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ECMOve – A device to support patient mobilization on ECMO

Optimization, verification, and testing by stakeholders

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Declaration

I hereby declare that I have written this thesis independently. Only the sources and aids expressly named in the thesis have been used. I have marked as such any ideas taken over verbatim or in spirit.

Signature:

Place; Date: Dedemsvaart, 20-11-2024

Preface or Acknowledgement

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Problem Definition

Extracorporeal Membrane Oxygenation (ECMO) is a therapy for patients with severe respiratory or cardiac failure. ECMO acts as an artificial lung or heart-lung support system. The ECMO device drains blood from the body, facilitates gas exchange via an oxygenator, and returns the oxygenated blood to the patient. ECMO is often used as a bridge to transplant or recovery.

Active ECMO protocols enable patients to remain awake and engaged during treatment, which has been associated with improved outcomes such as reduced ICU stay [1-4]. Ambulatory ECMO allows critically ill patients to walk while being on ECMO to improve physical condition of the patient and prevent neuromuscular weakness. However, implementation of ambulatory ECMO is complex and requires a multidisciplinary team for patient assistance and equipment management. Additionally, there is no solution for stabilizing the cannula during mobilization.

Van Galen et al. [5] developed an ambulatory ECMO device for Veno-Venous (V-V) ECMO patients, the ECMOve version 1 (ECMOve V1). This walking support system is designed to facilitate safe ambulation while accommodating all necessary V-V ECMO equipment. ECMOve prevents stress and strain on the cannula and is engineered in a way that only two caregivers are required for its operation.

ECMOve V1's design represents a significant step towards safe ambulatory ECMO. However, while currently at Technology Readiness Level (TRL) 3 as a proof of concept, ECMOve requires further refinement to progress to TRL 4. Reaching TRL 4 is essential to ensure the device's safety, functionality, and usability in a clinical environment. To reach TRL 4, ECMOve V1 needs to be optimized, verified according to design requirements (DRS), and tested by clinical stakeholders to ensure the device meets all specified user requirements (URS) [5]. Achieving TRL 4 will prepare ECMOve V2 for TRL 5, where the device will undergo real-world clinical trials to validate performance with experts in the (ambulatory) V-V ECMO field.

Abstract

Ambulatory Extracorporeal Membrane Oxygenation (ECMO) allows critically ill patients to mobilize, aiding recovery and preventing neuromuscular weakness. However, its implementation is complex and requires a multidisciplinary team for equipment management and patient assistance. Additionally, there is no solution for stabilizing the cannula during mobilization. Van Galen et al. [5] developed an innovative device for ambulatory Veno-Venous (V-V) ECMO patients, the ECMOve version 1 (ECMOve V1). This walking support system is designed to facilitate safe ambulation while accommodating all necessary V-V ECMO equipment for both stationary and ambulatory use. ECMOve prevents stress and strain on the cannula and is engineered in a way that only two caregivers are required for its operation. Building on the basic functionalities demonstrated by ECMOve V1 (proof of concept), this work aimed to optimize several core components of ECMOve V1 to meet key user-and design requirements. This work focused on optimizing the extendable walking frame, seat, and backrest. Additionally, the incorporation of an adjustable intravenous (IV) stand, an adjustable pushing handle, a gas tank holder, and safety brakes were implemented. Verification procedures, carried out in alignment with relevant ISO standards and design requirements, alongside testing by stakeholders at Medisch Spectrum Twente (MST), have advanced ECMOve V2 from TRL 3 to TRL 4. Verification of ECMOve V2 confirmed that the device meets most ISO standards for strength and stability, along with design requirements including ergonomics, ease of cleaning, and manoeuverability. Stakeholder tests at MST highlighted the importance of tailored ISO standards for V-V ECMO patients, addition of mechanical ventilation and vital monitoring, and suggested the development of multiple ECMOve versions aligned with particular needs of various clinics. To conclude, ECMOve V2 is advancing towards achieving Technology Readiness Level (TRL) 5, with ongoing development aimed at preparing the device for clinical testing in specialized (ambulatory) V-V ECMO environments.

Keywords: Ambulatory ECMO; Veno-Venous (V-V); ECMOve V1; Device optimization; Design requirements (DRS); User requirements (URS); Verification; ISO standards; Testing by stakeholders; ECMOve V2; Technology Readiness Level (TRL)

Content

1 Introduction

Extracorporeal membrane oxygenation (ECMO) is an established therapy for critically ill patients with acute respiratory distress syndrome (ARDS) or cardiogenic shock [6]. The use of ECMO grows globally and shows signs of reduced mortality rates compared to conventional mechanical ventilation strategies[7]. There are two types of ECMO: Veno-arterial (V-A) for heart or heart-lung failure, and veno-venous (V-V) for lung failure.

Intensive care unit acquired weakness (ICUAW) can occur in critically ill sedated patient several days after intensive care unit (ICU) admission, potentially leading to prolonged hospitalization [8]. Subsequently, a shift has taken place from keeping ECMO patients under deep sedation in the ICU towards awake treatment including active rehabilitation strategies [9]. Spontaneous breathing and early mobilization of the patient could reduce mortality rates and recovery time by mitigating deconditioning of the patient [1-4].

Recent studies show that early mobilization of ECMO patients is feasible [10, 11]. However, ambulatory ECMO requires an experienced multidisciplinary team to effectively manage the significant risks involved for the patient. Risks include decannulation, patient fatigue, and hemodynamic instability amongst others [12]. Careful patient selection and proper planning and execution is necessary when performing ambulatory ECMO [13, 14].

Development of compact ambulatory ECMO devices is essential for unhindered active rehabilitation [15]. Recent advancements in portable ambulatory ECMO systems show promising results towards safe mobilization of the patient, however these devices do not include safety measurements for decannulation, support for the patient in case of fatigue, and do not carry all necessary V-V ECMO equipment in a single device [16, 17]. To address these shortcomings, Van Galen et al. developed a new cart-in-cart system, the ECMOve version 1 (ECMOve V1) [5].

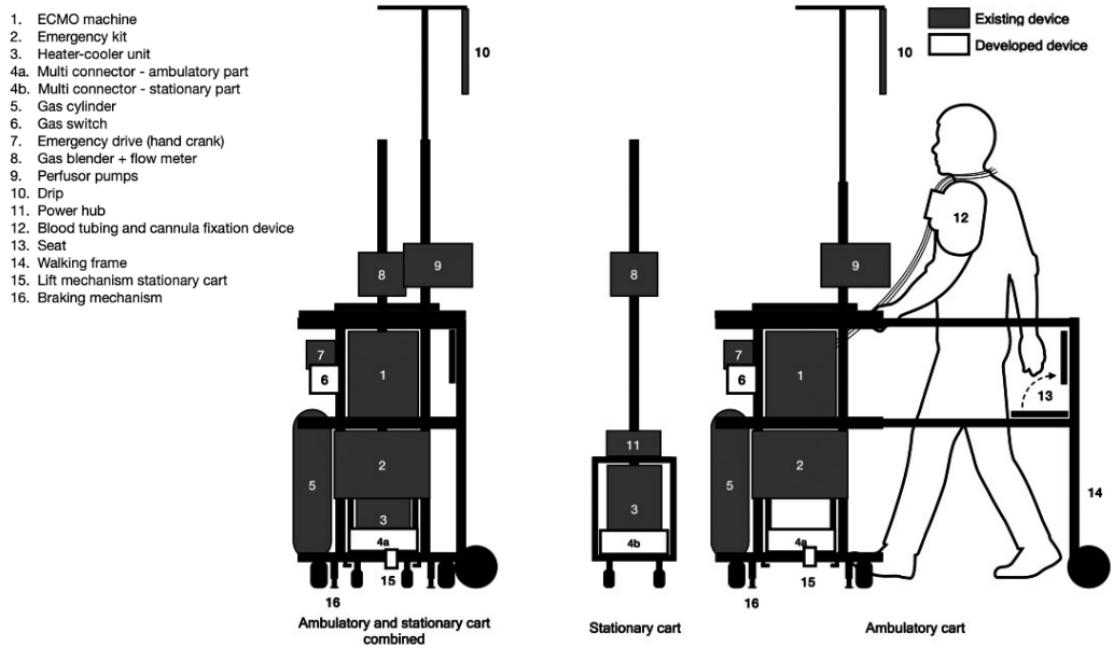

Figure 1: ECMOve V1 design described by Van Galen et al. [5].

Figure 1 illustrates ECMOve V1 initial design. ECMOve provides a folding seat in case of patient fatigue, a shoulder brace for tube fixation- and stress relief for the cannula, and carries all necessary V-V ECMO equipment for both stationary and ambulatory use. The stationary cart transports devices needed solely for stationary use and connects gases, fluids, and electricity to the devices on the ambulatory cart during stationary ECMO. Van Galen et al. systematically organized ECMOve V1 into six distinct modules, each designed to address specific user requirements (URS) to ensure complete and clear system design [5].

The primary objective of this thesis is to advance ECMOve V1 from technology readiness level (TRL) 3 to TRL 4, bringing the device closer to clinical testing and real-world applications. Van Galen et al. verified ECMOve V1 proof of concept in a simulated ICU environment to evaluate design functionality and performance, without the involvement of medical professionals or real patients. The simulation results concluded, while the device meets most design requirements (DRS), that design optimization is required to solve identified shortcomings and achieve adequate support, safety and accessibility of the device before proceeding with clinical testing [5]. The optimized prototype, ECMOve V2, requires full verification and testing by medical professional stakeholders to ensure the device also meets URS, serving as the final step in achieving TRL 4.

This work focuses solely on optimizing and achieving TRL 4 of the ambulatory cart. The stationary cart is optimized in a separate study. The combined outcomes of these studies position ECMOve for TRL 5. Once all requirements are met, the device will be ready for clinical trials, marking a significant step toward real-world deployment.

2 Materials and methods

The complex and dynamic nature of the ICU, challenges healthcare professionals to maintain patient safety during ambulatory ECMO procedures [18]. Therefore, optimizing ECMOve V1 is essential in unhindered, safe, and easy ambulatory ECMO.

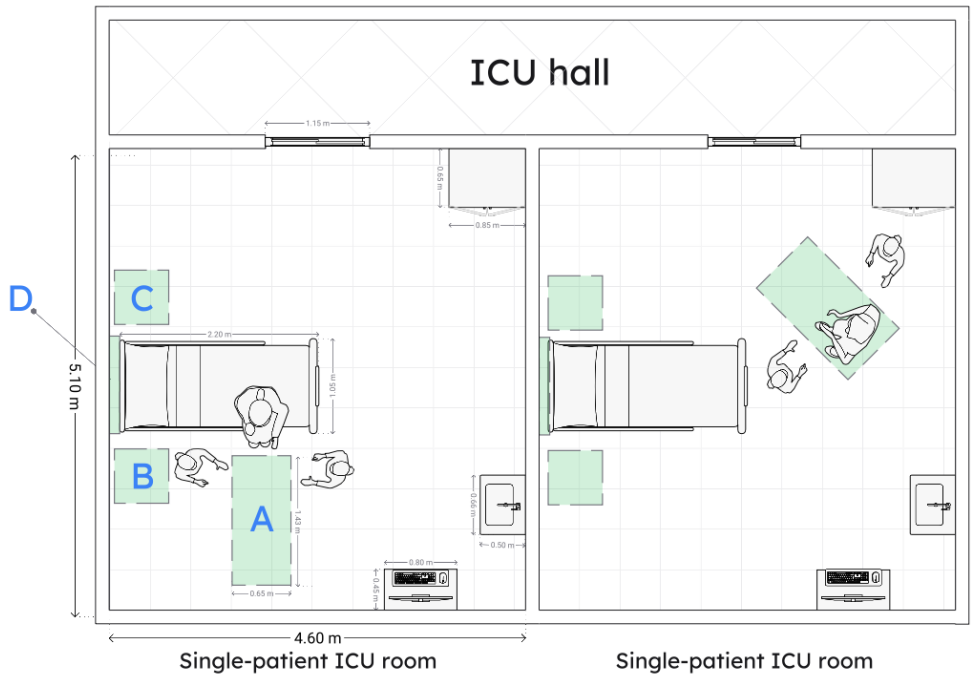

Figure 2: Schematic overview integration ECMOve (**A**) in single-patient ICU. The minimum room and door dimensions are based on Facility Guidelines Institute (FGI) standards [19] and Thompson et al. [21]. The bed dimensions are derived from market research. The dimensions of IV stand (**B**), tower monitor (**C**), and wall gas/electricity (**D**) are estimated.

Figure 2 illustrates how ECMOve V1 effectively integrates into the dimensions of single-patient ICUs, as outlined by facility guidelines institute (FGI) [19] and Thompson et al. [20]. To ensure that caregivers can comfortably support the patient during stationary and ambulatory ECMO, ECMOve V2 design should maintain a maximum width of 650 mm ± 50 mm and maximum length of 1450 ± 50 mm. Exceeding these dimensions could hinder caregivers' ability to assist the patient, particularly when positioned next to the patient's bed. Given the limited space in single-patient ICU rooms, all devices and components must remain securely attached to both the stationary and ambulatory ECMOve carts at all times. The only exception occurs when the two ECMOve carts are disconnected during patient mobilization.

In addition to space-efficient design, ECMOve's design shall solely rely on mechanically activated solutions, similar to ECMOve V1 [5]. This excludes ECMO related components such as the ECMO device. This design approach ensures that ECMOve remains classified as a Class 1 device under Rule 9 of Annex VIII of the medical device regulation (MDR) [21].

These design constraints represent general guidelines for ECMOve optimization, ensuring it complies with space limitations and regulatory requirements while maintaining functionality during both stationary and ambulatory ECMO.

2.1 Optimization ECMOve V1 – General overview

Development of ECMOve V2 was performed according to the V-model [22] and Van den Kroonenberg's methodical design method [23]. This hybrid framework allows for iterative design and concept generation. Morphological schemes and scoring systems, guided by the constantly updating DRS and risk analysis (RIA), were used to evaluate the most effective concepts to solve shortcomings of ECMOve V1. The highest scoring concept was further developed. 2D sketches of the final concepts were converted to 3D models using SolidWorks Computer-Aided-Design (CAD) software (Dassault Systèmes SolidWorks Corporation, Waltham, Massachusetts, USA). MATLAB (MathWorks, Natick, Massachusetts, USA) calculation models were developed to ensure device strength and failure-free design. Calculations and MATLAB models can be found in Annex B – Calculations. Design requirement specification and risk analysis can be found in Annex C – Design Requirement Specification and Annex D – Risk Analysis respectively.

Van Galen et al. described the DINED anthropometric database of TU Delft [24] to gather anthropometric measurements. These measurements are relevant to ensure ergonomic ECMOve V2 design and device suitability for a wide range of patients. In this study, the 90% confidence level was used (P5 – P95 percentile of the population). The used dataset was Dutch adults, dined 2004 (aged 31 – 60) and Dutch adults, dined 2004 (aged 20 – 30). A limitation of Van Galen et al.'s study is that it mainly focused on standing anthropometric measurements, whereas the scope of this research also included sitting measurements and strength measurements including pushing and pulling forces. Refer to Table 1 for measurements used.

Table 1: Anthropometric measurements DINED dataset [25].

Measure	Dimensions					
	Men			Women		
	P5	P50	P95	P5	P50	P95
Stature height (mm)	1645	1770	1895	1563	1652	1746
Eye height (mm)	1534	1659	1784	1465	1551	1641
Chest depth (mm)	236	300	364	245	310	379
Shoulder width (bi-deltoid) (mm)	422	461	500	380	424	470
Chest circumference (mm)	876	1044	1212	828	1013	1209
Waist circumference (mm)	771	949	1127	661	863	1077
Elbow height, standing (mm)	947	1018	1089	1005	1099	1193
Hip width (mm)	288	328	368	292	339	388
Buttock – Popliteal depth (mm)	459	503	547	457	499	543
Popliteal height, sitting (mm)	428	481	534	394	434	477
Abdominal depth (mm)	241	299	357	234	293	356
Hip width, sitting (mm)	354	397	440	366	414	465
Head circumference (mm)	548	576	604	528	551	576
Neck circumference (mm)	436	497	558	393	447	505
Width over the elbows (mm)	472	472	543	502	502	565
Body mass (kg)	62	82	102	53	70	88
Pushing force with 2 hands (N)*	306	508	710	185	333	481
Maximum gripping force (N)*	403	543	683	248	343	438
Pulling force 1 hand (N)*	229	349	469	148	240	332

* Dutch adults, dined 2004 (aged 20 – 30), data for people aged 31 – 60 was unavailable.

The anthropometric data from this dataset were converted into 3D CAD models using the DINED mannequin tool. This process ensured accurate representation of human body proportions and variations. The 3D models were equipped with a skeletal structure and posed in both sitting and standing configurations using Blender software (Blender Foundation, Amsterdam, Netherlands). The generated 3D personas serve as a valuable tool for illustrating user interaction with the ECMOve device. Figure 3

showcases samples of each persona. A guide in using Dined/Blender can be found in Annex A – Dined and blender guide.

