DESIGN HISTORY FILE
ROUND 3

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January 8 – May 1, 2024

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Project Background

Device Selection

The stair chair, also known as an evacuation chair, serves as a crucial medical device for Emergency Medical Service (EMS) responders, facilitating the safe transportation of patients across stairs. Its operation necessitates three users for maximum safety: two lift the device using the handles on either end, while the third serves as a spotter.[1] However, the physical demands for using the stair chair contribute significantly to EMS responder injuries, with overexertion and bodily reaction causing more than half of the 4,000 sprain and strain injuries recorded in 2020.[2] Although data does not directly implicate the stair chair, interviews and research highlight issues like lower back pain, ineffective handles, footing challenges, and patient instability. These underscore the urgent need for an ergonomic redesign to minimize risks and improve usability for EMS responders.

Physiological Needs

EMS responders transporting patients in stair chairs face significant physiological stresses that heighten the risk of various back injuries, such as muscle strain, ligament sprain, and stiff joints. Chronic back injuries can result in increased time off, elevated worker compensation costs, or potential permanent disability. This report specifically investigates EMS responders who develop an L5-S1 herniated disc due to spinal compression while lifting and transporting patients in stair chairs.[3]

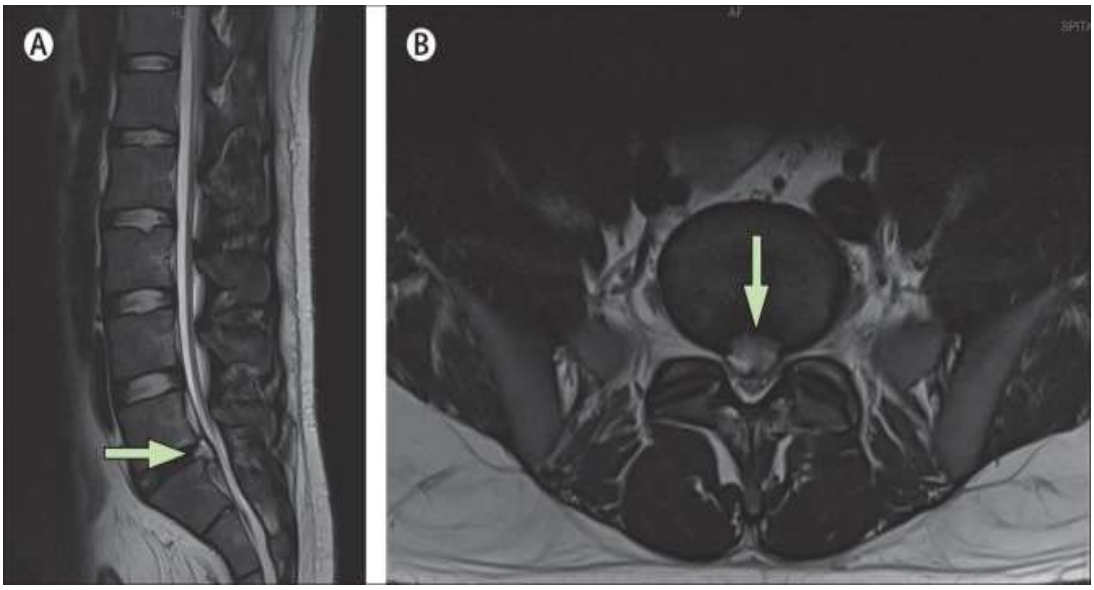


Figure 1. (A) Sagittal view of lumbar MRI, with arrow pointing to L5-S1 intervertebral disc. (B) Axial view showing L5-S1 herniated disc. Nucleus pushing through annulus, beyond intervertebral disc space.

The spinal canal consists of 33 stacked vertebrae, encompassing seven cervical, twelve thoracic, five lumbar, five sacral, and four coccygeal vertebrae.[4] Intervertebral discs positioned between each vertebra consist of cartilaginous structures and include the annulus fibrosus, a tough outer layer surrounding the nucleus pulposus.[2] These discs function as shock absorbers for the spinal bones and provide support for the anterior and posterior longitudinal ligaments.[4] Herniation of the lumbar disc occurs when the annulus tears or ruptures, displacing the nucleus beyond the intervertebral disc space (*Figure 1*).[5]

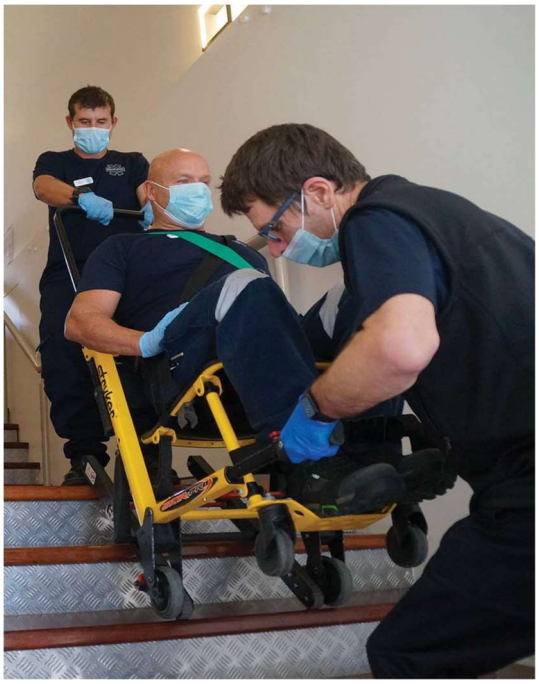


Figure 2. EMT to the right exhibits trunk flexion and spine rotation while lifting patient up the stairs using stair chair - example of unsafe motions that place increasing load on spine.

EMS responders who often use stair chairs perform repetitive actions. These actions include using incorrect lifting techniques, relying on back muscles instead of leg and thigh muscles, and twisting and turning while lifting (*Figure 2)*. In addition, a survey of EMS responders found that the handles of their stair chairs placed the responders very close to the patient's head and feet. Therefore, first responders lift with their hands extended from their body to prevent contact with the patient, rounding their back as a result.[6] These practices can potentially lead to herniated discs. The average spinal compression load on the L5-S1 intervertebral disc is greater than 3400 N for both the EMS responder positioned behind the patient and lifting forward (follower) and the EMS responder facing the patient and lifting backward on the stairs (leader).[7] The average shear loads are greater than 500 N for the follower and leader as well.[7] These loads exceed the recommended limits as calculated by the National Institute for Occupational Safety and Health Lifting Equation (NLE) and are the result of unsafe motions that exert additional pressure on the L5-S1 intervertebral disc, including trunk flexion and spine rotation (*Figure 3)*.[3,7] Additionally, cumulative spinal loading is observed in three dimensions: firstly, as the combined load from carrying and transferring a single patient; secondly, as the accumulated loads over a work shift; and thirdly, as the amassed loads throughout an EMS responder's career.[3] The repetitive use of the stair chair to transport patients incrementally builds the spinal load on an EMS responder, causing wear and tear on the annulus of the L5-S1 intervertebral disc and ultimately increasing the risk for a herniated disc.

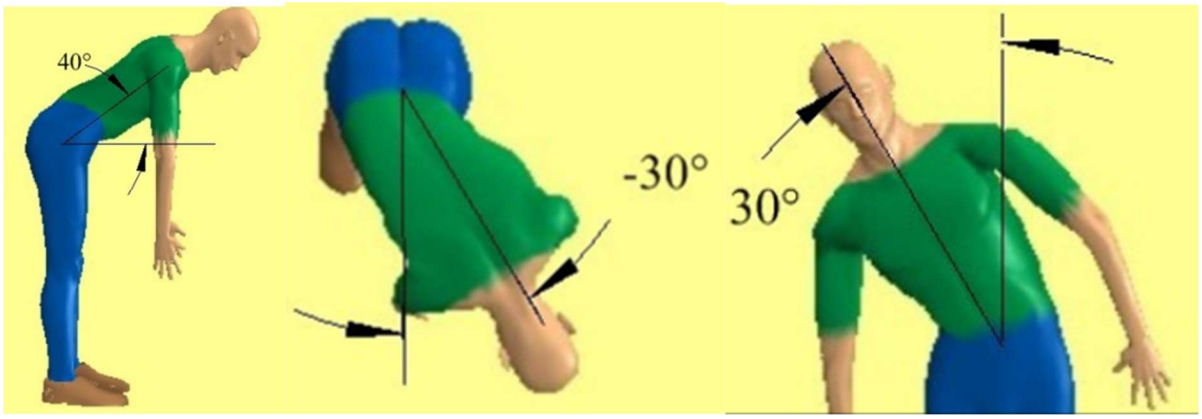


Figure 3. Images from 3D SSPP displaying trunk axial rotation, defined as the rotation of the torso around the axis created by the line extending from the L5-S1 disc to the center of the shoulders.

A logistic regression model considering factors such as lifting rate per hour, maximum load moment during lift, peak lateral bending velocity, amount of forward (sagittal) bending during the lift, and average twisting velocity, identified a 14.1% risk for low back disorder (LBD) among EMS responders lifting the stair chair as followers and 18.4% as leaders.[3] Moreover, 82.1% of EMS responders diagnosed with a low back disorder experienced a herniated disc.[7] Consequently, redesigning stair chairs to decrease spinal

compression and shear loads on the L5-S1 vertebral discs is imperative in preventing the heightened risk of herniated discs among EMS responders.

User Profile and Stakeholders

Various stakeholders involved in the design of the stair chair possess distinct motivations and perspectives regarding its desired features. The value of a redesigned stair chair for each stakeholder are outlined as follows:

(1) EMS Responders
EMS personnel are primary users as they routinely employ stair chairs to transport patients when faced with stairs, steps, or confined spaces. They would greatly benefit from an ergonomic device that not only efficiently transports patients but also minimizes the risk of injuries, such as herniated discs at the L5-S1 level, which may occur due to prolonged use.

(2) Patients
Another primary user group comprises non-ambulatory patients with non-life-threatening injuries, who often favor the comfort provided by a stair chair for accessing the ambulance over stretchers or backboards. Enhancements to the device would be of significant value to them, particularly in the form of a redesigned stair chair that safely and quickly transports them, thereby averting any potential worsening of their condition.

(3) Hospitals
Secondary users such as hospitals and other entities involved in patient care rely on the stair chair to swiftly and securely transport patients, aiming to prevent any potential complications in their condition. The value hospitals would derive from a redesigned stair chair lies in its ability to streamline patient transport processes, enhance safety measures, and minimize the risk of exacerbating patient conditions during transit.

(4) Locations with Multi-level Environments
Another secondary user group includes public or private locations with multi-level environments, as they may opt to invest in a stair chair to facilitate emergency evacuation protocols or ensure ease of access in situations where elevators are unavailable. The value they stand to receive from an ideal stair chair design lies in enhancing overall safety measures, ensuring compliance with accessibility regulations, and being better equipped to handle emergency situations effectively.

(5) Stair Chair Manufactures
The manufacturers of the stair chairs have a vested interest in the success of their product to generate profit and bear responsibility for negative consequences. A better final concept design would likely be popular and have a higher demand, providing additional revenue to the company.

User Needs and Unmet Needs

There are various essential user needs that are inherent in the usage of the stair chair. These include:

(1) Complies with safety standards, ensuring minimal risk to users and the environment.
The stair chair needs to be designed to avoid worsening injuries for seated patients and to eliminate the risk of injury to first responders during transport. The material chosen for manufacturing should be environmentally friendly and ensures no damage to property while navigating stairs or transporting the patient to the ambulance.

(2) Lightweight and durable for effortless transport, easy storage, and convenience.
The stair chair should be compact, allowing seamless storage within the limited space of an ambulance. Its lightweight design needs to facilitate easy transportation from the ambulance to the scene by one personnel, leaving others free to carry essential medical equipment. Once the patient

is secured, the chair should have minimal weight compared to the patient to reduce the load on EMS personnel. The chair needs to remain compact when expanded, enabling smooth navigation through enclosed hallways or stairs.

