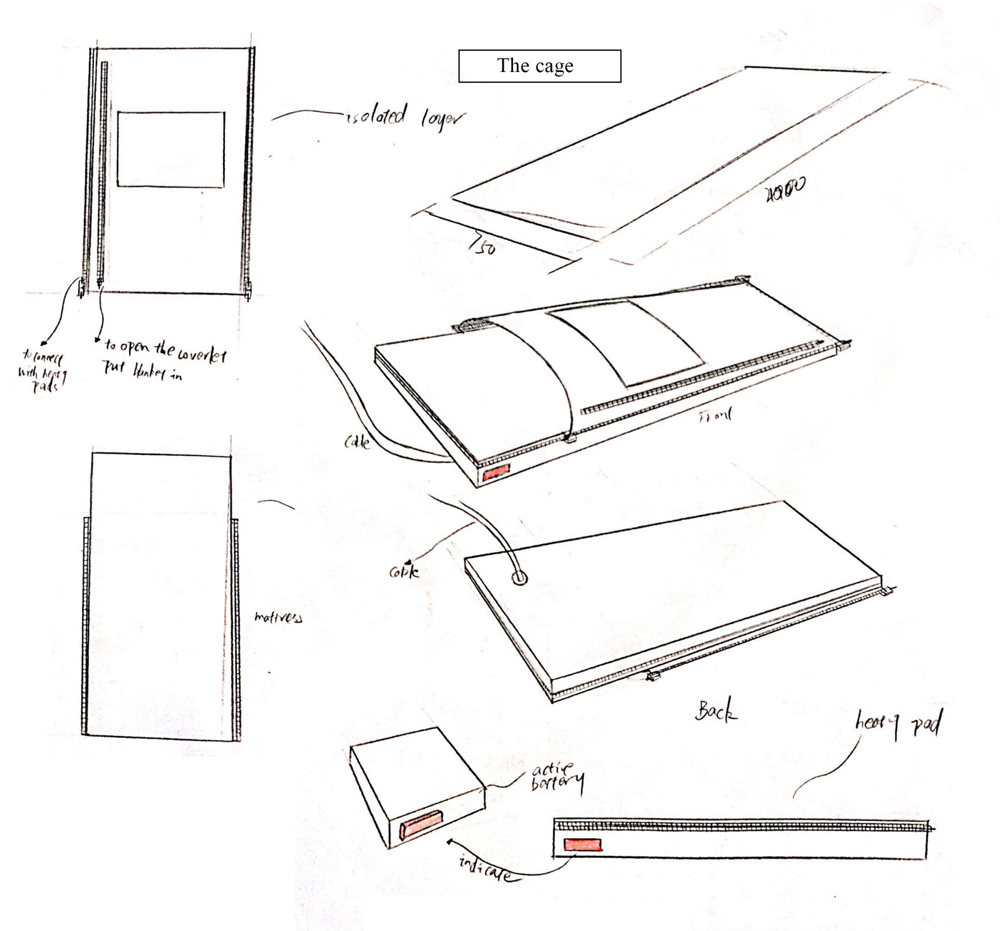

Figure 56: Loop 3 of design: The cage

The Cage In this design loop, detailing how this concept is used in different scenarios was defined. Passive warming for the head was added on the mattress to increase heat efficiency according to stakeholder suggestion. When a patient is placed on the mattress the head warming can be wrapped around the head while it does not cover the mouth, nose, or ears. On top of the passive blanket, a hole and a piece of the separated cover blanket were designed to make this concept more compatible with different situations. As can be seen in Figure 55 and 56. This addition divided the body into three parts: upper torso, lower torso, and lower limbs. Therefore, each area can be uncovered to be accessible. The addition of a hole and flexibility in coverage made this concept easier to use and operate. Portability is a strength of this concept since it is integrated into the stretcher. A smaller-sized battery was added inside the mattress to allow for active heating outside the ambulance. A cable was also added to charge the battery and power the concept while in an ambulance or an operational theater.

6.6 Loop 3 - Screening

For Loop 3 it was decided to use a tool that could compare the concepts on a more detailed level. The tool should also be able to quantify the differences between the concepts. The tool for this evaluation was thus decided to be a Kesselring matrix. This method allowed for a greater comparison of the concepts to a high degree. But for using this matrix each of the concepts needed to be detailed to a higher level than before. As can be observed in the previous section, this has been done.

6.6.1 Loop 3 - Kesselring

Below in Figure 57 one can observe weighing of criteria. The criteria chosen for this evaluation was based on previous customer needs and requirements, see Figure 13.

		Criterias							SUM	SUM/Total	Weight
		Cost	Portability	Burn prevention	Compability	Performance	Ease of use	Reusability			
Criterias	Cost		0	0	0	0	0	0,5	0,5	0,02	1
	Portability	1		0	0,5	0	0,5	0,5	2,5	0,12	3
	Burn prevention	1	1		1	0,5	1	1	5,5	0,26	6
	Compability	1	0,5	0		0	0	0,5	2	0,10	2
	Performance	1	1	0,5	1		1	1	5,5	0,26	6
	Ease of use	1	0,5	0	1	0		0,5	3	0,14	4
	Reusability	0,5	0,5	0	0,5	0	0,5		2	0,10	2

Figure 57: The weighing of Kesselring criteria

The result of the weighting was that the criteria which regard performance and burn prevention were the most important. This can be explained due to the fact that the device cannot bring any harm to the patient in form of burns while also heating the patient adequately. Next up was the Ease of use criterion, which indicated that the use of the device should be prioritized. Further, portability ranked high since a highly portable device was desirable. In the second to last spot was the Re-usability and Compatibility criteria, which indicates the possibility of re-use for each concept and what scenarios each concept can be used in. Lastly, there was the cost associated with each concept. Cost should always be in focus for development, though these concepts are early in the development and would need further cost estimates as it progresses.

Firstly, the scale for each parameter had to be defined. The scale was defined using rough estimations and assumptions. Therefore some of the values may not represent the final concept. The scale and identified parameters can be observed below in Table 4.

Table 4: Identified parameters and corresponding scale

Parameter	**Score 1**	**Score 2**	**Score 3**
Number of unique parts	60%	40%	30%
Complexity	Not been used in medical field	Has been used in a specific medical field	Common in medical field
Weight	5 kg	3 kg	1 kg
Shape	Irregular	-	Regular
Controllable	Minimal control	Visual control	Signal control
Risk of heating	Additional risk for injury	Potential risk for injury	Minimal risk for injury
Number of scenarios	Ambulance	Ambulance and hospital	Ambulance, hospital and stretcher
Modularity	No	-	Yes
Time to heat	<1 min	=30 seconds	<30 seconds
Time to cool	<10 min	<5 min	< 3min
Heating surface area	30%	50%	70%
Insulating surface area	20 %	30%	50 %
Mounting time	<5 min	<3 min	<2 min
Carrying method	No carrying method	Handle	Does not need to be carried
Automation level	Full manual	Semi-manual	Full automatic
Heat spread	all around	Paramedic and patient	Patient
Impact on surroundings	Great impact	Moderate impact	Minor impact
Sterility	One time use	Washable	Surface disinfectant

The Kesselring matrix was now performed, the result can be observed in Figure 58. The result of the evaluation was that the concept *The cage* got the highest score.

Criterion	Weight	Parameters	Measurement	Ideal score	Ideal weighted score	Cage			FAW v.2			Infrared fan		
						Value	Score	Weighted score	Value	Score	Weighted score	Value	Score	Weighted score
Cost	1	Number of unique parts	Scale			30%	5		40%	3		40%	3	
		Complexity	Scale	5	5	Common tech	5	5	Special tech	3	3	no medical history	1	2
Portability	3	Weight	Kg			3 kg	3		5 kg	1		3 kg	3	
		Shape	Form	5	15	Regular	5	12	Irregular	1	3	Irregular	1	6
Burn prevention	6	Controllable	Scale			No control	1,0		No control	1,0		Visual	3,0	
		Risk of heating	Scale	5	30	Minimal	5,0	18	Potential risk	3,0	12	Additional	1,0	12
Compatibility	2	Number of scenario	#			All	5,0		All except one	3,0		Just one	1,0	
		Modularity	Yes/No	5	10	Yes	5,0	10	Yes	5,0	8	No	1,0	2
Performance	6	Time to heat	Seconds			30 sec	3,0		1 min	1,0		<30	5,0	
		Time to cool	Seconds			>5	3,0		>3	5,0		>10	1,0	
		Heating surface area	%			50%	3,0		30%	1,0		30%	1,0	
		Isolation surface area	%	5	30	<50%	5,0	18	30%	3,0	18	20%	1,0	18
Ease of use	4	Mounting time	Minutes			<2 min	5,0		<3 min	3,0		<3 min	3,0	
		Carrying method	Scale			Does not need to be carried	5,0		Handle	3,0		No carrying method	1,0	
		Automation level	Scale			Semi-manual	3,0		Semi-manual	3,0		Semi-manual	3,0	
		Thermal area	Scale			Patient only	5,0		Paramedic+patient	3,0		All around	1,0	
		Impact on surroundings	Scale	5	20	Almost none	5,0	18,4	Some impact	3,0	12	Great impact	1,0	7,2
Reusability	2	Sterility	Scale	5	10	Surface disinfecant	5,0	10	Washable	3,0	6	Surface disinfectant	5,0	10
Total Score				35	110			91,4			62			57,2

Figure 58: Loop 3 - Kesselring matrix

As can be observed in the matrix, the concept *The cage* had the highest score. Followed by the concept *FAW v.2* and on the last spot was *The infrared fan*. When looking closer at the results some interesting aspects can be found. The concepts had an equivalent performance according to the weighted score, but the parameter score differed between the concepts. The burn prevention was more or less equivalent between the concepts except that *The cage* had a higher weighted score. For other criteria, *The cage* had the overall highest weighted score. *FAW v.2* and *The infrared fan* performed similarly in many criteria and the final weighted score did not differ greatly. Though criteria that set the concepts apart were the criteria regarding portability where the *The infrared fan* was determined to have a higher degree of portability. Whereas the *FAW v.2* performed better in the criteria Ease of Use and Compatibility. But regardless *The cage* performed the best. Accordingly,*FAW v.2* and the *The infrared fan* will be rejected. The final concept to be developed further was *The cage*. More details about the concept can be seen in the next section, the Final concept.

6.7 Final Concept

This section presents the chosen concept to be developed further. Here a detailed sketch of the concept together with the most prominent feature are presented. The final concept is visible in Figure 59.

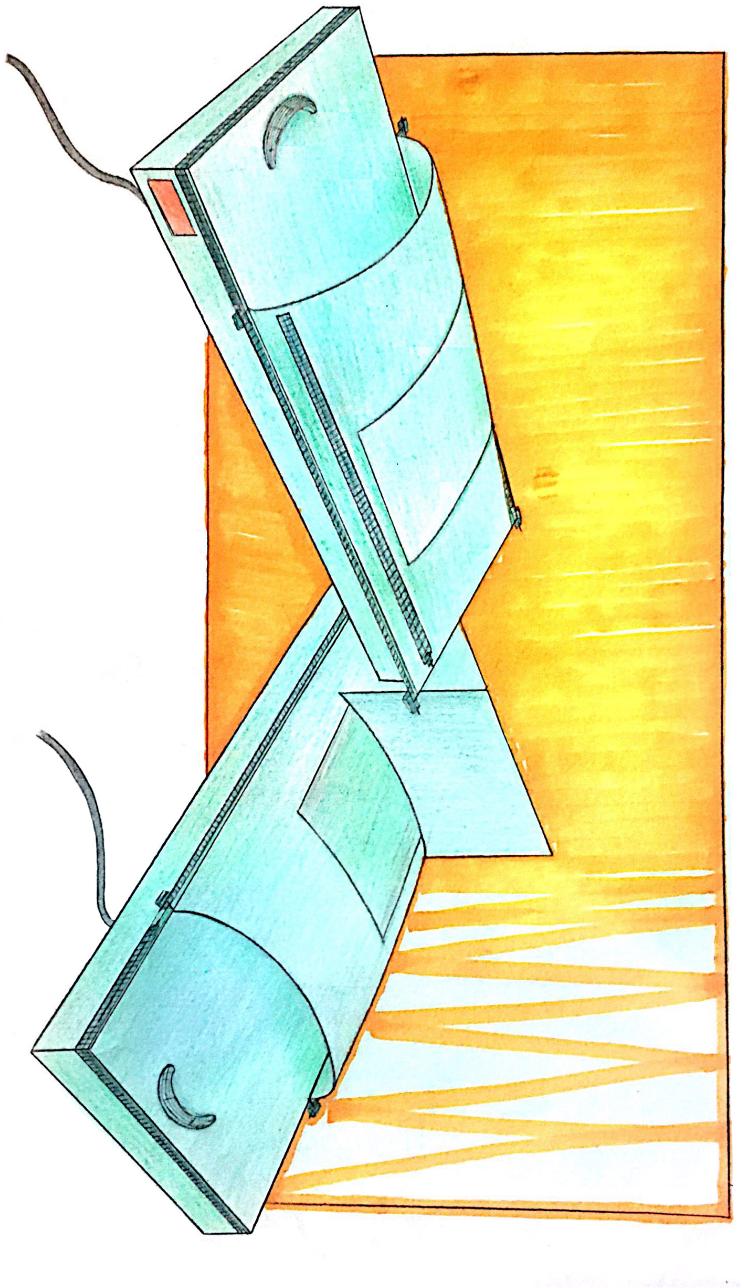

Figure 59: A sketch of the final concept

Table 5: Features of the final concept

Feature	**Explanation**
High heating efficiency	The combination of passive heating and active heating achieves a large heat transfer and keeping of heat; the direct skin contact decreases heat loss during transportation; a large contact surface area allows for high efficiency.
Safety	A fixed heating temperature of 38 °C is just above normal body temperature and therefore minimising risk for burn injuries
Portable	The shape of the concept allowed it to replace the existing mattress on stretchers or operation tables. A battery in the mattress allows for the concept to be moved outside the ambulance.
Ease of use	An on/off-button make the usage easier for paramedics. In addition, the fixed heating temperature meant that attention to heating temperature or burn prevention could be minimised. Further, the mounting of the concept is minimal making it easier to use.
Reusable	An detachable outer sheet made the concept water-proof but also resistant to surface disinfection. Since this sheet is the layer in contact with patients it can be easily disinfected or washed.
Cost-efficiency	The heating method used in the concept is common technology and thus accessible. The re-usability aspect make the concept cost-efficient.
Compatible	The concept can be used in all scenes to cover different body parts based on the situation. To fit with different uses, a battery and a cable was integrated as power sources.

