Patient Transfer

Team 31

ME 450 Section 008

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EXECUTIVE SUMMARY

Problem Statement

Patients at the Poovanthi Institute of Rehabilitation and Elder Care need to be moved safely between wheelchairs/stretchers and beds. Patients lack mobility and trunk control limiting the healthcare providers and other caregivers' ability to move patients easily when unassisted, putting them at risk for injury. Our task is to develop a device to assist caregivers in the transfer process.

Final Design

The final design consists of an inflatable cushion, foldover armrest bridge and wheelchair sling. All of these components will remain in the wheelchair to reduce the number of components the caregiver has to carry from patient to patient. When performing the transfer, the caregiver will position the wheelchair as close as possible to the therapy bed and fold over the armrest bridge onto the bed. They will then use an external pump to inflate the cushion until the patient is at bed height. Using the handles on the wheelchair sling, the caregiver will pivot and slide the patient laterally across to the bed. The cushion will remain inflated while the patient is using the therapy bed. To move the patient back to the wheelchair, the patient will sit in the wheelchair sling again and be slid back onto the inflated cushion. Once they are on the cushion, the caregiver will use the pump to slowly deflate the cushion and bring them back to seat height.

Design Concerns for Engineering Analysis

We discussed potential design concerns regarding our current design and ranked them in order to determine which analysis needed to be performed before moving forward with the design build. Our top four design concerns were patient and caregiver safety, ability to lift 150 kgs and ability to perform the transfer in less than four minutes. The patient safety was addressed using a solidworks displacement analysis on the inflatable cushion to ensure patient stability when inflating the cushion. Once we build a prototype of the inflatable cushion, we plan to do empirical testing to confirm these results. Because it is very difficult to measure caregiver safety without performing clinical trials, we utilized the Rapid Entire Body Assessment to ensure the transfer process using our design posed a low risk of a musculoskeletal disorder occurring. Lastly, we performed calculations to determine what flow rate and pressure rating was necessary for the air pump to lift at least 150 kg in the time needed. These results demonstrated that our current design was safe for patients and caregivers and there was a pump that fulfilled our design needs, giving us the confidence to move forward with our final design.

Verification Results

Our final design has met 7 out of 12 engineering requirements, and while we're satisfied with its performance, usability testing highlighted areas for improvement. These include enhancing the security of link fastening, adding holes for wheelchair sling attachment, refining internal inflatable structures, and using different hardware for smoother link movement. Given more project time, these improvements could help meet all requirements, emphasizing our commitment to continuous refinement based on user feedback.

Abstract

Current wheelchair/stretcher-to-beds patient transfer methods are ineffective for Poovanthi Institute of Rehabilitation and Elder Care's patients. Patients lack mobility and trunk control, limiting the healthcare providers and other caregivers' ability to move patients easily when unassisted, putting them at risk for injury. This report describes the design process in developing a device that solves the Institute's issue. Engineering analysis and verification tests were conducted on the final design to determine if it meets the engineering requirements created earlier in the design process.

Project Introduction

Every year, 15 million people around the world suffer from a stroke (Rago, 2020). It is estimated that half of these individuals will live with permanent or chronic disability as a result of their stroke (Rago, 2020). Another 250-500 thousand people suffer from a spinal cord injury (SCI) each year (WHO, 2013). These individuals can require long-term care from nurses, family members, and hired caretakers. It can be humiliating for these patients to go from being physically independent to needing assistance with basic, daily tasks. The once elementary act of getting out of bed is suddenly a herculean task requiring assistance from another person, even multiple people. However, the patient experience is only part of the story. These conditions take a toll on caregivers as well.

The act of caring for these people with disabilities has significant physical risks associated with it. In the hospital setting, day-to-day care of patients is entrusted to nurses. Nurses face a higher risk of low back pain (LBP) and a higher prevalence of heavy lifting than any other occupation (Tariq et al., 2023). This risk comes from the need to move patients who lack the strength and muscle control to move themselves. The most common injuries experienced among nurses and healthcare workers include strains and sprains in their shoulders or lower back and even slipped discs in their spine ("Common Injuries with Nurses & Healthcare | NC Workplace Injury Lawyers," n.d.). Many nurses leave their jobs due to the high physical costs that come with the job, which only exacerbates the shortage of nurses (Tariq et al., 2023). These injury risks necessitate the use of assistive devices for patient transfers between wheelchairs and beds, and other similar movements. Many hospitals and nursing homes have even implemented "no-lift" policies in an attempt to reduce injuries (Sun et al., 2018, Quinn et al, 2021). This phenomenon is not unique to nurses in healthcare settings. Family members and home care (HC) aids face many of the same injury risks that nurses must overcome on top of the emotional and psychological tolls endured (Gustafsson et al., 2022, Rooney, Thomas, personal communication, 2023). There is a clear global need for practical solutions for reducing the risk of injury to nurses and caregivers and supporting the autonomy and mobility of disabled and elderly patients. This need is even more prevalent in low and middle income countries (LMICs) like India.

Outside of the hospital, caretaking duties are carried out by family members and hired home care (HC) aides. On top of the emotional and psychological tolls endured by these caregivers, they face many of the same injury risks that nurses in hospitals must overcome. But

while the nurses can rely on transfer devices, professional knowledge, and other nurses for aid, family members and HC aides of patients with disabilities lack these resources. If one of these caregivers is injured, their services can be difficult to replace and their ability to care for the patient may be impacted (Mozes, 2023). The article "Ergonomic evaluation of slide boards used by home care aides to assist client transfers" discusses the lack of access to patient transfer technologies:

> ...technologies to eliminate client lifting in home care are lacking. Focus groups of home care aides and interviews with home care managers reported that there are very few client-lifting and mobility technologies that are technically and economically feasible in home care…In a survey of home care aides in Massachusetts, nearly 40% reported having no access to equipment to move clients. (Sun et al., 2018, p. 913)

There is a clear global need for practical solutions for reducing the risk of injury to nurses and caregivers and supporting the autonomy and mobility of disabled and elderly patients. This need is even more prevalent in low and middle income countries (LMICs) like India.

Individuals who act as caretakers for family members experience "caregiver burden," the psychological, social, and emotional toll that comes from providing for a disabled or elderly loved one (Gustafsson et al., 2022). It can be draining to see a person one loves in such a poor physical state. It can be frustrating feeling the need to sacrifice one's social life and hobbies because of caretaking duties. Caregiver burden is experienced by caregivers in every country. However, many of the factors that contribute to caregiver burden are exacerbated in LMICs. A lack of healthcare services in LMICs means that people in these countries turn to other, "informal" means of getting the care they need (Gustafsson et al., 2022).While HC aides are hired frequently in Western countries to support the efforts of a patient's family, there is a cultural expectation in many LMICs that caregiving duties should be borne by family members (Gustafsson et al., 2022). This cultural expectation is especially present in India. On top of cultural expectations, there is a lack of government support for Indian caregivers. In India, "There are no government supported care services for the informal care given by family members who are crucial to dependent old parents" (Gustafsson et al., 2022, p. 3).

In India, it is estimated that 185 thousand people suffer a stroke every year (*India Today*). There are 1.5 million Indians with a SCI, with 20 thousand new cases every year (Singh, 2012). The Poovanthi Institute of Rehabilitation and Elder Care in Tamil Nadu, India treats patients in these demographics. Of the 85 patients at Poovanthi, 90% were either stroke (70%) or SCI patients (20%) (Spicher, 2023). Dutiful family members pay out-of-pocket to accompany these patients and care for them during their stay at the facility, which usually lasts for around 6 months (Spicher, 2023). Patients and their families typically come from low-income backgrounds, and the Poovanthi Institute is a low-resource environment. The patients who come to Poovanthi lack mobility and trunk control, so they are reliant on others to move them throughout the rehab facility. Most of the patients use wheelchairs, and some are reliant on

stretchers. Poovanthi has physical and occupational therapists on staff, but the therapist-to-patient ratio is only 1:12. The recommended ratio is 1:8. Due to this poor ratio, therapy sessions are conducted in large therapy halls with many beds. Sessions are supervised by 2-3 therapists, but the transport and repositioning of patients largely falls on their caregivers. Patients have 1-2 caregivers each, most being family members and the rest being minimally trained HC nurses (Spicher, 2023). Caregivers struggle to move patients between their mobility aids and their beds – both the beds in patients' private rooms and the beds in the larger therapy halls. The transfer-assist device currently in the facility, a sit-to-stand device called a Sara Stedy, can only be used by more mobile patients. Even in those cases, the device is rarely used. Patients express discomfort because their knees are forced into the knee pads on the device. Many are fearful because they face opposite the direction in which they are moving when they are in the device. From a caregiver perspective, it takes a long time to find the device, bring it to the bedside, and the transfer process itself is tedious (Spicher, Lucy, personal communication, September 7, 2023a). The transfer method that is most frequently used for patients at Poovanthi involves the physical or occupational therapist grabbing the patient by the waistband, lifting the patient off the wheelchair, and pivoting the patient onto the bed (Spicher, Lucy, personal communication, October 3, 2023). The motions associated with this style of transfer resemble a gait-belt and slide-board transfer, shown in Figure 1.

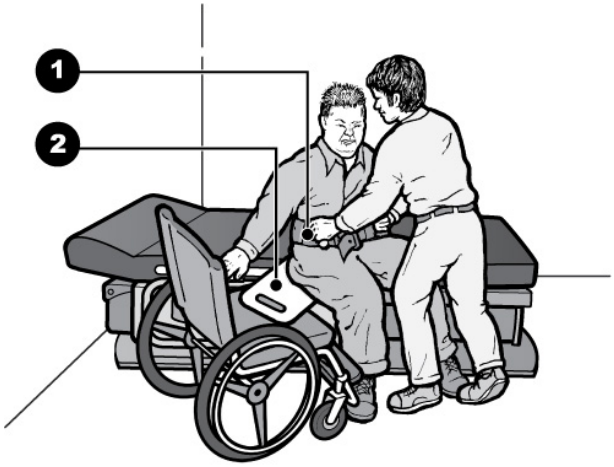


Figure 1. Gait Belt and Slide Board Transfer (*Assisted Transfer Using a Transfer Board and Gait Belt with Handles*, n.d.).

The motions involved with this style of transfer are a vertical lifting and a lateral sliding. There are gait belts available at Poovanthi, but much like the Sara Stedy, they go unused because they are inconvenient to attach to patients (Spicher, Lucy, personal communication, October 3, 2023). Additionally, this style of transfer, even with the use of a gait belt and slide board, is not ideal for more immobile patients, as there is an increased fall risk for the patient, and the patient cannot use their own strength to reduce the force exerted by the caregiver (D. Shin, personal communication, November 17, 2023). Attempting the motions required to position the patient

this way without the use of any assistive devices only exacerbates the injury risk for caregivers (Sun et al., 2018).

The lack of assistive devices that meet the needs of the caretakers and patients at Poovanthi presents an injury risk for moving patients. A low-priced, easy-to-use device that is actually compatible with the mobility level of the patients at Poovanthi would alleviate the immense physical toll on the caretakers and improve the quality of care the patients receive.

Information Sources

The development of a novel patient transfer device for caregivers at Poovanthi Institute is informed by problem research, interviews with medical professionals, engineering professors at the University of Michigan, and collaboration with key stakeholders, including Lucy Spicher and Dr. Shibu. Lucy Spicher, a PhD student in Mechanical Engineering at the University of Michigan, spent a year in India observing the day-to-day operations of the institute. Much of the information about the needs and ability of patients and caregivers at the Poovanthi Institute presented in this report was obtained through conversations with Lucy or through documentation prepared by Lucy. Our team has also spoken with Dr. Shibu, the Chief Medical Officer (CMO) at Poovanthi. Dr. Shibu is the source for several of the requirements and specifications presented in this report. To gain insight from a caregiving perspective, the team has conducted interviews with registered nurses and an occupational therapist. These interviews have informed decisions on specifications and design considerations. Statistics, standards, and information on existing patient transfer products were found through thorough independent research conducted by team members. Along with research articles, the team consulted OSHA lifting standards, US VA patient handling and mobility design criteria, and ISO standards for medical devices. Medical device requirements from the Central Drugs Standard Control Organisation (CDSCO) in India and the Food and Drug Administration (FDA) in the United States were also considered.

Existing Solutions

The various patient transfer devices used in healthcare settings can be categorized into four primary types: sit-to-stand aids, mechanical lifts, slide sheets, and transfer boards. Although this is not a comprehensive list of existing solutions, the limitations of the categories presented in this report are representative of all of the devices that fall into that category.

The first category of device implemented in these settings is the "sit-to-stand" device. Patients are moved from a wheelchair or a bed onto the device and rolled into a favorable position for transferring them to a new surface. While useful in some circumstances, this style of device is limited in its application. Patients who are compatible with the device have at least some level of core strength and a capability to use their arms to grip the support handle on the device. The Poovanthi Institute is in possession of a sit-to-stand device called a Sara Stedy, but the device is rarely used, even on patients who have the ability to use it (Spicher, Lucy, personal communication, September 7, 2023a). Patients express discomfort in the knees when in the Sara Stedy and cannot see where they are moving when in the device because they face opposite to the direction of motion. A picture of the Sara Stedy is shown in Figure 2.

Figure 2. The Sara Stedy sit-to-stand patient transfer device (*Sara Stedy Sit to Stand Manual Patient Lift*, n.d.).

Another category of devices are portable patient lifts or floor lifts. There are electronically powered and mechanical varieties of these devices, but the function is the same between the two. These lifts work well for many patients, but there are drawbacks. According to the CMO at Poovanthi, the institute considered purchasing one of these lifts, but decided against it because the patients are placed in a sling anchored to the lift at two points, which can cause the patient to feel unstable and unsafe (B Shibu, personal communication, September 11, 2023) In an interview with Thomas Rooney, a Registered Nurse with hospital and homecare experience, he explained these lifts are hardly ever used even when they are available. Transfers using these devices are time-consuming and difficult, and many prefer to move the patient with

no assistive device (T. Rooney, personal communication, September 19, 2023).The nurse noted that this mentality was present for both trained nurses and home caregivers. He also stated that these lifts are not fit for all patients, and are more suited for wheelchair users than stretcher patients. An example of one of these lifts is pictured in Figure 3.

Figure 3. A mechanical Hoyer lift, an example of a portable patient lift (*Hoyer Deluxe Electric Power Patient Lift*, n.d.).

Another quite simple device is the draw sheet. A large fabric sheet with handles is worked underneath the patient, and the patient is simply lifted and set on top of the bed or stretcher. While these devices are easy to use, they require more than one person to lift the patient, and are only able to be used on patients who are laying down, not on patients sitting upright in a wheelchair (T. Rooney, personal communication, September 19, 2023). One study found that the transfer process using floor lifts took 311 seconds while the transfer process using a draw sheet only took 115 seconds. The same study found that manual transfers with no assistive devices took less time than either of these methods, only 74 seconds (Reimer et al., 2014). An example of a draw sheet is pictured in Figure 4.

Figure 4. A caregiver holding on to the top handles of a draw sheet, which is underneath a patient. A top-down view of the draw sheet is pictured in the top right corner of the figure (*Amazon.Com: Bed Positioning Pad with Reinforced Handles, 45" X 36" Multipurpose Waterproof Transfer Sheet for Turning, Lifting & Sliding, Reusable Washable Patient Positioning Sheet for Bedridden, Caregiver, Dark : Health & Household*, n.d.).

The last category of devices examined by the team are slide boards. Some slide boards are very simplistic, consisting of just a board that is placed under the patient and then lifted up, while others incorporate rollers or friction-reducing fabric, and some feature a sliding mechanism. Caregivers in one study expressed that the boards with sliding mechanisms, such as the Beasy Board, required less physical effort than other varieties. Measurements of hand force in the study supported the claims from caregivers (Sun et al., 2018). For this reason, the team primarily considered the style of slide board with a sliding mechanism in our analysis. Nurses like these slide boards, but it can be difficult to get them underneath the patient, and they are not able to be used for patients who require the use of a stretcher (T. Rooney, personal communication, September 19, 2023, C. Bray, personal communication, September 10, 2023) These boards also need to be level with the surface the patient is being transferred to, or tilted downward. The caregiver should never push the patient “uphill” (Sun et al., 2018). For this reason, a cushion is placed underneath the patient so that the board is level with the bed during transfer. An image of a Beasy Board slide board is shown in Figure 5.

Figure 5. A Beasy Board slide board, the style of slide board considered by the team for benchmarking (*Amazon.Com: Beasy Premium Transfer Board - BeasyGlyder, Model 1300 (32 in.) - No-Lift Transfer System, Ideal for Wheelchair & Vehicle Transfers : Health & Household*, n.d.).

Table 1 shows a summary of the advantages, disadvantages, and limitations of the four categories of device discussed in this section.

Table 1. Summary of transfer device category capabilities.

Device Category	Low Price (≤ $1,987)	Operated by one caregiver	Low Physical Exertion for Caregiver	Transfers patient to and from wheelchair	Transfers patient to and from stretcher	Low time to transfer
Sit-to-Stand	Y/N	Y	Y	Y	N	N
Floor Lifts	Y/N	Y	Y	Y	N	N
Draw Sheets	Y	N	N	N	Y	Y
Slide Boards	Y	Y	N	Y	N	Y

Table 1 contains several criteria that each category of device either meets or does not meet. If the category meets the criterion in a column, it is labeled “Y” for “yes” and colored green. If the category does not meet the criterion, it is labeled “N” for “no” and colored red. If some devices in the category meet the criterion and others do not, the box for the category in that column is labeled “Y/N” and colored yellow. Explanations for how these criteria are quantified and specifications for the criteria are provided later in this report.

An ideal device for use at Poovanthi would meet all of the criteria shown in Table 1. All of the device categories examined in this report fail to meet at least two criteria shown in Table 1. The team found no devices in our research that could meet Poovanthi’s price requirement, be

operated by a single caregiver without exceeding a safe level of force, move both wheelchair and stretcher users, and complete the transfer process conveniently and quickly.

Design Process

The problem we are attempting to solve, as well as our team's approach to solving it, can best be described by IDEO's Human Centered Design process (*Design Kit*, n.d.). An improved, low-cost patient transfer device can improve safety for not only the patient being transferred, but also the nurse performing the transfer so it is very important that we understand the primary stakeholders and design from their perspective. In addition to the Human Centered Design model, we also considered a problem-oriented model because we started our design process by analyzing and framing the problem before generating concepts (Wynn D., Clarkson J. (2005) Models of designing). Ultimately, we opted for the Human-Centered Design process because it is imperative that we continuously reference the needs of the individuals we are designing for, ensuring the creation of a solution that is genuinely effective and user-centric. So far, our design process has not differed from the standard design process outlined in the first lecture of ME 450 (Cooper, n.d.). We have followed the basic outline for defining the problem, but our strategy for concept exploration might differ from this process because there is a wide variety of approaches for concept exploration.

