UNIVERSITY
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Chair of Engineering Organ Support Technology

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ECMOve

ECMO Mobilizing Device

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Problem Definition

Today, patients who cannot be successfully ventilated any more, are put on so called Extracorporeal Membrane Oxygenation (ECMO). ECMO is basically an artificial lung (or lung & heart) support treatment where the blood of the patient is partially pumped out of the body, through a so-called oxygenator for oxygen and carbon monoxide exchange and pumped back into the body. This treatment, due to its complexity, is regarded as a last resort treatment. Nevertheless, it is used e.g., as bridge to lung transplant for patients on the waiting list for a transplantation. For lung transplantations it is understood that the long-term outcome of the transplantation is better in patients, that were able to walk and be a little active prior to the transplantation compared to immobilized patients. However, only a couple of years ago, patients on ECMO were mainly sedated during the treatment, but today, more and more of these patients are awake and taking active part in their treatment increasing the outcome. Unfortunately, both the technical systems and the vascular access used are not really designed for mobilizing patients as they are bulky and require a lot of support by hospital staff to carry everything around. Additionally, these patients can be very weak and need to be supported in order to keep them safely on their feet.

The assignment will focus on designing, building, and (patient) testing a walking aid for the patients described above, that allows them to walk safely from their hospital room into and around a hospital hallway, while at the same time holding all necessary equipment needed for their treatment. Additional attention should be paid to the fixation of the cannula in the patient's neck (Vena jugularis interna) safely preventing a mispositioning (or even a ripping-out) of the cannula.

Abstract

Extracorporeal Membrane Oxygenation (ECMO) is a temporary lifesaving treatment for critically ill patients suffering from severe respiratory and/or cardiac failure. Studies have demonstrated the feasibility of mobilization in ECMO patients within the hospital during their bridge to recovery or transplantation. Ambulatory ECMO is a comprehensive form of mobilization aimed at preventing neuromuscular weakness and impaired physical functioning during and after treatment.

Despite more compact and mobile ECMO devices, the implementation of ambulatory ECMO remains a labour-intensive, complex, and challenging operation. Ambulatory ECMO requires a large multidisciplinary team to carry all the equipment, to monitor and physically support the patient, and to provide a back-up wheelchair in case of patient fatigue. Additionally, current configuration of devices contributes to unnecessary device transport. Moreover, there is no adequate solution for ensuring the stability of the patient's cannula and circuit management during ambulation.

We designed and developed a system that contributes to the improvement and innovation of current ambulatory ECMO patient programs. The modular cart-in-cart system carries the necessary ECMO equipment, features an extendable walking frame, and contains a folding seat for patient transport. A universal-sized shoulder brace with integrated blood tubing connector facilitates secure fixation of the blood tubing.

This system provides safety, support and accessibility while performing ambulatory ECMO for both patient and healthcare provider. Evaluation of the prototype in a simulated ICU environment shows the suitability for use in a clinical setting. The patent for this invention has been filed and is currently pending.

Keywords

ECMO; Veno-Venous; Ambulatory; Mobilization; Patient; Safety; Support; Walking

Content

1 Introduction

Extracorporeal Membrane Oxygenation (ECMO) is a temporary lifesaving treatment for critically ill patients suffering from severe respiratory and/or cardiac failure [1, 2]. Over the past years, a paradigm shift has taken place from keeping Intensive Care Unit (ICU) patients under deep sedation and immobilization towards participation and mobilized patients [3]. Multiple studies show that awake veno-venous (VV) ECMO in end stage lung disease patients can be used as a bridge to lung transplantation [4-8]. Awake ECMO treatment may avoid the use of heavy long-term sedation required for oral intubation. This strategy reduces the risk of serious sedation side effects including prolonged mechanical ventilation, delirium and longer stay in the ICU [9, 10]. Moreover, the use of ECMO without mechanical ventilation allows for active patient rehabilitation and is associated with improved patient survival rates compared to mechanical ventilation based bridging strategies [11].

Physical therapy in critically ill patients during their ICU stay has shown to be safe and effective in preventing neuromuscular weakness and impaired physical functioning [12-15]. Subsequently, active rehabilitation during ECMO progressed towards studies showing the feasibility and safety of early mobilization in ECMO patients [16-23]. A positive response to early mobilization during ECMO has been associated with improved clinical outcomes such as lower mortality, decreased length of hospital stay and improved level of independence after hospital discharge [16, 24-27]. These improved patient outcomes may lead to lower hospital costs compared to non-ambulatory ECMO [27].

New technologies and innovations have led to more compact ECMO devices with increased mobility [28, 29]. Despite these technological developments, ambulatory ECMO remains a labour-intensive, challenging, and risky operation requiring highly trained multidisciplinary staff [30]. Patient falls, cannula related complications, and fatigue are serious risks and may result in life-threatening situations [12, 20-23, 31-33]. These conditions may prevent many ICUs, especially low-volume centers lacking experienced staff, from using ambulatory ECMO [26].

A recent study collected and analysed a compilation of ambulatory ECMO videos [34]. These videos highlight the current state of ambulatory ECMO and reveal the challenges that need to be addressed. The current situation shows that there is no adequate solution for the safety and stability of the patient's cannula and circuit management. In addition, multiple not strictly necessary devices (e.g., heater-cooler unit) are transported during mobilization, which further complicates the situation. Moreover, a large multidisciplinary team is required to monitor and physically support the patient and the equipment. This leads to the demand for further improvements in patient safety, staff support, and accessibility in performing ambulatory ECMO.

We designed and developed a system that contributes to the improvement and innovation of current ambulatory ECMO patient programs. This system provides safety, support, and accessibility while performing ambulatory VV ECMO for both patient and healthcare provider.

2 Fundamentals and state of the art

A thorough analysis of the state of the art on ambulatory ECMO was performed based on scientific and medical literature and openly accessible video material.

2.1 Current ambulatory ECMO procedure

It is important to describe the current working method of ambulatory ECMO to gain insight into the problems encountered. Several preparatory steps must be completed to start the ambulatory ECMO procedure:

1. Manually switch from wall gas to bottled gas by disconnecting the gas tubing from the gas blender and the flow meter (connected to wall gas). Attach the gas tubing to the flow meter on the gas cylinder. This step must be provided rather quickly to ensure a continuous supply of gas to the ECMO device.
2. Manually unplug the power cable to switch to battery mode of the power-requiring devices, including the ECMO device and perfusor pumps.
3. Move the transport cart(s) with all the devices and equipment, including the heater-cooler unit (non-functional, because heater-cooler unit is not used during ambulatory ECMO) with the patient. One or more caregivers are needed for device transport.

During ambulation, the patient walks with the support of a walking support device and is physically supported by one or more caregivers. An additional caregiver walks with a backup wheelchair in case of sudden events such as patient fatigue or unexpected hemodynamic instability. The blood tubing connected to the patient's cannula is often held by a caregiver or the patient to prevent strain on the cannulation site.

The same preparatory steps must be completed to go back to stationary ECMO, but in reversed order. The transport cart(s) with all the devices must be moved back to the original location, and the power supply must be switched back to wall power. The gas tubing must be disconnected from the gas cylinder and reattached to the gas blender and flow meter which are connected to wall gas.

Performing intermittent ambulatory ECMO can be divided into four distinct phases as depicted in Figure 1.

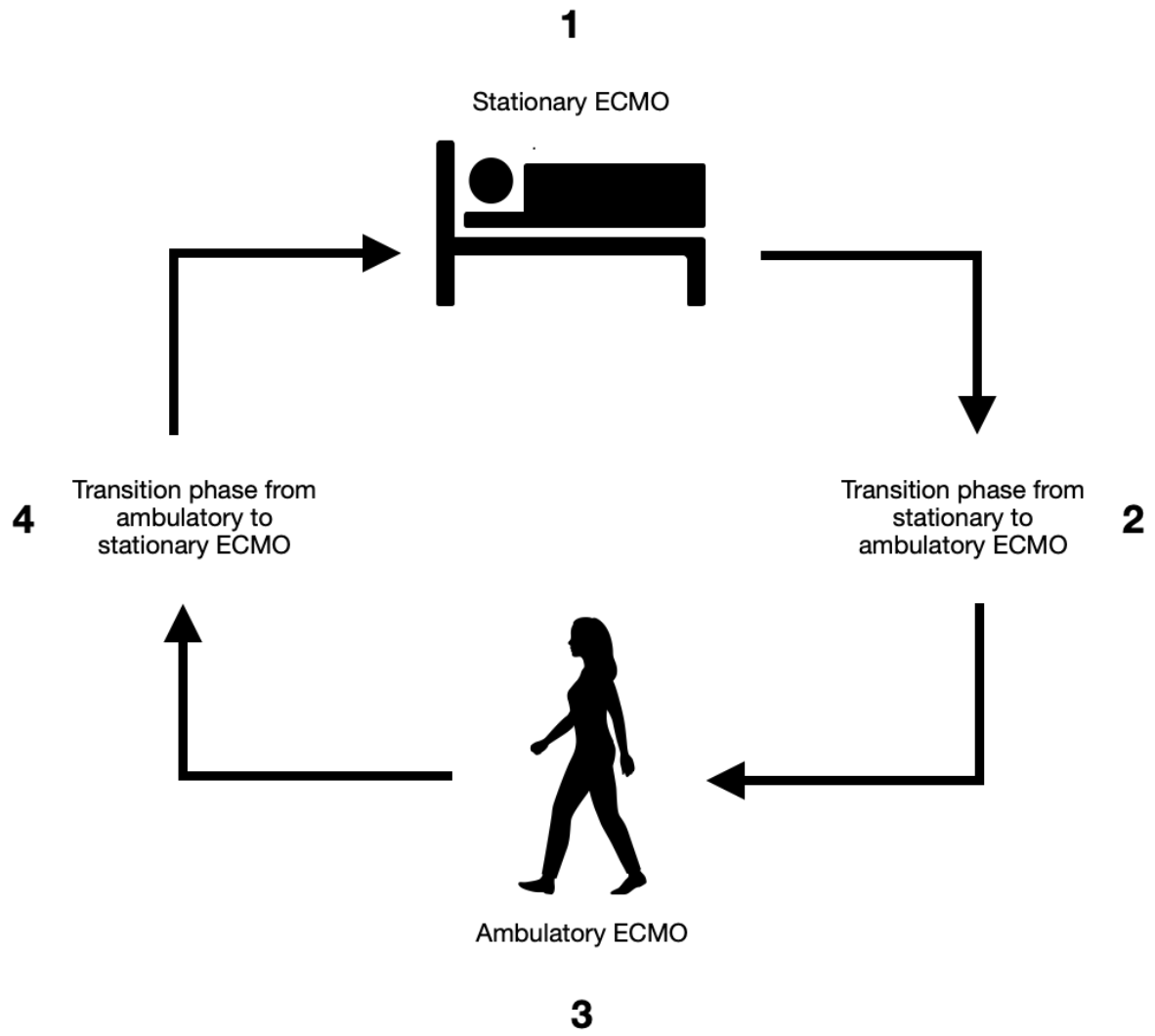


Figure 1: The four different phases of performing ambulatory ECMO

2.2 Shortcomings current ambulatory ECMO procedure

In current ambulatory ECMO, several shortcomings complicate the performance of the ambulatory ECMO procedure:

1. The current method of attaching the blood tubing to the patient's head using a bandage construction or manually held by a caregiver or the patient while walking, carries a significant risk of stress on the cannula and the insertion site. This could lead to severe complications such as bleeding and rupture of the cannula-tube connection.
2. There is no clear solution for transporting the necessary devices in both stationary and ambulatory ECMO conditions. Transporting these devices requires multiple caregivers and often necessitates the use of separate transport carts during ambulatory ECMO. This leads to unnecessary device transport and contributes to additional burden on the ICU staff.
3. There is no adequate solution to provide physical patient support during walking. The current method of using a rollator or a walking frame, which is not mechanically connected to the device cart, poses a considerable risk of tension on the patient’s cannula. Caregivers need to move the

device carts manually at the same pace as the patient during ambulation to guarantee a continuous distance between the patient's cannula and the devices.

4. An extra caregiver is required to bring a wheelchair in case of sudden events such as patient fatigue or unexpected hemodynamic instability.
5. There is no clear solution for easy switching between wall-mounted gas and bottled gas nor easy attachment and detachment of devices required for stationary ECMO only. This limitation poses a challenge in terms of flexibility, efficiency, and safety of device management to perform ambulatory ECMO.

The shortcomings in current clinical care emphasize the need for proper system design that contributes to patient safety and ease of operation of ambulatory ECMO.

2.3 List of included devices and their function

A list of devices with their corresponding function has been generated in Table 1 to get an overview of all devices used during both stationary and ambulatory ECMO.

Table 1: General devices required for ECMO treatment

Device	**Purpose**
ECMO device	Comprising a blood pump, oxygenator, ECMO console with integrated back-up batteries. Supports the heart and/or lungs with a blood pump and an artificial lung.
Oxygen cylinder	A pressurized container used to store and transport oxygen.
Gas blender	A medical device to mix medical grade air with oxygen to a certain oxygen concentration.
Flow meter	A device used to measure the real-time flow rate of fluid or gas to give either volumetric or mass flow readings.
Emergency drive	A manual pump drive to take over the pump function of the ECMO machine in case of failure of the automatic pump (not included in Figure 2).
Emergency kit	A kit containing ECMO related supplies allowing an immediate response to the most likely adverse events (not included in Figure 2).
Perfusor pump(s)	A medical device that delivers fluids, medications, or nutrients into a patient's bloodstream at a controlled rate.
Drip(s)	A medical device that provides a slow and steady flow of liquid through intravenous infusion (e.g., physiological saline solution).
Heater-cooler unit	Medical device for providing tempered water to cool or warm the blood.
Wall gas	Gas that can be drawn from a wall outlet in the hospital (oxygen, nitrogen, etc.).
Wall power	Electricity that can be drawn from a wall outlet in the hospital.
Power hub	A power source designed to isolate the patient and the operator from an electric shock and to protect the equipment from power surges or faulty components.

2.4 System flowchart of ECMO treatment

A system flowchart (Figure 2) was created to gain a better understanding of the connections and interactions between the devices required for ECMO treatment. The flowchart distinguishes between the devices necessary for the ambulatory and stationary situation. Stationary devices and resources are only needed during stationary ECMO. Devices and resources depicted in the ambulatory and patient section are required during both stationary and ambulatory ECMO. The patient section of the flowchart illustrates where the patient interacts with the system.

