ECMO

Lina Trulsson APD2 5ID201 Degree Project JANUARY - JUNE 2016

Last chance treatment in the event of respiratory failure





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ECMO

Extracorporeal Membrane Oxygenation

or

Extracorporeal Life Support

.... means that there is a membrane outside of the body that provides the patient with oxygen

ECMO is indicated in severe respiratory failure

The survival rate is 60-70 %

ABSTRACT ECMO - Extracorporeal Membrane Oxygenation

ECMO is out of body oxygenation through an artificial lung in the event of severe respiratory failure where conventional care is not enough. Today the treament is complex, overwhelming and it is hard for staff to get a good overview. The usage of ECMO is increasing stready and therefore the treament needs to be simplified, better structured and fit the right context to become accessible to a larger scope of patients. With a user centered design approach and ethnographic research the ICU environment was studied in two hospitals in Sweden to gather information about ECMO. Interviews were held with doctors, nurses and perfusionists (responsible for the ECMO machine).

The creative work consisted of brainstorms with both designers, clinical experts and engineers. Mock-ups were built combined with sketching and feedback-sessions with clinical experts to create three different concept directions. One direction was taken further due to compactness, flexibility and integration.

The final concept is called Adoxy and creates one compact ECMO system that reduces cables and hides connections for an easier usage and cleaner apperance in a complex environment. The oxygenator (disposible part) placement is easier and more hidden for safety and usability.

The final product comes with two different carts, a ward cart, used internally in the hospital and an transportation cart, used outside of the hospital. The ward cart enables the staff to a safer internal transportation by connecting the EMCO to the patient bed. The transportation cart is lower in profile to fit in an airplane or helicopter.

Priming possibilities of the machine are designed for complete integration to be able to use when needed, otherwise hidden. There is a bigger screen on the ECMO for visibility but it is also connected to a general monitor that will show alarms when they occur. This is to give the nurses a chance to easier prioritize work from a distance and to get a better overview.

For this project I have worked and collaborate with the ECMO Center at Karolinska University hospital in Stockholm to find interesting design opportunities in the field of ECMO treatment and its surroundings. Patients come from all over Scandinavia to this specific department for a last chance to survive, both newly born and adults. A common practice in the hospitals now is to use the ECMO machine as a last effort for more severe lung and heart diseases. These patients are usually diagnosed with a less than 20 percent chance of survival. The ECMO machine oxygenates the blood outside of the the body, through a artificial lung, giving the lungs and heart a chance to rest and heal. The treatment is considered to be more gentle than respiratory therapy and gives the patient more time to recover. The survival rate is today 60-70 %.

My hypothesis is therefore that the ECMO treatment would have far greater impact and getting more

patients to benefit from it. if the current treatment was simplified, more user friendly and therefore cheaper. The current treatment is a very expensive treatment, about 100 000 SEK per patient per day, this is because the need of ten full time employed workers (physicians and nurses) per patient.

The treatment was brought to Sweden from the US by the Swedish physicians Kenneth Palmér, Inger Mossberg and professor Björn Freckner. At the ECMO Center in Stockholm, more than 900 patients have been treated since its inception in 1987. Today the survival rate on the ward is 75 %. In ten years the number of ECMO Centers in the world have more than doubled, and so far more than 60 000 cases are registered. So there is no doubts that more centers are needed and that the treatment will grow in the future.

ECMO is a shortening for Extracorporeal membrane oxygenation or extracorporeal life

support (ECLS). Extracorporeal means that something is happening outside of the body, and in this case ECMO is a technique providing both cardiac and respiratory support to people whose heart and lungs are unable to provide the right amount of gas exchange to sustain life. The goal is to give the heart and lungs the time needed for self healing. Today the distribution of patients on the ward is 40% newly born (neonatal), 10% children (pediatrics) and 50% adults.

Conditions

Most common conditions for patients at the ECMO Center are the following:

Adults:

Sepsis (severe blood poisoning) or Pneumonia

Neonatal:

Congenital diaphragmatic hernia and Meconium aspiration (MAS)



ECMO CENTERS BY YEAR



RESEARCH Study visits

ECMO-Center, Stockholm

The first study visit at ECMO Center was in September 2015 where I was able to see the the ward for the first time. Here, I was able to shadow an internal transportation of a patient for an x-ray.