Design Context

Stakeholder Analysis

The design context for our problem can be informed by the stakeholders who are either influenced by or can influence the design outcome. Our primary stakeholders whose quality of life or livelihoods are most drastically affected by our potential solution are the individuals within the Poovanthi Rehabilitation Institute. Primary stakeholders at Poovanthi with whom we communicate directly are Chief Medical Officer, Dr. Shibu, as well as Mrs. Punitha, head of physical therapy. Other primary stakeholders at Poovanthi with whom we do not communicate directly are patients of the facility needing assistance with transportation to and from therapy beds, family caregivers who stay in the hospital to assist those patients and the physical therapists working in the therapy hall.

Stakeholders whose lives are not centered around the problem but are still impacted by a potential solution are Lucy Spicher, a PhD mechanical engineering student who is the sponsor/mentor of this project, and patients or caregivers outside of Poovanthi Institute who deal with patient transport daily. The stakeholders that we classified as tertiary are indirectly involved in the outcome of our design problem. This includes the University of Michigan Global Health Initiative and Amazon India, the main product supplier (Spicher, L. September 5, 2023. An Introduction to India.).

Our primary stakeholders within Poovanthi that are directly affected by our design solution deal with a lower therapist to patient ratio than recommended (Spicher, L.). Their current patient transfer method can cause musculoskeletal disorders that result in chronic pain for

caregivers and therapists (Healthcare - Safe Patient Handling | Occupational Safety and Health Administration. OSHA.). According to Spicher, patients experience uncomfortable pressure on their knees and are frightened by the dynamics of the current device used for transfer, the Sara Stedy (Spicher, Lucy, personal communication, September 7, 2023.).

Our team has not come up with many possible stakeholders that could be negatively impacted by our design. One party that may be adversely affected are competing medical devices looking to solve the same issue. Our design would potentially serve as a competitor for their product. Since the product is intended to be durable and not mass produced, disposal or manufacturing should not be a large enough issue to negatively impact a stakeholder.

Beyond sponsor interest, physical therapists everywhere experience pain from patient handling that can affect their jobs and daily lives. This may also affect people taking care of older family members or family with limited mobility, especially in cultures where family is highly valued. Social impact to our sponsor is most likely more important than profit or affordability, but less important than patient/caregiver safety, reliability and portability. This will most likely affect some of our design decisions, but Dr. Shibu expressed affordability is important to him as well.

Shown in the figure below is a stakeholder diagram to help visualize the stakeholders' position in relation to the design context.

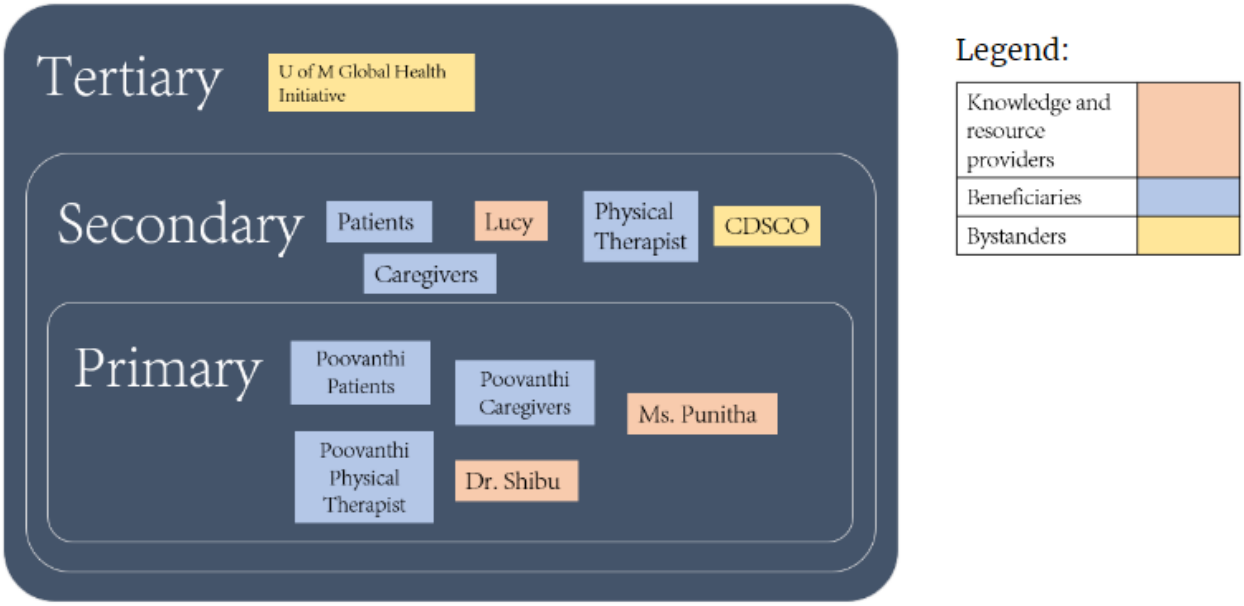


Figure 6. Stakeholder diagram of primary, secondary, and tertiary stakeholders. Color coding categorizes the stakeholders as either knowledge/resource providers, beneficiaries, or bystanders.

Benchmarking and Intellectual Property

The benchmarking process informed us of current patented, patient transfer devices related to our project. The benchmarking process allowed us to thoroughly analyze the intellectual property associated with these patented devices. From this analysis, gaps were identified within the market of patient transfer devices and we observed what does and does not work well for the patients, therapists and other relevant stakeholders. Intellectual property protections that could be relevant are patents for medical devices that intend to solve the same design problem as us. We want to make sure not to infringe on those patents or cause any copyright disputes. Our team owns the intellectual property for our project, and we have granted the University of Michigan non-exclusive rights to our intellectual property.

Economic Context

Poovanthi is located in a very low-resource environment. All of the patients are paying out of pocket for their stay and many times they run out of money during their stay. This puts a lot of pressure on the families of the patients, adding to the existing caregivers burden. This emphasizes the need for our solution to be low cost so that it can be affordable for the institution and even individual patients (Spicher, n.d.).

Institutional Context

In healthcare environments, a standard therapist to patient ratio is typically 1:8. However, in Poovanthi, the ratio stands at 1:12, underscoring a notable shortage of therapists. This underscores the urgency for a streamlined patient transfer solution—one that therapists are inclined to adopt willingly, as opposed to relying on forceful measures. Given the rapid pace at which therapists navigate between patients, the likelihood of adhering to recommended sanitation practices is minimal. Complicating matters, some caretakers are family members with minimal training in homecare nursing. Therefore, an effective solution must be both straightforward and intuitively easy to use (Spicher, n.d.).

Infrastructure Context

In India, frequent power outages are a norm, emphasizing the critical necessity for a solution independent of traditional electrical outlets. Adding to this challenge, Poovanthi is situated more than a 30-minute drive away from the nearest hospital. While ensuring the safety of both patients and caregivers is our paramount concern, the distance from the hospital in Poovanthi intensifies the urgency for a solution that prioritizes safety in an environment where immediate medical assistance may be less accessible (Spicher, n.d.).

Industrial Context

Considering the industrial context of Poovanthi, our intention is to have the device manufactured in India, ensuring its ready availability for the institute. The institute routinely relies on Amazon India for acquiring off-the-shelf products, typically delivered via trucks or

lorries. A crucial aspect to highlight is that broken devices often go unrepaired due to limited resources and difficulty in accessing hired assistance within the institute. To address this challenge, our priority is to design a device that is not only user-friendly but also easily repairable, with cost-effective replacement parts readily accessible. This approach aligns with the institute's constraints, fostering a sustainable solution that can be maintained and serviced with minimal resources (Spicher, n.d.).

Political Context

Understanding the context of Poovanthi as an independent, private facility actively involved in subsidy programs, such as Motivation India offering a substantial 60% discount on wheelchairs, is crucial. It's noteworthy that Poovanthi benefits significantly from these programs. Considering this, it becomes imperative for our device to be a distinct and separate entity from the wheelchair, ensuring that individuals at Poovanthi can still take advantage of the discounted wheelchairs provided through the subsidy program. This design approach not only respects the cost-saving benefits of such programs but also underscores our commitment to seamlessly integrating our device with existing infrastructure while maximizing the advantages offered by subsidy initiatives (Spicher, n.d.).

Sustainability

With our current stage of design, we are unsure whether the solution will be a disposable, lower lifetime device, or a durable long-term solution. If the solution is durable, sustainability would be less impactful of an issue, since manufacturing and disposal would occur at a much lower scale (though it would still be an issue to some extent). If our design were to have a lower lifetime, sustainability is important to consider. If we used recyclable materials (or less realistically, compostable materials), then materials would not be wasted on disposal and our design would not contribute to growing landfills or pollution. However, these materials could be less durable (shorter lifetime and lower strength) or less compatible with the weather conditions surrounding Poovanthi Institute. If using less durable materials impacts the functionality of being able to transfer patients, this would no longer be an option.

Ethics and Inclusivity

Our personal ethics are the same as the University of Michigan’s standards. The Global Health Design Initiative seeks to design based on immersive fieldwork experience. It also intends to obtain a meaningful understanding of the cultural context of which communities they are designing for, with the hopes of respecting and aiding those cultures and communities (*About Us | Global Health Design*, n.d.). This is also representative of our team’s intentions.

Our project is not above the possibility of power dynamics that currently affect relations between different groups involved with this project. One possible example of this is with our sponsor, Lucy Spicher. She has more experience within the Poovanthi Institute and more experience as an engineer since she is a graduate student. She also is older than us, so seniority

gives her some authority over our team. Within our team, we are all within the same age range and experience range. However, some of us have less experience in professional engineering environments compared to other teammates. Some design decisions may also be influenced by conflicting opinions between team members. The power dynamics between end users is a bit more complex. Some stakeholders hold more priority than others. Dr. Shibu, as CMO, will have more influence over design decisions than patients within the facility, who would be more directly involved as end users. And since stakeholders have more intimate knowledge of the problem context, it's important that they have some power over our project. However, since our team will be executing the steps of the design process, we have power over the end users by the fact that we have more of a final say on their experience as end users.

To address possible inclusivity issues that we have not identified, we will attempt to communicate with any surrogate stakeholders who are affected by the wider problem we are addressing. We will also attempt to communicate with Dr. Shibu over WhatsApp to keep us up-to-date on the needs of the therapists and patients, especially on what is relevant to their wants and needs.

User Requirements and Specifications

The user requirements and specifications were formed through discussions with key stakeholders, benchmarking research and general problem research. From our initial meeting with Lucy Spicher, design ethnographer, and Dr. Shibu, CMO of Poovanthi Rehabilitation Institute, we determined the features they prioritize in a solution along with the gaps in their current solution, the Sara Stedy (*Sara Stedy Sit to Stand Manual Patient Lift*, n.d.). There are two levels of requirements: High and Medium. The levels of these requirements were determined by interviews with key stakeholders. The high priority requirements are considered necessary while the medium priority requirements are considered ideal. The requirements are color-coded for clarity. A green highlight signifies that the requirement is well-established with ample background research. Yellow indicates that further research is required to specify the requirement fully, while red denotes that the specification is entirely absent, with minimal to no research conducted.

Table 2. Requirements and specifications along with their priority and corresponding sources.

Priority	Requirement	Specification	Source
High	Meets Poovanthi's price requirements	Must cost ≤ $1987 or 165,193.52 INR.	• (B Shibu, personal communication, September 11, 2023)
High	Meets Poovanthi's transfer time requirements	**Necessary:** Time to transfer ≤ 4 minutes for transfer from wheelchair.	• (B Shibu, personal communication, September 11, 2023) • (Spicher, Lucy,

		Ideal: Time to transfer ≤ 2 minutes for transfer from stretcher.	personal communication, September 7, 2023a) ● (Rooney, Thomas, personal communication, September 19, 2023)
High	Operable by available personnel at Poovanthi	Only requires a single nurse/caregiver to complete transfer	● (B Shibu, personal communication, September 11, 2023) ● (Spicher, Lucy, personal communication, September 7, 2023a)
High	Compatible with the Poovanthi facility's spatial dimensions	1. Must be no more than 4 feet wide(1.22 meters). 2. Must be less than 6 feet 8 in. (2.03 meters) tall.	● (B Shibu, personal communication, September 11, 2023) ● (Spicher, Lucy, personal communication, September 7, 2023a) ● (What Are the Standard Door Sizes in Your Country? | Doors Direct, n.d.)
High	Can transfer disabled patients	**Necessary:** 1. Can transfer patients with fall risk (defined by Berg Balance scale) from wheelchair to therapy bed and vice versa. 2. Can support a weight of at least 150 kg.	● (B Shibu, personal communication, September 11, 2023) ● (Spicher, Lucy, personal communication, September 7, 2023) ● (Miranda-Cantellops & Tiu, 2023)

		Ideal : Can transport patients with fall risk (defined by Berg Balance Scale) from stretcher to therapy bed and vice versa.	
High	Meets patient and caregiver safety standards	All Risk Priority Numbers must be below 300 in FMEA performed according to ISO 14971.	• (Spicher, Lucy, n.d.) • *(VA Safe Patient Handling and Mobility Design Criteria, 2021)* • *(ISO - ISO 13485 — Medical Devices, n.d.)* • (*ISO 14971:2019 - Medical Devices — Application of Risk Management to Medical Devices*, n.d.) • (Rezaei et al., 2018)
High	Can be cleaned with cleaning supplies available at Poovanthi	Surfaces can be cleaned with standard alcohol-based disinfectants.	• (*Best Practices for Environmental Cleaning in Healthcare Facilities*, n.d.) • (*National Guidelines for Clean Hospitals*, 2015)
High	Has commercialization potential	1. Complies with CDSCO, *specifically The Medical Device Rules, 2017 (Medical Device Rules, 2017, 2016).* 2. Does not infringe on existing patents.	• (*Medical Device & Diagnostics*, n.d.) • (*Medical Device Rules, 2017*, 2016)

High	Can withstand Poovanthi environment	1. Can withstand temperatures up to 43 ℃ and humidity up to 100%. 2. Can withstand 12 uses/ patient/ day for 5 years.	• (Spicher, Lucy, n.d.) • (*India | Humidity Statistics | CEIC*, n.d.) • (*Amazon.Com: Beasy Premium Transfer Board - BeasyGlyder, Model 1300 (32 in.) - No-Lift Transfer System, Ideal for Wheelchair & Vehicle Transfers : Health & Household*, n.d.)
High	Complies with OSHA lifting standards.	Does not exceed a lifting factor of 1.0.	• (*Healthcare - Safe Patient Handling | Occupational Safety and Health Administration*, n.d.)
Medium	Ease of Manufacturability.	Must be manufactured in India.	• (Kosmochem Home Healthcare, n.d.) • (Medical Devices Industry in India – Market Share, Reports, Growth & Scope	IBEF, n.d.

Low Price

The interview with Dr. Shibu provided the team with a unique perspective on the requirements, as he would be the prospective purchaser of the product. The price indicated above corresponds to their existing solution, the Sara Stedy, for which Dr. Shibu has provided the maximum price he is willing to consider for an alternative solution. The amount is $1,987 which is equivalent to 165,193.52 INR. This amount is how much it would cost for the Institution to buy, not the amount it would cost to make the solution. We do not have a limit on cost to make the solution nor will we know more about the parameters to calculate total cost until deciding on a solution.

Meets Poovanthi's Transfer Time Requirement and Operable by One Caregiver

The ease of use requirement was emphasized through conversations with many different stakeholders. Due to the 1:12 ratio of therapists to patients at Poovanthi, it is very important that the device can be operated by one person. Also, the transfer must be fast so the caretaker can move on to the next patient in the therapy hall. Initially, Lucy explained that she wanted the transfer to be performed in less than 2 minutes. Through further benchmarking and conversations with nurses, we found that the transfer from wheelchair to bed typically takes longer than the transfer from stretcher to bed; therefore, this specification was split up based on transfer type. The transfer from stretcher to bed was kept at a 2 minute limit while the specification for wheelchair transfer was extended to 4 minutes. This adjustment was made following input from an interview with a nurse (T. Rooney, personal communication, September 19, 2023). This requirement is very important because current solutions can cause transfers to be time-consuming and difficult, so many nurses prefer to use no assistive devices, putting them at risk for injury.

Compatible with Poovanthi Facility's Spatial Dimensions

Because the device is portable and will be moved from bed to bed, we know that it must be compatible with the dimensions of the facility. If the device were to move, it would have to fit between each therapy bed in order to transfer the patient. Lucy supplied us with images of the therapy hall and the dimension specifying the distance between each bed, which is 3 feet or approximately 0.914 meters. There are therapy halls on multiple floors of Poovanthi so the solution would have to fit through the doors to the halls. When going through doorways, the width is not a concern because we have already set a 3 foot limit which is less than the width of a door. However, it's important to note that the height of the device should not surpass the height of the doorway. In India, typical doorways measure 6 feet 8 inches or approximately 2.03 meters, so the device's height must stay within these dimensions.

Patient Transport

The priority for transferring patients from wheelchairs to beds was set as "necessary", while transferring patients from stretchers to beds was said to be "ideal" due to the center's predominantly wheelchair-dependent patient population. This transfer is specifically for patients "with fall risk" defined by the Berg Balance Scale, a scale used at Poovanthi (Miranda-Cantellops & Tiu, 2023). Addressing this requirement is central to addressing one of the primary challenges we aim to solve with our solution.

Patient and Caregiver Safety

When developing a medical device, it is always necessary to prioritize patient and user safety during the design process and there are internationally recognized ISO standards that are applicable to the development of our solution. ISO 14971 focuses on the risk management for medical devices and ISO 13485 addresses the quality management system for medical devices. ISO 14971 outlines a process for managing risks associated with medical devices. It defines risk

as “the probability of occurrence of *harm* and the consequences of that *harm*, that is, how severe it might be” (*ISO 14971:2019 - Medical Devices — Application of Risk Management to Medical Devices*, n.d.). ISO 13485 outlines requirements for a quality management system for medical devices which includes “design and development, production, storage and distribution, installation, servicing and final decommissioning and disposal of medical devices, and provisions of associated activities” (*ISO - ISO 13485 — Medical Devices*, n.d.). Adhering to these ISO standards is essential as it will help ensure patient safety when using our device, aligning us with globally recognized best practices in the industry.