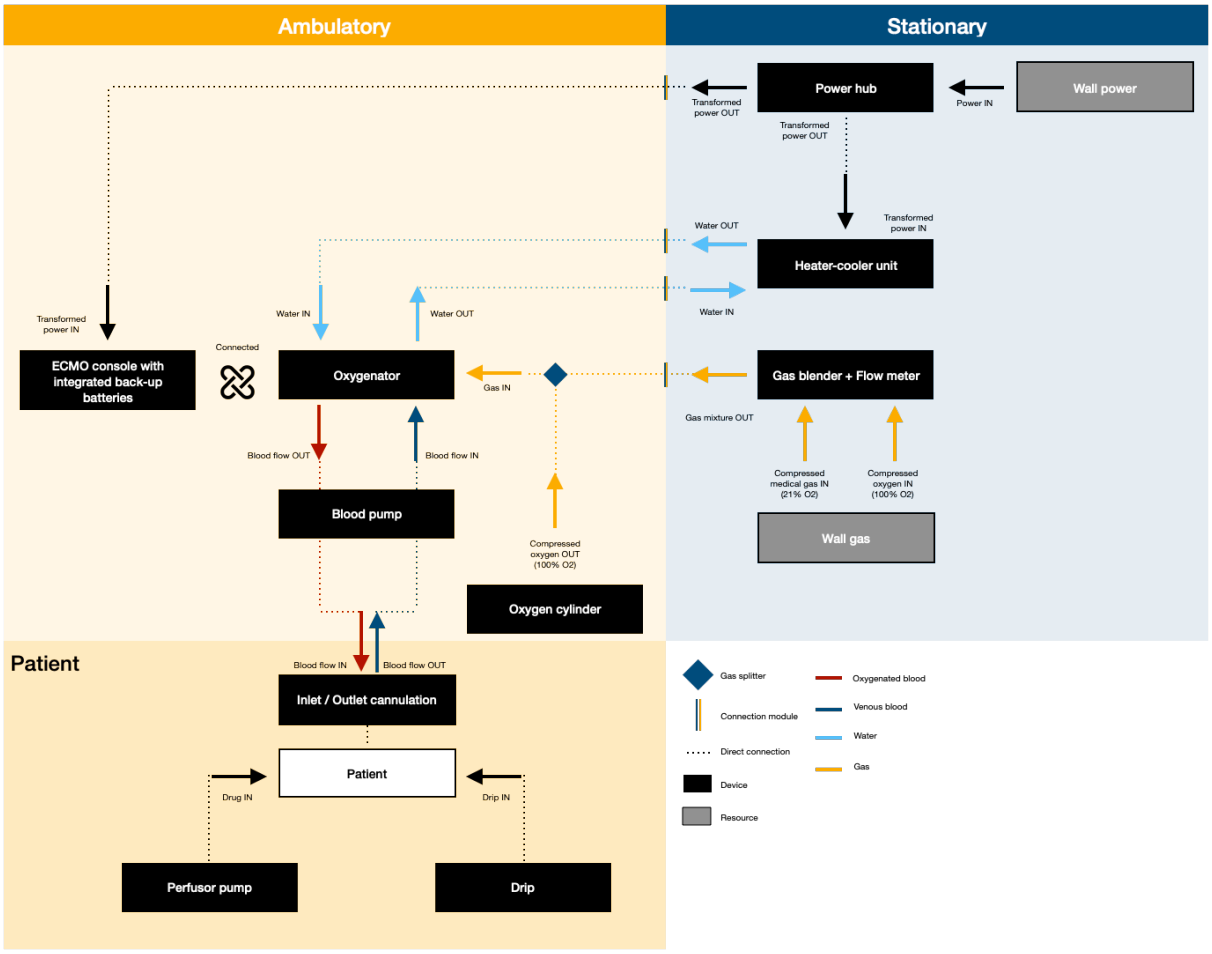


Figure 2: System flowchart of the connections and interactions between the devices required for stationary and ambulatory ECMO treatment

The transition from stationary to ambulatory ECMO involves a transition phase. During the transition phase several device configuration changes are made. These changes include (1) switching from wall gas to bottled gas, (2) transitioning from wall power to battery power, and (3) disconnecting the heat-cooler unit. These transitions are visualized with connection module indications in Figure 2 between the ambulatory and stationary section.

3 Material and Methods

System development was performed according to the V-model. For each module, detailed user requirements were defined and translated to design requirements to develop a system that complies with the user's needs. A thorough risk analysis was performed to identify risks for both the patient and the care givers. Where necessary, countermeasures to minimize the probability of occurrence were defined and translated into additional design requirements. All user requirements are documented in the user requirements specification (URS) which can be found in Annex A. A full design requirements specification (DRS) is documented and can be found in Annex B. The risk analysis can be found in Annex C.

3.1 System design – General

User requirements were defined based on the problem definition and current clinical care. Six key user requirements were defined at the start of the project to set the scope for the design process:

1. A component to provide transport of ECMO hardware necessary in both stationary and ambulatory conditions including: ECMO device, oxygen cylinder, emergency drive, emergency kit, perfusor pump(s), and drip(s).
2. A component to provide transport of ECMO equipment only necessary in stationary conditions including: gas blender, flow meter, and heater-cooler unit.
3. A component to provide physical patient support during walking and in case of sudden events such as patient fatigue or unexpected hemodynamic instability.
4. A component to provide safety and stability of the patient's cannula and circuit management during ambulatory ECMO.
5. A component to provide easy switching between wall-mounted gas and bottled gas.
6. A component to provide easy attachment and detachment of devices needed for stationary ECMO.

3.2 System design – Modules

The system was divided into six distinct modules to ensure a clear and complete system design. Each module solves a specific problem originating from the corresponding key user requirement. A visual representation of the interaction between the different system modules is presented in Figure 3.

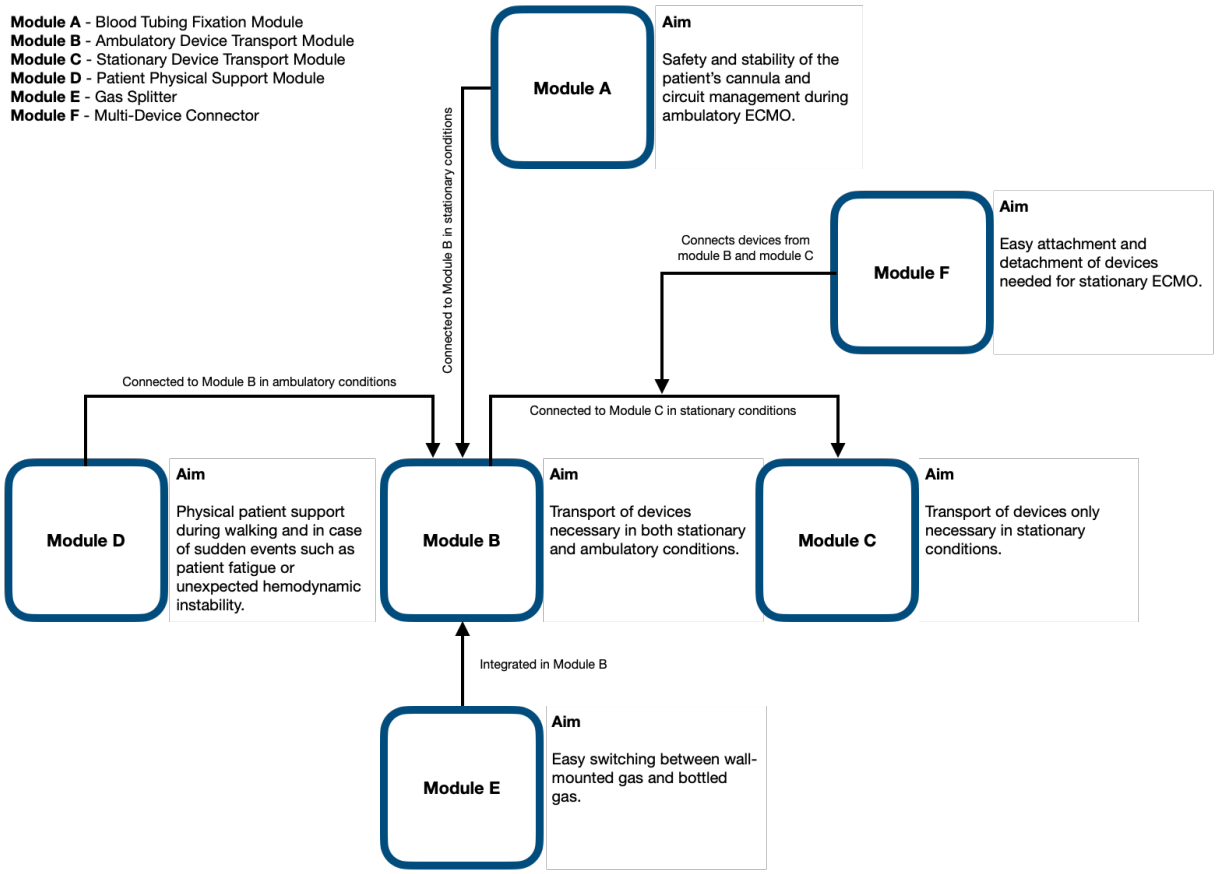


Figure 3: Visual representation of the aims of the different system modules and their interaction

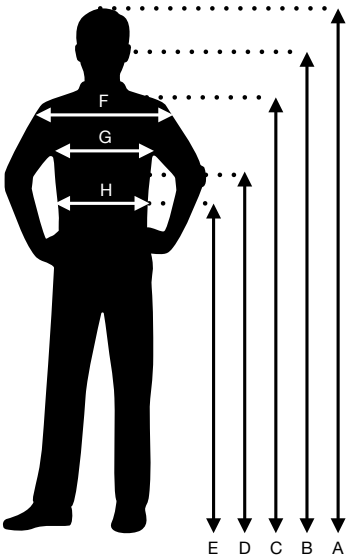
Each module's design process involved generating multiple pre-concepts based on the design requirements. Morphological schemes were utilized for pre-concept generation of the modules (Annex D). Each pre-concept was evaluated by weighing its pros and cons without using a dedicated scoring system. Thereafter, one concept was selected for further development. Subsequently, 2D sketches of the chosen pre-concept were elaborated and transformed into 3D models using Shapr3D computer-aided design (CAD) software for MacOS (Shapr3D Zrt., Budapest, Hungary). Multiple design iterations were performed to generate the final design of each module. All 3D model designs were optimized for prototype assembly. Only the final module designs have been elaborated in this report. The remaining pre-concepts for each module can be found in Annex E.

3.3 Patient profile generation

3.3.1 Use of DINED tool and CAD profile generation

In order to design a patient-centred system suitable for a wide range of patients, anthropometric data was used to create four different personas. The anthropometric data was collected using the DINED anthropometric database of the TU Delft (https://dined.io.tudelft.nl/en). Measures were based on a population with an age of 31 – 60 years. Two profiles with male gender and two profiles with female gender were generated. For both genders, anthropometric data for the P5 (5th percentile) and P95 (95th percentile) were defined. This resulted in a small and a large patient profile for both genders. To create each persona, multiple body measures were considered (Table 2).

Table 2: Anthropometric data from DINED database used for patient profile generation



#	Measure*	Dimension					
		Men			Women		
		P5 (persona 1)	P95 (persona 2)	Mean	P5 (persona 3)	P95 (persona 4)	Mean
A	Stature (mm)	1645	1895	1770	1558	1746	1652
B	Eye height (mm)	1534	1784	1659	1461	1641	1551
C	Shoulder height (mm)	1337	1577	1457	1266	1438	1352
D	Elbow height (mm)	1005	1193	1099	947	1089	1018
E	Hip height (mm)	901	1079	990	863	1001	932
F	Shoulder breadth (mm)	422	500	461	378	470	424
G	Chest circumference (mm)	876	1212	1044	817	1209	1013
H	Waist circumference (mm)	771	1127	949	649	1077	863
I	Hip circumference (mm)	906	1156	1031	911	1221	1066
	Body mass (kg)	62	102	82	52	88	70

*Measures are based on a population with an age between 31-60 years old. Anthropometric data was conducted using the DINED database of the TU Delft.

A measures-based 3D CAD profile was generated and exported using the DINED tool for each persona. The 3D CAD profiles were used to further define the design requirements of the system. Figure 4 shows an overview of the generated 3D CAD profiles. These personas were used as a reference to guide the design of a patient-centred system that can accommodate a wide range of patients with varying anthropometric measures.

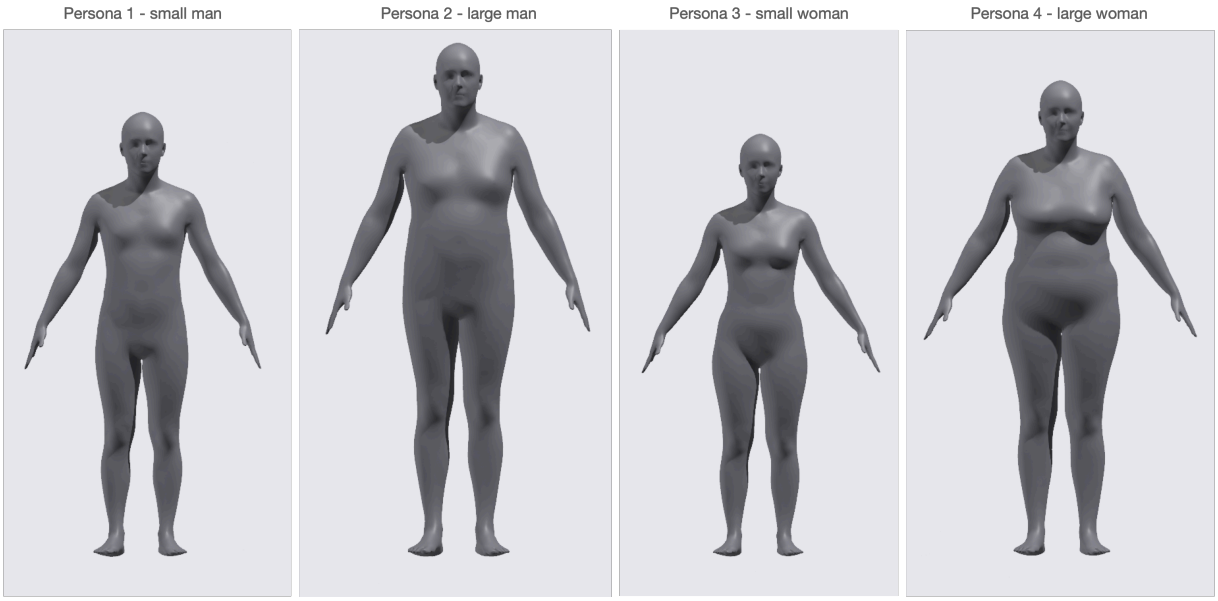


Figure 4: Anthropometric measures-based 3D computer-aided design (CAD) patient profiles generated and used for design purposes.

3.3.2 User requirements (URS) based on patient profile data

User requirements for patient types were established based on the profile data generated. The main user requirements regarding patient type include that the product shall be designed for:

- Adult ICU patients receiving ECMO support in a VV configuration through a dual lumen cannula placed through the jugular vein who receive ambulation by walking
- Patients with a weight of 50 – 102 kg
- Patients with a height of 155 – 190 cm

- Patients with a chest size of 817 – 1212 mm

All the necessary information regarding the user and design requirements related to the patient can be found in the User Requirements Specification (URS) and Design Requirements Specification (DRS) which are provided in Annex A and Annex B, respectively.