The table above, Table 5, present prominent features of the final concept. Despite identified parameters there were some uncertainties regarding the final concept. As mentioned before, the material and structure had not be determined among other aspects. Therefore, further detailing was needed. In the next Chapter 7, theoretical and practical tests will be done to assist the design of structure and materials.

7
Concept Detailing

The concept detailing consisted of several steps. Each step was designed to gain more knowledge about the actual workings of the final concept. When knowledge was gained it was also put back into the concept to detail it to a higher degree. As the detailing proceeded the concept moved towards being more complete. The steps involved in the concept detailing were theoretical investigation, testing, prototyping and digital rendering.

7.1 Result of Theoretical Investigation

The decisions of the material and structure of the final concept were based on theoretical analysis and calculations. In this section, the final concept was divided into two parts: the mattress and the blanket. The results of the investigation are elaborated on below.

7.1.1 Mattress

Figure 60: The quick illustration of the mattress

The mattress itself combined both active and passive warming to ensure that more heat reaches the patient while keeping as much heat as possible. In the following sections, the design of the mattress and how it works will be introduced. The figure 60 gave a rough structure of the mattress.

7.1.1.1 Active Warming

The mattress's main purpose is to provide active warming. The resistive heating in the mattress generate heat and transfer to the patients. To increase heating efficiency and to make patients more comfortable, additional layers can be added both above and below the heating layer.

Heating Method

There exist different technologies within resistive heating. The most common technology is Resistance heating also called Joule heating. Resistance heating relies on the heat generated when a conductor is supplied with a voltage and current. As the power is supplied it is partly converted to heat energy while transporting the electrical energy through the conductor. It is a common method used in heating elements and is a well-proven technology. The advantage of using this technology is that it is easy to use and readily available. It is capable of generating a large amount of heat but it is also a drawback. There are no safety measures built into the technology. Rather, it is the dimension of the resistance and power that determines generated heat. (E. Distrelec, 2021c)

Another technology that is of interest is called Positive Temperature Current heater, in short PTC-heater. The PTC-heater is a conductive ink that is printed on plastic. The ink is sensitive to the surrounding temperature, thus reacting to hot and cold temperatures. If the heater is cold the current will pass through the ink and generating heat. But as soon as the temperature rises either through increased current or ambient temperature the resistance within the ink will increase as well. There is a temperature limit where the resistance will be more or less be infinite, which also means that there is a maximum temperature for the heating. A benefit of the PTC-heater is that the maximum heating temperature can be determined by the property of the ink. Setting the maximum temperature to a safe heating temperature allows for burn injury prevention. This without the usage of any electronics to control the heating. Another benefit is that the ink allows for uniform heating to occur, this since the ink will be spread evenly across the surface of the plastic sheet.(Herndon, 2017)

As mentioned above, each heating method has its advantages and disadvantages. But there is a factor that has not yet been considered and that is price. The price of a resistance wire is low, for example, Elfa Distrelec sells resistance wires for 337.5 SEK for five meters of wire (E. Distrelec, 2021a). The five meters of wire can cover a large surface area depending on the shape and size. PTC-heaters in comparison have a high price. For a $98\,\text{cm}^2$ large rectangle of PTC-heaters the price is 484.32 SEK (Distrelec, 2021). In turn, that means in order to cover $1\,\text{m}^2$ of surface 102 pieces are needed. Which correlates to a cost of 49400 SEK. Thus, if PTC-heaters will be used the cost of the final concept will be significantly higher compared to the usage of resistance wire.

Battery Pack

To heat patients outside the ambulance, a battery is crucial. Thus power the heating method since patients may not be in reach of the ambulance. The battery would have, according to requirements, at least a capacity of one hour. To be able to charge the battery when back in the ambulance, the power outlets available had to be investigated. A visit to SU ambulance, as described in Chapter 5, brought the necessary knowledge. The available power outlets were 12 volts and 230 volts. At this end, the design of the battery pack started. But before that, the actual heating method has to be determined.

Heat Transfer Layer

A layer that has to be investigated is a layer that could improve heat transfer. Heat transfer can be improved by less loss to the environment while also spreading heat more evenly across the surface. An idea was to use thermal paste used in computers. Since computers generate a lot of heat, the thermal paste help with transferring heat and reduces air trapped between contact surfaces. Thus improving the efficiency of heat transfer.

A safety layer was also investigated. The layer should act as an extra precaution to prevent burn injuries. It will prevent injuries by protecting skin from direct contact with the heating method. A standard layer in any heating product. Normally, a thin cotton layer is used to insulate the heating method. For this reason, a cotton layer was included in this mattress.

7.1.1.2 Passive warming

Although the main task of the mattress is to provide active warming, passive warming should also be integrated to prevent heat loss. This means that an addition of passive layers could force heat to be kept in the mattress rather than escaping to the environment.

Immersion Layer

An immersion layer was also investigated further. The idea of this immersion layer was to create an increase in surface area that could be heated. In addition, some immersion of patients would also make the mattress adjustable to different bodies. The layer could also act as an insulating layer. This due to the property of immersion material, which is commonly a type of foam. If the layer is placed beneath the heating method the loss of heat can be reduced. Also, the foam should not prevent CPR to be done. This mainly relates to the thickness of the foam, since a thicker foam does not have a hard stop built-in. Resulting in a continuous movement of the patient instead of the applied force to the torso. In summary, the immersion layer allows the mattress to elastically deform and recover while allowing for CPR to be performed. Lastly, it should also reduce heat loss.

Polyurethane foam, memory foam, reflex foam, latex foam, and convoluted foam were candidates for the immersion layer. To make a further choice, the attributes of these materials should be investigated. An important metric for comparing insulating properties the R-value can be used. R-value is how well a material resists conductive heat transfer, the different forms of heat transfer are described in Section 7.1.1.1. Below in Table 6 the R-value for mentioned foams are presented, a higher value is better.

Table 6: R-value for different insulating materials to be used in the insulating layer

Material	**R-value**
Polyurethane foam	$1.18\,\mathrm{W/m^2 \cdot K}$ (Seymour & Kauffman, 1992)
Memory foam	$1.58\,\mathrm{W/m^2 \cdot K}$ (Wild, 2011)
Reflex foam	$0.63\,\mathrm{W/m^2 \cdot K}$ (Cottonthermal, 2021)
Latex foam	$0.67\,\mathrm{W/m^2 \cdot K}$ (foam, 2021)
Convoluted foam	$0.67\,\mathrm{W/m^2 \cdot K}$ (foam, 2021)

As can be seen above in Table 6, polyurethane foam and memory foam had a higher R-value than the other foams. Therefore, these two foams were of interest for further investigation.

Softness and resilience for the layer are important to achieve the desired elastic behavior and support. Among the foams, the memory foams stand out (Morse, 2021). Although all of the mentioned foam can be elastically deformed, memory foam is still superior. This why memory foam is commonly used in mattresses (Morse, 2021). Therefore, memory foam was chosen as the material for the immersion layer.

Insulating Layer

To further prevent heat loss to the surrounding environment, an insulating layer is added below the immersion layer. Heat loss occurring at the side of the mattress is ignored, the main focus is to prevent loss through the bottom of the mattress.

Material of the layer should have the capability to minimize heat flow. The R-value can be used again to determine what material is appropriate to choose. Out of the most common insulating materials, the choice was between cotton, wool, fleece, down, acrylic, and polyester. In Table 7 below the R-values of each material are presented.

Table 7: R-value for different insulating materials to be used in the insulating layer

Material	**R-value**
Cotton	$0.53\,\mathrm{W/m^2 \cdot K}$ (sandium, 2020)
Wool	$0.67\,\mathrm{W/m^2 \cdot K}$ (Roberts, 2019)
Fleece	$0.67\,\mathrm{W/m^2 \cdot K}$ (?, ?)
Down	$0.75\,\mathrm{W/m^2 \cdot K}$ (foilboard, 2021)
Acrylic	$0.7\,\mathrm{W/m^2 \cdot K}$ (Gerfen, 2021)
Polyester	$0.67\,\mathrm{W/m^2 \cdot K}$ (Gerfen, 2021)

As can be seen in Table 7 above, down has the highest R-value. Investigating down as a layer, revealed that it is not good at dehumidify. It means that the moisture generated from patients and weather is kept within the material for a longer time. This is not a desired attribute of the insulating layer, therefore down was not a suitable material. Acrylic has the second-highest R-value. It is also resistant to damage, relatively cheap, and has a low weight. One advantage of acrylic is that it is hypoallergenic, which is suitable in a mattress with close contact with patients. The advantages of acrylic render it a solid choice for the layer. In conclusion, acrylic is the material chosen for the insulating layer. Another clue that this is a good choice is that acrylic is already established as a material in the medical field.

Cover Sheet for Mattress

A function of the cover sheet was to protect the inner structure of the mattress. The sheet protects from liquids and dirt penetrating the mattress structure. For this application, the sheet should be water-proof. The sheet should also be of multiple uses to be sustainable and cost-effective. To be able to be used multiple times the layer should be able to be cleaned with surface disinfectant or be washed in a washing machine. Since this is an issue for all mattresses used in the medical field, this problem has already been solved. The material used for a cover sheet is a fabric coated with polyurethane rubber. This material can fulfill the needs mentioned before while allowing for heat transfer from the mattress to patients. To attach the blanket two double-zip structures are integrated at the side of the sheet.

Passive Head Warming

In the final concept, a hood structure was added on the top of the mattress to cover the head. As said in 7, acrylic was an excellent material for keeping heat, so this material could also be used to produce the hood. But since the hood should fit different head shapes, an elastic band can be used to adjust the shape and size of the hood.

7.1.1.3 Evaluating Surface Temperature

To evaluate whether the proposed layers above would affect heating efficiency. It was decided to do a one-dimensional analysis of the problem. The point of interest is the surface temperature on top of the mattress. Another point of interest is whether the layers would affect the heating to a certain degree.

Heat can be transferred in different forms, the three ways of transferring heat. Those are Conduction, Convection, and Radiation. Conduction transfer happens when in direct contact with the heating object, Convection is when the heat is lost to the environment through gas or liquids, and Radiation is in form of non-visible heat emitting waves (W. University, 2021). Each of the heating transfer methods has a unique equation to calculate heat transfer. Each of the equations can be visible below in Equation 1, 2 and 3 (Lewis, Nithiarasu, & Seetharamu, 2004).

$$Q_{conduction} = -k \cdot A \cdot \frac{T_2 - T_1}{L} \tag{1}$$

$$Q_{convection} = h \cdot A \cdot (T_2 - T_a) \tag{2}$$

$$Q_{Radiation} = \epsilon \cdot \sigma \cdot A \cdot (T_2^4 - T_e^4) \tag{3}$$

The variable Q is the heat transfer for all equations above.

For Equation1, the variable k is the thermal conductivity of the material used to transfer the heat, A is the surface area, T_2 is the temperature on the outside surface, T_1 is the temperature on the inside surface and L is the thickness of material (Lewis et al., 2004).