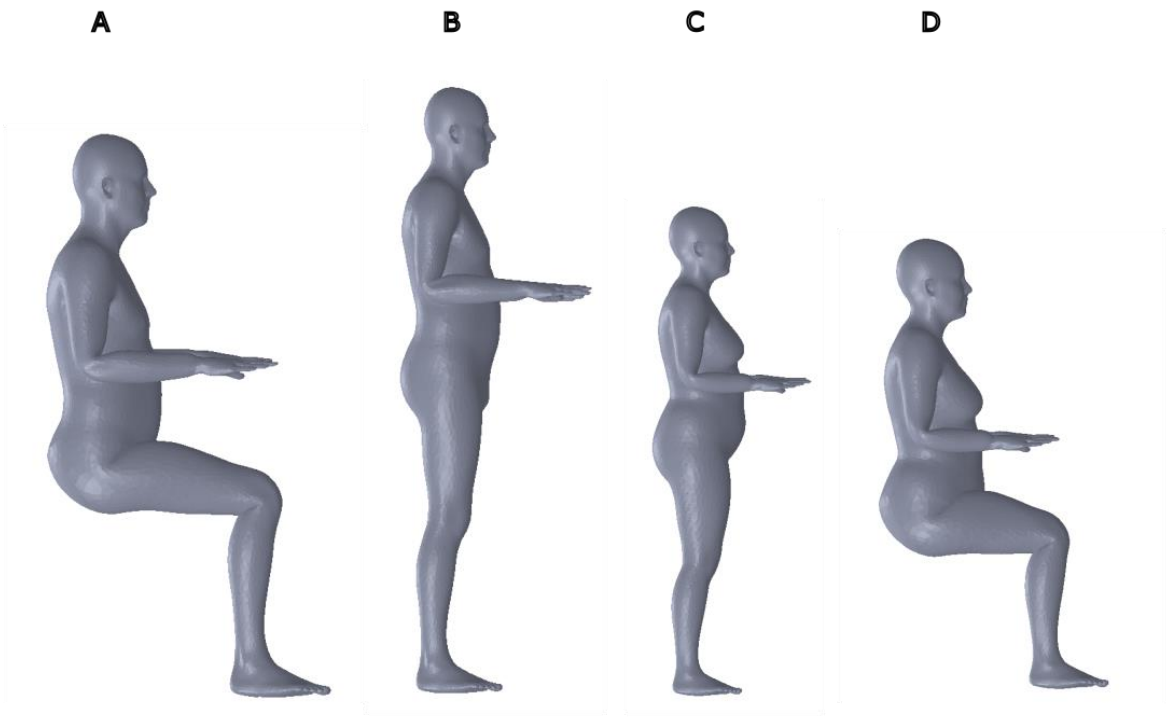

Figure 3: 3D models generated with DINED and Blender. Large man sitting (**A**), large man standing (**B**), small woman standing (**C**), small woman sitting (**D**).

The new ECMOve V2 prototype integrates custom-made and pre-fabricated components, replacing parts from the disassembled ECMOve V1 prototype. Custom-made parts consisted primarily of 3D-printed Selective Laser Sintered (SLS) polyamide (PA) parts and laser-cut stainless steel sheet metal with a thickness of 3 mm. The only post-processing required for the custom-made parts was threading/tapping. Several pre-fabricated components underwent post-processing using machining techniques such as milling, turning, drilling, metal sawing, grinding, reaming, and tapping.

Only the final results are shown in this report. Other pre-concepts, including morphologic schemes, scoring systems, and rationales behind concept selection can be found in Annex E – Pre-concepts.

2.1.1 Optimization ECMOve V1 – Patient physical support module

The patient physical support module facilitates safe and unimpeded ambulatory ECMO by surrounding the patient with an extendable walking frame, shown in Figure 4. The walking frame is shortened during stationary ECMO conditions. The module includes a foldable seat and backrest for immediate support if the patient experiences fatigue or sudden hemodynamic instability.

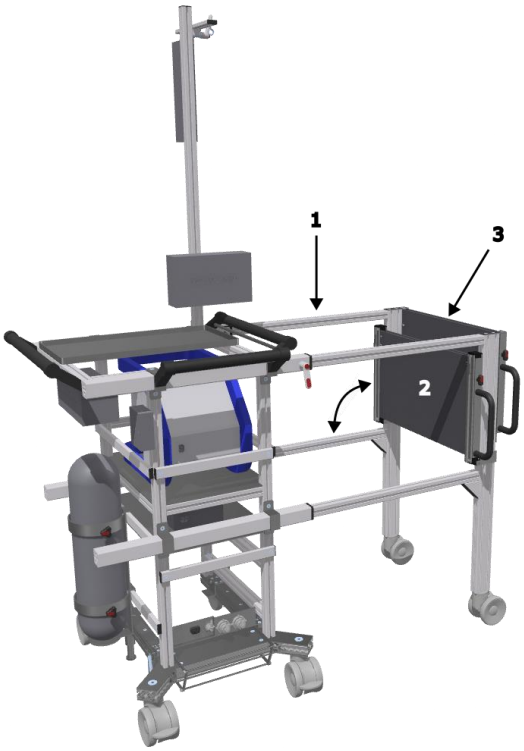

Figure 4: Patient physical support module ECMOve V1, comprising an extendable walking frame (1) seat (2) and backrest (3).

Van Galen et al. defined three key user requirements for this module [5]. ECMOve V1 satisfied the first two requirements: Ensuring patient safety and providing effective walking support. However, the module does not yet fulfil the third requirement, which is to enable a single caregiver to independently operate the patient support module throughout all phases of the ambulatory ECMO process. This process includes stationary ECMO, transition phase from stationary to ambulatory ECMO, ambulatory ECMO, and transition phase from ambulatory ECMO to stationary ECMO.

The goal was to optimize the three components shown in Figure 4 to fully meet all URS. The results section addresses the resolved shortcomings of these components and highlights updated DRS used to develop final concepts.

2.1.2 Optimization ECMOve V1 – Ambulatory device transport module

The ambulatory device transport module facilitates transport of all devices required for both stationary and ambulatory V-V ECMO, shown in Figure 5.

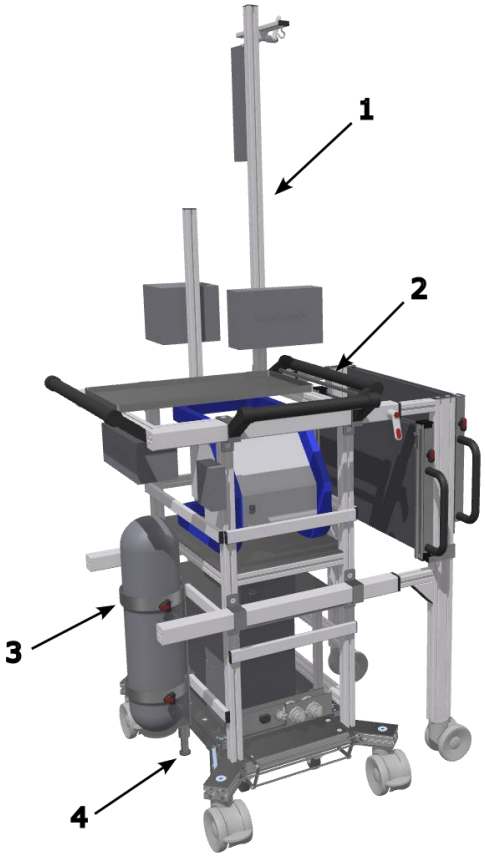

Figure 5: Ambulatory cart module ECMOve V1, comprising an intravenous (IV) stand (1), patient's pushing handle (2), gas tank holders (3), and safety brakes (4).

Van Galen et al. defined six key user requirements for this module [5]. ECMOve V1 satisfied the first requirement: Carrying all necessary equipment for both stationary and ambulatory ECMO. However, ECMOve V1 did not fully meet requirements 2 to 4, which specified that the system should be patient controlled during ambulatory ECMO, caregiver controlled in both configurations, and capable of moving only when initiated by the user. The components that require optimization to fully address these user requirements include the intravenous (IV) stand (which holds the perfusor pumps and dripper bag), the patient's pushing handle, the gas tank holders (which holds the medical grade oxygen cylinder), and the safety brake mechanism. ECMOve V1 satisfied the fifth and sixth user requirement: (de)coupling of the stationary cart during both ECMO configurations (i.e. stationary and ambulatory ECMO).

The results section addresses the resolved shortcomings of these components and highlights updated DRS used to develop final concepts.

2.2 Verification – General overview

Verification of ECMOve V2 is relevant to ensure the device meets DRS. The DRS consist of relevant parameters and tests given in ISO standards, RIA assessment according to failure mode effect analysis (FMEA), and other relevant design requirements that were gathered from both literature and ECMOve simulation testing in an ICU environment by Van Galen et al. [5]. Verifying DRS is vital to assure the device functions safely and effectively, mitigating risks during testing by stakeholders.

The complete verification document is found in Annex F.

2.2.1 Verification – DRS according to ISO standards

The ECMOve does not fit into any specific existing device category, therefore the closest relevant ISO standards have been selected.

Strength and stability of the ECMOve were assessed using ISO 11199-2 for assistive products manipulated by both arms and ISO 19894 for walking trolleys. Stability tests (forward, rearward, sideways) were performed with the ECMOve on a 16° inclined plane, while strength tests involved applying ISO standard defined weights to the seat, backrest, and pushing handles. ISO 3411 for minimum operator space envelope and ISO 11228-2 for manual handling of pushing and pulling tasks were used as a supplement to DINED to develop ergonomic designs. ISO 10993-22 for guidance on nanomaterials and ISO 17664-1 for processing of health care products were used to guide cleanability evaluation of ECMOve. ISO 286-1 and ISO 286-2 were used to define shaft and hole tolerances for the extendable walking frame.

2.2.2 Verification – DRS according to RIA, literature, and tests

Design requirements from RIA, literature, and simulation testing in an ICU environment were verified with experiments, visual feedback, measurements, and literature review. Verified DRS mentioned in this thesis are cleanability and manoeuverability.

ECMOve cleanability was evaluated with both water and 70% isopropyl alcohol (IPA) disinfectant. The minimum contact time for proper disinfection with 70% IPA is 1-3 minutes [26]. The contact time is relevant for the disinfection to be effective and to ensure thorough microbial inactivation. Granta EduPack (Granta Design, Cambridge, UK) material database and literature review were used to gather material properties related to water and alcohol resistance. Note that cleanability protocols can vary per clinic and may also involve the use of other chemicals, such as hydrogen peroxide or chloride solvents. These were not taken into account. Cleanability is also assessed for the blood tubing fixation module.

The manoeuverability of ECMOve V1 was evaluated using the test setup shown in Figure 6. The base weight of ECMOve was 67 kg (ambulatory cart and ECMO device), with additional weights added to reach 70 kg and 74 kg (increments of 3 kg and 7 kg). The device was pulled over a distance of 5 m using a force gauge. This test was repeated three times for each weight configuration (67 kg, 70 kg, and 74 kg). The tests were recorded at a rate of 16 frames per second, and the forces of every fourth frame were extracted and documented in an Excel spreadsheet. The results were analyzed to assess whether the relationship between weight and the required initial and sustained forces followed a linear trend. Using this linear trend, predictive models using MATLAB were made to estimate initial and sustained forces for the ECMOve V2 prototype.

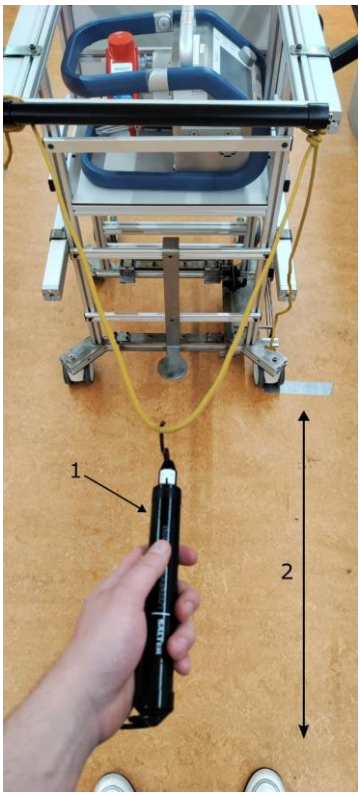

Figure 6: Experimental test setup to determine initial and sustained forces ECMOve V1. Forces are measured with a force gauge (1) over a distance of 5 meters (2).

2.3 Testing by stakeholders – General overview

ECMOve V2 was tested in a clinical environment by hospital staff at 'Medisch Spectrum Twente' (MST). An ethical review was submitted to the University of Twente, as the testing process involved filming with human participants. The test was performed with a simulated patient – a woman with a height of 1.70 m – and clinical stakeholders, including physiotherapists, physician assistants, and cardiologists. The test covered and evaluated the entire ambulatory ECMO procedure as described in Chapter 3.1.8. Clinical stakeholders gave opinion-based feedback through discussion and a survey. The stakeholders were not informed beforehand about the ambulatory procedure.

The complete testing document including (filled in) surveys are found in Annex G.

3 Results

The following results show the outcome of the optimization of the patient support module and ambulatory cart module, verified DRS, and ECMOve V2 evaluation with medical professional stakeholders.

3.1 Optimization ECMOve V1

This chapter outlines the results from the optimization of both patient physical support module and ambulatory device transport module. For each component the chapters are outlined as follows: Shortcomings of ECMOve V1 with technical background, updated DRS, and the final solution with calculations where necessary.

3.1.1 Patient physical support module – Extendable walking frame

The extendable walking frame V1 consists of extrusion profiles that slide telescopically within an aluminum housing, shown in Figure 7. A polyoxymethylene (POM) bearing provides the contact interface between housing and extrusion profile. Erratic motion and alignment issues make telescopic adjustments slow and unpredictable, adding to the caregiver's workload and potentially compromising patient safety. As a result, the current design does not meet the user requirement of enabling one caregiver to assist the patient through the entire ambulatory ECMO procedure.

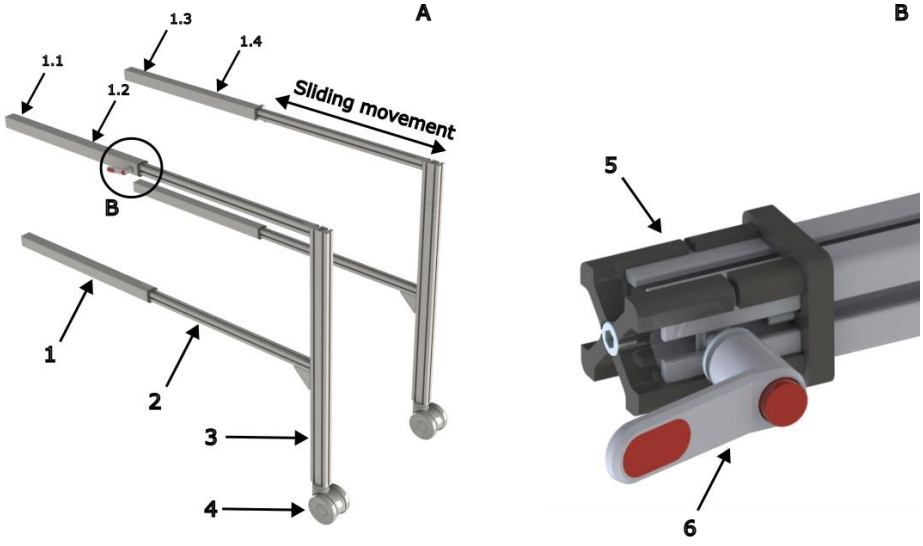

Figure 7: Extendable walking frame V1 (**A** and **B**) comprising aluminum housings (1), aluminium extrusion profiles (2–3), swiveling wheels (4), POM bearings (5), and locking handles (6).

3.1.1.1 Extendable walking frame V1 – Shortcomings

- **Telescopic assembly**: The injection moulding process of POM dry bearing incorporates a draft angle for easy mould ejection. This results in a slight taper, creating a press-fit with the housing. The housing, made of EN AW-6060-T66 aluminium without anodization, possesses a low Brinell Hardness (HB) of 75 kgf/mm², making it prone to wear. Initially, the press-fit and the surface roughness of the aluminium housing contribute to high friction and resistance during linear motion. Over time, wear on both the soft aluminium housing and the bearing increases the tolerance between them. This increased tolerance results in undesirable stick-slip-and erratic motion.
- **Locking mechanism:** The extendable walking frame is locked by turning the clamp lever clockwise, engaging a t-slot nut. However, when unlocked, partial contact of the locking mechanism with the aluminum extrusion profile causes additional frictional forces. This leads to increased resistance during sliding movement.
- **Alignment:** Misalignment in the assembly process causes the extendable walking frame to be 1.37 mm higher (height difference between 1.2 and 1.1) and 0.56 mm lower (height difference between 1.4 and 1.3), see Figure 7. This unevenness causes increased resistance during sliding movement. Furthermore, alignment is challenging because the walking frame's left and right side are not connected.
- **Cleanability:** The aluminum housings are not cleanable during clinical practice, creating a breeding ground for bacteria that could lead to patient infections over time.

3.1.1.2 Extendable walking frame V2 – Design requirements

A complete overview of design requirements is given in Annex C.

- The extendable walking frame shall be able to carry the load of the patient, with a maximum defined body weight of 102 kg (DINED tool P95-male, body mass). A safety factor of 2.13 [27] is applied due to the possibility of impact loading when hard sitting down. Subsequently, the walking frame should be able to withstand a maximum weight of 217.6 kg.
- The extendable walking frame misalignment should not exceed 0.0833° (SKF AB, Gothenburg, Sweden) during assembly in all directions.
- The extendable walking frame misalignment should not exceed 0.0833° (SKF AB, Gothenburg, Sweden) during seated patient transport to ensure unhindered frame length adjustments.
- The extendable walking frame shall be adjustable to a fixed position with a center-to-center swiveling wheel distance of 227.49 mm, preventing any movability errors due to collision of wheels.
- The extendable walking frame shall have a clearance fit, with a tolerance between bearing and housing of 0.001 mm – 0.169 mm, which is a H9/d9 fit [28] (ISO 286-1, ISO 286-2).
- The extendable walking frame’s left-and right side should be connected to ensure easy alignment.
- The telescoping profile shall not contain any integrated or internal locking mechanisms.
- The extendable walking frame shall ensure a free walking space of 350 mm on all sides [29].
- The extendable walking frame shall ensure a clearance at the front of the legs of the patient of at least 438 mm [29].
- The extendable walking frame shall ensure a minimum width of 500 mm to ensure unhindered entering and exiting ECMOve (DINED tool P95-male, shoulder width (bi-deltoid)).
- The telescopic profile should be a round tube with a diameter between 20 mm and 50 mm (ISO 11199-2) to ensure ergonomic use.
- The extendable walking frame shall ensure a cleanable surface by reducing contact area between shaft and bearing.