3.4 Prototype fabrication

The prototypes were built by combining pre-fabricated components with custom-made parts. The custom-made sheet materials were obtained through the process of laser cutting from 3 mm thick steel, 6 mm Trespa, and 12 mm plywood. Other custom parts were fabricated using Selective Laser Sintering (SLS) 3D printing. Various machining techniques such as drilling, sawing, milling, bending, and grinding were used in the assembly of the prototypes.

3.5 Patent

The patent for this invention was filed at the Netherlands Patent Office and is currently pending.

3.6 Design Verification

Prototype verification was performed in a simulated ICU environment at the Techmed Centre, University of Twente, Enschede. Usability and functionality of the device were assessed for use in a clinical setting. Multiple user scenarios were simulated using healthy subjects (n = 5) with varying body profiles (body height 1.62 – 1.89 m) to check for suitability across a wide range of patients. The use of a Cardiohelp ECMO system (Getinge AB, Rastatt, Germany) and a heater-cooler device (HICO-Aquatherm 660, pfm medical hico GmbH, Köln, Germany) enabled realistic simulation testing.

4 Results

4.1 Final concept

The final concept of the system as depicted in Figure 5 comprises a modular cart-in-cart system (A) consisting of two distinct carts – the stationary cart (B) and the ambulatory cart (C). The stationary cart carries the devices not required during ambulation (e.g., the heater-cooler unit and the gas blender) and remains in the ICU next to the patient's bed. The ambulatory cart carries all the necessary devices during ambulation (e.g., ECMO machine, perfusor pumps, etc.) and features an extendable walking frame (14) that ensures safe walking support for the patient. The foldable seat (13) allows the patient to sit and facilitates transport back to the ICU in case of patient fatigue or intra-hospital transport. Additionally, a safety brake system (16) prevents unintentional movement of the ambulatory cart. Devices on both carts can be (dis)connected through a multi-connector hub (4a, 4b), enabling easy configuration of necessary fluids (tempered water from heater-cooler unit), gases, and electricity. The connection between the stationary and ambulatory cart is maintained by a foot-pedal-controlled lift mechanism (15) that prevents accidental disconnection of the multi-connector and enables transport of both carts simultaneously. The system also features a gas switching device (6) that allows for convenient switching between wall-mounted gas and bottled gas. A universal-sized shoulder brace (12) with integrated blood tubing connector that can be adjusted to the patient via Velcro closure, facilitates secure fixation of the blood tubing, and minimizes strain on the cannula.

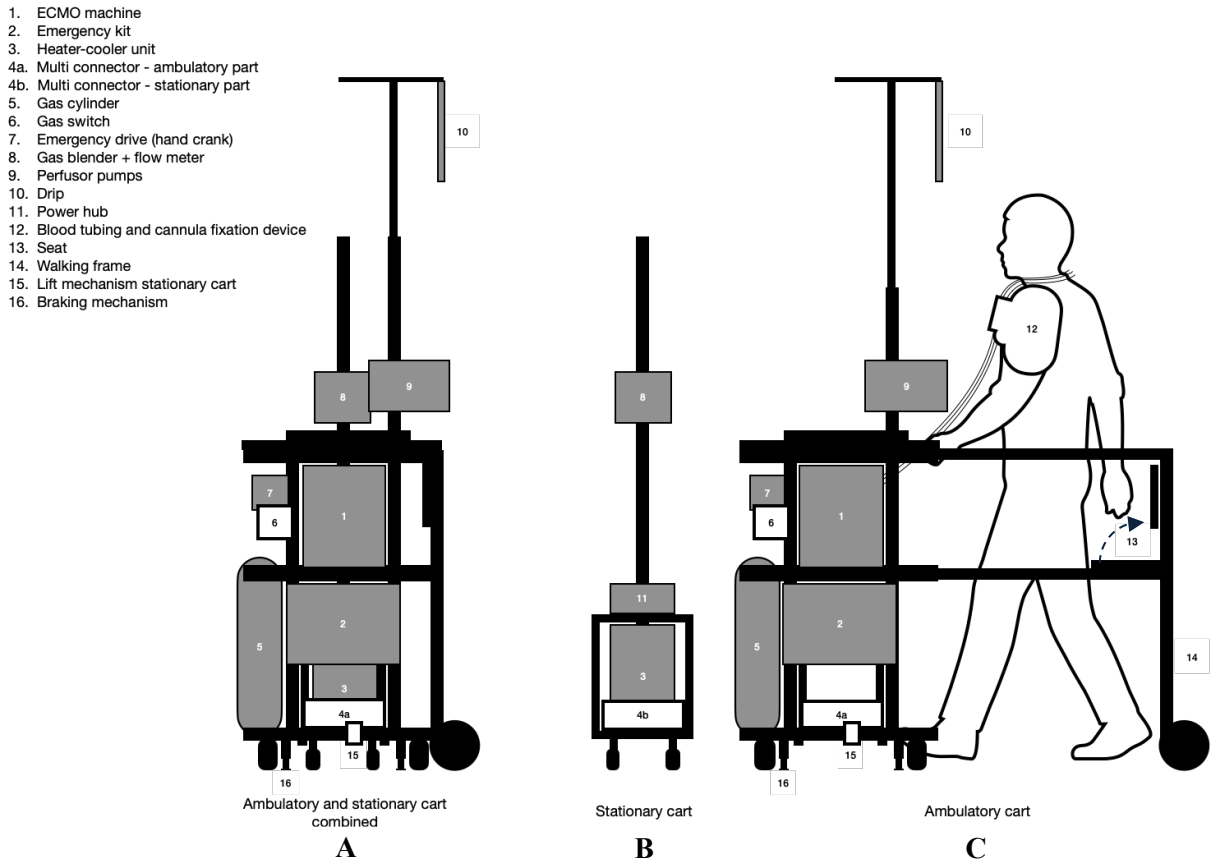


Figure 5: Final concept of the developed system

4.2 Module specification

4.2.1 Module A – Blood tubing fixation module

The aim of the blood tubing fixation module is to provide safety and stability of the patient's cannula and circuit management during ambulatory ECMO.

4.2.1.1 User requirements

- The product shall maintain blood tubing in a fixed position.
- The product shall prevent tension on the cannula.
- The product shall prevent tripping over blood tubing.
- The product shall be easily attached and detached from the patient.
- The product shall be carried by the patient.
- The product shall be comfortable for the patient, e.g., not constrain head movement.

4.2.1.2 Concept design & description

The concept design is depicted in Figure 6 and consists of the following ten features.

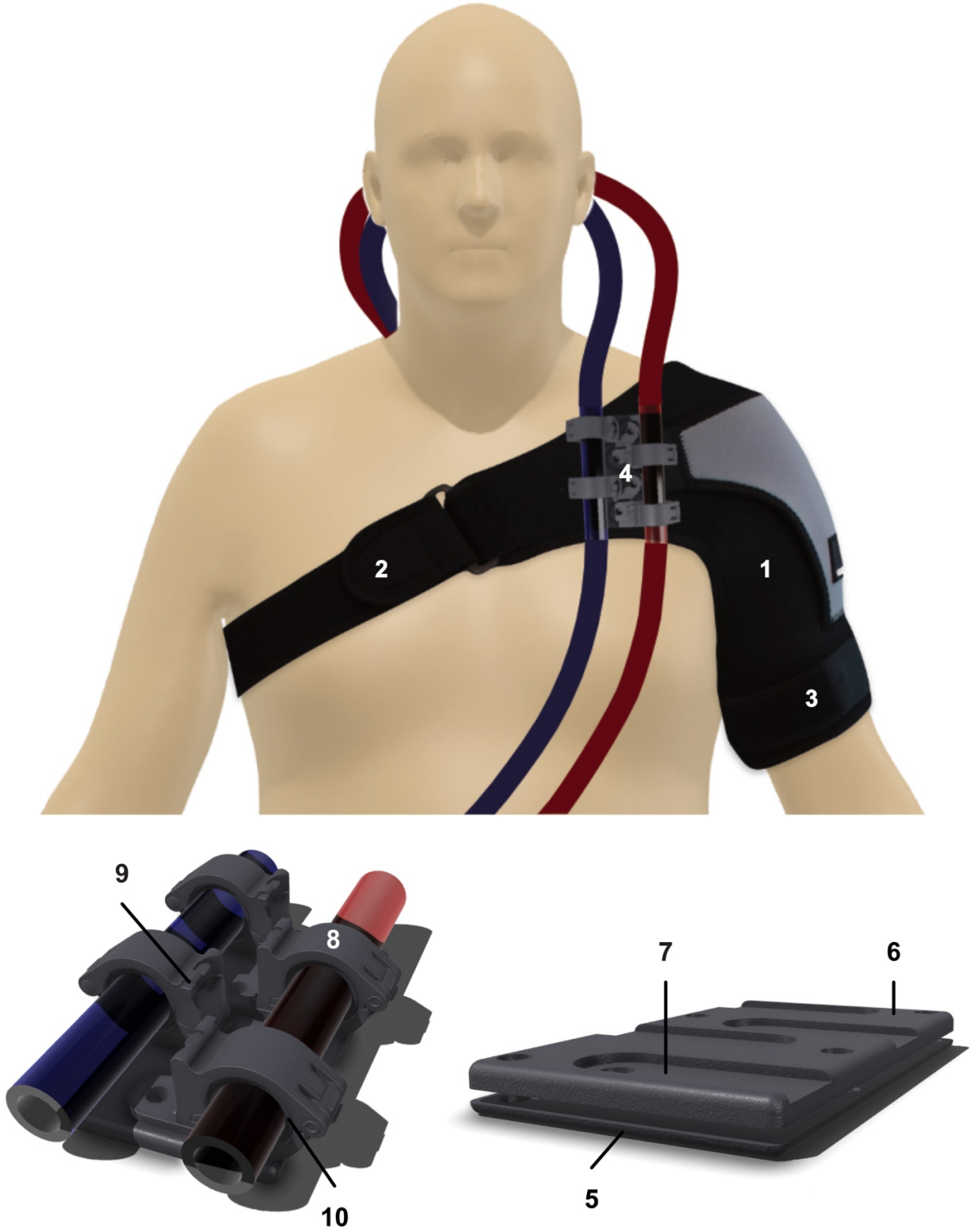


Figure 6: Concept design of the blood tubing fixation module providing safety and stability of the patient's cannula and circuit management during ambulatory ECMO

1. **Universal shoulder brace**
   Secures the blood tubing fixation module to the body of the patient without limiting movement of the upper body and head.
2. **Velcro chest closure**
   Adjustable primary fixation of the shoulder brace to the patient.

3. **Velcro upper arm closure**
   Adjustable secondary fixation of the shoulder brace to the patient.
4. **Blood tubing connector**
   Fixates the blood tubing itself and is directly connected to the shoulder brace. The double plate structure prevents disconnection of the connector during ambulation.
5. **Bottom plate**
   Part of the blood tubing connector that is positioned on the inside of the shoulder brace and mechanically fixed with the base plate.
6. **Base plate**
   Part of the blood tubing connector that is positioned on the outside of the shoulder brace and mechanically fixed with the bottom plate. It keeps the tubing clamps in position.
7. **Countersunk for tubing clamp mounts**
   To prevent rotation of the tubing clamps with the base plate when large forces are exerted.
8. **Blood tubing clamp**
   Fixates the blood tubing using a double strain relieve to prevent tension on the cannula when forces on the blood tubing are exerted.
9. **Locking pin**
   Additional safety locking system to prevent the clamps to open unintentionally.
10. **Anti-slip rings**
    Prevents sliding, bending, and rotational movement of the blood tubing inside the tubing clamps.

4.2.1.3 Prototype

Figure 7: Simulated ECMO patients wearing the blood tubing fixation module prototype during (A-C) a static standing position, (D) lying in bed, (E) walking with the ambulatory cart

4.2.2 Module B – Ambulatory device transport module

The aim of the ambulatory device transport module is to provide transport of devices necessary in both stationary and ambulatory conditions.

4.2.2.1 User requirements

- The product shall carry all necessary equipment during both ambulatory and stationary ECMO.
- The product shall be controlled by the patient during ambulatory ECMO.
- The product shall be controlled by the caregiver during both stationary and ambulatory ECMO.
- The product shall be able to move only when the user initiates.

- The product shall be able to connect to the stationary device transport cart (module C) during stationary conditions.
- The product shall be able to disconnect from the stationary device transport cart (module C) during ambulatory conditions.

4.2.2.2 Concept design & description

The concept design of the ambulatory device transport module is shown in Figure 8 and consists of the following 27 features.

1. **Drip**
   Provides a slow and steady flow of liquid through intravenous infusion (e.g. normal saline) (not part of the invention).
2. **Drip connection pole**
   Provides attachment of multiple drips and is height adjustable (up to 2 m).
3. **Perfusor pump**
   A medical device that delivers fluids, medications, or nutrients into a patient's bloodstream at a controlled rate.
4. **Perfusor pump connection pole**
   Allows the connection of multiple perfusor pumps using a universal clamp.
5. **Accessory plate**
   Offers space for placing accessories. The raised edge prevents accessories from falling during movement.
6. **Patient pushing handle**
   Provides walking support for the patient and allows the patient to move the ambulatory cart.
7. **Caregiver pushing handle**
   Allows the caregiver to move the ambulatory cart when the patient is sitting.
8. **Caregiver side handle**
   Allows the caregiver to attach and detach the ambulatory cart to the stationary cart.