For Equation 2, the variable h is the heat transfer coefficient, A is the surface area, T_2 is the temperature on the outside surface and T_a is the ambient temperature (Lewis et al., 2004).

For Equation 3, the variable ϵ is the emissivity of the material, σ is the Stefan-Boltzmann constant, A is the surface area, T_2 is the temperature on the outside surface and T_e is the temperature at surface around the actual surface (Lewis et al., 2004).

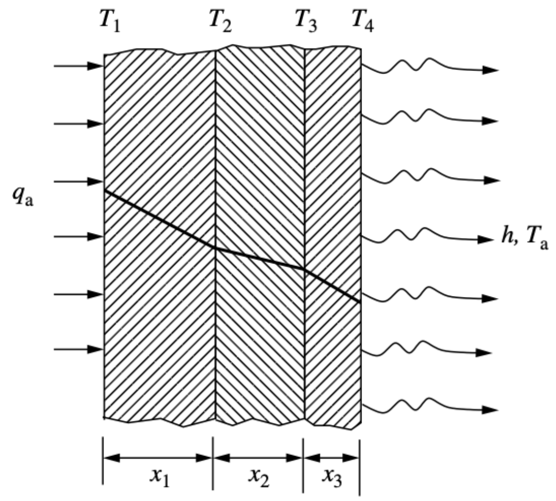

Figure 61: Shows the layers of a wall and how to define each layer of the wall (Lewis et al., 2004)

To achieve a surface energy balance, all the three equations need to be equivalent to zero at the intended surface, which can be observed as T_4 in Figure 61. All modes of transfer can be evaluated after that. The equation looks like the one below in Equation 4.

$$0 = Q_{Conduction} - Q_{Convective} - Q_{Radiation} \tag{4}$$

Solving for T_1 moves the term $Q_conduction$ over the other side of the equal sign and then T_1 can be extracted. Since the surface area is common among all the terms in the equations it can be removed. The equation will then look as below in Equation 5.

$$T_1 = T_2 + \frac{L_t}{k_t} \cdot h \cdot (T_2 - T_a) + \frac{L_t}{k_t} \cdot \epsilon \cdot \sigma \cdot (T_2^4 - T_e^4) \tag{5}$$

Where L_t and k_t are the total thickness of the layers and the total thermal conductivity of all the layers. These terms are the addition of thickness and thermal conductivity for each layer. The materials used in the layers are cotton, polyurethane rubber(PU) and a thermal conductivity layer.

- The cotton has thickness of 5 mm and thermal conductivity of 0.04 W/m ∗ K (toolbox, 2021d)
- The PU-rubber has a thickness of 2 mm and thermal conductivity of 0.29 W/m ∗ K (Lasance, 2001)
- The thermal conductivity layer has a thickness of 1 mm and thermal conductivity of 7 W/m ∗ K (Inet, 2021)

Thus, L_t and k_t can be calculated. Using equations below, Equation 6 and 7. The equations were set up using Figure 61.

$$L_t = x_1 + x_2 + x_3... + x_n \tag{6}$$

$$k_t = k_1 + k_2 + k_3... + k_n \tag{7}$$

Using Equation 6 and Equation 7 above, the variables and each respective value can be compiled. The known variables can now be inserted into Equation 5. See Table 8 below.

Table 8: Values of variables

Variable	**Value**
L_t	0.008m
k_t	7.33 W/m · K
h	15 W/m^2 · °C (Lewis et al., 2004)
ϵ	0.86 (toolbox, 2021a)
σ	Constant (Lewis et al., 2004)
T_2	38 °C
T_a	22 °C
T_e	22 °C

The result of inserting known variables in Equation 5 and solving for T_1, is that the inner temperature of all the layers will be 38.76 °C. When the intended surface temperature of 38 °C. Resulting in a difference of 0.76 °C between the heating source and the top layer's surface. Thus proving that the layers work as intended and that the heat loss is not significant.

7.1.2 Blanket

Figure 62: The quick illustration of the blanket

The blanket above provides passive warming to patients. This blanket would work in conjunction with the mattress to keep the temperature. To achieve this, the core of this passive blanket should consist of a material that can prevent heat from escaping. The reusability aspect of the blanket also has to be investigated. The figure 62 displayed the structure of the blanket. The detailing of material and shape are explained below.

7.1.2.1 Inner Blanket

The material of the inner blanket should be able to keep heat. The material acrylic mentioned before can be used since similar properties are desired from the inner blanket.

7.1.2.2 Cover Sheet for Blanket

The blanket in use today in ambulances and at operational theaters is made of fabric and does not have a cover sheet. In turn, the blanket has to be washed after usage. However, this is not always possible and the washing may not remove stains. Hence, the blanket may be thrown away. To reduce the number of blankets in usage and washing of blankets, it is recommended to introduce a cover sheet. The sheet can be made in polyurethane-coated fabric like the cover sheet for the mattress. Which prevents liquid and dirt to penetrate the fabric. As with the normal cover sheet, a zip on the sheet allows putting the inner blanket in or out. Besides, the foldable middle part made this blanket compatible with the heating area adjustable.

7.1.2.3 Attachment to Mattress

To be able to attach the blanket with the mattress, an attachment method had to be investigated. The attachment should be fast and easy to use, prevent major heat loss, be precise in attaching and be reliable. Common attachments like Velcro, zippers, and strings were investigated. Strings were ruled out since this is a method that is time-consuming and will not prevent heat loss. Velcro is a good candidate for the application, it is fast and easy to use with good reliability. The downside to this method is the precision, Velcro may be attached easily but the precision of the attachment can vary. After further investigation, regular zippers are the most appropriate method. It is fast and easy to use, has good precision, prevents heat loss, and provides a reliable attachment.

To connect the blanket with the mattress, double-zip structures were used on both sides of the cover sheet. This to prevent heat from escaping from gaps of the zip structure. In the final concept, the double-zip structures on all sides of the mattress make the blanket flexible. As stated previously, it is possible to uncover a part of the body by unzipping.

7.2 Result of Testing

The result of the theoretical investigation, seen in Section 7.1, shows that the layers perform as intended in a theoretical setting. However, the layers need to be investigated in a real-world setting as well. The result of real-world testing can be seen below. The results have been divided according to what testing was performed. The test method for each of the test can be read about in Section 2.5.3.

7.2.1 Test of Active Warming

In order for the test to be conducted some equipment had to be defined. The equipment used to conduct this testing are a warming pad (Hjärtat, 2021) and a Infrared thermometer (Biltema, 2021a). This equipment was used for all the tests mentioned below.

7.2.1.1 Result of Test 1

Setting the warming pad on the maximum heating setting should allow it to put out 100 W according to the technical specification (Beurer, 2021). Measuring the surface temperature of the warming pad on three spots resulted in an average of 40.1 °C. Relation between power and surface temperature could be extracted.

7.2.1.2 Result of Test 2-4

Next up was to investigate the heat transfer that occurs between a body and a heat source. The tests aimed to provide a clear indication of the heat transfer and its ability to heat an object. The test would provide the amount of heat that would be transferred and how the intended layers affect the heat transfer. Tests related to this objective was the second to the fourth test described in Section 2.5.2.

The result of second, third and fourth test can be observed below in Table 9.

Table 9: Result of the heat transfer tests

Attribute	**Direct contact**	**Layers**	**Layers & Insulation**
Initial water temperature	17.5 °C	20.6 °C	22.5 °C
Initial surface temperature	40.1 °C	36 °C	36 °C
End water temperature	21.9 °C	22.6 °C	26 °C

As can be observed above in Table 9 the initial water temperature differs between the tests. This due to a higher ambient temperature in the testing space. Using Equation 8 below, heat transferred for each of the test can be calculated (Toppr, 2021).

$$Q = m \cdot C \cdot (T_e - T_i) \tag{8}$$

The term m is the weight of the water, the C is the specific heat capacity of water, T_e and T_i is the end temperature and the initial temperature of the water. Inserting the known variables and calculating using Equation 8, the power transferred to the plastic bags could be calculated with Equation 9. Where Q is heat generated in joules and t is time in seconds. The result of using Equation 9 is seen in Table 10 below.

$$P = \frac{Q}{t} \tag{9}$$

Table 10: Result of the equations

Attribute	**Direct contact**	**Layers**	**Layers & Insulation**
Heat generated	5527.368 J	2512.44 J	4396.77 J
Heat per second	9.21 W	4.1874 W	7.32 W

The results of the heat transfer tests showed that direct contact produced the highest heat transfer. The second highest is using all layers and an insulation wrap. Last is just using all the layers. The results showed that the layers reduce the heating transferred, which according to the theoretical investigation, was expected. An interesting result was the insulation wrap. Which showed that a passive warming layer makes a difference in heat transfer. The results showed that despite a power output of 100 W of the warming pad, the actual heat transferred is significantly lower.

7.2.1.3 Result of Test 5

The fifth test, investigated the idea of having a thermal conductivity layer in the mattress. The result of the test can be seen in Table 11 together with results from Table 9 in order to provide a comparison.

Table 11: Result of Test 5

Attribute	**Thermal conductive layer**	**Without thermal conductive layer**
Warming pad temperature	38 °C	40 °C
Surface temperature of layers	36 °C	36 °C

Using the results observed in Table 11 to compare the efficiency of heat transfer, it can be observed that the thermally conductive layer improved the heat transfer. The layer improves the heat transfer by 2 °C. The result indicated that the heat loss was less when this layer was used. The uniform heating of the layer was not investigated since a thermal camera was not accessible.

7.2.2 Test of Passive Warming

The test results of the passive warming can be observed below. The test regarded the capability of foam to keep the temperature and provide the effect of insulation for heated bodies. A smaller increase in temperature indicates a better insulating material.

The test showed an initial surface temperature of 24.2 °C and an end temperature of 24.3 °C. The raised temperature of 0.1 °C indicated that the material acted like an insulator. This test showed that the insulating foam with a thickness of roughly 6 cm will perform as intended. By keeping the heat within the body rather than dissipate into the environment.

7.3 Investigating Resistance Heating

This section investigated the dimension of the heating method, the battery that was needed to power the device and the performance of the heating method. The chosen heating method can be read about in Section 7.1.1.1.

7.3.1 Evaluating Appropriate Dimension of the Heating Method

To determine the dimension and performance of the Resistance heating. The first step would be to determine what length of the wire should be. The length of the wire affects both the power and cost of the concept. To determine the length, the area of the mattress had to be taken into consideration. The area was calculated using Equation 10 below.

$$A = Length * width \tag{10}$$

Where the length was 1.97 m and width was 0.57 m. The result is an area of 1.13 m^2. The wire of the mattress can then be fitted in the mattress, see Figure 63. The approximate length of the wire will be 9 m.

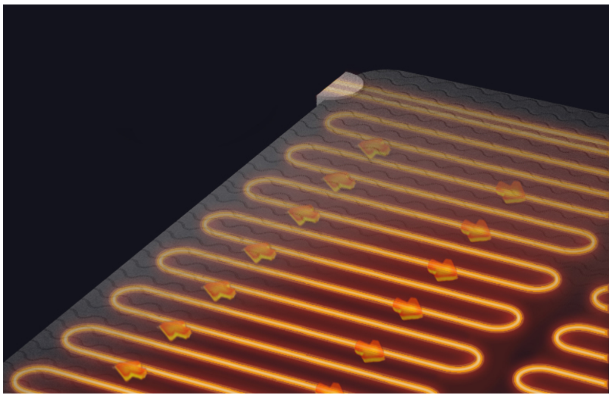

Figure 63: Resistance heating (manyanu, 2019)

Next up was to evaluate which resistance wire to use. Here the power needed to provide a sufficient heating temperature is the design constraint. The desired heating temperature was set to 38 °C as can be seen in Section 7.1.1.3. Unfortunately, the amount of power needed to provide this temperature is unknown. But Costanzo S. Et. al. (2014) had determined a correlation between power and temperature for a Warming blanket. The warming blanket delivers, at the highest setting, 71.41 W (Costanzo, Cusumano, Giaconia, & Mazzacane, 2014). Comparing the power delivered and the generated skin temperature of the test subject, viewed in Figure 64 below, a correlation can be established.