3.1.1.3 Extendable walking frame V2 – Final concept

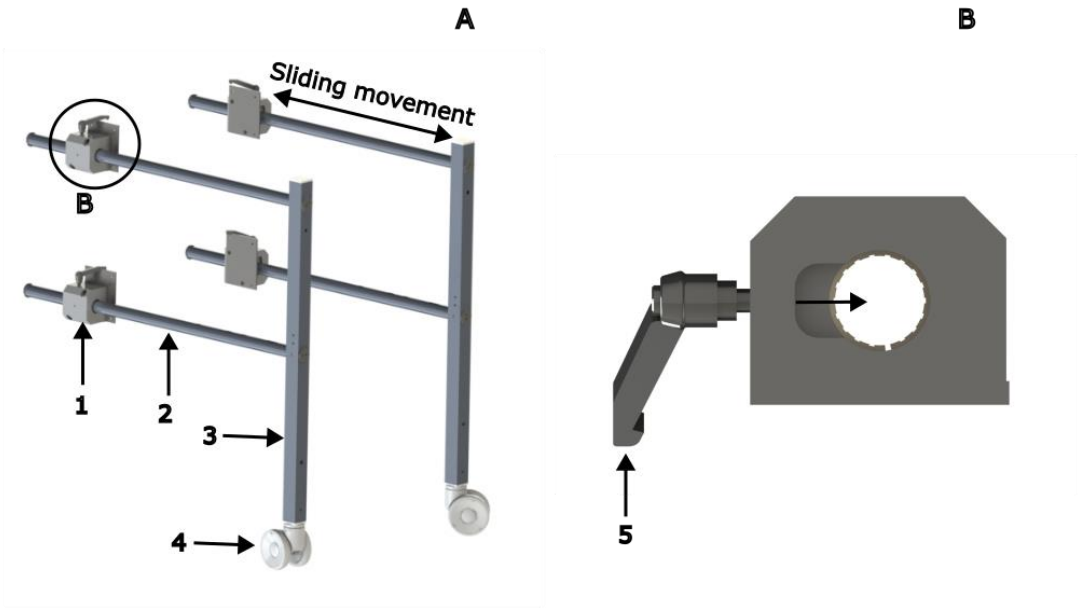

Figure 8: Extendable walking frame V2 (**A** and **B**) comprising dry linear bearings with fixation plates (1), anodized aluminium shafts (2), aluminum square tubes (3), swiveling wheels (4), and locking handles (5).

The final design features a telescopic assembly incorporating a dry linear bearing paired with an anodized aluminium shaft , see Figure 8. The shaft's high HB (428 – 523 kgf/mm²) provides wear resistance, while the bearing's bushing, composed of Iglidur J polymer, offers low-friction (0.06 – 0.18) and self-lubricating properties. The injection moulded bushing is press-fitted into the housing bore to ensure a secure fit. The inner diameter tolerance of the bushing adjusts only after the bushing is pressed, ensuring no interference of draft angle on telescopic motion. The hole/shaft tolerance is +0,040 +0,110 mm/h8 respectively and bearing fixation plates ensures near-perfect alignment in the assembly process.

The extendable walking frame V2 is designed for optimal user mobility and ease of use. The locking handles (un)lock the frame without interfering with telescopic motion, as the locking mechanisms are not integrated within the shaft and bushing. The frame accommodates patients within the DINED anthropometric measurement range, with a free walking space of 759 mm and a width of 536 mm. The shaft has a diameter of 30 mm to ensure ergonomic handling. The limited contact area between the bearing and shaft improves hygiene by reducing spaces where contaminants could accumulate, thereby reducing the risk of patient infections.

The final assembly in both extended and shortened position is shown in Figure 9.

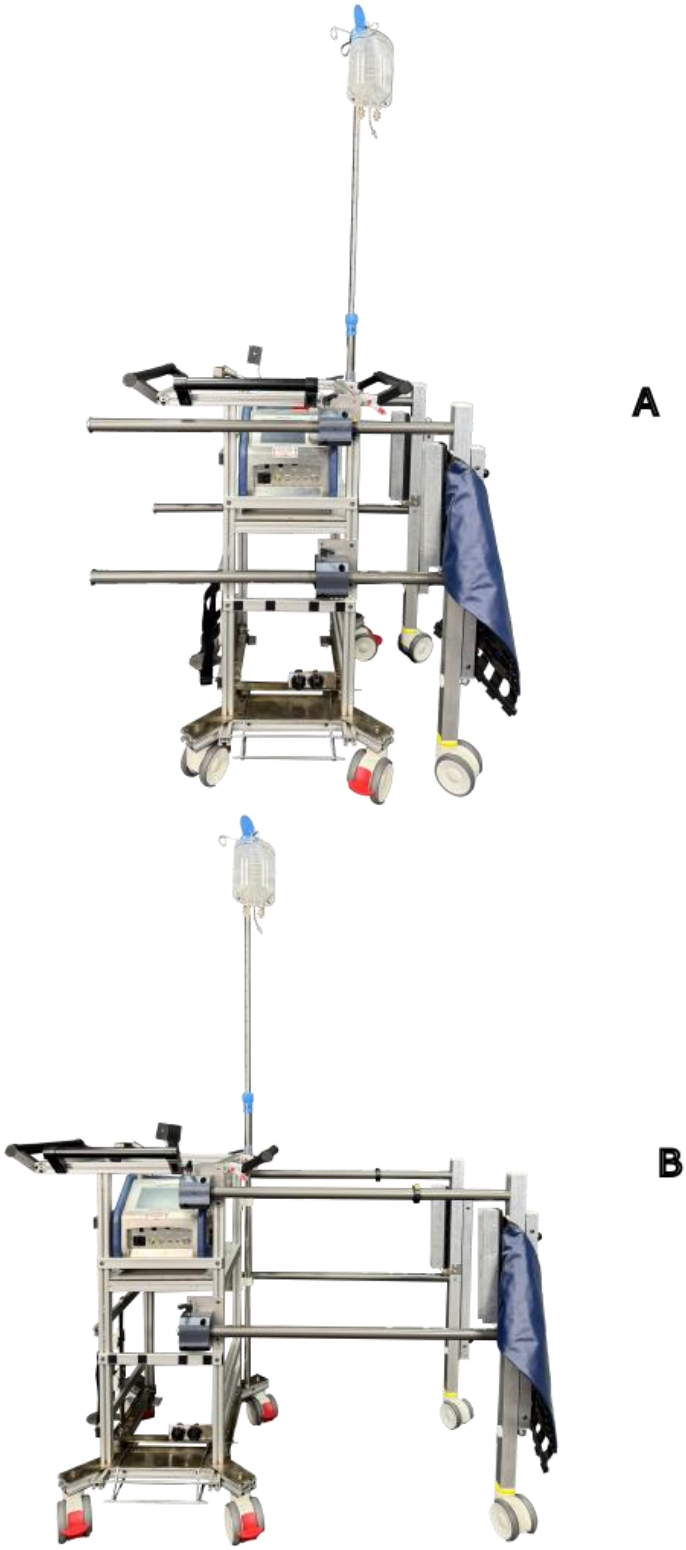

Figure 9: Extendable walking frame in minimum extended position (**A**) and in maximum extended position (**B**).

3.1.2 Patient physical support module – Seat

The seat V1 provides quick, downward hinging to ensure immediate patient support, see Figure 10. The caregiver can shift the seat sideways using the handle for patient entry or exit. However, when shifted sideways, the seat obstructs the caregiver's ability to assist the patient effectively. As a result, the current design does not meet the user requirement of enabling one caregiver to assist the patient through the entire ambulatory ECMO procedure.

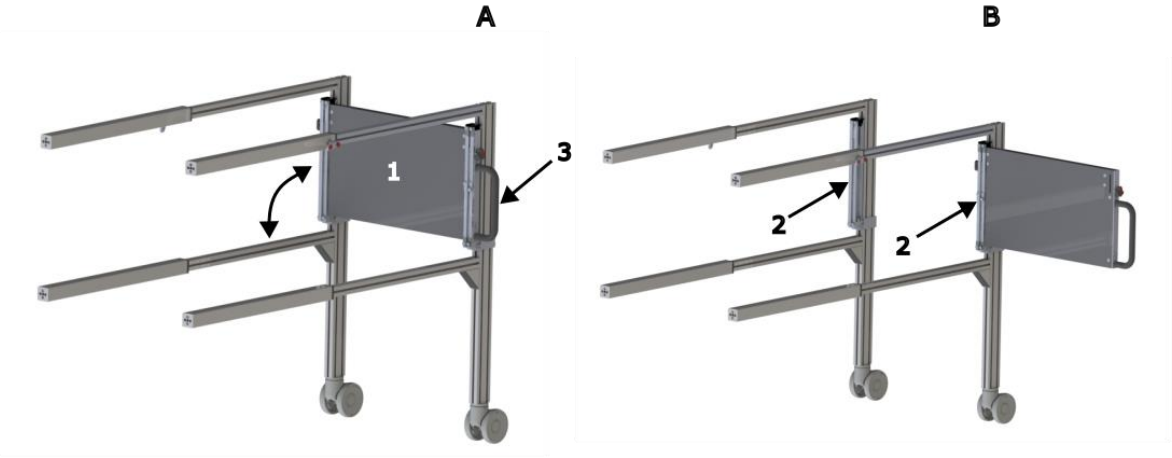

Figure 10: Seat V1 (**A** and **B**) comprising seat (1), seat holders (2), and handle (3).

3.1.2.1 Seat V1 – Shortcomings

- **ICU integration:** The position of the seat when the patient enters or exits the ECMOve does not align with the requirement of ECMOve's maximum width of 650 mm ± 50 mm, see Materials and methods.
- **Ergonomics:** The seat's materials are Trespa and Plywood, a hard surface impacting patient comfort. Furthermore, weight of these materials impact ECMOve manoeuvrability.
- **Alignment:** The seat has a tendency to move at an angle when pushed with the handle, making it difficult to keep it properly aligned within its holders.
- **Functionality:** Vibrations of the seat during ambulatory ECMO causes the seat to hinge downward unintentionally, leading to physical pain of the patient.
- **Cleanability:** The seat holder's design includes hard-to-reach areas and the sliding mechanism traps bacteria between the seat and holder.

3.1.2.2 Seat V2 – Design requirements

A complete overview of design requirements is given in Annex C.

- The seat shall be able to carry the load of the patient, with a maximum defined body weight of 102 kg (DINED tool P95-male, body mass). A safety factor of 2.13 [27] is applied due to the possibility of impact loading when hard sitting down. Subsequently, the walking frame should be able to withstand a maximum weight of 217.6 kg.
- The seat shall ensure a depth between 200 mm (ISO 11199-2) and 457 mm (DINED tool P5-female, Buttock – Popliteal depth) to ensure no discomfort around the popliteal fossa or thighs.
- The seat shall ensure a minimum width of 465 mm (DINED tool P95-female, hip breadth, sitting).

- The seat shall ensure a height between 350 mm (ISO 19894) and 500 mm (ISO 3411) to ensure no discomfort around the popliteal fossa or thighs.
- The seat should incorporate cushioning or flexible materials to ensure comfortable seating for the patient.
- The seat shall be designed without sliding mechanisms.
- The seat shall remain within the ECMOve device frame of 650 mm ± 50 mm.
- The seat shall incorporate a mechanism enabling the caregiver to lower the seat in one motion, providing immediate patient support in urgent situations.
- The seat shall incorporate a mechanism, which holds the seat in vertical position during ambulatory ECMO. The clamping force of this mechanism shall not exceed 148 N to ensure unhindered lowering of the seat (DINED tool P5-female, pulling force 1 hand).

3.1.2.3 Seat V2 – Final concept

The final design features a flexible seat, which can be closed and opened with two magnetic connectors on both walking frame sides, as shown in Figure 11. The seat is made from a flexible polypropylene (PP) webbing, topped with synthetic leather. This synthetic leather is watertight and has an easy to clean smooth surface, making it particularly suitable for cases of patient incontinence. The webbing is designed with a plain weave pattern to enhance strength and prevent the patient from slipping through the seat. The webbing and seat can be detached from each other using four sew-on snap fasterners.

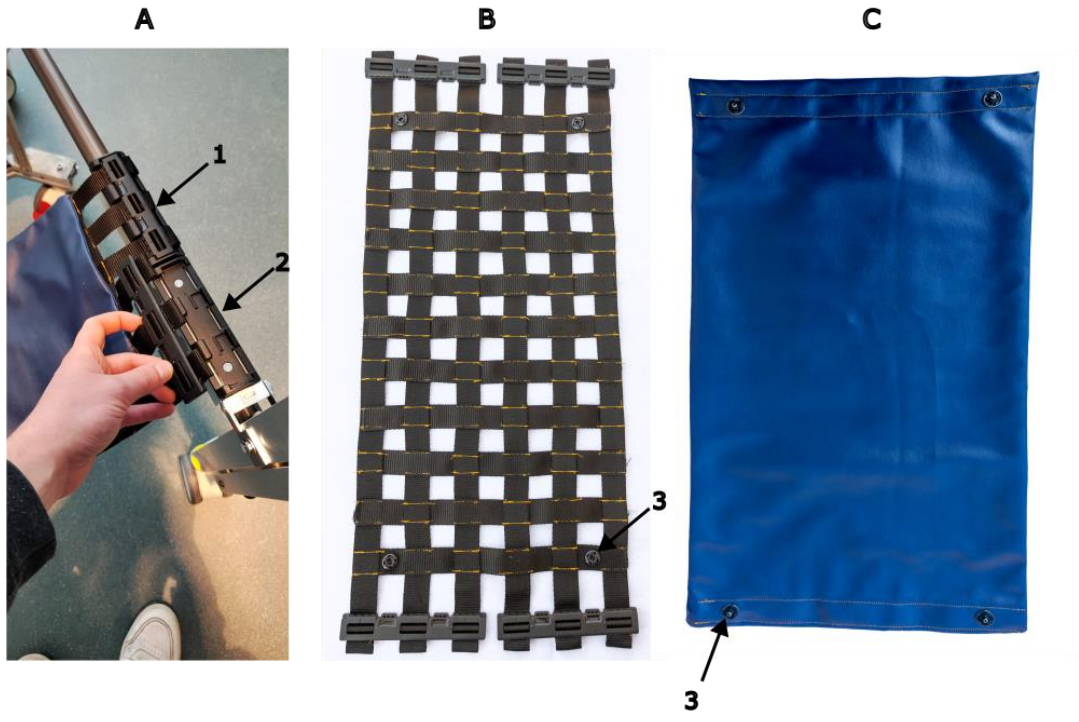

Figure 11: Seat V2 comprising four magnetic connectors (**A**), connected (1) and unconnected (2) position. The seat is a plain weave PP webbing (**B**) topped with synthetic leather (**C**), fastened with sew-on snaps (3).

Seat V2 functionality during the different phases is shown in Figure 12. The magnetic connectors allow for the seat to be positioned on either side of the cart, wherever it is most convenient in the respective situation without causing obstruction for the caregiver (Figure 12, **A**). The seat is magnetically connected during ambulatory ECMO and hold in upright position with magnets with a clamping force of 1.5 kg (Figure 12, **B**). The seat is hinged downwards for immediate support in case of patient fatigue or hemodynamic instability.

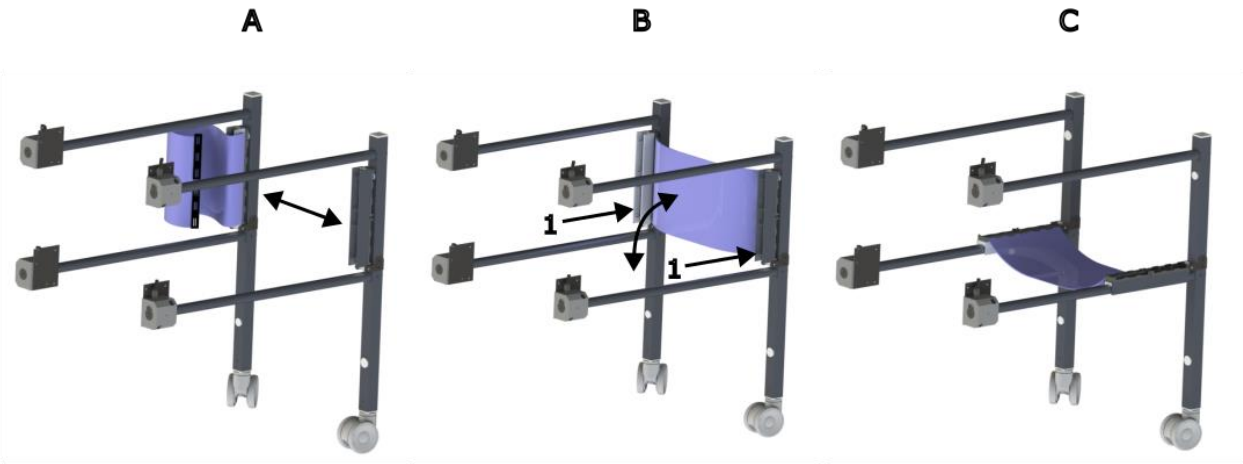

Figure 12: Seat V2 in transition or stationary phase (**A**), seat is magnetically connected and placed between the holders (1) during the ambulatory phase (**B**), seat is hinged downwards in case of patient fatigue or hemodynamic instability (**C**).