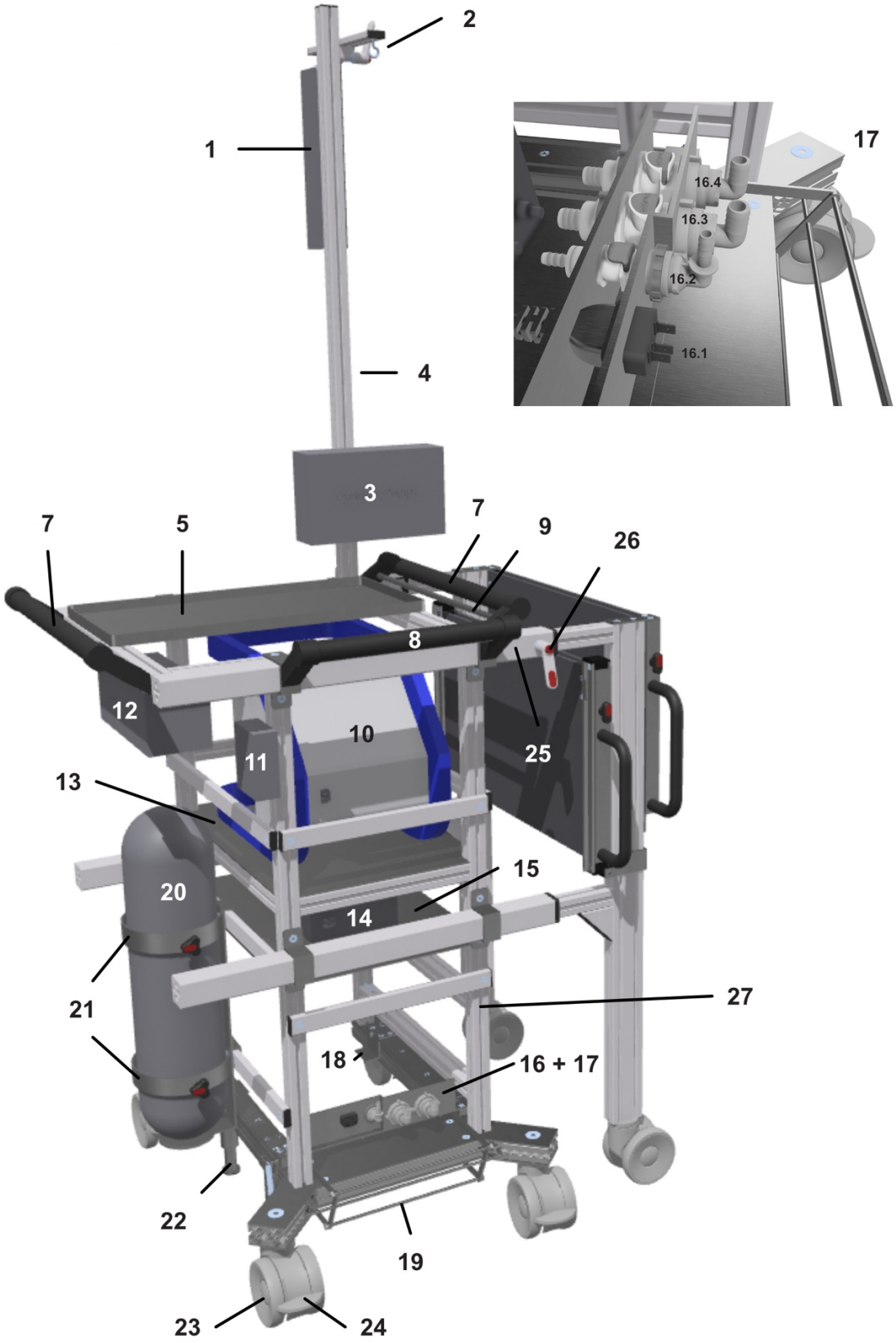


Figure 8: Concept design of ambulatory device transport module providing transport of devices necessary in both stationary and ambulatory conditions.

9. **(De)braking handles**
   When pulled it provides lifting of the braking poles (22) from the ground to enable movement of the ambulatory cart.

10. **ECMO device**
    Supports the heart and/or lungs with a blood pump and an artificial lung (not part of the invention).

11. **Gas splitter (Module E)**
    Enables continuous gas/oxygen support. It connects the oxygenator with both bottled gas and wall gas (stationary conditions only).

12. **Emergency drive**
    A manual pump drive to take over the pump function of the ECMO machine in case of failure of the automatic pump (not part of the invention).

13. **ECMO device plate**
    Provides support for the ECMO device.

14. **Power hub**
    A power source designed to isolate the patient and the operator from an electric shock and to protect the equipment from power surges or faulty components.

15. **Power hub device plate**
    Provides support for a power hub to charge multiple devices at the same time during stationary ECMO.

16. **Ambulatory hub part**
    Provides the connection of necessary fluids, gasses and electricity for devices on the ambulatory cart during stationary ECMO.

    16.1 – power connector

    16.2 – gas connector

    16.3 – water connector (inlet)

    16.4 – water connector (outlet)

17. **Multi-connector hub (Module F)**
    Exists of a stationary and ambulatory hub part. The multi-connector hub provides easy attachment and detachment of devices needed for stationary ECMO.

18. **Lift mechanism**
    Provides lifting of the stationary cart to enable (non-patient) system transport and to secure device connections.

19. **Lift mechanism foot pedal**
    Enables lifting of the stationary cart using a foot pedal.

20. **Oxygen bottle**
    A pressurized container used to store and transport oxygen (not part of the invention).

21. **Oxygen bottle holder**
    Provides support for one oxygen bottle.

22. **(De)braking safety system**
    Prevents unintentional movement of the ambulatory cart. Two braking poles connected to the (de)braking handles (9) cause friction with the ground. When a (de)braking handle is pulled, it lifts the braking poles from the ground to allow movement of the ambulatory cart.

23. **Swiveling wheels**
    Provides 360 degrees movement of the ambulatory cart.
24. **Parking brake**
    Prevents unintentional movement of the stationary cart when activated.
25. **Telescope frame**
    Provides connection and guidance of the patient support module to the stationary cart.
26. **Telescope locking handle**
    Provides locking and unlocking for extension of the patient support module.
27. **Main ambulatory cart frame**
    Provides transport and connection of devices necessary in both stationary and ambulatory conditions.

4.2.2.3 Prototype

Figure 9: (A) front view and (B) rear view of the prototype of the ambulatory device transport module which provides transport of devices necessary in both stationary and ambulatory conditions

4.2.3 Module C – Stationary device transport module

The aim of the stationary device transport module is to provide transport of devices only necessary in stationary conditions.

4.2.3.1 User requirements

- The product shall carry all necessary equipment during stationary ECMO.
- The product shall be moveable by one caregiver.
- The product shall be operable by one caregiver.
- The product be positioned next to the patient's bed and stays in ICU during ambulatory ECMO.

- The product shall be able to connect to the ambulatory device transport cart (module B) during stationary conditions.
- The product shall be able to disconnect from the ambulatory device transport cart (module B) during ambulatory conditions.

4.2.3.2 Concept design & description

Figure 10 shows the concept design of the stationary device transport module. This consists of the nine features described in the following.

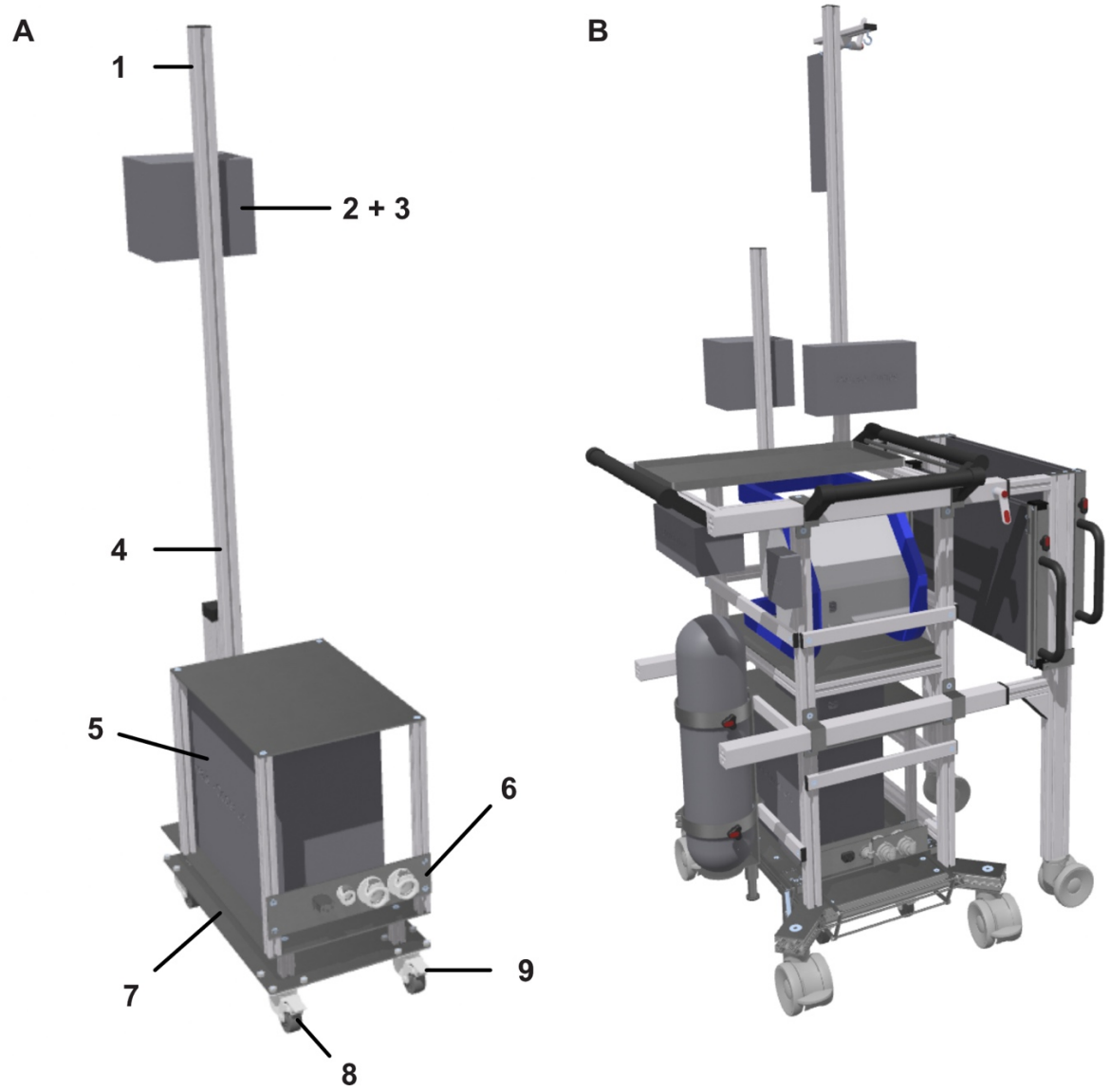


Figure 10: (A) Concept design of stationary device transport module providing transport of devices only necessary in stationary conditions, (B) Ambulatory ECMO cart combined with the stationary cart as used in stationary ECMO conditions

1. **Gas blender, flow meter and power hub connection pole**
   Allows the connection of a gas blender, flow meter and a power hub using a universal clamp.
2. **Gas blender**
   A medical device to mix medical grade air with oxygen to a certain oxygen concentration.

3. **Flow meter**
   A device used to measure the real-time material flow of fluid or gas to give either volumetric or mass flow readings.

4. **Power strip**
   Provides continuous power supply for the heater-cooler unit and the stationary hub electricity connector. The power strip is connected to the wall power.

5. **Heater-cooler unit**
   A medical device to cool or warm the blood.

6. **Stationary hub part**
   Provides the connection of necessary fluids, gasses, and electricity for devices on the ambulatory cart during stationary ECMO with

   - power connector
   - gas connector
   - water connector (inlet)
   - water connector (outlet)

7. **Double bottom**
   Provides space to hide and organize cables and other lines.

8. **Swiveling wheels**
   Provides 360 degrees movement of the stationary cart.

9. **Parking brake**
   Prevents unintentional movement of the stationary cart when activated.

4.2.3.3 Prototype

Figure 11: (A) Prototype of the stationary device transport module (left) providing transport of devices only necessary in stationary conditions, (B) prototype of the ambulatory device transport module, (C) Ambulatory ECMO cart combined with the stationary cart as used in stationary ECMO conditions

4.2.4 Module D – Patient support module

The aim of the patient support module is to provide physical patient support during walking and in case of sudden events such as patient fatigue or unexpected hemodynamic instability.

4.2.4.1 User requirements

- The product shall provide safe walking support for the patient during ambulatory ECMO.
- The product shall provide patient transport in case of patient fatigue or unexpected hemodynamic instability during ambulatory ECMO.
- The product shall ensure that the patient can always be moved back to the ICU including all equipment by one caregiver.

4.2.4.2 Concept design & description

The concept design of the patient support module is shown in Figure 12 and consists of the following eight features.

1. **Extendable walking frame**
   Surrounds the patient and ensures a safe and unobstructed walking support. Moreover, it connects the patient support module to the ambulatory device transport module.
2. **Folding seat**
   Facilitates sitting patient transport in case of patient fatigue or unexpected hemodynamic instability.

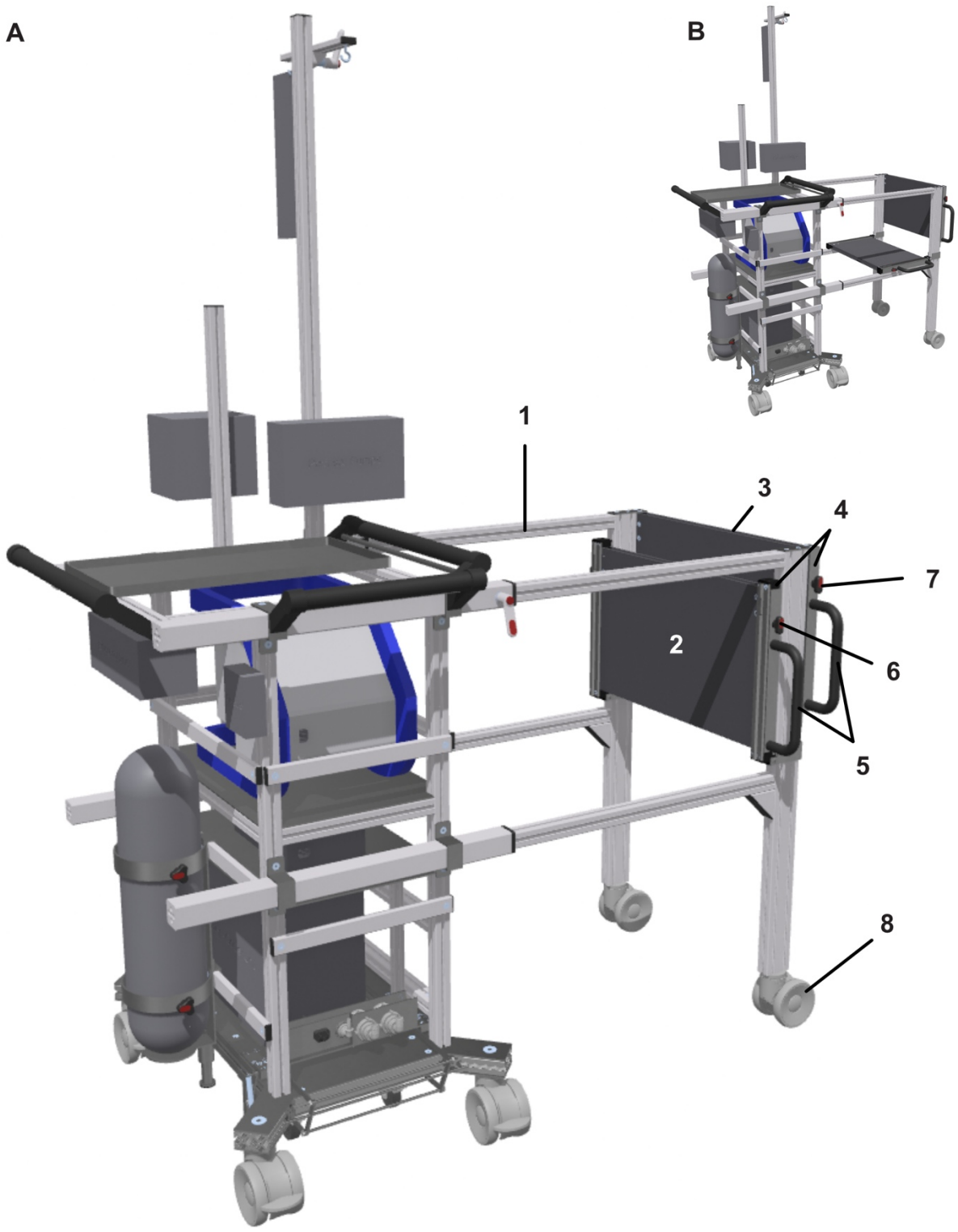


Figure 12: (A) Concept design of patient support module providing physical patient support during walking and (B) sitting support in case of sudden events such as patient fatigue or unexpected hemodynamic instability

3. **Backrest**
   Provides back support for the patient during sitting transport.