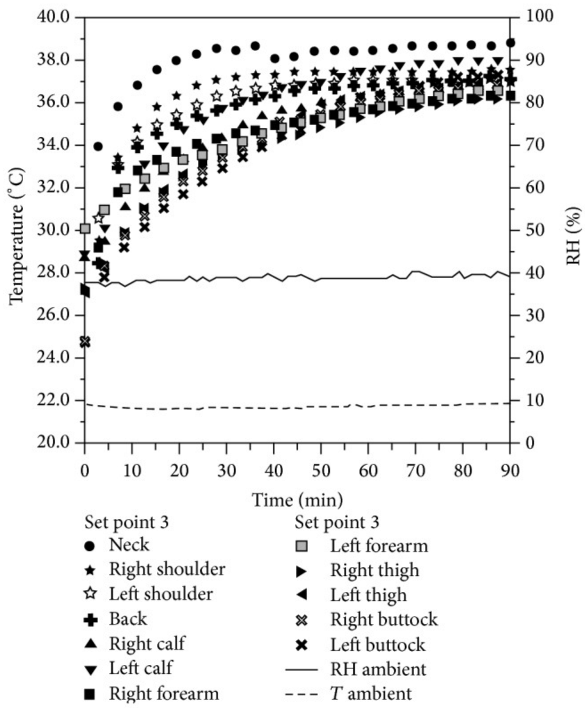

Figure 64: The skin temperature generated by the highest power setting (Costanzo et al., 2014)

The correlation establishes that power of 71.41 W generates a maximum skin temperature of roughly 38 °C, as observed above in Figure 64. The area in which the maximum skin temperature occurs is at the neck. The area is not of concern, the main takeaway is that the temperature should not rise any higher than that since a burn can occur. To confirm this correlation, another reference can be used. According to Aléx A. Et. al. (2015) a prototype of a warming mattress performing 50 W, resulted in a surface temperature of 35 °C on the surface of the mattress. Another result that can be used to evaluate the power necessary is the result from the practical testing where an output of 100 W resulted in a surface temperature of 40.1 °C, which can be found in Section 7.2. With several correlations established between power and temperature, an interval between 50 W and 100 W should be able to provide enough heating for the patient. An initially estimated power of 70 W would be a good starting point for estimating the resistance, the voltage and the current needed to perform this power.

To calculated the required resistance and voltage, Equation 11 has been used (toolbox, 2021c). It is assumed that the electrical energy is converted 100 % into heat energy.

$$P = \frac{V^2}{R} \tag{11}$$

Assuming that 12 V is set as a power source. Hence $P = 70$ and $V = 12$ can be inserted into Equation 11 to calculate the resistance. The resistance is calculated to 2.057 Ω. Dividing the total resistance with the total length of the wire, the resistance per meter can be calculated and determined. This unit is desired to determine which resistance wire to use, as the manufacturer often states this unit for wires. Dividing $R = 2.057$ with $L = 9$ result in 0.2286 Ω/m. In Elfa's catalog of resistance wires, there is a wire that has the property of 0.277 Ω/m. The wire, named RD 100/1.5, is the wire that comes closest to specification (E. Distrelec, 2021b). Using the defined properties of the wire, all is re-calculated in order to determine the power it can generate. First, the total resistance is calculated, multiplying the resistance with the length of the wire. The result is a total resistance of 2.493 Ω across the wire length. Inserting the total resistance and the voltage in Equation 11, power can be calculated. The power is calculated to 57.76 W when using this specific resistance wire. Which is close to the intended power of 70 W and within the interval determined previously.

7.3.2 Investigation of Battery Options

Now that the power is defined the sizing and performance of the battery can be determined. The battery size depends on the voltage that it needs to be supplied. For this device, a voltage of 12 would be sufficient as proved before. Using Equation 12 below (toolbox, 2021c), the current can be calculated.

$$P = I^2 \cdot R \tag{12}$$

With an input of $P = 57.6$ and $R = 2.493$ the current I can be calculated as 4.813 A. Since the concept has a requirement of providing heat for an hour outside an ambulance, the longevity of a charge has to be one hour. Converting the requirement in ampere-hours is the equivalent of 4.8 Ah.

Researching suitable 12 V batteries an issue was discovered. There is a downside to using a 12 V battery and that is the size and weight of it. For example, a 12 V battery made for motorcycles is often the smallest and lightest. Still one of those had a weight of 4.35 kg and a size of 13.4 cm × 8 cm × 16 cm (Biltema, 2021b). This would increase the weight and the thickness of the mattress. The thickness would increase since the battery needs to be mounted horizontally. This issue had to be solved by finding another way of providing 12 V.

Another idea that then surfaced was laptop batteries. A laptop can be used several hours in tough conditions on battery power. A further investigation found that a laptop battery has a voltage of either 11.1 V or 14.8 V. The batteries in a laptop battery are called ICR18650-battery. These batteries are slightly larger than an AA battery but provide a higher voltage and current. Studying the specification of ICR18650-battery from Biltema, one battery can provide 3.7 V and 2.95 A each (Biltema, 2021c). But that is not enough to provide power for an hour. To supply enough voltage and charge, there is a way to increase voltage and a way to increase current. This by connecting the batteries in different manners. By connecting the batteries in series increases the voltage with the combined voltage of the batteries used. The current can be increased by connecting the batteries in parallel. Equation 13 and 14 (B. University, 2020), where the former is used to calculate the voltage generated by connecting in series and the latter for calculating the current when connecting in parallel.

$$V_t = V_1 + V_2 + ... + V_n \tag{13}$$

$$I_t = I_1 + I_2 + ... + I_n \tag{14}$$

Using Equation 13 results in a voltage of 11.1 when connecting three ICR18650 batteries in series. Equation 14 calculates that two battery packs in parallel generates 5.9 Ah. With regards to both voltage and current, this battery pack would provide ample performance. An added benefit of using ICR18650- batteries was that a normal computer charger can be used to charge the batteries. This would allow for an easy way of charging with access to a 230V-outlet in the ambulance. In summary, the battery pack will consist of two packs connect in parallel, with three ICR18650-batteries connect in series for each.

7.3.3 Performance of the Heating Method

To evaluate the performance of the proposed set up of resistance wire and battery, it was necessary to evaluate whether it could fulfill the requirement set for the heating level. The requirement states that the concept should be able to heat a person 0.5 °C per hour.

Using Equation 16 the heat necessary to raise the temperature of a person can be calculated. The variables are m which is the weight of the person, C is the specific heat capacity, $T_a - T_b$ is the temperature change. This equation can be used both for women and men, altering the weight to accommodate for gender differences. Therefore a weight of 84 Kilogram for men and 68 Kilogram for women was determined (Centralbyrån, 2019). The term $T_a - T_b$ was set to 0.5 since the temperature change should be 0.5 °C. The specific heat capacity of a human body is 3.5 kJ/(Kg/°C). But the number do not take body fat percentage in consideration, therefore Equation 15 can be used (Faber & Garby, 1995). Where m_f is the body fat percentage. The average body fat percentage was set to 20 %.

$$C = 3.72 - (1.84 \cdot m_f) \tag{15}$$

$$Q = m \cdot C \cdot (T_a - T_b) \tag{16}$$

Using Equation 15 the specific heat capacity, C can be calculated to 3.352 kJ/(kg/°C) (toolbox, 2021b). Inserting all known variables in Equation 16, the heat needed to raise the body temperature by 0.5 °C can be calculated. The required heat energy to warm a male is 140 784 Joule and 113 968 Joule for a female.

Further, the amount of heat that can be transferred has to be estimated since the amount of heat is known. The heat transferred is not equivalent to the heat generated by the resistance wire. Therefore an approximation has to be made. Results from testing suggest that 100 W of power only produced 4.1874 W of heat transfer when using all layers. An assumption can be made that this result is tied to the contact area between the layers and the water bag. The surface area of the water bag was 0.0198 m^2 while the area of the warming pad was 0.1452 m^2. Comparing the surface areas results in coverage of roughly 13.6 %. Assuming uniform heating across the surface, the actual power heating the water bag was calculated with Equation 17 below. Where Q_p is the heat generated by the pad, A_s is the coverage of the surface area and Q_t is the total heat generated by the pad.

$$Q_p = A_s \cdot Q_t \tag{17}$$

Using Equation 17 calculates the power generated to warm the bag to 13.64 W. Using results of the tests, the actual heat transfer can be compared with the heat output. A worst-case scenario, using results for the Layers column in Table 10, indicates a loss of 9.45 W during transfer. The best-case scenario, using results of the Layers & Insulation column in the same table, indicates a loss of 6.32 W. Translated into a loss of roughly 70% for the worst-case scenario and 46 % for the best-case scenario. Using these two percentage losses in heat transfer, the amount of heat that can be transferred by the proposed heating method can be evaluated.

Total surface area of the mattress was 1.13 m^2 as calculated previously. The actual surface area in contact with patients is more difficult to estimate. Utilizing the Lunder and Browder chart (of Health & Services, 2013), the surface area in contact with the mattress can be calculated.

Adding the surface body areas in the chart results in a surface body area in contact with the mattress to be 51.5%. Assuming that an average body has a total surface body area of 1.79 m^2 (Sacco, Botten, Macbeth, Bagust, & Clark, 2010), results in a surface body area of 0.921 85 m^2 in contact with the mattress. Comparing the body surface area in contact and the surface area of the mattress, the coverage of the mattress can be calculated. This results in coverage of 61.45%. Using similar assumptions done when calculating heat loss for the warming pad, resulting in a heat transfer that heats a patient with 35.5 W. The loss, if utilizing the equivalent losses identified in the practice tests, the actually transferred heat will roughly be 11 W for the worst-case scenario and 19 W for the best-case scenario. Returning to the initial investigation, what is the performance of the heating method, the rate of warming can be determined using this information. Dividing the amount of Joules needed to heat a person 0.5 °C with the estimated heat transfer per second, as can be seen in Equation 18, the time to heat can be estimated. Where t_{total} is the time in seconds, Q is the amount of Joules needed to heat a person 0.5 °C and Q_m is the heat per second transferred from the mattress.

$$t_{total} = \frac{Q}{Q_m} \tag{18}$$

Resulting in a heating time of 3.55 hours for a male and 2.878 hours for a female when using results from the worst-case scenario. For the best-case scenario, the time is 2 hours for a male and 1.67 hours for a female. These results mean that the requirement of warming a person 0.5 °C per hour would not be fulfilled for both of the scenarios.

7.3.4 Material Cost Estimation

Now that major aspects of the concept have been investigated it was possible to perform cost estimation. A material cost estimation had to be done to evaluate if the final concept delivers any value in terms of both performance and cost. The former has been investigated while the latter is investigated in this section. To evaluate the total material costs, the cost can be split into two major parts. One that concerns the mattress and one that concerns the blanket. Below was the summarized cost for the mattress, visible in Table 12.

Table 12: The cost estimation made for the mattress

Material	**Amount**	**Cost**	**Total cost**
Rubber fabric	2 m	119 SEK/m (tyger, 2021a)	238 SEK
Cotton fabric	2 m	44 SEK/m (tyger, 2021b)	88 SEK
Acrylic fabric	2 m	129 SEK/m (Skapamer.se, 2021)	258 SEK
Thermal pad	53 pieces	137 SEK/piece (Amazon, 2021)	7261 SEK
Resistance wire	9 m	337.5 SEK/5 m (E. Distrelec, 2021b)	675 SEK
ICR18650 battery	6 pieces	99 SEK/piece (Biltema, 2021c)	594 SEK
Total cost	-	-	9114 SEK

The result of the summarization was that the total material cost of the mattress was 9114 SEK. To evaluate the amount of fabric to be used, the surface area of the mattress has been used as calculated in Section 7.3.1. Other materials had the amount predefined in earlier sections.

Below in Table 13 the material costs related to the blanket can be observed.

Table 13: The cost estimation made for the blanket

Material	Amount	Cost	Total cost
Rubber fabric	2 m	119 SEK/m (tyger, 2021a)	238 SEK
Acrylic fabric	2 m	129 SEK/m (Skapamer.se, 2021)	258 SEK
Zip	4 m	35 SEK/m (Tygverket, 2021a)	140 SEK
Zip runner	2 pieces	5 SEK/piece (Tygverket, 2021b)	10 SEK
Total cost	-	-	646 SEK

The result of the summarization above was that the total material cost of the blanket was 646 SEK.

Summarizing the total material cost of both the mattress and the blanket results in a total material cost of 9760 SEK for the final concept. Among the costs in the mattress table, a certain post was prominent, the thermally conductive layer. The layer had a cost of 7261 SEK. Which is roughly 74 % of the total cost. In comparison to the performance that it brings, it needs to be discussed whether this layer is of importance. Without the layer, the total cost of the final concept would be 2499 SEK.

7.4 Decisions of the Concept Detailing

The result of the detailing was that the layers of the mattress and the blanket were chosen. The mattress consisted of six layers each with a specific purpose. The outer and inner sheets consist of a polyurethane-coated fabric, a middle cotton layer to convert the heat, a heating layer to generate heat, an immersion layer made of foam, and an insulating layer made of acrylic. The blanket consisted of an acrylic inner layer and a polyurethane-coated fabric outer layer. For the attachment of the blanket with the mattress, zippers were the method chosen.

The heating method determined for the final concept was Resistance heating. The heating will be provided by a resistance wire that will supply 58 W. To supply this power, the concept needed a battery pack. The battery pack consisted of six ICR18650-batteries divided into two packs which are connected in series and then parallel between the packs. This setup will generate the power necessary for an hour of use outside of an ambulance. Resulting in a capacity of 11.1 V and 5.9 Ah.

