

Integrative Design of Biomedical Products

ECMOVE

Increasing the mobility of VV-ECMO patients

Group 6

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Abstract

Extracorporeal membrane oxygenation (ECMO) is used to manage pulmonary or cardiac failure, or both. This project focuses on ECMO patients who are solely dependent on Veno-Venous-ECMO, which provides pulmonary support. Currently, patients that are dependent on VV-ECMO stay in the ICU where they are closely monitored by the ICU nurses. However, to improve the transplantation success rate and shorten the patient recovery time, it is important to improve the physical condition of the patient. Because walking has been shown to work best for improving fitness, mobility of the ECMO device is necessary. The current machines have limited mobility and a lot of staff support is needed to let a patient walk safely. Therefore, in this project, a system has been designed to allow the ECMO patient to walk safely requiring only one person of assistance. A cause-effect diagram was made to determine the main problem by analyzing all minor problems. Using a stakeholder analysis, the preferences and requirements for each stakeholder were determined. Hereafter, a list of requirements for the final product was composed, categorized, and analysed using an analytic hierarchy process. Besides, a function analysis was performed to describe all the system functions needed. Based on the functions, a morphological scheme was made to determine all solutions to fulfil a certain function. Using this information, multiple pre-concepts were designed. All pre-concepts were discussed and scored using a ranking system. The pre-concepts that scored the highest were included in synthesis II for further elaboration and defining the concepts in more detail. Based on ranking for these three concepts, the final concept was selected. For the final concept, a detailed description of individual components was described, technical drawings were composed, and calculations of forces were performed. This resulted in a final product named ECMOVE. It consists of two parts: a patient harness for safe bloodline guidance and an electric driven walking aid device to enable a safe mobility solution for ECMO patients. The ECMOVE was analysed in terms of costs and the market potential of the product was described. The final product was evaluated and a CE-marking proposal including risk management and a METC research protocol were included.

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1. Introduction

The purpose of this report is to produce a solution for ICU-admitted patients that are currently dependent on extracorporeal membrane oxygenation (ECMO) and are not able to leave their bed due to limitations of the ECMO-system. This section aims to describe how the system works and present its current state of the art.

1.1 Extracorporeal membrane oxygenation

Extracorporeal membrane oxygenation (ECMO) is used to manage pulmonary, cardiac failure or both [1]. It may be applied as a last resort, when no other treatment is or is likely to be successful, but is usually used as temporary support when awaiting recovery or transplantation of organs. ECMO is a system that takes over the functions of the lung and/or heart outside the body of the patient. Following the description of Akoumianaki et al. (2021) in figure 1, the first step is withdrawing blood from a vein via a central venous catheter. The blood is then pumped through a membrane oxygenator where gas exchange takes place. In the oxygenator, CO₂ is removed from the blood and O₂ is added to the blood. The oxygenated blood is transported through a heat exchanger in order to regulate the temperature. The final step is to return the blood back to the body with a cannula, which may be done in two different ways: via an arterial insertion or a venous insertion [2]. Using an arterial insertion, usually the femoral artery or ascending aorta, the catheter transports blood directly to the arterial system [3]. This is referred to as Veno-Arterial ECMO (VA-ECMO). As the heart gets bypassed in this way, VA-ECMO may provide both respiratory and hemodynamic support. This is in contrast to Veno-Venous ECMO (VV-ECMO), where a venous insertion (usually in the internal jugular vein) is used for the blood-returning catheter [2]. In VV-ECMO, the heart is not bypassed, meaning that it is only capable of giving pulmonary support and that the patient requires a functioning heart that is able to provide enough cardiac output. As shown in figure 1, blood may be subtracted from the femoral vein in the upper leg. However, in VV-ECMO a double lumen cannula might also be used, which means that there is a single cannula in the internal jugular vein that is capable of both withdrawing deoxygenated blood from the vein and returns oxygenated blood back to the vein. This makes it possible to connect the patient to the ECMO machine with just a single bloodline. This project focuses on ECMO patients who are solely dependent on respiratory support, which means that in the following sections only VV-ECMO is considered.

1.1.1 VV-ECMO

Many patients all over the world are currently dependent on VV-ECMO and the numbers have increased over the past decades. The incidence of VV-ECMO has risen from 1.0:100,000 inhabitants per year in 2007 to 3.0:100,000 per year in 2012 [4]. This increase is mainly due to the system being more accessible and applicable in various forms of respiratory failure. VV-ECMO can be used in various pulmonary conditions that are reversible. Application in patients with acute respiratory distress syndrome (ARDS) is the most common, which may be caused by either bronchopulmonary aspiration, bacterial/viral pneumonia, barotrauma or interstitial pneumonitis [5]. The goal of applying VV-ECMO in these patients is to give the lungs rest and time to recover while preventing hypoxemia and hypercarbia [6]. Patients with advanced, irreversible diseases are usually not candidates for VV-ECMO, but the system can still be used as a temporary measure when these patients are on a waiting list for transplantation.

Patients that fall into this group may be suffering from chronic obstructive pulmonary disorder (COPD) or other forms of chronic respiratory failure. According to the Extracorporeal Life Support Organization, the average duration of VV-ECMO in ARDS-patients is 12 days [7]. The durations may however vary a lot between patients, as in 2010, a 107-day bridge to transplant with venovenous ECMO in a patient with ARDS was reported.

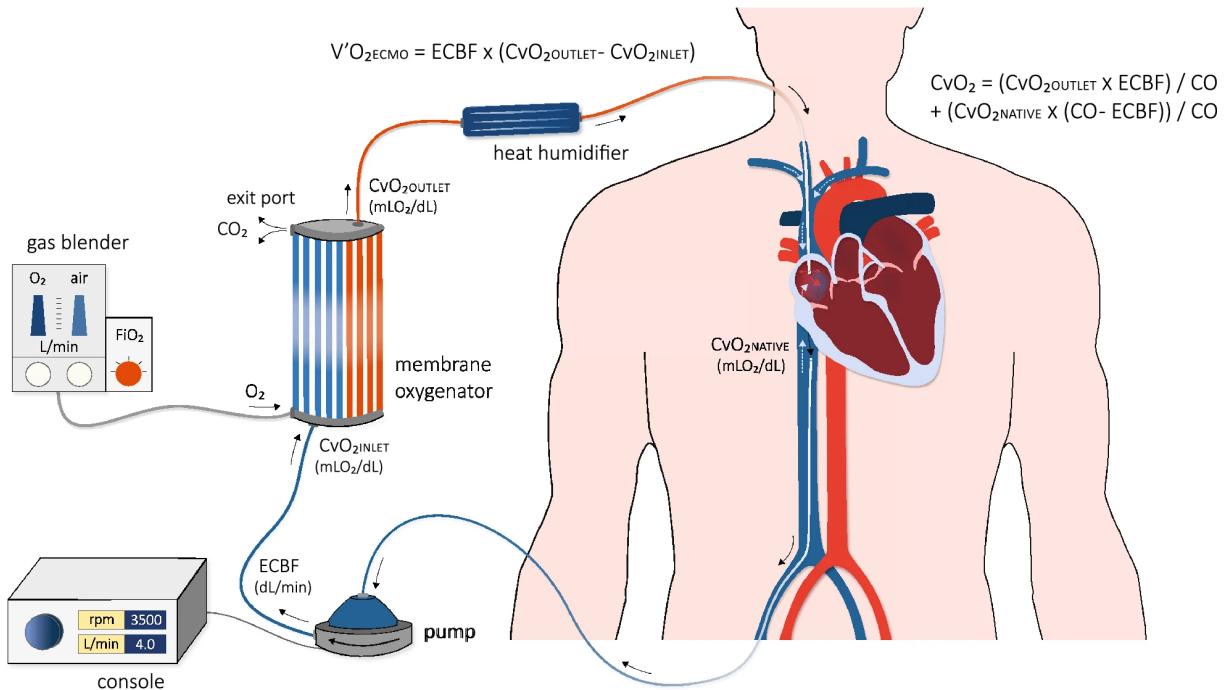


Figure 1: The different parts of the ECMO-system by Akoumianaki et al. [2]

1.1.2 The current situation

Currently, patients that are dependent on VV-ECMO stay in the ICU where they are closely monitored by the ICU nurses. These patients usually lie flat all day, as they are not able to leave their beds easily. This may however have severe consequences for the patient, since low mobility leads to longer recovery times, worse outcomes after transplantation and poorer mental state [8]. Although patients are sometimes able to perform physiotherapy and/or cycling exercises in bed, research shows that leaving the bed would lead to more active participation and would thus be more effective in training muscles and improving both physical and mental condition [8], [9]. However, as of today, patients are not able to leave their beds easily. A major reason for this is that the current ECMO machines are bulky and have heavier parts which make it difficult for the patients to mobilise. Patients require the assistance of at least 4 to 5 staff members to walk while they are on VV-ECMO. One should hold the cannula, another person to hold the patient, a third to grab all the tubes passing from and to the patient and two people to move the ECMO machine. Figure 2 illustrates the assistance requirements for when a patient wants to go out of bed.

Over the past years, several advances have been made in making the ECMO-system more compact. The smallest ECMO machines currently available in the market are Cardiohelp (Maquet Getinge) [10] and Getinge's Rotaflow II Extracorporeal Life Support (ECLS) System. Getinge's Rotaflow II Extracorporeal Life Support (ECLS) System, in conjunction with the Permanent Life Support (PLS) Set, presents as long as 14 days of cardiopulmonary help in



Figure 2: A patient walking while on a VV-ECMO machine

a minimal, convenient, portable, secure and dependable way. This gives medical care staff the flexibility they need to give quality patient care. It tends to be used for both veno-arterial and veno-venous ECMO [11]. It's light and compact enough to be used for intra-hospital transport [12]. Alongside the Compact Holder, the Rotaflow II Drive and the prepared PLS Set, the framework weighs around 6.3 kg. The PLS Set is made to help patients requiring respiratory help with blood levels from 0.5 l/min to 7.0 l/min [13]. A complete portrayal of the system can be found in figure 3.



Figure 3: Rotaflow II ECLS machine [13]

Cardiohelp (Maquet Getinge) [10] has a weight of approximately 10 kg. This system has all the required components of a regular ECMO machine, albeit a bit smaller in size, and can be used independently from the hospital

wall oxygen. The duration for use of the respiratory assist is 30 days with flow from 5.0 L/min to 7.0 L/min. The core of this machine is an integrated low-trauma centrifugal pump. With the HLS Set Advanced, patient safety is integrated into the system [14]. A complete representation of the system can be seen in figure 4.

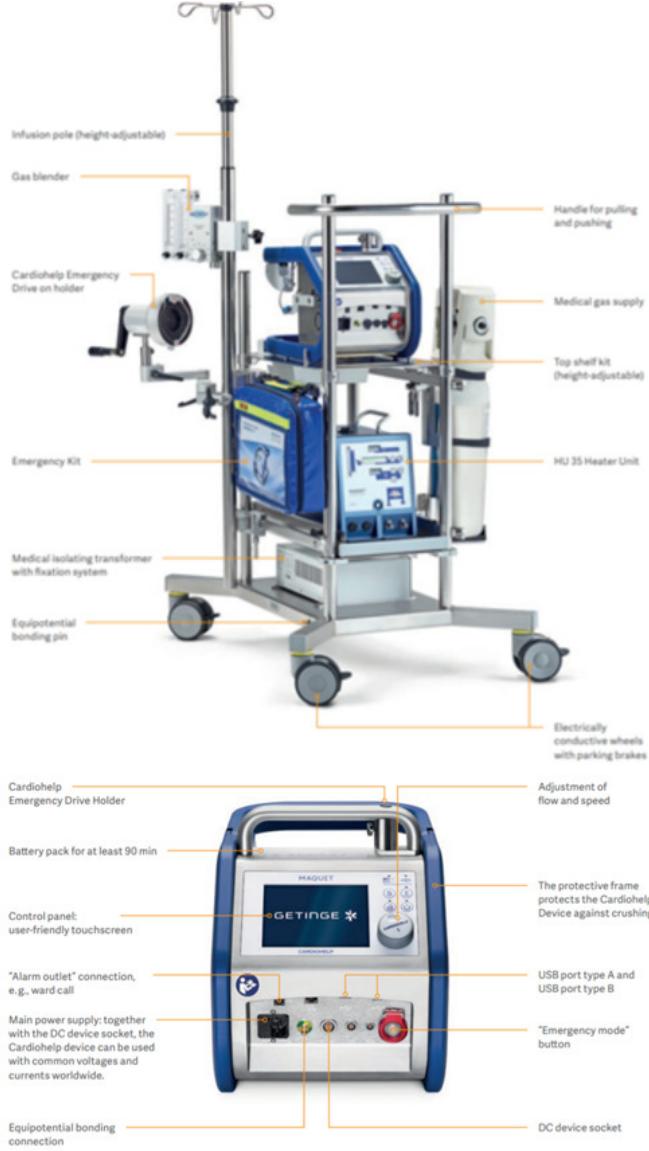


Figure 4: Cardiohelp ECMO machine [14]

Mobile ECMO devices make it possible for the patient to exercise and walk, and provide the best outcome for high risk patients in severe respiratory failure. Priority for patients in respiratory failure waiting for transplantation should be active physiotherapy. If that cannot be achieved during invasive ventilation, mobile ECMO should be considered. Mobile ECMO and spontaneous breathing might even be better than ventilator support [8]. Although the design of Rotaflow II is smaller, Cardiohelp is widely used in many hospitals. This is because the oxygenator and pump are integrated into the system making it very compact with less danger. According to Getinge, Rotaflow II is more suitable for lower budget hospitals and will not have huge market potential. Even if the design of the Cardiohelp is a good step in the direction towards mobile ECMO, it is mostly used in patient transport and not

mobile enough yet for patients to walk independently.

1.1.3 The exercise of the patient

As mentioned before, an important factor for a good outcome is the physiological status of the patient when accepted for transplantation. Patients that are waiting for lung transplantation undergo a 6-minute walk test. This is a useful tool in the assessment of when to list patients for transplantation. A 6-minute walk test result of fewer than 400 meters appears to be a reasonable marker with regard to when a patient should be listed for transplantation [15]. This gives an additional reason to promote walking while on ECMO. Another reason for suggesting walking is the Frank-Starling mechanism. The ability of the heart to change its force of contraction and therefore stroke volume in response to changes in venous return is called the Frank-Starling mechanism (or Starling's Law of the heart)[16]. The functional importance of the Frank-Starling mechanism lies mainly in adapting left to right ventricular output. During upright physical exercise, an increase in end-diastolic volume due to the action of the peripheral muscle pump and increased venous tone can assist in enhancing stroke volume [17]. Therefore, it can be concluded that walking is important for patients that are dependent on VV-ECMO.

One might wonder why it is important that patients are able to walk, as biking can be considered as an alternative for exercise. However, not all hospitals have facilities for biking. They might not have a bike that would fit in the ICU, and installing a bike in the ICU would alter the actual structure of the ICU. Also, transferring patients from the ICU bed to a bike is difficult. As opposed to cycling, walking also satisfies the patient psychologically as they are in the ICU for a very long time. The ECMO patients might have not seen the world outside of ICU for weeks or even months. Walking enables the patients to leave their room which improves them psychologically and provides space for interaction with others [18], [19].

2. Analysis

This chapter aims to define the problem, state the goal for the current project, analyse the problem in terms of the stakeholders involved and provide a cause-effect diagram of all problems and goals. Finally, the design assignment of the current project is stated along with the requirements and functions that the proposed solution has to fulfill.

2.1 Problem definition

The technological problem under analysis in this report is that current VV-ECMO devices have limited mobility. The technological problem causes the VV-ECMO dependent patients unable to leave their beds, without a lot of support from ICU-nurses. Therefore, these patients have difficulty keeping up with their physical and psychological health.

2.2 Goal

The aim of this project is to develop a system that allows VV-ECMO patients to walk in the hospital, requiring only one person of assistance.

2.3 Stakeholder analysis

A healthcare problem is a multidimensional concept; due to this, there is a plenitude of parties that take part in it. These parties are seen as the stakeholders and they take part in the decision-making of the numerous steps necessary for the discovery of the most optimal solution. These stakeholders are not the same in every situation. In this project, the stakeholders stated in table 1 are essential.

The aforementioned table takes into consideration the characteristics, expectations, potentials and/or deficiencies and implications and conclusions for the project of each stakeholder. The stakeholders can be divided into two groups: the first composed of the ones who are directly involved in the problem and the second the ones are responsible for the solution. The patient and the ICU-nurses belong to the first group since the patient is the one affected by the problem and the ICU-nurses responsible for helping the patient deal with it. The ICU-nurses themselves are indirectly affected by the problem too. Some members of society (e.g. relatives, colleagues) also belong to the first group, as the healthcare problem has an indirect impact on them as well. Subsequently, the second group consists of society, insurance and industry. These are directly involved in the solution for the obstacle because firstly, society has the power to decide if the idea goes forward, secondly insurance has the resources, such as money, to invest in the solution and lastly industry will facilitate the production.

Seldom do people realize how important each one of these stakeholders is to the solution of the health problem. For it to be concluded, every stakeholder has to give their take on the topic. Each stakeholder has their own preferences and requirements for the product, which most of the time differ between each other; this may influence the final decision.