Two additional visits have then been done to do interviews with doctors and nurses to understand the ECMO machine, the users and the environment. I could also take part of an internal training session that was held to go through problems that had occured with one of their ECMO machines. These internal sessions are common at the ECMO Center, to get updated on new machines and bring up topics for discussion.

Intensive care ward Parkview Hospital, Indiana

A short visit was arranged during december 2015 at the Intensive care Unit in Parkview Regional Hospital in Fort Wayne, Indiana. Here I got to talk to one ECMO nurse and one doctor. At the time they did not have any patients on ECMO, but they took out the machine so I could study it.

Maquet Academy, Rastatt

I was invited to visit Maguet in Rastatt, Germany, to meet with clinical experts (perfusionists), R&D and the Software team. The objective was to get in contact with the right people for later on in the project.

Norrlands University Hospital, Umeå

When the ECMO Center in Stockholm is filled to capacity, patients will be sent to nearby ECMO Centers or Thoracic ICU's. This happened in February of 2016, when the Thoracic ICU at Norrlands University hospital (NUS) received one ECMO patient. I had the chance to visit and ask questions to doctors and perfusionists. The hospital in Umeå usually have 5-10 patients per year on ECMO.

4. Levitronic Centrimag







EXPERTS

ECMO Center, Stockholm



Doctor Michael Broomé

ECMO Nurse Per Åberg



ECMO Nurse Susanne Lilja



ECMO Assistant Nurse Katja Andersson

EXPERTS

Maquet Academy



Perfusionist

Stefan Koch



Perfusionist Frank Stickel



Alexander Hegel

Software team

Heiko Schmidt

PRIMARY USERS Cardiac & Thoraic ICU, Umeå





Doctor Micke Svanström

Perfusionist Micael Appelblad

SECONDARY USERS Patients and their relatives





Patient Lars Andersson

Relative Sanna Wikström



ICU Nurse Gabriel Boström



ICU Nurse Jimmy Holm



Relative Helen Ahlgren



Relative Maria Hult



Relative Ann-Louise Larsson

At the ECMO Center there are specially trained doctors, nurses and assistant nurses to handle everything with and aound the ECMO treatment. I had the chance to interview Michael Broomé who has been working as a doctor at the ECMO Center for 10 years.

Doctors

Michael explained to me that there are two different types of ECMO devices, defined by their manufacturing. These types are; the *closed construction*, which is a more compact and simpler solution due to less complexity (Maquet's Cardiohelp); and the open construction, which is free standing components connected to form an complete ECMO system (Lecitronix Centrimag and Stöckert, S5).

The benefits for these two types are that the closed version is more suited for Thorax ICU's that have less patients every year because of an easier and more compact solution, while the open construction has the

flexibility to be more custom made and single parts can be replaced more easily.

At the ECMO Center in Stockholm they today prefer to use the open construction to have the flexibility and the possibility to change components when complications occure. Michael says that the challenge is to change the right part during an emergency situation and also points out the pressure of taking the right descision in an extremely stressful situation is sometimes hard.



It is motivating to help seriously ill patients, intellectually challenging to understand severe



SECONDARY USERS ECMO Patients and their relatives

Lars Andersson 34 years ECMO Patient, June 2015

Lars was on ECMO for 7 days in Stockholm, he suffered from Antisynthetase syndrome, which is an autoimmune lung disease. During his time at the ICU in Skövde Lars experienced the Intensive Care Syndrome, which in his case was hallucinations. He describes the feeling as beeing in a nightmare where he created a world that was very dark. The hallucinations stopped when he was put on ECMO. During his ECMO treatment Lars was awake the whole time. A few times he had the strength to sit up. He lost the grasp of time and describes his time in the ICU as a movie, where he can only remember fregments of what happened.

f *I* was lying in bed and stared at the ceiling, I saw some stains and asked what it was. It was blood...



Images used with permission by Lars Andersson, from his blogg Exil by Nature.