Ease of Sanitation

Although not mentioned as a priority by our stakeholders, sanitation is very important for any device used in a healthcare setting. With the possibility of many different patients using the device, the device should be easily cleaned with alcohol based disinfectants. Lucy explained that even though the device should be cleaned in between use, it is likely this will not happen. Regardless, we decided as a group that the device should be compatible with common alcohol-based disinfectants that are commonly used in Indian healthcare settings (*National Guidelines for Clean Hospitals*, 2015). This compatibility ensures that hygiene standards can be maintained, even under real-world conditions where frequent cleaning may not occur consistently.

Commercialization Potential

Another requirement that was important to Dr. Shibu was the commercialization potential of our design. In order for a medical device to be commercialized in India, it must comply with the Central Drug Standard Control Organization (CDSCO) standards. The CDSCO is the FDA equivalent in India. According to the CDSCO, our patient transfer solution would be classified as a “device notified from time to time under sub-clause (iv) of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940”. Therefore it must comply with the Rules outlined in *The Medical Device Rules, 2017* (*Medical Device Rules, 2017*, 2016). It also cannot infringe on any current patents for patient transfer solutions.

Durable for India’s healthcare facility conditions

The device needs to cater to the needs of all patients in the center including obese patients. While we do not have specific weight data from the patients at Poovanthi, we were able to use benchmarking to determine an appropriate maximum weight of 400 lbs. Also, it is important that the device can withstand the humid weather conditions in India. From historical weather data, we determined that the device should be able to operate in temperatures up to 43 ℃ and humidity up to 100%. The last specification for durability is that the device can be used 12 times per patient per day. We are not certain on a specification for the overall lifetime of the device. Currently, the lifetime is 10 years which is based on benchmarking.

Complies with OSHA Lifting Standards

The objective of existing patient transfer solutions is to alleviate this burden and prevent lower back injuries among nurses and caregivers. Consequently, we have established a nurse safety requirement, mandating compliance with The Occupational Safety and Health Administration's (OSHA) Safe Patient Handling Guidelines in our design. (*Healthcare - Safe Patient Handling | Occupational Safety and Health Administration*, n.d.).OSHA has specific standards and guidelines that ensure nurse and caregiver safety when transferring patients. Part of these guidelines is a lifting factor which is calculated by the NIOSH lifting equation (Appendix A) (Waters, 2021). This equation takes many factors into account including the weight lifted, horizontal distance of load from the lifter's body, degree of bodily twist required and vertical location relative to the floor. Achieving a lifting factor below 1.0 is essential as it signifies a significantly reduced risk of injury, aligning with our commitment to prioritize the well-being of both patients and caregivers.

Accessibility and Ease of Manufacturing

When factoring in manufacturability, we want the design to be manufactured in India so it is accessible to Poovanthi and the rest of the Indian population. With 750-800 distinct medical device manufacturers in India, fulfilling this requirement is highly achievable (*Medical Devices Industry in India – Market Share, Reports, Growth & Scope | IBEF*, n.d.). Dr. Shibu expressed a desire for a solution that is easy to manufacture, but creating a solution-neutral specification for this requirement is challenging.

All engineering requirements in green and yellow have been successfully translated into specifications. However, it's important to note that the specifications highlighted in yellow require additional research and attention. Among these specifications, the high-priority requirements take precedence over the medium-priority ones. Nonetheless, it's crucial to emphasize that the most paramount considerations revolve around patient and nurse safety, making these requirements our topmost priority.

Concept Generation

Design Heuristics (*Design Heuristics*, n.d.) and IDEO's guidelines for brainstorming (*IDEO | Global Design & Innovation Company*, n.d.)were used to generate many concepts prior to coming together and organizing the ideas. Each of us generated 40 concepts individually using a variety of the brainstorming methods discussed in the Concept Exploration module (*1.6 Brainstorming: ME 450 Learning Blocks FA 2023*, n.d., p. 450). Before our collaborative concept generation session, we employed IDEO's "Gut Check exercise" to eliminate ideas that might jeopardize patient and caregiver safety, prioritizing their well-being. This initial filtering reduced our pool of 160 concepts to 80, ensuring we maintained our safety focus. With the remaining 80 concepts, we utilized design heuristics to iterate and combine the concepts generated. Design heuristics was the chosen concept generation method due to the variety of

concepts produced. It forced us to think outside of the box, allowing us to fully explore the solution space. For instance, design heuristics card 42 says “Make components attachable/ detachable”. We used this card to iterate on the “Inflatable Cushion with Tracks” seen in Figure 11. The backrest was made as an attachable component to provide additional trunk support for the patients during the transfer process. After utilizing design heuristics to iterate on our current ideas, we applied “filters” as a part of our concept selection process. These filters were high priority requirements outlined by our stakeholders. The filters can be seen in Figure 7 below. Once we got to around 40 concepts, we categorized them based on their transfer method (Appendix B). These categories were board, lift, sit-to-stand, and other. This categorization, combined with the application of filters, allowed us to identify our top four concepts. The top four concepts are explained below.

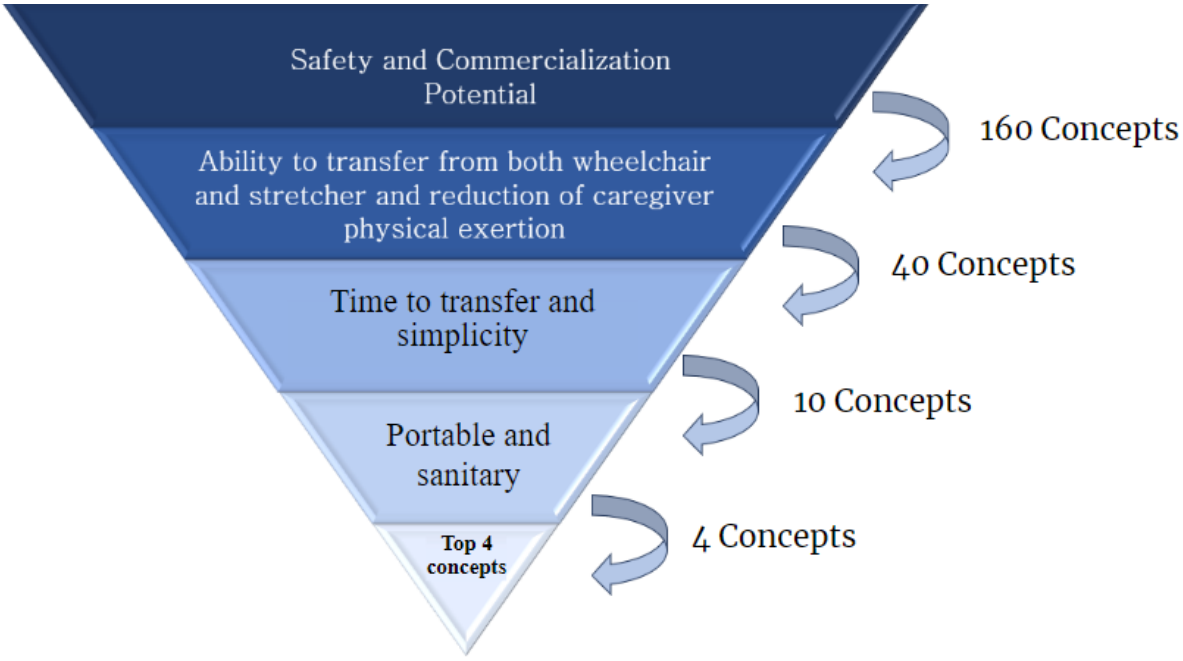


Figure 7. The levels of filters applied to our 160 initial concepts. The filters aided us in determining our top four concepts.

Sliding Transfer Board

The sliding transfer board concept is an iteration on current transfer boards on the market. Traditional patient transfer boards lack back support, particularly for patients with limited trunk control. These boards also require the nurse to physically push the patient across, putting them at risk for lower back injury. This concept incorporates a back-rest with securing straps to hold the patient upright if they have poor trunk control. Additionally, the seat’s rotation allows for easy patient positioning once the transfer board is underneath them. The sliding seat will not only reduce physical exertion of the nurse but will also expedite the transfer process. During discussions with key stakeholders, a concern emerged regarding the initial placement of the patient onto the seat and the potential strain it might place on the caretaker's back. This design is

also limited to only transfers from wheelchair to therapy bed. This design is shown in Figure 8 below.

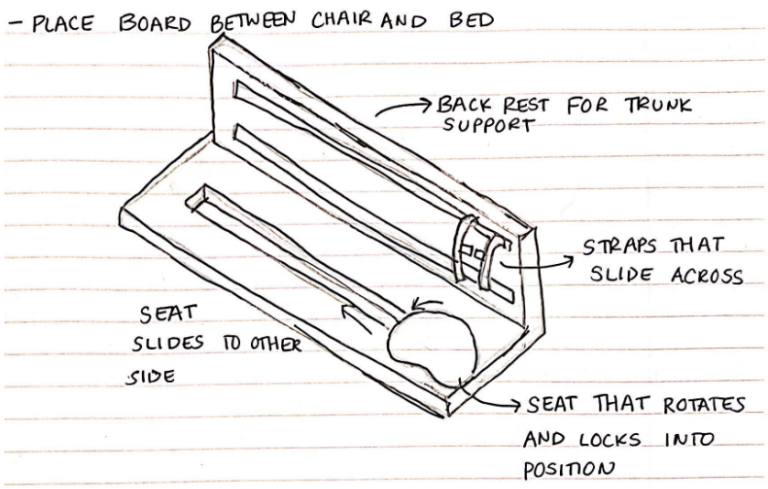


Figure 8. Sliding Transfer Board Concept.

Pallet-Jack Lift

The pallet-jack lift incorporates a hydraulic pump to lift and transfer the patient from their wheelchair to the bed. Initially, a thin inflatable seat would be slid under the patient that would inflate and raise the patient to a level allowing the pallet-jack mechanism to smoothly slide underneath. A user-friendly handle facilitates manual operation, eliminating the need for healthcare providers to physically lift the patient. It would also have a wheeled base, allowing for easy patient rotation and transfer to the bed. This concept could be applied to stretcher transfers using a larger board to lift the patient. With only 3 feet between therapy beds, there were concerns that there would not be enough room for the pallet-jack lifting mechanism to function. Additionally, there are concerns about patient comfort. The jolts generated by the hydraulic lifting mechanism may lead to discomfort and anxiety among patients. This concept offers substantial advantages in reducing physical strain on the caretakers, but space constraints and patient comfort need to be addressed in the design. A sketch of this concept can be seen in Figure 9.

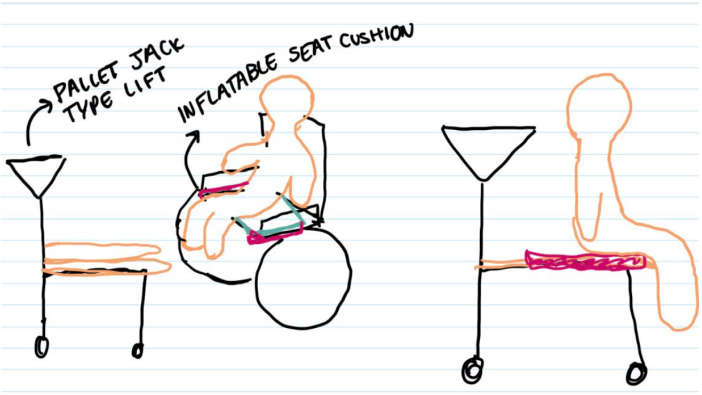


Figure 9. Pallet-Jack Lift Concept.

Counterweight Lift

The counterweight lift concept represents an iteration on current patient mechanical lifts such as the *Hoyer Deluxe Electric Power Patient Lift* (*Hoyer Deluxe Electric Power Patient Lift*, 2023). Instead of relying on a motor to lift the patient, this concept would utilize adjustable counterweights to lift the patient, reducing the physical strain on the caretaker. The mechanism would be similar to that of cable machines commonly found at gyms. The use of counterweights as opposed to a motor would simplify the design and make it easier for the Institute to fix the device if it were to break. The Institute currently has a device similar to the *Hoyer Lift*, but it is broken and has yet to be fixed due to lack of resources. There would be different slings that could be attached to the lift so that it could perform wheelchair and stretcher transfers. However, during discussions with stakeholders, concerns were raised about controlling the speed of the lifting mechanism. Because the mechanism is driven by the force of gravity, a damper would have to be implemented to control the lifting action. A sketch of the counterweight lift concept is shown in Figure 10.

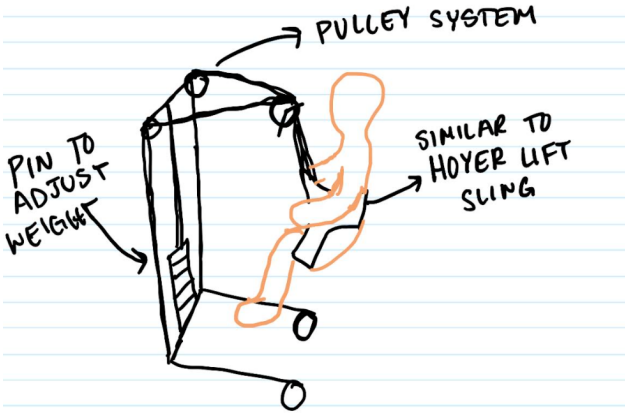


Figure 10. Counterweight Lift Concept

Inflatable Cushion with Tracks

The Inflatable Cushion with Tracks concept is a novel solution that comprises three components for patient transfer. First, a thin, low-friction seat would be slid underneath the patient. The seat would have an inflatable component which can be easily inflated using a standard, off-the-shelf air pump. When inflated, it raises the patient to the same level as the therapy bed, ensuring a smooth transfer. The second component is a backrest attached to the seat to provide trunk support for the patient during the transfer. The third component of the design, the transfer tracks, would be attached to the underside of the seat, providing a bridge between the wheelchair and the therapy bed. In order to slide the seat across, the seat would be deflated and the patient would be slid across the tracks. The seat's bottom is equipped with wheels that align with the tracks, making the sliding action effortless for the caretaker. Analysis would have to be completed to determine whether the inflatable could lift our maximum weight of 400 lbs to the height we need within our time limit of four minutes. This concept could also be applied to stretcher transfers with the use of two tracks and a longer board that would be slid under the patient. This concept is depicted in the sketch shown in Figure 11.

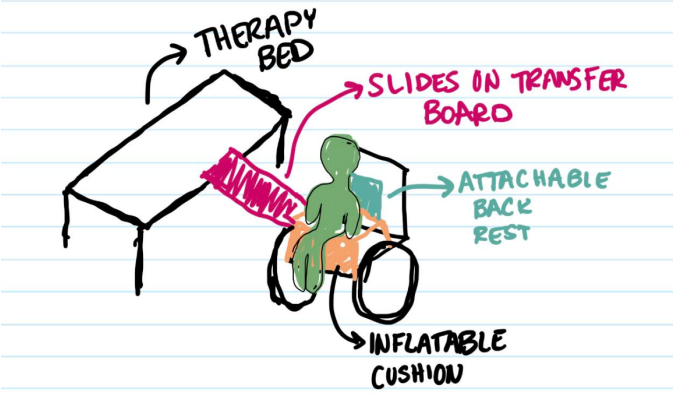


Figure 11. Inflatable Cushion with Tracks concept.

The four top concepts discussed above are characterized by their distinct lifting mechanisms, each offering unique advantages in reducing the physical effort required by nurses during patient transfers from a wheelchair to a therapy bed. The sliding transfer board concept uses the sliding seat to easily move the patient laterally, but would still require some force from the nurse to put the board underneath the patient. The pallet-jack type lift utilizes a self-contained hydraulics system to lift the patient from the seat of the wheelchair. The counter-weight system makes use of the force of gravity and counterweights to lift the patient. Lastly, the inflatable cushion with tracks uses pneumatics to raise the patient to the height of the tracks between the wheelchair and therapy bed.

Concept Selection Process

After narrowing our generated concept pool down to the top four most eligible concepts to fulfill our design requirements, we used stakeholder interviews, a design priority survey, a

pugh chart, and our collective judgment to decide which design we believed to best suit the needs of Poovanthi.

Lucy Spicher Interview

We held interviews with multiple different stakeholders to assess their first impressions of our top designs, how these designs would compare to current design solutions, and thoughts on feasibility and usability of the concepts. Our first interview was with Lucy Spicher, our sponsor. Her first impressions for each design were the following. For the sliding transfer board she was confused how it would lessen caregiver exertion, and that strapping the shoulders would be time-consuming. However, she liked the rotating seat, since it would reduce fall risk. For the pallet-jack lift, she said that using a hydraulic system that moves smoothly would be heavier and more expensive, suggesting possible alternatives for vertical motion. For the counterweight lift, she felt the design lacked some key details, particularly concerning how the patient would transition from the wheelchair position to the bed after being lifted up. When discussing the inflatable cushion, she raised concerns about the design having multiple components, but liked the idea of a compact inflatable raising them out of the wheelchair. We discussed the possibility of each patient having their own seat and backrest with them at all times. She also mentioned that many of the wheelchairs had removable arms. (Spicher, Lucy, personal communication, October 3, 2023.)

Danny Shin Interview

Our second interviewee was OT Danny Shin. His first impressions for the top four designs were the following. For the sliding transfer board, he felt the backrest would make it difficult to get under a patient in a wheelchair. For the pallet-jack lift, he felt the pallet-jack would make patients with low trunk control feel scared and unsecured. For the counterweight lift, he liked the use of gravity to reduce strain on the caregiver. However, he did not feel a 4 minute transfer time would be feasible. For the inflatable cushion, he was concerned about keeping the track steady and making the design fit in the space between beds. He also mentioned any design we choose should be reversible and easy to teach. (Shin, Danny, personal communication, October 5, 2023.)

Dr. Shibu Interview

Our third interviewee was Poovanthi CMO Dr. Shibu. By this point, we had decided on our top solution based on the pugh chart and previous stakeholder interviews, so the majority of the meeting was focused on the inflatable cushion concept. His first impressions for our selected design was the following. He was curious about the stability of the track and whether it could handle stress from the patients. He also inquired about the speed at which the cushion would inflate and raised questions about its capability to fully inflate while a patient is positioned on it. He liked the concept of breaking the transfer down into lifting combined with a sliding motion akin to a slide board. However, he was apprehensive about using an inflatable cushion,

suggesting hydraulics as an alternative more familiar to Poovanthi staff. He also raised concern about maintaining the patient's upright position when inflating the cushion. He also wanted to know what the plan for maintenance is in case of the inflating material being damaged. (Shibu, B, personal communication, October 6, 2023.)