(3) **User-friendly, intuitive design with minimal training requirements.**
The stair chair prioritizes intuitive use for quick deployment in emergencies. Easy patient securing, transport, transfer to ambulance, and folding for storage should be seamlessly executed. These features ensure efficient patient transport to the hospital.

(4) **Simple maintenance, resilient to frequent use, and reliable after extended storage.**
The material used to manufacture the device should not be worn easily and be durable for frequent use. Whether stored in an ambulance or facility for an extended period without use, the stair chair needs to reliably function when needed.

(5) **Compatible with diverse stair configurations and suitable for various individuals.**
The stair chair needs to excel in ascending or descending patients across stairs with varying heights, depths, and materials (e.g. stone, carpet, wood steps). Additionally, it should accommodate diverse individuals, including bariatric, pediatric, and geriatric individuals.

While these needs are underlying requirements for the stair chair to function correctly, several critical needs were identified through conducting user interviews. These needs focus on the EMS personnel and inform the design inputs to engineer an improved device. The first need emphasizes the importance of ensuring that the patient remains seated perpendicular to the ground during transportation. This consideration stems from the potential for the patient's head to roll forward and backward when transported at an angle, increasing the risk for further injury or leading to a sense of insecurity. The second critical need centers on addressing the challenges posed during breaks in the transportation process. EMS personnel can encounter situations where the weight becomes burdensome, necessitating a quick break, personnel switch, or grip adjustment. To accommodate such scenarios, it is crucial to design the chair with the capability to be safely set on the stairs when needed. The third critical need revolves around the chair's handles, highlighting the importance of adjustable lengths and heights. This customization is essential to cater to the diverse range of users within the EMS community, ensuring that the chair is ergonomically suitable for all individuals involved in its operation. The fourth critical need incorporates a tread system that redistributes weight onto the stairs rather than on the EMS personnel. However, it is imperative for this system to be adaptable to various staircase configurations, ensuring versatility and effectiveness across different environments. The last critical need emphasizes the necessity of an easily deployable system for transporting the patient on flat ground, extending from the stairs or building to the ambulance. This feature should enhance the overall efficiency of patient transportation and seamless transition from steps to flat surfaces.

The needs identified for the EMS personnel using the current stair chair design highlight several deficiencies that are driving the motivation to prototype and redesign the device. Primarily, the lack of a mechanism to stabilize the chair on stairs is a significant issue. Furthermore, existing designs predominately feature only torso, waist, and leg straps for the patient, which although protective, allow for some patient movement, encouraging improper lifting techniques by the operators. Additionally, the absence of front wheels on the predicate device makes quick and safe transportation to the ambulance challenging, underscoring the necessity for a more efficient system for patient transport on flat ground. Lastly, while adjustable handles are present in front of the chair in many existing designs, the lack of adjustability in the handles located behind the chair hinders ergonomic lifting, which is crucial given the varying dimensions of users.

State of the Art/Prior Art

The Power 900 Evacuation Chair by EVAC+CHAIR stands as the gold standard in robust, single-operator transportation chairs designed for the evacuation of individuals over stairs. Featuring intuitive restraining straps, strategically placed handles, and a battery-powered track system, this chair ensures the stabilization of patients during evacuation (*Figure 4*).[8] The adjustable track system emphasizes the direct support of the evacuee's weight by the stairs rather than human muscle and ensuring smooth passage by sliding over at least two stair nosing's simultaneously.[9] While the gold standard model boasts a comfortable chair design and smart load balancing, it is characterized by its bulkiness, weight, and high cost. Through comprehensive research into existing designs, it becomes evident that certain components, such as durable design, are worth emulating, while others, including a large footprint and heavy weight, should be discarded. The team's focus on developing a compact and operator-safe design aligns with the goal of overcoming these existing shortcomings in stair chair technology.

Figure 4. EVAC+CHAIR Evacuation Chair Model Power 900.

Solution Uniqueness

In comparison to the currently marketed stair chairs, the team's solution places a stronger emphasis on improving the experience and safety of EMS responders. While the current standard of care prioritizes quick and safe patient transport, it often overlooks the potential risks of injury to EMS responders, particularly in terms of spinal health.

The team's solutions offer versatility by facilitating usage on both flat surfaces and stairs. Many existing stair chairs lack ease of use on either surface, which poses challenges for EMS responders during patient transport. To address this, proposed solutions include deployable wheels for flat surface use, ensuring stability during patient loading and unloading, along with a kickstand for momentary stabilization on stairs. Additionally, the solution enhances patient security through a five-point harness system, which better restrains the patient and prevents movement during transport. This not only improves patient safety but also helps distribute the force of the patient's weight more evenly between the EMS responders, reducing strain on their intervertebral discs. Finally, the added component of adjustable handles for the operator behind the chair enables ergonomic lifting by a diverse range of users. Overall, the solutions provided better adapt the stair chair to different situations while reducing the risk of spinal injury for EMS responders.

Problem Statement

Emergency Medical Service (EMS) personnel encountering stairs while transporting non-ambulatory patients need a device that safely and easily transports patients without increasing their risk for an L5-S1 herniated disc.

Design Process

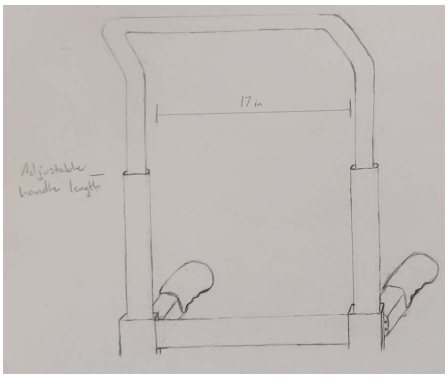
Concept Ideation

During round one, each team member engaged in rapid prototyping to explore one of the designated ideation prompts below.

(1) Various grip methods for the EMS responders on the stair chair.
(2) Comfortable design to encourage equal weight distribution between EMS responders.
(3) Improved methods for wheeling patients on flat surfaces.
(4) Methods to lower the force required by EMS responders to lift the chair.
(5) Methods to encourage minimal movement of the patient during transport.

Utilizing materials readily available, the team then aimed to produce prototypes closely resembling the most promising conceptual sketches previously developed. While most prototypes remained nonfunctional, they provided insights into proof of concept, allowing for discussions on handling, potential functionalities, and suitable materials. During rounds two and three, the team integrated user feedback to refine and iterate upon the most viable ideas identified during the initial prototyping phase. These ideas were evaluated against the detailed evaluation criteria provided in the next section.

The team has identified four influential prototypes that merit further discussion, refinement, and iteration. In round one, the first low fidelity prototype created includes vertically adjustable handles for the EMS personnel positioned behind the patient (*Figure 5)*.

(a) 

(b) 

Figure 5. Vertically adjustable handles for the EMS personnel positioned behind the patient. (A) Generated concept sketch. (B) Rapid prototype.

This feature is designed to accommodate varying heights and arm lengths among EMS personnel, enabling operators to set the handles at an optimal position for lifting. This adjustment helps minimize incorrect lifting techniques that can lead to increased strain on the L5-S1 intervertebral disc. A key constraint to consider is maintaining a back handle height range of 69.50-84.75 cm above ground level.[10] These values were determined by analyzing anthropometric data for the minimum and maximum heights from ground to wrist, as well as taking in the height of the device. The prototype, constructed using PVC pipes, features a curved handle design with adjustable height. Although the prototype is not permanently affixed to the device, testing confirmed that the handles could be adjusted within a range of 35.56 cm. However, a drawback of this design is the absence of a locking mechanism to prevent the handles from sliding freely. An iteration of this prototype was developed with a different handle design (*Figure 6)*.

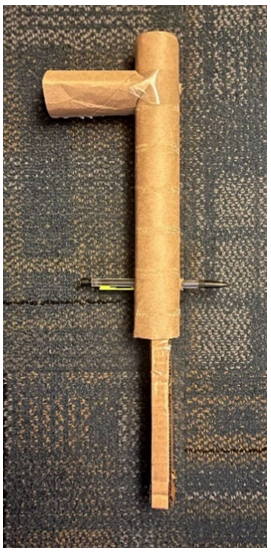
(a)  (b) 

Figure 6. Vertically adjustable handles for the EMS personnel positioned behind the patient, iteration two. (A) Minimum height. (B) Maximum height.

The second iteration of the device features handles like the existing device and includes the ability to adjust within a 32.2 cm range. Constructed from cardboard, this iteration lacks the structural integrity to support heavy weights. In addition, a pencil was used to act as a locking mechanism to prevent the handles from sliding freely.

Both prototypes are look-like models to test proof of concept. Engineering analyses revealed that varying handlebar placements affect weight distribution among the top and bottom EMS personnel operating the stair chair, suggesting that this concept may offer a viable solution to the stated problem.

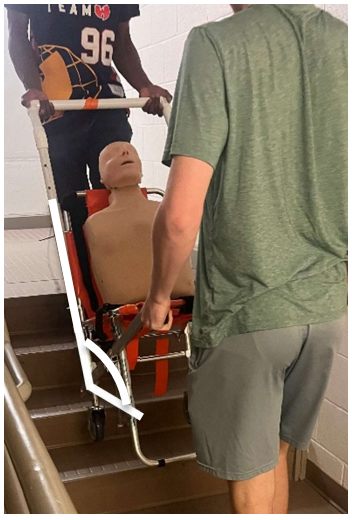
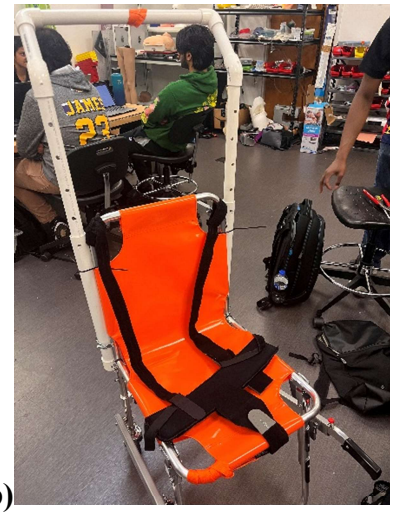
(a)  (b)  (c) 

Figure 7. Vertically adjustable handles for the EMS personnel positioned behind the patient, iteration three. (A) Testing shows increased angle of device relative to ground. (B) Maximum height. (C) Minimum Height.

Through consulting with an EMT, the team recognized the importance of incorporating adjustable handles. However, no further feedback was provided beyond the need to cater to the diverse range of users in the EMS community. Therefore, in the second round, a third prototype resembling the first iteration was

developed, with holes drilled along the PVC pipe's length to facilitate adjustable length and a locking mechanism using a pin (*Figure 7).* This iteration was secured onto the device using zip ties. However, during iterative testing, it was noted that while the prototype extended a range of 35.56 cm, increasing the handle length vertically led to an undesirable tilt of the chair relative to the ground, making it challenging to maintain perpendicularity – a critical design input. Additionally, the PVC pipes proved insufficient in supporting the maximum load of the predicate device. Consequently, in the third round, the team prototyped vertically adjustable handles with metal components. While this design could not support the maximum load, the team was able to perform verification testing.