Further details of the improved and detailed concept can be seen in the Chapter 9, where the final concept is revealed.

8
Business Plan

Part of developing a product was to make sure that the product will actually be able to sell on the market. This was to make sure that the effort put into the development is not a waste. Forming a business plan is a way of exploring the market options that exist for a particular product. A method for doing this is a Business model canvas where the plan can be visualized and structured.

8.1 Business Model

The business model has been translated to a business model canvas to achieve a visualization of the model. The Canvas can be observed below in figure 65. The different boxes highlights key aspects of a business model.

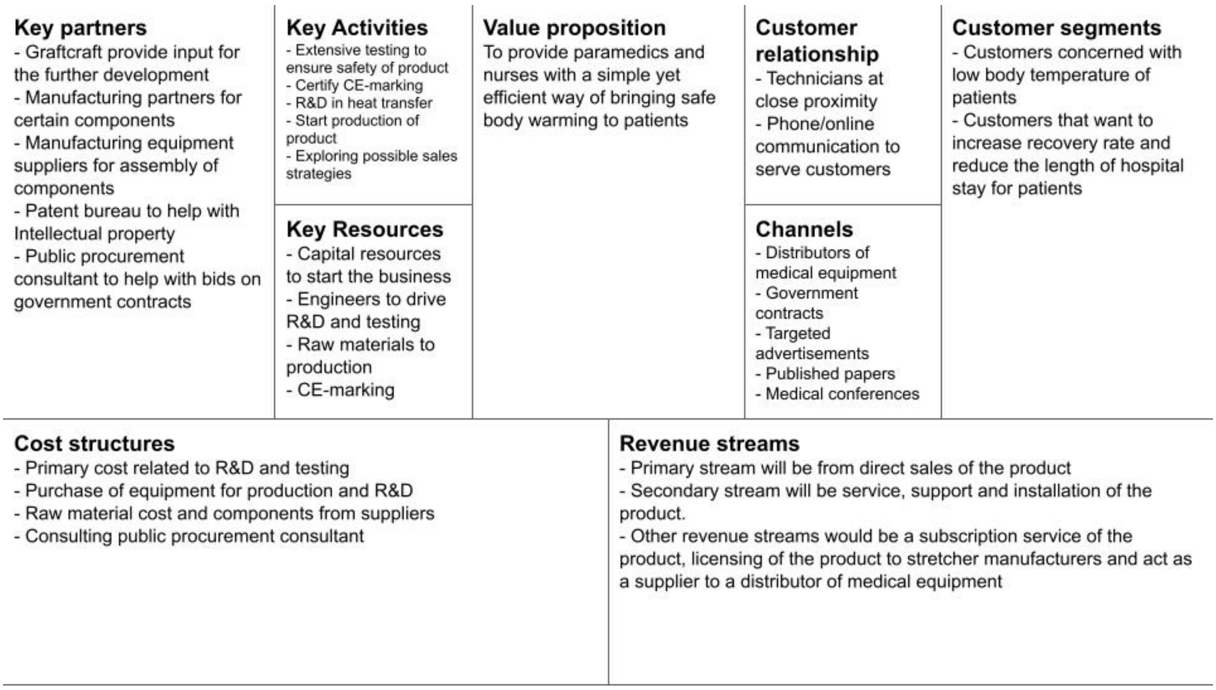

Figure 65: The business model canvas created for the product

Key Partners
Key partners represented the partners that forms a strategic relationship for the business. Partners for this business would be Graftcraft, one of the supervisors for this thesis is engaged in this company. The supervisor has previous experience with medical equipment and running a start-up company. There also needs partners that can supply production experience and equipment to be able to assemble the product in-house. Although there is some assembly and manufacturing in-house the majority of the components will be bought from partner suppliers. Lastly, strategic partnerships regarding Immaterial rights and CE-marking is essential. Here a business would be needed to support the management the IP-rights and to make the product CE-marked.

Key Activities
Key activities are tasks or activities that needs to be performed in order to operate the business. Here the activities regards research and development but also testing. These are important activities for a new product that is to be launched. Extensive research and testing would improve the performance and drive the further development of the product. The testing is necessary to make sure it complies to regulations and legislation's. The CE-marking is essential for launching the product on the EU market, every product that is to be sold in this market requires a CE-marking. Further, the production of units needs to be underway as well which requires planning. An important activity is also to evaluate the sales strategies that exist for the product, which would need to be determined as the product is launched.

Key Resources
Key resources are the assets that are required to run the business. The initial resources that needs to be sourced is capital. The capital will allow for the business to get started: both the production and the management of the product. Next up is the engineers required to drive the development and testing forward, without the engineers alterations to the product cannot be made. Another assets are staff, equipment and materials for the production. It is essential that the production of the product will be done in-house to be able to solve early issues of the product and have short lead time. Last but no least, the CE-marking is an important aspect of the product in many ways. To be a certified CE product is necessary for selling the product in the EU.

Cost Structure
Cost structure is the costs associated with the operation of the business. For this business the primary cost will related to research and testing since this will be the primary focus of the company. The product needs to be further developed and that requires both manpower, time and equipment. This is also related to the production equipment. This equipment needs to be bought and maintained as the production starts. Raw material and components will always be a cost for the company. However, it is not only physical costs there is also costs related to selling of the product. Here the consultant for public procurement will be a short time cost.

Value Proposition
The value proposition is an essential need that the product is trying to solve for its customers. The value proposition for the business is to provide paramedics and nurses with a simple yet efficient way of bringing safe body warming to patients.

Customer Relationship
The customer relationship states the relationship and interactions the company will have with its customers. It is also important to highlight what level of supports customer has. The model would incorporate technicians that has a close proximity to the different customers. They can help the customers with installation, tailoring the product for each customer and trouble shooting. Another interaction with the customer would be online and phone communication to solve minor issues and to allow for a quicker communication.

Channels
Channels describes what methods will be used to deliver the value proposition to the customers. The canvas allowed for the identification of several methods. The first was an distributor of medical equipment, here the idea is that major distributors already have several similar products in their inventory and can therefor also sell this product. Another method would be public procurement through government contract. Here it is up to the supplier, in other words this business, to put in a bid and describe why this product fulfills the desired need. This could either be if it has additional performance, low cost or a combination of these. Other ways of interacting with the customer are a visual and learning method. The visual method would be to have targeted advertisements that would let the customer know more about the product. The learning method can be split into two, one is to publish papers about the product and one is to attend medical conferences. The former has its advantage of being able to show the performance and that the product is evaluated from a scientific reasoning. The latter has a vocal interaction with the customer and allowing for a continuous conversation.

Revenue Streams
The revenue streams describe how revenue will be generated in this business and the different ways that it can be generated. Revenue can come from different types of sales. Here the business model can be altered depending on the sale tactic. There is three main ways of selling the product, these are direct sales, subscription service and licensing. The direct sales would be to sell the product straight to the customers, this could be from for example government contracts. Then there is the subscription service where the customer would pay a fee per annual for example. In return the customer would have the product at their hands to use and all associated costs with the product would be paid for by the seller. Thus if the customer(s) does not or do not want to pay for the service the product is going back to the seller. Lastly, there is the possibility of licensing the product to a distributor which would pay for the unique design of the product. The distributor would pay to access these designs and would manufacture them by themselves. In this way the seller would only be responsible for the licensing part and not the finished product.

Customer Segments
The customer segment tells what customers the business intends to interact with. Intended customer segments for the business model is customers concerned of low body temperature. This customer has experienced the problem in either a pre-hospital or hospital environment. The customer will have the ability to address this problem by the product with its performance. The other customer is one that wants to increase recovery rate and shorten the hospital stay for patients. This customer would be interested in the product due to its ability to keep the patients at the optimal body temperature. Accord-

ingly, the patient will not risk any severe consequences of low body temperature. Thus reducing the length of hospital stay and increase the recovery rate.

9

Final Product

This chapter presents the final concept. The illustrations were added to assist the presentation. Then, the use scenarios would also be displayed by the use of digital renderings. At the end of this chapter, the drawing and exploded view of the final concept was made, to easily understand the material choice and structure of the final product.

9.1 Features of the Product

This concept was made with the intention of replacing the normal mattress in a stretcher or an operating table. This provides external heat energy to patients suffering from low body temperature. This concept consists of two main parts: the passive warming blanket and the underneath active warming mattress. The combination of parts allows for higher heating efficiency.

The passive warming blanket is assembled with the active warming mattress by a double zip structure on both sides, as can be seen in Figure 66. With this structure, the whole upper or lower part of the blanket can be folded separately to uncover the upper torso or lower limbs of patients. Visible in Figure 67 and 68.

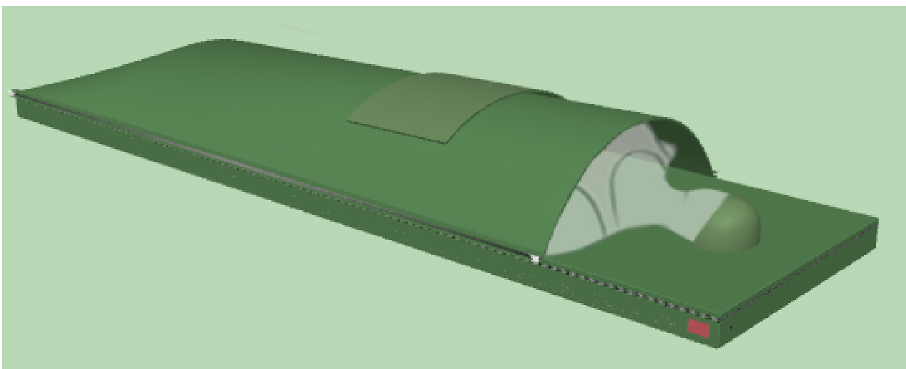

Figure 66: The final product: Showing the complete cover of a patient

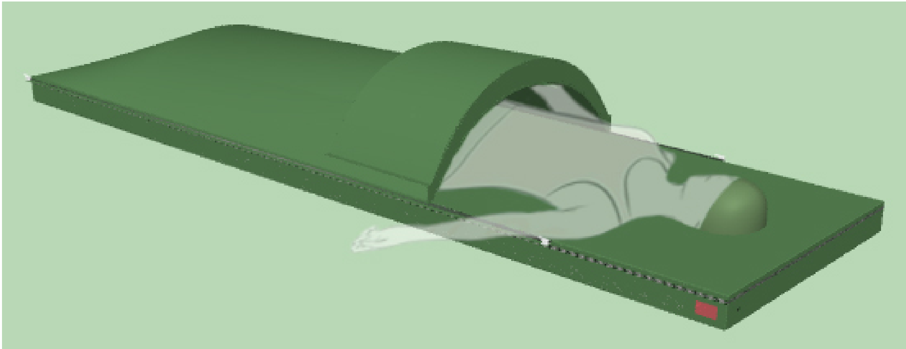

Figure 67: The final product: Showing the uncovering of the upper torso

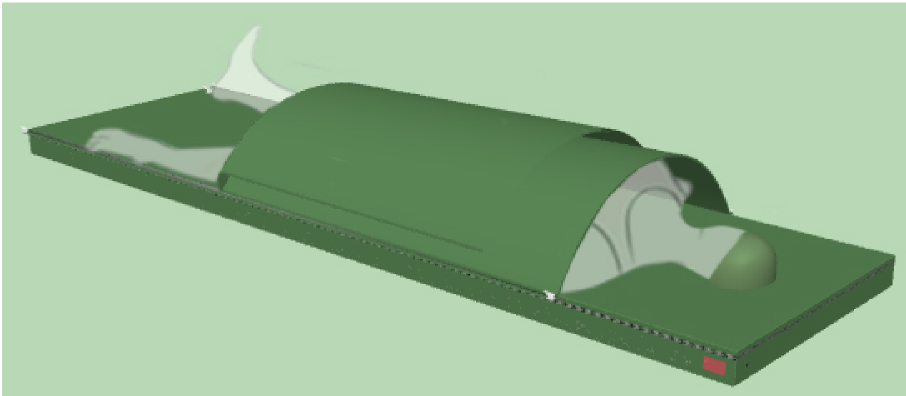

Figure 68: The final product: Showing the uncovering of the lower limbs

An additional feature of the blanket is that there is access to the body parts beneath the blanket. The access is a hole made in the middle of the blanket. The hole primary usage would be in operational theaters since certain body parts have to be accessed while the patient is covered by the blanket. As shown in Figure 69 below, a piece can be folded back to expose the hole. Compared with opening the complete zip structure, this hole allows for passive warming to be in effect since only the hole is uncovered.