The seat has a width of 532 mm and a depth of 290 mm to provide ample sitting space. The seat is positioned at a height of 496 mm from the floor for easy acces. These dimensions align with the DINED anthropometric standards.

The final assembly in is shown in Figure 13.

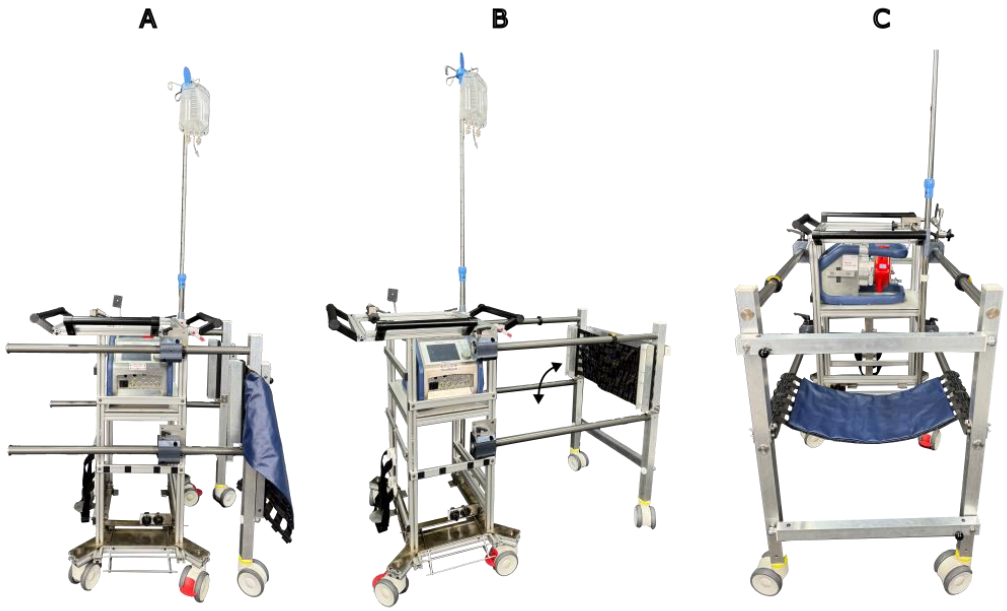

Figure 13: Seat V2 assembly in stationary or transition phase (**A**), ambulatory phase (**B**), seated patient transport phase (**C**).

3.1.3 Calculations – Extendable walking frame and seat V2

The patient's load affects both the seat and the extendable walking frame, as shown in Figure 14. The most critical condition is during impact loading, which occurs when the patient sits down abruptly, such as in case of a fall. This impact load can reach up to 2.13 times the weight of a 102 kg patient, as specified in the DRS, which serves as a safety factor in the calculations.

The seated patient creates a pressure distribution across the entire sitting area. However, this is simplified to two evenly distributed point loads (Figure 14, **F**) distanced between the ischial tuberosities (sitting bones). This simplification acts as an additional safety factor by accounting for higher localized stress in the design.

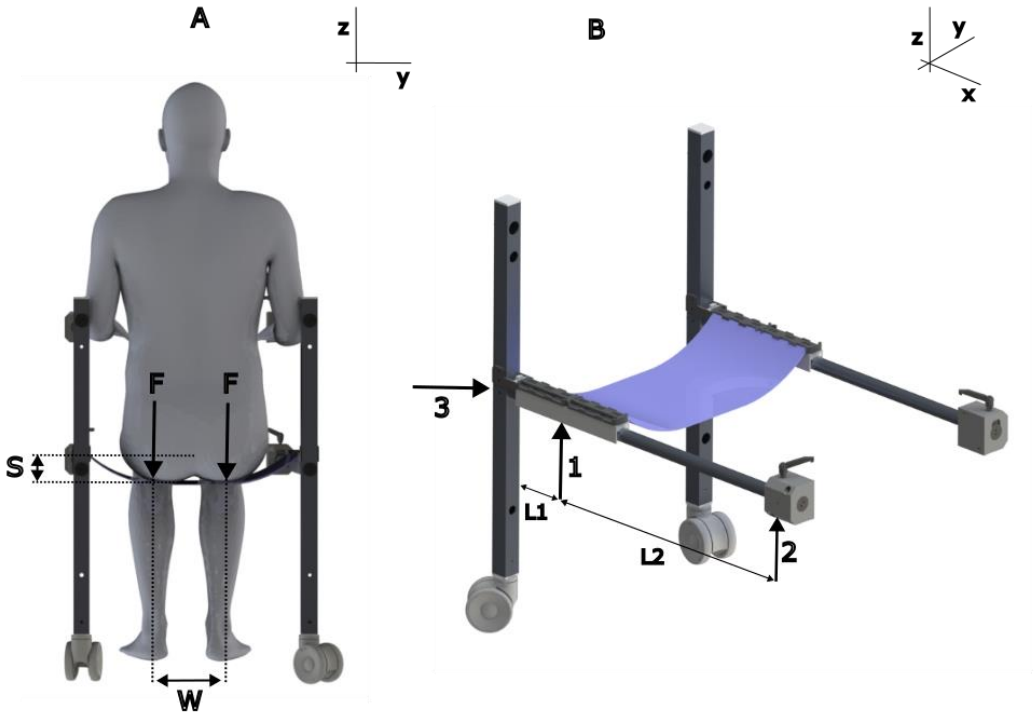

Figure 14: Patient sitting down (**A**) generates two point loads (F) between the ischial tuberosities (W), creating downward seat deflection (sag, S). The sag generates point loads at the seat holders (1), aluminum tubes (2) at a distance L1, and bearings (3) at a distance L2 (**B**).

The point loads generate a downward deflection (Figure 14, sag (S)) of the seat. The sag introduces forces and moments in the design, which are calculated and shown in Table 2, to maintain structural integrity of the design.

Table 2: Calculations to ensure structural integrity of extendable walking frame and seat.

Component	Theory used	Calculation results	Conclusions
Seat	Cable theorem	• Minimum sag of seat: 76.42 mm • Force 1 (y-direction): 2943 N • Force 1 (z-direction): 1067.3 N • Torque: 164 Nm	• The ultimate tensile strength of the magnetic connectors (300 kg) is sufficient with a sag of 76.42 mm or above. • Rotational torque of the seat shall be counteracted.
Telescopic tube	Statically indeterminate beam	• Maximum bending moment: 414.88 Nm • Maximum bending stress: 166 MPa • Maximum deflection: 1.4 mm	• Shaft's tensile strength of 274 MPa (Granta EduPack) is sufficient, no failure occurs due to bending stresses. • Deflection of 1.4 mm results in 0.11° misalignment during seated patient transport, exceeding the 0.0833° misalignment limit specified in the DRS, therefore slightly affecting linear telescopic performance.
Bearing	Statically indeterminate beam	• Maximum force 2 (y-direction): 290.5 N. • Maximum bending moment 2 (z-direction): 80.67 Nm	• Dry bearings will not fail with the given loading conditions (maximum static load of 3639 kg).
Aluminum square tube	Statically indeterminate beam	• Force 3 (y-direction): 2652.5 N. • Force 3 (z-direction): 961.93 N. • Bending moment 3 (y-direction): 121.20 Nm • Bending moment 3 (z-direction): 334.21 Nm	• Bearings and swiveling wheels counteract force in z-direction and bending moment in y-direction. • Forces in y-direction and bending moments in z-direction are counteracted primarily by the backrest.

The torque of the seat, as outlined in Table 2, is counteracted with 5 mm pins that fit perfectly in milled slots of the shaft as shown in Figure 15. The pin diameter is sufficient to resist shear and bearing stresses encountered during seated patient transport. These pins prevent excessive stress on the hinge brackets. Additionally, 8 mm dowel pins prevent the shaft from rotating.

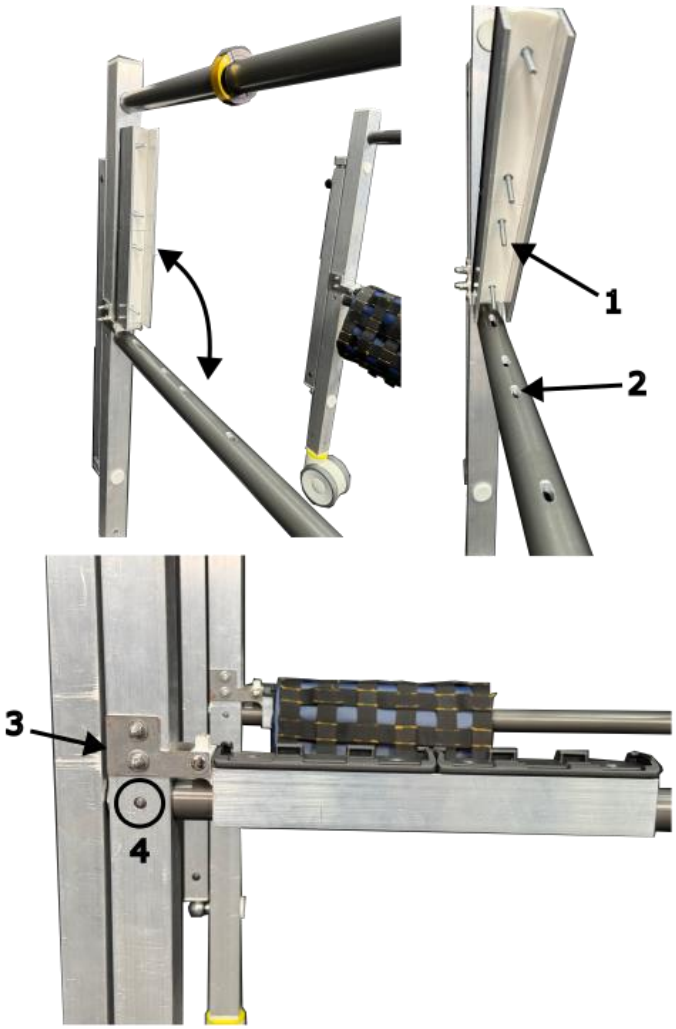

Figure 15: Downward hinging seat holders (**A**) with four pins (1) each, fitting into milled slots (2) of the shaft (**B**), and secured by hinge brackets (3) and dowel pins (4) (**C**).

3.1.4 Patient physical support module – Backrest

The backrest, see Figure 16, shares similar shortcomings with the seat (Seat V1 – Shortcomings). As a result, the current design does not meet the user requirement of enabling one caregiver to assist the patient through the entire ambulatory ECMO procedure.

The key difference is that the backrest does not have a hinge mechanism compared to the seat. The seat forms a rigid connection between left–and right extendable walking frames in ECMOve V1, however this is not possible with a flexible seat in ECMOve V2. Therefore, it is essential for the backrest to maintain a rigid connection between both sides. Inadequate support could lead to inward bending of the patient's physical support module, affecting patient safety.

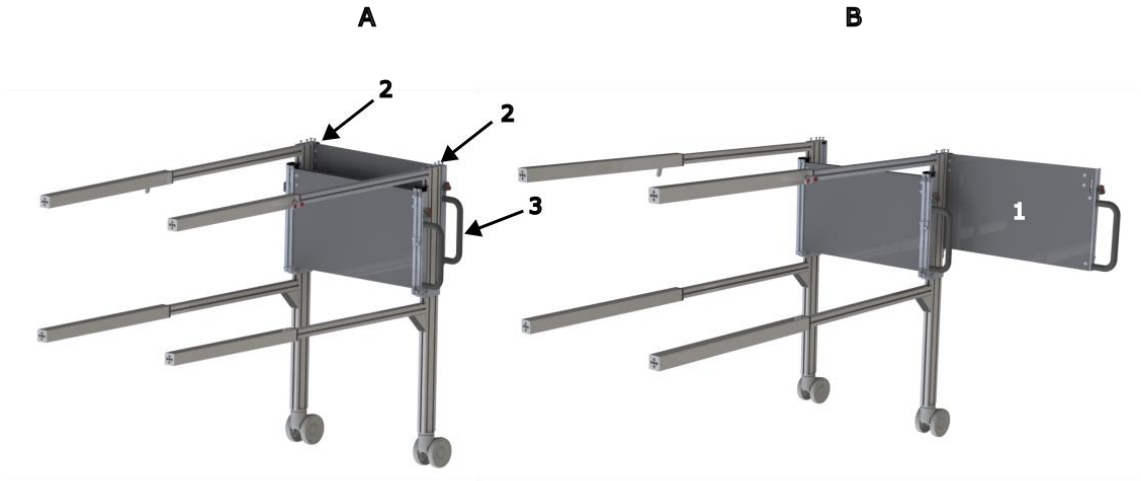

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Figure 16: Backrest V1 (**A** and **B**) comprising backrest (1), backrest holders (2), and handle (3).

3.1.4.1 Backrest V2 – Design requirements

Complete overview of design requirements is given in Annex C.

- The backrest shall ensure a minimum width of 500 mm to ensure full back support. (DINED tool P95-male, Shoulder width (bi-deltoid)).
- The backrest should incorporate cushioning or flexible materials to ensure comfortable seating for the patient.
- The backrest should ensure a height between 149 mm – 439 mm with respect to the seat, to provide lumbar vertebrae support (coccyx and sacral length [30], vertebral body height anterior and disc height [31]).
- The backrest shall be able to carry a maximum horizontal force of 459 N ± 9.2 N. (ISO 11199-2)
- The backrest shall be designed without sliding mechanisms.
- The backrest shall remain within the ECMOve device frame of 650 mm ± 50 mm.
- The backrest shall ensure a rigid connection between both the left-and right extendable walking frame sides.
- The backrest should have a smooth/levelled surface without any gaps or holes to ensure ergonomics for the patient.

3.1.4.2 Backrest V2 – Final concept description

The final design features a dual-beam configuration, as depicted in Figure 17. The backrest hinges from a vertical to a horizontal position with ball-joint assemblies (Figure 17, **A – B**). The ball-joint assemblies allow for 15° of internal and external rotation, enabling the beams to move over one another. The upper and lower beam provide necessary structural support. The lower beam should be positioned 250 mm above the ground in which the beam does not impede the patient during gait. A spring-loaded pin mechanism securely locks the beams in all orientations (Figure 17, **C**). This design reduces the risk of unintentional displacement caused by the patient or caregiver, which could lead to patient falling backwards. The pin locks of the upper and lower beam provide a rigid connection of both walking frame sides and mitigates inward bending during seated patient transport. The pin (Figure 17, 5) has a 45° cut to automatically secure the beams in place, similar to a door lock. Users unlock the beam by pushing the knob sideways (Figure 17, **D**). To compress the spring and engage the unlocking mechanism, a maximum force of 5.2 N is required.

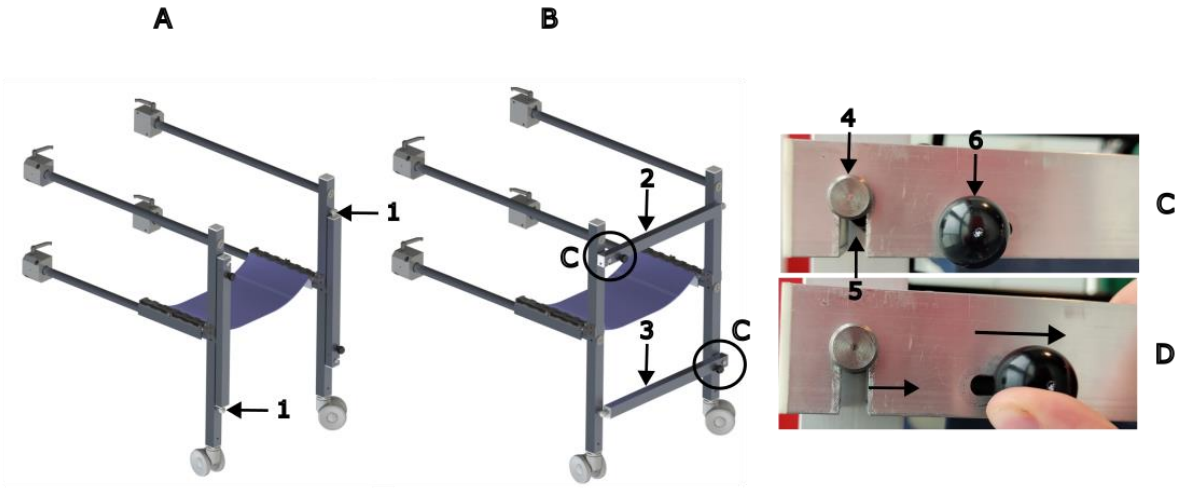

Figure 17: Backrest V2 (**A** and **B**) comprising ball joint assemblies (1), upper beam (2), and lower beam (3). Backrest V2 fastens horizontally (**C**) with two pins (4,5). The backrest is unlocked by pushing the knobs (6) sideways, activating the spring-loaded mechanism (**D**).

The backrest has a fixed height of 348 mm and a width of 40 mm, focusing on lumbar support. The backrest accommodates patients within the DINED anthropometric measurement range, with a width of 536 mm.

The final assembly in is shown in Figure 18.