The second concept prototyped during round 1 includes the five-point harness, an improved patient restraint system (*Figure 8).*

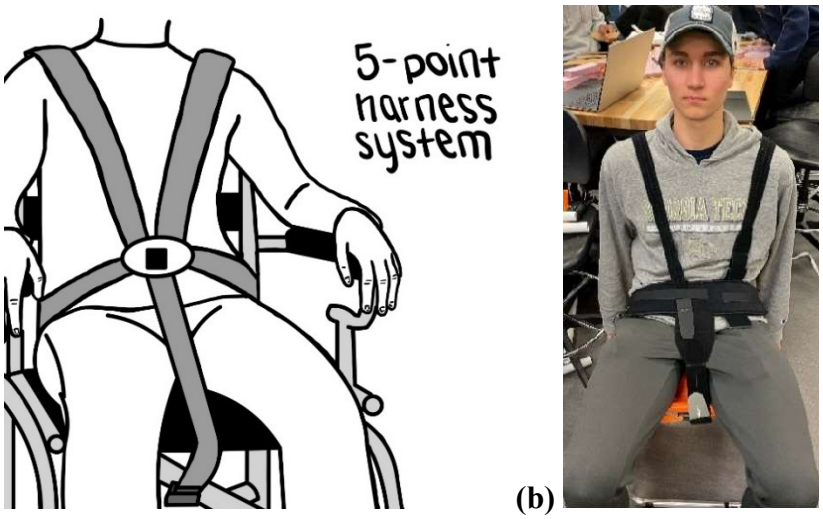


Figure 8. Five-point harness. (A) Generated concept sketch. (B) Rapid prototype.

An engineering analysis comparing minimal (0 degrees) and maximal (50 degrees) patient spinal flexion revealed that patient movement lead to varying weight distributions on EMS personnel operating the device, prompting the development of a concept to restrain patient movement.[11] Constraints to consider include maintaining patient spinal flexion close to 0 degrees while ensuring patient safety without aggravating existing injuries. Additionally, the new restraint system should streamline the patient strapping process, aiming for a quicker time than the existing system (26.37 seconds).

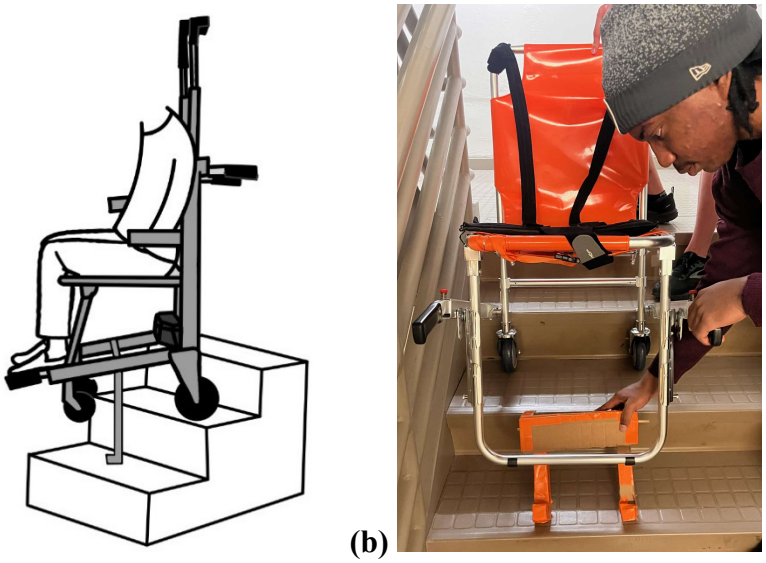
The mid-fidelity prototype, utilizing Velcro straps and a lap cushion to create a 5-point harness that tightens near the waist, serves as a functional prototype. Testing indicated that the seated user experienced minimal spinal flexion. However, the non-adjustable straps designed for a taller individual may offer smaller users excessive mobility. On average, it took 20.91 seconds to secure the patient.

User feedback acknowledged the simplicity and potential effectiveness of the harness but suggested including leg straps for EMT protection in case of combative patients. In response, the team developed a second and final iteration (*Figure 9)*. This version incorporates torso straps, one with Velcro and one with a buckle, along with waist and leg buckle straps. The over the shoulder strap system showed minimal spinal

Figure 9. Five-point harness, iteration two.

flexion across various user heights, but the average time to secure the user increased to 62 seconds compared to 32 seconds with the predicate device. This trade off was anticipated, and from both user input and the team's intuition, the decision was made to prioritize security.

The third concept designed during round one of the prototyping phase is a kickstand to allow EMS personnel to rest the device against the stairs during transportation (*Figure 10)*.



(a) **(b)**

Figure 10. Kickstand to enable device to rest on stairs. (A) Generated concept sketch. (B) Rapid prototype.

Through user interviews, a critical user need emerged: the ability to take breaks while ascending or descending stairs while lifting patients. These breaks are essential when EMS personnel feel the weight has become too burdensome and need to switch personnel or adjust their grip. Without a feature allowing the device to rest momentarily against the staircase, EMS personnel may strain to lift all the way across the stairs, potentially leading to incorrect lifting techniques and increased compression and shear loads on the L5-S1 disc. This need led to the concept of the kickstand design. Constraints to consider include designing a structure capable of supporting upwards of 1500 N, as calculated through an engineering analysis. Additionally, the international residential stair riser code typically requires a height of around 7.75 inches, while commercial stair heights can vary between 4 and 7 inches. The kickstand should be designed to accommodate stair heights of 7.25 inches, with a variability range of half an inch.

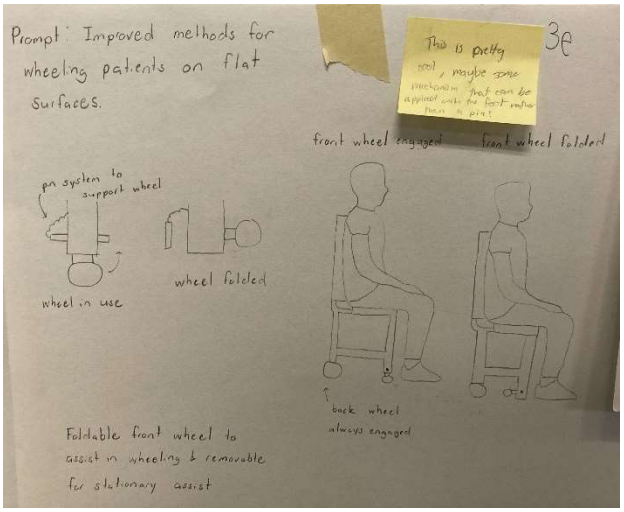
Figure 11. Kickstand to enable device to rest on stairs, iteration two.

The first prototype, constructed from cardboard and pink foam, lacks structural integrity. However, testing confirmed that the kickstand will not protrude from the stair chair, as it features 105-degree rotational ability when not in use. During the second round, an iteration was developed using PVC pipes, wood, and duct tape (*Figure 11)*. The kickstand successfully rotated 105 degrees again, meeting the required

height of 8 inches to keep the chair upright when deployed. However, the prototype failed to support the weight of the chair due to inadequate attachment to the device. Further testing revealed that relying on a single hinge for kickstand rotation compromised stability.

Feedback from users was positive regarding the concept, but concerns were raised about the chair's stability on stairs and in situations involving combative patients, where both patients and EMS personnel are at risk of injury. Due to the time restraint for prototyping, the team did not move forward with the kickstand in the final design concept. However, given more time, future iterations of the kickstand will prioritize stability by incorporating two hinges and a locking mechanism to improve the rotating function and prevent unintended movement.

The final influential prototype designed during round one includes a deployable front wheel system (*Figure 12)*.

(a) 

(b) 

Figure 12. Front wheel system. (A) Generated concept sketch. (B) Rapid prototype.

The current device lacks front wheels, making it challenging to transport patients safely and efficiently on flat surfaces. EMS professionals positioned behind the patient must tilt the chair to wheel it to the ambulance. Through interaction with the device and user interviews, the team identified that this action places strain on EMS responders due to trunk flexion and spinal rotation, thus increasing their risk for an L5-S1 herniated disc. This observation led to a design concept centered around a deployable front wheel system. Constraints include ensuring that the wheels can support the weight of the chair and the maximum weight of the patient that the existing chair can hold (227 kg).[12]

The prototype was constructed using pink foam, with the rotational capabilities achieved using a skewer. An engineering analysis determined that each wheel must support a maximum force of 750 N. Through testing of the low-fidelity prototype, the team discovered that the optimal angle for the wheels while deployed is -90 degrees, and while not in use is 90 degrees, with 0 degrees representing the positive x-axis. This demonstrates the two locking positions for the wheels, providing stability during transport and patient loading onto the ambulance. The prototype currently deploys to -93 degrees, which is not ideal. User feedback emphasized the importance of verifying and ensuring that the wheels securely lock in place, preventing the device from rolling away.

During round two, the team designed a front wheel system with a long PVC pipe and two swiveling rubber wheels. However, the wheels could not retract full, leading to instability when placing a load. Therefore, in

round three, the team integrated the wheels into the frame of the design and utilized a braking mechanism rather than a pivot system for locking the wheels in place.

While all four prototypes offer creative solutions to the stated problem, the team must conduct further evaluation based on the criteria identified in the next section and gather user feedback to refine the ideation space and develop a high-fidelity functional prototype. The attached DEEM table provides a detailed analysis of each prototype created in round one and two for reference. In addition, a thread was created to visualize the series of multiple generations of designs (*See Appendix A).*

Concept Evaluation

During the initial creation phase, the team generated five concept sketches for each identified ideation prompt, resulting in 25 concept sketches. However, the team opted to select four concepts for prototyping. The selection was made by first narrowing down the pool of sketches from 25 to 7, based on feedback received from peers and instructors. This external perspective allowed the team to uncover aspects of the designs that might have been overlooked, potentially hindering the functionality or benefiting from incorporation into the final design. The final four sketches were chosen based on evaluation criteria, primarily utilizing a Pugh matrix to compare the benefit versus effort of each concept (*See Appendix B)*. Benefit was primarily assessed by considering the value brought to users through pursuing the idea. Effort, on the other hand, was determined by factors such as the potential time and resources required to bring the idea to fruition, such as time spent on prototyping, the scale of the prototype, and the price of commonly found materials (e.g. pink foam, cardboard, etc.), among others. Following the selection of concepts, the team proceeded with rapid prototyping and evaluated the prototypes using a different set of criteria.

The evaluation criteria used to refine and iterate prototypes encompassed several key aspects:

(1) Benefit to the User
This criterion was analyzed through various means. Firstly, direct user feedback was obtained by consulting with an EMT who provided insights into the advantages and disadvantages of each prototype concept. The EMT also identified key aspects of the design essential to operating the stair chair missed in the initial prototypes. This feedback informed the designs of further iterations. Additionally, the team assessed whether each concept would effectively reduce compression and shear loads on the L5-S1 disc, primarily through engineering analyses. To validate these theoretical analyses, the team plans to utilize 3D SSPP in verification testing to determine the effectiveness of the prototypes.

(2) Benefit to Other Stakeholders
This aspect was analyzed through research and conceptual thinking. Questions such as whether hospitals and companies with multi-level buildings would invest in the design for their evacuation protocols, or how the design might affect patient comfort and injuries, were considered. Moreover, the team evaluated whether manufacturers could easily produce the design and if there was potential for profit. Answering these questions helped assess the value the design brought to other users and stakeholders.

(3) Simplicity of Design
The team evaluated whether the design and future iterations could be easily prototyped, balancing benefit against effort. The team also considered whether the design was intuitive to operators, recognizing that a bulkier and complicated design could result in lower efficiency and slower deployment, whereas a simple design would enable smoother and faster deployment, crucial in emergency situations.

(4) Iterative Testing
Simple testing procedures were performed to verify the proof of concept for each iteration and prototype. The team evaluated whether the design inputs were met. This initial testing provided a

basic understanding of whether the prototype was viable for further modifications and deeper testing, as outlined in the verification protocol.

By considering these evaluation criteria, the team ensured that the prototypes were not only effective in addressing the needs of users but also feasible for production and implementation, with potential benefits for various stakeholders.

Verification Testing

(1) Patient Restraint System

Testing Objective and Purpose
During testing, the primary objective was to assess whether the prototyped patient restraint system effectively minimizes patient spinal flexion compared to the existing system on the predicate device. Additionally, the efficiency of the prototyped device in terms of the time required to strap the patient in was evaluated against that of the predicate device.