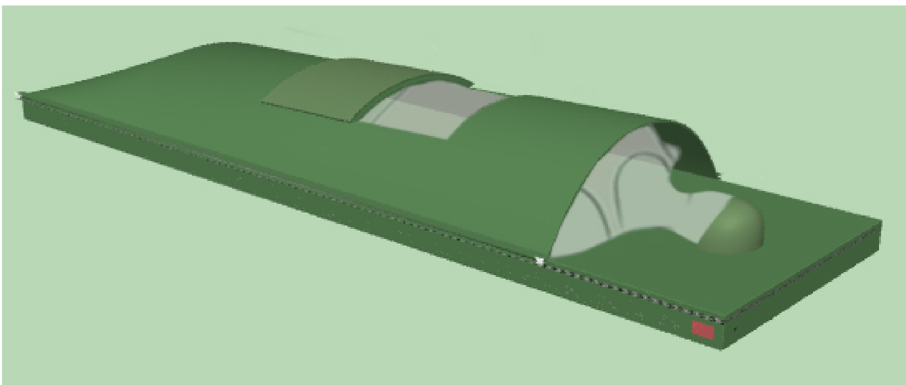

Figure 69: The final product: Uncovering of the middle part to access the lower abdomen

The active warming mattress uses resistance heating as the heating method. Due to the layers which were shown in 73, the heat generated by the resistance heating will mainly flow upwards to patients. Moreover, to prevent the heat loss from the gap generated by the zip structure two layers of fabric were added. This to cover the zip structure, which looks similar to that of a water- and wind-proof jacket. The structure is visible in Figure 70.

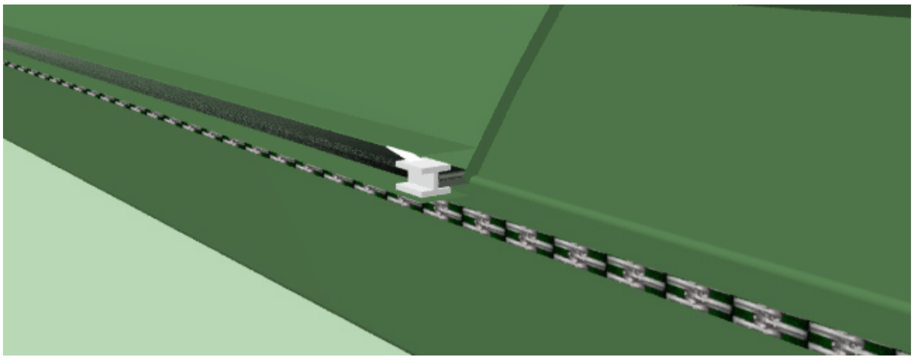

Figure 70: The final product: Showing the developed protection sheet for the zips

An isolated hood is integrated into the cover sheet, placed where the head of patients will be. Once patients lying on the mattress, the paramedic can wrap the hood to cover the head and ears of patients. In turn, the heat loss will be reduced. It is visible in Figure 71.

To be able to provide heating outside of the ambulance, especially at the location of the patient, a battery was designed and implemented into the mattress. In this way, the heating can be powered regardless of location. An on/off button was added to be able to turn it on/off with a red indicator stating its status. The indicator and cable can be seen in Figure 71. When not in an outdoor or remote location, the battery can be charged and plugged into a normal power outlet for almost 1 hour. Therefore providing direct power to the heating. The cable is stored in the cable box when not in use, seen in Figure 72.

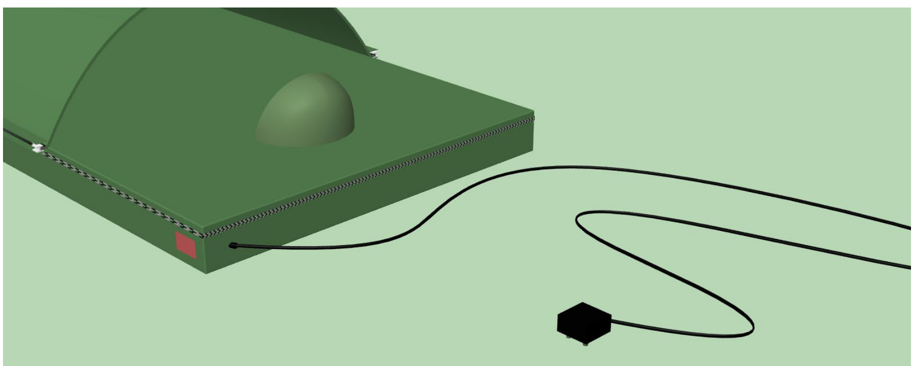

Figure 71: The final product: Showing the charging cable and red on/off-button

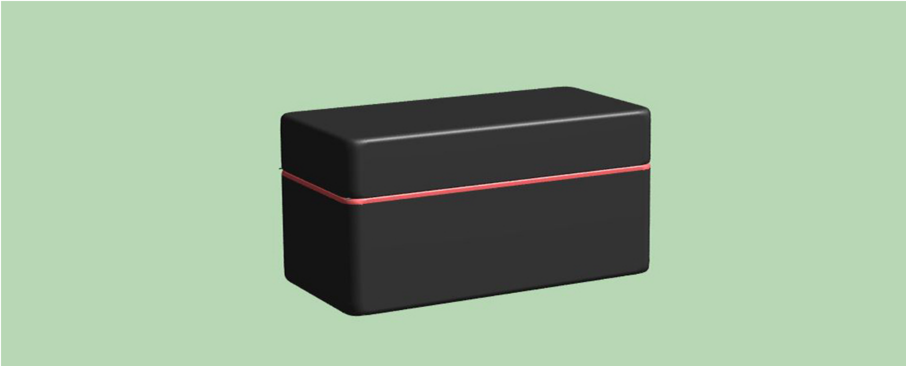

Figure 72: The final product: Showing the cable box where the charging cable is stored

The heating system of the concept has proven to be safe enough for patient use. The usage of only one heating level ensures that the heating temperature is not raised to a dangerous level. This to prevent any burn injuries to occur. The heating temperature was set to one level. The one heating level also allows for paramedics to pay less attention during transportation due to the inherent safety of the system. Hence, a simple operation of the system.

The reason why this concept can replace the normal mattress was that this mattress can adjust to the shape of different bodies. Thus supporting patients well due to the foam layer of the mattress and similar to that of a normal mattress. With this layer, the mattress can be bent a maximum of 75 degrees. It is also a modular concept, where the size and shape of the mattress can be altered to fit different scenarios and patient carrying systems.

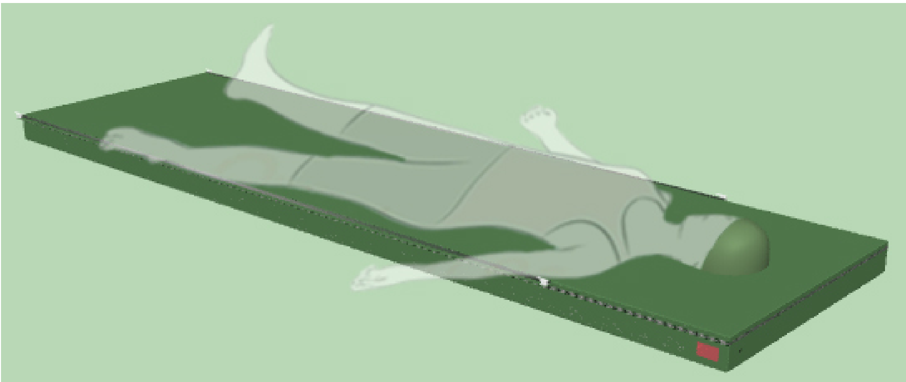

Figure 73: The final product: Showing the mattress beneath a patient

The mattress and the blanket are defined as re-usable since the usage of a cover sheet was used. The cover sheet is made of a polyurethane-coated fabric which is water-proof and prevents any debris to penetrate the inner structure. The cover sheet can easily be clean with surface disinfectant or thrown in the washing machine. Allowing for a quick clean to be able to be used in again. The cover sheet can be detached from the mattress by zips.

9.2 Use Scenarios

The concept's primary use scenario is pre-hospital care. A combination of safe warming and portability allows for the concept to be used in an ambulance and at scenes of accidents. However, special features allow it to work in operational theaters. The modular mattress grants the possibility of accommodating different stretchers and operation tables. Both the shape and size of the mattress can be altered to fit appropriately. The concept can be seen in different use scenarios in Figures 74, 75, 76 and 77.

Figure 74: The concept used on a regular stretcher, modified from (Supply, 2021).

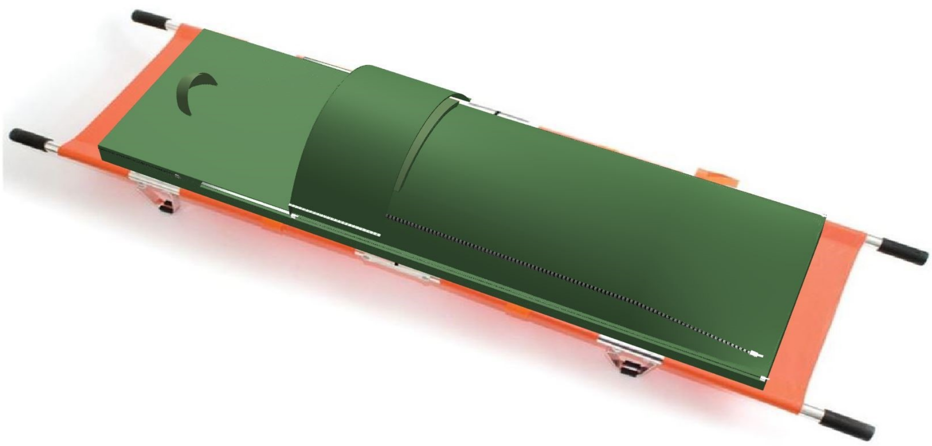

Figure 75: The concept used on a foldable stretcher, modified from (Cross, 2021).

Figure 76: The concept used on a handle stretcher, modified from (FERNO, 2021).

Figure 77: The concept used on a operation table, modified from (Hospital, 2021)

9.3 Product Size

The dimensions associated with the blanket mattress and cable box can be seen in the figures below. Figure 78 for the blanket, Figure 79 for the mattress and Figure 80 for the cable box.