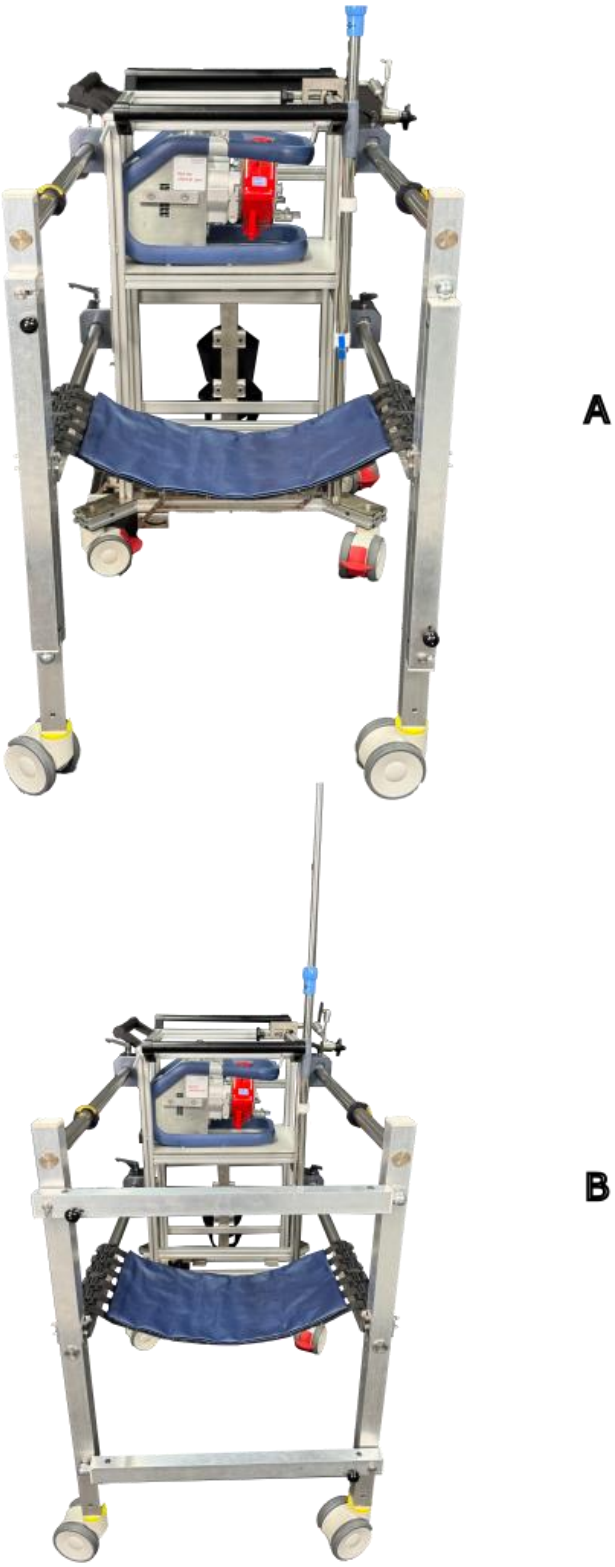

Figure 18: Backrest in opened position (**A**), backrest in closed position (**B**).

3.1.5 Calculations – Backrest V2

Force analysis of ECMOve V2 highlights four load scenarios, as illustrated in Figure 19. Forces in the z-direction are not considered, as they are effectively counteracted by the bearings and swiveling wheels.

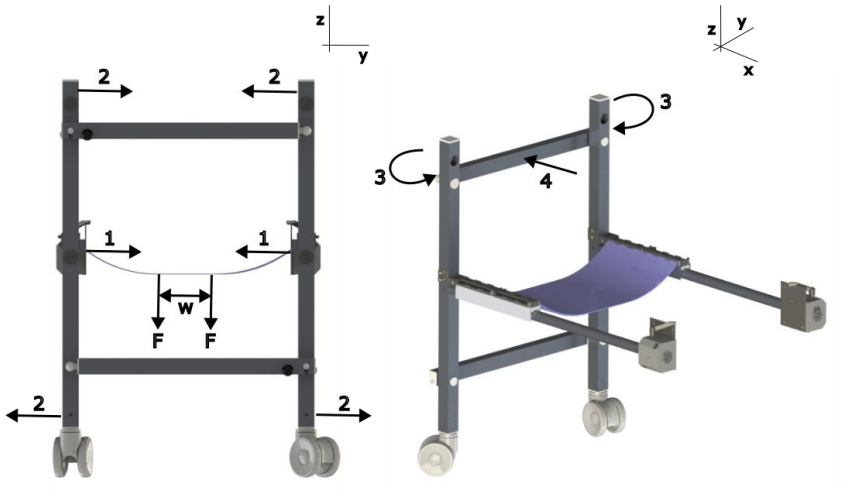

Figure 19: ECMOve V2's patient physical support module has inward forces (1), shear (2), and torque (3) due to patient loading (F). The load (F) is distanced between the ischial tuberosities (W). Patient leaning against the backrest creates an additional force (4).

Table 3 outlines the effect of the forces on the backrest. The fixation pins (Figure 17, 4) are assumed to fail primarily due to shear stress, therefore 8 mm stainless steel pins suffice (see Annex B – Calculations). The ball joint assemblies (Figure 17, 1) are loaded in both push and pull directions. Due to symmetrical force distribution, M10 zinc-plated steel ball joints with a 200 kg load rating are adequate.

Table 3: Effect of load scenarios on the backrest, shown in Figure 19.

#	Theory	Forces on backrest
1	Patient loading introduces inward forces in the y-direction, causing shear on the pins (Figure 17, 4).	The backrest should hold a maximum shear force of 2943 N.
2	Patient loading introduces torque in the anodized aluminium shafts and shear on the aluminum square tubes.	The backrest should hold a maximum torque (with respect to the x-axis) of 164 Nm.
3	Patient loading introduces inward forces in the y-direction, causing torque on the aluminum square tubes.	The backrest should hold a maximum torque (with respect to the z-axis) of 334 Nm.
4	Patient loading introduces forces in the x-direction when leaning against the backrest.	The backrest should hold a maximum bending force of 459 N ± 9.2 N

3.1.6 Ambulatory device transport module – IV stand, Pushing handle, gas tank holders

ECMOve V1 ambulatory device transport module does not meet user requirements for patient control during ambulatory ECMO and caregiver control in both configurations, see Figure 20.

The fixed-height IV stand (V1) limits proper transport of ECMOve and restricts control of dripper medicine infusion flow rates. The current height of the IV stand is 1941 mm with respect to the ground. To ensure sufficient hydrostatic pressure for gravity-fed IV bags during stationary and ambulatory ECMO (Bernoulli's theorem) [32], the stand should be able to telescope and extend to a maximum of 2115 mm, in line with FGI [19] guidelines for minimum hospital door dimensions.

The fixed-height patient's pushing handle (V1) does not accommodate every patient in the DINED anthropometric range. Tall patients are forced into slouched postures and smaller patients are forced to bend elbow joints beyond 90°, leading to increased muscle strain and fatigue.

The gas tank holders (V1) are not compatible with various medical oxygen tank sizes and require tanks to be lifted through the transport module's frame for (re)placement, a manoeuvre that is physically not possible. The current design is ergonomically inefficient, requiring the tank to be lifted at least 534 mm from the ground.

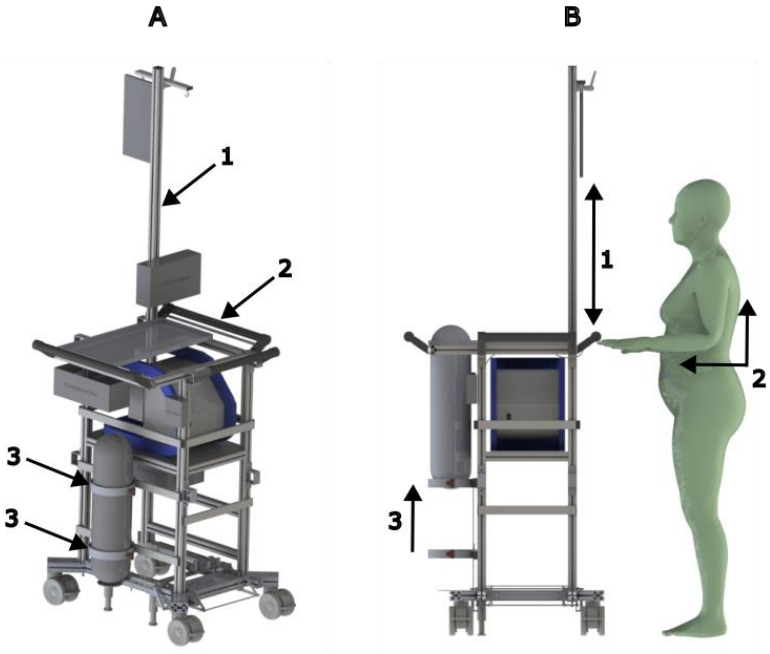

Figure 20: Ambulatory device transport module (**A**) comprising IV stand (1), patient's pushing handle (2), gas tank holders (3). Side view ambulatory device transport module (**B**) with height difference from dipper bag to patient's hands (1), patient posture (2), and medical oxygen tank lifting height (3).

3.1.6.1 IV stand, Pushing handle, gas tank holders – Design requirements

A complete overview of design requirements is given in Annex C.

IV stand:

- The IV stand should be a round tube with a diameter between 20 mm and 50 mm (ISO 11199-2) to ensure ergonomic use.
- The IV stand shall hold a maximum of five perfusor pumps and one dripper bag with a total maximum weight of 9 kg.
- The IV stand should be height adjustable to a maximum of 2115 mm according to FGI guidelines [19]for ICU doors. This requirement is also to ensure enough hydrostatic pressure to ensure sufficient infusion rates [32].
- The IV stand should incorporate a telescoping mechanism for easy device transport and control of infusion flow rates.

Patient's pushing handle:

- The distance between the pushing handle (part intended to be grabbed) and any construction part of the ECMOve shall not be less than 35 mm (ISO 11199-2).
- The pushing handle should be a round tube with a diameter between 20 mm and 50 mm (ISO 11199-2) to ensure ergonomic use.
- The pushing handle shall incorporate a hinge mechanism to rotate the handle. The working height should be between 947-1193 mm (DINED tool P5-female, elbow height, standing – DINED tool P95-male, elbow height, standing).
- The pushing handle should hold a downward force of 200 N at $1/4^{th}$ of the handle length (ISO 19894).

Gas tank holders:

- The gas tank holder should not influence other functional units of the ECMOve.
- The gas tank holder should hold a maximum weight of 15 kg, which is the maximum safe individual lifting load for a female aged < 20 or > 45 years (ISO 11228-1).
- The gas tank holder should hold a variety of medical grade oxygen cylinders dependent on the availability. A range of at least 620 mm in height and 140 mm in diameter is sufficient according to Conoxia Liv IQC 5 liters [33].
- The gas tank holder shall provide low lifting heights, below the knee joints, for ergonomic use.

3.1.6.2 IV stand, Pushing handle, gas tank holders V2 – Final concept

The final design features a telescopic IV stand with an outer/inner diameter of 25/18 mm and height range of 1055 – 2230 mm, see Figure 21. The IV stand is capable of withstanding a maximum static load of 10 kg. The pushing handle has a diameter of 30 mm and is height-adjustable, with a range of 885 to 1065 mm from the ground. The gas tank holders have two Velcro cable ties with eyelet, each capable of supporting up to 15 kg. The holder accommodates gas tanks with maximum dimensions of 804 mm in height and 200 mm in diameter and requires a lifting height of 153.5 mm.

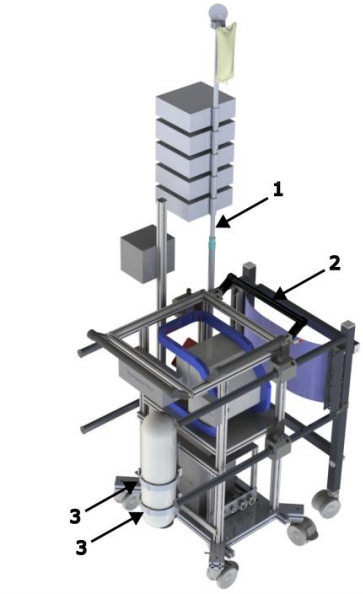

Figure 21: Ambulatory device transport module comprising telescopic IV stand (1), adjustable patient's pushing handle (2), and gas tank holders (3).

The final assembly in is shown in Figure 22.

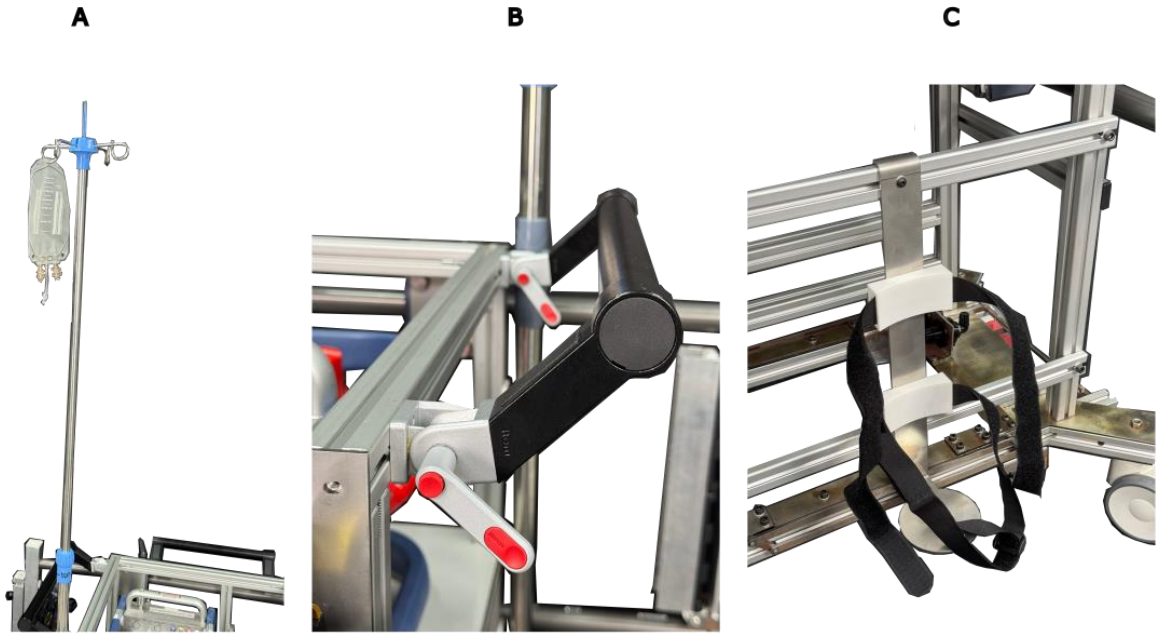

Figure 22: Assembly telescopic IV stand (**A**), adjustable patient's pushing handle (**B**), and gas tank holders (**C**).

3.1.7 Ambulatory device transport module – Safety brakes V1

The braking system is designed to enhance patient safety by automatically stopping the device in the event of instability or a fall, shown in Figure 23. The safety brakes V1 is a concept and not integrated in the prototype as of yet.

The braking system is activated when the patient pulls the braking rod, which in turn tensions the Bowden cables, compresses the springs, and lifts the braking poles. The brakes can only be operated by either the patient or caregiver. However, during seated patient transport, the patient cannot actively engage the brakes. Subsequently, the caregiver should activate the patients' braking rods while moving and supporting the patient back to the ICU, which is very impractical. The concept V1 does therefore not fully align with the fourth user requirement, which states that the ECMOve should only move when initiated by the user.

The spring-loaded mechanism relies solely on friction with the ground. Friction increases when the spring is partially compressed due to its natural tendency to return to its original length. This restoring force, which is primarily dependent on the compression distance according to Hooke's law, contributes to the braking of the cart. The maximum allowable amount of gripping force is 248 N (DINED tool P5-female, maximum gripping force N). Assuming the brakes are positioned 1 cm above the ground, the minimum braking distance is 1.26 m at a normal walking speed of 1.4 m/s (see Annex B – Calculations). Subsequently, this can cause safety issues, such as collision between the patient and the seat or backrest.

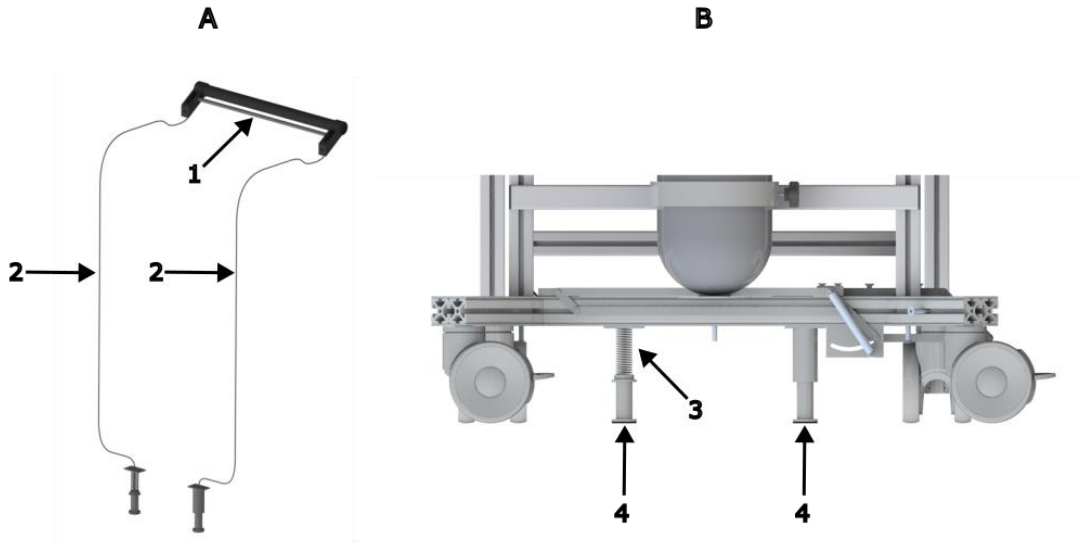

Figure 23: The brakes (**A – B**) comprises a brake rod (1), Bowden cables (2), compression springs (3), and brake poles (4).