Table 1: Stakeholder analysis

Stakeholder	Characteristics	Expectations	Potentials and deficiencies	Implications and conclusions for the project
Patient	Adult ICU-patient needing lung support using ECMO; Reduced mobility; psychological;	Leaving their ICU room for a walk of around 20 minutes, while under ECMO support, with 1 person helping; without being the centre of attention; Leaving ICU room for a wardroom	Limited to VV-ECMO; not suitable for children; Potential better outcome of e.g. transplantation by having better physical condition; improved mental health by having more social interaction and leaving the ICU; High demand, almost all (future) patients on the ICU with VV-ECMO do want to walk / leave the ICU for a moment	Might be adverse to getting other treatment (e.g. no transplantation because of high risk)
ICU-nurses	The ICU-nurses want the best for their patients, so they want them to be more mobile and more ready for e.g. transplantation.	Fewer tasks for communication between many ICU-nurses; Being able to provide more personal care; Relieve burden (work intensity, carry load)	Potentially more nurses available; Adapting to new ECMO-system;	Adverse to new solutions; Less work for ICU-nurses (either positive or negative)
Society	Consume optimal healthcare for the lowest price; Patients' close contacts want; the best outcome for the patient; They also want social interaction with the patient.	If they are in the same situation they expect to use this solution as well; Better recovery of the patient to return to society; Possibility for social interaction with the patient	Potential: There is demand for the product among members of society since family members also want to walk together with the patient	Recovery may take place outside of the ICU by mobilizing the ECMO system; Social interaction with patients is easier
Insurance	Provide optimal health care for lowest price;	Reduced hospital stay and lower chance on complications later cost-effectiveness could be disappointing	Device should not be too expensive, cost-effectiveness	
Industry	Interested in making profitable product; Easy manufacturing;	Longer return on investment	Applied to a wide range of patients, so they can sell it to a lot of patients	

2.4 Cause-effect diagrams

The cause-effect diagram describes the causes and effects of a patient who is waiting for lung transplantation and in the meantime depends on VV-ECMO. The diagram is split up into two parts: the cause-effect diagram of all problems and the cause-effect diagram of all goals, see figure 5. Ideally, one would try to intervene on the highest level of the problem cause-effect diagram, so that all goals in the goals cause-effect diagram are achieved. The goal of this project, however, is to intervene at the level of “the patient is given VV-ECMO, which is very bulky”. If a solution can be found for this problem, it would mean that all problems below this level are solved.

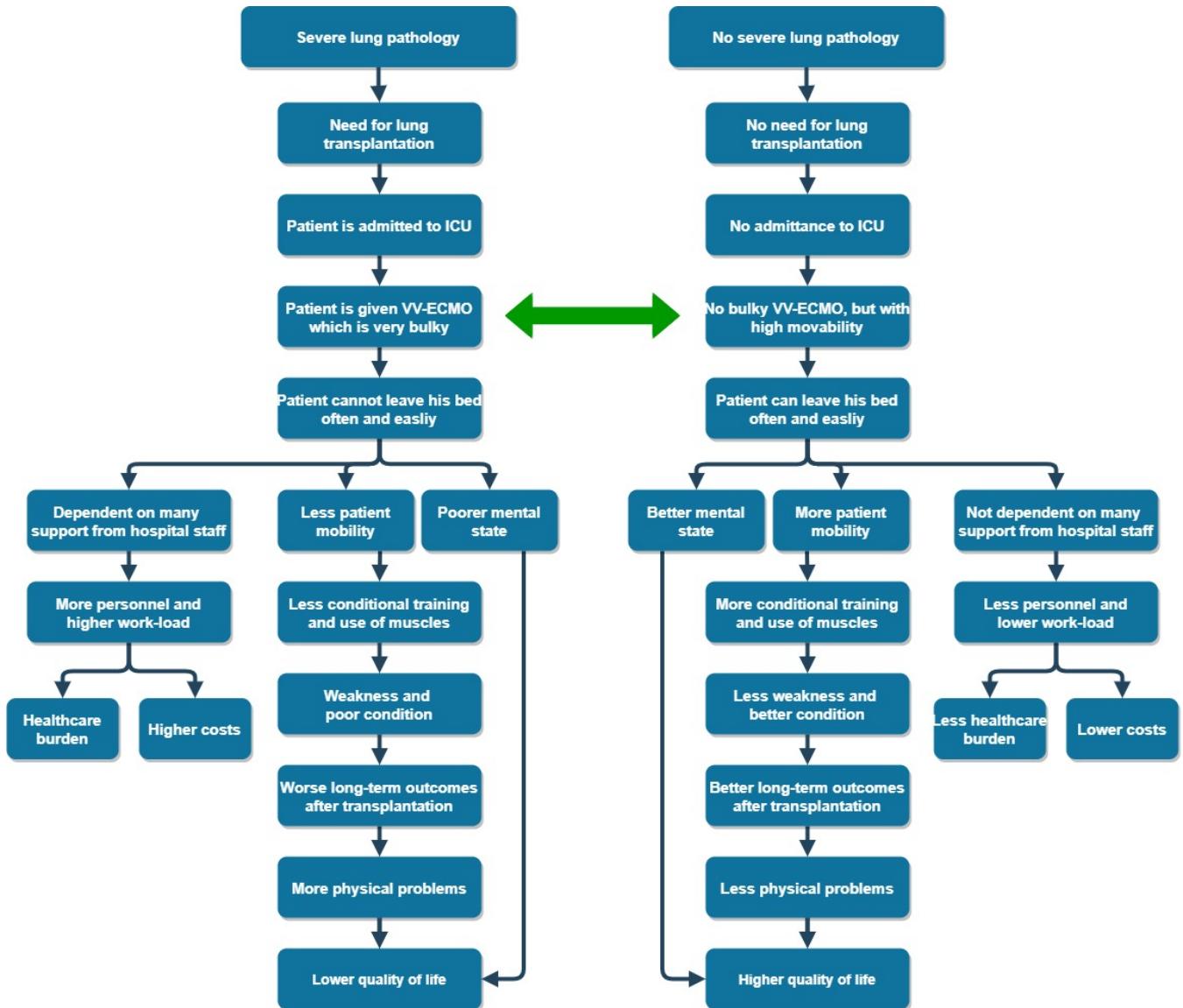


Figure 5: Cause-effect diagram of all problems (left) and of all goals (right). The green arrow marks the level at which this project aims to intervene

2.5 Design assignment and demarcations

The scope of this project is to design a device that makes currently used VV-ECMO systems more portable, so that an adult patient who is dependent on VV-ECMO can take a short walk inside of the hospital with only one person of assistance. This may include dismissing parts of the VV-ECMO that are not necessary for a short walk but will not include redesigning the entire ECMO system for the sole purpose of increasing its movability. Instead, the focus of this project will be on designing a form of walking aid where all required parts of the ECMO can be integrated.

This project specifically focuses on patients who have a double lumen catheter in the internal jugular vein. This is an important demarcation, as it limits the scope of the project to only come up with a solution for patients with a single insertion place (internal jugular vein) connected to the ECMO system. On top of this, the heat exchanger will be dismissed from the ECMO system, since for most patients this component is not necessary for a short walk and only adds extra weight. The reason for this is that patients will provide the heat themselves while walking. Other than these demarcations, the system should be applicable to all patients that do not have a condition impairing their ability to walk besides ECMO.

The main focus of this project is to fulfill the expectations of patients, ICU-nurses, and society. The project does not include a comprehensive analysis of the final concept with respect to total costs, expected profit, investments, and ease of manufacturing. This means that the expectations of the industry and insurance may not be met and/or only minimally answered. The total costs of the final design will only be roughly estimated and this does not form a criterion or limitation during the development process. Hence, there will not be any requirements taken into account regarding the industry and insurance stakeholders for the final design. The selection of a final concept for a walking aid and technical drawings will mark the endpoint of the project, meaning that prototype development and testing will not be included.

2.6 List of requirements

After analyzing the problem and the aim for the solution, the first step in arriving at a feasible solution is to consider the requirements that such a solution should meet. The specified criteria should be able to be tested at the conclusion of the system's production. If one of these requirements is not met, the device is considered to be defective. As a result, it is critical that the criteria not only match the stakeholders' expectations but also be reasonable and realistic. Despite the fact that health insurance companies and the industry are regarded to be stakeholders in the solution of the health problem, it is opted not to specify their potential needs since it would not be possible to test them at the completion of the project.

Requirements of the patient, ICU nurses, and society, were grouped in six categories: applicability, size, safety, duration, assistance and interaction. These criteria are based on scientific literature, but mostly via conversations with Prof. Jutta Arens, a knowledgeable researcher in the field of artificial lungs, who also served as the client for this project.

- 1. Applicability** - The system should be applicable for a wide range of patients
 - The system should be applicable for patients with a weight between 50 - 150 kg
 - The system should be applicable for patients with a height between 150 - 205 cm
- 2. Size** - The system should have dimensions that are appropriate for in hospital use
 - The weight of the system that the patient carries should be less than 3 kg
 - The system should fit through the hospital door (maximum size: 130 x 250 cm)
- 3. Safety** - The system should be safe for use
 - The system should have a safety margin of run time of 50%
 - The cannula should be kept in place during the walk
 - The system should provide an emergency alert to staff
 - The system should give real time feedback about its status
- 4. Duration** - The system's duration should be long enough
 - The system should have a run time of 20 minutes
- 5. Assistance** - The system should require minimal assistance
 - The system should provide to the person of assistance all the settings of the ECMO
 - The system should only require one person of assistance
 - The system should only be able to move based on the patient's intent
 - The system should be able to move by assistance of the patient only
- 6. Interaction** - The system should leave room for social interaction
 - The system should not impede the patient's front vision so that interaction between the patient and his or her relatives and friends may take place.
- Besides these criteria, some wishes can be established. In the wishes, also the criteria of the health insurance companies and industry can be found. These wishes could be checked for at the evaluation of the project.
- 7. Wishes** - The system should be able to be transported by the ICU nurse passively, with the patient, in case of an emergency
 - Neither the patient nor his or her family and friends should be confronted with the patient's blood that goes through the system
 - The system should be cost-effective to be reimbursed
 - The system should have a small manufacturing time and use easy manufacturing materials
 - The system should have a large return on investment

2.6.1 AHP analysis

The analytic hierarchy process (AHP) is progressively being used in healthcare as a tool for multi-criteria decision making. The AHP can help decision makers, especially stakeholders, choose the most beneficial technology while taking into consideration various, and often competing, choice factors [20]. First and foremost, before evaluating various technologies or products, the weights that each criterion will need to be determined. Instead of comparing each individual requirement as specified in section 2.6, it was decided to only compare the six criteria groups to reduce the comprehension of the AHP analysis. All criteria were compared to each other in which the most important criterion was chosen. A score was allocated to the importance of this criteria over the other one. Table 2 shows the results of the AHP analysis concerning its criteria and weights. The full analysis can be found in Appendix III.

For this analysis, each of the five team members assumed the role of each one stakeholder: the patient, the ICU nurses, and society. Additionally, Prof. Jutta Arens was asked to fill in the analysis using the same strategy, but without knowing the project team's results. Therefore, this analysis is made up of 18 data sets. This is not a flawless method, since there is the chance of bias because the team can only envision their function as any of these stakeholders. For this project, it was not within the scope to contact patients, ICU nurses and a representative group from society. To limit the bias, the weights from the team was adjusted by the results of the expert, Prof. Jutta Arens.

Table 2: Criteria and respective weights

Criterion	Weight (percent) by group	Weight (percent) by Prof. Arens	Average weight (percent)
Applicability	9.7	19.0	14.35
Size	6.1	2.4	4.25
Safety	48.9	52.9	50.9
Duration	10.7	5.1	7.9
Assistance	15.0	14.8	14.9
Interaction	9.6	5.8	7.7

From table 2 it can be observed that the team members and Prof. Arens agree that safety is the most important criterion whereas size is the least important. The average weight of the criteria will be used to compare the different pre-concepts in synthesis I.

2.7 Function analysis

In the following function analysis, the different functionalities of the system will be described. These functions are abstract in order to leave the possibilities for the design and implementation open. The product is about the transportation of the ECMO system and thus not the ECMO system itself. The following categories can be distinguished to lead to the main functionality of main transportation: power supply, oxygen supply, stability, movement, feedback system and emergency as represented in figure 6. In addition, these categories can consist of sub-functionalities.

The power supply of the system consists of storing energy, which thereafter needs to be transported and converted in order to be finally transported to the ECMO device itself. The oxygen supply has to store material, or the oxygen,

and transport this to the ECMO device. For the stability of the transportation of the ECMO device, the cannula needs to be transported safely and kept in place. The movement of the system is decided by the driving force that induces the motion and the movement direction which can be obtained by information conversion from the user to the system. Furthermore, the feedback category encompasses the output that the system gives, by converting information and transferring this information. The function of the feedback system is to provide continuous real-time information about the status of the oxygen level and energy level. Lastly, the system has the additional function of alerting the ICU staff in an emergency situation.

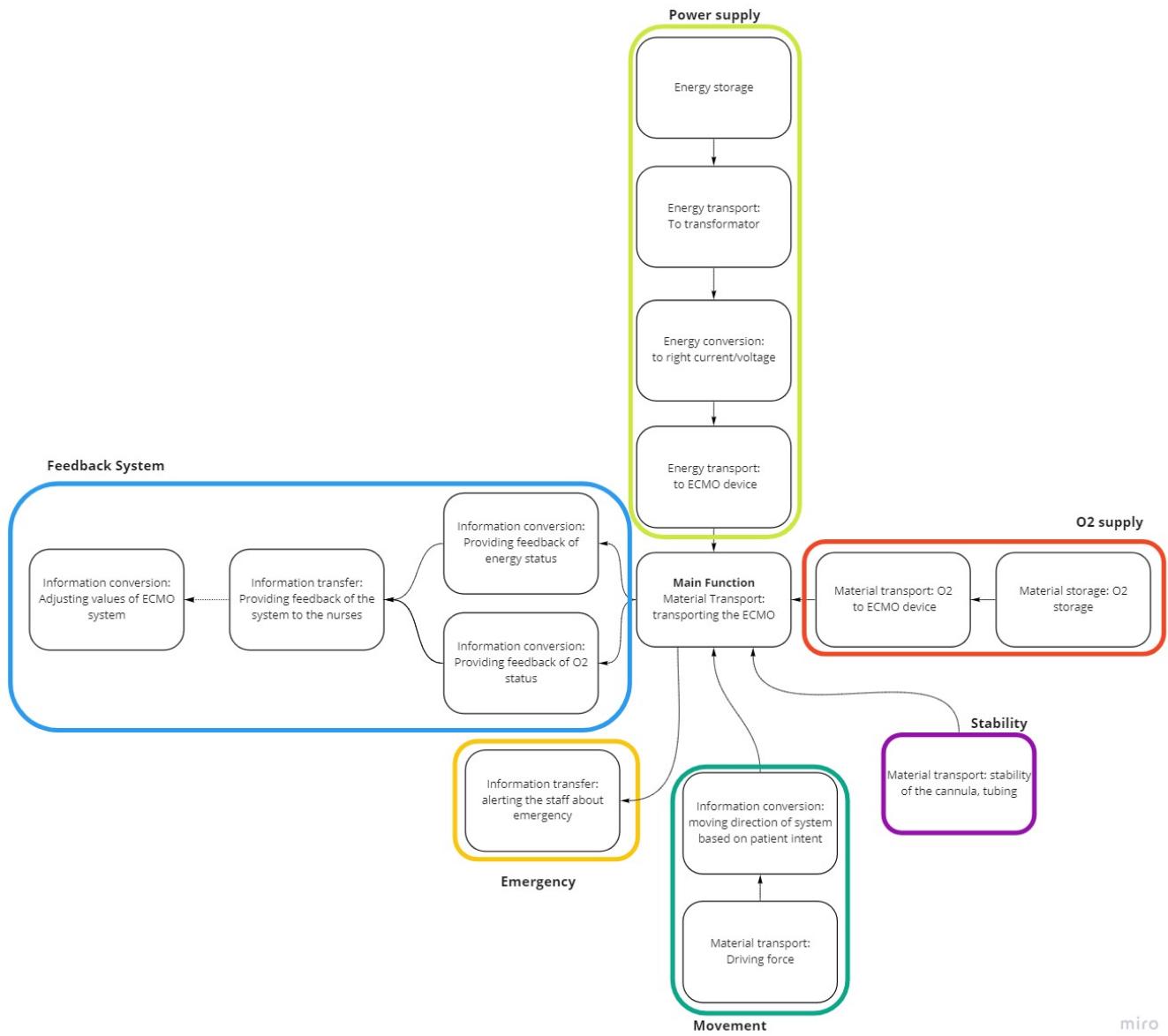


Figure 6: Function analysis of the system to be designed.

3. Synthesis

There are three phases in the synthesis process, from creating ideas to the final solution. In the following subsections, these will be discussed in further detail.

3.1 Synthesis I

The first synthesis phase is used for generating ideas and solutions, resulting in pre-concepts. By using a morphological scheme, the functionalities as stated in chapter 2.7 can be accomplished. After these solutions have been found, the project team started brainstorming about the pre-concepts.

3.1.1 Morphological scheme

To come up with different designs for the mobility of ECMO devices, a morphological scheme is used. In the first column, the functions that must be fulfilled are positioned. The morphological scheme is then filled by a brainstorming session with the project team where different solutions are written down for every function. The morphological overview can be found in figure 7.

	1	2	3	4	5	6	7	8	9	10
Power Supply										
Oxygen Supply										
Cannula Stability										
Driving Force										
Movement Direction										
Movement Support										
Feedback System										
Emergency Alert										
Emergency Mobility (Wish)										

Figure 7: Morphological overview.

3.1.2 Pre-concepts

Pre-concept 1

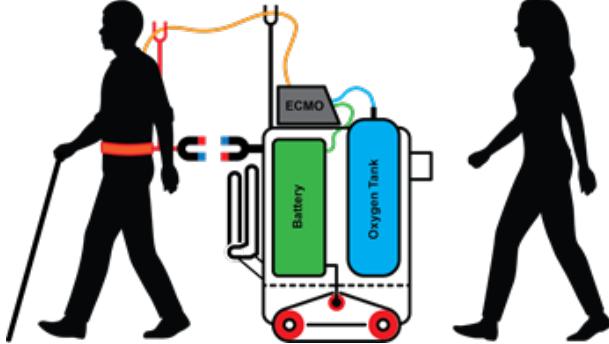


Figure 8: Pre-concept 1.

The concept uses a battery that supplies the ECMO. The ECMO is connected to the patient through a belt. Oxygen is supplied through a small oxygen tank that is attached to the ECMO. The O₂ tank is attached to a sensor and the feedback about the level of oxygen can be provided through vibrations to avoid noise pollution inside the hospital. The cannula can be made of a flexible tube that changes in length as the patient moves. A belt is worn by the patient in which the support for the cannula and a permanent magnet is attached. The ECMO system has an electromagnet. The magnetic field maintains the distance between the patient and the machine. The magnet can also be connected to the wheels to stop the movement if the distance is too small or too large. A DC motor can be attached to provide additional support to move the ECMO machine. The power for this motor can be provided by the existing battery. The entire ECMO system can be moved by conveyor belt wheels. The system can also have a flip chair attached to it on the front side (near the patient) to hold the patient in case of a patient's fall. The system also has an alarm attached to the ICU/nurse unit that activates during an emergency.