4. **Sliding mechanism**
   Provides sliding of both the folding seat and backrest to ensure easy patient entry.

5. **Hand grips**
   Can be used to rotate the seat and to slide both the seat and backrest.
6. **Seat locking mechanism**
   Enables (un)locking to provide or prevent sliding and rotation of the seat depending on the position of the rotation knob.
7. **Backrest locking mechanism**
   Enables (un)locking to provide or prevent sliding of the backrest depending on the position of the rotation knob.
8. **Swiveling wheels**
   Provides 360 degrees movement of the ambulatory cart when the walking frame is extended.

4.2.4.3 Prototype

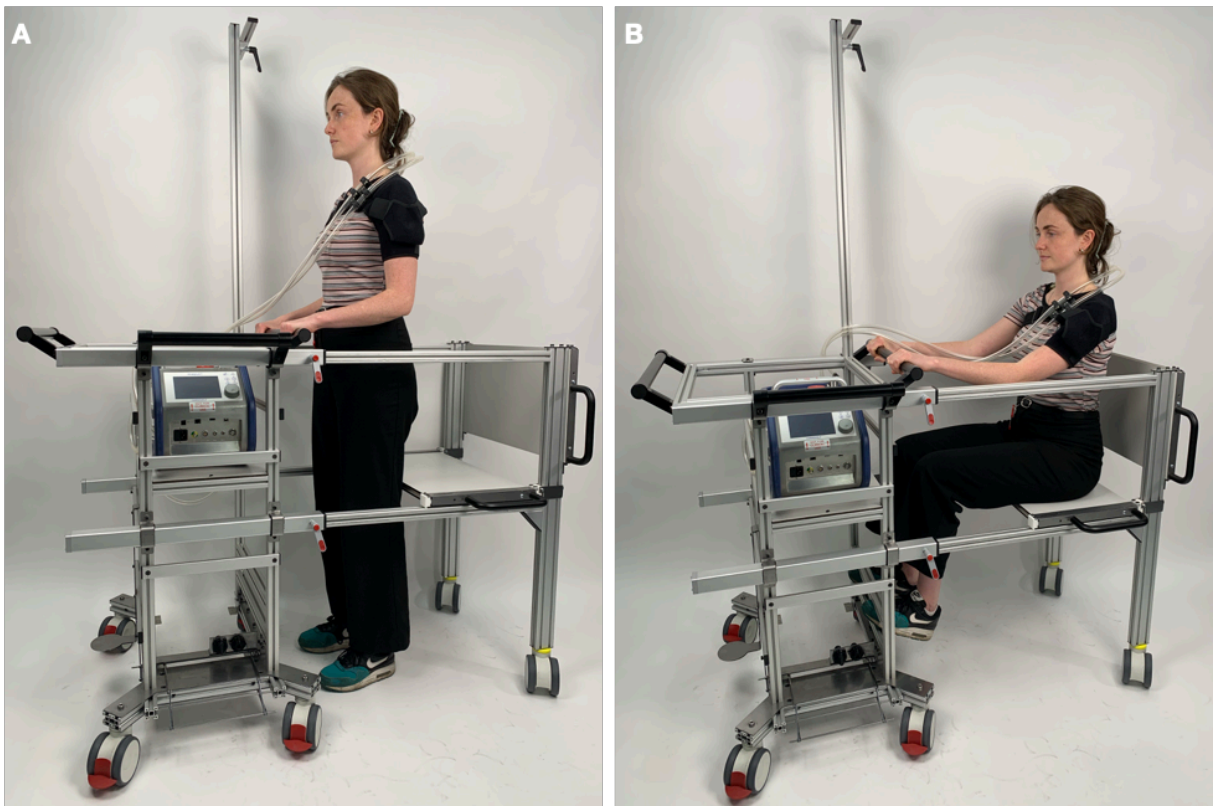


Figure 13: (A) Prototype of the ambulatory cart with integrated patient support module providing physical patient support during walking and (B) sitting support in case of sudden events such as patient fatigue or unexpected hemodynamic instability

4.2.5 Module E – Gas splitter

The aim of the gas splitter is to provide easy switching between wall-mounted gas and bottled gas.

4.2.5.1 User requirements

- The product shall enable continuous gas/oxygen support during the transition from stationary to ambulatory ECMO and vice versa.

- The product shall enable continuous gas/oxygen support during replacement of the oxygen cylinder under stationary ECMO conditions.

4.2.5.2 Concept design & description

The proposed concept involves a gas splitter consisting of two inlets and one outlet. One of the inlets is intended for the oxygen cylinder. The oxygen flow needs to be regulated using a medical flow regulator before it enters the gas splitter inlet. The other inlet is meant for the wall gas. The wall gas can exist of a mixture of oxygen and medical air. A dedicated gas blender and flow meter need to be used before the wall gas enters the gas splitter inlet. The outlet of the gas splitter is connected to the gas inlet of the oxygenator. The gas splitter must be capable of switching between the two inlets, necessitating the incorporation of a change-over valve. Moreover, when one inlet is in use, the other inlet must be blocked. The change-over valve can be implemented using either a solenoid valve or a mechanical mechanism. Switching between stationary and ambulatory ECMO necessitates the consideration of various phases and configurations. In the example provided, an electrical driven solenoid valve is employed. The proposed concept is illustrated schematically in Figure 14.

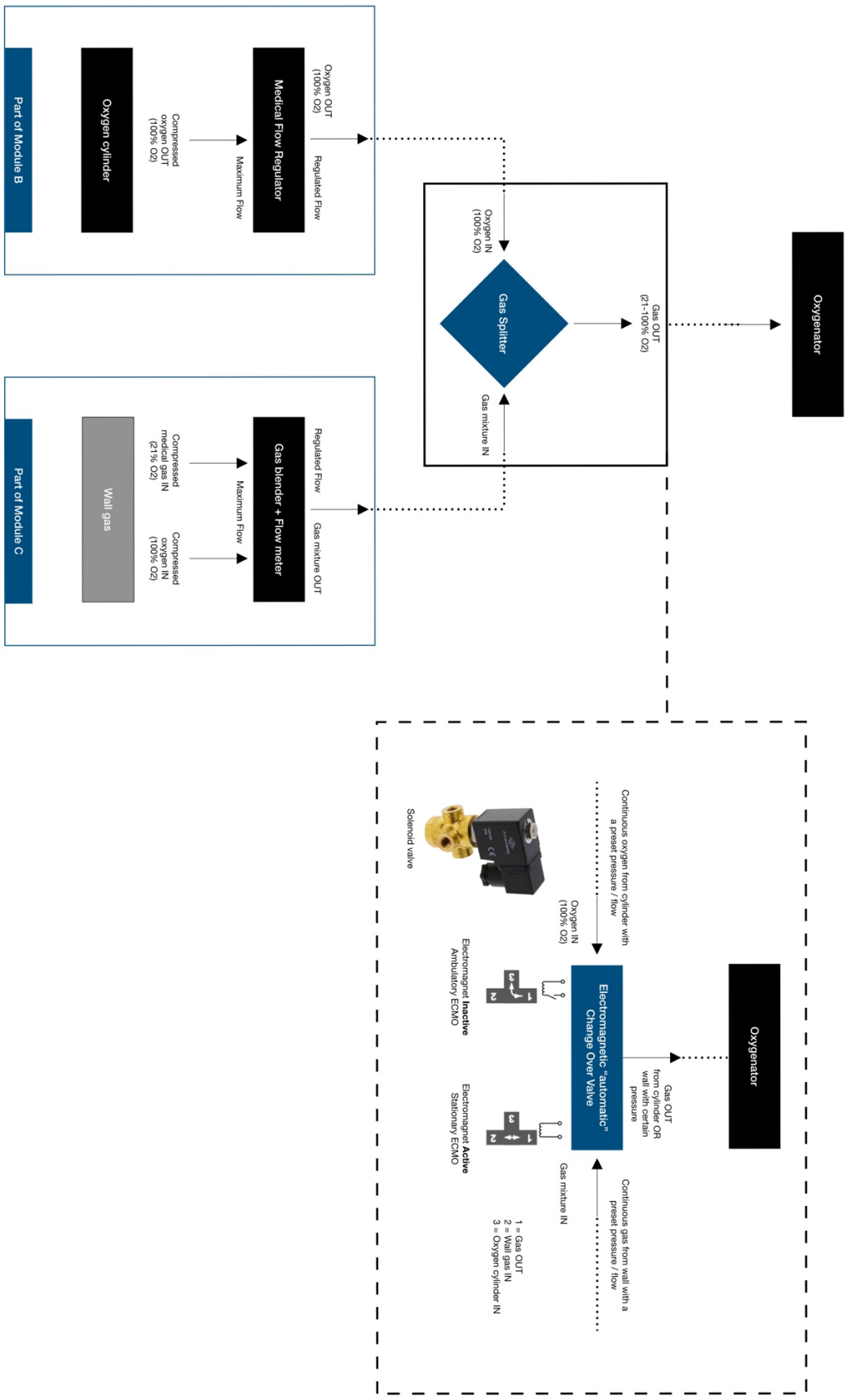


Figure 14: Conceptual configuration of a solenoid change-over valve to provide easy switching between wall-mounted gas and bottled gas.

Stationary condition

Both the oxygen cylinder and the wall gas are connected to the inlets of the solenoid valve. The solenoid valve must be powered when the wall-gas connector is connected. The power connection is established by an additional connector. Under powered conditions, the electromagnet in the solenoid is active. Therefore, the valve position blocks the inlet of the oxygen cylinder. At the same time, the inlet of the wall gas is open. The outlet only receives the gas mixture coming from the wall gas to the oxygenator.

Transition phase (stationary to ambulatory)

The wall-gas connector must be detached. At the same time, the power of the solenoid needs to be detached. This results in an inactive electromagnet which switches the solenoid valve. In this situation, the oxygen cylinder inlet is open, and the wall gas inlet is blocked. This allows the oxygen from the cylinder to flow towards the outlet. A valved connector on the wall-gas tube prevents the escape of wall gas after disconnection.

Ambulatory phase

Only the oxygen cylinder is connected to the inlet of the change-over valve. The electromagnet is still inactive as it is unpowered. The outlet of the change-over valve only receives the oxygen from the oxygen cylinder.

Transition phase (ambulatory to stationary)

The wall-gas connector must be attached. At the same time, the power of the solenoid needs to be attached. This results in an active electromagnet which switches the valve. This blocks the oxygen cylinder inlet and opens the wall-gas inlet. This allows the wall gas to flow towards the outlet. The outlet only receives the gas mixture coming from the wall gas.

Note: the oxygen cylinder inlet does not have to be closed or detached when wall gas is used.

4.2.6 Module F – Multi-connector hub

The aim of the multi-connector hub is to provide easy attachment and detachment of devices needed for stationary ECMO.

4.2.6.1 User requirements

- The product shall enable continuous support of necessary fluids, gasses, and electricity.
- The product shall enable easy configuration of necessary fluids, gasses, and electricity.

4.2.6.2 Concept design & description

To facilitate easy configuration of necessary fluids, gases, and electricity between devices required for stationary ECMO a multi-connector hub was designed as depicted in Figure 15. This hub comprises two parts: a stationary part and an ambulatory part. In stationary conditions, the two parts must be connected to each other, while in ambulatory conditions, they must be disconnected. Both the stationary and ambulatory hub parts consist of a plate in which the necessary connectors are mounted with a plate mount connection ring. When the two carts are pushed together, the connectors of both hub parts are connected by sliding into each other.

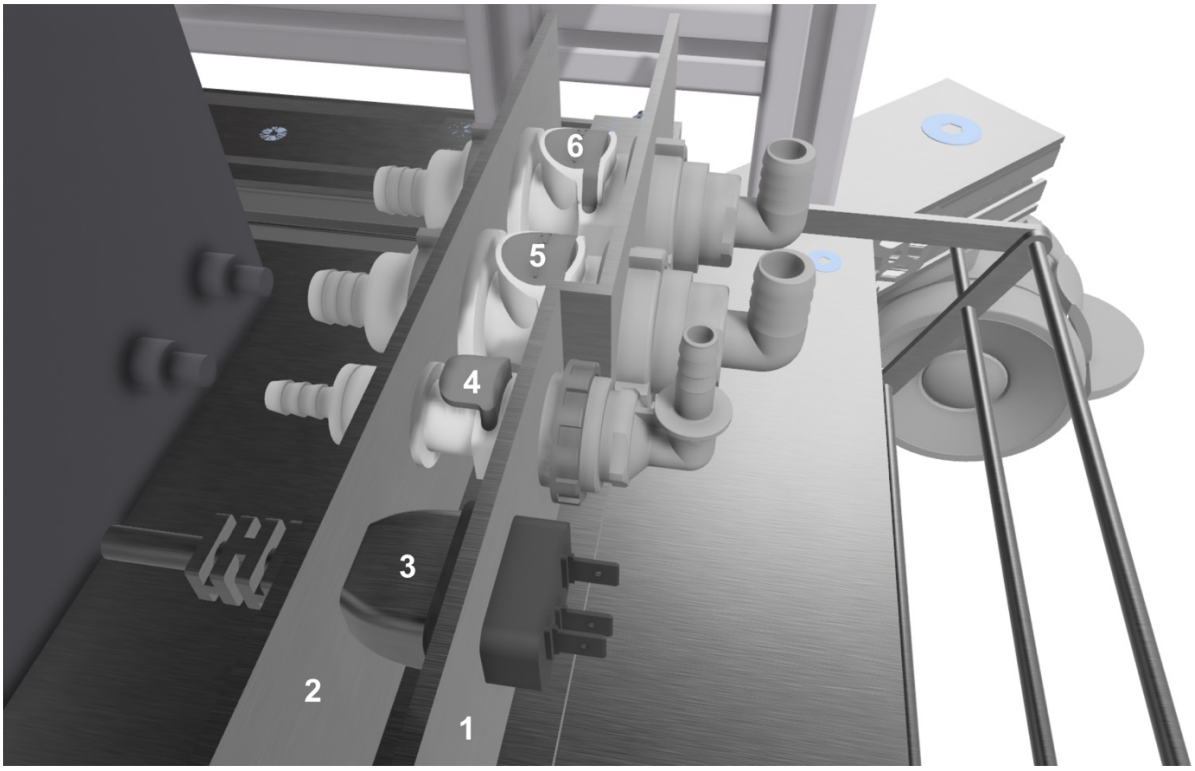


Figure 15: Concept design of the multi-connector hub providing easy attachment and detachment of devices needed for stationary ECMO

The stationary hub part is attached to the stationary cart, while the ambulatory hub part is attached to the lift mechanism of the ambulatory cart. This ensures that when both hub parts are connected, there is no positional displacement between the stationary and ambulatory connectors when lifting the stationary cart.