Required Materials
The materials necessary for conducting verification testing included a stopwatch for timing the efficiency of the system and a tape measurer for measuring the patient's spinal flexion.

Experimental Procedure
The detailed procedure below outlines the methods for data collection. Before each trial, the team educated the users on both the prototyped and existing strap system.

(1) The system starts in a buckled state, with the following straps engaged:
    a. lap belt with airplane harness
    b. Velcro connectors
    c. upper body compression band with plastic buckle
    d. leg stabilizing band with plastic buckle
(2) Start the stopwatch when the participant (acting as EMS personnel) begins to unbuckle the straps.
(3) Instruct another participant (acting as patient) to sit down on the chair.
(4) Have the EMS personnel secure the patient in the chair with all the straps and stop the stopwatch when the EMS personnel is finished.
(5) With the straps still engaged, instruct the patient to lean forward and measure the distance from the back of the chair to the base of the patient's neck.
(6) Record the time and length, then repeat steps 1-5.
(7) Ask the users to switch positions, and repeat steps 1-6.
(8) Repeat for strap system on predicate device.
(9) Repeat for 5 pairs of participants.

Sample Size
To verify the effectiveness of the tests, the team conducted 10 trials with 5 pairs of participants acting as EMS personnel and patients, each pair performing the tests two times. 10 trials will still be significant to observe a difference between the prototyped and predicate devices.

Collected Data
The team gathered data on the time required to secure both the prototyped and existing restraint systems. Additionally, the team recorded the distance from the back of the stair chair to the base of the seated participant's neck during maximum spinal flexion. Displayed are tables organizing the data for both systems.

Prototyped Device Setup Time (min:sec)

	Pair 1	Pair 2	Pair 3	Pair 4	Pair 5	Pair 6	Pair 7	Pair 8	Pair 9	Pair 10
1	1:34.90	1:32.84	47.93	1:07.63	1:21.82	1:27.94	1:41.55	0:43.50	0:52.37	1:03.73
2	1:03.65	1:18.17	0:43.52	1:05.83	0:56.82	1:12.82	1:01.76	0:48.97	0:40.45	0:54.41
Avg	01:19	01:26	0:46	01:07	01:10	01:20	01:22	0:47	0:46	0:59
Total Avg	01:02									

Prototyped Device Separation Distance (in)

	Pair 1	Pair 2	Pair 3	Pair 4	Pair 5	Pair 6	Pair 7	Pair 8	Pair 9	Pair 10
1	2 ¾	1 ½	1 ¼	1 ⅜	1 ⅝	4 ⅛	½	⅛	½	1 ¾
2	⅞	1 ⅞	2 ⅛	1 ⅞	1 ¼	2 1/8	¾	¼	⅛	1 ⅛
Avg	1.8125	1.6875	1.6875	1.625	1.4375	3.125	0.625	0.1875	0.3125	1.4375
Total Avg	1.39									

Predicate Device Setup Time (min:sec)

	Pair 1	Pair 2	Pair 3	Pair 4	Pair 5	Pair 6	Pair 7	Pair 8	Pair 9	Pair 10
1	0:38.20	0:32.44	0:24.72	0:35.13	0:48.63	0:34.32	0:31.65	0:27.60	0:29.82	0:24.78
2	0:32.05	0:30.84	0:28.57	0:39.74	0:31.69	0:40.03	0:26.53	0:23.80	0:30.99	0:25.71
Avg	0:35.0	0:31.5	0:27.0	0:37.5	0:40.5	0:37.0	0:29.5	0:26.0	0:30.5	0:25.5
Total Avg	0:32.00									

Predicate Device Separation Distance

Trial	Pair 1	Pair 2	Pair 3	Pair 4	Pair 5	Pair 6	Pair 7	Pair 8	Pair 9	Pair 10
1	2 15/16	5 3/4	6 ¼	12 ⅝	4 ¾	5 ¾	3 ¾	¼	3 ⅜	9
2	4 1/8	7 3/4	4	10 ⅛	4 ½	5 ½	2 1/16	¼	3 ½	13 ¼
Avg	3.53125	6.75	5.125	11.375	4.625	5.625	2.90625	0.25	3.4375	11.125
Total Avg	5.475									

Data and Statistical Analysis

Efficiency and security ratings were calculated for both the setup time and movement distance. The setup time efficiency was calculated by dividing the average time taken to strap the patient using the prototyped device by the average time taken using the predicate device. The security rating was calculated by dividing the average movement distance of a patient secured by the prototyped device by the average movement distance of the patient in the predicate device. A value less than one indicates success, while a value greater than one indicates failure. This provides a clear visual indicator to assess whether the prototyped designs

meets or exceeds the required standard. Setup Efficiency has 20% weight, and Security Score has 80% of the weight towards success.

A t test was preformed between the average strap in time for the predicate device vs the average strap in time for the prototype. Another t test was preformed between the average separation distance with predicate straps vs the average separation distance with the prototype straps. These tests gave a p value which represents if there was a significant difference between the two strap types. An alpha of 0.95 was used meaning, a p value less than 0.05 represents statistical significance. A t test was chosen to verify that the results were not just by chance, but instead represented an overall trend in the data.

Interpretation of Results

Predicate baseline

	Strap Time(s)	Separation(in)
Mean	32	5.48
Standard Deviation	5.25	3.51

Gen 2 prototype

	Strap Time(s)	Separation(in)
Mean	62	1.39
Standard Deviation	15.8	0.74

Statistical Analysis

- **Strap Time ->** p value of 0.000013
- **Separation ->** p value of 0.0016

The results for setup up efficiency was a score of 1.93:1, meaning the prototype was 1.93 times less efficient than the predicate device. The average setup time for the predicate device was 32 seconds while the prototype's average setup time was 62 seconds. The standard deviations represent how different the results were from the first trial to the second. The prototype had a much higher standard deviation for the strap time at 15.8 seconds. This shows that the participants significantly decreased the strap in time once they had some experience using it. This is promising as an EMT will be using the device many times and will become proficient at using it. For this reason, it is expected that their strap in time will continually decrease over time and trend towards some of the faster times like the 45 second average that 3 participants were around. For the separation results, a lower standard deviation is desired. This means that the straps offer consistent security, and the patients will not be able to move much. The prototype had a very small deviation of 0.74 inches throughout the testing which represents how consistent the results are with different size patients. While the predicate had a much higher standard deviation at 3.51 inches meaning that different size patients had wide varying security. The tradeoff between setup time and security can be seen in the results for the security score. The result for the security score was 0.25:1 meaning the prototype system was four times more secure than the predicate strap system. There was a higher emphasis put on keeping the patient secure, reflected in the total score's weights. The prototype earned a score of 0.59:1, which represents that overall, the prototype straps outperformed the predicate device.

The statistical t test performed gave a p value of 0.000013 for the strap times. This means the results achieved between the predicate device and prototype were very different. The same can also be said about the separation tests. The t test preformed between the predicate and prototype for the separation was 0.0016. Both tests are far below the required 0.05 p value that represents statistical significance. This can be attributed to the differences in focus for both the predicate device and the prototype. The predicate was optimized for speed and lacked the security needed to keep the patient and EMT's safe. While the team's prototype focused on keeping the patient secure and had to compromise the strap in speed.

Roadblocks that occurred during the testing procedure mainly came from instances of improper strapping. Taller patients had much more spinal flexion and discomfort from the frame when being strapped in with the predicate device as the straps went under their rib cage. The prototype handled the taller fine, but very small patients presented some difficulties as the straps could not tighten completely around them. There was also some confusion at times on what straps to use despite the demonstration before trials. The team thinks that numbering straps or color coding could be used to solve this issue. One last roadblock that was noticed was difficulty in tightening straps. This occurred since some straps tightened one way while others tightened in the opposite direction. This problem could be mitigated by having all the straps tightened in the same direction. Overall, the roadblocks were there, but the predicate device had more issues than the prototype so once again the prototype was a better design.

(2) Vertically Adjustable Handles

Testing Objective and Purpose
For the vertically adjustable handles, the objective of testing is to analyze whether the compression load on the L5-S1 intervertebral disc varies for users of varying heights at each handle setting. The results of this testing will inform whether having adjustable handles for the user lifting behind the patient is an ergonomic design.

Required Materials
The materials needed for testing the vertically adjustable handles include a weigh scale and tape measurer to measure the height and weight of the user. A video camera and protractor will also be useful to record the lifting movements to determine posture and joint angles to input in 3D SSPP to analyze the compression load on the L4-L5 intervertebral disc.

Experimental Procedure
The detailed procedure below outlines the methods for data collection.

1) Measure the height and weight of each user.
2) Calculate the load to be lifted.
3) Using a video camera, record the flexion or extension of the top user's elbow joint as they lift the stair chair.
4) Using a protractor and video analysis, estimate the joint angle.
5) Orient the posture of the user on 3D SSPP and input the height, weight, and lifting load.
6) Record the compression forces on the L4-L5 intervertebral disc from 3D SSPP.
7) Repeat for each handle setting on the prototyped device.
8) Repeat for second user.

Other design components include: (1) having a third person act as the bottom EMS personnel lifting the chair for all trials, (2) having a mannequin simulate added lifting weight, (3) estimating top EMS personnel's lifting load from engineering analysis, and (4) assuming the compression load on the L4-L5 intervertebral disc is comparable to the load on the L5-S1 disc.

Sample Size
A sample size of 2 will be utilized for preliminary verification testing, and the standard of reference will be the predicate device's handle height. While a larger sample size drawn from the EMS population would offer greater representation, testing with 2 users will serve as a valuable initial step. This approach allows for preliminary assessment and sets the groundwork for future iterations and more extensive testing, particularly with high-fidelity prototypes.

Collected Data
The following table contains the data recorded.

Compression Loads on L4-L5 Intervertebral Disc

Name	Height	Weight	0”	2”	4”	6”	8”
Avanti	5’ 3”	113 lbs	165 N	140 N	110 N	95 N	75 N
Ryan	6’ 3”	170 lbs	130 N	110 N	120 N	175 N	120 N
Lifting Load	12.3 lbs						

Data Analysis

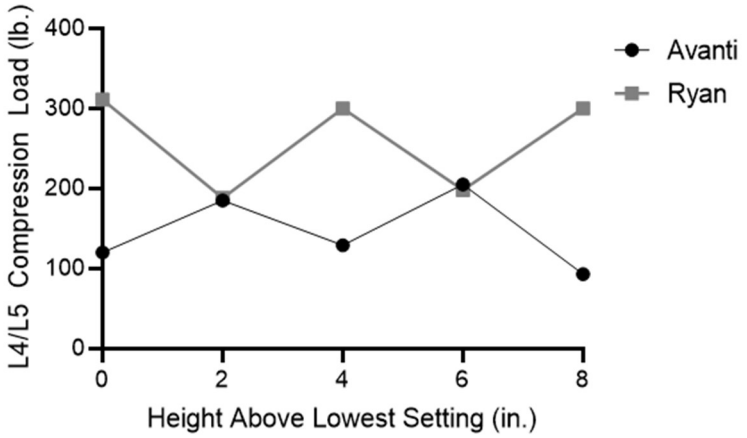


Figure 13. Graphed results from Verification Testing for Vertically Adjustable Handles

Compression forces on the L4-L5 intervertebral disc were graphed on a line chart to visualize the differences in loads between the two users for each handle setting (*Figure 13*). A standard T-test was used to compare the significance between the two groups. The null hypothesis states that the true difference between the compression load for two users of significant height difference is zero, while the alternate hypothesis suggests a difference exists. The p value calculated was 0.0110, suggesting a significant difference.