Pre-concept 2

The concept uses wheels to move the ECMO machine. The force for the movement of the machine is provided by a DC motor which draws energy from a rechargeable battery. A sensor that detects the movement of the patient is attached to their wrist in the form of a band. The movement direction can be controlled by an AI-based software. In this way, the patient need not carry the weight of the ECMO machine. A processor is attached to the ECMO system to enable AI software. Only the cannula will be attached to the ECMO and the patient. The patient can have a walking stick that is more stable to support the patient. The cannula can be flexible in length. The patient also wears a belt that has the support for the cannula attached to it. A foldable chair can be attached to the ECMO machine to hold the patient in case of an emergency. The ECMO machine is also powered by the same battery. The oxygen is supplied through a small oxygen tank. The O₂ tank is attached to a sensor and the feedback about the low level of oxygen can be provided through audio feedback so that the assistant does not miss the status of O₂. The emergency alert can be given through a sound alarm to gain the immediate attention of the nurses.

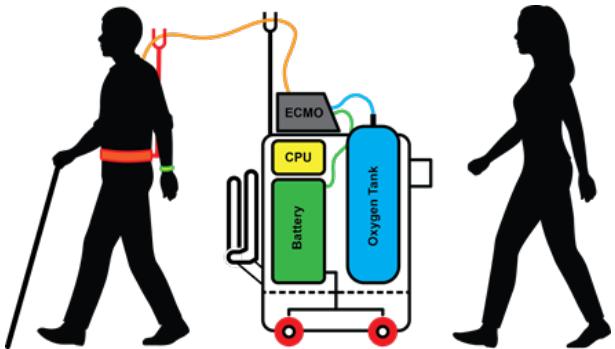


Figure 9: Pre-concept 2.

Pre-concept 3

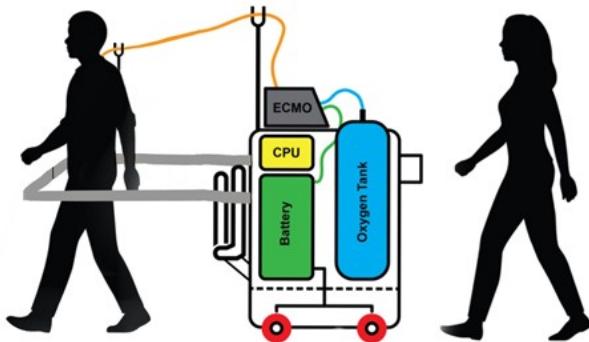


Figure 10: Pre-concept 3.

The concept would be on wheels, similar to a wheelchair, with the possibility of blocking the wheels so the device stops. It would have a metal bar that “goes around” the patient, not being an obstruction, just something for the patient to grab on to be able to make the device move with him. This movement would be aided by a motor similar to the ones used in electric bikes. Behind the patient would be the system itself, with a bench that closes. The bench is attached to a storage area that keeps the oxygen tank, the battery and has a screen where the nurses can monitor the status. For this, it uses software that would also provide information to the ICU in case of an emergency. The pulling down of the chair would activate

the emergency, 5 seconds after, giving time to the nurse to turn it off in case it is not an emergency. On one of the sides of the storage area would be a pole where it is attached the tubing for the cannula and other types of fluid bags, if necessary.

Pre-concept 4

In this concept, the device is placed behind the patient. A rechargeable battery provides power for both the ECMO device and the electric motor. The electric motor actively drives the wheels when the patient starts to walk. The patient is connected to the device by means of an elastic line. Tension on the line is translated to a force on the attachment point of the device. This force is used to control the speed and direction of movement of the device. The stability of the cannula is achieved by attaching a beam with a pulley to the patient using a harness. The device itself is also equipped with a beam with a pulley system. In this way, the blood tube runs safely from the patient to the device. Oxygen supply is realized by using an external oxygen tank attached to the device. The device is equipped with a sound alarm and flashing light which can be activated during an emergency situation. In addition, the device is equipped with a fold-out seat for when the patient is not feeling well. This also provides the option to manually push the patient back to the ICU if needed.

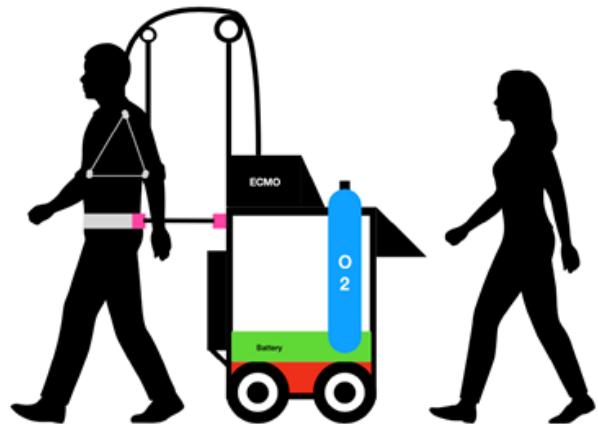


Figure 11: Pre-concept 4.

Pre-concept 5

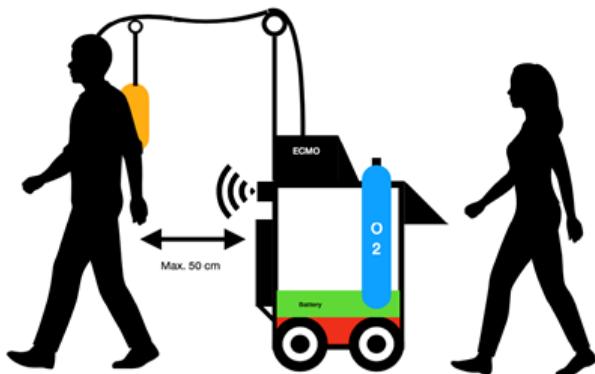


Figure 12: Pre-concept 5.

This concept is similar to pre-concept 4. However, the difference lies in the technology used to activate the electric motor. In this concept, a LIDAR laser technology is used. This system continuously measures the distance between the patient and the device. This offers the possibility to keep a fixed distance between the patient and the device (e.g. 50 cm). A controller must compensate for an increase and decrease in this distance by increasing or decreasing the drive of the wheels respectively. In this concept, a beam with a pulley is used, mounted on a backpack. This may be more comfortable than using a harness, as the beam in this solution is located a little further from the body.

Pre-concept 6

In this concept, a regular walking aid is taken into account.

The device is placed in front of the patient. This provides support and grip for the patient while walking. A rechargeable battery provides power for both the ECMO device and the electric motor. The electric motor actively drives the wheels when the patient starts to walk and pushes the device forward. This assistive driving force can be compared to that of an electric bicycle. The stability of the cannula is achieved by attaching a short beam with a double pulley to the patient using a harness. This double pulley guides the arterial and venous blood tubes separately. After the pulley, the blood tubes run diagonally over the patient's back and end up under the patient's left arm at the front of the patient. At the front of the patient, both blood tubes are attached to the harness with a clip system. This ensures the stability of the tubings. The device itself is also equipped with a small beam with a double pulley system. In this way, the blood tube runs safely from the patient to the device. Oxygen supply is realized by using an external oxygen tank attached to the side of the device. The device is equipped with a sound alarm and flashing light which can be activated during an emergency situation.

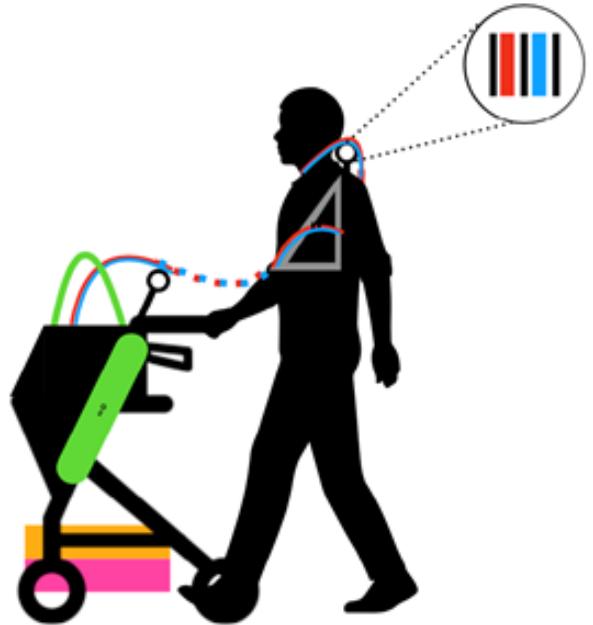


Figure 13: Pre-concept 6.

Pre-concept 7

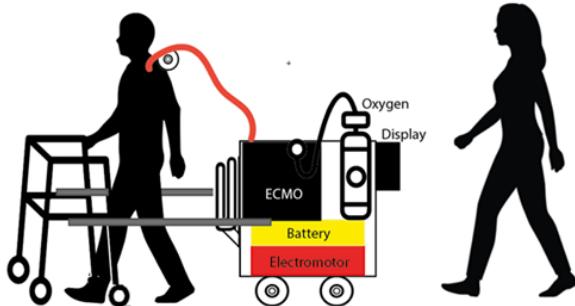


Figure 14: Pre-concept 7.

The whole system is on wheels in order to move it. The system consists of a front part and a back part, which are connected. Patients can manually push the part in front of them to control the movement direction of the entire system. At the back part, a display is installed to give feedback about the status of the system (O_2 reserve and power reserve). At the back part, oxygen is saved in a small, portable tank. A battery is used to supply both the ECMO and an electric motor. The electric motor functions as a support for the patient to push the weight forward during walking. The motor should automatically switch on when the patient is walking and should have different levels of support (just like an e-bike).

Flexible tubing is used to allow the head movement of the patient. A sort of harness is worn with a pulley to keep the cannula in place. If the O_2 or power reserves are low, or if there is too much force on the tubing, a sound alarm should go off to warn the nearby ICU nurse. There is a small chair behind the patient (connected to the back part) where he can sit if there is an emergency.

Pre-concept 8

The whole system consists of one part behind the patient that is on wheels in order to move it. Oxygen is saved in a small, portable oxygen tank. A belt is worn to connect the system to the patient. The concept uses a battery to supply the ECMO and an electric motor. The system uses an electric motor to support the patient to push the weight forward during walking. The motor should automatically switch on when the patient is walking and should have different levels of support (just like an e-bike). A standard tube can be used, without a pulley, as there is not much space for movement of the cannula. No emergency chair/stretcher is used, as the patient is fixed to the system and there is no space for this behind him. A display is installed to give feedback about the status of the system (O_2 reserve and power reserve).

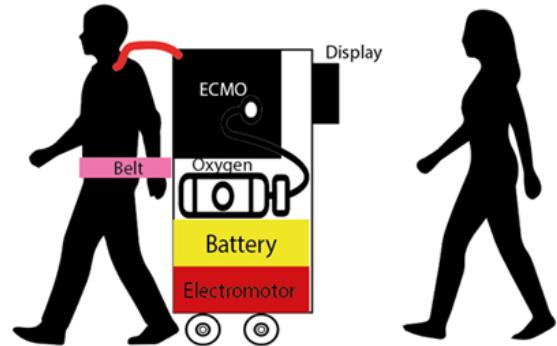


Figure 15: Pre-concept 8.

Pre-concept 9

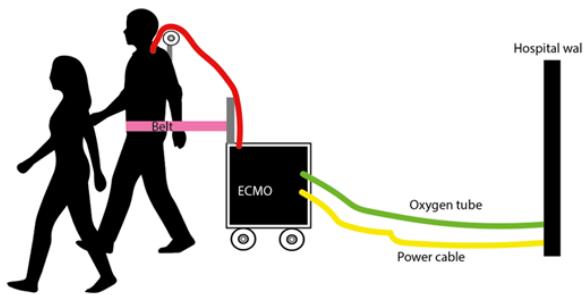


Figure 16: Pre-concept 9.

Minimal weight design: The system uses a power socket to supply the ECMO, connected to a very long cable. Oxygen is supplied by a very long flexible tubing connected to the hospital wall. The patient only carries the essential parts of the ECMO (oxygenator, blood tubing and pump) with him. No feedback system and alerting are required, as the power socket and hospital wall are assumed to give way more than enough supply for a short walk. No driving force is required, as the system is already compact and light enough. Manual pushing/pulling suffices. No emergency support is installed to reduce weight. The whole system is on wheels, behind the patient. The system can be connected to the patient with a belt, to keep it at all times close to the patient. The cannula uses flexible tubing, and a harness with a pulley is used to keep the cannula in place.

Pre-concept 10

This system is a cart that is steered by the patient. The wheels are powered and the speed can be managed at the steer by the patient. The components of the ECMO system are inside the cart. Therefore, nobody can read the medical data of the system without opening the door. Inside, the oxygen tank, battery, motor and ECMO monitor can be found. The ECMO monitor provides the status of the ECMO system. The cannula has some extra stability by the grip hook holding up the tubing on the machine. In case the patient gets tired, the patient can stand on the little step and drive themselves back to their room.

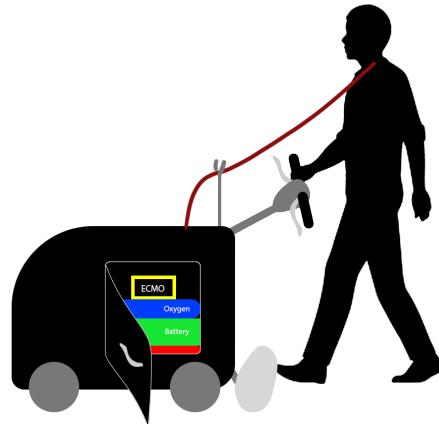


Figure 17: Pre-concept 10.

Pre-concept 11

In this concept, the patient is very closely attached to the system, e.g. via a backpack. The weight of this backpack is not carried by the patient but by the wheels underneath the backpack. In addition, there are springs to counteract the bouncing when walking. The backpack is attached with a strap-on-harness made of velcro and thus fully adjustable. This system allows for a short tubing from the cannula to the ECMO system.

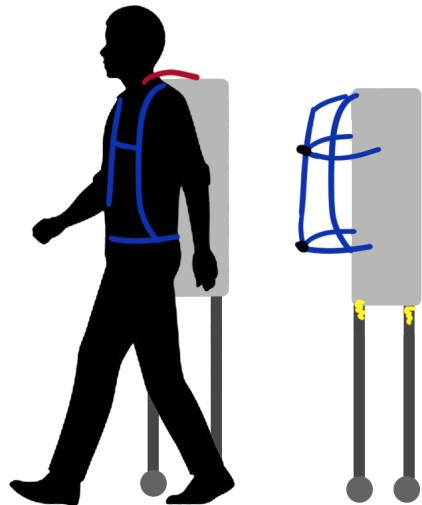


Figure 18: Pre-concept 11.

Pre-concept 12

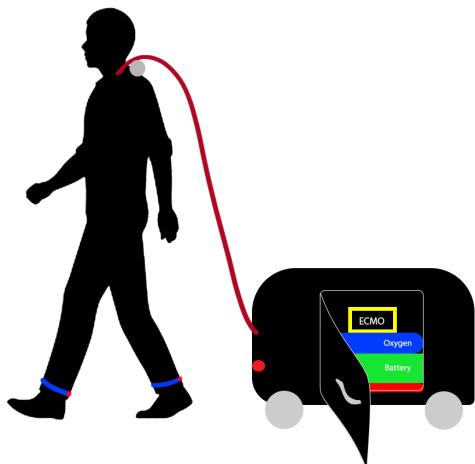


Figure 19: Pre-concept 12.

The system follows the patient around based on infrared sensors. The distance from the system to the patient's feet is kept by the control of the system. The cart moves based on electric motors. This cart is steered by using two feet that need to be in range of the system. Therefore, if one foot goes towards the left, the system turns to the left as well. The oxygen tank, battery, ECMO and motors are inside the cart. In addition, the cannula tubing is secured in the neck of the patient with a pulley to guide the tubing down to the machine.

3.1.3 Ranking of pre-concepts

By ranking the pre-concepts based on the weights of the requirements, a selection of the three best concepts can be made, see table 3. It can be observed that pre-concepts 4, 5 and 6 perform the best overall, as these concepts received the highest total weighted grade. These three pre-concepts are further worked out and adapted in the following chapter.

Table 3: Ranking of the pre-concepts.

	Applicability (14.35%)	Size (4.25%)	Safety (50.9%)	Duration (7.9%)	Assistance (14.9%)	Interaction (7.7%)	Total (100%)	Total (weighted)
Pre-concept 1	6	6	6	8	4	9	39	6.09
Pre-concept 2	7	7	6	8	5	9	42	6.43
Pre-concept 3	7	4	6	8	3	8	36	5.92
Pre-concept 4	7	7	7	8	8	9	46	7.38
Pre-concept 5	8	7	6	8	8	9	46	7.02
Pre-concept 6	7	8	7	8	9	7	46	7.42
Pre-concept 7	7	3	7	8	5	8	38	6.69
Pre-concept 8	4	7	6	8	6	9	40	6.14
Pre-concept 9	7	9	4	10	7	9	46	5.95
Pre-concept 10	7	8	6	8	8	8	45	6.84
Pre-concept 11	4	7	7	8	7	9	42	6.80
Pre-concept 12	8	8	4	8	5	9	42	5.59

3.2 Synthesis II

During this phase, three concepts from synthesis I are chosen based on the ranking in section 3.1.3. These concepts are elaborated in more detail and developed into three final concepts. The pre-concepts that are chosen from synthesis I are concepts 4, 5 and 6, as these concepts received the overall highest grade.

3.2.1 Concept 1

This section describes the functionality of and materials used in pre-concept 4 in more detail.

3.2.1.1 Functionality

Power supply

The system contains a battery to store energy. Electrical wiring is used to transport power from the battery to the ECMO and the electric motor. Due to its weight, the battery is located close to the ground, so that the centre of mass is as low as possible.