Design Priority Survey and Pugh Chart

We sent a design priority survey to every stakeholder we could reach to receive their input on which requirements were the most important to them. We received 8 responses. The survey asked about background information (such as name, job, employer), and to rank the priority of 6 aspects of the design: transfer time, ability to transfer, simplicity for use, reducing caregiver exertion, portability, and ability to sanitize (Appendix D). We used the results to create a pugh chart, with Dr. Shibu's response given the most weight, Lucy Spicher's response as the second most, and other caregivers with equal weighting. The results of the pugh chart can be seen in Figure 12 below:

Selected Priority Requirements	Weight	Sliding Transfer Board	Inflatable Cushion with Tracks	"Pallet-Jack Lift"	Counterweight Lift
Transfer from wheelchair or stretcher instead of only wheelchair	6	0	1	0	0
Reduction of caregiver physical exertion	5	0	1	1	1
Time to transfer	4	0	-1	-1	-1
Simplicity	3	0	-1	-1	-1
Portable	2	0	-1	0	-1
Ease of sanitation	1	0	0	0	0
Weighted Total:		0	2	-2	-4

Figure 12. Pugh chart used to determine how well design meets requirements. The sliding transfer board design was used as a standard for comparison to the other designs based on the chosen requirements.

We decided the score of each design using the aforementioned survey and our personal judgment on whether the requirements performed better or worse than the design we were using as the standard, the sliding transfer board. Using the results of the pugh chart and the feedback we received from stakeholders, we determined that the design that had the best chance of meeting our needs was the inflatable cushion design.

Initial Design Concept Descriptions

Alpha Design Concept

The initial version of the inflatable cushion concept selected by the team consisted of a single straight track supported by legs, a thin plate seat cushion with an inflatable attachment, and a removable back rest with straps to support the patient. The back rest and straps would prevent the patient from falling forward, as the patients lack the trunk control to support themselves. CAD models depicting this design and the steps for utilizing the design for patient transfer are depicted in Figure 13 below.

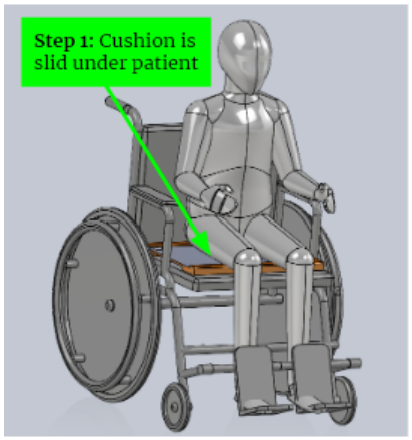


Figure 13a)

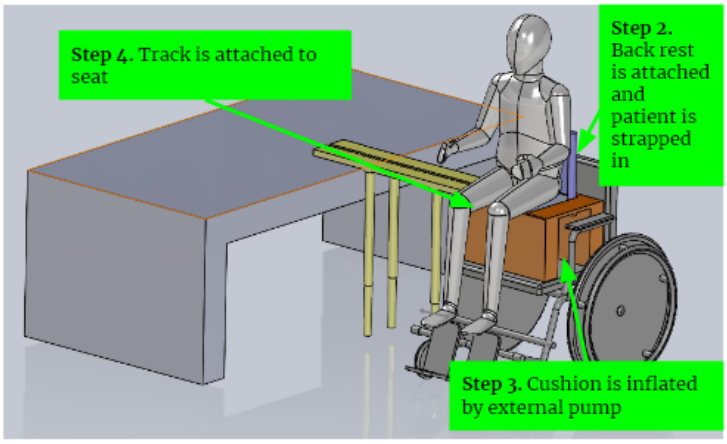


Figure 13b)

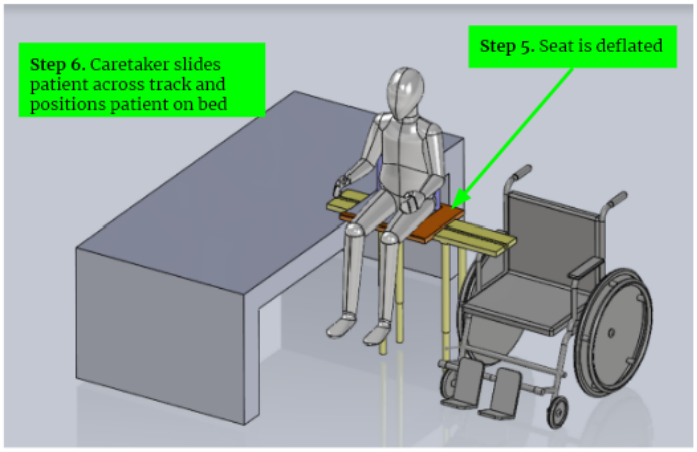


Figure 13c)

Figure 13. The steps for transfer using the initial selected concept are shown in Figure 13a, Figure 13b, and Figure 13c. The steps are labeled in order and are shown in the green boxes. The same process could be used to complete transfers from bed to wheelchair. The inflatable part of the seat cushion is shown in brown, the track is shown in green, the back rest is shown in blue, and the flat plate component of the cushion is shown in silver.

In this design, the inflatable component of the seat cushion has a “U” shape so that it does not obstruct the motion of the cushion when it is slid along the track. At Poovanthi, there are two different heights for the therapy beds, 26.38 in. and 18.9 in. (Spicher, Lucy, personal communication, September 7, 2023b) . To address this variability, the team intended to incorporate adjustable legs on the track so that the desired height could be set prior to the transfer.

A version of this design was also developed for use with stretchers. The CAD model for this design is shown in Figure 14.

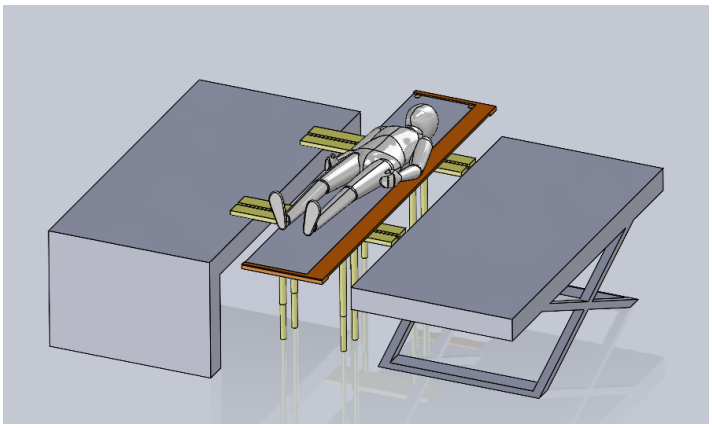


Figure 14. A version of the alpha concept that is compatible with stretchers. The stretcher is shown on the right of the image and a model of the therapy bed is shown on the left.

For usage with stretchers, a long, flat board version of the inflatable cushion would be slid under the patient, and two tracks would be used for the transfer: one near the patient’s head and another near the patient’s feet.

Beta Design

When the team began engineering analysis for the alpha design, a critical flaw was identified. One of the requirements for the design states that the device must be compatible with the spatial dimensions of the environment it would be used in. The distance between the therapy beds at Poovanthi is 3 feet, or 0.914 m (B Shibu, personal communication, September 11, 2023, Spicher, Lucy, personal communication, September 7, 2023). At the time of working on the alpha design, the team believed that the spacing between therapy beds could not be adjusted. We have since learned from Dr. Shibu that the spacing can be adjusted, which is reflected by the change from three feet to four feet in our specifications (see page 16) (B. Shibu, personal communication, November 7, 2023). With the knowledge that the team had at the time, the part of the track that does not overlap the bed should not exceed 3 feet in length. In order for the alpha design to be safe for the patient, the seat cushion should be completely secure on the track

before the inflatable is deflated. This means that the length of the track that overlaps the wheelchair must be at least equal to the width of the flat plate that the patient is sitting on. Additionally, the plate must be wide enough such that the patient is not hanging off of its edge. In the design shown in Figure 15, the flat plate is 16 inches wide. This means that the sections that overlap the bed and the wheelchair respectively must each be at least 16 inches long. In the least conservative case, where we assume the legs are positioned in the center of the track without any thickness, only 16 inches would obstruct the space between beds. Although this hypothetical scenario lacks practicality, there would be 20 inches of open space between the track and the adjacent therapy bed. Most wheelchairs are between 24 and 27 inches wide from wheel to wheel (*Determining the Seat Width for a Wheelchair*, n.d.). Prior to sliding the track underneath the patient, the caregiver would need to position the wheelchair. With a straight track, the caregiver would not be able to position the wheelchair correctly before the transfer. To solve this perceived issue, the team elected to change the shape of the track to be curved. The spacing issue presented by the straight track design and the team's solution to this issue are demonstrated in Figure 15.

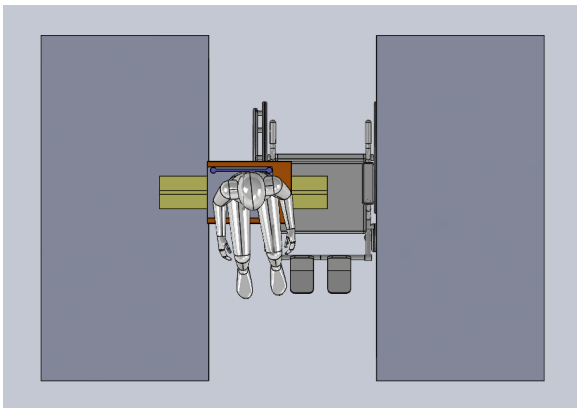


Figure 15a)

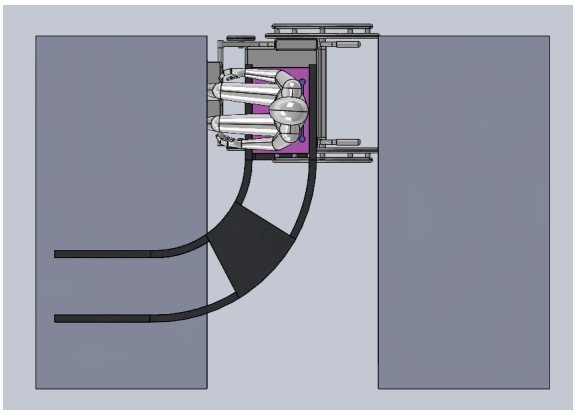


Figure 15b)

Figure 15. A top-down view of the straight track design is shown in Figure 15a) and the same view of the curved track design is shown in Figure 15b). The large grey rectangles represent two therapy beds with three feet of space between them. The straight track design does not allow for space for rolling the wheelchair into place next to the track before transfer, while the curved track design does.

In addition to the change from a straight track to a curved track, the beta design includes an inner and outer rail, not a single rail as was the case in the first rendition of the concept. Views of the dual-rail track are shown in Figure 16.

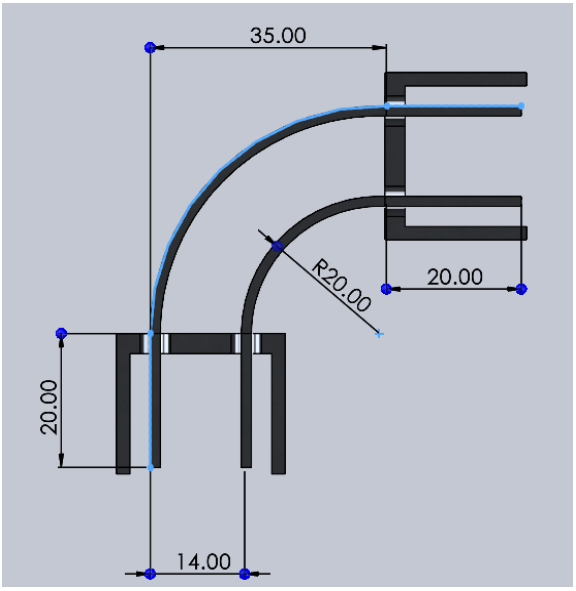


Figure 16a)

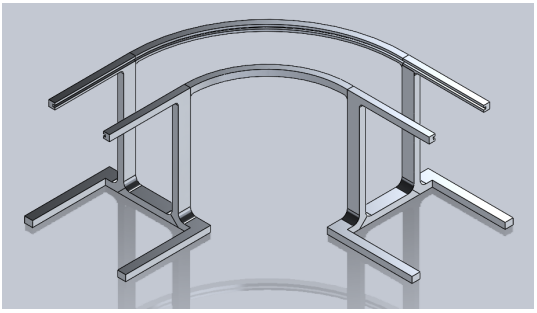


Figure 16b)

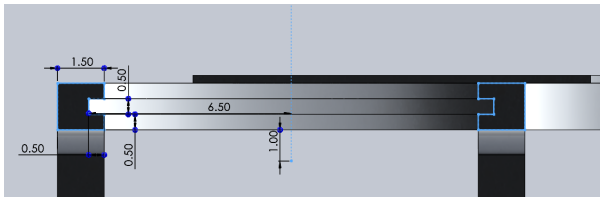


Figure 16c)

Figure 16. Top-down and isometric views of the track system are shown in Figure 16a and Figure 16b, respectively. A cross-sectional view of the rails is shown in Figure 16c. All dimensions shown in the figures are in inches.

The change from a single rail to a dual-rail system was brought about due to changes in the geometry of the inflatable explained below:

To gain insight into the design of the inflatable component of the design, the team consulted Dr. Jon Luntz, an instructor and researcher in the Mechanical Engineering Department at the University of Michigan who runs an inflatables lab. Dr. Luntz advised that to provide stability to the inflatable structure when it is fully inflated, cables should be connected in "X" shapes on the sides, front, and back of the structure to provide tension that would eliminate the risk of the patient wobbling from side-to-side or from front-to-back (J. Luntz, personal communication, October 16, 2023). These inelastic, metal cables would only provide tension when the cushion is fully inflated, so while the cushion is inflating, the caregiver would be responsible for stabilizing the patient. Even though this process would require some effort from the caregiver, the caregiver would not be required to lift the patient, the most physically dangerous and difficult part of the transfer process (C. Bray, personal communication, September 10, 2023, T. Rooney, personal communication, September 19, 2023, Tariq et al., 2023). Further analysis would be needed to determine how much stabilizing force the caregivers would need to provide. The cables would require two surfaces to anchor to, so Dr. Luntz recommended that the design should include a top plate that the patient sits on, a bottom plate, and the inflatable in between the two plates. The cables would be connected to the two plates. With such a design, it would be difficult to slide the patient along a single track without the cables getting caught on the board. For this reason, the team opted for a dual-rail design.

The inclusion of a bottom plate addresses another problem with the first design. When the team presented the initial design concept to Poovanthi's CMO, he expressed concern that the friction between the inflatable and the wheelchair seat would be high, which would make it difficult for the caregiver to slide the cushion underneath the patient (B Shibu, personal communication, October 6, 2023). Dr. Luntz echoed this sentiment (J. Luntz, personal communication, October 16, 2023). High friction rubbing on the inflatable material also increases the risk of tears and holes in the material. In the new design, there is no direct contact between the inflatable material and the wheelchair seat. The wheelchair seat would be in contact with the bottom plate of the cushion, which would reduce the friction.

The change from a single-rail to a dual-rail track system allowed for another design change: a simplification of the inflatable's geometry. Because the track no longer slides in right through the middle of the cushion, the inflatable cushion shape was changed to a simple rectangular prism shape. An isometric view of the inflatable cushion system is shown in Figure 17.

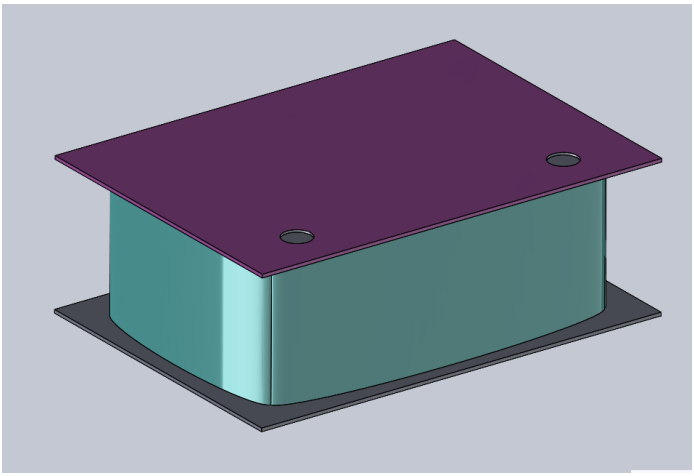


Figure 17. Isometric view of inflatable cushion sub-system. The inflatable component is shown in tiel and the top plate is shown in purple.

Dimensioned top-down and side views of the cushion sub-system are provided in Figure 18.

Figure 18a)

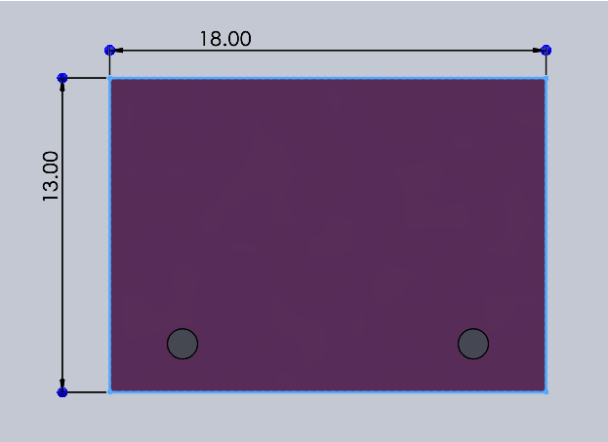


Figure 18 b)

Figure 18. A side view of the inflated cushion is shown in Figure 18a. The height shown by the blue line is 6.3 inches. A top-down view of the top plate is shown in Figure 18b.

The steps to the transfer process using the beta design remain identical to those described in Figure 13 (see page 28). A visual of a patient on the new curved track design is shown in Figure 19.