Interpretation of Results

Considering that users possess diverse heights, their distinct body proportions and ergonomic preferences will inevitably lead to varying compression loads on the lower back. Consequently, it is logical that there exists a significant difference in compression loads at each handle setting for users with differing heights. Therefore, in pursuit of potentially mitigating strain on the lower back when using the device, the adjustable handles in the prototype aim to cater to users’ individual anthropometric characteristics, particularly height, with the goal of enhancing user comfort and minimizing the likelihood of an L5-S1 herniated disc.

However, the observed difference is less significant than expected, particularly regarding the compression loads measured at 2 inches above the lowest setting, where both users exhibited similar loads. Notably, this setting corresponds to the height of the handles on the predicate device. This discrepancy could be attributed to the small sample size and potential testing inaccuracies. A sample size of two lacks reliability in generating conclusive results. Moreover, the testing methodology was simplified by solely focusing on measuring the flexion and extension angles of the elbow joint. Adopting a more comprehensive approach, involving the measurement of multiple body segment angles including limbs, trunk, and head angles, would improve the assessment of posture in 3D SSPP. Precise angle measurements would mitigate estimation errors inherent in posture determination, leading to more accurate calculations of compression loads.

Nevertheless, lower compression loads were observed for settings other than those of the predicate device, suggesting that adjustable handles have the potential to alleviate strain by enabling users to customize their grip for optimal comfort.

(3) Front Wheel System

Testing Objective and Purpose
For the front wheel system, the only testing objective is to record the time needed to deploy the front wheels. This relates to the user interface aspect of the design inputs, which state that the deploy time for the stair chair should be done by one person in under ten seconds. By recording the time needed to deploy the front wheel system, the design can be tested to ensure it is quickly deployed, reducing transport times for the EMS responder.

Required Materials
The required materials for the testing include a stopwatch, allowing the recording of the time needed to deploy the front wheel system. This ensures that the time is recorded as a quantitative value and allows for various test metrics to be completed with the collected data.

Experimental Procedures
To collect data about the time needed to deploy the wheels, the following procedure will be followed:

1) Find an individual to test the ideation by simulating the deployment of the wheels. If the individual is unfamiliar with stair chairs, explain the purpose of stair chairs and how they function. However, do not explain how to use the front wheel system ideation.
2) Have another individual sit in the chair to simulate a patient being transported. Ensure the same individual acts as the patient for all trials.
3) Tell the individual to deploy the front wheels without explaining how to complete this task. Provide the individual with time to analyze the design with and without the patient present. This will ensure that EMS responders who may not be unfamiliar with the design and who do not have time to research the design and intuitively understand how to deploy the wheels.
4) Once the individual is ready to start, begin the stopwatch and record the time for the individual to deploy the front wheel system, stopping the stopwatch once the front wheel system is properly deployed. Record the time needed for this to occur.
5) Repeat Step 4 now that the individual testing the design better understands it. Additionally, explain the design and the thought process behind the design to the individual for greater understanding. Answer all questions the individual has and explain how the design should function, if needed. Ensure the wheels are not deployed before the trial begins.
6) Repeat Step 1 through Step 5 at least five times with different individual each time. Ensure the data is recorded properly throughout the samples.

Sample Size
The sample size will be ten, as ten different individuals are tested to see the deploy times. Most individuals who test the model will be Georgia Tech students, causing the sample population to be different than the intended population, which are EMS responders. However, the testing will provide important insights into how quickly the device can be deployed by those who have not worked with stair chairs in the past, compared to EMS responders who have likely been educated on and worked with stair chairs.

There will be two trials for each volunteer. One trial will be completed by the individual with no prior knowledge of the design, and the other will be completed after the individual better understands the design. This will allow comparison between the deployment times for each volunteer and provide information about the deployment time for the entire sample.

Collected Data

The only data collected for the testing includes the individual's name, first deployment time, second deployment time, and observations.

Volunteer Name	Initial Deployment Time (s)	Final Deployment Time (s)
Colten	11.41	6.40
Shaq	10.25	7.18
Ryan	11.91	7.40
Marc	19.31	8.51
Avanti	10.80	12.91
Ameris	12.13	9.07
Andre	15.23	7.31
Sam	10.75	7.98
Emma	11.86	8.91
Maxi	14.34	8.31

Data Analysis

There is a noticeable difference between the values of the initial and final deployment times for most volunteers. The statistics of the data are shown in the following table.

	Initial Deployment	Final Deployment
Mean	12.799 s	8.398 s
Standard Deviation	2.7773 s	1.7926 s
Degrees of Freedom	9	9
One Sample T-test (assumes hypothetical mean of 10 s)	3.1870	2.8260
Mean Confidence Interval (95%)	10.8123 s to 14.7857 s	7.1156 s to 9.6804 s
One-sided p-value	0.00553	0.0099

Using the data provided, a paired t-test was conducted to analyze the significance of instructing users on how to deploy the wheels. The results can be found in the following table.

	Value
Paired t-test	4.0345
One-sided p-value	0.0015

The one-sample t–test was used to compare the sample mean to the hypothetical mean of 10 seconds. The corresponding design input was that the deployment time of the front wheel system should be under 10 seconds. This was used to compare the data to the design input to ensure the verification tests meet the design inputs proposed for the prototype.

Using a paired t-test was appropriate for the data due to the testing's purpose. The verification testing was conducted to analyze the difference between the initial and final deployment times for the front wheel system due to exposure to how the prototype works and an explanation of how the prototype can best be used. Using a one-sided p-value was also appropriate as the verification testing looked to analyze the decrease in means between the initial and final deployment times. Other statistics were done to measure the average and variation of the data, with the mean and standard deviation of both samples used to portray the data.

Interpretation of Results

The results show that the iteration upheld the proposed design input of maintaining a deployment time of under 10 seconds. For a user's first interaction with the iteration, the mean time of deployment was greater than 12 seconds. Although the design input specified 10 seconds, this deployment time was due to the users' first interaction with the device with no explanation of how to use the device. However, after interaction with the iteration and an explanation of the best way to use the iteration, most users were able to reduce the time it took to deploy the front wheel system significantly, resulting in a final deployment time of 8.3 seconds. The difference between the means was approximately 4.5 seconds, showing a noticeable decrease in deployment time. Additionally, the final deployment time mean was lower than the design input of 10 seconds, showing the iteration was able to uphold the design inputs.

The one-sample t-test for the initial deployment showed that there was a significant difference between the mean deployment time and hypothetical deployment time of 10 seconds, seen in the low p-value. Additionally, a 95% confidence interval from 10.8123 seconds to 14.7857 seconds was calculated. Because 10 seconds was not included in the confidence interval, this further proves the significance of the data. This shows that the data was significantly different from the design input for deployment time, and it can be concluded that the initial deployment time was greater than the needed hypothetical deployment time.

Contrary to the initial deployment time, the final deployment time was lower than the necessary design input of 10 seconds. Shown in both the confidence interval from 7.1156 seconds to 9.6804 seconds, which is lower than the hypothetical mean of 10 seconds, and the low one-sided p-value of 0.0099 seconds, there is a significant difference between the hypothetical mean and final deployment time. It can be concluded that the final deployment time is lower than the hypothetical mean of 10 seconds. Overall, this proves that instructing individuals on how to use the front wheel prototype or allowing individuals to gain experience using the prototype allows for the mean deployment time to be under 10 seconds, satisfying the corresponding design input.

The standard deviation decreased, showing less variability in data as users understood how to properly use the iteration. The standard deviation for the initial deployment time had more variability as some users were able to understand the iteration through initial observations, but others took longer to understand and first interacted with the device before understanding it. Additionally, the paired t-test resulted in a p-value of 0.0015, allowing a null hypothesis stating "There is no impact to instructing users on how to use the iteration on the deployment time" to be rejected. Therefore, an alternative hypothesis stating "There will be a decrease in the deployment time for users who become informed on the iteration function and deployment" was proposed.

Users in the samples were students in BMED 2310 at the Georgia Institute of Technology, meaning they had little experience interacting with stair chairs. The intended users are EMS responders, who likely have experience with stair chairs. Therefore, the deployment time will likely be lower for the EMS responders compared to the students at Georgia Tech. Ideal verification testing would be completed with EMS responders to ensure the user group is able to meet the design inputs proposed.

One observation from the testing was that taller individuals were less likely to deploy the front wheel system with their hands and opted to use their feet to engage the brake. Additionally, other users mentioned the smaller braking mechanism on the wheel was harder to engage with their foot. Therefore, a final iteration would have the same sized wheel but a larger braking mechanism for easier deployment. Increasing the size of the wheel would likely cause the patient to be transported at a greater angle than desired. Therefore, increasing the size and usability of the braking mechanism would solve most of the problems that arose during the verification testing and likely decrease the deployment time further.

Validation Plan

(1) Patient Restraint System

Testing Objective and Purpose
The goal of strap validation testing will be to make sure the strap system secures the patient so that the EMT's will not experience the excessive moments and forces that unstable movements create.

Required Materials
The materials necessary for conducting validation include the stair chair, basic strap system, production strap system, ten pairs of former or current EMT's, ten patient participants varying in size, and force sensors.

Experimental Procedure
The detailed procedure below outlines the methods for data collection.

(1) A participant is placed on the chair and is strapped in tightly in the same way a patient would be.
(2) The chair is suspended in the air by force sensors connected to each of the four handles. Two EMS responders lift the chair by holding the other end of the force sensors with both hands.
(3) The patient participant's legs, arms, and body are then moved as much as the straps will allow in four positions: standard, forward, left, and right.
(4) Force measurements on each handle during each position are recorded in a table.
(5) The process above is first done with basic straps, and then done with the production straps.
(6) The pair of EMTs will perform two trials with their corresponding patient participant at each position.
(7) A different EMT pair and different patient will then be tested using the protocol above until all ten patient sizes are tested.

Sample Size
To verify the effectiveness of the tests, two trials with each patient's body size will be completed which equals a sample size of 20 samples per strap system. Detailed documentation will be recorded including procedures, pictures of positions, variations, and force outputs. Using ten pairs of EMS responders would result in 20 EMS responders being surveyed and providing input on the strap system design. This will allow for more feedback and input on the overall design and allow for any possible improvements to be made.

Data Collected
The collected data will likely be expressed in a table like the following made for each patient size.

	EMS Responder Pair	Relevant Patient size Information	Basic strap force distribution (N)	Production strap force distribution (N)	Observations	EMS Responder Feedback
Trial 1			LL= LR= UL= UR=	LL= LR= UL= UR=		
Trial 2			LL= LR= UL= UR=	LL= LR= UL= UR=		

The table above shows how the data from the procedures will be collected, from the EMS responder relevant information to the recorded forces on each handle. From there, relevant statistics can be calculated from the forces, trends can be noticed based on size inputs and possible improvements to the strap system can be made from the observations and EMS responder feedback.

Potential Roadblocks

One potential roadblock to collecting data would be an overall increase in fatigue if the trials for each EMS responder pair are conducted without rest time. This would likely result in unstable force measurements. Another potential roadblock would be varying force measurements. To combat this, the maximum force experience by each handle will be the recorded value.

Data Analysis

To analyze the data, the standard deviation for the force exerted on each handle between different body positions will be calculated. This will be done for both the basic strap and the production model. Additionally, t-tests will be completed comparing the basic strap to the production model. Trends in the data can be modeled to give standardized force requirements at each EMT position needed to lift patients. This will give EMTs a better understanding of how much force they will have to input to lift patients.

Interpretation of Results

The standard deviation will give an idea of how much the forces will range at each handle while a patient is being carried over the stairs. This will be useful to know for the EMTs as there will be an expected force distribution. Keeping the distribution as close to even between the left and right handles is the goal. The distribution between the top and bottom EMT would also ideally be even, but most likely the top EMT will have more load to carry. Keeping the loads even will reduce excessive forces on one EMT's spine. The t-test and subsequent calculated p-values allow for an analysis to determine if there is a significant difference between the basic straps and the production ones. If there is a significant difference between the straps, then the production design is likely working better.