Oxygen supply

Oxygen supply is realized by using an external oxygen tank, which is connected to the ECMO via an oxygen tube. The exit of the oxygen tank should be close to the top so that the connection from the tank to the ECMO is as short as possible.

Cannula stability

The cannula used during ECMO is a double lumen cannula, inserted in the internal jugular vein. The system is connected to the patient via an elastic band that is stretchable in diameter based on the patients' size. The band is worn at the height of L1-L3 vertebrae, just above the iliac crest, which makes sure that the band is less likely to fall down. This position also makes sure that head movements and arm movements are not disturbed and that breathing remains as comfortable as possible due to the position being below the diaphragm. The elastic band should also be stretchable in length to make sure that the patient can walk as naturally as possible and that the patient does not get stopped by the elastic connection to the device behind him. The elastic band also serves an additional purpose, which is that based on the force that the patient exerts on the band, the electric motor should give a level of support. This means that the elastic connection should contain a stretch sensor, for instance, an electrical conductor that changes its electrical resistance based on the amount of deformation.

Next to the elastic band, the patient also wears a harness with a beam on top of this which makes sure that the bloodlines are controlled properly. Due to physical differences between patients, these harnesses should come in different sizes and the beam should be adjustable in length based on the height of the patient. The beam with the pulley is mainly used to make sure that the cannula always remains in the same position at the first few centimetres from the insertion point to the body. Connecting the beam (with the pulley on top) to the body of the patient rather than the head makes sure that head movements do not disturb the fixation of the cannula.

Driving force

The system makes use of an electric motor. The electric motor adapts its level of support to the will of the patient. To increase the safety of the device, a stopping mechanism should be implemented that makes sure that the device stops when the speed is too high for the patient to keep up (e.g. due to a defect of the electric motor). The system should also have brakes that can be activated manually for when the patient wants to stop walking for a moment, or when attaching the patient to the system to ensure that it does not roll away.

Movement direction

As mentioned before, the patient is in full control of his movement direction. The patient can turn whenever and wherever he wants, and the device will follow him due to the sensors in the elastic band that control the electric motor.

Movement support

The device is on wheels. This ensures that the movement of the device is easy to realize.

Feedback system

As mentioned in section 3.1, the status of the system in terms of power supply and oxygen reserve should be provided to the ICU nurse. To do so, the oxygen tank should contain a sensing mechanism that is connected to the display at the back end of the system with electric cables. The same goes for the battery compartment. Ideally, the display should show at all times how long it can still function before running out of oxygen and power supply. When the oxygen or power level reaches below a certain threshold, the emergency alarm should go off.

Emergency

When an emergency occurs, a sound alarm and flashing light can be activated. In this case, the patient can be transported passively by the ICU nurse by making sure that the patient sits on the foldable chair. It is important to note that this should not change the fixation of the cannula and that the bloodline is long enough to make this possible. In order to achieve this, the length of the beam on the device should also be adjustable in length. On top of that, it should be made sure that the system does not flip over when the patient sits down. Extra weight on the device itself might be necessary to prevent this from happening.

3.2.1.2 Materials

The elastic band is made of rubber to guarantee its flexibility. It is covered in fabric to make it more comfortable for the patient. For the cannula itself, a standard flexible double-lumen tube is used that is already widely used in clinical practice. The vest is also made of fabric, with its beam and pulley made of plastic. The device itself (which contains the ECMO, battery, oxygen, etc.) is mainly made out of aluminium, which is a strong metal yet lightweight. This is important because the device has to carry many different parts and yet weigh as little as possible to ease movement. The foldable chair is made out of plastic.

3.2.2 Concept 2

This section describes the functionality of and materials used in pre-concept 5 in more detail.

3.2.2.1 Functionality

Power Supply

The system is powered by a rechargeable battery. Power is sent from the battery to the ECMO and DC motor through the power line. The battery is near to the ground due to its weight, lowering the center of gravity as much as feasible.

Oxygen Supply

An oxygen tank is used to provide oxygen, which is connected to the ECMO through an oxygen tube. The oxygen tank's outflow should be at the top, making the connection between the tank and the ECMO as short as possible and enabling the replacement or refilling of the oxygen tank easier.

Cannula Stability

The cannula used during ECMO is a double lumen cannula. The cannula runs from the ECMO device to the internal jugular vein. The patient wears a backpack with a beam attached. The backpack is small and thin such that it does not cause discomfort to the patient. The beam has a pulley on top of it in order to hold the cannula in place. The ECMO system also holds a beam above the LIDAR system setup. This beam can be kept fixed with a pulley on the top to hold the cannula. As it is a pulley system, the length of the cannula can be adjusted according to the motion of the patient.

Driving Force

The driving force for movement of the ECMO system is provided by a DC motor. As said in “Power Supply”, the DC motor is powered by the battery. For safety purposes, the ECMO device should stop if the distance between the patient and the device increases. Also, if the speed of the ECMO device increases abruptly or if there occurs a situation where the ECMO device runs out of control of the DC motor, the systems should stop all of a sudden or there should be a control given to the assistant that is walking close to the patient.

Movement Direction

The direction of the device’s movement is completely under the control of the patient. The movement direction is assisted by the Light Detection and Ranging (LIDAR) system. The maximum distance between the patient and the system can be set to 50 cm. The device will move freely in any direction whichever the patient wishes.

Movement Support

The entire movement of the system is supported by wheels. The wheels are driven by the DC motor.

Feedback System

It is very important for the ICU nurse to monitor the O₂ supply to the ECMO device and the battery status of the system. To make sure their duty is easy, a sensor can be fixed in the battery as well as the O₂ supply tank. The sensor is attached to a display device. The display device should show both the values of the power and O₂ supply along with the remaining duration of runtime continuously. To avoid further complications (in case of emergency), the system should provide an emergency alarm to the ICU unit or the nurse station if the status reaches a minimum threshold.

Emergency

During an emergency, an audible alarm and a flashing light can be activated. In this case, the patient can be transferred passively from the ICU nurse by ensuring the patient is seated in a chair. To support the patient while sitting, the length of this beam can be adjusted manually to ensure that the cannula stays in place. The cannula must also be adjusted for support in this situation. Also, it should be made sure that the system does not tip over when the patient is seated. The additional load on the device itself may be needed to prevent this from happening.

3.2.2.2 Materials

The backpack with the beam is made of fabric while the beam and pulley are made of high-strength plastic. The double lumen cannula that is currently in clinical use is made of biocompatible polyurethane. The same cannula is used for this device. The emergency use foldable chair is made of plastic or strong aluminium that is capable of withstanding the weight of the patient without any damage. The other parts of the entire device are made of strong aluminium alloy to ensure lightweight.

3.2.3 Concept 3

This section describes the functionality of and materials used in pre-concept 6 in more detail.

3.2.3.1 Functionality

This concept is based on a walking aid design that provides walking support and grip for the patient. This design differs from concepts 1 and 2 as the device is in front of the patient instead of behind him.

Power Supply

The system contains a battery to store energy. Electrical wiring is used to transport power from the battery to the ECMO and the electric motor. Due to its weight, the battery is located close to the ground, so that the centre of mass is as low as possible.

Oxygen Supply

Oxygen supply is realized by using an external oxygen tank, which is connected to the ECMO via an oxygen tube. The exit of the oxygen tank should be close to the top so that the connection from the tank to the ECMO is as short as possible.

Cannula Stability

Stability of the cannula must be achieved by stable support of the bloodline to the patient's body and a supportive connection to the ECMO machine. This is done by having the patient wear a harness with a double pulley system. This pulley system guides both the arterial and venous bloodline separately. The bloodline runs from the patient's neck to the right shoulder and then runs diagonally across the patient's back toward the left flank. Here the bloodline runs from the left side of the chest to the front of the patient. At this height, the bloodline is attached to the harness using a clipping system to provide stability of the bloodlines and prevent tension and rupture of the bloodline. From here, the bloodline runs to the pulley system that is attached to the walking aid. The bloodline here makes a slight bend towards the blood input of the ECMO device.

Driving Force

The two back wheels of the system are driven by an electric motor. The electric motor is supplied with power by the rechargeable battery. To allow the system to move in a safe and controllable manner, the electric motor must only provide support when the patient applies force to the system. Think of the operation of the pedal assistance on an electric bicycle. Depending on the force given by the patient, the electric motor must provide more or less support.

Movement Direction

The direction of movement of the system is made possible by two non-driven (passive) front wheels that can be rotated 360 degrees. Due to the force of the patient, which is supported by the electric motor, the system can therefore be moved in the direction of your choice.

Movement Support

Movement support is achieved by a combination of two fixed actively driven rear wheels and two passive non-driven steerable front wheels.

Feedback System

The feedback system of the device features an alarm system including a flashing light which will be automatically activated when power or oxygen supply is low. Moreover, the alarm system can be manually activated in case of another emergency situation. Besides, the system is equipped with a screen on which the oxygen supply level and battery percentage can be monitored. The system is designed in a way that the visibility and controllability of the ECMO device are guaranteed.

Emergency

In this concept, no emergency transport solutions are integrated into the design. However, further optimization of this design could be done by including a sliding chair system or a universal wheelchair connection.

3.2.3.2 Materials

The patient harness will be made of a firm but soft material that can be comfortably worn by the patient. The walking aid should be made of a strong but light material. It must be strong enough to support the weight of all equipment, but light enough to be easily moved. The use of aluminum can be a good choice of material.

3.2.4 Final concept selection

Now that all three concepts are explored and described in more detail, a selection of the final concept can be made. To do so, once again the concepts are ranked using the weights of the criteria that followed from the AHP analysis in section 2.6.1. The difference with the selection from synthesis I (section 3.1.3) is that this selection is more detailed, which is necessary to guarantee that the absolute best concept is chosen for the final solution. In the final concept selection, the three concepts are graded on all 15 requirements between 1 and 10, separately, to indicate how well the concept performs. The grades for the requirements are then averaged for each criterion, and the criteria weights are again used to obtain a total weighted score for every concept. The results are summarized in table 4. It can be observed that concept 3 performs the overall best on all requirements. Therefore, this concept will be translated into a final solution in synthesis III.

Table 4: Ranking of the three concepts.

Criterion	Requirement	Concept 1	Concept 2	Concept 3
Applicability (14.35%)	Applicable for patients with a weight between 50 - 150 kg	6	8	6
	Applicable for patients with a length between 150 - 205 cm	7	7	7
Size (4.25%)	The weight that the patient carries is less than 3 kg	7	6	8
	Fits through the hospital door (maximum size: 130 x 250 cm)	6	6	8
	A safety margin of run time of 50%	8	8	8
	The cannula keeps in place during the walk	5	4	8
Safety (50.9%)	Able to be transported by the ICU nurse passively, with the patient, in case of an emergency	7	7	4
	Provide an emergency alert to staff	10	10	10
	Give real time feedback about its status	10	10	10
Duration (7.9%)	A run time of 20 minutes	8	8	8
	Provide to the person of assistance all the settings of the ECMO	10	10	10
Assistance (14.9%)	Only require one person of assistance	6	6	9
	Only be able to move based on the patient's intent	6	5	8
	Able to move by assistance of the patient only	7	7	8
Interaction (7.7%)	Does not impede the patient's front vision so that interaction between the patient and his or her relatives and friends may take place	9	9	7
Total		112	111	119
Total (weighted)		7.69	7.67	7.82

3.3 Synthesis III: ECMOVE

The final concept is based on concept 3 with a few additions from the other two concepts of Synthesis II. In addition, the idea is shaped by the meetings with Professor Jutta Arens, where the benefits and drawbacks of each design were discussed. This led to the design of the final concept: ECMOVE. From synthesis II, it was concluded that the third proposal is the most promising, although it needs some tweaking. The modifications included:

- To ensure the safety of the patient, the patient must press a lever to activate the motor support. When this lever is released, the support of the electric motor stops and the system comes to a standstill.
- The harness is put together with velcro and with side release buckles, in order to facilitate its positioning on the patient and its quick removal.
- Instead of the pulley system near the patient's neck, it will now have a U-shaped bloodline guidance system to prevent kinking of the tubing and prevent tension near the cannula insertion site.
- The tubing will now be at the front of the patient instead of in the back.
- The length of the tubing was extended to be able to ensure safety in case the patient has to sit down during an emergency or due to fatigue.
- The electric motor will now be located near the front wheels instead at the rear wheels. This leaves more space for the patient to walk.

3.3.1 Detailed description of the individual components

The ECMOVE is split up into two parts: one part that carries all the required components of the ECMO and one part that aims to carry the bloodlines and guarantee cannula stability. Table 5 summarises all the weights and dimensions

of the individual components that are used in the first part of the ECMOVE. A description of the components can be found below the table. Similarly, table 6 summarises the components that are used in the second part of the ECMOVE, which are all carried by the patient. A description of these components can be found below table 6.

Table 5: Weights and dimensions of each component used in the first part of the device, which aims to support the patient during walking and carries the components of the ECMO.

Components	Weight	Dimensions
ECMO (Cardiohelp)	10 kg (this includes all necessary parts of the ECMO + a battery) [21]	315×255×427 mm
Oxygen tank (cylinder type: 101-ZA)	1.6 kg [22]	Length: 385 mm Diameter: 85 mm
Battery (2 × 24V, 6 AH Lithium)	2 × 3 = 6 kg [23]	100×151×98 mm (2×) [24]
Electric motor	5 kg [25]	208×159×110 mm
Framework	33.21 kg	655×920×570 mm
Wheels	Front: approx. 2 × 0.5 = 1 kg Back: approx. 2 × 0.3 = 0.6 kg	Front: diameter 245 mm Back: diameter 200 mm
Total	Approx. 57.5 kg	655×920×570 mm

ECMO

As mentioned earlier, the design of the system revolves around the Cardiohelp ECMO, which is one of the most compact and lightweight ECMO devices on the market. The Cardiohelp has an incorporated battery with a sufficient duration (90 minutes) so that no additional battery is necessary to supply the ECMO. Moreover, the Cardiohelp has an integrated display that is able to provide information about its battery status. Detailed information about this device can be found in the brochure of Getinge [21].



Figure 20: Cardiohelp ECMO device

Oxygen tank

The choice of the oxygen tank (figure 21a) was based on the amount of oxygen that is necessary for a short walk of 20 minutes. Literature describes that the maximum volume of O₂ in the lungs can be up to approximately 50 mL/kg×min [26]. The system needs to be applicable for patients up to 150 kg, for at least 30 minutes (20min + 10min safety margin). This means that the oxygen tank should carry at least $50 \times 150 \times 30 = 225$ L O₂. There exist multiple cylinder types that are able to do so. The 101-ZA is one of the most compact and lightweight types. It is able to store 300 litres of oxygen under a pressure of 300 bar. It also provided adequate, adjustable flow rates between 0.1-15 L/min [22].

Battery

Two rechargeable 24V 6AH Lithium batteries (figure 21b) are used, which are already widely applied in electric wheelchairs and are able to provide sufficient duration for the electric motor of the ECMOVE [27].

Electric motor

A single dual-axis 1000 W electric motor (figure 21c) is used, meaning that both front wheels are on the same axis and always move in the same direction. The weight and dimensions of the electric motor were approximated by investigating the types of electric motors used in electric bikes. To prevent uncontrolled movement of the device, the patient is able to switch off the electric motor by releasing the lever near the handles of the ECMOVE. The handles of the framework contain strain gauges that measure the force that the patient exerts on the ECMOVE. The resulting electrical signal is sent to the control system of the electric motor. This way, the amount of support can change based on the force that the patient exerts on the device. Substantiation for the power of the electric motor can be found in section 3.3.3.

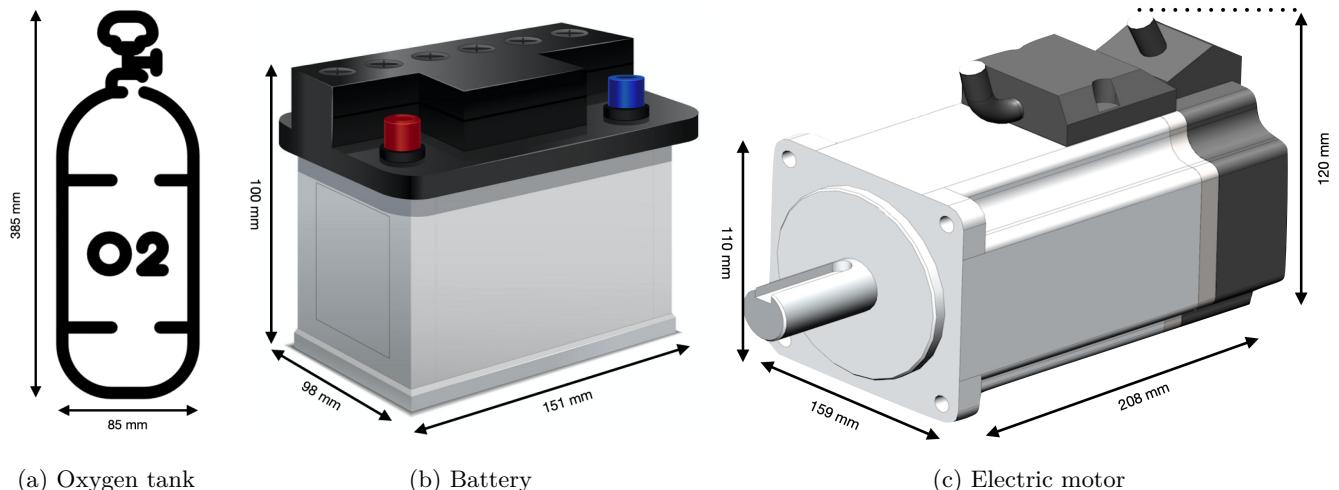


Figure 21: Schematics and dimensions.

Framework

The framework (figures 25, 26 and 27) consists of eight aluminium parts which serve to support the weight of the

patient and the components of the ECMO. On top of that, there are two plates on which the individual components can be placed. More information on the specifications of the framework can be found in table 7. The handles of the framework are adjustable in height between 82-102 cm. Because of this, the height of the handles can always be set within the range of 48% - 55% of the total body length, between 150-205 cm, which is the optimal handle height based on literature regarding walking aids [28].

Wheels

The whole system is on four wheels: two front wheels which are driven by the electric motor and two smaller back wheels.