When the ambulatory cart is disconnected from the stationary cart, the connection between the connectors of the two hub parts is also disconnected. The use of valved connectors for both fluids and gasses prevent spillage or leakage.

The multi-connector hub as seen in Figure 15 can be divided into several components, each with a specific function.

1. **Ambulatory hub plate**
   Provides a mounted connection for all ambulatory connectors.
2. **Stationary hub plate**
   Provides a mounted connection for all stationary connectors.
3. **Electricity connector**
   Provides the connection of electricity for devices on the ambulatory cart to charge batteries during stationary ECMO.
4. **Gas connector**
   Provides the connection of wall gas to the gas splitter during stationary ECMO.
5. **Water connector (inlet)**
   Provides the connection of water from the oxygenator towards the heater-cooler unit during stationary ECMO.

6. **Water connector (outlet)**
   Provides the connection of water from the heater-cooler unit towards the oxygenator during stationary ECMO.

4.2.6.3 Prototype:

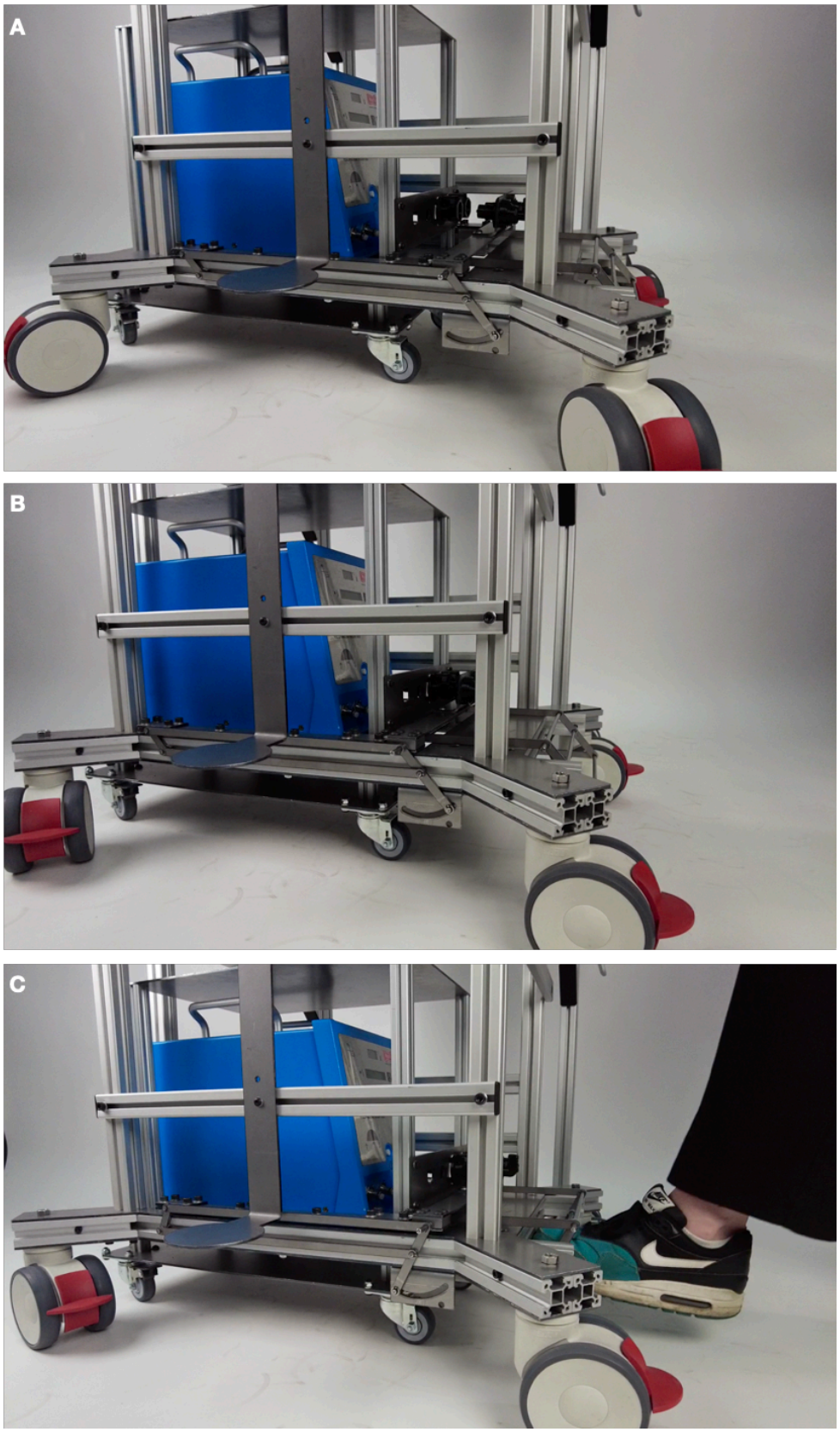


Figure 16: Prototype of the stationary cart lift mechanism and the multi-connector hub providing easy attachment and detachment of devices needed for stationary ECMO. (A) Stationary cart detached and lift mechanism lowered, (B) Stationary cart attached and lift mechanism lowered, (C) Stationary cart attached and lift mechanism lifted

4.3 Product User Scenario

To describe the intended use of the system, a user scenario has been described in 12 steps. Each step describes how the patient and caregiver interact with the system. Each step is visually supported by a 3D image.

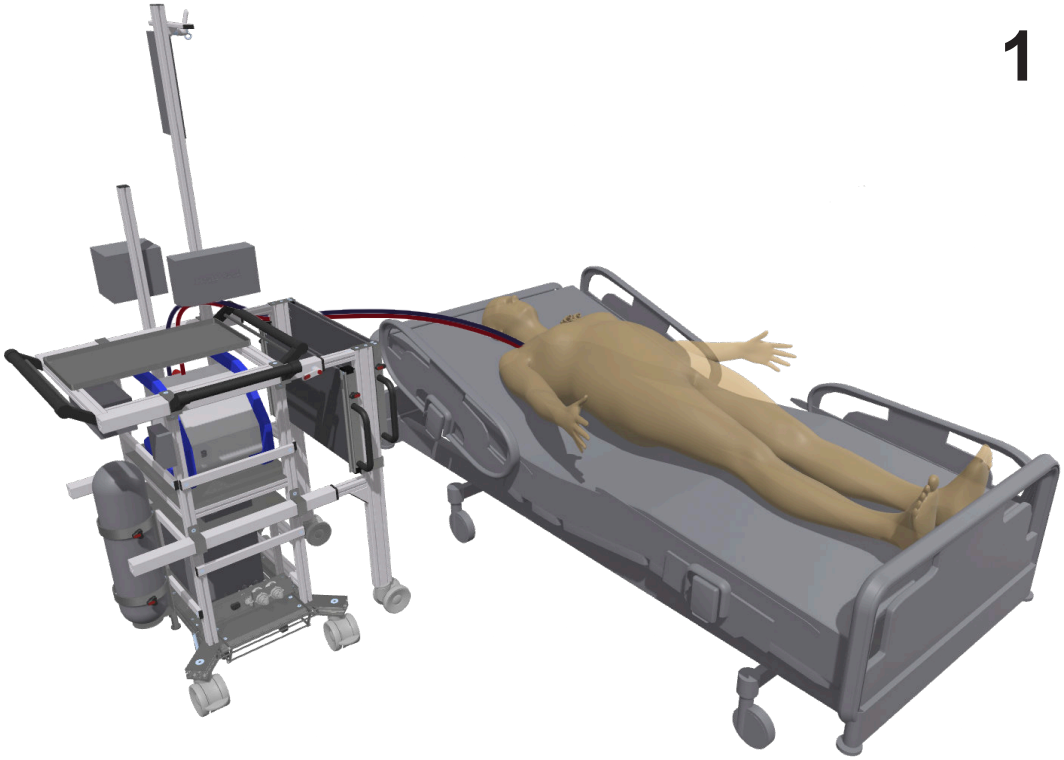


Figure 17: User scenario, step 1 – Initial stationary ECMO configuration. The system is positioned close to the patient's bed and put on parking brakes to prevent unintended movement of the system.

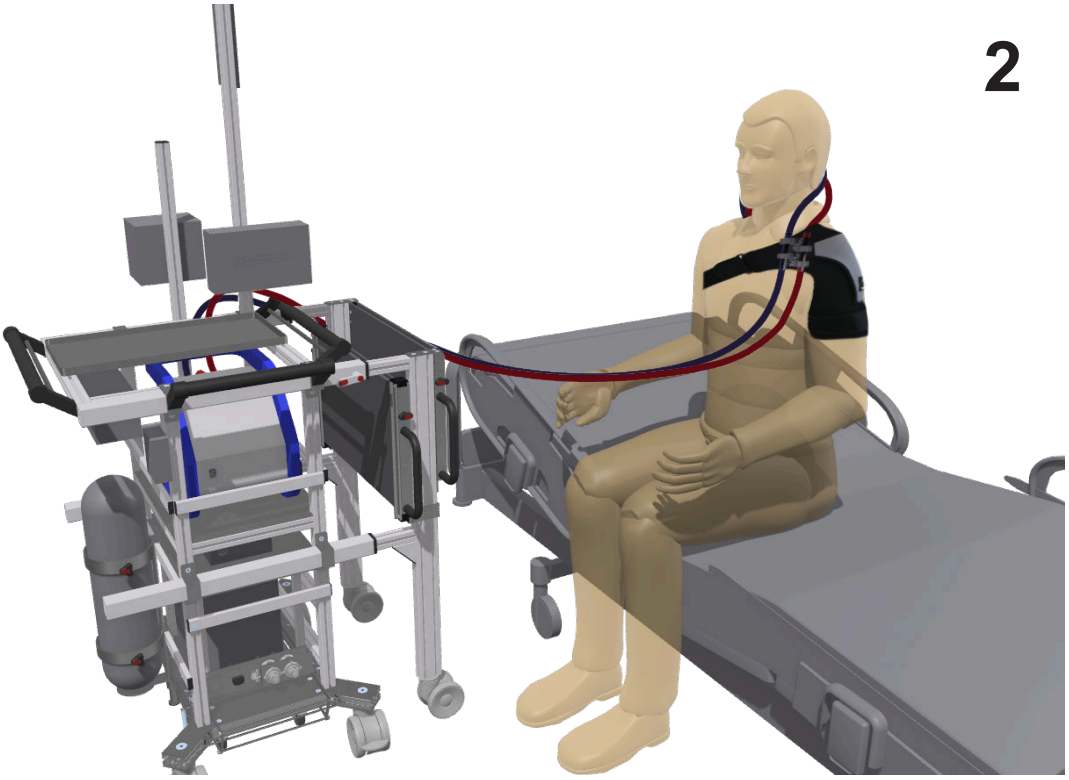


Figure 18: User scenario, step 2 – Patient gets upright and sits on the edge of the bed. The blood tubing fixation module is attached by the caregiver.

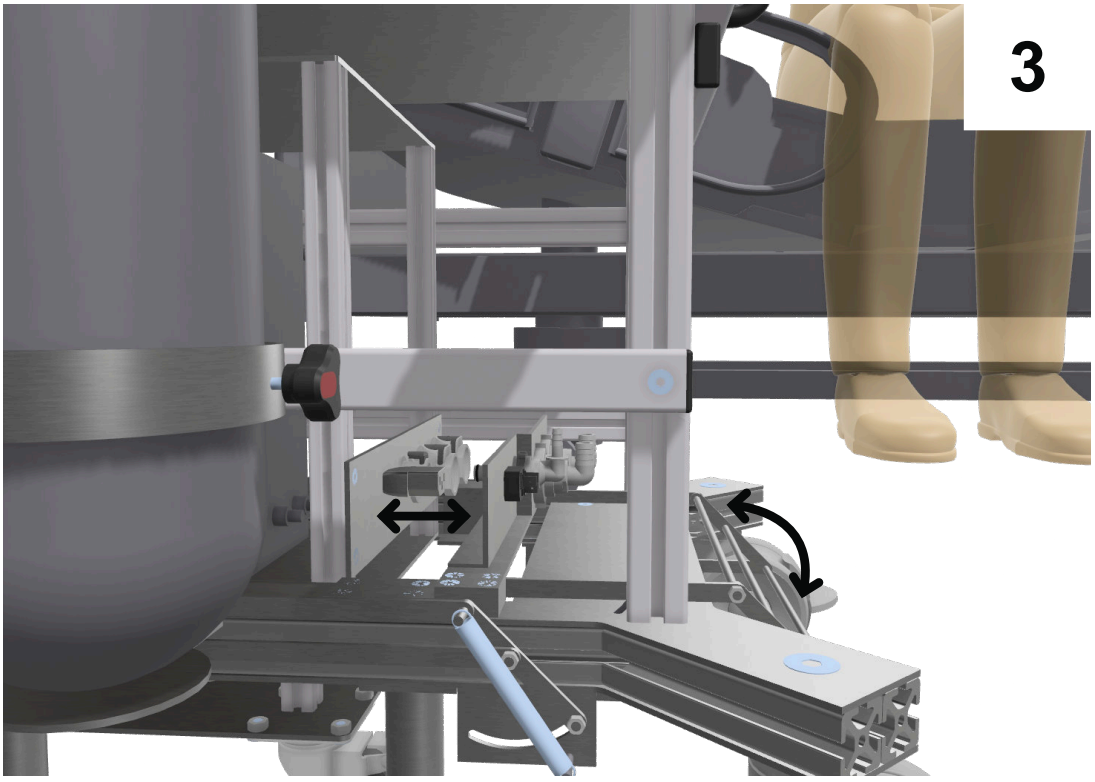


Figure 19: User scenario, step 3 – The caregiver lowers the lift mechanism using the foot pedal and disconnects the multi-connector by pulling the ambulatory cart. Electricity, gas, and fluids are switched automatically to ambulatory mode.