Helen Ahlgren Daughter Linn 10 years **ECMO Patient, November 2014**

Helen is mother to Linn who was an ECMO patient for 6 days in November 2014. The family was on their way back on a plane from a vacation in the US when suddenly Linn's lungs stoped working. A female doctor from Uganda made the plane do an emergency landing in Ireland. Linn was taken to a hospital and after a day they realized that the ventilator was not enough for Linn. The ECMOteam in Sweden then flew over and brought Linn back to Sweden to treat her at the ECMO Center. She was in such bad condition that they predicted that she would be on the ECMO for 5-10 weeks. But after only 6 days Linn could be taken off the ECMO machine. Afterwards they know that it was five very aggressive bacterias that had attacked Linn's lungs.





Images used with permission by Helen Ahlgren.

f It was a nightmare to think about how to buty Linn & what kind of music we should play in the church.



MACHINE SETUP ECMO Center Stockholm

This is Linn in the ward in Stockholm. To her left you can see the ECMO machine with a bigger monitor. This one is connected to a dialysis machine that you can find close to the ECMO. Above the patient bed is a general/patient monitor, showing blood pressure and puls of the patient, also one pressure from the ECMO is displayed on this monitor because of lack of space on the ECMO screen. Right above the bed is a feeding pump providing Linn with nutrition. On the right side of the bed is the ventilator.

1. Dialysis machine

- 2. ECMO
- 3. General monitor
- 4. Feeding pump
- 5. Ventilator







What if the treatment could be simplified and therefor more accessible to a larger scope of patients?

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CONCLUSIONS Tubes on floor, Area of Interest hygiene? Connectors form clots Problems that have been spotte highlighted during the research of them, fit into these three chategories: • Equipment overview and stru • Cable and tube management Patient walking • Mobility and flexibility with ECMO Tubes and See the previous page to see th cables everywhere Moving ECMO + dialysis + underlying problems leading to 10 alarms for bed + ventilator three bigger chategories. Some one incident the problems fit in two of the chategories. Packing ambulance/plane Where is Area of interest Find blood the problem? These cathegories of interest clots? together with a focus on the gro patient group; adults, could lead Switch an interesting project. the right Hard to component? clean In this extreme environment, wh Maquet closed seconds matter during an emer

MOBILITY &

350 kg

Heavy lifting

construction

overview and an unstructured environment. I therefor see an

importance of improving this

False alarm

Maquet, oxygenator & pump in back

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Problems that have been spotted and highlighted during the research, most of them, fit into these three chategories:	aspect of the treatment to get a better <i>structure and overview of the</i> <i>equipment</i> involved in the ECMO treatment.
• Equipment overview and structure	The more simple circuit the better,
	and simplify and structure is definatly
 Cable and tube management 	key words while talking about the
	cable and tube management. The
 Mobility and flexibility 	more simple solution, the less risks of complications.
See the previous page to see the	
underlying problems leading to the	<i>Mobility and flexibility</i> is important
three bigger chategories. Some of	both internaly, when patients need to
the problems fit in two of the	be transported to an x-ray or surgery,
chategories.	and also externally when the ECMO
	team is picking up patients remotely
Area of interest	and bringing them back to a
These cathegories of interest	hospital that can provide ECMO.
together with a focus on the growing	Mobility concerning how easy the
patient group; adults, could lead to	machine is to move together with
an interesting project.	the patient and additional machines,
	and flexibility refers to the ability to
In this extreme environment, where	change parts needed during an
seconds matter during an emergency,	emergency situation. For example
we can't have the problem of bad	changing the oxygenator due to
overview and an unstructured	clogging.



Re-design and simplify handling of the ECMO machine

To make the treatment accessible to more patients that suffers from severe respiratory failure

For staff handling machine (ICU Nurse, Doctors, Perfusionists) and adult ecmo patients (growing target group)

During treatment in the ICU ward but also during the transport of patients internally in the hospital

GOALS & WISHES Defining the project

- create a solution that helps the patient with ambulatory movement

- a solution that also is suitable for neonatal and pediatric patients

- involve the relatives in the treatment in whatever way they are capable

Goals:

- simplify handling of machine during priming, in ward and internal transport

- reduce/hide cables and tubes of machine

- create a ECMO machine enabling the staff to a faster and more accurate decision making through a better structure and overview

> - safer internal transportation of the patient (avoid ECMO in bed or rolling cart beside the bed)

Wishes:

- simplify handling of machine during external transport outside of the hospital

- an easier and more intuitive and userfriendly interface

BRAINSTORM Three different sessions

Group sessions

Two different group brainstorms were put together to ideate on the three areas of interest;

- Cable and Tube Management
- Structure and Overview
- Mobility and Flexibility

The first session was together with my family, containing medically trained dentists and an electrotechnology engineer. The second session was held with industrial designers at Umeå Institute of Design, all familiar with my research around the ECMO.