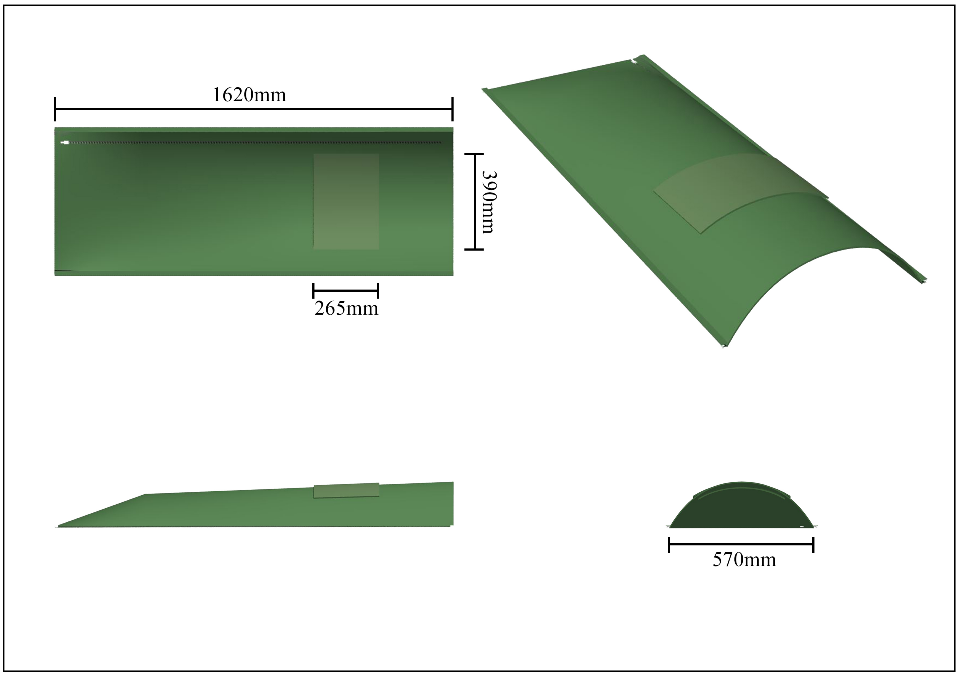

Figure 78: The figure shows the dimensions of the blanket

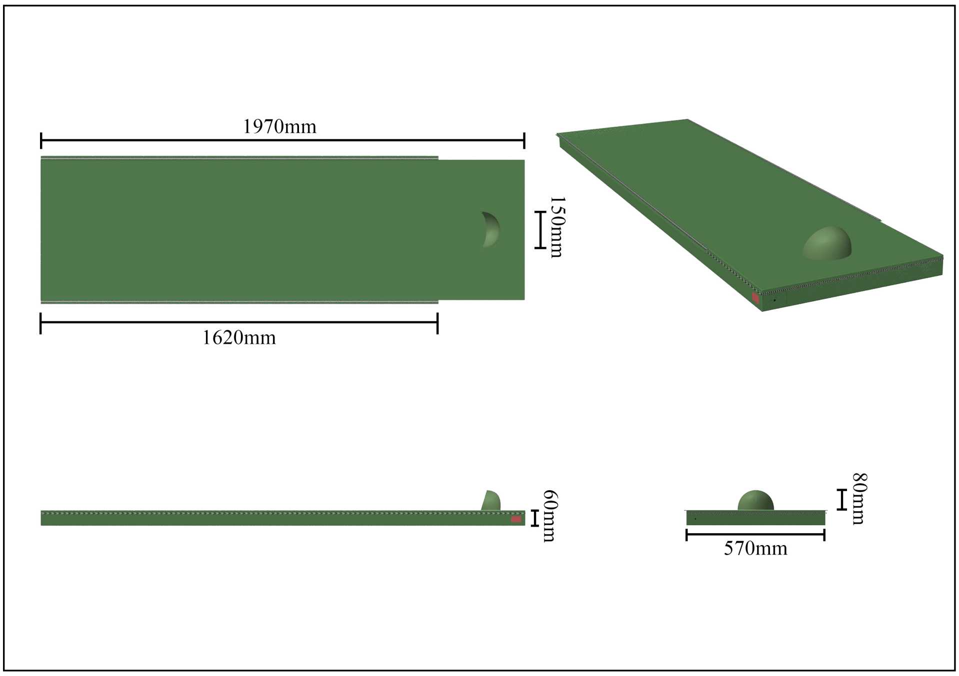

Figure 79: The figure shows the dimensions of the mattress

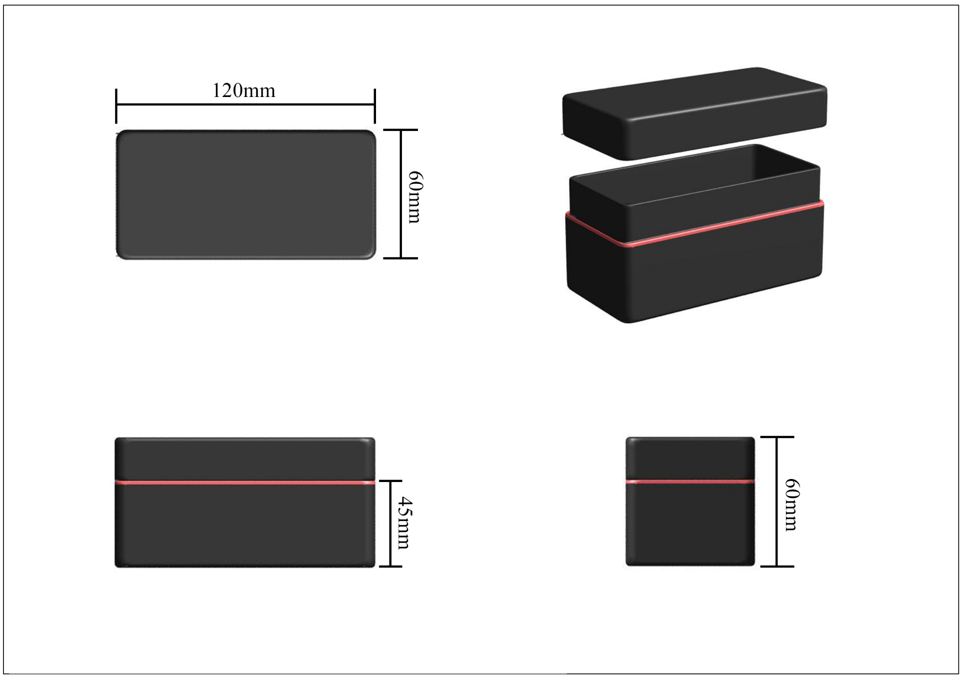

Figure 80: The figure shows the dimensions of the cable box

9.4 Layers & Material Choice

This section will present the layers for the two major parts of the concepts. It will also present the material choices that has been made for each of the layers.

9.4.1 Passive Warming Blanket

The passive blanket is made of an inner blanket, an outer sheet, and zip structures. The layers can be observed in an exploded view in Figure 81. The inner blanket was made of acrylic fabric which has an excellent capability of preventing heat loss while providing comfort for patients. The outer sheet was made by polyurethane coated fabric which is water-proof and can prevent infiltration of fluids and debris. The zipper structure on the top of the sheet allowed the inner blanket to be put inside or taken out. Therefore, the sheet can be removed to be washed after each usage.

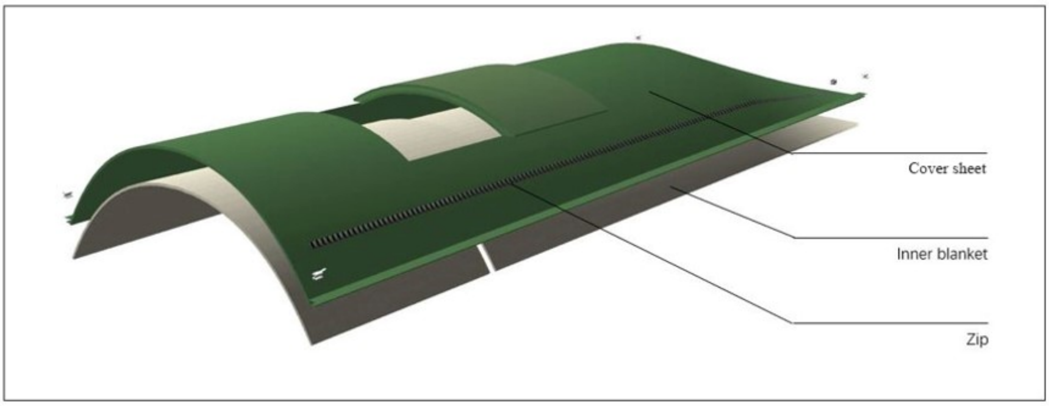

Figure 81: An exploded view of the blankets

9.4.2 Active Warming Mattress

The mattress was constituted of six different layers, all the layers are visible in an exploded view of the mattress in Figure 82. The cross-section of the mattress is visible in Figure 83.

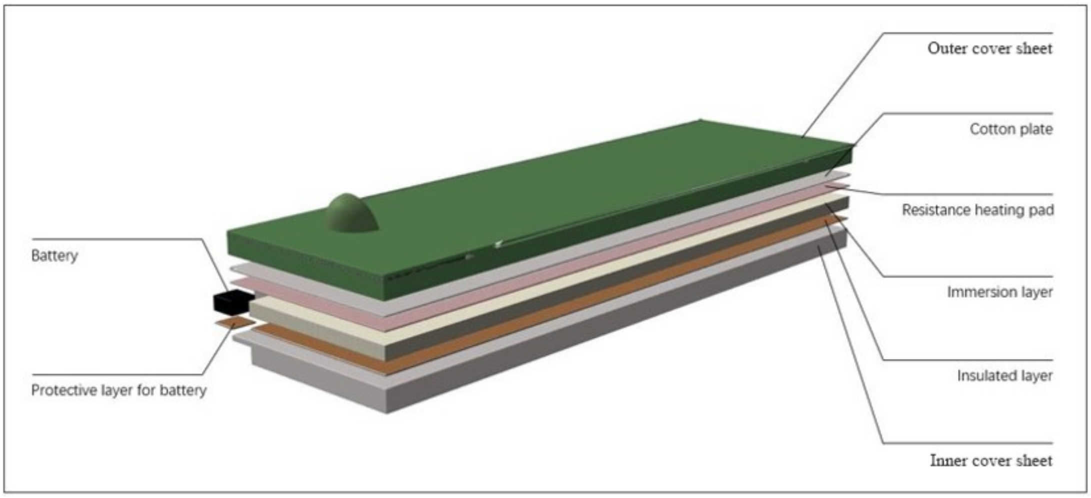

Figure 82: Exploded view of the mattress

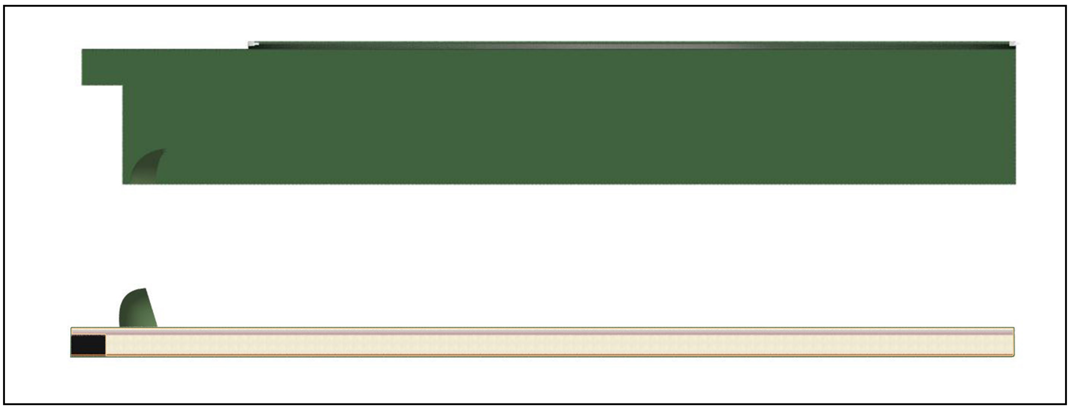

Figure 83: Cross section of the mattress

The cover sheet of the mattress was at the outermost periphery in Figure 82, which covers the inner structure. This sheet was also made by polyurethane coated fabric, as the passive blanket, due to its ability to be water-proof and easily disinfected.

The next layer is the cotton plate, this layer acts as a protective barrier for patients. The cotton layer allows for a barrier to be created to prevent direct skin contact with the resistance heating pad.

The resistance heating pad consists of a resistance wire. The wire is laid across the complete surface area to be able to heat patients. The wire is from Elfa Distrelec with properties that enable a heating effect of 57.76 W over the surface (E. Distrelec, 2021b). The performance of the heating can be divided into a worst- and best-case scenario. Where the worst-case scenario is when the passive blanket is not used and the best-case scenario when it is used. For an average man it takes 3.55 hours in worst-case scenario and 2 hours in best-case scenario. For a average women the performance is 2.878 hours respective 1.67 hours.

The immersion layer is made of memory foam to be able to provide comfort to patients. The foam was chosen for its ability to handle different body shapes and weights. But also the ability to prevent heat loss. Further, the foam intended to achieve an immersion of patients. The immersion is believed to increase the heating surface area and therefore increase the heat transfer efficiency.

An insulating layer is added at the bottom of the inner structure, this layer is meant to keep as much heat as possible within the mattress. It is also meant to prevent the environment to penetrate the mattress so it protects the inner structures. The material chosen was acrylic fiber since it has good insulating properties.

The battery which is at the same level as the immersion layer in the structure occupies a small space in the mattress. The box in which it is mounted can be seen in Figure 80. To be able to change this battery a hole has been made in the cover sheet. To protect the five layers of the inner structure these should be separated from the battery. Therefore, an inner sheet was used to sealed these layers using acrylic fabric.

9.5 Final Requirement List & Fulfillment of Requirements

When developing a concept, the requirement list is review throughout the development. The results of the constant revision of requirements can be seen in the final requirement list displayed below in Figure 84. Then, a comparison of features of the final product and the final requirement list was done to evaluate the fulfillment.

9.5.1 Final Requirement list

Requirement	Demand/Wish	Value	Metric
Applicability to different scenes	Wish	2	0- Ambulance stretcher 1- Ambulance strentcher + operation 2- Ambulance+stretcher+chair + operation
Applicability to different scenes	Demand	0	0- Ambulance stretcher 1- Ambulance strentcher + operation 2- Ambulance+stretcher+chair + operation
Automatic level	Demand	1	0 - User operated 1 - On/Off 2- Adjustable heating 3- Feedback loop
Maximum contact temperature	Demand	<40	Celsius
Body parts not to cover	Demand	Head and left arm	Body parts
Level of complexity	Wish	Std.>unique	Nmb. of comp.
Minimum life time	Wish	5475	Uses
Minimum life time	Demand	3650	Uses
Maximum heat loss to patient	Demand	5	%
Minimal heat loss to the surrounding area	Demand	30	%
Maximum mounting time	Demand	90	seconds
Maximum mounting time	Wish	60	seconds
Must be able to be disassembled to the degree that the parts can be recycled	Demand	30	%
Maximum noise level	Demand	30	dB
Maximum heating level	Demand	0.5	Celsius/hour
Reusable when washed	Demand	40	degree wash
Reusable when cleaned with surface disinfectant w/tensid	Wish	Yes/no	Yes/no
Minimum shelf lifetime	Demand	5	years
Should be able to be dissambled in order to facilitate recycling of materials	Wish		
Minimum surface contact area	Demand	36	% of human body
Maximum time to cool	Demand	5	min
Maximum time to heat	Demand	5	min
Maximum material cost of product	Demand	3000	SEK
Maximum weight	Demand	5	kg
Maximum weight	Wish	<3	kg
Minimal working time outside of the ambulance	Demand	1	Hr

Figure 84: The figure shows the final requirement list

Compared with the target requirement list made in Chapter 2.3, some changes were made. The *Maximum burn level* was turned to be *Maximum contact temperature* since the *Maximum contact temperature* could more directly reflect the risks of burn injuries. It was determined that the maximum contact temperature should not be higher than 40 °C.