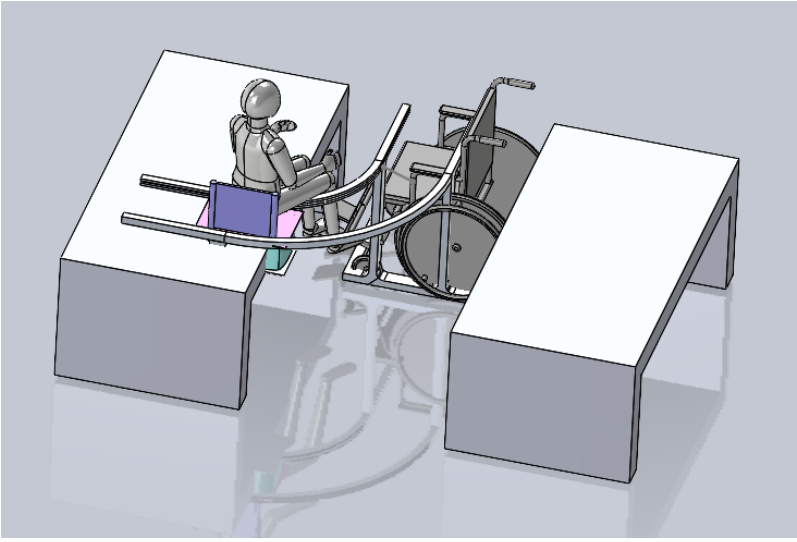


Figure 19. A patient is depicted sliding along the curved, dual-rail transfer system

Unlike the alpha design, there is no version of the beta design that is compatible with stretchers. Even though the Pugh chart and survey detailed in the concept selection section (see page 27) indicate that compatibility for both stretchers and wheelchairs were deemed important to stakeholders, communications with the project's sponsor and with Poovanthi's CMO that took place after the survey was conducted informed the team that stretcher compatibility is not as important as was initially thought (B Shibu, personal communication, October 6, 2023). A majority of the patients requiring transfer assistance use wheelchairs, and stretcher transfers are easier to perform than wheelchair transfers (B Shibu, personal communication, October 6, 2023, Spicher, Lucy, personal communication, October 3, 2023, C. Bray, personal communication, September 10, 2023, T. Rooney, personal communication, September 19, 2023). After further communication with prominent stakeholders, it was decided that compatibility with stretchers should no longer be a priority for the design.

With some refinement, the beta design would meet most of the high priority requirements. The design allows for patient transfer between wheelchair and bed and the patient is secure through all steps of the transfer process. As stated, while the design would still require the caregiver to stabilize the patient from swaying side-to-side as the cushion inflates, it eliminates the need for lifting the patient up manually. The track also decreases the effort required to move the patient laterally from the wheelchair to the bed. As is shown in the Engineering Analysis for Beta Design section of this report (see pages 35-38), the track can withstand the maximum load of 400 lbs that would be applied to it for the desired number of loading cycles. The design would be easy to sanitize in between uses. The only surfaces that come into direct contact with patients are the top plate of the seat cushion and the back rest and straps, which would be easy to clean with a standard disinfectant wipe.

The beta design had some gaps, primarily concerning the backrest and straps, cushion wheels, and stabilizing cables. Before the designs of these components were thoroughly

explored, significant changes were made to the design. The primary reason the team moved away from the beta design was the inconvenience of the tracks. The shape, size, and weight of the rail system would make it cumbersome to transport throughout the Poovanthi Institute. This conflicts with the portability requirement for the design. Locking wheels could be added to the tracks to mitigate this issue, but consultations with stakeholders have informed the team that caregivers may be unlikely to lock the wheels, raising safety concerns (Spicher, Lucy, personal communication, September 7, 2023). Even with wheels, the track would be inconvenient to move, and the facility would most likely not be able or willing to purchase a track for every bed (B Shibu, personal communication, September 11, 2023). Stakeholders have advised the team that if the transfer process is too lengthy or inconvenient, caregivers would most likely continue to use their own strength to move patients instead of adopting a new method (T. Rooney, personal communication, September 19, 2023, D. Shin, personal communication, November 17, 2023, Spicher, Lucy, personal communication, September 7, 2023). While not explicitly stated in our requirements and specifications, the team placed a lot of importance on caregivers' desire to actually utilize our device. We felt that if the large track could be eliminated from the design, it would be more practical and more likely to be used.

We anticipate that the inflatable is the most likely component to fail before the 5 year lifespan requirement. The team is proposing to make the inflatable part of the design replaceable. If the inflatables are able to be manufactured quickly and are cheap to buy, the Institute could buy them in bulk. A cost analysis has not yet been performed. Depending on the results of the cost analysis, this plan may change and the design may change significantly. The pump selected to inflate the cushion should be off-the-shelf and battery-powered. The Institute faces frequent, short power outages that make a plug-in pump a poor choice for this design (B Shibu, personal communication, October 6, 2023, Spicher, 2023).

Engineering Analysis for Beta Design

Three analyses were performed to assess the feasibility of our beta concept. First, finite element analysis (FEA) was performed on the track system of our design to determine stresses and strains across the track, and to determine the number of loading cycles the track could survive. Second, a statics analysis was performed to determine how to design the legs supporting the track such that the track would not tip over. Finally, calculations were performed for the required rated volumetric flow rate of the pump used on the inflatable component of the design, and the amount of time the inflation process will take depending on the mass of the patient. Given the absence of a physical prototype at this stage, our analysis consisted of calculations and simulations.

Stress, deflection and fatigue analysis of Transfer Rail

The transfer rail functions as a way to move the patient on the cushion from the wheelchair to the therapy bed. Based on our requirements, it needs to support a weight of 400 lbs and last for 12 uses per patient per day for five years. With 85 patients in the institution, that totals to 1,861,500 cycles. Using the Solidworks model for the rail and Solidworks simulation,

the stress, deflection, and fatigue analyses were performed to determine if the rail would meet our engineering requirements. These analyses were performed at the center of the rail between the legs because our intuition tells us that is where the maximum bending moment would occur. The material of the rail is currently set as aluminum, but this is subject to change throughout the design process. The stress analysis can be seen in Figure 20 below.

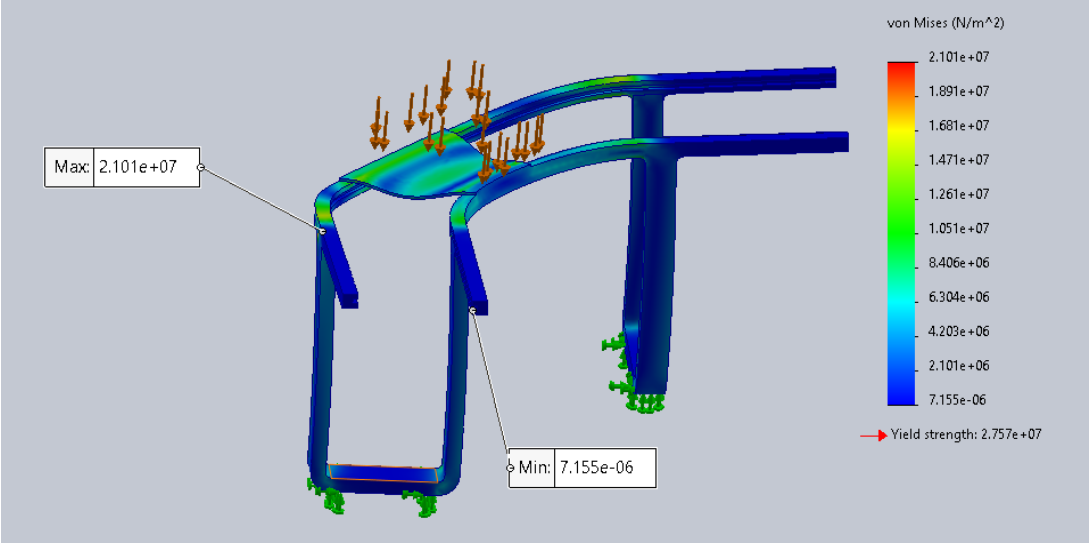


Figure 20. Solidworks stress analysis performed on transfer rail design.

As seen by the scale on the right, the yield strength of aluminum is around 276 MPa. The location of highest stress is identified, but it only has a value of 210.1 MPa which does not exceed the yield strength of aluminum. Next, the deflection analysis was performed. The results can be seen in Figure 21 below.

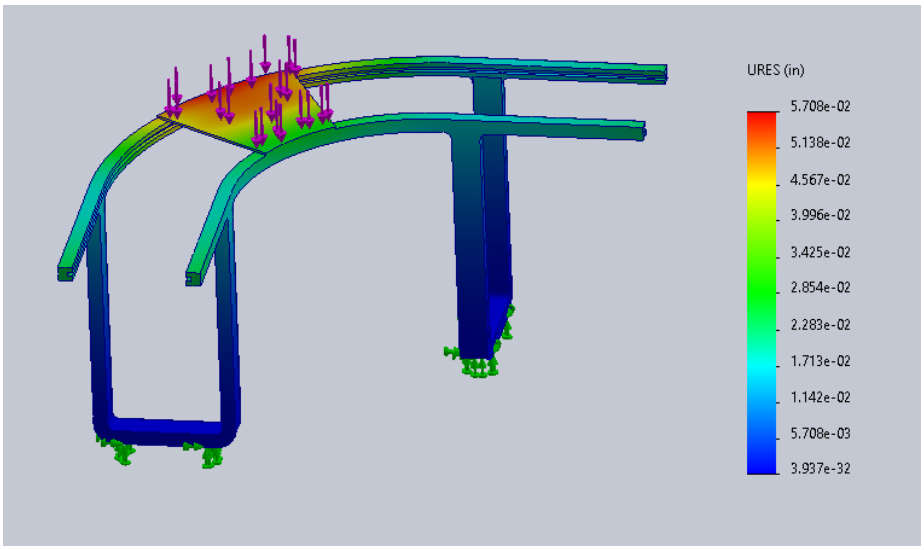


Figure 21. Solidworks deflection analysis performed on transfer rail design.

The maximum deflection, which measures at .057 inches, initially appears small. However, there's a potential concern that over time, this deflection could accumulate, possibly impeding the seat's smooth movement along the tracks. While this slight displacement could present a challenge in sliding the seat, its practical impact remains uncertain and would need to be assessed with a physical prototype to determine whether it becomes problematic.

To further evaluate the long-term durability of the track, a fatigue analysis was conducted. This analysis aimed to ascertain whether the repeated stress and strain endured by the track during use would lead to damage. After subjecting the design to 1,861,500 cycles of simulation, the results from Solidworks indicated that "Alternating stresses everywhere in the model are below the minimum S-N Curve value, resulting in no damage." According to the simulation, the rail design should withstand its intended use over the specified lifetime of 5 years. These simulations were used to determine if the transfer rail design was feasible, but we will have to do additional testing on a physical prototype to ensure that it can meet our engineering requirements.

Tipping Analysis

The transfer rail should not be at risk of tipping over during the transfer process to ensure patient safety. To mitigate this concern, “feet” were added to the bottom of the legs on the transfer rail. To determine the necessary length of these feet, a tipping analysis was performed. The analysis was performed for when the patient is at the very edge of the track when the inflatable is deflated because this is where the maximum bending moment occurs. To conduct this analysis, we split the rail system into two components – the inner rail and the outer rail – and evaluated them as separate systems. Five assumptions were made to simplify the analysis. These assumptions are as follows:

1. All components of the track and track legs are treated as rigid
2. The maximum applied load of 400 lbs is split evenly between the inner rail and outer rail, such that the applied load on each rail was 200 lbs.
3. When the rail is about to tip, there is no force transmitted to the track leg that furthest from the patient.
4. When the rail is about to tip, the force at the tip of the foot of the track leg is equal to the weight that the leg is supporting.
5. Only the mass of the rail itself is considered, the legs of the rail are treated as massless.

The analysis that was performed, expressed in the form of variables, is shown in Figure 22.

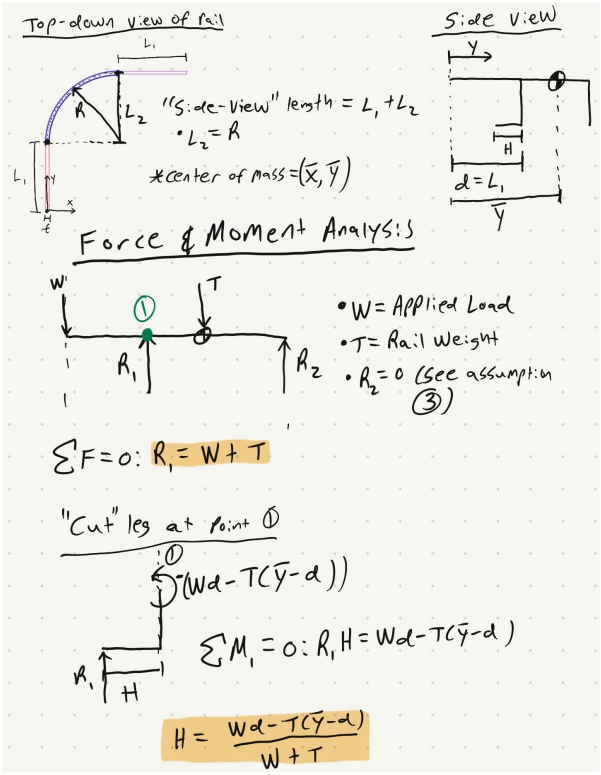


Figure 22. The force and moment analysis of each individual rail provides an expression for the length of the horizontal component of the track leg length, *H*.

The expression found for the length of the foot *H* for an individual rail component is shown in Equation 1.

$$H = [Wd - T(\bar{y} - d)]/(W + T) \quad (1)$$

Where *W* is the applied load at the end of the track, *d* is the distance from the edge of the rail to the top of the rail leg, *T* is the weight of the track itself, and $\bar{y}$ is the location of the y-coordinate of the center of mass using the coordinate system defined in Figure 22. For both the inner and outer rail, *W* = 200 lbs, and *d* = 20 in. From the CAD model of the rails, *T* is 14.04 lbs for the inner rail and 18.21 lbs for the outer rail. The center of mass $\bar{y}$ is 28.89 inches from y = 0 for the inner rail and 37.03 inches from y = 0 for the outer rail. For the derivations of the center of mass locations for an individual rail, see Appendix C.

Substituting these values into Equation 1 for each track, the foot length *H* must be at least 18.10 inches for the inner rail and 16.91 inches for the outer rail. In the dual-rail design, the lengths of the horizontal component of the rail legs are equal, so this length must be at least 18.10 inches. In the current version of the design, *H* = 20 inches, so the track will not tip. In reality, the weight of the cushion and backrest would need to be added to the applied load. However, given that these weights are much less than the weight of the patient and that the

weight of the track legs (which were not considered in this analysis) would somewhat counterbalance the weight of the patient, the chosen value for *H* should be sufficient to prevent tipping.

Inflating cushion analysis when a patient is seated in the wheelchair

For the inflating cushion phase of our patient transfer process, we spoke with Dr. Jonathan Luntz and Professor Aaron Towne, instructors in the College of Engineering at the University of Michigan, for fluid mechanics guidance. Dr. Luntz conducts research in inflatables and Professor Towne is a fluid mechanics professor.

From our initial intuition, we confirmed with Dr. Luntz that inflating a cushion requires a constant pressure and changing volume to lift the mass of the patient (J. Luntz, personal communication, October 16, 2023). He recommended simplifying our analysis by researching air pumps with maximum volumetric flow rate for zero gauge pressure and zero volumetric flow rate for maximum gauge pressure of different air pumps from which air pump manufacturers experimented (J. Luntz, personal communication, November 7, 2023). This simplification approximates a linear regression between a volumetric flow rate at a particular pressure and the required height (J. Luntz, personal communication, October 16, 2023). This approximation classifies the inflation process time associated with each air pump rated pressure and the mass of the patient being lifted (J. Luntz, personal communication, October 16, 2023).

Alongside the advice from Dr. Luntz, we discussed with Professor Towne a theoretical model that approximates the inflation process: conservation of mass of air for a control volume and the simplified mechanical equation of an incompressible fluid derived from conservation of energy for a control volume (A. Towne, personal communication, October 19, 2023).
Figure 23, shown below, is the simplified diagram of the inflatable cushion that Professor Towne suggested we consider.

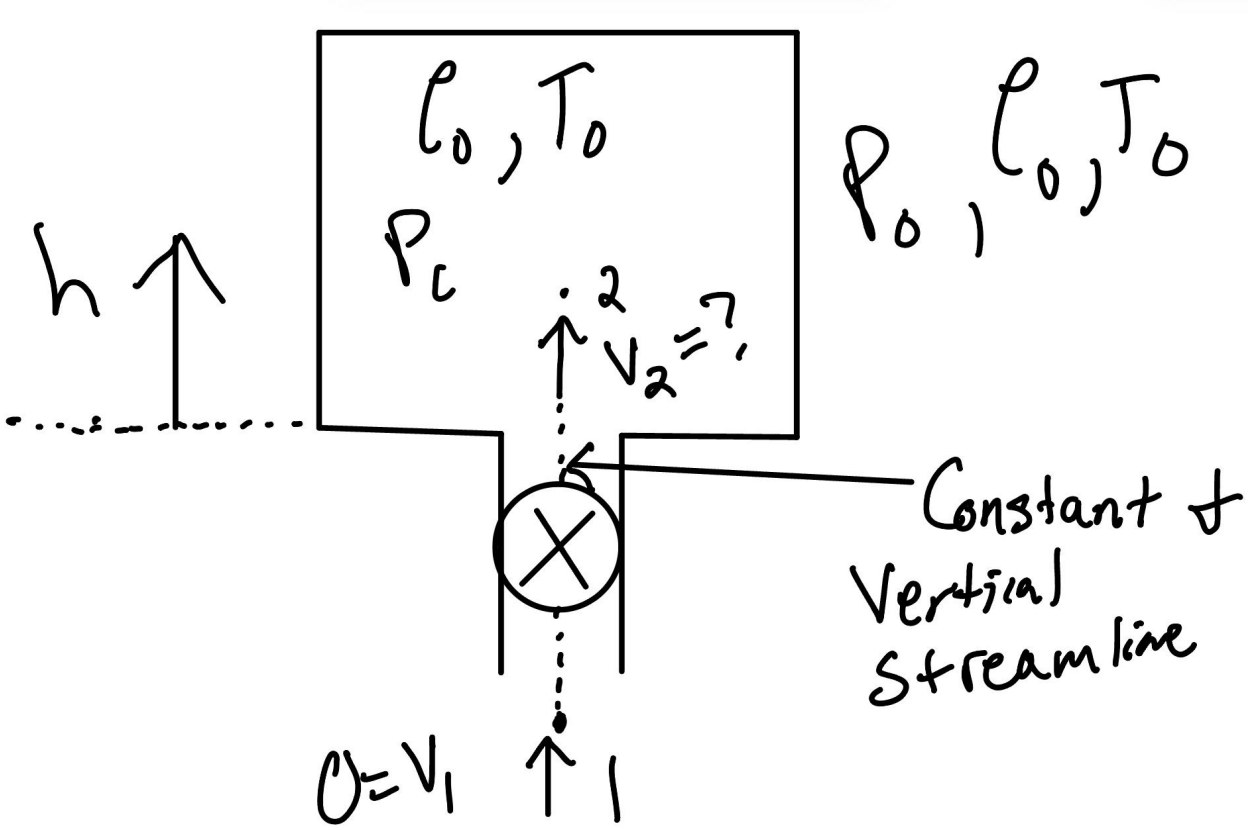


Figure 23. This diagram shows a simplified fluid mechanics process for inflating the cushion with an air pump. Stage 1 happens before the pump applies shaft work to the inlet flow rate, $V_1 = 0$. Stage 2 happens after the pump applies shaft work and results in the unknown outlet flow rate, V_2. h is the changing height of the inflatable cushion, starting from 0 meters and ends at 0.2 meters. $\rho_0 = 1.18$ kg/m^3 and P_0 are the atmospheric density and pressure of air at ground level, respectively. P_c is the unknown constant pressure inside the inflatable cushion. And, $T_0 = 273.15$ K is standard temperature.