Other qualitative data can be analyzed to determine if user needs are properly met. From the EMS responder relevant information and feedback, possible conclusions can be drawn about the size of responders and the issues that arise with their different dimensions. Observations about the challenges that come with patient movement or a patient's size will also be made. Those conducting the validation testing that can then improve the design and safety of the EMT's based on what is observed.

(2) Vertically Adjustable Handles

Testing Objective and Purpose
An earlier identified unmet user need highlighted the lack of adjustability in handles positioned behind the chair, which prevented accommodating the diverse range of users within the EMS community to their comfort. Therefore, the primary objective of validation testing is to ascertain whether the handle height range will indeed cater to the wide spectrum of EMS users.

Required Materials
The materials needed for testing the vertically adjustable handles include a weight scale and tape measurer to measure the height and weight of the user. A video camera will also be useful to record the lifting movements to determine posture and calculate joint angles through video analysis. Finally, a computer will be needed to run 3D SSPP to analyze the compression load on the L4-L5 intervertebral disc.

Experimental Procedure
1. Calculate the load to be lifted based on the user's weight and the desired weight to be lifted.
2. Measure the height and weight of the user.
3. Place optical markers strategically on the user's body to aid in measuring body segment angles during lifting.
4. Instruct the user to lift from the top position at a comfortable handle height.
5. Record the lifting motion of the user using a video camera.
6. Utilize video analysis to calculate the joint angles during the lifting motion.
7. Input the user's posture, height, weight, and lifting load into the 3D SSPP software.
8. Record the compression forces on the L4-L5 intervertebral disc as calculated by the 3D SSPP.
9. Repeat two more times.
10. Repeat the process for the handle setting at the predicate device level.
11. Repeat the entire procedure for all users in the study group.

Sample Size
Validation testing will be with a sample size of at least 100 randomly picked EMS personnel to better represent the EMS population. A sample size this large leads to better estimates because it reduces sampling error, improves representation, and boosts statistical power.

Collected Data
Data for validation testing of the vertically adjustable handles will be as follows.

			Compression Load (N)	
User	**Height (feet)**	**Weight (lb)**	**Avg New Device**	**Avg Predicate Device**

Potential Roadblocks
One potential challenge in validation testing is the difficulty in obtaining a sufficiently large sample size that accurately represents the diverse population of EMS professionals. With approximately one million licensed EMS professionals in the United States, operating in various environments, capturing this diversity can be complex. Factors such as the height of stairs can significantly influence where an EMS professional positions the handles during lifting tasks.[2] For example, suburban homes may have higher step heights compared to commercial buildings in urban areas, which adhere to standard stair codes. These variations in environmental factors can greatly impact the effectiveness of the final design of adjustable handles in catering to the ergonomic needs of EMS personnel.

Data Analysis
Compression forces on the L5-S1 intervertebral disc will be graphed on a grouped bar chart to visualize the differences between the prototyped and predicate devices. A paired T-test will be used to compare the significance between the two groups. The null hypothesis states that the true difference between the prototyped device and predicate device is zero, while the alternate hypothesis suggests a difference exists.

To interpret the results, if the null hypothesis holds true, the alternate hypothesis will be rejected, indicating no significant difference in compression loads on the L5-S1 interverbal disc between EMS personnel using the prototyped adjustable handles and the set handle height in the predicate device. Conversely, if the alternate hypothesis is confirmed, the null hypothesis will be rejected, concluding a significant difference.

Interpretation of Results
If the statistical test indicates a significant difference in compression loads between users lifting with the final device compared to the predicate device, the team can infer that the final device better addresses the user needs by accommodating a diverse range of users with an ergonomic design to reduce lower back strain. Conversely, if the statistical test does not reveal a significant difference, it suggests the new handle design may not effectively cater to most EMS responders.

(3) Front Wheel System

Testing Objective and Purpose
Testing the front wheel system would involve analyzing the change in time and EMS responder exertion when using the front wheel system and when using the predicate device. For the two user needs of having an intuitive design and being compatible with various individuals and stairs, testing on the front wheel system can be used to determine if these needs are met. Previously unmet needs involving ease of transport on flat surfaces can be explored during this validation testing.

Required Materials
The required materials include both the predicate device, final design, and a stopwatch. This will allow for the recording of time for the EMS responders to transport a patient a set distance with both stair chair designs, so a comparison can be made.

Experimental Procedure
To collect data about the users' interactions with the stair chair, the following procedures will be followed:

1) Select one individual to act as the patient for all trials. Then, select two current or former EMS responders to act as a pair and transport the patient. Instruct the EMS responders on a route using flat hallways and stairs and provide directions on where to go.
2) Instruct the EMS responder pair to first transport the patient along a specified route using the predicate device. Before the trial begins, ensure the patient is secured to the chair with the provided restraint system. Start the stopwatch once the EMS responders begin the transport.
3) Record the time it takes the EMS responders to complete the route and place the patient and chair in a specified area. Have the patient and EMS responders return to the start of the route.
4) Secure the patient to the newly designed stair chair and allow the EMS responders to observe and interact with the front wheel system before transporting the patient.
5) Start the stopwatch and record the time it takes the EMS responders to transport the patient to the ending location on the route using the newly designed chair. Record any observations and question the EMS responders about any noticeable changes in their exertion between the two designs.
6) For a third time, reset the trial by bringing the final design stair chair, patient, and EMS responders to the beginning of the route. This time, instruct the EMS responders on any possible improvements

to their methods of transporting the patient using the front wheel system. Repeat Step 5 now that the EMS responders understand the design better.

7) Repeat Steps 1-5 for at least ten pairs of EMS responders. Allow EMS responders to switch positions between top and bottom carrier if desired.

Sample Size

There will be at least ten pairs of EMS responders used in the validation testing. This will allow for a range of EMS responder sizes to be tested. Additionally, it will allow for more possible variation in data to be expressed and allow the sample data to be more representative of the overall population. By including more EMS responders in the sample, the data becomes more representative of all EMS responders who frequently interact with stair chairs. Using ten pairs of EMS responders would result in 20 EMS responders being surveyed and providing input on the front wheel system design. This will allow for more feedback and input on the overall design and allow for any possible improvements to be made.

Collected Data

The collected data will likely be expressed in a table like the following:

EMS Responder Pair	**Relevant Information**	**Predicate Device Transport Time (s)**	**Initial New Device Design Transport Time (s)**	**Final New Device Design Transport Time (s)**	**Observations**	**EMS Responder Feedback**

The table above shows how the data from the procedures will be collected, from the EMS responder relevant information to the recorded times from transporting the patient along the designated route. From there, relevant statistics can be calculated from the recorded times, and possible improvements to the front wheel system can be made from the observations and EMS responder feedback.

Potential Roadblocks

One potential roadblock to collecting data would an overall increase in fatigue if the trials for each EMS responder pair are conducted without rest time. This would likely result in slower times for each consecutive trial compared to fully rested participants. Another potential roadblock would be possible damage to both the predicate device and the new design if used for all trials. This could possibly delay future trials and cause previous trials to be invalid if a new chair is used for subsequent trials. Therefore, the chair should be tested for stability through verification testing before the validation testing is conducted.

Data Analysis

To analyze the data, the mean time for all recorded times, including the predicate device transport time, initial new device design transport time, and final new device design transport time, can be compared to analyze possible differences. Additionally, one-sample t-tests can be completed for each recorded time. Between the initial and final new device design transport times, a two-sample paired t-test can also be conducted to analyze the reduction of time because of explaining the front wheel system if needed. Overall, various tests can be done to analyze the quantitative data collected from the recorded transport times.

Interpretation of Results

The one-sample t-test and subsequent calculated p-values allow for an analysis to determine if there is a significant difference between the recorded mean and hypothetical mean. Using the mean from the predicate device transport time in the initial and final new device design transport time one-sample t-tests as a hypothetical mean will allow the evaluation if the new device design is statistically significant in reducing transport times. This can be done by calculating a subsequent p-value from the one-sample t-tests and seeing how low the value is compared to a set alpha value. Additionally, the two-sample paired t-test can be used to determine if instructing the EMS responders on how to use the device is necessary. If there is a significant difference between the initial and final recorded transport times, then the design is likely not intuitive and fails to satisfy the user needs proposed.

Other qualitative data can be analyzed to determine if user needs are properly met. From the EMS responder relevant information and feedback, possible conclusions can be drawn about the responder and the issues that arise. From this, conclusions can be drawn about EMS responder size and possible issues about the transport process. Observations about the transport made from those conducting the validation testing can also be used to improve the design or improve the efficiency of the transport process using the front wheels.

Final Design Concept & Justification

Figure 14. Final Design in Fusion 360

The ultimate design concept incorporates vertically adjustable handles, a front wheel system, and restraining straps seamlessly into the stair chair's structure *(Figure 14)*. The adjustable handles cater to a diverse range of user heights within the EMS community, ensuring enhanced usability. The front wheel system facilitates smooth ground transportation, while the restraining straps effectively limit patient movement, thereby minimizing potential strain on users caused by irregular weight distribution. Extensive engineering analyses, iterative testing, and verification have validated that the final prototype surpasses the predicate device in ergonomic design and meeting unmet user needs. This enhancement promises significant benefits to users and stakeholders, primarily by mitigating the risk of L5-S1 herniated discs. Please refer to the Fusion file for more renderings and close views of the final design.

Business Case

Regulatory Pathway

The FDA defines the stair chair as a Class I device that is 510(k) exempt[16]. The title of the medical device category is "Stretcher, Hand-Carried".[13] Due to the stair chair being low-risk and having substantially equivalent predicate devices on the market, it does not require pre-market approval. Additionally, the device category is 510(k) exempt, allowing manufacturers to bypass the 510(k)-submission process, demonstrating similarity to another legally marketed predicate device. There is not a de novo pathway due to the number of currently existing predicate devices for all medical devices in the hand-carrier stretcher category.[13]

Figure 12. The Stryker Evacuation Chair Model 6254.[20]

One currently approved predicate device is the Stryker Evacuation Chair Model 6254 (*Figure 12*).[14] The only regulations of the final design concepts involve the safety of the patient being transported. This includes a range of final inputs, such as proper restraints for the patient, lack of sharp or protruding edges on the chair, and ability to transport the patient safe and stable. Additionally, the chair must have handles with a high resistance to prevent the chair from slipping out of EMS responders' grip and be sturdy to prevent collapse during transport of the patient. A search into the testing procedures of the product code yielded no applicable results. A registration number was found and searched in the Code of Federal Regulations Title 21, Volume 8. This yielded a section for identification, explaining the medical devices in the category, and classification, listing the device as exempt from premarket notification procedures and good manufacturing practice requirements.[13]

The final design proposed combining the three prototypes into one chair will meet the FDA requirements. Ensuring the front wheel system and adjustable handles are secure and will not break easily, these prototypes will not impact the patient's safety and only result in increased comfortability of transport for the EMS responders. The only change in safety and security for the transported patient is a result of the added five-point harness. The new harness system will increase the patient's safety by preventing excessive movement of the patient during transport.

Additional verification and validation testing will likely be done to ensure the safety of the device for FDA regulations. This involves testing the deflection of the adjustable handles and front wheels to ensure they do not bend more than necessary during transport. Additionally, ensuring all prototype additions to the stair chair can support the maximum patient weight are necessary to guarantee the safety of the patient during transport. Overall, testing must be done to ensure that the prototype additions to the stair chair are able to support the weight and not break during transport. Testing must also be done for the patient restraint system to ensure it can fit around different patient sizes while still providing the necessary safety to the patient. Testing all prototypes with a range of patient sizes and weights, as well as ensuring the prototypes are built sturdily to prevent breakage during transport are necessary to gain FDA approval for the new device.