The value of *Maximum noise level* was turned down to the 30dB. Although the regulation allows a maximum of 77dB inside the ambulance, this value was too high since it would interrupt the communication between paramedic and patient. Normally, 50 dB was a good choice which can make people comfortable with the noise level. In addition, the impact of other noises should also be taken into considerations. Therefore, it was determined that *Maximum noise level* of the final product cannot exceed 30dB.

The performance was not to be measured by the output temperature anymore but by the heating rate. To rectify low body temperature, the heating rate should at least reached 0.5 °C per hour.

Then, the requirements *Time to cool* and *Time to heat* were assumed to have similar values. It was determined that 10 minutes was too slow since there is limited time to heat patients during pre-hospital care, this since the transportation to the hospital may not be that long. But 3 minutes to heat was too quick and may cause a burn injury. Therefore, the final value for these two criteria was set to 5 minutes.

The *Maximum total cost of product* was changed to be *Maximum material cost of product* since it was difficult to evaluate the total cost later due to the limited resources. Besides, the value was raised to 3000 SEK to accommodate the number of materials needed.

The demand of weight was also be adjusted because the previous setting might be hard to achieve. The maximum demand weight was set to be no more than 5kg now while it was hoped that the product can be less than 3kg.

When reviewing the final requirement list, this concept fulfilled almost all the demands. The demands that may not be fulfilled are *Life time* and *Heat loss to patients.* These two demands cannot be evaluated with limited testing resources. From testing, see Section 7.3.3, it seems that the heat loss when transferring heat to patients is larger than 5 %. But to confirm this further testing was needed. In this project, these two criteria were only be assumed to fulfill the demands based on research and experience.

It should be noted that the heating rate may not achieve the set demand. Estimations using calculations show that the fastest time to heat was 1.67 hours with the passive blanket included. Thus, the demand is not fulfilled for this concept.

10

Discussion

This chapter will conclude what was achieved as well as what had not to be covered in this thesis. Some abstract suggestions were also introduced based on the testing result.

10.1 Heating Rate

The calculation of heating rate gave an indicate whether the concept could perform as a way of heating patients. The results from the calculations showed that the heating rate was too low to fulfill the requirement of 0.5 °C per hour. Rather, the best result was in 1.67 hours to heat 0.5 °C which is a bit off target. But a factor that has not been taken into consideration was how effective passive warming from the blanket will be. The test showed that an insulating layer will keep more of the heat. An assumption was made from the test results, which was that the blanket provides a similar effect. Hence, the calculations depend on this assumption. However, the actual effect of the designed passive blanket is unknown and may keep more or less heat. Additional development and testing of the passive blanket is recommended to provide more a accurate calculated heating rate.

Another explanation for the lack of heating rate was the heating effect. The designed heating effect of 57.76 W resulted in a low heating rate. This due to the assumptions made from the tests. Where assumptions were made regarding the correlation between surface heating area and heating effect. The correlation established that the coverage of the surface area in a percentage correlates to a percentage of available heating effect. Thus the heating effect transferred to a patient was based on the maximum heating effect available over the whole surface and the coverage of the surface area of a patient. This was an easy way of calculating the available heating effect for the surface area that was covered. By incorporating the losses found in the tests, the calculations could provide the heat transferred to a patient. But, these assumptions may not be accurate or correct in the real world. Which made this heating effect questionable.

However, the heating rate is not proven to be insufficient yet. Testing would allow for further investigation into the optimal heating effect to achieve the desired heating rate. With more investigation, if real test results show that the heat provided by the resistance pad is too low, a higher power resistance pad can be used in the mattress. In this project, the lower power resistance pad was chosen to prevent burn injuries. This means that the power can be revised easily to be able to produce a higher heating effect. But one must still remember that a balance between burn injury risk and heat effect should be accomplished.

10.2 Proof of Concept

The calculated heating rate showed that the product could fulfill one of the main objectives. The objective of providing heating equivalent to established products was fulfilled. The heating rate was low, but in comparison with established products, it was equivalent or better. The established products in pre-hospital care were mainly blankets and chemical pads. The blanket only keeps the temperature and does not add any heat, in this regard the product was superior. Another established product was the chemical pad, the chemical pad performed better in regards to actual heating rate. But its disadvantages were the lack of safety and re-usability. The pad can only be used for a certain amount of hours until it no longer warms. Safety was also lacking since there is a need for a safety layer between the pad and the patient. Otherwise, burn injuries would occur. With these established products in mind, the product performed superior. When making a comparison to established products in the secondary target market, the operational theater, the product performs admirably. The product has a larger amount of passive warming than the standard forced-air warmers used. Although the forced-air warmers have a higher heating rate they also have a higher risk of causing burn injuries. While the product has a combination of active and passive warming which allowed for safer heating.

10.3 Heating Method

The choice of heating method was determined in Section 7.1.1.1. The heating method chosen was resistance heating. This due to its proven concept, cost, and reliability. However, another heating method that was investigated was PTC-heater. The reason why it was not chosen as the heating source was the associated cost. Although PTC-heater was not chosen in this concept, it is still a viable heating source. It provides uniform heat across the surface, has built-in passive safety and no control system is needed. There were a lot of features identified in PTC-heaters which was of great interest. The features would have provided a better concept. But since the cost of the heater was too steep compared to the established heating method it was ruled out. If the cost of PTC-heaters can be reduced it would have been the obvious choice.

10.4 Thermal Conductive Layer

In this project, the thermally conductive layer was excluded due to low cost-efficiency. The tests showed that the performance of this layer can be relevant. However, the cost that the layer ruled it out. The cost of the layer did not balance the minor impact it had on the heating. As stated previously, further sourcing of thermal compounds at a lower cost would be good. This since the test showed that the layer could improve the heating efficiency. What also needs to be discussed is the usage of the layer, it may increase the heating efficiency. But that is also tied to the heating method used. If the heating method is changed, to PTC- heaters as an example, the layer may not be useful.

10.5 Control System

In addition, the heating control system could also be redesigned in the future. Currently, the heating system has constant heat for the patient. With the fixed effect, the heating temperature would not be higher than 40 °C to prevent burn injuries. Detailed information can be found in section 7.1.1.3. However, this fixed heating system limits the options for paramedics. For example, the energy provided by this concept might not need to be so high for patients close to normal body temperature. In this case, only keeping the temperature is needed, so a lesser heating effect could be a better choice. On the other hand, the heating rate could also be raised to heat moderate hypothermia patients. Who is in need of more heat? When applying a higher heating effect, sensors should be added inside the mattress structure to measure the temperature of the contacting skin to prevent burns. Therefore, the design of smart heat regulators will be an addition worthwhile.

The heating control system can also be further designed for serious hypothermia. This design process had the delimitation of not including serious hypothermia. But for the concept to be able to rectify serious hypothermia, other heating rates and special considerations of the heartbeat have to be taken into account. Making the concept completely different from its current shape and form. Additions can be made, however, education of paramedics about the issue but also to adjust the heating method to accommodate for the serious hypothermia.

10.6 Business Plan

The business plan which was visible in the Chapter 8 described the initial business model canvas plan of how to cooperate with others to sell this product in the market to get the benefits. But the statements were all from the abstract level since the final product should be further confirmed and there was still a lack of knowledge and information of the business plan. With the current plan, it was even hard to determine the price setting. Thus, this plan should be updated to a high detail level once the product will be ready for production. For example, the manufacturers and material suppliers should be contacted to get first-hand data for the precise total cost estimation. At the same time, the promotion method, expected benefits, the transport channel, and other factors should be modified with the market trend which can allow the business man to follow. To set a reference, a financial plan about how much the company can earn from this product can also be included in the business report, which in turn makes this plan reviewable and measurable. More important, through this financial plan, the businessman can have an estimation of it is necessary to have this business and how big the investment should be to take this project. To get the best planning report, a team that focuses on this field can be contacted in the future if the resources are available.

11
Conclusion

The aim of this thesis was to develop a product that can solve the issue of low body temperature. This using active heating to provide additional heat to the patient. The developed product aimed to be used in pre-hospital care as well as in the operational theater, where the issue is most common.

The four main objectives were to provide equivalent heating as established products, provide safe heating without causing burn injuries, be comfortable for paramedic and patient to use and to do it at a lower cost than other products. With regard to these four objectives, the developed product fulfilled each without exception. The main competitor for the developed product was a blanket for the pre-hospital care and a forced-air warmer for the operational theater. The blanket does not provide any additional heat to the patient and therefore it does not solve the problem of low body temperature. Though the forced-air warmer provides a better heating rate, the heat provided can burn patients. The cost of forced-air warmer also surpassed the developed product which in turn fulfills the objective. Thus, the developed product performed better with regard to the competitors.

The developed product in this thesis brings reliable and safe heating to patients in a pre-hospital setting. Due to its portable properties, the product can be brought to the scene of accidents. This to provide immediate heating at the first possible moment. Providing a sense of comfort while raising the body temperature. The heating can continue until the ambulance reaches the hospital, contributing to the process of rewarming for a long time. In addition, the product can be reused after cleaning with surface disinfectant. Thus, ready for the next call almost immediately. The cost of this performance is minimal compared to established products. The product can be easily integrated into an ambulance by replacing the existing mattress.

With the stated above, it can be concluded that the developed product will solve the problem of low body temperature in pre-hospital care. The lack of active heating products was the reason for developing this product. It is believed that using this product in this setting can be solved. The predictor for mortality, which is low body temperature, will be reduced while a reduction in recovery time for patients will be observed. Thus, the cost for society will be less when the recovery time is shortened. Resulting in a lower cost in time and money. The recoup time will be short due to the low price of this product.

In conclusion, the product developed should be put into service in order to save patients from suffering low body temperature. It can be done in a heartbeat at a low cost. This should be implemented in most ambulances to make a difference. However, additional development is necessary to provide a proof of concept.

12
Recommendations

This chapter presents recommendations for further development of the final concept. Recommendations regard the fulfillment of requirements, heating rate, control system among others.

Further Testing

First of all, the designed final product requires further testing. As stated in Section 9.5, two demands cannot be evaluated due to limited testing resources, only assumptions could be made. The demands were the heating rate and the lifetime of the device. Therefore, a prototype of the complete final product should be made together with appropriate tests to determine the actual lifetime and heating rate.

Passive Blanket

The actual effect on heat transfer is unknown for the designed passive blanket. Assumptions were made regarding the effect which affects the calculations to a degree. Additional development and testing of the passive blanket is recommended to provide more a accurate calculated heating rate.

Control System

An intelligent control system was of interest for this product. The addition of such a system would provide more adjustable heating which can tailor the heating effect to different body temperatures. The control system could be a combination of sensors and a PID regulator. Together with a feedback loop, this control system could be adequate for the problem.

Compatibility With Different Scenarios

The current product was only compatible with operation tables and stretchers, but it was not suitable to be used on the chair inside the ambulance. According to the experts, sometimes patients sit on the side chair instead since some injuries are not severe. In this case, this product cannot achieve the goal of heating patients. It is better to develop a solution that can be compatible with all the scenes. If it is impossible to achieve because of the complexity, a series of products that can be used on the chair should be developed.

Cable Management

To make this product more attractive, certain details could be refined. One detail was the cable management, where it is stored in a cable box. Incorporating the cable in the mattress would be more practical and easier to use for the paramedic. Therefore, the paramedic can always take the cable with this product rather than paying attention to the cable box. Moreover, the storage of the cable would not be necessary.

Exotic Materials

The materials of this product could be considered to see whether it is possible to find similar or new materials which are the cheaper and better performance to replace the existing ones. For instance, could it be possible to replace the material inside the blanket to improve passive warming?

Thermal Conductive Layer

Through tests and calculation of the cost, it was found that the cost of the thermally conductive layer was high while the performance gain was marginal. The thermally conductive layer was removed due to the low cost-efficiency. However, if further tests can demonstrate that this layer would cause a difference in heat transfer, it could still be added to the product.

PTC-heater

The focus of further development maybe how to reduce the material cost of PTC-heater. This means that the development can be from two perspectives: one is to reduce the consumption of PTC-heater to reduce the cost while the other is to find alternative sourcing to find a low price PTC-heater. If there is a possibility to use the PTC-heater in this product with acceptable costs, the performance of this concept would be better than the current one.

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