Professor Towne suggested seven assumptions to simplify and approximate the theoretical model according to our requirements (A. Towne, personal communication, October 19, 2023):

1. *Incompressible air*: As shown in Fig. 22, we assumed that the amount of air compression needed to begin lifting the patient is insignificant compared to atmospheric pressure.
2. *Isothermal process*: Because heat is not being added to the control volume, we assumed that the air inside the control volume is the same air on the outside.
3. *Standard temperature, pressure, and 30-50% relative humidity*: India's average temperature and humidity is typically around 300 K and 100%, respectively, according to Lucy (Spicher, n.d.). However, because the mass density of air does not significantly vary between standard temperature and 300 K, and relative humidity up to 100%, we assumed a mass density at standard temperature and pressure and relative humidity of 30-50%.

4. *Constant and vertical flow rate along the same streamline*: As shown in Fig. 22, between stages one and two, the flow rate does not change with respect to time and is assumed to travel in the same direction throughout the inflation process.
5. *Inlet flow rate is zero*: As shown in Fig. 22, the outlet flow rate is induced by the shaft work of the air pump while the inlet flow rate, or the outside air is stagnant.
6. *Potential energy is zero*: Because the mass of the air is very light, we can assume that the mechanical potential for the air to fall towards the ground is zero.
7. *Zero losses*: Because this theoretical model is an approximation, we assumed that there would be zero losses for which to account. If we find during testing that losses are significant, we will account for them.

Considering these seven assumptions, we derived a theoretical model shown by Equations 2.1-2.3.

$$\frac{d}{dt}\int \rho \, dV + \int \rho \, \overrightarrow{v_2} \cdot \hat{n} \, dA = 0 \tag{2.1}$$

$$Q_2 + [v_2\hat{j}] \cdot [-\hat{j}]A_c = 0$$

$$Q_2 = v_2 A_c$$

$$\frac{p_1}{\rho} + \frac{1}{2}{v_1}^2 + gz_1 + W_{in} = \frac{p_2}{\rho} + \frac{1}{2}{v_2}^2 + gz_2 \tag{2.2}$$

$$\frac{p_0}{\rho_0} + W_{in} = \frac{p_0 + p_p}{\rho_0} + \frac{1}{2}\left(\frac{Q_2}{A_c}\right)^2$$

$$Q_2 = \left(\sqrt{2\left(W_{in} - \frac{p_p}{\rho_0}\right)}\right)A_c$$

$$W_{in} = W_{rated} = \frac{p_{max}}{\rho_0} = \frac{1}{2}\left(\frac{Q_{max}}{A_c}\right)^2$$

$$\frac{Q_2}{A_s} = \frac{h}{t}$$

(2.3)

$$t = \frac{hA_s}{Q_2}$$

Figure 24. This diagram shows the derivation for the volumetric flow rate as a function of pump work rate, W_{rated}, outlet area, A_c, and pressure of a patient, P_p. As shown in the diagram, (3) the final formula is derived from (1) conservation of mass and (2) the simplified mechanical equation of conservation of energy for a control volume. Using the assumptions suggested above, losses, potential energy, and V_1 all are zero. P_{max} is the maximum rated pressure, which is part of the calculation for the constant shaft work of the pump.

From our derived volumetric flow rate equation, we plotted theoretical volumetric flow rate versus mass graphs with the use of the volumetric flow rate and gauge pressure maximums stated under technical specifications from three different air pumps posted on Amazon.com and one from Lowe's.

(a)

(b)

(c)

(d)

Figure 25. Pictures (a)-(d) show the four different air pumps we researched from Amazon.com and Lowe's. (a), further classified as "Pump A," is from Amazon.com with a MSRP of $59.99 as of November 20, 2023 (INTEX 66638E QuickFill Battery Pump: Inflates and Deflates Air Mattresses, Kayaks, Boats – Includes 3 Interconnecting Nozzles – Sleek and Compact Design – 420 L/Min Air Flow – Indoor and Outdoor Use, Amazon.com). (b), further classified as "Pump B," is from Amazon.com with a MSRP of $119.99 as of November 20, 2023 (20PSI High Pressure SUP Air Pump - Rechargeable SUP Pump 12V Stand Up Paddle Board Electric Pump Inflator/Deflator - Portable Air Compressor for Inflatables Boats,Tent,Stand Up Paddle Boards, Amazon.com).. (c), further classified as "Pump C," is from Amazon.com with a MSRP of $14.99 as of November 20, 2023 (LEXIN P5 Tire Inflator Portable Air Compressor, 150PSI Cordless Air Pump, Electric Tire Pump with Pressure Gauge, 2X Faster Inflation, LCD Display, 5000mAh Battery for Car, Motorcycle, E-Bike, Bicycle, Amazon.com). (d), further classified as "Pump D," is from Lowe's with a MSRP of $119 as of November 20, 2023 (DEWALT 110-volt Lithium Ion (li-ion) Air Inflator (Power Source: Battery/Car/Electric, Lowes.com).

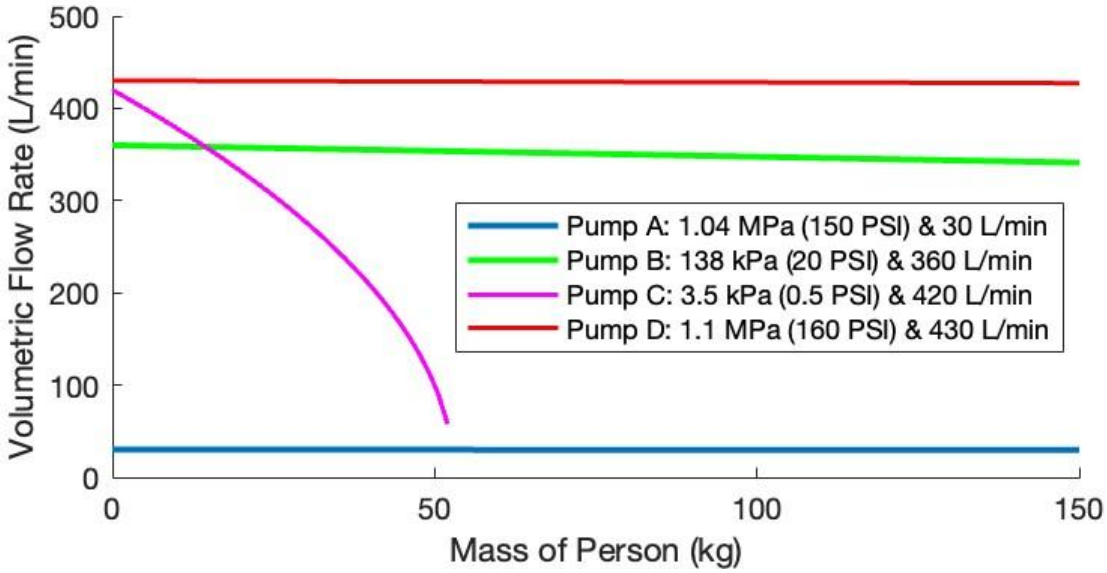


Figure 26. These volumetric flow rate versus mass of person graphs show the inverse relationship between volumetric flow rate and mass of person of four different air pumps, as inferred from Fig. 23. Pump A is rated at 1.04 MPa (150 PSI) & 30 L/min; Pump B at 138 kPa (20 PSI) & 360 L/min; Pump C at 3.5 kPa (0.5 PSI) & 420 L/min; and Pump D at 1.1 MPa (160 PSI) & 430 L/min.

As inferred from Fig. 25 and 26, the greater the pressure and volumetric flow rate of a pump, the higher the pump price. This means that we would need to use a pump that sufficiently handles the inflation process without impeding on our cost requirement. Pump B sufficiently matches our pump requirements, which are discussed on page 57. Fig. 27 analyzes the time of transfer versus mass of person for Pumps A-D to see if time of transfer effectively correlates with Pump B, according to our theoretical analysis.

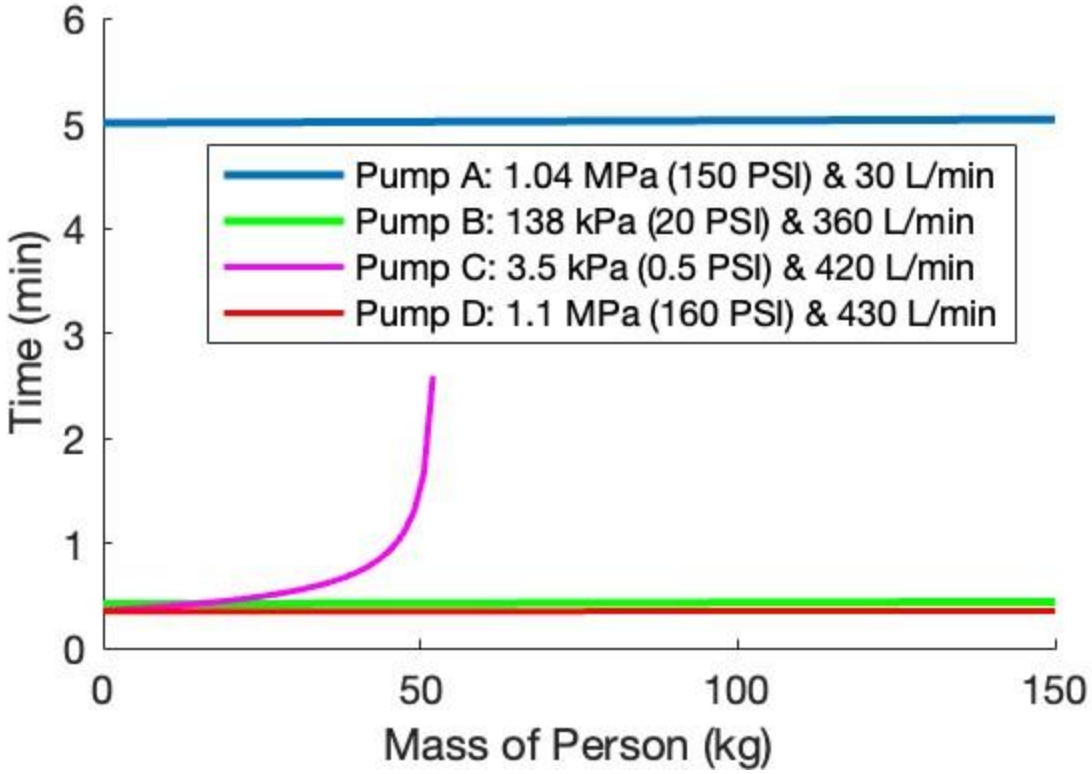


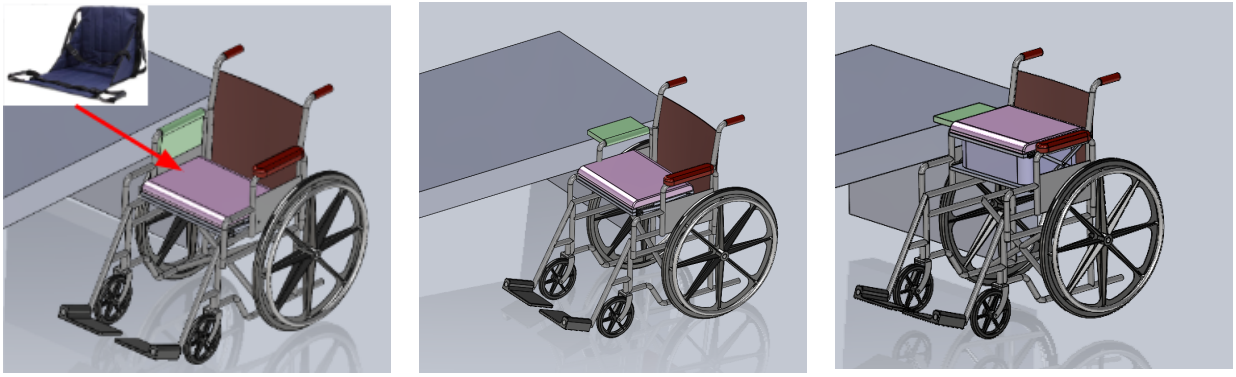
Figure 27. These time versus mass of person graphs show the positive relationship between time and mass of person due to the inverse relationship between time and volumetric flow rate with respect to the final height of the inflatable cushion for Pumps A-D.

Fig. 27 indicates the inverse relationship between time and volumetric flow rate because time is proportional to the mass of a person, whereas volumetric flow rate is inversely proportional to the mass of a person. This is valid because the heavier the person is, the more time the pump takes to inflate the cushion to 15 centimeters. Because of this relationship, the higher the pump rate, the less time the pump takes to inflate the cushion. This draws from Fig. 24 because the same relationship applies for an increase in the volumetric flow rate: the inverse of time with respect to a height of 15 centimeters. To satisfy our two minute inflation transfer time requirement, Pump B is effective because, at the required 150 kg mass of the person, the transfer time is less than two minutes. However, as a backup pump, we plan to use Pump D as a substitute for Pump B in case any of our theoretical model's assumptions violate our empirical tests that we will conduct after design review three. From there, we will analyze any significant energy losses associated with the violation (e.g. input air flow leakages and viscous effects). If Pump B is insufficient, and we use Pump D instead, we will account for the use of the pump with respect to our cost requirement and the number of uses from the "withstanding Poovanthi environment" requirement. Accounting for this involves calculating the number of pumps needed

to withstand the number of uses per day - this will be presented in the final report after we do a weight test to see how long the pump can last. See page 63 for the description of our weight test.

Final Design

Our final design utilizes an inflatable wheelchair seat cushion that will raise the patient to the height of the bed and a foldover arm rest component and wheelchair sling that will provide extra support for the patient when the caregiver is transferring them laterally onto the therapy bed. The inflatable cushion, armrest bridge and wheelchair sling will remain at every wheelchair for each patient that uses our device. This will prevent the caregiver from having to carry around multiple components from patient to patient, making it more likely for them to actually use the device. By making it more likely for them to use the device, it reduces the risk of lower back injury caused by caregivers using only their own strength to move the patient. The steps for using the device are outlined in Figure 28 below. When performing the transfer, the caregiver will position the wheelchair as close as possible to the therapy bed on the patient's strong side. They will then fold over the armrest bridge onto the therapy bed (Figure 28 b). Using an external pump, the caregiver will inflate the cushion until the patient is at bed height (Figure 28 c). The caregiver then will position themselves in front of the wheelchair facing the patient. They will grab the handles on the wheelchair sling and pivot the patient onto the therapy bed. Specific components are explained in further detail below.



(a) (b) (c)

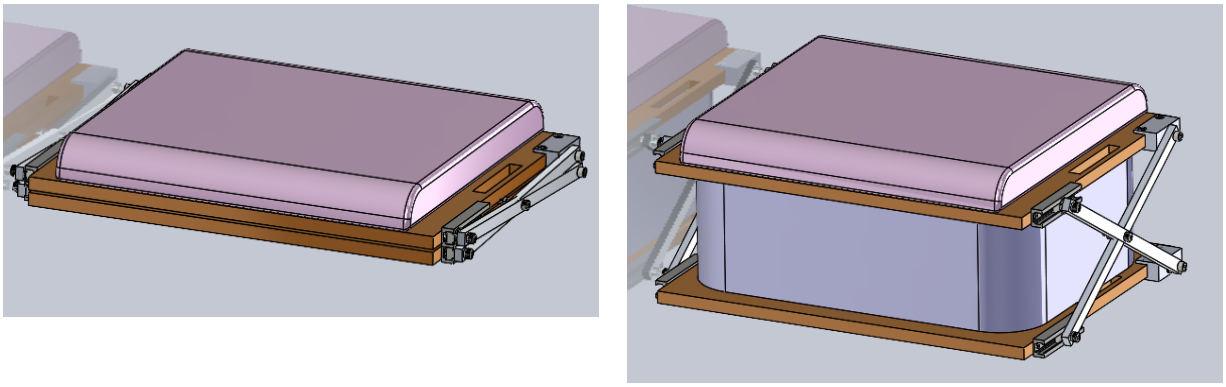
Figure 28. The inflatable cushion (pink), armrest bridge (green) and wheelchair sling (Figure 28 a) will be a part of every wheelchair for each patient that uses the device. The inflatable cushion raises the patient to bed height and the armrest bridge and sling supports the patient as they are transferred laterally.

Once the patient is on the therapy bed, the cushion will remain inflated and the armrest bridge can be folded back over so that it is out of the way. When the patient needs to be transferred back to the wheelchair, the caregiver will position them into the wheelchair sling, fold the armrest

bridge back onto the bed and slide them back over onto the inflatable cushion in a pivoting motion. There will be one air pump per therapy hall and it will be stored in a location that is most convenient for the caregivers.

Inflatable Cushion

The inflatable cushion component in Figure 29 below is used to raise the patient to bed height. It will remain a part of the patient's wheelchair so it will have a comfortable cushion on top of the top plate. To address patient stability concerns, we added scissor link supports to the sides of the cushion assembly. The scissor links allow the cushion to collapse completely when not in use, but prevent it from moving front to back and side to side when inflating with a patient on top. When discussing the inflatable cushion design with Dr. Luntz, he initially suggested using cables as supports, but the cables would only provide stability once the cushion is completely inflated. The rigid scissor links provide stability for the cushion throughout the inflation process.



(a) (b)

Figure 29. Scissor link supports were added to the inflatable cushion assembly in order to stabilize the patient while the cushion is inflating.