Table 6: Weights and dimensions of each component used in the second part of the device, which aims to guide the bloodlines and provide cannula stability.

Components	Weight	Dimensions
Harness	Approx. 0.3 kg	Adjustable based on the patient's size
tubing: approx. $2 \times 0.3 = 0.6$ kg		
Cannula + blood	Blood: $V = \pi \times r^2 \times h = \pi \times 0.004125^2 \times 1.5 = 80$ mL → approx. $m = 2 \times 0.080 \times 1.060 = 0.17$ kg	Length: approx. 150 cm Inner diameter: 8.25 mm Outer diameter: 13 mm
Total	1.07 kg	-

Harness

The harness is able to provide cannula stability and guide the bloodlines that are connected to the ECMO. The harness is made out of fabric, which is lightweight and comfortable to wear for the patient. The harness contains three strips of fabric: two of which go over the shoulder and one that is around the patient's chest, just under the scapula. At the back of the patient, the two strips around the shoulder are fixed to the strip around the chest. On the front side, these two strips can also be connected to the third strip by using closing clips that can be adjusted based on the patient's size, to make sure that the harness fits well. On the right strip that goes over the shoulder, a plastic U-shaped guiding mechanism is located above the right shoulder where the tubing can be clipped into. This prevents kinking of the tubing and prevents tension near the cannula insertion site, because it keeps the tubing in a constant place near the insertion site. The beam of this guiding mechanism is fixed to the right strip, at the back. On top of that, a clipping system is used on the strip around the chest to reduce tubing movement and kinking. Shoulder paddings are used at the shoulders to increase wearing comfort of the harness.

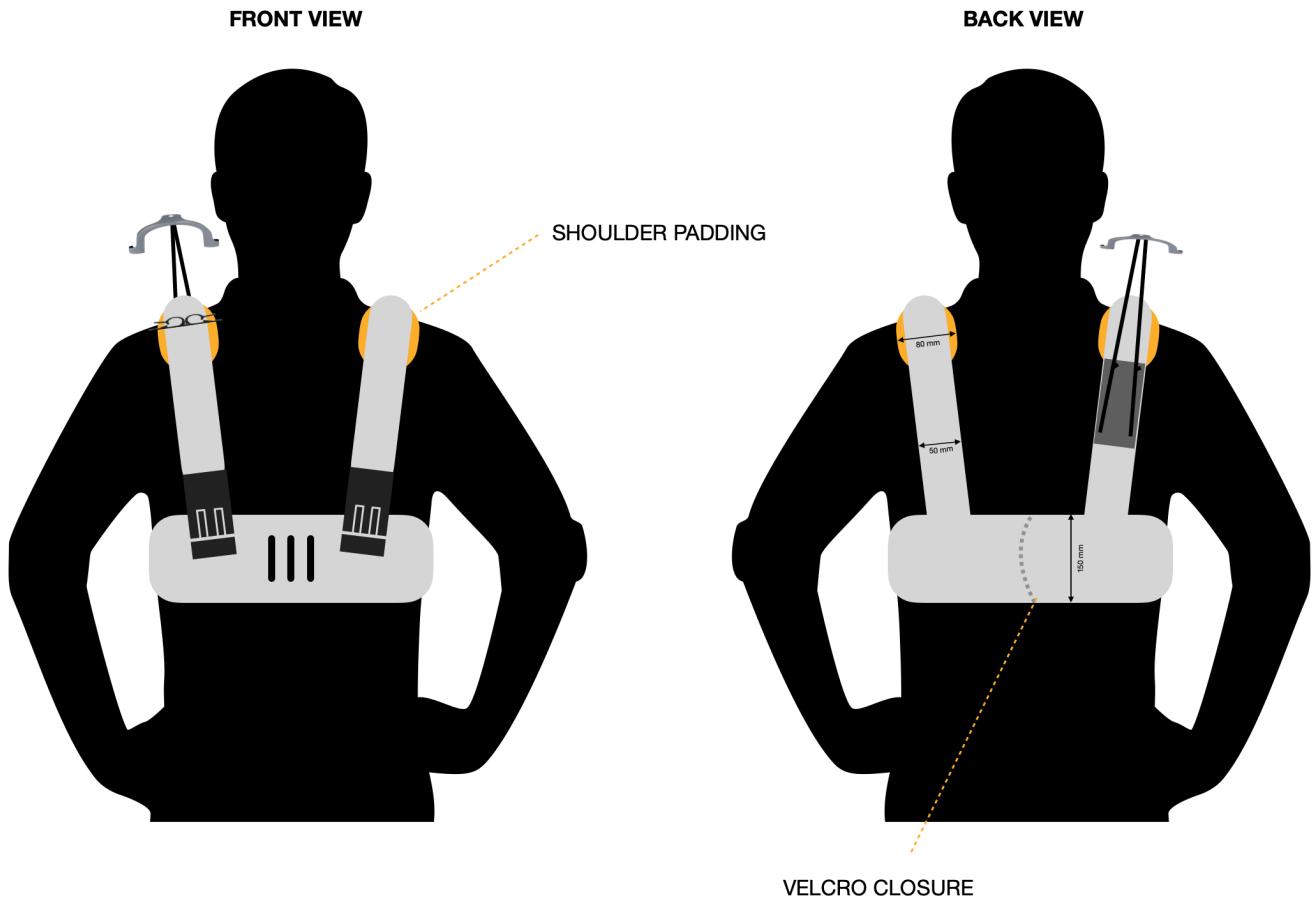


Figure 22: Front and back view of patient harness.

Tubing

Standard tubing is used to transport deoxygenated blood to the Cardiohelp and oxygenated blood back to the body. The double lumen cannula that is currently in clinical use is made of biocompatible polyurethane [29].

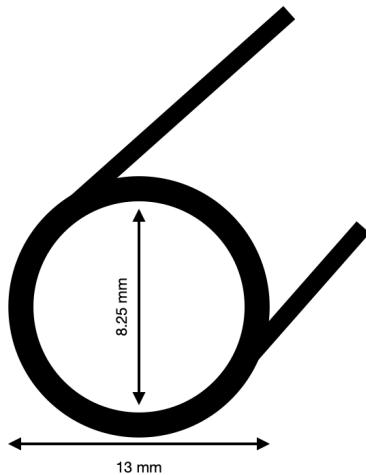


Figure 23: Dimensions of the tubing

3.3.2 Technical drawings of the complete system

Figures 24, 25, 26 and 27 show drawings of the different views of the complete system.

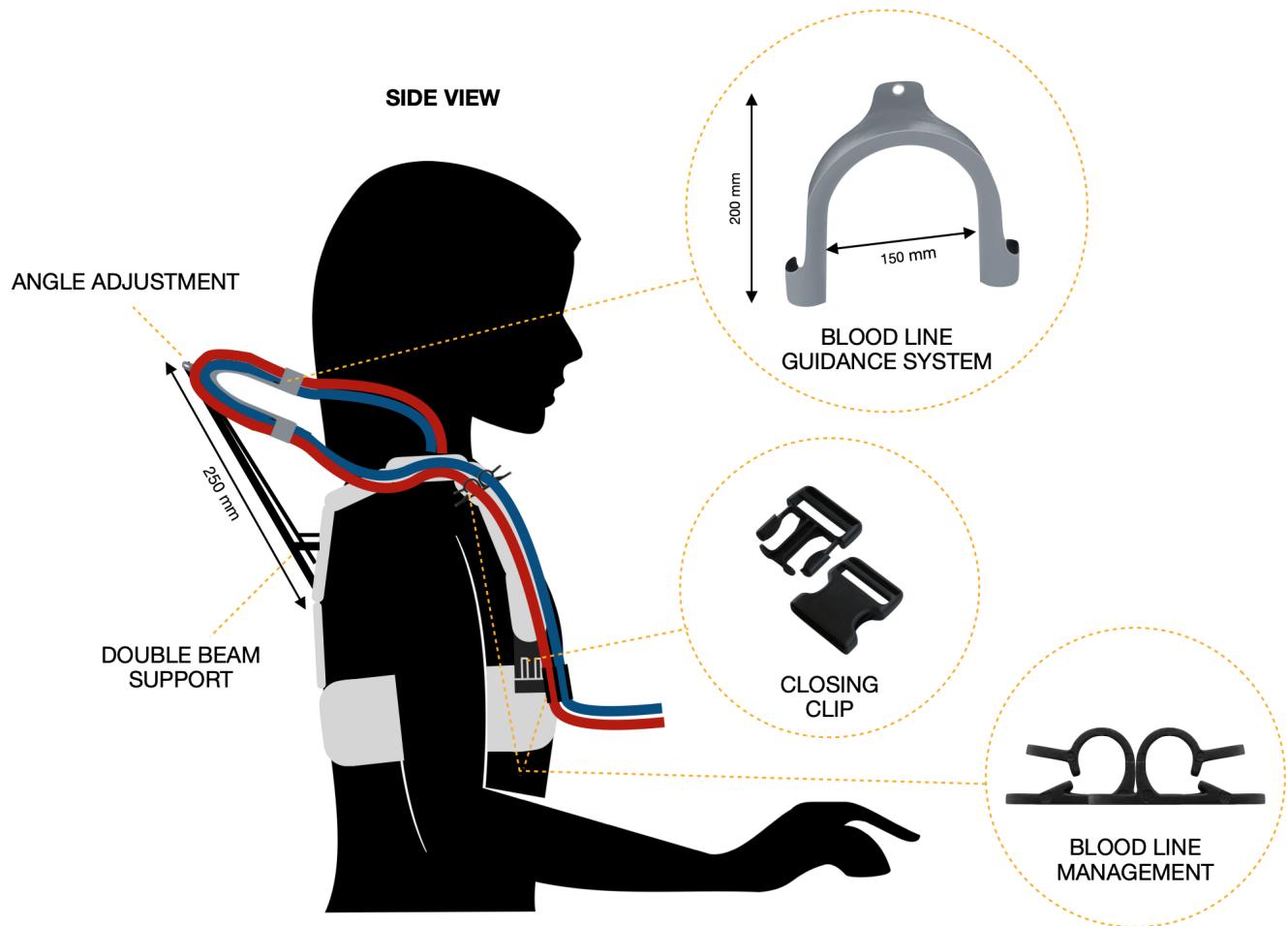


Figure 24: Side view patient harness including bloodlines.

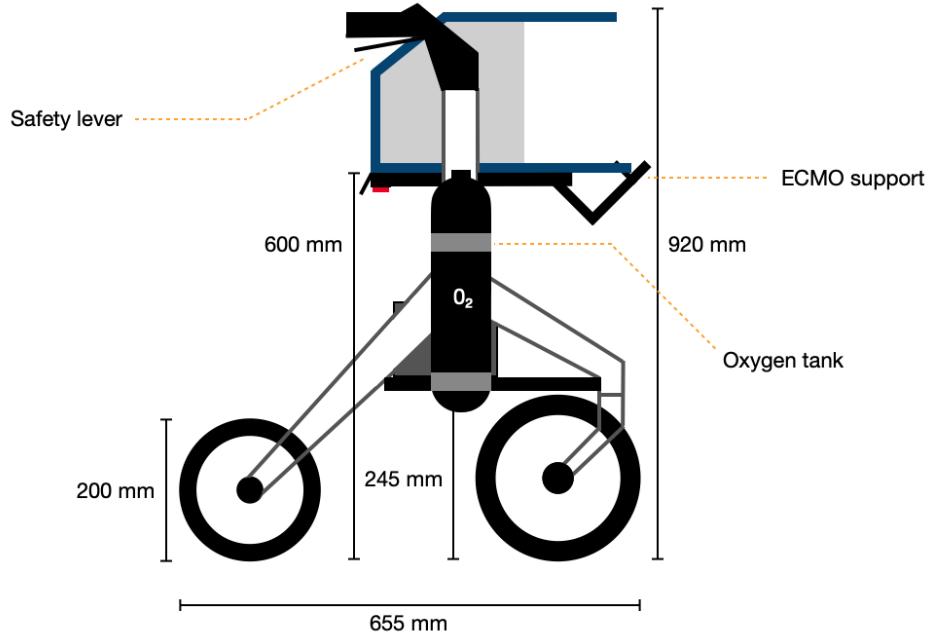


Figure 25: Side view of the ECMOVE.

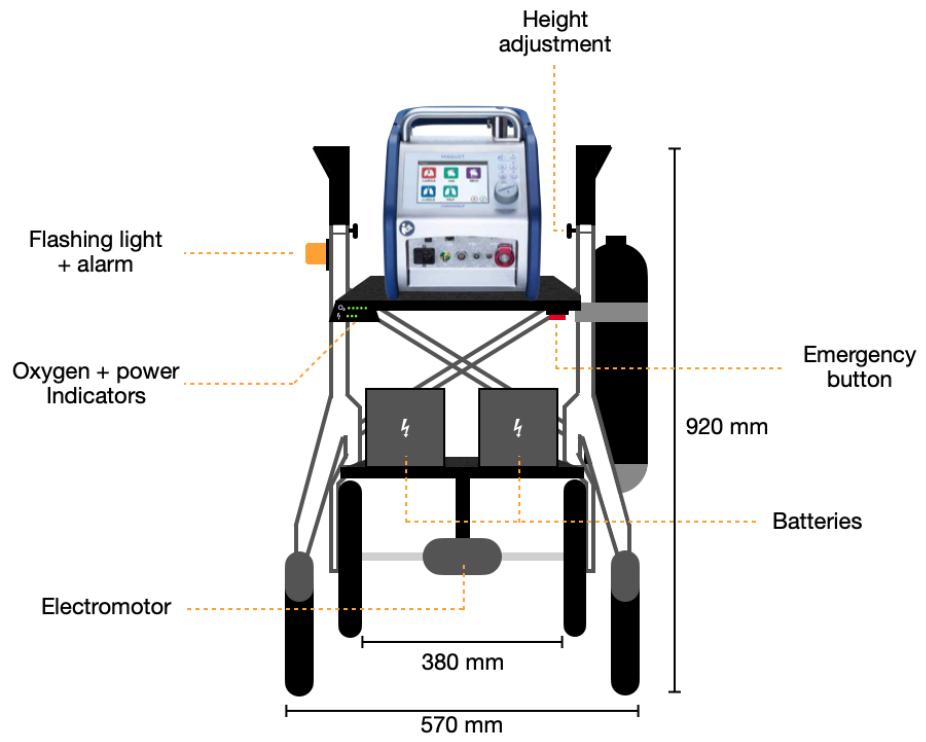
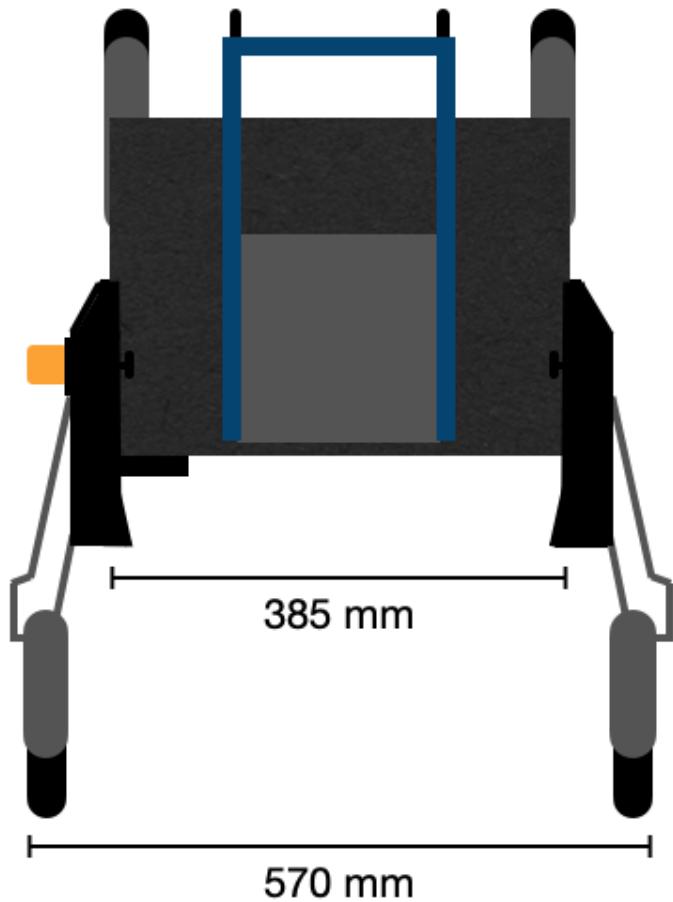


Figure 26: Back view of the ECMOVE.



TOP VIEW

Figure 27: Top view of the ECMOVE.

3.3.3 Calculation of the center of gravity & forces

It is important that the whole ECMOVE is stable so it does not flip over. To check whether this is the case, the center of gravity has to be determined. For this, the framework was split into components and all masses of the individual components were determined. The dimensions and weights of each component are shown in table 7 and its location can be found in figure 28. It can be observed that the center of gravity (COG) is near the center of the device in the x-direction in figure 28, which is perfect to guarantee stability.