3.1.7.1 Safety brakes V2 – Design requirements

Complete overview of design requirements is given in Annex C.

- The maximum operating force of the brakes shall be below 40 N for the patient (ISO 11199-2).
- The maximum operating force of the brakes shall be below 185 N for the caregiver (DINED tool P5-female, Maximum gripping force).
- The braking system shall be able to be activated by both the caregiver and the patient independently.
- The braking rod should be a round tube with a diameter between 20 mm and 50 mm (ISO 11199-2) to ensure ergonomic use.

3.1.7.2 Safety brakes V2 – Final concept

The final design features a dead-man's braking system that automatically keeps the ECMOve brakes engaged under stationary conditions, shown in Figure 24.

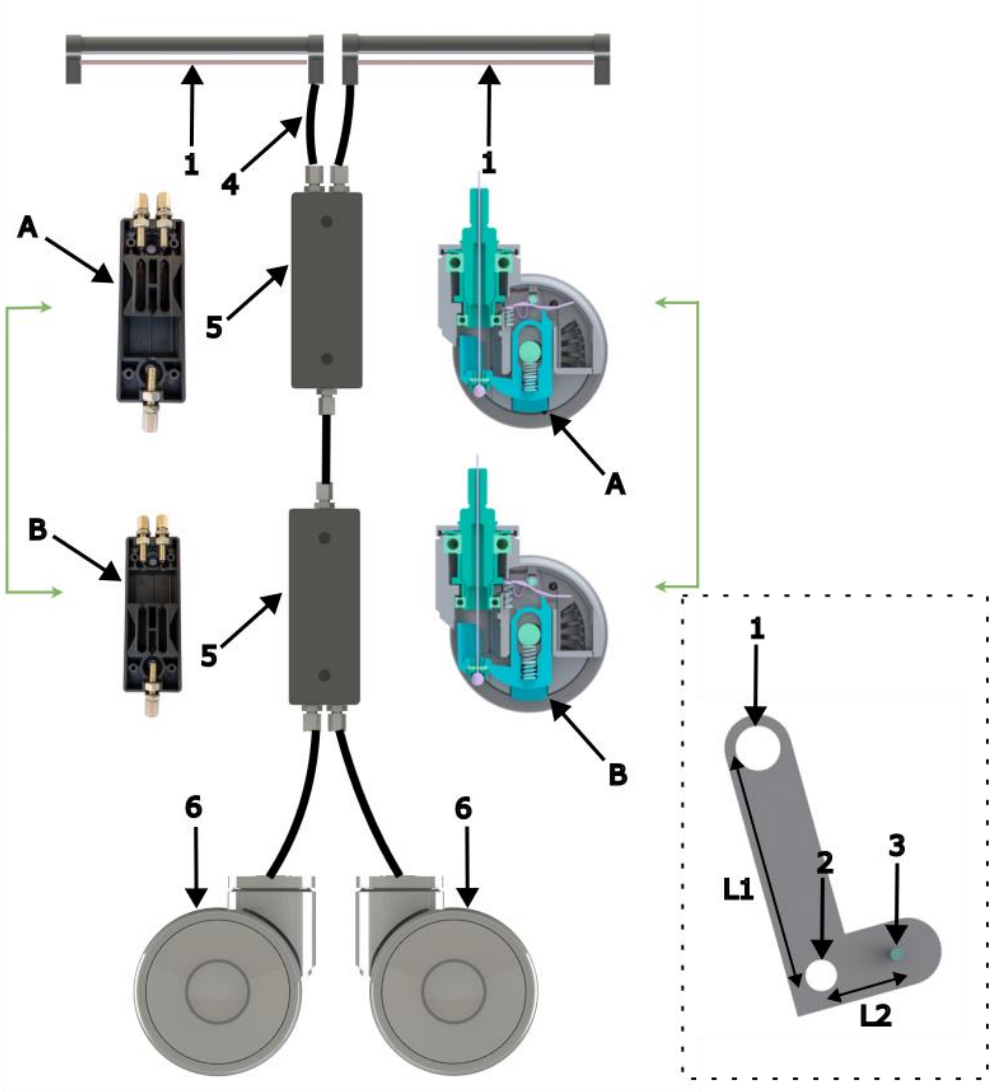

Figure 24: Safety brakes activate by engaging (rotating) either one of the braking rods (1), enabling ECMOve to move. Mechanical advantage is achieved by making L2 (rod (1) to pivot (2)) longer than L1 (pivot (2) to Bowden eyelet (3)). Tension in Bowden cables (4) shift the distributors (5) and swiveling wheels (6) from state **A** to state **B**.

The dead-man brake activates by pulling and rotating either one of the braking rods mounted on the pushing handles. These rods connect to Bowden cable assemblies with a maximum outer sheath diameter of 7 mm and an inner wire diameter of 3 mm (including ferrules). Bowden cable distributors merge the Bowden cables from both pushing handles into a single cable, which is then split back into two cables and routed to the swivelling wheels. The Bowden cable is fixed to the pushing handle with an eyelet or thimble nipple, and to the distributor with a screw nipple and cable adjusters for adjusting inner wire tension. When the braking rod rotates, it (dis)engages both the slide thermoplastic and die-cast ball (Figure 24, state **A** – **B**), enabling the swivelling wheels to either rotate freely or lock.

Engaging the compression springs requires a force of 32 N per wheel, totalling 64 N, which may be excessive for patients on V-V ECMO. To address this concern, the braking mechanism should incorporate mechanical advantage, such as a first-class lever. The mechanical advantage is calculated as the length from the pivot to the braking rod (L2) divided by the length from the pivot to the Bowden cable fixation point (L1).

The design ensures that caregivers can concentrate on patient care without the risk of forgetting to lock the ECMOve. The user case is illustrated in Figure 25.

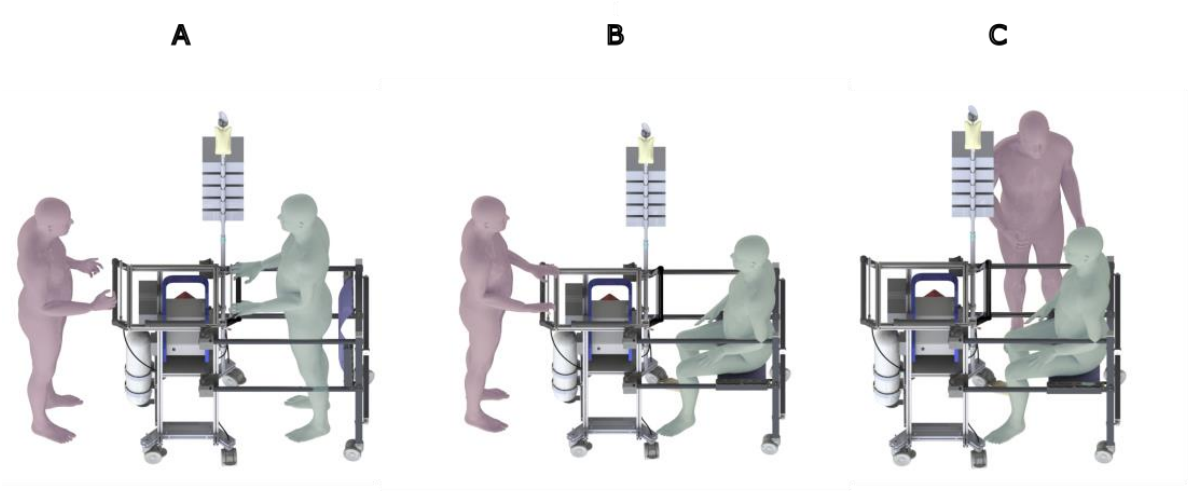

Figure 25: (**A**) Ambulatory ECMO, patient engages brakes. (**B**) Seated patient transport, caregiver engages brakes. (**C**) Brakes disengaged, caregiver can assist the patient.

3.1.8 User case scenario final design

The user case for stationary phase, transition phase (stationary – ambulatory), ambulatory phase, and seated transport phase is shown in Figure 26.

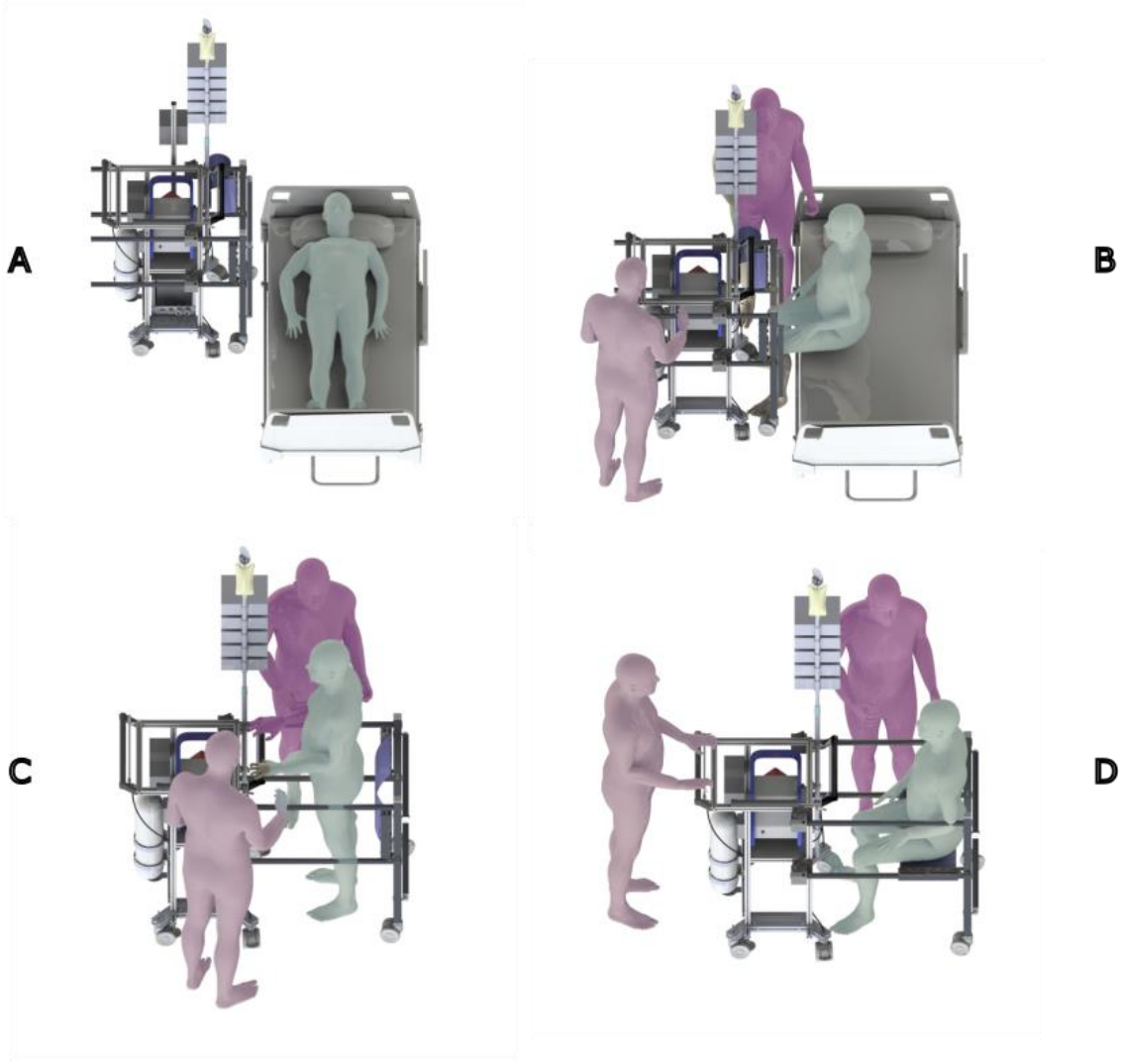

Figure 26: Stationary Phase (**A**): The ECMOve is positioned on the right side of the bed. A shoulder brace is attached to the patient, and the tubing is secured in its connectors (not shown in the image). Transition phase; stationary – ambulatory (**B**): The ECMOve's stationary cart is disconnected and ECMOve is moved in front of the patient. Caregivers assist the patient in standing up, while continuously monitoring patient vitals. Ambulatory phase (**C**): The walking frame is extended. The backrest and seat are connected to both frame sides, the seat is now standby in case of patient fatigue. The patient de-brakes the system by engaging the braking rod, while caregivers assist and monitor the patient throughout. Seated transport phase (**D**): If the patient becomes fatigued, one caregiver takes control of the braking system and guides the patient back to bed.

The user case for transition phase (ambulatory – stationary) is shown in Figure 27.

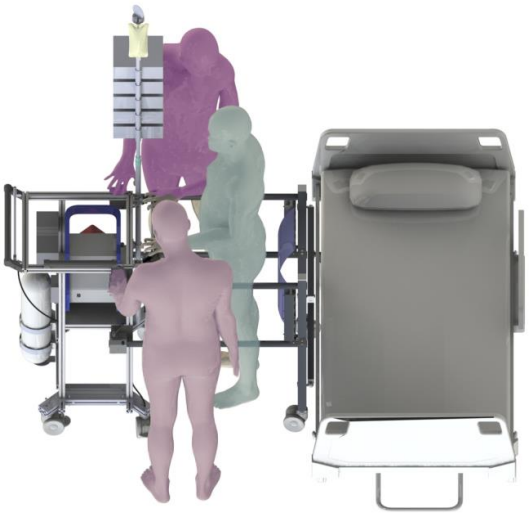

Figure 27: Transition phase; ambulatory – stationary: The patient is assisted back to bed and helped into a standing position. After standing up, the walking frame's levers can be safely disengaged, allowing the walking frame to slide freely.

There are three operational modes in how to support the patient back to bed, shown in Figure 28.

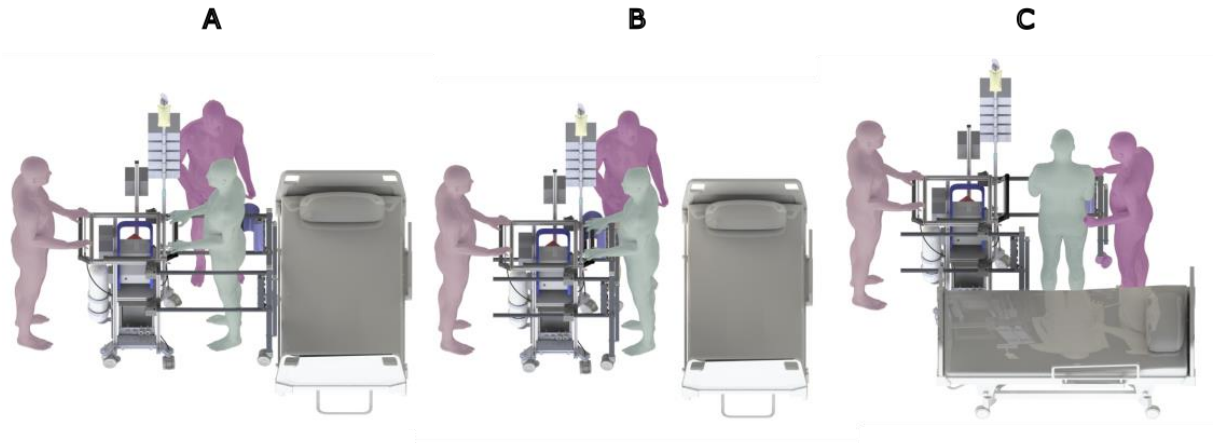

Figure 28: Operational Mode **A**: The walking frame is pushed against the bed, allowing both sides of the frame to shorten simultaneously as the patient walks backward, supported by a caregiver. Operational Mode **B**: The extendable walking frame sides are both retracted individually, the patient has to walk backwards step-by-step with caregiver's assistance. Operational Mode **C**: Only one side of the walking frame is shortened, the patient needs to make a 90° turn and could lean against the walking frame which is still extended for support. The patient can now sit down safely.

3.2 ECMOve V2 – Design verification

Complete ECMOve verification documentation can be found in Annex F – Verification. Highlighted are ISO standard tests, initial and sustained force calculations, and cleaning/disinfection evaluation.

3.2.1 Verification – DRS according to ISO standards

Verification testing regarding stability was carried out following ISO 19894, see Figure 29.