The same stimulus material was provided the both groups. To get the teams to think outside of the conventional ECMO treatment, image boards showing other brands, not connected to medical products, were provided such as; Apple, Tesla and Disney.

Individual sessions

Together with other designers smaller one-to-one sessions and brainstorms was arranged to ideate more freely on ideas. One of these sessions were with a doctor from ECMO Center, where a feedback meeting was combined with brainstorming.

How would Disney design an ECMO machine?





THREE CONCEPTS Different form factors

To get a quick understanding of the volumes I was working with, full scale mock-ups in foam core with a wooden base was created. Component such as ECMO, water heater and disposible parts were made in foam core.

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Rules I had to follow regarding the ECMO was for example that the disposible parts (artificial lung and pump) could not exceed higher than the excisting hight of the Cardiohelp. Therfor a taped version on a big board was created and used as a reference. The rule is to have the lung beneath the patient for improved safety.

The three concept directions were build as mock-ups to try out the four different scenarios (priming of machine, in ward, internal and external transportation). An ICU hospital bed with the right measurements was illustrated using tapeon the wall for reference. 0,65 m (maximum heigh of oxygenator)

2.



USER FEEDBACK NUS, Thoracic & Cardiac ICU staff

Another feedback session was arranged where I had the opportunity to invite staff from the nearby hospital, NUS, to take part in a meeting at the school, Umeå Institute of Design. The benefit was to show them 3D mock-ups that they could interact with. Full scale sketches and complimenting smaller sketches was shown to describe the concepts.

The outcome of the meeting was clear that they liked the second concept because of the flexibility and mobility. Other features that they liked were: integrated hand crank, automatic connections and integrated sensors for the oxygenator.

During discussions around the GUI it was clear that they preffered a dark background rather than a white background like they have today. The contrast is bigger using a darker background and more comfortable light in a dark patient room during the night. Concerning the monitors size, they thought the bigger the better but it was also a question about balance of the machine. So discussion of having a bigger screen on the ECMO or connecting it to a patient monitor was brought up. The outcome was, equal to the discussions with ECMO Center, that a smaller machine with a connection to a bigger monitor during alarms would be the most beneficial, concerning space management.



Gabriel Boström ICU Nurse

> Micael Appelblad Perfusionist

FEEDBACK & EVALUATION

Maguet, Rastatt

The last feedback session was together with Maquet, Rastatt, where I got to present my three concept directions to clinical expert Frank Stickel through a skype meeting.

The outcome of the meeting was that all the three directions were interesting but he especially liked the legs on concept 1 because of the possibility of getting closer to the product and screen. That is a problem today.

We also discussed that todays monitors and conncected systems are not compatible between different brands. But I should not focus on that in this situation. My focus is to create the best possible solution for the user.

After hearing all stakeholders oppinions, ECMO Center, Maquet and NUS, pros and cons were listed for every concept to find a direction to move forward with.



Stand alone Modular System

- + Priming bag backside of screen
- + Integrated connections oxygenator
- + Big monitor
- High (balance)
- Conventional







Connection to ICU Bed

- + Bed connection
- + Integrated connections oxygenator
- + Big external monitor
- + Low (good for balance)
- No IV pole for priming

Technical and Patient side

- + Calm patient side
- + Thin (hang on bedside)
- Thin (unbalanced)
- Connections hidden on backside
- No IV pole for priming

SELECTED CONCEPTS

Development of handles, screen and priming possibilities

The selected concept needed development and decision making concerning placement and hierarchy of handles and big screen versus a smaller screen on the ECMO.

Mock-ups were adjusted and tested to find the most intuitive way of placing two handles, one for moving the whole cart and one for removing the ECMO from the cart and placing eather closer to the patient or placing in the external transport cart.

Also placement of the integrated handcrank needed to be settled, but this was more constraint to techincal possibilities.

An integrated priming IV pole was considered that could be pulled up only when needed during the set up of the machine.