Table 7: Weight and dimension of each component

Framework components	Weight (kg)	Dimensions (length x diameter in mm)
Fr1 (2x)	3.95	455x64
Fr2 (2x)	0.24	110x32
Fr3 (2x)	0.28	84x40
Fr4 (2x)	2.07	271x60
Fr5 (2x)	1.90	359x50
Fr6 (2x)	0.48	90x50
Fr7 (2x)	0.30	115x35
Fr8 (2x)	1.18	455x35
Component	Weight (kg)	Dimensions (length x height x width in mm)
Plate 1	6.40	312x20x380
Plate 2	6.01	293x20x380
TOTAL	33.22	655x920x570

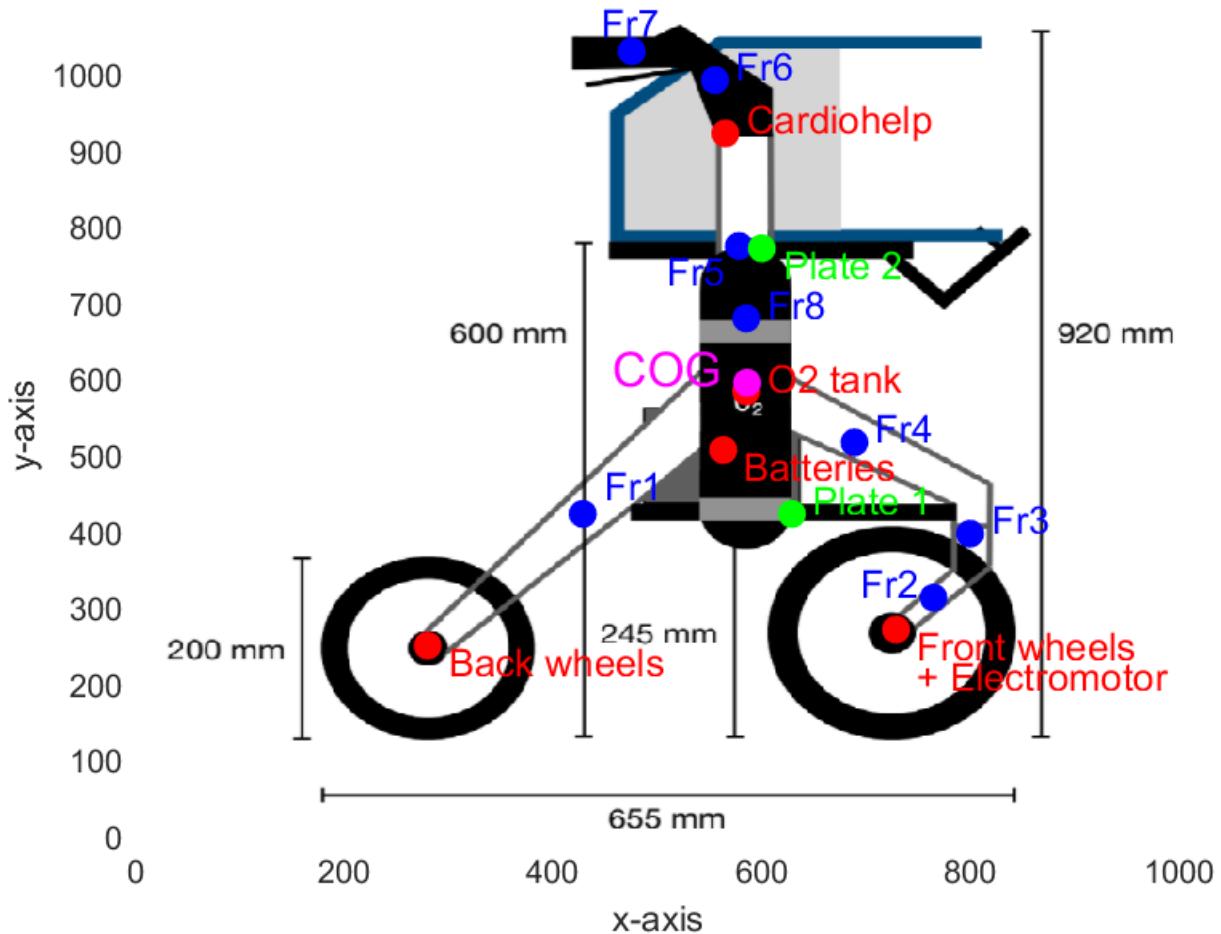


Figure 28: Centers of gravity xOy.

Because the device is almost perfectly symmetric in the z-direction, the COG in the z-direction is also close to the center of the device. The oxygen tank adjusts the COG slightly to the right, as can be seen in figure 29.

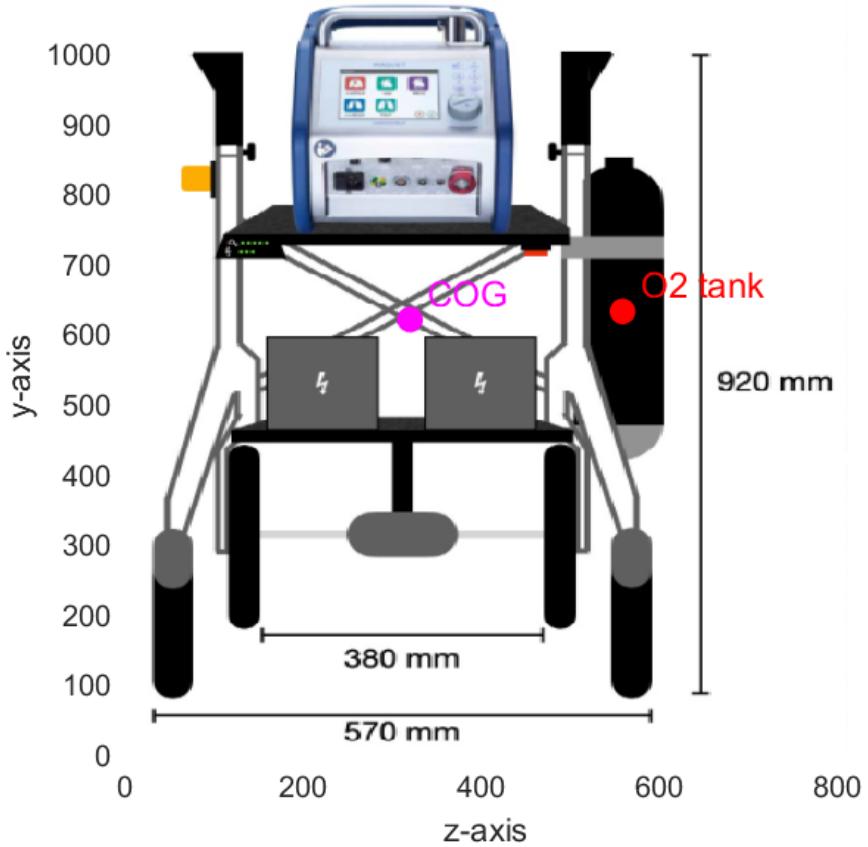


Figure 29: Centers of gravity zOy.

In conclusion, the COG is in the center of the device (between the four wheels) in both x and z directions, meaning that the ECMOVE has high stability. The way that the ECMOVE is designed makes sure that the device will never flip over no matter how much the patient leans on it, as long as the patient leans on it in the vertical direction. This is because the handles of the ECMOVE are between the four wheels, which serve as the support points for the device, in both x and z directions.

Next, it is important to calculate the power that the electric motor needs to deliver to support the movement of the ECMOVE. In order to do so, the friction that the system needs to overcome has to be calculated. This starts off with drawing all the forces that are acting on the ECMOVE, which is shown in figure 30.

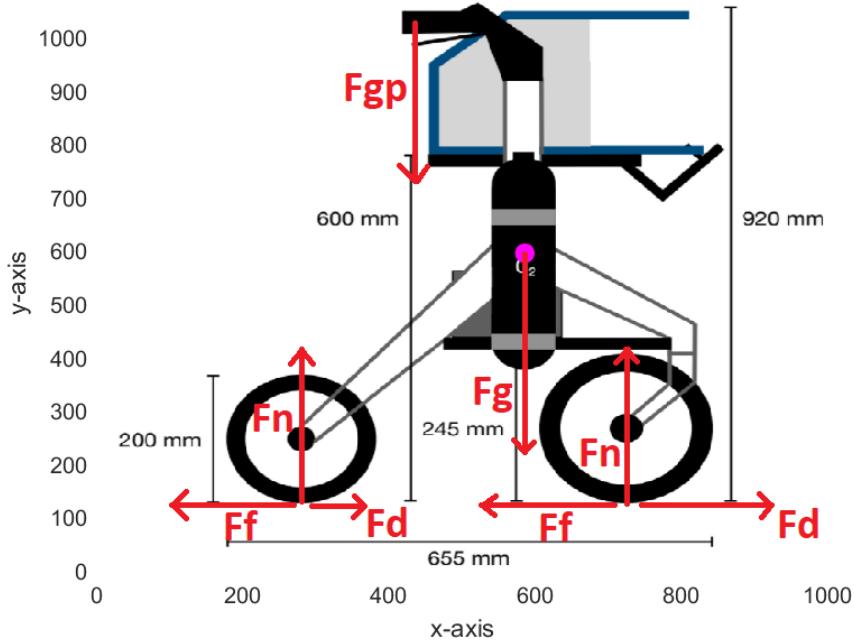


Figure 30: All net forces on the ECMOVE, without the harness and tubing. F_g = gravitational force, F_{gp} = gravitational force due to leaning of the patient, F_n = normal force, F_d = driving force, F_f = frictional force

The power that the electric motor has to deliver for movement of the ECMOVE (P_e) can be calculated by using the following equation: $P_e = F_e \times v$, with F_e = force that is generated by the electric motor. In order to do so, F_e has to be determined. This is done as follows:

$$F_n = F_g + F_{gp} = (m_{\text{ECMOVE}} + m_{\text{patient}}) \cdot g \quad (1)$$

Using the maximum weight of the patient (150 kg) and assuming that the patient leans with the weight of his full upper body on the ECMOVE, which is 55% of his total weight [30], equation 1 becomes:

$$F_n = 57.8 \cdot 9.81 + (0.55 \cdot 150) \cdot 9.81 = 1376 \text{ N} \quad (2)$$

The driving force is given by:

$$F_d = F_f = \mu_F \cdot F_n \quad (3)$$

Assuming a friction coefficient (μ_F) of 0.6, replacing the values in equation 3:

$$F_d = 0.6 \cdot 1376 = 826 \text{ N} \quad (4)$$

Assuming the ‘worst case scenario’, in which 100% of the driving force has to be delivered by the electric motor, this gives:

$$F_e = F_d = 826 \text{ N} \quad (5)$$

Finally, assuming you want to move at a maximum constant speed of 1 m/s:

$$P_e = F_e \cdot v = 826 \cdot 1 = 826 \text{ W} \quad (6)$$

This result shows that the maximal possible power that the electric motor has to deliver is 826 W. The ECMOVE consists of a 1000 W electric motor, which meets this necessity.

3.3.4 Ergonomics

The ergonomics of ECMOVE are related to usability, for both the patient and the ICU nurse in question. Therefore, as stated before in the requirements, the force that the patient needs to move the device should be less than 3kg. In addition, the product makes use of so-called deadman switches to power the motor of the device. When the patient releases these, the motor stops operating and ECMOVE comes to a stop. These deadman switches are intuitive as the patient already has their hands on the walking aid when they want more stability for walking. In addition, they can move the device of their own volition. A walker helps the patient to walk comfortably and with more confidence. Furthermore, the walker can help the patient to walk with good posture and keep their balance. The harness used to secure the ECMO tubing can be adjusted to the patient’s size. In addition, the harness has shoulder padding to make it more comfortable and less tiring to wear.

3.3.5 Evaluation of requirements

Now that the complete design and specifications of the ECMOVE are described in detail, a final evaluation of the requirements can be performed. First of all, the device is applicable for a wide range of patients. The handles are adjustable in height so that patients with different lengths are able to use the ECMOVE. The vest is adjustable in size, making it applicable to any patient with a weight between 50-150 kg and a length between 150-205 cm. Moreover, the ECMOVE is designed in a way that the center of gravity is at all times between the back and front wheels. This is independent of the weight of the patient and how hard he leans on the handles, provided that the patient lean in an approximate vertical direction on the ECMOVE. This makes it nearly impossible for the device to flip over.

Secondly, the size of the ECMOVE is appropriate for in-hospital use. The small dimensions of the system

(65.5x92x57 cm) make it possible to fit through a hospital door (width = 130 cm, height = 250 cm). On top of that, the patient does not have to carry any weight of the system by himself, except for the vest and blood tubing. The weight that the patient has to carry is well below 3 kg, which means that even the weakest ICU-admitted patients are able to use this device.

Thirdly, the ECMOVE is expected to perform well on safety and duration. The power supplies for the Cardiohelp and electric motor are well able to last for at least 20 minutes plus a 50% safety margin. The same goes for the oxygen tank, which stores enough oxygen for a walk of this duration including the safety margin. The built-in feedback system of the Cardiohelp is capable of showing its battery status to nearby ICU staff and can provide an alert if this is too low. Moreover, the integrated display of the ECMOVE is able to express the status of the oxygen tank and the battery status of the electric motor. This feedback system is also able to provide an emergency alert if one of these is too low. On top of that, the design of the vest should make sure that cannula stability is maintained during walking. There are however some uncertainties and possible risks involved around this, which are further discussed in section 4.3. The absence of the possibility for passive transport of the patient and the device by the ICU nurse in case of an emergency form a current limitation on the ECMOVE. A possible future solution could be to include handles on the device so that a separate wheelchair can be connected to the ECMOVE quickly when an emergency situation occurs.

Fourthly, the ECMOVE requires minimal assistance. Only one person of assistance (an ICU nurse) is required at all times. When the patient wants or has to go for a walk, the nurse should make sure that the batteries are fully charged, make sure that the oxygen tank is full and place the Cardiohelp on the designated place of the ECMOVE. Next, the nurse should help the patient with getting out of bed, by first of all helping him sit in bed, putting on the harness and making sure that the tubing is secured in the clips and guided properly. The patient is then able to walk with the ECMOVE, without requiring physical support from the nurse. The ECMOVE will only move based on the patient's intent and by the assistance of the patient only. In addition, the nurse is able to access all the settings of the ECMO at all times. When the patient returns to bed, the nurse should help him with turning off the electric motor, detaching the harness and making sure that there is not too much tension on the cannula and tubing in the process.

Finally, it is expected that there is plenty of room for interaction while the patient is walking with the ECMOVE. The system's height makes sure that it does not impede the patient's front vision so that interaction with relatives and friends may take place. The developers would like to include patient experiences on this in future studies, which is further described in section 4.4.

3.3.6 Persuasive design

Concerning the design's persuasiveness, it is vital to consider this subject and develop it in a way that would urge patients to utilize the device. It is true that, considering their situation and knowing they would enhance their health by utilizing it is a sufficient method to encourage patients to utilize the device. All of this, however, could be accomplished with the currently used solution. The main contrasts and motivating factors are that there is less stigma associated with walking with an ECMO machine as there is less personnel aiding the patient and the equipment is less bulky. As a result of these factors, the patient does not attract as much attention from others, they

feel more comfortable using it, and consequently, they will use the device more willingly.

3.3.7 Societal impact

As mentioned before, patients are currently very limited to leaving their beds while they are on ECMO. As a result, patients may suffer from physical and/or mental problems after they are discharged from the hospital, which gives them a poorer quality of life. However, this does not only affect the quality of life of patients but also has an enormous impact on relatives of the patient. Research describes that family members often suffer from emotional problems due to feelings of helplessness and lack of control, which may lead to depression and a poor mental state [31]. The burden on relatives caring for a person with a poor quality of life also has a negative impact on their social lives, as they might have to quit hobbies and lose friends in the process. The presence of disease can furthermore lead to long-term financial problems for patient relatives when the patient originally had a financial income and is no longer able to work. The EMOVE aims to increase patient mobility, thereby improving the quality of life of patients which should relieve earlier mentioned problems for relatives as well.

3.3.8 Estimation of costs

The prices of each part of the design are listed in table 8. It is important to state that the prices are given EURO, not all of them in the currency presented by their sellers.

Table 8: Cost estimation of each component of the design. *The prices shown are not given in the same currency presented by their sellers. The conversion was made on the 3rd of November of 2021, at 1PM (GMT+1).

Part	Price	Observations
Oxygen tank (cylinder type: 101-ZA)*	€ 20 [32]	The tank has to be changed after each usage
Battery (2 x 24V, 6 AH Lithium)*	€ 2 × 72.22 [33]	Rechargeable
Framework + wheels*	€ 69 - 518 [34] € 93.9**	This is the price of a four wheeled walker, similar to the framework that is needed for the device. Thus, this is an estimation cost for this part.
Electric motor	€ 635.56 [25]	-
Vest	€ 50 [35]	The price of the vest is actually 46€, but there are additional costs associated to the small plastic component.
Strain gauge	€ 25	-
Small (electrical) components	€ 25	These include buttons, alarm, light, wiring
Total	€ 1,418	Worst case scenario

To have a better approximation of the framework price, considering that its composition is mostly of aluminium, some calculations of the price are executed. It is worth noting that this price does not include the industrial process, but, having a mould for the fabrication of the exact design will not have a big burden in terms of costs. The price, per ounce, of aluminium as of the 10th of November of 2021 is \$0.08011 [36]. In EURO, this corresponds to 0.07€.

The total weight of the framework is 33.22 kg which is 1171.801 oz. With all these values it is possible to estimate the framework cost:

$$\text{cost}^{**} = 1171.801 \cdot 0.08011 \approx 93.9\text{€} \quad (7)$$

In table 9 the cost of the Cardio Help device and the tubing are presented, even though they are not part of the design.

Table 9: Cost of each component used with the device but not included in it.

Part	Price
Cardio Help - control & motor	\$ 110,250 [37]
Cardio Help - blood pump	\$ 13,781 [37]
Tubing	\$ 11.99 - 5 feet (152.4 cm) \$ 99.99 - 100 feet (3,048 cm) [38]

3.3.9 Market potential

As of September 27, 2021, the average yearly income for an ICU nurse in the United States is 66,780€¹, with a normal range of 60,170€¹ to 72,568€¹ [39]. Our design's overall cost is much lower, at approximately 1418€ and it may be able to cut the number of ICU nurses on some wards. According to a 2021 study, the cost per day in an ICU ward in the United States is at least 19,242€¹ [40], thus having this technology that will very surely minimize the time required for treatment would also lower expenditures for the ICU. Due to these reasons, it will undoubtedly have a high commercial potential.

An early health technology evaluation is required to have a better understanding and accurate calculation of the whole market potential. It is also worth emphasizing that this approach is supposed to benefit the industry. It is likely that they will be offered lower pricing for each component of the equipment when purchasing in bulk, and the assembly procedure will not be incredibly expensive. They will be able to create a large quantity and profit from it in this manner.

It is expected that this design will be bought by ICU wards that already have the Cardiohelp ECMO system.

¹The conversion was made on the 3rd of November of 2021, at 1PM (GMT+1).