Manufacturing Plan

To produce each stair chair, a variety of techniques will be used to shape the parts and attach them together. One technique that will be used frequently is computer numerical control (CNC) machining.[15] This type of machining automates the control of the machining processes, including forming, drilling, and overall shaping. The stair chair frame will be made from an aluminum alloy already shaped into hollow tubes. From there, holes will be drilled to support the screws and rivets that will be attached to the frame, and the tubes will be bent to match the designated shape required for the chair. Additionally, the aluminum tubes will be ordered longer than necessary, so they will be cut using the same processes. Overall, the CNC machining will reduce the labor costs and improve overall efficiency in creating the frame.

In addition to the CNC machining, injection molding will be used to create the seat cover for the frame. The seat is made from waterproof polyvinyl chloride (PVC), which can be bought as plastic pellets that can be melted for use in plastic injection molding.[16] The plastic injection molding will press the melted PVC into sheets, which can be cut into the required pieces. From there, the zipper can be attached to the cut seat piece and an industrial sewing machine will be used to join the seat pieces together around the frame. Other materials shown in the bill of materials (Appendix C) will likely be added once the overall frame and seat cover are completed. These pieces will likely be added by hand by workers with various tools, such as power drills.

Injection molding will also be used to create the rubber handles used by the EMS responders to better grip the chair. Instead of PVC being used like the seat cover, the injection molding will use rubber to mold in the handle shape. Once molded, the rubber will likely be cut to match the desired size. While straps will likely be bought already stitched, they will be cut to the desired length using cutting machines. These processes allow the outsourced materials to be changed to match the desired specifications for the stair chair design.

Standard Operating Procedures

1. Ambulance stair chairs will be stowed on a rack inside of the ambulance.
2. Residential and commercial stair chairs will have a home near the stairway and be in view for ease of use.
3. The stair chair will be unfolded by separating the top of the chair from the bottom until it has reached its locking position.
4. The stair chair will then be rolled or carried to the location of the non-ambulatory person
5. Each of the straps that are buckled together will be unbuckled and cast to the side so the patient can be put in the chair.
6. The patient, if able, will move into the chair's sitting position; if unable, they will be picked up and placed on the seat.
7. The shoulder straps will be placed over the patient’s shoulder, the lap buckle fastened, midsection strap clicked into place, and the leg strap buckled to secure the patient.
8. Each strap will then be tightened to the point where the patient is securely fastened.
9. The vertical handles will then be adjusted and locked into place for the top EMT so that while standing their arms can be locked out in the down position and their back not bent.
10. The bottom EMT will extend the lower handles to give room between the patient’s legs and their carrying position.

11. The chair will then be rolled on flat surface by the top EMT until the stairs are reached.
12. The bottom EMT will then assume position of the bottom handles and the top his handles.
13. Both EMT's will lift the patient so that the chair is perpendicular to the stairs.
14. The EMT's will then descend the stairs until the bottom is reached.
15. The patient will then be placed down slowly and the bottom EMT will retract his handles.
16. The top EMT will then roll the patient out of the building to the ambulance or location of interest.
17. The patient will then be unstrapped and taken out of the chair.
18. The straps will be reengaged, and the chair folded back up and returned to its original location.

Go-to-Market Strategy

To get the device to market, it would require both investments and time. First, the stair chair design must be registered with the FDA. Because the stair chair is a Class I medical device and is 510(k) exempt, it will likely take one to three months to gain approval from the FDA. This would be done after completing the verification and validation testing that must be done to prove the safety of the device. The testing could take up to five months to complete, resulting in a time of at most eight months before the device is ready to market.

The users, both private buyers and possible ambulance companies, would likely get access to the device through online sales. There are currently no relevant reimbursement codes for this device. Because the device is not likely to be bought by the public, having online sales with a few in-person locations would limit costs of renting locations to sell and allow for ease of distribution to the desired locations. Additionally, advertising would likely be conducted once FDA approval is granted, allowing users to gain awareness of the device and improvements over the predicate device. There are few environmental consequences for the production and distribution of medical devices. The environmental consequences include greenhouse gas emissions from transporting raw materials and completed devices, and the use of plastic for the seat cover would result in additional waste. Overall, the consequences for creating the device do not outweigh the benefits in providing the stair chair to users.

The main selling point of this stair chair and the reason why consumers would purchase this model as opposed to other models is the investment in comfortability and prolonged spinal health. Over 4,000 sprain and strain injuries sustained by EMS responders in 2020, half of which were connected to overexertion and bodily reaction.[2] EMS responders are always looking for new ways to limit bodily exertion throughout their shift to conserve energy and maintain their own safety. This device was designed with those needs in mind, as the chair's key features were generated in conjunction with constant feedback from current EMS responders. That feedback, along with particular and precise engineering has led to a device that is the most ergonomically and functionally suitable for respondents. EMS responders will appreciate that extra care and will advocate for these chairs in their department.

FDA approval of a class 1 medical device typically takes less than 90 days (about 3 months). The submission process would require paying an initial annual registration fee, which for the fiscal year 2024 is $7,653.[17] The device manufacturer would then need to submit the device and manufacturer information to the FDA for approval, which could take anywhere from a week to a few months depending on the speed of the FDA, as well as any potential concerns. Once approval is granted, initial manufacturing

would be outsourced to save both time and money. Average manufacturing cost in the United States range between $100 to $150 per hour.[18] These rates would be subject to change depending on the independent rates of the manufacturer. Average production time would be between 30 to 60 days, with an additional 15-day sample period to ensure that both parties approve of the product before production.[19] To meet a goal of 10,000 units ready for market release, under the assumption that the manufacturer can hit a manufacturing rate of 20 units per hour, this would bring the cost of outsourcing to anywhere between $50,000 to $75,000. The bill of materials for the chair itself was calculated to be approximately $320. This included the cost of aluminum tubing, stainless steel, harness system, and wheels. At 10,000 units, this brings the cost of materials to $3,200,000. This presents a high-end initial go-to-market cost of $3,282,653 before storage and distribution expenses. The per unit cost on this scale is $328.65, taking around 165 days (about 5 and a half months) to go from initial concept to shipping.

For the stair chair industry, there is an estimated total addressable market (TAM) of $5.60 billion dollars. This number was calculated from first estimating the number of fire departments in urban areas. This was calculated from discovering that 27,000 fire departments in the U.S. serve 274 million people in urban or suburban areas.[20,21] From this, about 10,000 people are served per fire department, which was scaled up to 4.5 billion people in urban areas worldwide, to find that there are about 450,000 fire departments in the world.[21] Fire departments were used for the TAM calculation because fire trucks are typically the first to arrive at a scene, allowing the calculation for the maximum number of stair chairs that can be bought by first responders.

Additionally, the number of non-ambulatory individuals were used to determine the maximum number of private buyers for the stair chairs. There were found to be about 2.3 billion households in the world.[22] From there, it was assumed that there are only approximately 5% of households that have two or more stories (estimated from there being around 30% of households in the U.S. being two or more stories).[23] Also, about seven percent of these households would require a stair chair due to non-ambulatory individuals and 84% of households around the world do not have an elevator.[24] Therefore, by filtering the number of households by those that are two more stories, have non-ambulatory individuals present, and have no elevator, the number of users would be 6.76 million. Additionally, it was assumed that there would be 250 thousand non-residential buildings that would require a stair chair. Overall, there are approximately 7.46 million users who would buy a stair chair. Sold at a cost of $750, the TAM would equal $5.60 billion.

The serviceable addressable market (SAM) was estimated using the number of ambulances instead of fire departments as ambulances would be the typical buyers for stair chairs. There are approximately 21,000 people served per ambulance in the U.S., and with approximately 1.2 billion people present in developed countries, there are approximately 57,100 ambulances that would purchase a stair chair.[25] Additionally, assuming only five percent of buildings, households or non-residential, would purchase a stair chair, this leaves a total number of buildings that would purchase a stair chair of 350,600. The five percent value of buildings was estimated due to those who would live alone or use other methods to move on stairs, such as stair lifts. Overall, selling these chairs for a price of $750 would result in a SAM of $305 million.

Finally, the serviceable obtainable market (SOM) was calculated using a market share of ten percent for buildings and five percent for ambulances. Due to the new design of the stair chair, it would likely be

popular with ambulances, resulting in a market share of five percent for ambulances. Additionally, there is not a saturated market for stair chairs in buildings and private buyers. Therefore, advertising to these users would allow for greater sales and a larger market share. Assuming these market shares are obtained, the SOM would result in a value of $28.4 million dollars.

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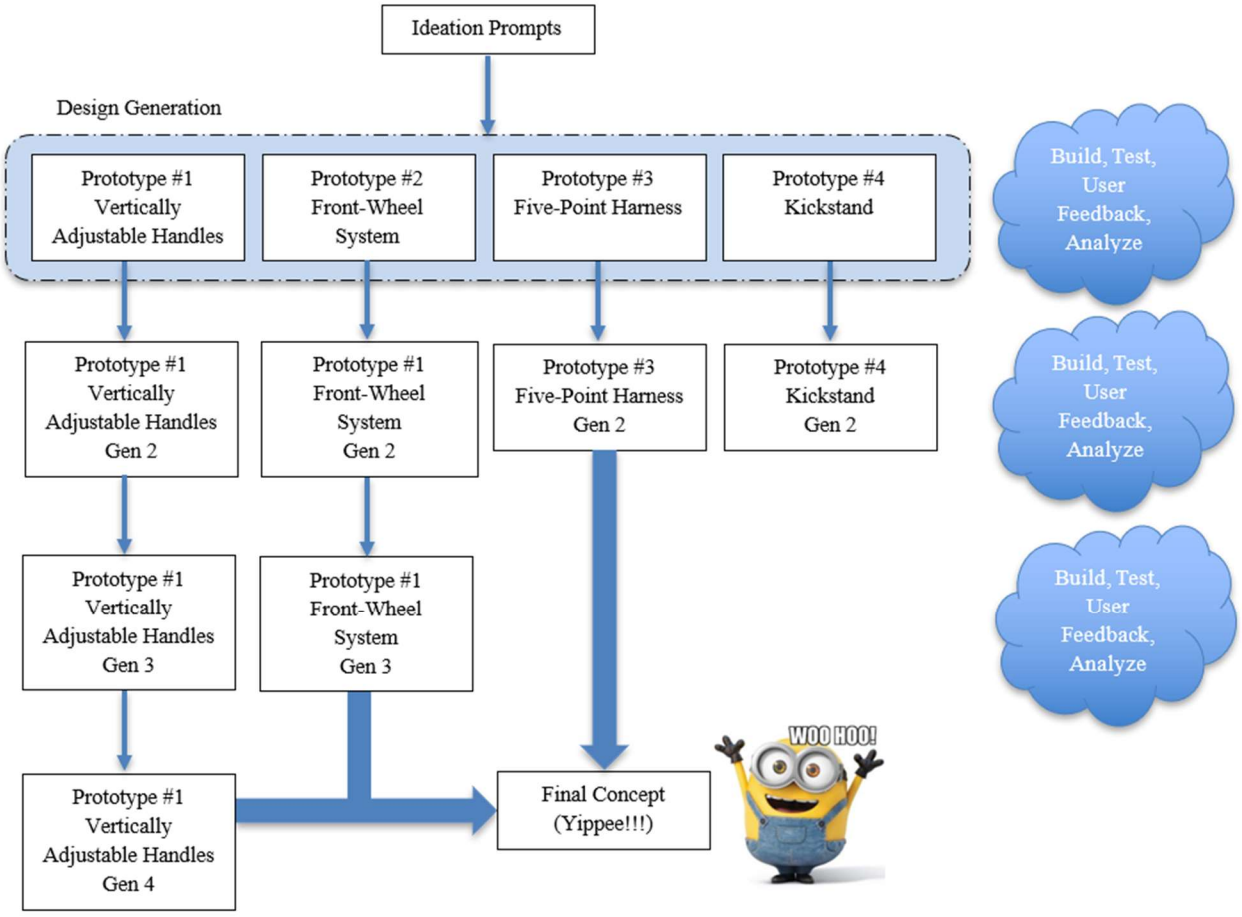
Appendix A