DESIGN LANGUAGE

Of Maquet and their products

A quick exploration of the Maquet product line was studied to get a understanding of where they are and where they are heading. The product



A lot of the form exploration was done in CAID to get accurate shapes and to have the possibility to print form scale mock-ups. The form exploration on the next page is the process I went through, from left to righ, up to down, where the concept function was iterated in the middle. The attachment functionality changed from rolling over the bed and the ECMO being inside of the bed to being attached from the backside instead and having the possibility to be lower than the patient at all times. Therefore the change in the shape.

The changes involes a placement change for the water heater, instead of being in the back of the machine, it is placed under the ECMO and the volume is distributed differently. This is beneficial for a lower center of gravity for the machine. The water heater is also more accessible for the user from the front, when the water needs to be changed.































FINAL MODEL

Model making

The final CAID model was created in Alias Automotive and had to be devided in to 27 pieces to get a ready file for the milling machine. These pieces, made out of polyurethane foam, were glued together and additional parts were 3D printed, in both plastic and plaster, and laser cut to build the final model. The physical model was made to have a physical representation of what the final design would look like, not a functional model, only for visual purpose.

The wheels were provided kindly by Tente AB and tubes and other disposible medical equipment from Maquet Sweden AB.











MAQUET ado₂xy

Compact ECMO System for last chance treatment



Adoxy is a compact and complete ECMO system where emphasism is put on **simplicity**, **integration** and a **small footprint**.

The vital components for an ECMO (ECMO, water heater, oxygenator and a gas blender) were combined into one product to optimize space and clean up the apperance, therefor getting rid of unneccissary tubing and connections that intstead could be integrated in the shape. The machine needed simplification to speed up processes, especially during set up but also simplicity in interaction with its users.

The name, Adoxy, is a combination of the words "add" and "oxygen", which resembles the main function of the ECMO system.

The final product is designed to give both the users and the patient a feel of a friendly product that is supportive and comforting in a tough situation. The soft shapes and an emphasism of not looking scary was important for the patient and not the least for their families and loved ones. But still giving a sensation of a reliable and professional machine that gives a good structure and overview for the staff. The machine also had to fulfill the needs of easy shapes, with few split lines and smooth glossy surfaces that easily could be cleaned in this demanding environment.



The multiple screens on the old ECMO, such as ECMO screen, gas blender screen and water heater interface, is now accessible from just one bigger screen for easier interaciton and a better workflow for the staff.

The backside of the machine has a storage space for the gas tubes and cords, this is covered by a door to clean up the apperance and keep things neat and tidy. This enabled by changing the volume of the water heater and therefor optimizing space and getting a better structure.

Adoxy compared to the Cardiohelp is more compact and integrated with an overall smaller footprint and fewer loose parts. The reason for aiming towards an even more "closed construction" machine was to similify the treatment so more patients in the future can benefit from ECMO.



Maquets Cardiohelp, the leading ECMO on the market right now.



General Monitor

Connected during alarms



GENERAL MONITOR *Extended screen for the nurses*

To help the users in their everday work, especially the nurses, it is important to give them an opportunity to fast understand alarms coming from the ECMO machine. Unfortunatly, todays solution offers a small screen with a alarm system that is not visible enough. It happens that the nurses needs to leave the excisting treatment of the patient to run to the ECMO's small screen to see what is alarming.

To address this issue Adoxy is connecting with the patient monitor that is always situated close to the patient bed. When the ECMO is alarming the information will be visible from the bigger screen which is more visible for the nurses. In this scenario the nurse might estimate the severness of the alarm and act according to the situation. Getting vital information from a distance could be life depependant in a severe situation.

BED CONNECTION

Flexible Interface

To avoid staff beeing tempted putting the removable part of the ECMO in the patient bed during internal transportation within the hospital, something had to be done. By offering another solution I hope to avoid these situations that acctually could be dangerous for the patient.

A flexible interface was created on the back side of the machine to enable an connection to a patient ICU bed. The reason to keep the connection as flexible and open as possible was to offer a connection that would work for as many beds as possible. There are a lot of different models of ICU beds, therfor a solution that enables imagination and creativeness was needed.

The connection is holes in the machine where staff can place straps, use clamps or other inventions to connect the machine to the bed. I have seen numerous home made solutions created within the hospital envionment today, and for this specific are I wanted to continue a solution where the staff needs to use their skills to invent new ways. One open solution fits all (with some DIY) instead of one solution for a specific ICU bed. Two different heights are offered for more alternatives.