4. CE - Marking proposal

It is necessary to make sure that the final product as described in synthesis III complies with the regulations that apply for it before bringing it on the market. According to article 2 of the Medical Device Regulation (MDR), the system should be described as a medical device, because it is used for human application and aims to alleviate disability, by improving outcomes after patients are discharged from the ICU and improving mental condition [41]. This finding was confirmed by performing the Quickscan [42]. Before medical devices can be put on the market, the device needs to have a CE-marking. This section aims to summarize the steps that need to be taken to obtain a CE mark.

4.1 Intended use

The product will be used by ICU admitted patients who are depending on VV-ECMO. The intended use of the product is to provide patients the opportunity to be able to take a walk for at least 20 minutes within the hospital, without requiring other persons or tools to support walking. The product supports all the necessary parts of the VV-ECMO for a short walk and can support the patient in walking.

4.2 Classification

Medical devices are classified into four categories: class I, IIa, IIb and III. A higher class indicates a higher risk for the patient in case of system failure and therefore requires more special controls and has to comply with extra legislation. To classify the final product in this project, the classification Quickscan was used [42]. Here the final project is just the walking aid device with its features. The Quickscan, see Appendix II, indicates that the product is a class IIa medical device, meaning that the risk of the product is relatively high. This is mainly because it contains multiple electrical components. Therefore, a notified body needs to assess the device. In this assessment, the intended use, safety requirements, quality assessment, risk management, laboratory tests and clinical tests will be evaluated. These aspects are further mentioned in the following sections.

4.3 Risk management

Risk management is related to potential risks that can occur when using ECMOVE. By doing these assessments, the risks can become visible and possibly averted.

4.3.1 General safety and performance requirements

The requirements of ECMOVE are stated in chapter 2.6, these requirements will be used to assess the risk of ECMOVE. In particular, the safety requirements will be assessed. These requirements are used to determine if the system is safe to use. By assessing the run time, the cannula stability, emergency alert and the system's feedback, safety can be determined. The performance requirements are related to the applicability, size, duration, assistance and interaction with/of the system.

4.3.2 Failure mode and effect analysis (FMEA)

FMEA is used to indicate the risk, in this case of the designed concept: ECMOVE. By identifying risks and the magnitude, the product will not be misleading and probably will not have any unaccounted problems. The following formula can be used to compute a score that indicates the risk of a product:

$$RPN = P \cdot S \cdot N \quad (8)$$

In this formula, all three factors are scored on a numerical scale of 1 through 10. The ‘P’ in the formula is related to the probability of failure which can range from 1) “very low (1 per 20 years)” to a score of 10) “sure”. The ‘S’ is related to the severity of the failure which can range from 1) “Possibly not detected (no costs)” to a score of 10) “Catastrophic (costs > 1M€ and/or more than 10 deaths)”. The last term ‘D’ is whether it’s not detected in time. The probability of the failure not being detected in time can range from 1) “Failure is immediately detected” to 10) “Failure is not detected in time”. With this formula the Risk Priority Number (RPN) is calculated, the higher the number, the higher the risk. When the Risk Priority Number is higher than 20, the risk is regarded as unacceptable.

In table 10, an overview can be found off the FMEA on ECMOVE. It can be observed that all failures have a low probability of being undetected. In addition, all failures related to cannula stability are perceived as unacceptable, e.g. $RPN > 20$. Therefore, a change or additional specification to the final concept has been made. Extra support for the cannula is needed and thus a plastic U-shaped guiding mechanism is added to the final implementation, see section 3.3.1. It has the goal to lower the probability of occurrence. The plastic U-shaped guiding mechanism bends the tubing from the cannula and reinforces a fixed position with the harness, supporting the weight of the tubing and therefore not directly impact the point of insertion in the patient. Therefore, the probability of the cannula moving and the effects are diminished. After this additional support is added, see figure 24, FMEA analysis is redone regarding the cannula stability, see table 11.

By observing these final results, the RPNs of all functionalities can be deemed sufficient. However, the FMEA analysis is based on predictions. Therefore, in the following section, possible lab tests are stated that can verify these indicated values.

Table 10: Risk management.

Function	Requirement	Potential Failure	Potential Effects	Potential Causes	Prevention	Control detection	Severity (S)	Probability (P)	Detection (D)	RPN
Power supply ECMO	The system should have a run time of 20 minutes; The system should have a safety margin of the run time of 50%	The ECMO system stops	No more circulating the patients blood	Empty battery	Checking battery status before going mobile	Feedback of the battery to the nurse	8	2	1	16
		The ECMO system stops	No more circulating the patients blood	Systems power disconnected	Checking the systems connections	Feedback of the battery to the nurse	8	2	1	16
Power Supply Motor	The system should have a run time of 20 minutes; The system should have a safety margin of the run time of 50%; The system should be able to move by assistance of the patient only	The motor receives less power, the cart is driven slower	The patient needs to use more of their own strength to push the system forward/ or the patient requires additional help from the nurse	The battery is almost empty	Checking battery status before going mobile	Feedback of the battery to the nurse	2	4	2	16
		The motor no power	No more motor support while walking	The battery is empty	Checking battery status before going mobile	Feedback of the battery to the nurse	2	3	2	12
	The system should provide an emergency alert to staff.	The powering of the motor does not cut off in emergency	The system is still moving forward in emergency	The handles are stuck in pressed	Check the response of clenching and unclenching handles every 0.5 years	Feedback to the patient, then to the nurse	8	2	1	16
Oxygen supply	The system should have a run time of 20 minutes; The system should have a safety margin of the run time of 50%	Empty oxygen tank	No oxygen to the patient	Leakage in the tank	Checking oxygen tank before going mobile	Feedback of the oxygen tank to the nurse	5	2	1	10
		Oxygen input being compressed	No oxygen to the patient	Restricted when positioned on the walking aid	Checking oxygen status on ECMO	Feedback to the nurse of the oxygenation	5	4	1	20
Cannula Stability	The cannula must stay in place	The cannula moves fully out of the body	Bleeding/Death	The patients moves too far away from the ECMO system	Clips holding the tubing in place	Observation by nurse and patient	8	5	1	40
		The cannula rotates	Blood gets circulated in the wrong direction	The patient turns around with too much tension on the tubing	Clips holding the tubing in place/ tape on the cannula	Observation by nurse and patient	8	5	1	40
		The tubing is moving slightly down	More pressure on the cannula connection to the patient	The vest opens	Properly checking the closing of the vest	Observation by the nurse	5	5	2	50
		The tubing is moving slightly down /cannula movement	More pressure on the cannula connection to the patient	The vest moves around	Adjusting the vest properly to the size of the patient by the nurse	Observation by the nurse	5	4	2	40
		The cannula moves fully out of the body	Bleeding/Death	The patient falls	Leaning on the walker and creating a safe space so the patient can communicate their health	Feeling by the patient, observation by the nurse	8	6	1	48
Feedback system	The system should give real time feedback about its status.	No feedback	The systems sensors are off	Broken hardware/ software bug	System updates, system checks	By the nurse or technical medical assistant	8	1	2	16

Table 11: Risk management of the cannula stability after added support.

Function	Requirement	Potential Failure	Potential Effects	Potential Causes	Prevention	Control detection	Severity (S)	Probability (P)	Detection (D)	RPN
Cannula Stability	The cannula must stay in place	The cannula moves fully out of the body	Bleeding/Death	The patients moves too far away from the ECMO system	Clips holding the tubing in place/ additional support holder for the tubing	Observation by nurse and patient	8	2	1	16
		The cannula rotates	Blood gets circulated in the wrong direction	The patient turns around with too much tension on the tubing	Clips holding the tubing in place/ tape on the cannula	Observation by nurse and patient	8	2	1	16
		The tubing is moving slightly down	More pressure on the cannula connection to the patient / worst case cannula rips out	The vest opens	Properly checking the closing of the vest	Observation by the nurse	5	1	2	10
		The tubing is moving slightly down /cannula movement	More pressure on the cannula connection to the patient / worst case cannula rips out	The vest moves around	Adjusting the vest properly to the size of the patient by the nurse	Observation by the nurse	5	2	2	20
		The cannula moves fully out of the body	Bleeding/Death	The patient falls	Leaning on the walker and creating a safe space so the patient can communicate their health	Feeling by the patient, observation by the nurse	8	2	1	16

4.3.3 Laboratory tests

In order to verify the probabilities and indicate the potential risks, the results from the FMEA can be verified. Most of the laboratory tests are related to the stability of the cannula, as this remains one of the highest RPNs. Therefore, laboratory tests are recommended to further inspect this risk and find the underlying reasons. In addition, from these laboratory tests, potentially different solutions can be proposed. Hence, by performing tests to test the cannula under different conditions, the device can be declared safe to continue to the METC research protocol.

The first laboratory test has the goal to test the strength with which the cannula is attached to the patient by ECMOVE. Therefore, a pulling test needs to be done. By applying forces on the tubing it can be observed if the probability of the cannula being removed from the body is high or if the clips holding the tubing in place are enough to prevent this. In order to test this scenario, a dummy needs to be used to emulate the skin and the cannula inside the skin as well as possible. In addition, pulling in different directions needs to be performed.

Secondly, a laboratory test simulating a patient falling needs to be executed. In the worst case, as the patient is already on life support, a patient can become unwell. There will always be a wheelchair nearby, making sure that the patient can sit and rest. However, when the patient falls without warning, the cannula should remain in position. Therefore, the tubing needs to allow for this fall, which has been calculated. However, there are different ways the patient can fall, possibly resulting in different harms. Fall tests can be executed with a dummy falling while walking with ECMOVE.

Lastly, an entire rundown of a real-life scenario needs to be executed. This means that the experiment starts

with the test subject needing to get up from the bed and being able to receive the harness. With this experiment, the last complications in the cannula stability, as well as the other functionalities can be tested, therefore preventing pitfalls before testing with patients themselves. In this scenario, the nurse needs to be able to prepare the walker-aid for mobile transportation. Starting with the harness, the nurse needs to safely connect the straps and adjust them to the test subject. The test subject needs to be able to get up from a lying position to be able to get up and walk with ECMOVE. After the walking test, the test subject needs to be able to come back to their room and in their bed. Therefore, the test subject needs to be released from the harness with ease by the nurse.

4.4 METC research protocol

This section describes the clinical study that will be performed in order to confirm the safety of the device and rule out unforeseen dangers and risks. It uses the template for research protocols by the Centrale Commissie Mensgebonden Onderzoek (CCMO) [43]. Only the introduction and rationale, objectives and study design are described, as the other contents from this template are beyond the scope of this project.

Study title

Increasing the mobility of VV-ECMO-dependent patients by using a newly developed walking aid: ECMOVE.

Introduction and rationale

Veno-Venous Extracorporeal membrane oxygenation (VV-ECMO) is used to manage pulmonary failure **MarasCO2008** and is a system that takes over the functions of the lung outside the body of the patient. It is usually applied as a temporary measure when patients are on a waiting list for lung transplantation, or to give the lungs rest and time to recover from disease while preventing hypoxemia and hypercarbia [6]. Due to VV-ECMO being more and more accessible and applicable over the past decades, its incidence has risen from 1.0:100,000 inhabitants per year in 2007 to 3.0:100,000 per year in 2012 [4].

In VV-ECMO, venous blood is withdrawn from the internal jugular vein via a central venous catheter. The blood is then pumped through a membrane oxygenator where gas exchange takes place. In the oxygenator, CO₂ is removed from the blood and O₂ is added to the blood. The oxygenated blood is transported through a heat exchanger in order to regulate the temperature. The final step is to return the blood back to the body, which can be done via the same insertion location: the internal jugular vein. Therefore, in VV-ECMO a double lumen catheter is used, which is capable of both withdrawing deoxygenated blood from the body as well as returning oxygenated blood to the body [2].

Currently, VV-ECMO-dependent patients have to stay in the ICU where they are closely monitored by ICU nurses. These patients are not able to leave their beds easily and therefore usually lie flat all day. This may however have severe consequences for the patient, since low mobility leads to longer recovery times, worse outcomes after transplantation and poorer mental state [8]. Since these patients may be admitted to the ICU for weeks or even months, severely limited mobility has a huge impact on their quality of life [7].

The reason behind the fact that patients are not able to leave their beds easily is that current VV-ECMO devices are bulky and complex which makes them difficult to mobilize. One of the smallest current VV-ECMO devices, the

Cardiohelp (Getinge), is a good step in the direction towards portable ECMO, but is mostly used in patient transport and not mobile enough yet for patients to walk independently [14]. This led to the development of the ECMOVE: a walking aid that is capable of supporting all necessary parts of the Cardiohelp and able to provide support to the patient. The full description and specifications of the ECMOVE can be found in section 3.3. Using the ECMOVE, patients may be able to walk independently while on VV-ECMO support by the Cardiohelp.

In this study, the performance of the ECMOVE will be evaluated in a clinical setting. A small group of VV-ECMO-dependent patients will be included, which enables the researchers to test the additional risks, applicability and comfort of the ECMOVE in clinical practice. This study forms the next step towards the implementation of the ECMOVE in ICU admitted patients, which could increase patient mobility and ultimately improve patient outcomes after leaving the hospital.

Objectives

Primary objective: Evaluate the safety of the ECMOVE in clinical practice and determine additional possible risks that were not predicted beforehand and not found in laboratory studies.

Secondary objectives:

- To investigate the ease and duration of putting the harness on the patient
- To investigate patient comfort of walking with ECMOVE, as well as wearing the harness
- To investigate the user-friendliness of the ECMOVE for both ICU nurses and patients
- To investigate possibilities for social interaction while walking with ECMOVE

Study design

The study will include a small group of around 10 patients that are on the Cardiohelp (Getinge) VV-ECMO. These patients are asked to walk with the ECMOVE three times on three separate days for around 20 minutes while under strict supervision by an ICU nurse. The reason for walking multiple times instead of once is to give the patient and nurse some time and opportunity to become familiar and possibly adapt to the ECMOVE.

After each walking session, the patient is invited to fill in a questionnaire about the experience. These are mainly questions that target the comfort of the patient. To keep it simple and understandable for all patients, the patient can give a score between 1 and 10 on each topic and provide possible additional remarks at the end of the questionnaire. A few examples of questions would be:

- How would you rank the comfort of walking?
- Would you rank the comfort of wearing the harness?
- How would you rank the comfort of performing head movements?
- How would you rank the possibility for social interaction while walking?
- How would you rank your feeling of safety while walking?

On top of that, the ICU nurse should also report about the walking session by answering a set of questions that mainly target safety and applicability. A few examples of questions would be:

- Were there any safety concerns, risks or dangerous situations during the procedure?
- How would you rank the ease of putting the harness on the patient and getting him to walk with the ECMOVE?
How long did this take (in minutes)?
- How would you rank the technical difficulty of using the ECMOVE?

If the nurse judges that walking is irresponsible or dangerous (at that moment), the patient should return to his bed immediately and the reason for interruption should be noted down. Moreover, if the patient does not feel well and wants to stop walking before the 20 minutes are over, this should also stop the walking session and the nurse should report the reason. To make sure that the walking session can be interrupted safely at any point, a wheelchair and additional staff should be nearby the patient at all times to facilitate passive transport to bed.

In order to investigate the applicability of the ECMOVE in clinical practice, the ICU nurse should also write down the length and weight of the patient. All data should be anonymized so that the participants are not identifiable from the collected data.

5. Final conclusions and recommendations

This project is the first step into the development and implementation of a walking aid for VV-ECMO dependent patients. Based on literature research, extensive analysis on necessary requirements, functions and the synthesis of a wide range of possible solutions, the optimal design was established. The ECMOVE walking aid is a promising solution for mobilising VV-ECMO dependent patients. It fulfils the stated requirements regarding applicability, size, duration, assistance, interaction and performs well on most safety requirements.

Future laboratory studies should focus on testing the stability of the cannula at the insertion point of the neck. If these studies continue to show positive results, the ECMOVE can be tested in clinical settings, where real patients must be included to test the performance of the device in clinical practice. If the outcomes from laboratory tests prove an unstable cannula connection, adjustment of the design is needed before clinical studies should be conducted. Once the ECMOVE is proven to be safe in laboratory studies and clinical practice, following the studies described in the CE marking proposal, the next step would be to determine the effectiveness of the ECMOVE. For this, large randomised controlled trials should be conducted, so that the usefulness of the ECMOVE can be determined in terms of quality of life improvement after leaving the hospital.

An important limitation of the ECMOVE is that passive transport of the patient and the device by the ICU nurse in case of an emergency is currently impossible. Future design studies can be conducted to explore the possibilities of reducing this limitation. The authors suggest that it may be an option to place handles on the ECMOVE so that a separate wheelchair can be quickly connected in the event of an emergency.

If the ECMOVE is fully developed and ready for use, there is a great impact expected on both the patient level and societal level. The ECMOVE increases patient mobility, which results in better physical preparation for transplantation and ultimately improves their quality of life after being discharged from the hospital. This also relieves emotional problems and stress from family members and friends. Finally, the authors expect a good market potential for the ECMOVE due to the large reduction in necessary costs and the high number of people that could benefit from this device.

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Appendix I

Team management - ECMOVE

Analysis of team composition

To be able to work successfully in a multidisciplinary team, good cooperation is essential. To ensure that the project runs as smoothly as possible, it is important to assign the roles within the team to the right people. All team roles should be covered by the team members. This can be done by performing a team composition analysis. When a certain role is not assigned, this will lead to a gap in the pursuit of ultimate team functionality. A Belbin's team role analysis has been performed, with results graphically displayed in figure 1.

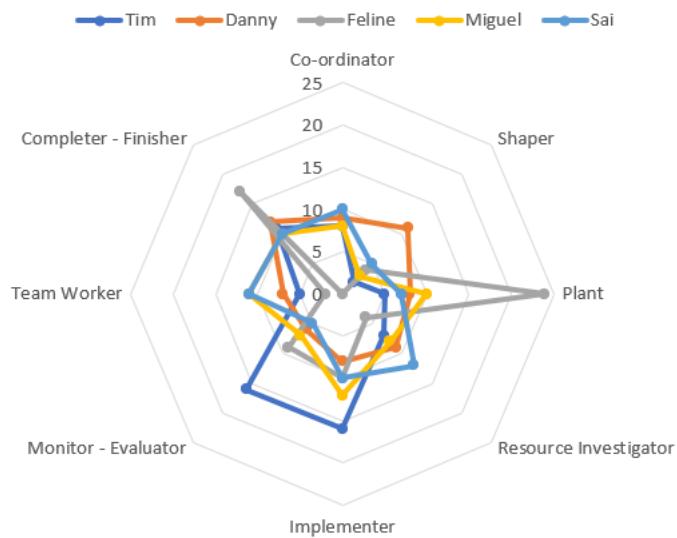


Figure 1: Results of Belbin's team roles analysis

The results of Belbin's analysis show an overall balanced distribution in the team roles. However, there are a couple of roles that stand out for specific group members. Team roles are assigned to the group members who score best on a specific role. When there were roles for several group members, it was discussed verbally which role each group member thought best suited him or herself. Ultimately, the following division of roles was established, seen in table 1.