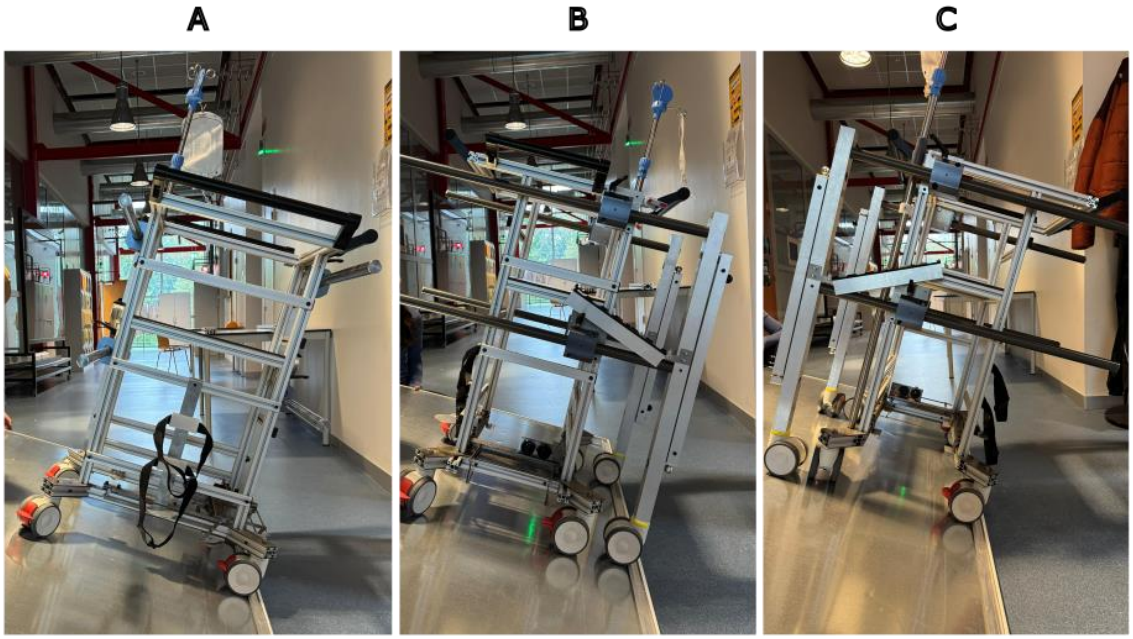

Figure 29: ISO 19894 Test set-up: sideways stability (**A**), rearward stability (**B**), forward stability (**C**).

The results in Table 4 show that ECMOve V2 successfully passed all tests. However, not all devices were included in the verification tests, such as the medical oxygen tank, ECMO device, and emergency drive amongst others. These were excluded due to unavailability or concerns about stability on an inclined plane. The tests are primarily focused on transport safety, rather than ambulatory ECMO, since hospital floors are typically smooth.

Table 4: ISO 19894 stability test results.

Test	ISO requirement	Result	Status
Forward stability	≥15°	≥16° ±1°	Pass
Backward stability	≥15°	≥16° ±1°	Pass
Sideways stability	≥15°	≥16° ±1°	Pass

Verification testing regarding strength was carried out following ISO 19894 and ISO 11199-2, see Figure 30 .

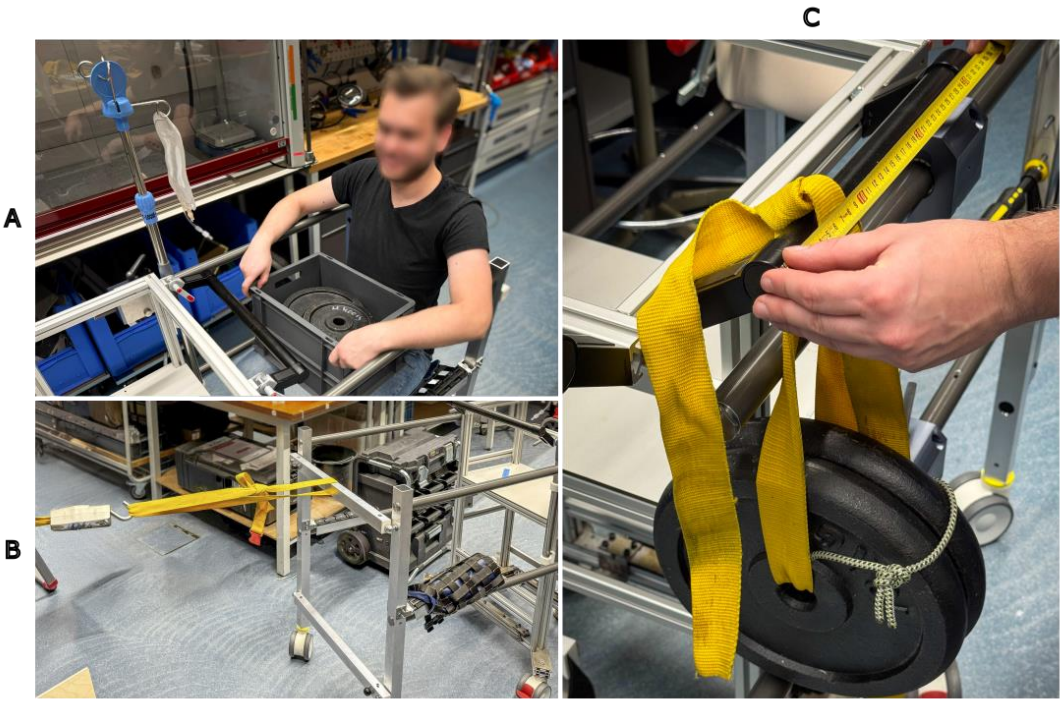

Figure 30: ISO 19894 test set-up: Strength resting seat (**A**), strength/stability pushing handle (**C**). ISO 11199-2 test set-up: Strength backrest (**B**).

The results in Table 5 show that ECMOve V2 successfully passed all tests, except for the patient's pushing handle. The hinges were not capable of withstanding the tested loads given in ISO 19894.

Table 5: ISO 19894 and ISO 11199-2 strength test results.

Component	**ISO – requirement**	**ISO – Time and simple size**	**Result**
Seat strength	Apply a load of 1224 N vertically downward to the centre of the seat	Time: 2 minutes. Sample size: 1.	**Pass**
Pushing handle strength	Apply a force of 200 N at 1/4th of the handle length from the either outer end of the handle	Time: 2 minutes. Sample size: 1.	**Pass/Fail** (patient's pushing handle)
Backrest strength	Apply a force of 459 N in a 50 mm wide region in the middle of the backrest	Time: 1 minute. Sample size: 10.	**Pass**

3.2.2 Verification – DRS according to RIA, literature, and tests

Cleanability assessment for the patient physical support module, ambulatory device transport module, and blood tubing fixation module is shown in Table 6. The table only shows key takeaways of the ECMOve V2 cleanability assessment, additional information is found in Annex F – Verification.

Table 6: Cleanability assessment patient physical support module, ambulatory device transport module, and blood tubing fixation module according to ISO 10993-22 and ISO 17664-1.

Module	Cleanable/ disinfectable*	Key takeaways
Patient physical support module	Partly	The porous nature of the seat's PP webbing makes it uncleanable, but coating it with polyvinylchloride (PVC) or thermoplastic polyurethane (TPU) offers a solution. Similarly, the magnetic connectors' polyamide 66 30% glass fibre reinforced (PA66GF30) material is porous and uncleanable. The bearings' bushing is hard to clean internally; disinfect or clean the telescopic tube before extending or retracting. Risks of the release of nanomaterials due to wear of the extendable walking frame should be evaluated with ISO 10993-22. However, as the frames only extend and retract several times per day, this is considered to be a low risk.
Ambulatory device transport module	Partly	Replace the aluminum extrusion profiles with uniform stainless steel, carbon fibre, or hard-anodized aluminum profiles to reduce hard-to-reach areas**. Replace the carbon steel laser-cut plates with stainless steel to prevent oxidation. Opt for uniform surfaces on the pushing handles with integrated hinge and brake mechanisms.
Blood tubing fixation module	Yes	The brace consists of non-breathable closed-cell neoprene, which is non-porous and therefore cleanable. The tubing connectors are made of cleanable polyether ether ketone (PEEK) with neoprene anti-slip rings. The neoprene is closed-cell and therefore cleanable.

*with water and 70% isopropyl alcohol, contact time is not evaluated.
**Avoid using carbon fibre and anodized aluminum together to prevent galvanic corrosion, as water can act as an electrolyte.

As an addition to Table 6, all SLS-printed PA components should be replaced with alternative polymers, such as PP or PEEK. PA12 (SLS-material) may exhibit sufficient density to ensure cleanability. However, this is not evaluated.

The initial and sustained forces of ECMOve V1 and V2 are shown in Figure 31. The peak and mean forces for ECMOve V2 (green line) are below the 30 N maximum allowable operating force for patients (ISO 11228-2). This remains true even if all devices are added for ambulatory V-V ECMO. The peak and mean forces for ECMOve V2 during seated patient transport (red line) are below the maximum allowable force of 185 N (DINED tool P5-female, Pushing force with 2 hands N) for caregivers.

The prediction models (green and red line) are based on force measurements of ECMOve V1 (blue line). A linear trend between weight and forces is verified in Annex B – Calculations. This verification facilitates efficient development of new production models for future prototyping.

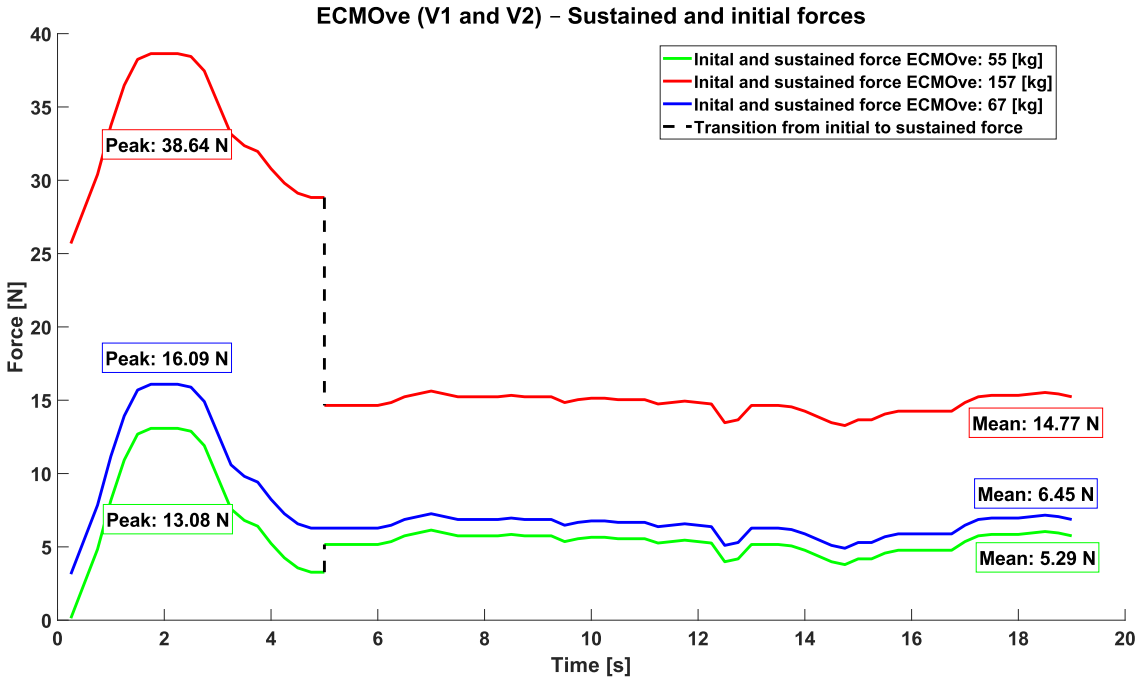

Figure 31: Results: Initial and sustained forces ECMOve V1 (67 kg), ECMOve V2 (55 kg), ECMOve V2 + patient of 102 kg (157 kg).

3.3 ECMOve V2 – Testing by stakeholders

The complete ambulatory ECMO process is demonstrated and evaluated with the help of physiotherapists, cardiologists and physician assistants. The stationary ECMO phase, shown in Figure 32, begins with attaching the shoulder brace. The brace can be easily secured to the patient by positioning the patient in fowler's position, which removes the need to pull the brace over the patient's head, reducing possible discomfort or pain.

ECMOve V3 could introduce a method to open and close the tubing clamps in a single movement, as closing the current clamps was time consuming (2 minutes and 30 seconds). Additionally, the shoulder brace could use the inclusion of an extra buckle to enhance safety and stability, reducing risk of accidental detachment with the current Velcro closures, which could lead to fatal consequences in rare cases. Adding a tubing clamp to the tubing connector to facilitate integration of mechanical ventilation could expand potential applications of the ECMOve device.

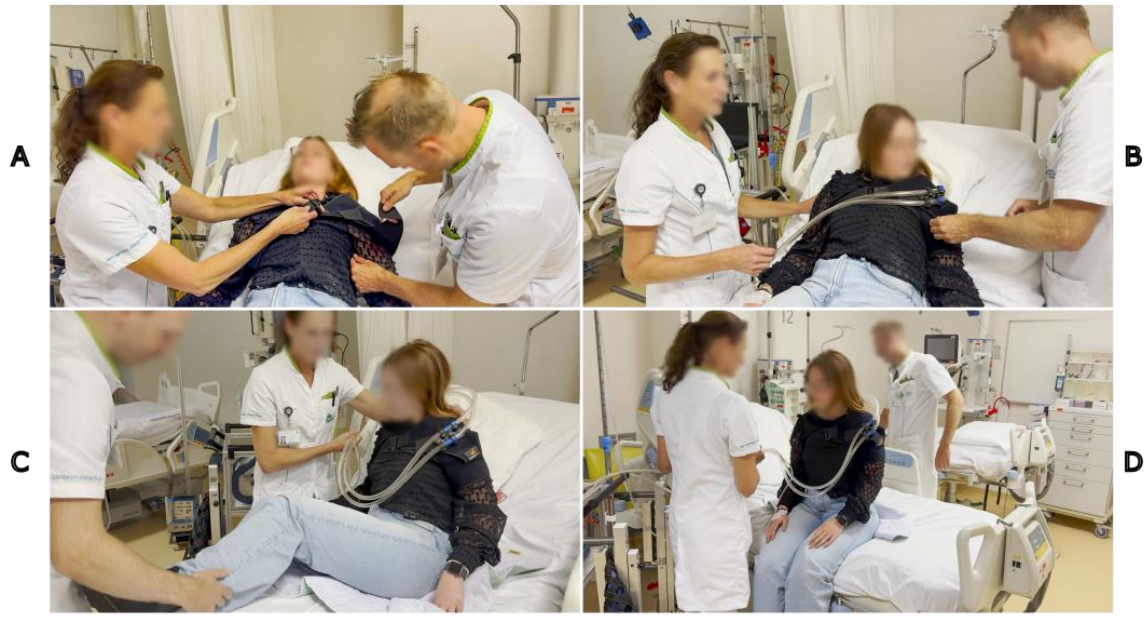

Figure 32: Stationary phase: Attaching the shoulder brace (**A**), securing tubing with blood tubing connectors (**B**), transitioning patient from fowler's to sitting position (**C** – **D**).

The transition phase (stationary to ambulatory), shown in Figure 33, begins with assisting the patient into a standing position. Prior to initiating ambulatory ECMO, the walking frame, seat, and backrest are prepared: The walking frame is extended, and the seat and backrest are attached to each side of the walking frame. The clinical stakeholders found this procedure easy and efficient.

ECMOve V3 could introduce a separate tubing guide (distinct from the tubing connectors on the brace) which could help effectively manage the tubes (blood- and mechanical ventilation tubing). This guide could be a multi-tube rack holder, which works similar to a terry clip, or a simple (u-shaped) guide without any fixation mechanism. The use of the same tubing connectors described by Van Galen et al. is not recommended [5]. ISO-guidelines for tubing length tailored to the patient' body profile would help minimize tubing length while ensuring safety. Shorter circuits reduce the risk of complications such as thrombosis.

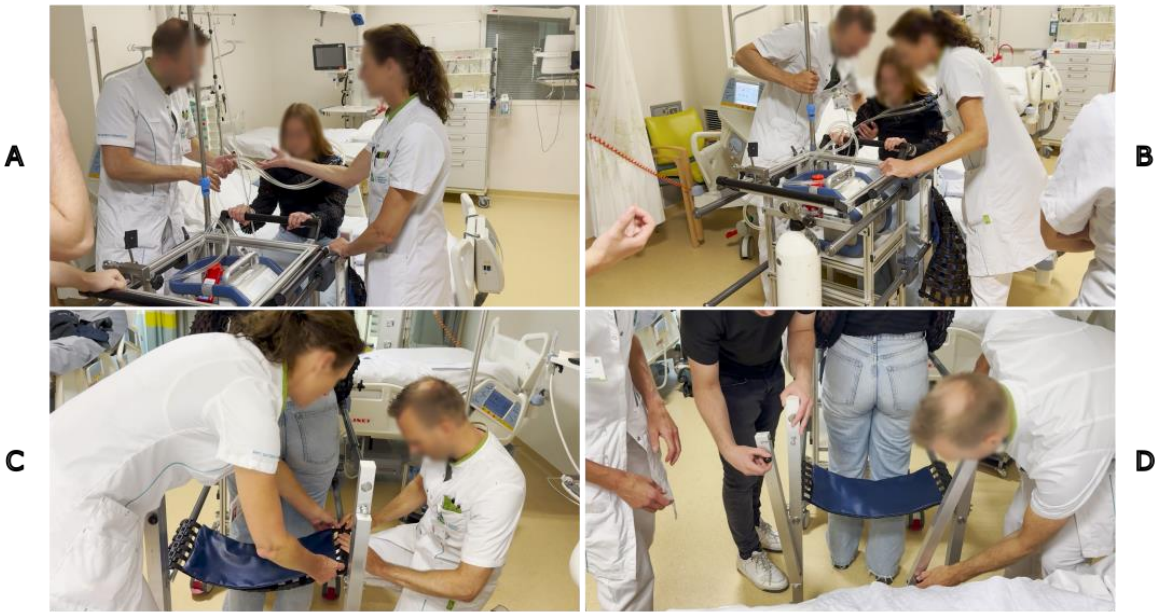

Figure 33: Transition phase (stationary to ambulatory): Discussing tubing length and positioning (**A**), helping patient stand up (**B**), securing the seat (**C**), securing the backrest (**D**).