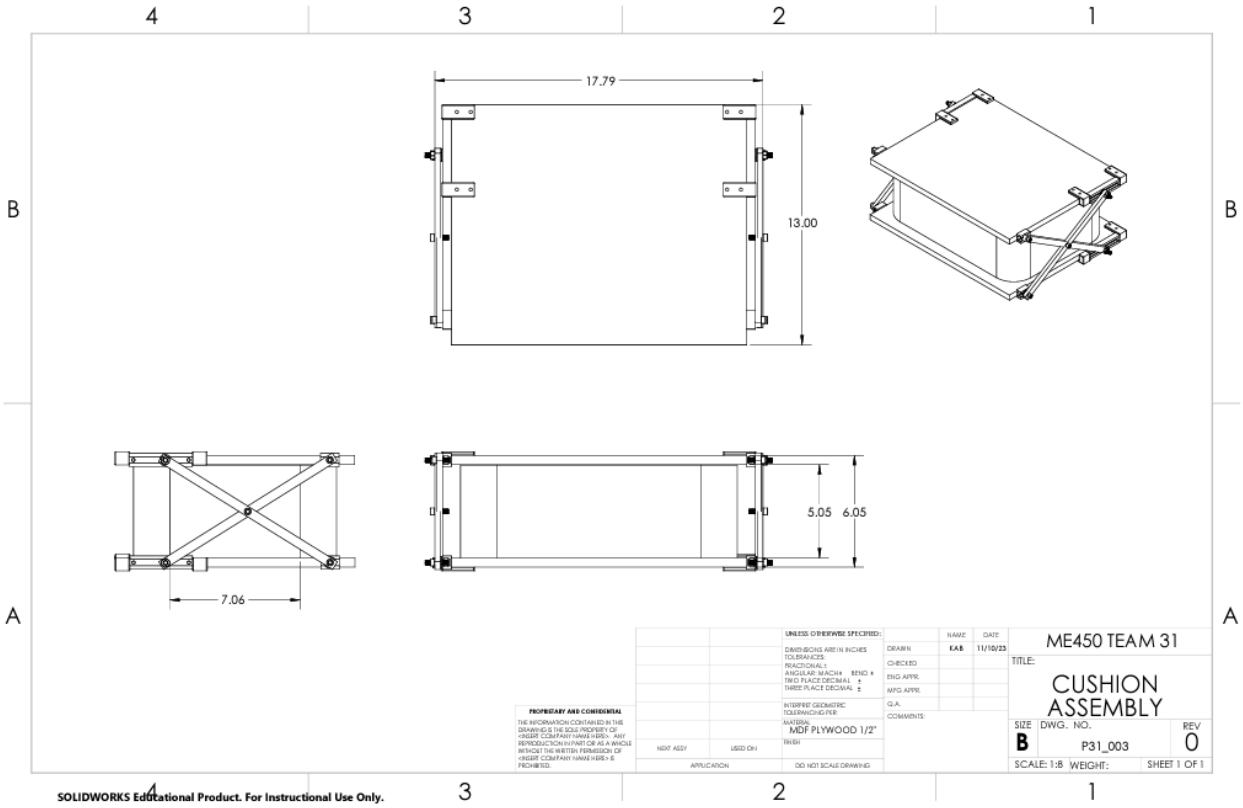


Figure 30. The cushion assembly with overall dimensions. Dimensions for individual components can be found in Appendix E.

Armrest Bridge

The foldover armrest bridge would slide onto the tube armrest of the wheelchair. It can go on either armrest depending on which is the patient's strong side. When not in use, the armrest bridge will fold down out of the patient's way for when they are moving in the wheelchair.

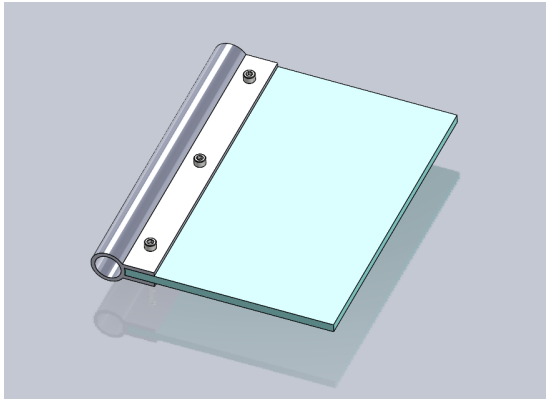


Figure 31. The foldover armrest bridge easily slides onto either armrest of the wheelchair and will remain on the wheelchair.

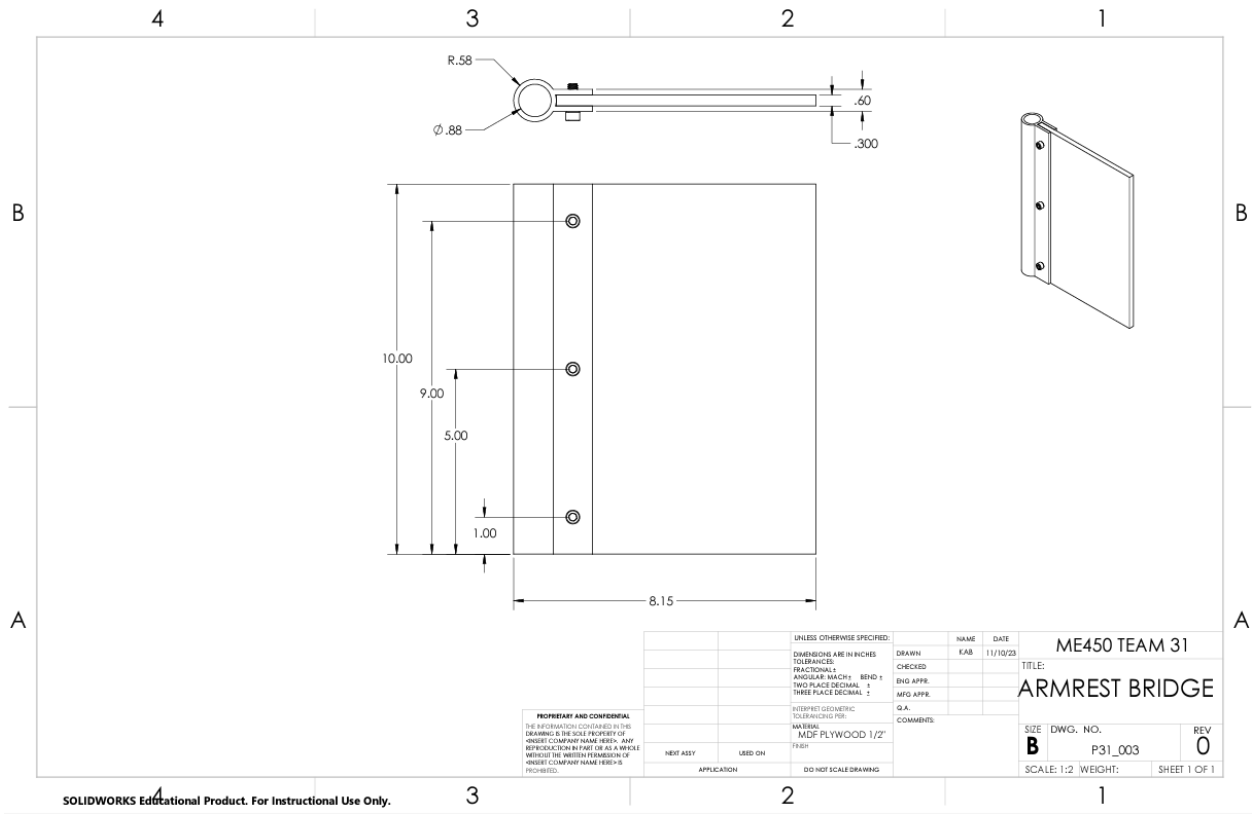


Figure 32. The armrest bridge with important overall dimensions labeled.

Wheelchair Sling

The wheelchair sling will also remain in the wheelchair and provide necessary trunk support for the patient and handles for the caregiver to make the transfer smoother. Initially, we considered using existing solutions like the sling in Figure 33 (a), but at a price of $40, it would be too expensive for Poovanthi to purchase one for each patient using our device(*Amazon.Com: Transfer Belts For Lifting Seniors Transfer Boards for Wheelchair User Patient Lift Assist Aid for Home Stair Slide Medical Emergency Evacuation Chair Safety Support Disabled Up & Down Stairs Devices : Health & Household*, n.d.). We then explored other options like the camping chair in Figure 33 (b) (*Amazon.Com : Coleman Red Portable Stadium Seat Cushion | Lightweight Padded Seat for Sporting Events and Outdoor Concerts | Bleacher Cushion with Backrest : Sports Stadium Seats And Cushions : Sports & Outdoors*, n.d.). The camping chair would provide the trunk support, but lacks the handles to assist the caregiver during the transfer. We would like to combine these two solutions into a lower cost option shown by the sketch in Figure 33 (c). This would be an iteration on the camping chair with the addition of handles to the diagonal straps and a strap that would secure the patient across their lap.

(a) (b) (c)

Figure 33. The three options we are considering for a wheelchair sling. Options (a) and (b) are existing solutions and option (c) is an iteration on option (b) to provide a less expensive alternative that meets our needs.

Engineering Analysis for Final Design

When determining what engineering analysis to perform with the time remaining in our project, we brainstormed our top design worries based on our alpha design and ranked the list to determine the priority of the worries. These design worries were then transformed into engineering analysis that we performed to prove that our design was viable. Our ranking of design worries is listed below:

Safety

1. Ability to stabilize patients on cushion
2. Ability to reduce caregiver exertion and minimize risk of injury
3. Need for a failsafe if the cushion ruptures
4. Inflation is comfortable and not too fast for patients

Functionality

1. Ability to inflate the cushion with a 150 kg patient
2. Transfer time is less than 4 minutes
3. Simplicity of design and desire for caretaker to use
4. Budget

Safety of the caregiver and patient is our highest priority and design consideration, so it was madea separate category from the functionality of the design. We wanted to address all of our safety concerns with our design first. When speaking to Dr. Luntz about the inflatable design, he expressed concerns for the safety and stability of the patient when inflating the cushion and the risk of injury for the caregiver when performing the transfer (J. Luntz, personal communication, October 16, 2023). These were the first two engineering analyses that we prioritized before moving forward with the design. Recognizing the need for a failsafe mechanism in case of cushion rupture, we plan for further iterations to enhance the inflatable component's durability. Some iterations we considered were a foam-filled inflatable or a layered

design with pressure valves to prevent the patient from falling suddenly if the cushion were to rupture. We don't believe we are able to simulate or prototype these failsafe concepts with the time remaining in the semester. Furthermore, we prioritized the comfort of patients during the cushion inflation process, steering clear of any distressing elements as they are lifted. Initial research into available air pumps on the market revealed a diverse range of products with varying flow rates and pressure ratings, providing us with the flexibility to choose a suitable option for our design. After addressing all of our safety concerns regarding the design, we decided to choose the top two functionality concerns to perform analysis on with the time we had before the DR3 presentation. The ability of our design to lift a 150 kg patient emerged as a critical requirement, given that Poovanthi's existing patient transfer solution is not suitable for larger patients, necessitating manual effort from caregivers. Also, achieving a transfer time of less than 4 minutes was identified as imperative for caregiver convenience. With a patient to therapist ratio of 12:1 at the Institute, our stakeholder placed this as one of our higher priorities for our design. The engineering analysis for the top two safety and top two functionality design worries are explained below.

Patient Safety: Stability of Cushion

With the safety of the patient and caregiving being of our highest priority, we needed to ensure that our inflatable cushion design would be able to support and stabilize the patient, minimizing fall risk during the transfer process. During our initial meeting with Dr. Luntz when we discussed our inflatable cushion design, he explained that inflating a cushion with 150 kg on top in the time needed was possible, but he was concerned about the stability of the cushion as it raises the patient to bed height (J. Luntz, personal communication, October 16, 2023). Unconstrained inflatables exhibit non-uniform inflation. The patients that would utilize the device would lack the strength to balance themselves, creating a fall risk. With this in mind, we added scissor link supports to the cushion assembly to prevent the cushion from moving front to back and side to side during inflation. Theoretically, the addition of the links restrains the plates from moving, but we needed to ensure that the links would not bend or displace significantly with the maximum weight on top. We considered two forms of analysis: SolidWorks simulation and empirical weight bearing testing on the constructed prototype. Because construction of a prototype would take a lot of time and money, we wanted to ensure that the scissor link concept would work prior to moving forward with the design. The solidworks analysis was an efficient way to determine the displacement of the links and give us confidence in moving forward with our design, so we determined it was the best option for testing this design worry.

The SolidWorks simulation was performed on the assembly containing the top and bottom plates along with the scissor link supports. All of the hardware that we intended on using in the prototype was also used in the assembly. The bottom plate was fixed to the ground and a distributed pressure of 1.4 psi was applied to the inside of the top and bottom plates to represent the support from the inflatable. A 150 kg load was applied to the top plate in two different scenarios. In the first scenario, Figure 34(a), the load is applied evenly over the entire top plate.

This is the ideal scenario for when the patient is centered on the cushion. In the second scenario or the worst-case scenario, Figure 34(b), the patient is off-centered on the cushion so the 150 kg of weight is only distributed on half of the top plate. After applying the supports and loads and assigning the appropriate material to the parts, we ran the simulation. The results are shown in Figures 34 (a) and (b) below.

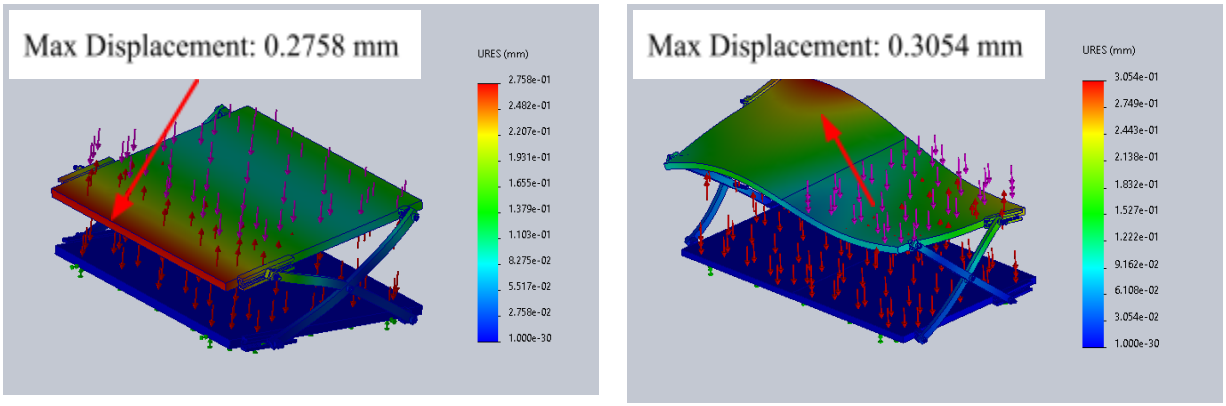


Figure 34 (a) and (b). Figure 34 (a) (left) demonstrates the instance where the patient is centered on the cushion. The results show the maximum displacement would be 0.2758 mm towards the front of the cushion. Figure 34 (b) (right) demonstrates the instance where the patient is off-centered on the cushion. The results show the maximum displacement would be 0.3054 mm on the opposite side of the weight.

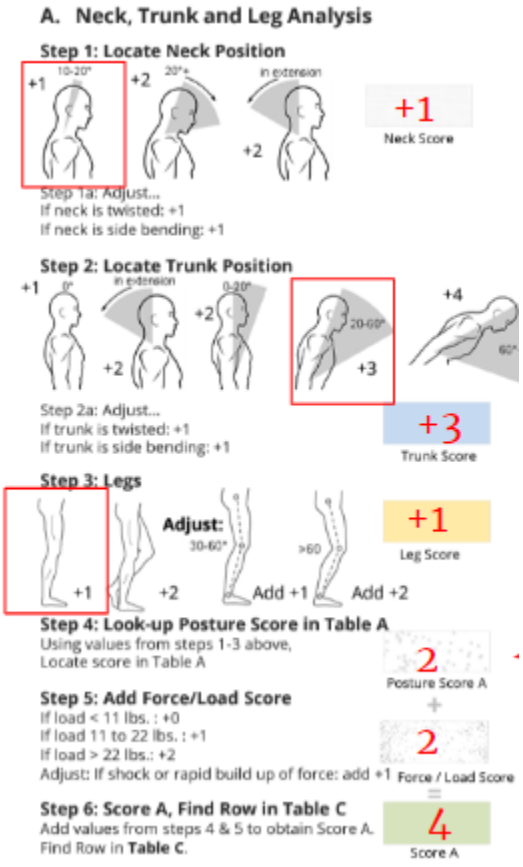
The simulation results in both scenarios show that the maximum displacement would be less than 1 mm. Note that SolidWorks exaggerates the simulation results to visually demonstrate where the maximum displacement occurs. Because the maximum displacement was less than a millimeter in both cases, we determined that the scissor link design would safely stabilize the patient while inflating the cushion. This simulation gave us the confidence to move forward in constructing a prototype of our design. If time permits in the remainder of our project, we would like to perform additional empirical testing on our constructed prototype to confirm the results of the SolidWorks simulation.

Caregiver Safety: Rapid Entire Body Assessment

The second design concern regarding safety that we wanted to perform engineering analysis on was the reduction of caregiver exertion in the design. Our original caregiver safety requirement utilized the NIOSH lifting equation to determine if the patient transfer process was safe for caregivers. Because our design does not have a vertical lifting component, the NIOSH lifting equation is not valid for our design. It is very difficult to measure caregiver exertion without performing clinical trials with our device so we decided to use another ergonomic tool called the Rapid Entire Body Assessment (REBA) (Hita-Gutiérrez et al., 2020). REBA is a tool

used to evaluate the risk of a musculoskeletal disorder (MSD) associated with a certain task. Lifting and transferring patients is the most significant risk factor for musculoskeletal injuries, especially back pain, in nurses (Tariq et al., 2023). Our design aims to minimize the risk of injury for caregivers during patient transfers. To assess our design's alignment with patient safety requirements, we determined that the REBA tool would be an appropriate method for evaluation. Our design specification states that the transfer process using our design must score a 3 or lower on the REBA scale which would indicate a low risk of an MSD occurring.

REBA is a worksheet that evaluates both the upper and lower parts of the body, specifically the posture and forceful exertions associated with the task (Middlesworth, n.d.). The figures below walk through the one page worksheet that will produce the final REBA score associated with the transfer task.