Organisation type

In addition, it is important to determine the type of organization before the start of the project. Both the structure and the culture within an organization determine the eventual type of organization in which the design assignment is carried out. This affects the quality and efficiency of the project. For a design project, a task-oriented organization is best suited. Achieving the ultimate goal is the most important here. Possible shortcomings and limitations are

Table 1: Assigned team roles based on Belbin's team roles analysis

Team Role	Team Member
Co-ordinator	Danny
Shaper	Danny
Plant	Feline
Resource investigator	Sai
Implementer	Miguel
Monitor - Evaluator	Tim
Team worker	Sai
Completer - Finisher	Feline

solved by using the right people in the right place during the project. A questionnaire regarding organisation culture preferences was performed by each team member, with results are displayed in figure 2.

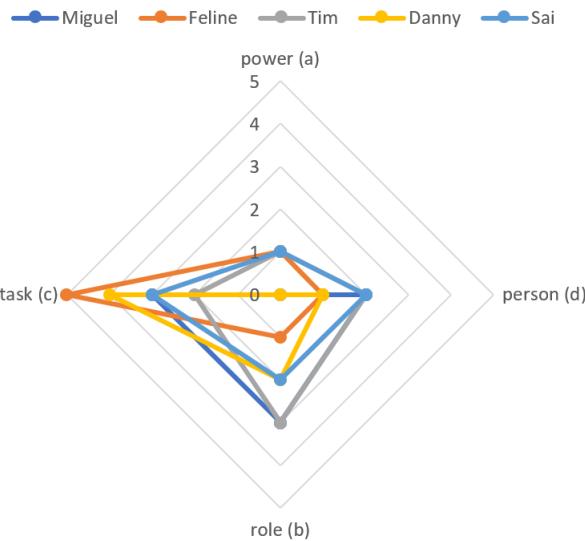


Figure 2: Results of organisation culture preferences analysis

The results of figure 2 tend towards both a culture of tasks and roles. However, the accumulated score points out that the culture of tasks is most preferred in this team. This corresponds to the recommended culture for the execution of this design project. Therefore, we will adopt a culture of tasks within our organisation performing this project.

Character analysis

Mapping out the different character traits of all group members can be valuable in detecting and preventing potential problems within the team. This can be done through character analysis. Through this analysis, the qualities, threats, challenges and allergies of each team member can be identified. By comparing these characteristics between the team members, possible opportunities and bottlenecks in the collaboration can be highlighted. Characteristics were analyzed using the quadrant conflict method. This method assumes that when the threat of one person resembles the allergy of someone else, this will lead to a conflict. On the other hand, qualities from one person can be used to

improve the challenge of another team member. Table 2 shows the results of the character analysis and highlights the possible conflicting and complementary characteristics.

Table 2: Results from character analysis using quadrant conflict method

Team member	Quality	Thread	Challenge	Allergy
Danny	Perfectionism	Worry about details → working slow	Continue/end the task	Sloppy / messy
	Perseverance	Tunnel-vision / counterproductive	Determine when something is good enough	unmotivated/bored people
	See connections	Unclear / obscurity	Stick to basics	Not innovative
Miguel	Perfectionism	Working slow	Finishing on time	Sloppiness
	Optimistic	Overconfidence	Being more realistic	Pessimists
	Listening to others	Passiveness	Sharing points of view	Not taking others into account
Feline	Perfectionism	Focused on details	Determine when something is finished	Rushing/negligence
	Driven	Overambitious	Relativise / down to earth	Unmotivated people
	Curiosity	Off-topic	Relevance	Thinking inside the box
Sai	Listening to others	Passive	Interacting/active	Being forced to be active/pushy
	Clear understanding of the concept	Slow progress	Submitting on time	Careless
	Team player	Dependent	Initiating	Independent
Tim	Precise	Perfectionism	Relaxed	Carelessness
	Down-to-earth	Conservative	Thinking out of the box	Dreamers
	Independent	Loneliness	Group-thinking	Dependency

Potential clashes

From the character analysis it can be concluded that four out of five people would describe themselves as having some degree of perfectionism. Although this can be a good quality in terms of wanting to strive for the best results, it may also slow down the process of the project and could lead to long discussions. This means that we as a group should watch out for this and maybe talk to each other if our perfectionism leads to slow progress. On the other hand, the fact that most of us strive for perfectionism also reduces the chance that people become unmotivated/careless. Hence, we should not expect confrontations about this topic. At the individual level, it can be found that Tim is allergic to dependents while Sai finds it difficult to work alone. Tim is conservative which Sai finds allergic. Danny, Feline and Sai are allergic to people who think inside the box which is a challenge for Tim.

Learning possibilities

It can be learnt from the quadrant that “Creative” as a quality could be “a teacher” for conservative/non-innovative and a “non - down to earth” attitude can be learned from those who find it a quality. The team, as a whole, is allergic to careless, pessimistic and unmotivated people which is a plus for the whole project. At the individual level, it can be observed that Miguel and Tim may learn from each other, with Miguel having the quality of being optimistic and Tim being more down-to-earth. Sai and Tim could also learn from each other, with Sai being more of a team player, but also more dependent on other people. Tim mostly does not have to depend on others, although this may lead to being less involved in the group process. Danny and Feline have perseverance and so they can drive the whole team to utilize the fullest of everyone.

Project management

Planning

In table 3, it is possible to get an idea of the planning that went through this project. Table 4 has the roles and contact information of each member of the project team.0

Table 3: Overall planning of the assignment

Week	Date	Activity
Analysis:		
1	Week 38 (20.09.2021 - 26.09.2021)	1. Problem Definition 2. Goals 3. Finish teamwork and project management parts in the report
Analysis:		
2	Week 39 (27.09.2021 - 03.10.2021)	1. Design assignment 2. List of requirements 3. Stakeholder analysis 4. Function analysis
3	Week 40 (04.10.2021 - 10.10.2021)	Synthesis I
4	Week 41 (11.10.2021 - 17.10.2021)	Synthesis II
5	Week 42 (18.10.2021 - 24.10.2021)	Synthesis III
6	Week 43 (25.10.2021 - 31.10.2021)	1. Risk analysis 2. CE 3. METc 4. Costs/market potential
7	Week 44 (01.11.2021 - 07.11.2021)	Prototype finished
8	08.11.2021 12.11.2021 11.11.2021 / 12.11.2021	1. Report done 2. Report submission 3. Final presentations

Table 4: Contacts of the team

Role	Name	Mail
Chairman	Danny van Galen	d.j.m.vangalen@student.utwente.nl
Secretary	Feline Waardenburg	f.h.waardenburg@student.utwente.nl
Team member	Miguel Baptista	m.mafrabaptista@student.utwente.nl
Team member	Sai Arunajatesan	s.arunajatesan@student.utwente.nl
Team member	Tim Heuker of Hoek	t.a.heukerofhoek@student.utwente.nl
Client	Prof.dr.-ing J. Arens	j.arens@utwente.nl
Tutor	Ir. E.E.G Hekman	e.e.g.hekman@utwente.nl

Communication plan

Table 5: Platforms used for communication

Platform	Use
Whatsapp	Short direct communication + short questions + scheduling new appointments
Google Drive	Storing and editing report files
MS Teams	Online meetings
Mail	Contact with client and tutor
Mendeley	Managing references and resources
Miro	Brainstorming
Matrix	Organise requirements
Overleaf	Final report

A distinction is made between a meeting and a work session. A meeting includes tutor conversations, conversations with the client and extra meetings with the team. The work sessions are always on campus and used for project collaboration. This includes brainstorming sessions, working on the prototype and discussion on division of tasks. It was also concluded that the work sessions will be held every week making sure every team member is available.

When a team member is unable to attend a meeting on campus, we all meet online. If a team member is unable to attend a work session on campus, the rest of the group will meet on campus. The team member who cannot be present will be assigned a task that he/she can do at home in order to contribute to the progress of the project.

Quality plan

In order to guarantee the quality and progress of the project, the expectations of each team member were discussed prior to the start of the project. In conclusion, every team member strives for an 8 or higher. However, we agreed that the final grade is not the most important aspect of the project. We want to design something that we can be proud of at the end of the project. Also it is the best example to prove that our team falls under “culture of tasks” as the goal of every team member was to obtain a “higher goal”. Some considered the goal to be a grade and some considered it as learning and implementing something interesting.

To make sure the project goes as planned, we as a team have set up the following rules:

- If you cannot attend a tutor meeting, you must notify the chairman 24 hours in advance.
- If you are late for a tutor meeting, do not come. This disrupts the precious time of the meeting.
- If you are late for a work session, let us know beforehand. If you do not, you will get a penalty point. If you have three penalty points, you need to treat the group to something delicious.
- If a team member does not contribute enough to the project, the person concerned will be spoken to for improvement, by the chairman. If this is not the case, the tutor will be contacted for possible sanctions.

To make scheduling tutor meetings and work sessions as smooth as possible, team members have been designated to fulfil specific tasks, as it can be observed in table 6.

Table 6: Regular tasks of the team members

Team Member	Task
Danny	Contact with tutor and client
Sai	Booking time slots for tutor meeting, scheduling meetings if online
Miguel	Booking rooms for work sessions
Feline	Making minutes of the meetings

Evaluation of teamwork and team members

The work of every team member was appreciable. Though we missed a team member due to unavoidable situation, we did our work with perfection and optimism. At that moment, our group was left with 5 biomedical engineers. Still, we managed to accomplish the prototype designs for the assignment. This proves the team work of our group.

Considering individually, Danny, as a coordinator, shaper and chairman did his work to the fullest. He had a good voice of command which was the driving force behind the entire teamwork. Also, he was a good communicator who maintained harmony among the team members and listened to the suggestions of everyone before obtaining a solution. He set the agenda for every meeting, which is the duty of a coordinator. He also contacted the tutor and researcher for confirming the availability for meetings and also for questions. Though Danny had the role of shaper as well, his coordinator characteristics dominated the shaper inside him, which led to a smooth teamwork.

Feline, the secretary, plant and finisher of the team did a great job. Being a plant, Feline came up with more original and radical - minded ideas. She also came up with some wild ideas for the technological problem which were quite innovative. Being a finisher, she did the final report correction and completion. She was a spark for creating more realistic ideas as well. Feline used her potential as much as possible to contribute to the project. She also did an excellent work of the minutes of the meetings with the tutor, as well as the client.

Tim was the monitor - evaluator of teamwork. He would caution the entire team if it would go out of track. He is a fair-minded person who is open to suggestions and ideas. He would evaluate the writings of the others and provide valuable feedback to them for improvement. He also made decisions in some situations which were perfect.

Miguel is the implementer, seeking feasibility in every idea given while still being able to be realistic. Being an implementer, he made sure that everyone knows what their works are and also ensures that work had been completed. He was perfect and punctual in every task that he undertook. As he was punctual, he was the one who was organising rooms for every work session.

Sai is the team player and resource investigator of the team. She was a very social, energetic and likable person in the team. This made her justify her role as resource investigator. She also came with all kind of wild ideas with the morphological scheme that we had. She fitted with everyone in the team so quickly and she was a stable extrovert. She booked slots for every tutor meeting and scheduled meeting links if it is online.

Overall, everyone in the team did their work at its best and there was no conflict with respect to work as well as character. Everyone in the team were asked to fill in the team member assessment form provided and all the total scores were 8, having a straight line in the graph without any crests or troughs, again confirming the harmony among the team members.

Evaluation of project management

The project was executed successfully as per the plan made during the first meeting. The tutor meetings were held in the afternoon session on Thursdays. The work sessions were conducted in the morning every Wednesday. Meeting every week and working as a group generated many new innovative ideas related to the project. It was very comfortable to interact and explain our views. Also, it decreased the possibility of conflicts among the team members as well as among ideas. Teamwork was the major reason behind the success of the execution of the planning. Apart from this general planning, a to-do list was made every week with the short planning on individual tasks for the week and tasks for the next work session. The tasks were divided among the team members based on their roles, responsibilities and interests. The work was discussed in the next work session and further suggestions were provided by other team members which were also corrected in the upcoming week. The communication platforms were also used wisely. The first three rules of the teamwork quality plan were met during the course and there was no need to implement any sanctions. Everyone carried out their tasks and went along with each other perfectly.

Evaluation of the assignment

The assignment provided was to design a walking aid for in-hospital walking of the patients under ECMO. The primary requirements of the client were more general and that gave us the freedom to put all our thoughts into action. There was a very smooth relationship between the client, Professor Jutta Arens and the team members. All the team members interacted with her efficiently and clarified their doubts in every meeting held with her. During the course of assignment, there were several meetings with the tutor, Professor Edsko Hekman in which topics such as the work done so far, team management, to do list and the confusions regarding the report and design were clarified with the help of the tutor. The assignment was well defined and gave us a room for more innovative thinking. It also made us learn information about ECMO, its patients, their characteristics, ECMO specifications and a lot more. It also gave us an opportunity to work as a team which was wonderful.

Evaluation of the course

The course made us understand the importance of teamwork and the steps to effectively implement the project management by making plans, dividing tasks, roles and responsibilities, etc. This course also taught us how to be a great team player and realize the inner qualities in a person. Through this course, the difficulties in designing a biomedical product were identified. It was also made possible to apply the design procedures, technology assessment and financial constraints on a product. It also improved the innovative skills. In addition to all these, the course gave knowledge about CE-marking and METc permission. With all this expertise, a biomedical product was designed to meet all the requirements and the assignment provided by the client.

Appendix II

The results of the Quickscan can be found in the table 7 below.

Table 7: Quick Scan of CE marking

Betreft het een medisch hulpmiddel, dat alleen uit software bestaat, bijvoorbeeld een app?	Nee
Dringt het medisch hulpmiddel het lichaam geheel of gedeeltelijk binnen door een lichaamsopening of door het lichaamsoppervlak?	Nee
Is het medisch hulpmiddel afhankelijk van een energiebron anders dan het lichaam of de zwaartekracht?	Ja
Heeft het hulpmiddel geen of slechts contact met de intakte huid van een patient (niet-invasief hulpmiddel)?	Ja
Is het bestemd voor het overbrengen of opslaan van bloed, lichaamsvloeistoffen, -cellen of -weefsel, vloeistoffen of gassen, met het oog op een infuus of toediening of inbrenging in het lichaam?	Nee
Is het hulpmiddel bestemd om de biologische of chemische samenstelling van menselijk weefsel of cellen, bloed of andere lichaams-vloeistoffen te wijzigen voor inbrenging in het lichaam?	Nee
Is het hulpmiddel een stof of een mengsel van stoffen en is deze bestemd om in vitro (buiten het lichaam) te worden gebruikt in rechtsstreeks contact met menselijke cellen, weefsel of organen of met menselijke embryos, voor inbrenging in het lichaam?	Nee
Komt het hulpmiddel in contact met de verwonde huid of verwond slijmvlies?	Nee
Is het een actief hulpmiddel om energie te leveren/ uit te wisselen?	Ja
Is het een actief hulpmiddel bestemd voor diagnose of monitoring?	Nee
Is het bestemd voor het uitzenden van ioniserende straling en voor diagnostische of therapeutische radiologie? Dit is inclusief hulpmiddelen voor interventionele radiologie en hulpmiddelen ter beheersing, monitoring of direct invloed heeft op de prestatie van dergelijke hulpmiddelen.	Nee
Is of bevat het hulpmiddel software, bedoeld voor het verstrekken van informatie die gebruikt wordt bij het nemen van beslissingen voor diagnostische of therapeutische doeleinden?	Nee
Is de software bedoeld voor monitoring van fysiologische processen?	Nee
Is het een actief hulpmiddel bestemd om geneesmiddelen, lichaamsvloeistoffen of andere stoffen aan het lichaam toe te dienen en/of te onttrekken?	Nee
Is het een ander actief hulpmiddel, anders dan benoemd in regel 9, 10, 11 of 12?	Ja
Bijzondere regel: Is het een hulpmiddel die een bestandsdeel bevat die, indien afzonderlijk gebruikt, beschouwd kan worden als een geneesmiddel? Dit is ook geldend bij geneesmiddelen bereid uit menselijk bloed of menselijk plasma en waarvan de werking die van de hulpmiddelen ondersteunt.	Nee
Bijzondere regel: Is het een hulpmiddelen voor contrageetie of ter preventie van seksueel overdraagbare ziekten?	Nee

Bijzondere regel: Is het hulpmiddel bedoeld voor het desinfecteren, reinigen, spoelen of hydrateren van contactlenzen?	Nee
Bijzondere regel: Is het hulpmiddel bedoeld voor het desinfecteren of steriliseren van medische hulpmiddelen (niet hulpmiddelen die bestemd zijn voor het schoonmaken van andere hulpmiddelen dmv fysieke kracht)?	Nee
Bijzondere regel: Is het hulpmiddel bedoeld voor het vastleggen van diagnostische beelden geproduceerd met behulp van röntgenstralen?	Nee
Bijzondere regel: Is het hulpmiddel gemaakt uit niet-levensvatbare menselijke of dierlijke weefsels of cellen, of afgeleide producten hiervan?	Nee
Bijzondere regel: Is het hulpmiddel gemaakt uit niet-levensvatbare dierlijke weefsels of cellen, of afgeleide producten hiervan en komt het niet uitsluitend in contact met de gave huid?	Nee

Appendix III

The excel sheet with Analytic Hierarchy Process (AHP) analysis of the requirements can be found as a separate document in the zip file.

Appendix IV

The requirements, specifications, risks and tests, filled in Matrix, can be found as a separate document in the zip file.