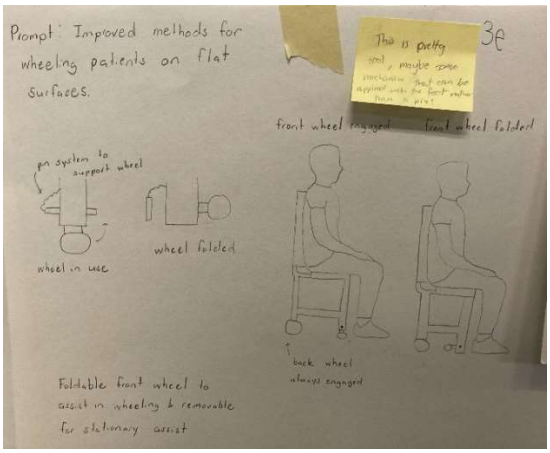

Ideation Prompts
Design Generation
Prototype #1 Vertically Adjustable Handles
Prototype #2 Front-Wheel System
Prototype #3 Five-Point Harness
Prototype #4 Kickstand
Build, Test, User Feedback, Analyze
Prototype #1 Vertically Adjustable Handles Gen 2
Prototype #1 Front-Wheel System Gen 2
Prototype #3 Five-Point Harness Gen 2
Prototype #4 Kickstand Gen 2
Build, Test, User Feedback, Analyze
Prototype #1 Vertically Adjustable Handles Gen 3
Prototype #1 Front-Wheel System Gen 3
Build, Test, User Feedback, Analyze
Prototype #1 Vertically Adjustable Handles Gen 4
Final Concept (Yippee!!!)
WOO HOO!

Appendix B

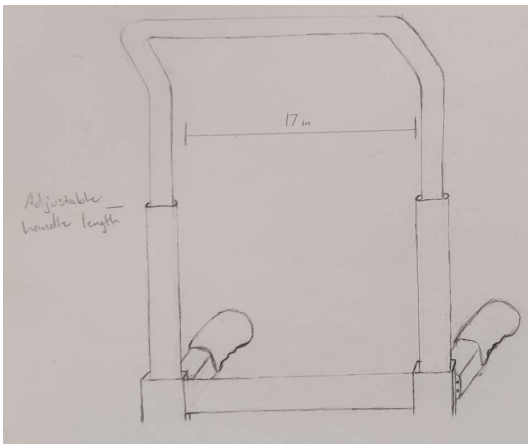
Pugh Matrix

The table below outlines the criteria evaluated for the top 7 concepts sketches generated to determine the promising ideas to move forward in prototyping.

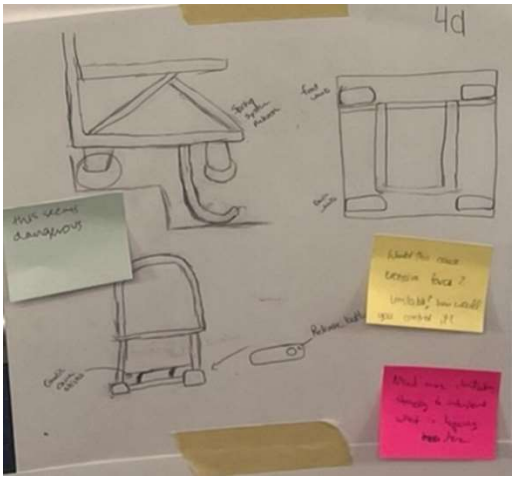
		Concept Sketches						
Criteria	**Weight**	**1**	**2**	**3**	**4**	**5**	**6**	**7**
Benefits User	5	+	+	+	+	-	S	S
Simplicity	4	+	+	S	+	S	-	-
Prototyped Quickly	3	+	S	S	+	+	-	-
Low-Cost Materials	2	+	+	+	+	+	+	-
Low to No Training Required	1	S	-	-	+	S	+	-
Weighted Sum of Positives (+)		14	11	7	15	+5	+3	0
Number of Sames (S)		1	1	2	0	2	1	1
Weighted Sum of Negatives (-)		0	-1	-1	0	-5	-7	-10
Total		14	10	6	15	0	-4	-10



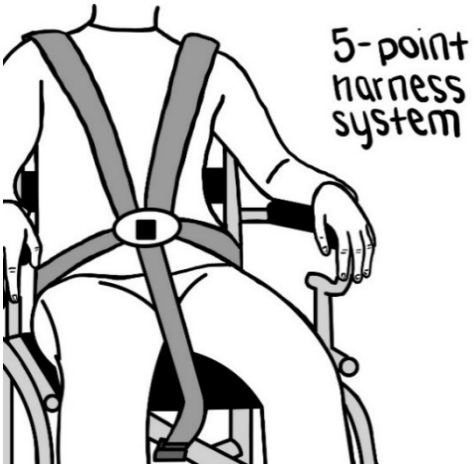
Sketch 1



Sketch 2

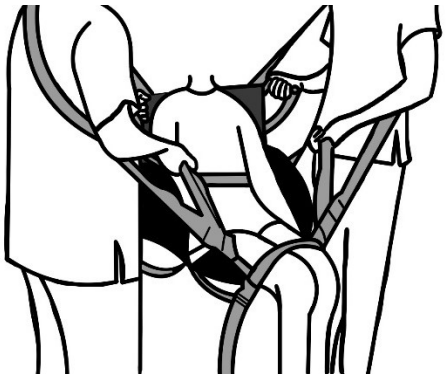


Sketch 3

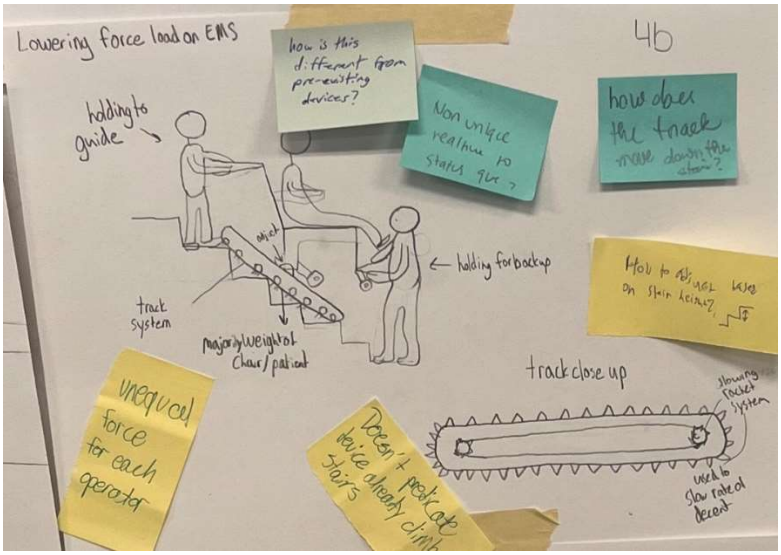


Sketch 4

Sketch 5



Sketch 6


Lowering force load on EMS
how is this different from pre-existing devices?
Non unique realtime to stairs yes
how does the track move down the stairs?
holding to guide
holding for backup
track system
major weight of chair/patient
How to adjust base on stair heights?
track close up
Unequal force for each operator
Doesn't pertain device already climb stairs
used to slow rate of decent

Sketch 7

Appendix C

The following is a bill of materials used to approximate the cost of one stair chair. The cost of each part was estimated using the costs of similar materials or finding the exact cost of the same part sold already, if applicable.

Material	Quantity	Source	Cost	Description
Aluminum tube	~200 inches in length	Outsourced as uncut hollow tube	$3.91 per foot (~$65)	Hollow circular aluminum tube (.5” inner diameter, .75” outer diameter)
Aluminum tube	~66 inches in length	Outsourced as uncut hollow tube	$3.71 per foot (~$20)	Hollow rectangular aluminum tube (1.75” L x .75” W outer, and 1.5” L x .5 W inner)
Aluminum tube	~48 inches in length	Outsourced as uncut hollow tube	$3.64 per foot (~$14.5)	Hollow rectangular aluminum tube (1.45” L x .45” W outer, and 1.2” L x .2” W inner)
L-shaped stainless-steel connector	2 pieces	Outsourced as pre-made	$3.15 per piece ($6.30)	Holes predrilled to support rivets and shape to match need
Sliding stainless steel support	2 pieces	Outsourced as pre-made	$3.20 per piece ($6.40)	Holes predrilled to support screws and hollow center to support sliding handles
U-shaped stainless-steel backing	1 piece	Outsourced as pre-made	$4.50	Holes predrilled to support screws
Hollow stainless-steel tubing	10 in length	Outsourced as uncut hollow tube	$2.19 per foot (~$1.83)	1/8" diameter
W-shaped stainless-steel support	2 pieces	Outsourced as pre-made	$6.20 per piece ($12.40)	Holes predrilled to support rivets and shape to match need
Wheel stainless-steel support	2 pieces	Outsourced as pre-made	$7.10 per piece ($14.20)	Holes predrilled to support screws and sized to support attached wheels
Large wheels	2 pieces	Outsourced as pre-made	$9.70 per piece ($19.40)	Rubber coated and 5.5” diameter

Small wheels and support	2 pieces	Outsourced as pre-made	$7.50 per piece ($15.00)	Rubber wheels with built-in braking system and 2” diameter
Waterproof Polyvinyl Chloride	~650 square inches	Outsourced as pre-made raw material	~$0.02 per square inch (~$13)	Will be used with injection molding to create the seat
Yarn/stitching	~36 in	Outsourced as pre-made	~$0.01 per inch (~$0.36)	Will be used to stitch the PVC seat
8 in length zipper system	2 pieces	Outsourced as pre-made	$3.60 per 8-inch system ($7.20)	Will be stitched into the seat. Bought as a slider and chain.
Straps	~48 in length	Outsourced as pre-made	$1.76 per foot (~$7.04)	1" width
Straps	~58 in length	Outsourced as pre-made	$2.42 per foot (~$11.68)	2" width
Buckle system	1 piece	Outsourced as pre-made	$0.98	Accommodates 1 in width straps
Buckle system	1 piece	Outsourced as pre-made	$1.67	Accommodates 2" width straps
Rivets	16 pieces	Outsourced as pre-made	$0.45 per piece ($7.20)	.25" diameter, 1" length
Rivets	6 pieces	Outsourced as pre-made	$0.76 per piece ($4.56)	.4" diameter, 1.25" length
Screws	6 pieces	Outsourced as pre-made	$0.29 per piece ($1.74)	1/8" diameter, 3" length
Screws	2 pieces	Outsourced as pre-made	$0.54 per piece ($1.08)	5/8" diameter, 2.75" length
Hex nut	2 pieces	Outsourced as pre-made	$0.48 per piece ($0.96)	5/8" diameter
Hex nut	4 pieces	Outsourced as pre-made	$0.23 per piece ($0.92)	1/8" diameter
Spring	2 pieces	Outsourced as pre-made	$0.70 per piece ($1.40)	½" diameter, 1" length uncompressed
Button	2 pieces	Outsourced as pre-made	$0.12 per piece ($0.24)	½" diameter, 1/8” thickness

Thin Stainless-steel sheets	~7 feet	Outsourced as pre-made	$4.78 per foot (~$33.46)	2" width (20" base length, 22" outer length)
5-point harness and strap mechanism	1 piece	Outsourced as pre-made	$30.19	Pre-constructed and attached directly to frame
T-handle ball lock pins	2 pieces	Outsourced as pre-made	$11.09 per piece ($22.18)	3/8” diameter, 1-37/64" length