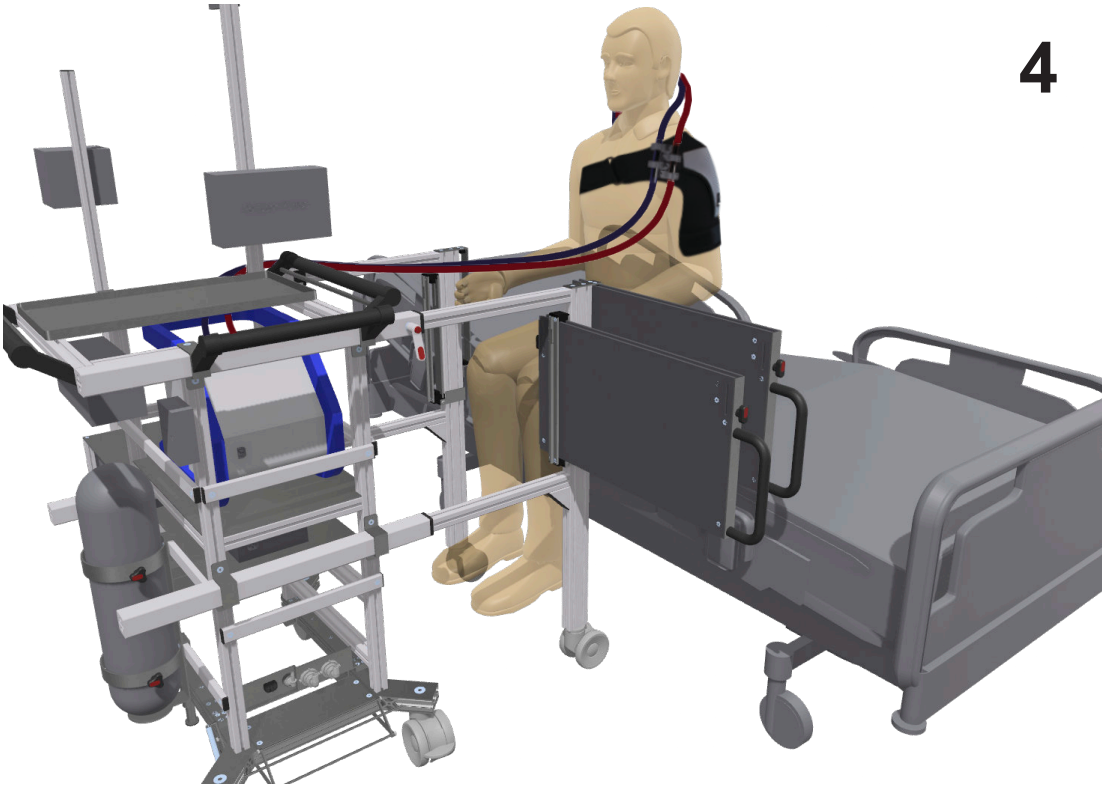


Figure 20: User scenario, step 4 – The caregiver positions the ambulatory cart in front of the patient, extents the walking frame and opens the seat and backrest. The caregiver activates the parking brakes.

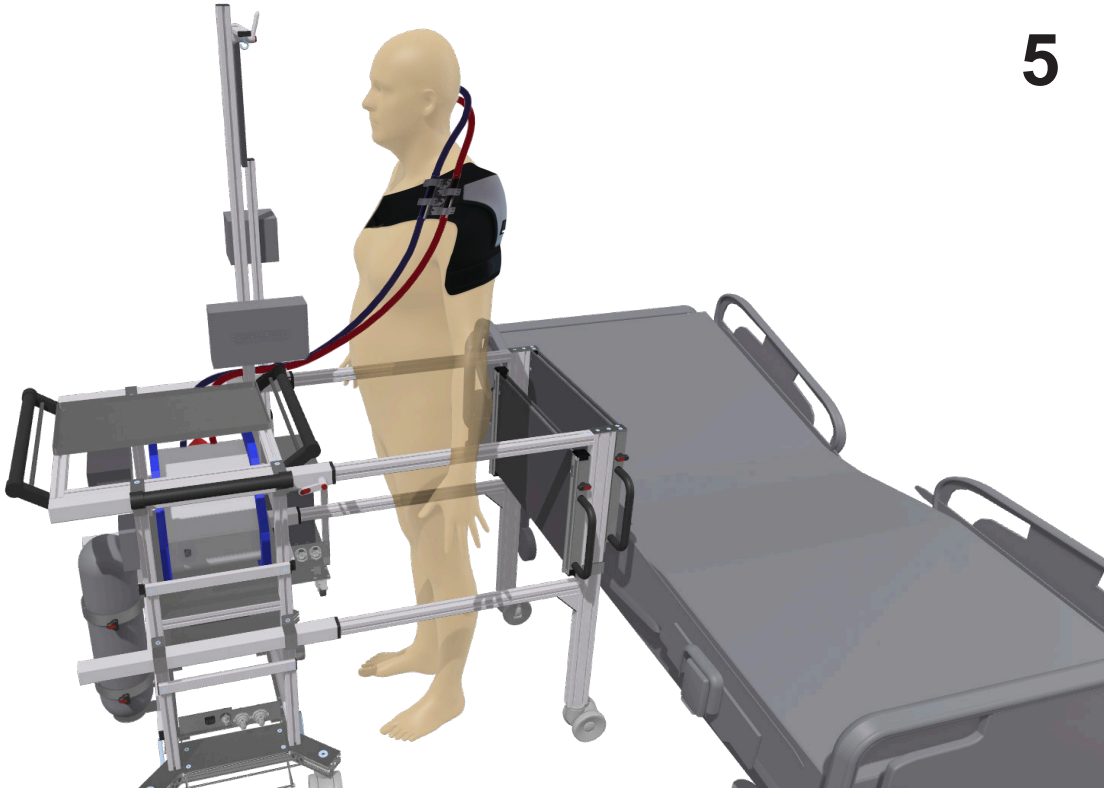


Figure 21: User scenario, step 5 – The patient stands up with manual support, if necessary, steps within the walking frame and grabs the pushing handle. The seat and backrest are closed. The walking frame is extended to the preferred position.

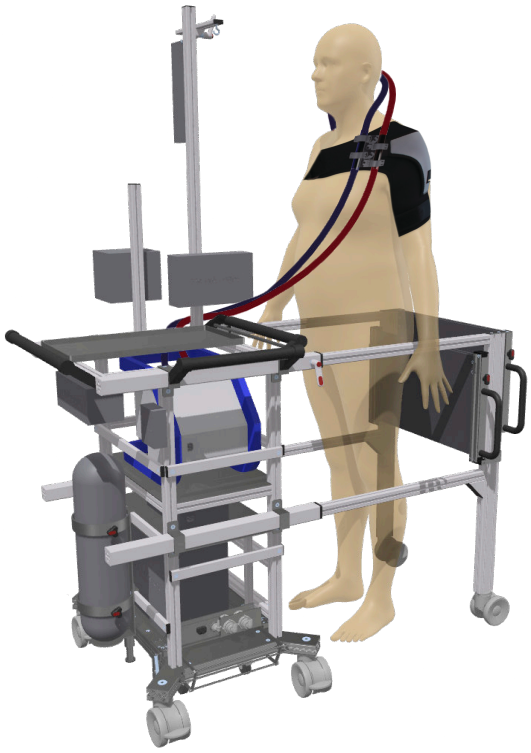


Figure 22: User scenario, step 6 – The caregiver releases the parking brakes. The patient pulls the (de)brake handle to release the safety brakes. The patient is now ready to walk. To go back to stationary ECMO, all previous steps can be applied in reversed order.

Figure 23: User scenario, step 7 – In case of patient fatigue, the foldable seat enables the patient to sit down. The caregiver unfolds the seat and assists the patient.

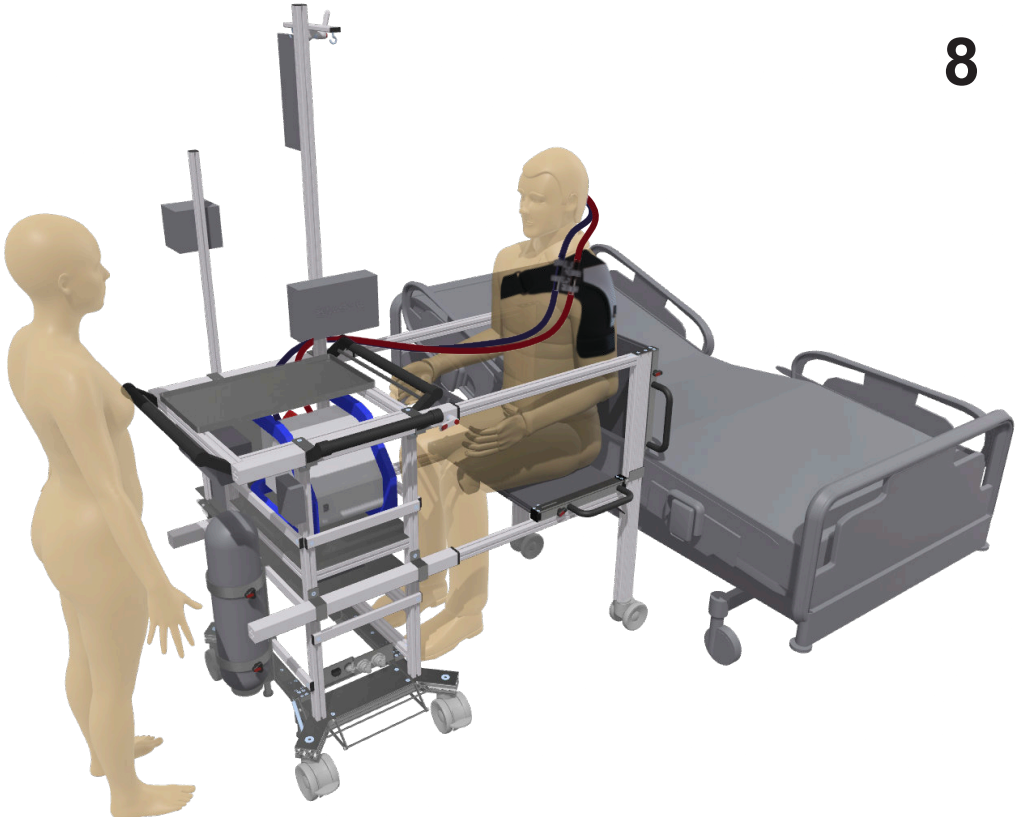


Figure 24: User scenario, step 8 – The caregiver pushes the patient back to the ICU while facing the patient. Returned at the ICU, the cart is positioned with the back of the walking frame against the edge of the bed. The caregiver activates the parking brakes.

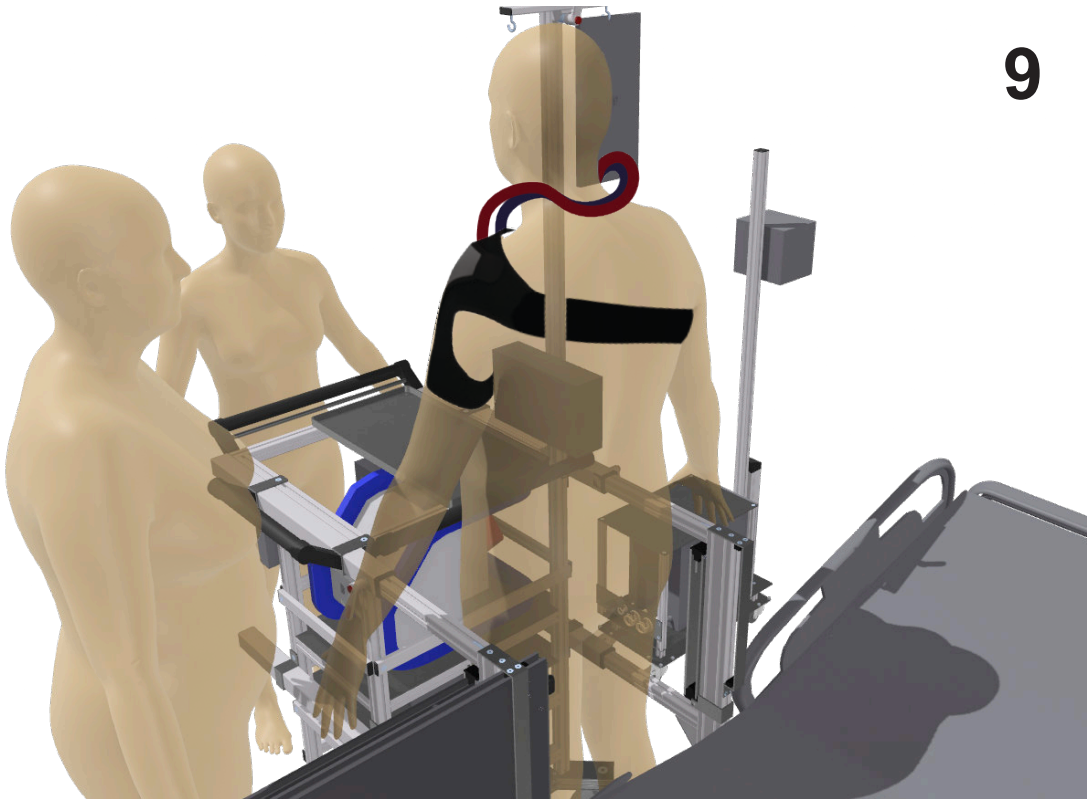


Figure 25: User scenario, step 9 – A secondary caregiver assists the patient to stand up, folds up the seat and opens the seat and backrest.

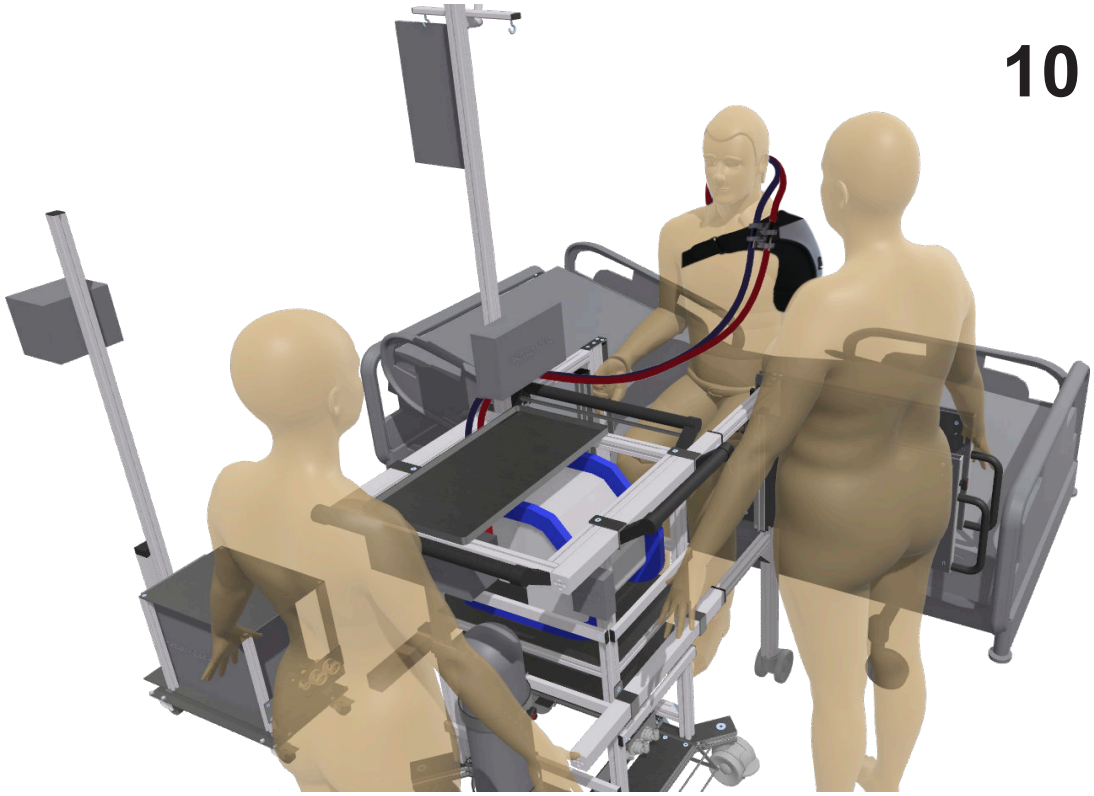


Figure 26: User scenario, step 10 – The secondary caregiver might assists the patient by making a small step backwards so that the patient positions his legs against the edge of the bed. At the same time, the primary caregiver moves the ambulatory cart in the direction of the patient to shorten the walking frame. The patient can now sit down on the bed. The blood tubing fixation module is detached.