The ambulatory phase is shown in Figure 34. The clinical stakeholders are positive about the minimal forces required to manoeuver ECMOve in both straight lines and bends, with the axis of rotation facilitating smooth movement even in tight spaces. The seat is easy to fold down for seated patient transport.

The concept of having safety brakes on the patient's pushing handle would be overly complicated for the patient while performing ambulatory ECMO. Additionally, the existing braking pedals (swiveling wheels) are sometimes ineffective during patient mobilization, as the pedals can be difficult or even impossible to reach. ECMOve V3 could introduce a passive braking system, only for the caregivers.

Figure 34: Ambulatory phase: Navigating ECMOve through a door (**A**), navigating ECMOve through hallway (**B**), patient sits down due to fatigue or hemodynamic instability (**C**), seated patient transport (**D**).

The transition phase (ambulatory to stationary) is shown in Figure 35. The clinical stakeholders suggest increasing sitting height, as it currently requires a considerate amount of force for patients to transition

from sitting- to standing position. ECMOve V3 could introduce a modular seat design for all patient body profiles, however this would require a pneumatic or hydraulic system, which would turn the device into a class-II (according to MDR) system. Additionally, removing the backrest was difficult when it was too close to the patient's bed.

The clinical stakeholders expressed positivity about the various ways the extendable walking frame can be used (Figure 35, D).

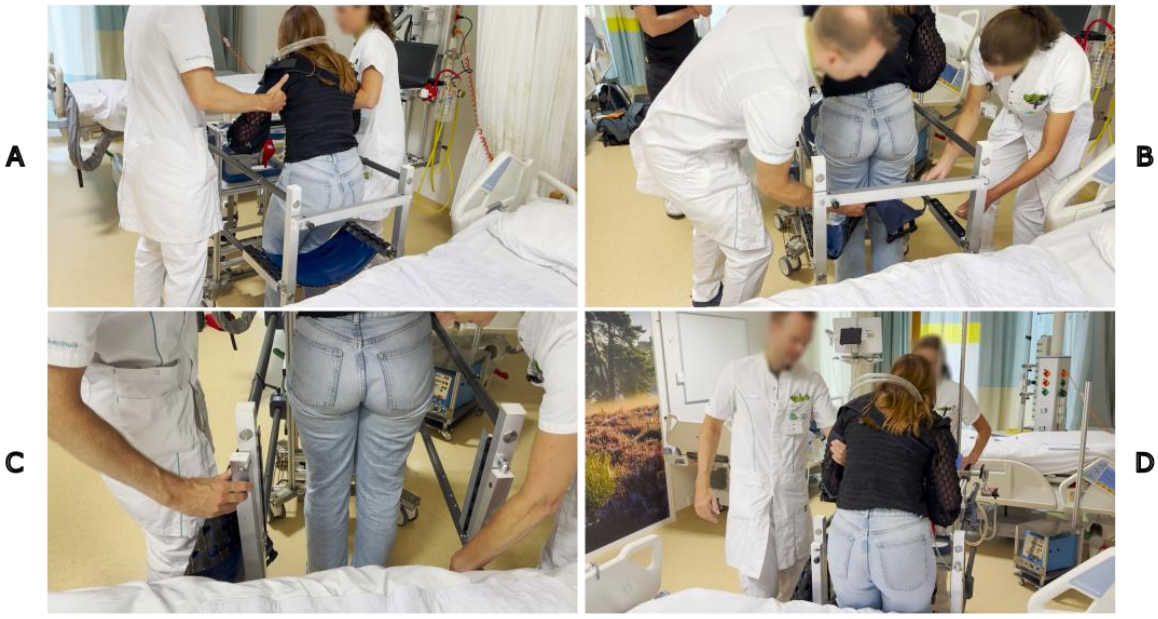

Figure 35: Transition phase (stationary to ambulatory): Helping patient stand up (**A**), removing seat (**B**), removing backrest (**C**), assisting the patient back to bed by pushing ECMOve against the bed, shortening the extendable walking frame (**D**).

Additional discussion points and tests are shown in Figure 36. The (blood) tubing moved 1 mm during the whole ambulatory ECMO process, which is expected to not pose a risk (Figure 36, **A**). Clinical stakeholders suggest using a Hill-Rom chair or similar for immediate patient support (Figure 36, **B** to **D**). This replaces the current patient physical support module, which might require too many steps during the transition phases, affecting patient safety.

ECMOve V3 could include enhanced back support inspired by the Sara Stedy device [34] or similar. This could aid very weak V-V ECMO patients not being able to stand up. However, ensuring proper foot placement presents a potential challenge in this design. Adding a patient body harness to ECMOve V3 could improve patient stability and reduce fall risks. However, this design would make V-A ECMO with femoral cannulation not feasible. Clinical stakeholders recommend continuous caregiver assistance during ambulatory ECMO to prevent such incidents.

Additional devices that clinical stakeholder suggest to implement in ECMOve V3 are a vital monitor, suction pump, and a defibrillator.

Figure 36: Blood tubing stability test using markers on both the tubing and the connectors (**A**), Hill-Rom chair for seated patient transport (**B**) navigating ECMOve and Hill-Rom through ICU (**C**), ECMOve and Hill-Rom chair next to patient's bed (**D**).

4 Discussion

The primary objective of this thesis was to advance ECMOve V1 from TRL 3 (proof of concept) to TRL 4 (ready for clinical validation) by ensuring the device meets all necessary DRS and URS, bringing the device closer to clinical testing and real-world applications. Ambulatory V-V ECMO could reduce mortality rates and recovery time of the patient, highlighting the importance of such techniques [1-4]. However safe, reliable, and compact ambulatory devices currently do not exist on the market, ECMOve tries to bridge this gap.

The results from the optimization process revealed that several shortcomings/limitations prevent ECMOve V1's design to fully meet all URS. The components that were addressed in this study were the extendable walking frame, seat, backrest, patient's pushing handle, IV stand, gas tank holders, and safety brakes.

The extendable walking frame (V1) was difficult to adjust in length due to erratic telescopic motion. In V2, the existing solution was replaced with dry linear bearings and anodized aluminum shafts (incorporating a clearance fit), reducing friction and successfully allowing smooth length adjustments. Version 3 (V3) could incorporate the use of floating bearings to improve performance under frame misalignment. Floating bearings are used in the event of high parallelism deviations, especially significant in seated patient transport, as calculated in Chapter 3.1.7 (0.11°). Additionally, V3 should reconsider the use of (dry linear) bearings, as the current design poses cleaning challenges inside the bearing itself, addressed by the patient infection prevention department at MST. Furthermore, the bearing fixation plates (Figure 8, 1) should be fixated to uniform profiles, as the t-slot nuts inherently have play within the extrusion profiles by design, which affects alignment. This was an issue encountered during prototype construction.

The seat (V1) hindered the caregiver's ability to assist the patient effectively, as it required sliding the seat beyond the ECMOve's maximum width of 650 mm (see Materials and methods). In V2, the existing solution was replaced with a flexible seat design made of PP webbing topped with synthetic leather. The seat (V2) attaches to both sides of the walking frame with magnetic connectors, successfully allowing the seat to be placed anywhere on either side of the ECMOve without obstructing the caregiver. V3 should replace the current webbing with PVC or TPU-coated material to improve ease of cleaning and disinfection, as the existing webbing is porous. The magnetic connectors could also be redesigned to feature a single connector on each side, simplifying the current two-piece configuration. Additionally, the material of the magnetic connectors should be changed, as the current PA66GF30 is porous. V3 should reconsider the use of the current magnetic connectors as a whole, as the prototype construction took around 10 hours. Furthermore, a full finite element method (FEM) analysis is required to ensure safety and stability of the seat's seamlines.

The backrest (V1) hindered the caregiver's ability to assist the patient effectively, as it required sliding the backrest beyond the ECMOve's maximum width of 650 mm (see Materials and methods). In V2,

the existing solution was replaced with a dual-beam configuration, eliminating the need for any sliding mechanisms. The backrest (V2) successfully secures both sides of the frame with a rigid connection and prevents inward bending due to patient loading. V3 could replace the upper beam (patient's backrest) with a more ergonomic shape or cushioning to improve comfort.

In V1, the IV stand lacked telescoping capabilities and could not maintain sufficient hydrostatic pressure for gravity-fed IV bags. The patient's pushing handle was fixed in height, and the gas tank holders required lifting through the ambulatory cart's frame, which was physically impossible. In V2, the IV stand features telescopic adjustment, allowing control over medicine inflow. The pushing handle is adjustable in height, allowing ergonomic patient posture. The gas tank holders enable ergonomic (re)placement of medical oxygen tanks. For V3, the IV stand height should be reduced by 115 mm to avoid interference with hospital doors. The pushing handle's height should be increased by 100 mm for ergonomic 90° elbow joint bending. The gas tank holders should be raised by 100 – 200 mm to properly secure the tank.

The safety brakes (V1) cannot be operated by either the caregiver or the patient during seated patient transport. Additionally, the used braking poles rely on friction with the ground, and low friction results in a long braking distance, affecting patient safety. In V2, the existing solution was replaced with a dead man's braking system. The system uses Bowden cable distributors to engage the swiveling wheels' spring mechanisms, operable via both the patient's or caregiver's braking rod. The ECMOve stops immediately when the brakes are disengaged. Although a functional prototype could not be developed within this work due to delivery delays, V3 could enhance the design by incorporating an additional Bowden cable distributor to extend braking control to all three pushing handles.

Verification testing according to ISO standards demonstrated that the device met most strength and stability tests, with the exception of the patient's pushing handle. The handle failed to withstand the specified load requirements, highlighting a structural weakness that requires further design optimization. ECMOve V3 could introduce a push button activated hinge to solve this problem. This design features a high-strength locking pin that secures the hinge in place. Pressing a release button against spring force disengages the locking pin, allowing the hinge to rotate freely. This mechanism is similar to those used in baby stroller hinges. ECMOve V3 would benefit from aligning the device with more specific ISO standards, providing clearer guidance for design, testing, and certification, ensuring improved compliance. The initial- and sustained forces required for ECMOve manoeuvrability are far below specified standards, weight of ECMOve should therefore not pose a risk in the design. ECMOve V3's cleanability assessment, as outlined in ISO 17664-1, is partially addressed in this work but requires further refinement. Future work should include mapping global cleaning and disinfection protocols and possible implications.

Testing by stakeholders resulted in valuable (opinion-based) feedback. A key takeaway was adding mechanical ventilation to expand possible applications of ECMOve, making it more attractive to the market. Example of additional equipment required for mechanical ventilation include: Oxylog 3000 plus ventilator, Oxylog patient single limb circuit with CO_2 monitoring and integrated flow monitoring, Dräger HME TwinStar filter, connector for ventilation data monitoring, medical air tank (21% oxygen, 79% nitrogen) and relevant connectors, endotracheal tube (depending on type of mechanical ventilation), and a test lung for system verification. and making the ECMOve device customizable into various versions based on specific needs of the clinic.

Another key insight was that the ECMOve could be customized into various versions based on specific needs of the clinic. For instance, some clinics may opt for a version without a patient physical support module, choosing instead to use a Hill-Rom chair or similar for immediate patient support. It is important

to note that this configuration increases the susceptibility of the ECMOve to tipping, which increases the risk of ECMOve instability in the event of a patient fall or otherwise. This statement is supported by the test setup shown in Figure 37, where the tipping force with the walking frame extended is 35 kg, compared to 12 kg when it is retracted (similar to replacing the patient physical support module with a Hill-Rom chair).

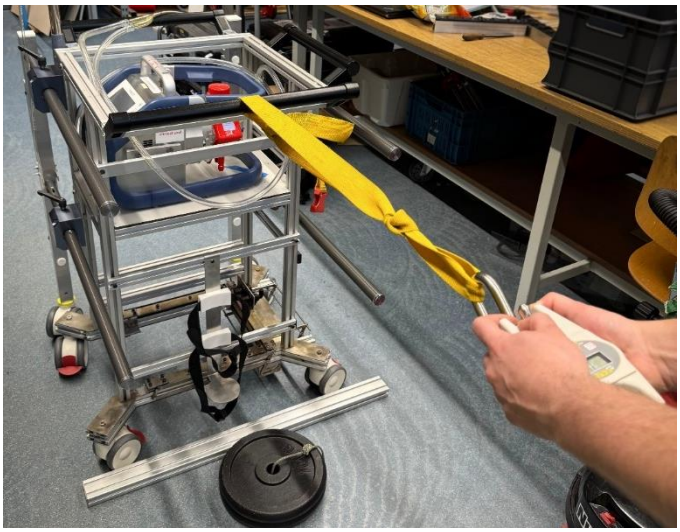

Figure 37: Test setup tipping forces ECMOve V1

In conclusion, the redesign (ECMOve V2) enables a single caregiver to independently operate the patient physical support module throughout the ambulatory ECMO process. Additionally, the ECMOve can be patient controlled during ambulatory ECMO, caregiver controlled in both configurations, and capable of moving only when initiated by the user. Compared to ECMOve V1, this redesign meets the specified user requirements. Overall, ECMOve V2 can be classified as TRL 4, provided the stationary cart is further optimized as well.

Future work should focus on addressing the device improvements outlined in this thesis. However, an ECMOve health technology assessment (HTA) is recommended first to evaluate clinical and cost-effectiveness, safety, real-world patient and caregiver experiences, and ethical considerations amongst others. This step is crucial for identifying potential barriers of bringing the device to the market and ensuring the device meets healthcare needs and regulatory requirements which might differ all around world. As feedback from testing by stakeholders came from clinicians who lack experience with (ambulatory) V-V ECMO, it is essential to consult specialized ECMO centers, such as those in Regensburg, to gather expert input and ensure the device meets the needs of specialized clinical settings. Additionally, it is proposed to develop tailored ISO standards for V-V ECMO patients, such as defining pre-determined tubing lengths based on the patient body profile and establishing patient strength requirements for safe ambulatory ECMO, potentially aligned with the Medical Research Council (MRC) muscle testing scale [35]. Future work outlined above is crucial to avoid unnecessary changes to ECMOve while identifying potential device improvements. Furthermore, prioritizing the cleanability assessment in the early stages of ECMOve V3 development is important, as designs that are difficult to clean/disinfect may be rejected. Lastly, incorporating mechanical ventilation into ECMOve V3 will enhance device's market potential.

5 Summary and Outlook

This work focused on advancing ECMOve V1 from TRL 3 to TRL 4, optimizing the device and bridging the gap between proof-of-concept and real-world clinical validation. Various components of ECMOve V1 were identified as needing improvement to meet the DRS and URS. Key optimizations made in ECMOve V2 include the extendable walking frame, seat, backrest, IV stand, pushing handle, gas tank holders, and safety brakes. Although ECMOve V2 improved usability, safety, and ergonomics compared to ECMOve V1, some components could require further refinement. Verification testing demonstrated that ECMOve V2 largely meets ISO standards for strength and stability, although the patient's pushing handle hinges failed the ISO-tests and therefore requires a redesign. Testing by stakeholders highlighted opportunities to expand ECMOve's capabilities, including the integration of mechanical ventilation and the development of customizable versions tailored to unique needs of different clinics. For example, future versions could include configurations where the patient physical support module is replaced with a Hill-Rom chair or similar. In conclusion, the primary objective of this thesis to advance ECMOve to TRL 4 by fully meeting URS is considered to be achieved.

Future development of ECMOve should prioritize improving cleanability of components by utilizing materials/surfaces that are easier to clean and disinfect. Additionally, an ECMOve HTA is recommended to evaluate clinical and cost-effectiveness, safety, real-world patient and caregiver experiences, and ethical considerations amongst others. Real-world patient and caregiver experience should be validated with expert input from specialized (ambulatory) V-V ECMO centers. Tailored ISO standards for ambulatory ECMO, including pre-determined tubing lengths and patient strength requirements, should be established as these characteristics remain unknown. Furthermore, expanding ECMOve's functionality to include mechanical ventilation would significantly increase its clinical applications and market attractiveness. Overall this work, together with the optimization of the stationary cart in a different study, act as a stepping stone towards advancing ECMOve to TRL 5.

6 Abbreviations

- ECMO: Extracorporeal membrane oxygenation
- ARDS: Acute respiratory distress syndrome
- VV: Veno-Venous
- VA: Veno-Arterial
- ICUAW: Intensive care unit acquired weakness
- ICU: Intensive care unit
- ECMOve V1: ECMOve version 1
- URS: User requirements
- TRL: Technology readiness level
- DRS: Design requirements
- FGI: Facility Guidelines Institute
- MDR: Medical device regulations
- RIA: Risk analysis
- CAD: Computer-Aided-Design
- SLS: Selective Laser Sintering
- PA: Polyamide
- IV: Intravenous
- FMEA: Failure mode effect analysis
- IPA: Isopropyl alcohol
- MST: Medisch spectrum Twente
- POM: Polyoxymethylene
- HB: Brinell Hardness
- PP: Polypropylene
- PVC: Polyvinylchloride
- TPU: Thermoplastic Polyurethane
- PA66GF30: Polyamide 66 30% glass fibre reinforced
- PEEK: Polyether Ether Ketone
- HTA: Health technology assessment
- MRC: Medical research council

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9 Annex

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9.2 Annex B – Calculations

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9.3 Annex C – Design Requirement Specification

See document attached

9.4 Annex D – Risk Analysis

See document attached

9.5 Annex E – Pre-concepts

See document attached

9.6 Annex F – Verification

See document attached

9.7 Annex G – Validation

See document attached

10 References

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