Home made solutions for connecting machines to hospital bed.



Placing the ECMO in the patient bed is not safe for the patient and should be avoided.



OXYGENATOR Gas exchange

BLOOD



Blood in From the body

Blood out To the body (oxygenated)

> - Gas in $O_2 \text{ or } CO_2$





PRIMING OF MACHINE Setting up the machine

Adoxy has an incorporated IV pole accessible. For example there is a that will be used during priming of space dedicated for clamps right the machine. The handle to the IV under the oxygenatror. The clamps pole is accessed from the top and are used to clamp the tubes and pulled straight up to reach the IV's the circuit therefor they were put as full height. It provides two hooks close to this as possible. The locking dedicated for the priming bag and mechanism is spring loaded which one hook on the side for the priming makes the clamps stay in place but when staff needs one you simply fluid. grab and pull for easy access.

On the back side if the machine there is a flip out handle that provides a dedicated space for the extra tubing. A structured and clearer system, where everything has its place, will help in stressful situations during priming and setting up of the machine.

The reason for a telescope IV pole is to make it accesible when needed. The IV pole that is attached to the machine today is filled with things just because it is there at all times, it's filled with e.g. clamps/measurement scales/ board for priming bag etc. These can be structured and placed in better places where they are more



IV pole today covered in clamps, cords and different boards.



MANUAL HAND CRANK Usage during emergency situations

In worst case scenario the machine needs to by-pass the main motor due to machine failure, to keep the patient alive a manual handcrank is incorporated in the machine. Today staff needs to move the oxygenator to do this maneauver but the movement will not be needed with Adoxy, and therefor precious time will be saved during an emergency situation.

To indicate that the by-pass is working and that the adequate RPM

UX000

MAQUET



is reached a scale will pop up on the side of the screen. This will in RPM x1000 show a visual indication how		
fast you need to turn the manual hand crank.		
	all he	Original manual hand crank solution from Cardiohelp, Maquet

Interaction when using the emergency hand crank. RPM x1000 visiual indication.

The screen interface has been changed in different ways, first of all size but also in layout. The screen has gone from a 5,7 inch screen to a 7,5 inch for better visibility, both from close and from a distance. The menu layout has changed from beeing on the screen bottom to be on the left side. The reason is to get a better workflow for the staff to have room to use both hands during interaction with the screen; the right for the knob, adjusting and finetuning values and the left hand for controlling the touch screen and have the menu as visible as possible for a faster workflow.

In Adoxy all the components needed for a ECMO treatmen is accessible from one screen only. This is what you can access from the bigger screen:

- ECMO
- Water heater
- Gas blender

The reason to not go 100% touch screen and still keep a physical knob was because of discussions with perfusionists. They appreciate physical knobs and describes that they get a better feeling using physical tangible buttons and knobs and also there is a stong tradition of using knobs to fine tune measurements on screens and gives a good feel to what you are doing. But the same functions can still all be done through the touch screen.

The background colour is also changed from white to a darker gray to the new machine. Partly because I wanted the style to resemble the Maqet look from the Servo-U, and therefor create a family DNA for Maquet over the globe but also to get a more pleasent screen for the eyes to look at. A darker background is more calm to interact with, especially in a night scenario where you do not want the screens to light up around the patient but still have good visibility for the staff.





EXTENDED SYSTEM Usage within and wihout of the hospital

The most vital part of the ECMO can be released from the hospital cart and placed closer the the patient if needed, or attached on a smaller and lower cart that is more suitable for transportations outside of the hospital. The placement of the water heater is different on the two carts. On the transportation cart the water heater is placed on the back to get a lower profile which would be beneficial e.g. in an airplane where the patient can be places pretty low. The sketch of the transportation cart is not designed and not a focus in this project, but since it has a big part of the whole eco-system thinking of this concept I wanted to include thoughts and rough sketches to clarify the usage.

Sketch of what a transport cart could look like...



"It is very smart to have the possibility to have two different carts optimized for different situations..."

skip to move the oxygenator during these

"The oxygenator feels less vulnerable when integrated in the ECMO."

Comments from staff at NUS Thoracic ICU, Umeå