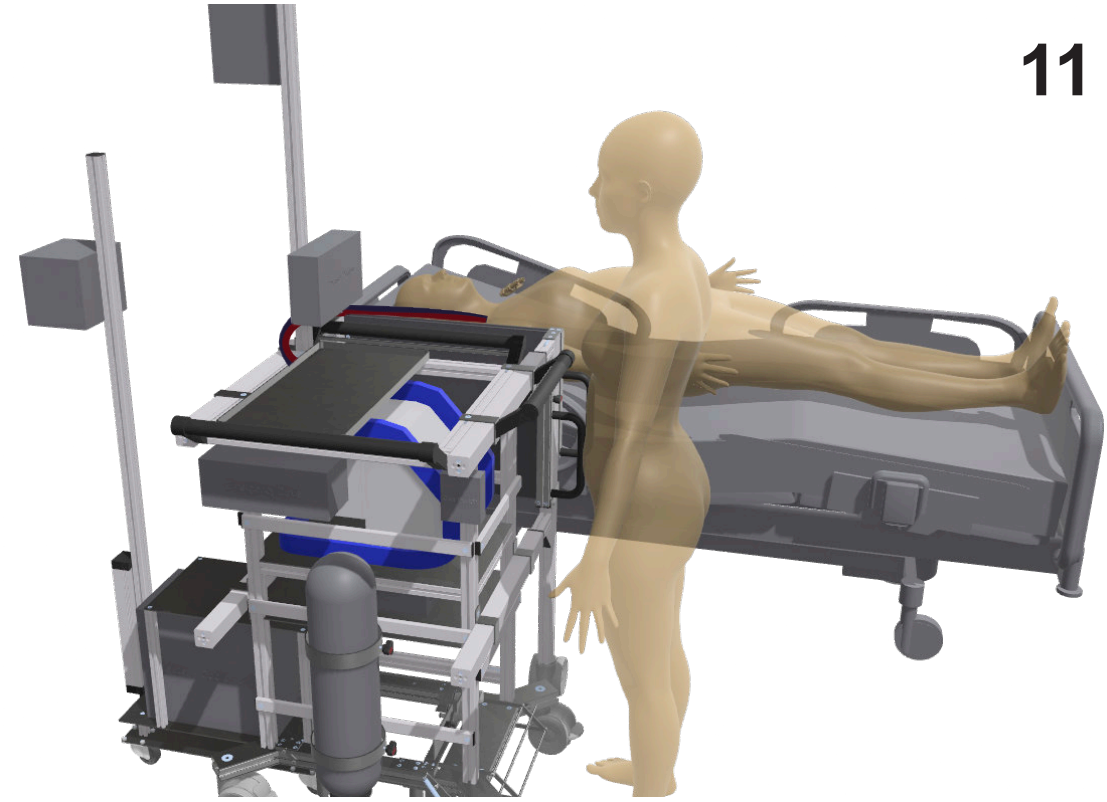


Figure 27: User scenario, step 11 – The caregiver closes the seat and backrest and slides in the walking frame completely. The ambulatory cart can now be connected to the stationary cart.

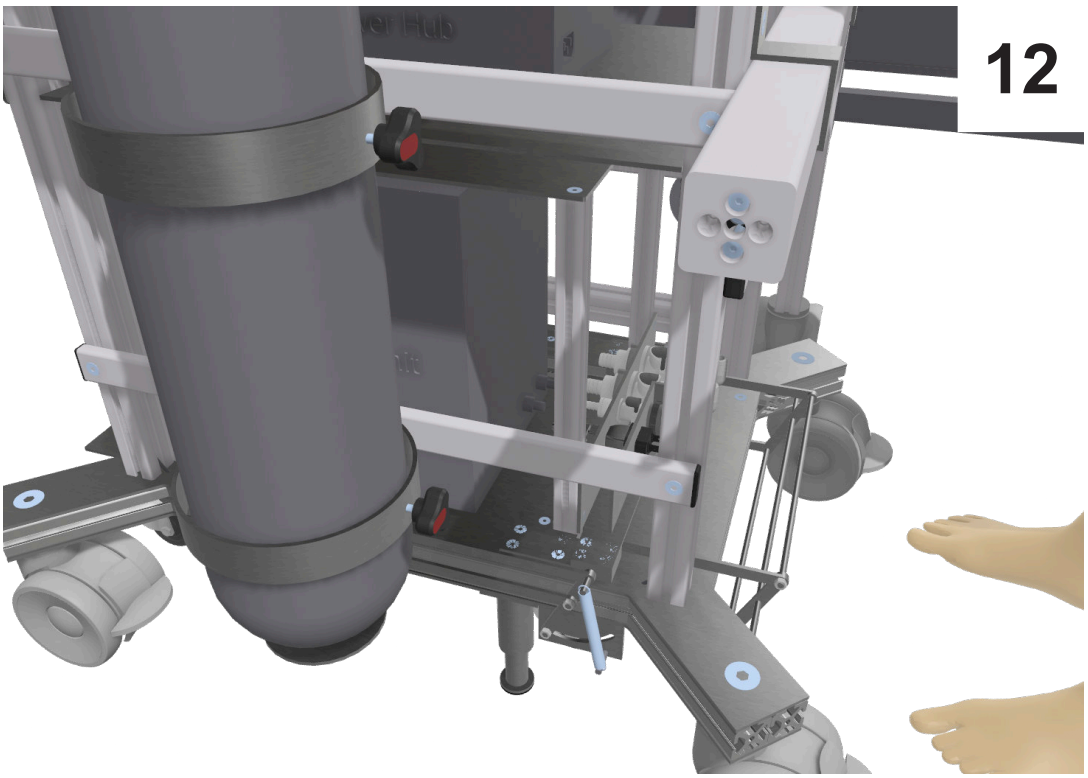


Figure 28: User scenario, step 12 – The foot pedal is used to lift the stationary cart from the ground and to secure the connections of the multi-connector hub. Electricity, gas, and fluids are switched automatically to stationary mode.

5 Discussion

During the simulation tests, the use of the shoulder brace with the blood tubing connector for the attachment of blood tubing during ambulation was evaluated. The findings suggest that the shoulder brace is a convenient tool for safely attaching blood tubing to patients, as it can be easily attached to a supine patient by a single caregiver and remains in position during ambulation. It is found that the blood tubing connector should be positioned slightly rotated (+- 5 degrees clockwise) to ensure the correct guidance direction of the blood tubing towards the oxygenator. Opening the individual clamps on the blood tubing connector is relatively easy, but a bit of pressure is required to close them. Keeping one hand at the back of the blood tubing connector inside the shoulder brace appears to be the most effective way to close the clamps. During ambulation, the shoulder brace and blood tubing connector remain in position. The double strain relief of the blood tubing connector prevents the cannula from any tension even when strong forces are applied on the tubing between the blood tubing connector and the oxygenator. The shoulder brace was successfully tested on both a large man and a small woman. Although it is safely used for both patient profiles, a smaller version of the shoulder brace would be more comfortable and better suited for smaller patients. To define the ideal position for the blood tubing connector, a Velcro connection between the connector and the shoulder brace is being used. In a final prototype, it is recommended to permanently fixate the blood tubing connector to the shoulder brace. This can be done using a second connector plate on the inside of the brace to prevent unintended detachment of the blood tubing connector.

The stationary cart easily moves in all directions when the ambulatory cart is detached. To facilitate easy refilling of the heater-cooler unit, it is suggested to create a recess in the top plate of the stationary cart or remove the whole top part. The latter option sacrifices the possibility of placing an additional device on top of the stationary cart. The long vertical frame part attached to the back of the stationary cart allows for placement of multiple devices required in stationary conditions (e.g., gas blender, flow meter, etc.), but requires additional attachment to the cart´s frame for more stability. The ambulatory cart successfully detaches from the stationary cart by lowering the lift mechanism using the foot pedal. However, it is recommended to increase the diameter of the foot pedal axes for longer-term use. The attachment of the ambulatory cart to the stationary cart is performed successfully, although the alignment between the two could be improved to enhance the docking experience. The lift mechanism lifts the stationary cart just enough to minimize the contact of the stationary cartwheels with the ground. A slight enlargement of several lift mechanism components would provide more lifting height, eliminating the likelihood of accidental wheel contact with the ground in the event of uneven ground.

The movement of the stationary and ambulatory cart together works as intended, allowing for easy transport of both carts including all devices. To demonstrate the concept of (de-)coupling of connectors between the stationary and ambulatory hub, non-functional 3D printed connectors were used. Although the positioning of both hub parts is successfully demonstrated, the hub system requires redesign and

optimization to enable simultaneous mechanical locking and unlocking of electricity, gas, and water connectors.

Simulation tests show that the ambulatory cart moves smoothly on flat hospital floors, with little force required to initiate movement. The cart's maneuverability is enhanced by its ability to move sideways, allowing for easy positioning in all intended directions. Applying the wheel brakes is simple and necessary to prevent the cart from moving when the patient uses the pushing handle to stand up. The current height of the pushing handle is suitable for taller patients but should be adjustable to accommodate smaller patients.

During testing, it is confirmed that the cart remains stable and does not tilt when the patient applies full body weight to the pushing handle. Furthermore, patients can easily move the cart themselves, despite its weight, resulting in a solid and safe walking experience. While steering the cart is straightforward, it is observed that very weak patients may require additional steering assistance from the caregiver. A side handle is included to facilitate such assistance. Additionally, implementing a (de)braking system to prevent unintended movement of the cart is recommended, although this feature is not implemented in this first prototype. Clamps can be used to provide a neat solution for blood tubing management on the ambulatory cart. The same clamps used in the blood tubing connector could be used. During testing, the height of the ECMO device plate was raised which allows for better visibility of the device's display during ambulation and easier placement and removal of the ECMO device from the cart. Utilizing adjustable locking pins to secure the ECMO device in a predefined position is found to be beneficial rather than using bars in a cage-like configuration. The locking pins would allow for better accessibility of the ECMO device and a lower risk of tube kinking when placing the machine on the cart while still providing safe positioning. Additionally, 90° elbow quick-coupling connectors should be used to attach the water tubing to the oxygenator rather than straight connectors in order to avoid kinking of the water tubing. Repositioning the accessory holder on the back of the cart would allow for easy removal of the oxygenator from the ECMO device in case of device failure. The oxygenator can then be taken out and being attached to the manual pump drive which can be attached to the ambulatory cart frame. Increasing the height of the ECMO device plate creates extra space for an additional support plate for accessories or a storage drawer. An easily removable accessory plate on top of the ambulatory cart has been designed to allow transport of additional devices or supplies (e.g., mechanical ventilator, syringes), but is not included in this first prototype.

The walking frame unlocks and extends as intended. However, the sliding mechanism of the walking frame could be optimized to improve ease of use and prevent faltering movements. It is challenging to align the left and right parts of the walking frame precisely, but incorporating multiple locking stops for both parts of the walking frame could potentially solve this issue. Color-coded labels on the walking frame could be matched to the patient’s corresponding body profile. Preliminary tests suggest that the walking frame prevents the patient from falling far to the back, sides, and front in worst-case scenarios. This reduces the risk of tension on the oxygenator connectors and improves patient safety. The seat and backrest are solid and sturdy, ensuring safe patient transport. The rotation of the seat is quick and easy, allowing patients to sit down immediately. The patient can be easily moved back to the ICU including all equipment by one caregiver. The seat height is suitable for patients of different heights, as it allows them to sit down without a deep squat. However, the position of the patient's footrest was a bit too high, which could be easily solved by lowering it. The backrest slides open as intended, but it does not run smoothly through the backrest holders due to friction between the plywood and aluminum parts. The positioning of the backrest changes when moved out of the holder, making it difficult to align for sliding back in. Guidance rollers could be used to improve alignment. The sliding of the seat is smoother, likely due to the use of materials with lower friction between the SLS printed material and plywood. The depth

of the seat could be shortened by about 12 cm without compromising safety but increasing comfort. Although the seat is comfortable, a fabric-type seat would be preferred instead of the hard materials used in the prototype. Similarly, the backrest surface could be made smaller while still providing a comfortable and supportive backrest.

A functional prototype of the gas splitter was not produced. The risk analysis indicated that a solenoid-based solution may be prone to errors, and therefore a mechanically actuated switch is recommended.

6 Summary and Outlook

In conclusion, the preliminary tests conducted in a simulated ICU environment have yielded promising results for the suitability of the ECMO mobilizing device in a clinical care setting. However, it is important to note that a full verification and validation process, including realistic testing with patients in a clinical environment, is still required to fully determine the device's capabilities. Additionally, the system must be classified into a specific device category to ensure compliance with relevant ISO standards and regulatory requirements. While further testing and optimization will be necessary to achieve our safety, support, and accessibility goals that are essential for successful clinical use, the design and development of the ECMO mobilizing device represents an important step forward in ambulatory ECMO improvement.

7 Terms and Abbreviations

7.1 Terms

Extracorporeal membrane oxygenation

Supports the heart and/or lungs with a blood pump and an artificial lung

Ambulatory (ECMO)

Under walking conditions, not stationary

Stationary (ECMO)

Not moving conditions, patient is in bed

Veno-venous

A connection from one vene to another vene

Mobility time

The duration the device can function without additional resources such as electricity and oxygen

Gas blender

A medical device to mix medical grade air with oxygen to a certain oxygen concentration

Flow meter

A device used to measure the real-time material flow of fluid or gas to give either volumetric or mass flow readings

Emergency drive

A manual pump drive to take over the pump function of the ECMO machine in case of failure of the automatic pump

Emergency kit

A kit containing ECMO related supplies allowing an immediate response to the most likely adverse events

Power hub

A power source designed to isolate the patient and the operator from an electric shock and to protect the equipment from power surges or faulty components

Blood tubing

Hollow tubes transporting blood

Wall oxygen

Oxygen that can be withdrawn from a wall outlet in the hospital

Cannula insertion place

The location at which a cannula is inserted in the body of the patient

Heater-cooler unit

Medical device to cool or warm the blood

Reusable

Can be used by multiple users one after the other

7.2 Abbreviations

- ECMO: Extracorporeal Membrane Oxygenation
- VV: Veno-Venous
- ICU: Intensive Care Unit
- URS: User Requirement Specification
- DRS: Design Requirement Specification

8 List of Figures

9 List of Tables

10 References

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11 Annex

11.1 Annex A – User Requirement Specification

See document attached

11.2 Annex B – Design Requirement Specification

See document attached

11.3 Annex C – Risk Analysis

See document attached

11.4 Annex D – Morphological Scheme

See document attached

11.5 Annex E – Pre-concept

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