(a)

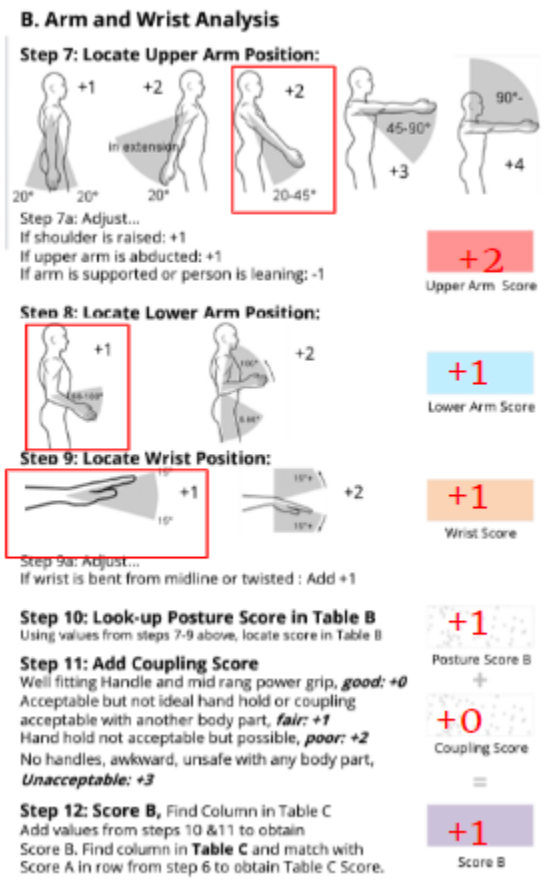
Scores

Table A		Neck											
		1				2				3			
	Legs	1	2	3	4	1	2	3	4	1	2	3	4
Trunk Posture Score	1	1	2	3	4	1	2	3	4	3	3	5	6
	2	2	3	4	5	3	4	5	6	4	5	6	7
	3	2	4	5	6	4	5	6	7	5	6	7	8
	4	3	5	6	7	5	6	7	8	6	7	8	9
	5	4	6	7	8	6	7	8	9	7	8	9	9

(b)

Figure 35 (a) and (b). The neck, trunk and leg analysis in Figure 35 (a) (left) gives us a final score A of 2 which will be combined with the score for the arm and wrist analysis to give us the final REBA score. Table A in Figure 35 (b) (right) is used to find the lower posture score which is added to the load score.

After analyzing the posture of caregivers when performing current transfer methods and relating that to the use of our device, we filled out the worksheet starting with the neck, trunk and leg analysis. The neck would be bent slightly between 10-20 degrees and the trunk would be bent between 30-60 degrees depending on how tall the caregiver is compared to the wheelchair height. The caregivers legs would have a slight bend in them to provide a strong base for the transfer, but not more than 30 degrees. The neck, trunk and leg score from Figure 35 (a) were combined in Table A in Figure 35 (b) to get a score of 2. This score was combined with the load score which was 2 because the load is greater than 22 lbs. Adding these two scores together, we get a score A of 4. Next we analyzed the arm and wrist position.



(a)

Table B		Lower Arm					
		1			2		
	Wrist	1	2	3	1	2	3
Upper Arm Score	1	1	2	2	1	2	3
	2	1	2	3	2	3	4
	3	3	4	5	4	5	5
	4	4	5	5	5	6	7
	5	6	7	8	7	8	8
	6	7	8	8	8	9	9

(b)

Figure 36 (a) and (b). The arm and wrist analysis in Figure 36 (a) (left) are combined in Table B in Figure 36 (b) (right) to give us an upper arm score of 1.

Score A	Table C Score B											
	1	2	3	4	5	6	7	8	9	10	11	12
1	1	1	1	2	3	3	4	5	6	7	7	7
2	1	2	2	3	4	4	5	6	6	7	7	8
3	2	3	3	3	4	5	6	7	7	8	8	8
4	3	4	4	4	5	6	7	8	8	9	9	9
5	4	4	4	5	6	7	8	8	9	9	9	9
6	6	6	6	7	8	8	9	9	10	10	10	10
7	7	7	7	8	9	9	9	10	10	11	11	11
8	8	8	8	9	10	10	10	10	10	11	11	11
9	9	9	9	10	10	10	11	11	11	12	12	12
10	10	10	10	11	11	11	11	12	12	12	12	12
11	11	11	11	11	12	12	12	12	12	12	12	12
12	12	12	12	12	12	12	12	12	12	12	12	12

Figure 37. Score A from the lower body analysis and score B from the upper body analysis are combined in Table C to get a Table C score of 3.

While transferring the patient, the caregiver's upper arm would be between a 20-45 degree angle from their body and their lower arm would be between a 60-100 degree angle because they would be grabbing the handles on the wheelchair sling. The wrist would not be bent more than 15 degrees. Using the scores from steps 7-9 in Figure 36 (a), we combine them in Table B in Figure 36 (b) to get an upper arm score of 1. This upper arm score is added to the coupling score in step 11. Because there are well fitted handles on the wheelchair sling for the caregiver to grab during the transfer, the coupling score is zero giving us a score B of 1. Score A and score B are combined in Table C in Figure 37 to give us a Table C score of 3. The final step is to add the activity score to the table C score. For the task we are examining, the activity score is zero because none of the activities applied to the transfer process. This gives us a final score of 3. Based on the scoring chart below in Figure 38, the patient transfer process using our device would have a low risk of an MSD occurring for the caregiver.

Score	Level of MSD Risk
1	negligible risk, no action required
2-3	low risk, change may be needed
4-7	medium risk, further investigation, change soon
8-10	high risk, investigate and implement change
11+	very high risk, implement change

Figure 38. The REBA scoring chart states that a score of 3 would mean the task has a low risk of MSD occurring.

The final REBA score of 3 meets our caregiver safety requirement and addresses our design worries regarding the reduction of caregiver exertion. During discussions with stakeholders, their satisfaction was evident as they recognized that our design eliminates the necessity to vertically lift patients to bed height. The incorporation of the REBA tool in our engineering analysis serves as additional evidence, reinforcing the confidence that our design effectively minimizes the risk of injuries for caregivers.

Ability to Transfer a 150 kg Patient in Four Minutes

The ability of the design to raise a 150 kg (331 lbs) patient is reliant on both the load-bearing capacity of the inflatable and the pressure that the external pump used to inflate the cushion can provide. The amount of time required to perform the transfer is reliant on the inflation process when raising the patient to the height of the bed and a caregiver's ability to slide the patient across the armrest bridge and position them on the bed.

From discussions with Dr. Luntz, we learned that using software to simulate loads on inflatable structures is difficult to achieve (J. Luntz, personal communication, October 16, 2023). Dr. Luntz advised that we should empirically test a prototype to estimate the strength of the inflatable design (J. Luntz, personal communication, October 16, 2023). The rated pressure capabilities of the pump are outlined in the pump's specifications. The time required to inflate the cushion is dependent on the volumetric flow rate provided by the pump and the volume of the fully-inflated inflatable cushion. The time required to slide and position the patient is dependent on the size and strength of the caregiver, so it is difficult to evaluate. From conversations with stakeholders who work in healthcare, the team determined that two minutes is a reasonable estimate for the time required to slide and position the patient (T. Rooney, personal communication, September 19, 2023, D. Shin, personal communication, November 17, 2023). Further research and knowledge about the caregiver demographic at Poovanthi could provide a more accurate estimate. Estimating that the lateral movement of the patient would take two minutes means that in order to meet the four minute maximum transfer requirement, the inflatable cushion should inflate in two minutes or less.

To begin classifying an ideal air pump for our final design, the minimum pressure rating of the external pump was assumed to withstand the weight of the 150 kg (330.7 lbs) patient, which was assumed to be evenly distributed across the top surface of the inflatable. Only the weight of the patient was considered, as the weights of the top plate and the scissor link structures are negligible by comparison. As the pressure ratings for the pumps we researched on Amazon.com and at Lowe's are expressed in pounds per square inch (psi), the required pressure was calculated from Equation 3.

$$p_{req} = \left(\frac{Weight\ of\ Patient\ (lbs)}{Area\ of\ Plate\ (in^2)}\right) \quad (3)$$

The area of the top surface of the inflatable in the CAD model of our design is 161.67 in^2, as shown in Figure 39.

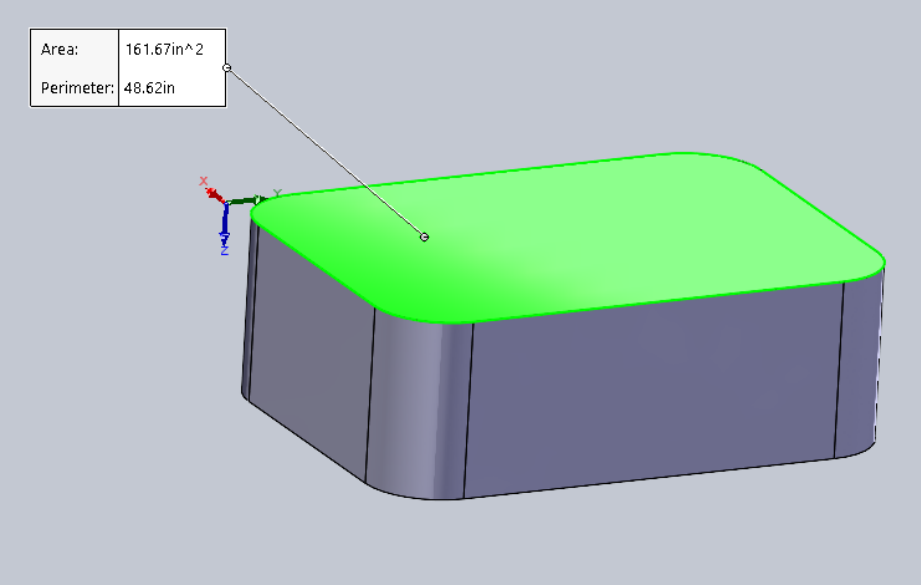


Figure 39. The top surface of the modeled inflatable, highlighted in green, has a surface area of 161.67 in^2

Using Eq. 3, a patient weight of 330.7 lbs and plate area of 161.67 in^2 yields a pressure of 2.05 psi. This means that the pump used to raise the inflatable cushion must be able to provide a pressure of at least 2.05 psi in order to meet the 150 kg specification.

To calculate the volumetric flow rate from the pump required to inflate the cushion in two minutes, Equation 4 was used.

$$Q_{in} = \left(\frac{Maximum\ Volume\ of\ Inflatable\ Cushion}{Inflation\ Time}\right) \qquad (4)$$

From our SolidWorks model, the volume of the inflatable is 808.37 in^3, or 13.25 liters. The pumps we researched on Amazon.com and at Lowe's provide volumetric flow rate in units of liters per minute (L/min). The minimum, required volumetric flow rate is dependent on the two minute time raising the patient. Therefore, using Eq. 4 provides a volumetric flow rate of 6.63 L/min at 2.05 psi. The theoretical analysis of the pump selection process to complete this requirement is provided on page 40. For this design review, the classification analysis of the ideal pump was completed after the pump selection process due to the chronological order of our decisions to find a pump.

Engineering Analysis for Final Design Summary

After performing the engineering analyses explained above, we decided to move forward in the construction of the inflatable cushion prototype due to the patient and caregiver safety implications. In addition to the patient stability and caregiver safety analysis, the theoretical inflation time calculations provided us with the air pump specifications necessary to inflate a cushion with a 150 kg patient on top in the time necessary.

Build Description

Materials and Parts

To assist in performing analysis on our design, the team constructed a physical prototype. The prototype consists of two wooden plates, an inflatable cushion, velcro, four links, four t-tracks, and various nuts, washers, bearings, and screws. The information on the materials in the build can be seen in Table 3 below.

Table 3: Bill of Materials for build

Part	Material	Manufacturer	Part Number	Cost per part	Quantity
Plates	MDF Plywood, 2’ x 4’ x ½”	Home Depot		$24.99	1
Inflatable Cushion	PVC	Yivibe	Yivibe2gvophyx0u	$9.99	1
Velcro	Nylon, Polyester, 1” x 7”	OmniSpecial	OmniSpecial-11	$3.99 per pack	1 Pack of 20
Scissor Links	6061 Aluminum, 6” x 12” x 5/16”	McMaster-Carr	9246k464	$23.30	1
T-Tracks	Anodized Aluminum Fixturing T-Track 36” Length	McMaster-Carr	1850a17	$19.65	1
Hex Head Screw	¼-20 Thread Steel Hex Head Screws	McMaster-Carr	1850a22	$1.66 per pack	1 Pack of 10
Medium Strength Hex	¼-20 Thread Steel Hex	McMaster-Carr	95462a029	$8.95 per pack	1 Pack of 100

Nut	Nut				
Washer	316 Stainless Steel Washer	McMaster-Carr	90107a029	X50 Assembly Room	8
Socket Head Screw	Black Oxide Steel ¼-20 Thread 1-½" length	McMaster-Carr	90044a123	$19.16 per pack	1 Pack of 50
Shoulder Screw	10-24 Thread Black Oxide Steel Shoulder Screw, ⅝" Shoulder Length	McMaster-Carr	91259a539	$1.70	2
Low Strength Hex Nut	10-24 Thread Low Strength Steel Hex Nut, Zinc Plated	McMaster-Carr	90480a011	$2.33 per pack	1 Pack of 100
Sleeve Bearing	4mm x 8mm x 6mm Bronze Bushing	uxcell	a21012200ux0528	$7.99 per pack	1 Pack of 4
Stopper	PLA Plastic				8

Manufacturing Plans

Upon purchasing the raw materials, some of the parts needed to be machined to properly fit the build. The first part to be manufactured is the link, used for the scissor lift. The manufacturing drawing and plan for the link can be found in Appendix E, parts a and b of figure 1E respectively. This part can be manufactured entirely in the ME 450 machine shop, using the waterjet and milling machines. The links can be found in Figure 40.

Figure 40. Scissor links after manufacturing.

The next parts are the top and bottom plates, the drawing for which can be seen in Appendix E, figure 2E. This part can also be manufactured in the ME 450 machine shop; since this part is made with plywood, it can be cut down to size in the bandsaw, and the holes can be made with a power drill. The holes drilled with the power drill have the most important tolerances on this part, since these holes are intended to secure the links and t-tracks.

The last parts to be machined are the track, the drawing and manufacturing plan for which can be seen in Appendix E, parts a and b of figure 3E. This part can be manufactured in the ME 450 machine shop, only the bandsaw and mill. The only tolerances for this part are the end of the track being machined, which is not a critical surface, and can have a looser tolerance than other surfaces on other parts being machined.

Comparison to Final Design

To meet the budgeting requirements of our project this semester, the build is different from the final design in some of the materials being used, and dimensions of some parts. The bottom and top plate will be made of aluminum rather than plywood, which will increase the cost and slightly increase weight. The inflatable material and plates will also have their dimensions changed to fit the wheelchair, meaning rather than using an already existing inflatable cushion, the cushion will have to be made with PVC material from scratch. The completed build can be seen in Figure 41 below.

Figure 41. Build with inflated cushion

The build is designed to use the materials at our disposal to prove the most important aspects of our design function safely. The build provides evidence to suggest that the patient can be stabilized by showing that the links won't give under load, and restrict degrees of freedom of the movement of the device. The build also shows that the caregiver exertion will be reduced by automating the vertical movement portion of the transfer, and that the cushion will provide comfortable motion for the patient. As well as safety, the build is proof-of-concept for functionality as well. It allows us to demonstrate that we can lift the expected higher end of weight (150 kg), and that we can perform the transfer within four minutes.

Verification

In order to determine if our design is successful, we must demonstrate that it meets all of our engineering requirements. Initial analyses for the design concerns of patient safety, caregiver safety, inflation time, and ability to lift 150 kg have been provided above. Plans for further analysis of those requirements and the remaining requirements are outlined below. A summary of the verification results can be seen in Table 4 below.

Table 4. Summary of verification test results.

Requirement	Specification	Verification Results
Meets Poovanthi's price requirements	Must cost ≤ $1987 or 165,193.52 INR.	Pass - Total cost for 11 units and two air pumps is $848.66.
Operable by available personnel at Poovanthi	Only requires a single nurse/caregiver to complete transfer	Pass - Usability testing performed by proxy physical therapist (D. Shin, personal communication, November 17, 2023).
Meets Poovanthi's transfer time requirement.	Time to transfer ≤ 4 minutes for transfer from wheelchair.	Inconclusive - Passes for patients of up to 250 lbs (113 kg). Testing could not be continued beyond 250 lbs.
Compatible with the Poovanthi facility's spatial dimensions	1. Must be no more than 4 feet wide(1.22 meters). 2. Must be less than 6 feet 8 in. (2.03 meters) tall.	Pass - Total design dimensions do not exceed the specified height and width.
Can transfer disabled patients	1. Can transfer patients with fall risk (defined by Berg Balance scale) from	1. Pass - Usability testing performed by proxy physical therapist (D. Shin, personal communication, November 17, 2023).

	wheelchair to therapy bed and vice versa. 2. Can support a weight of at least 150 kg.	2. Fail - Design failed at 250 lbs.
Meets patient and caregiver safety standards	All Risk Priority Numbers must be below 300 in FMEA performed according to ISO 14971.	Pass - Highest Risk Priority Number was 36.
Can be cleaned with cleaning supplies available at Poovanthi	Surfaces can be cleaned with standard alcohol-based disinfectants.	Pass - Alcohol-based disinfectants and majority of sanitizing chemicals do not corrode materials on device
Has commercialization potential	1. Complies with CDSCO, *specifically The Medical Device Rules, 2017 (Medical Device Rules, 2017, 2016).* 2. Does not infringe on existing patents.	1. Inconclusive 2. Pass - Benchmarking shows existing patents are different enough from current design
Can withstand Poovanthi environment	1. Can withstand temperatures up to 43 ℃ and humidity up to 100%. 2. Can withstand 12 uses/ patient/ day for 5 years.	1. Pass - All materials used in the design can withstand temperatures up to 43 ℃ and humidity up to 100%. 2. Fail - Not all locations in the solidworks model were able to endure 12,900 cycles.
Complies with OSHA lifting standards.	Does not exceed a lifting factor of 1.0.	Pass - No lifting involved so complies with OSHA lifting standards. Scored a 3 on REBA scale showing low risk of musculoskeletal disorder occurring.
Ease of Manufacturability.	Must be manufactured in India.	Pass - A manufacturer was identified in India that performs the manufacturing processes for our design. Also all of the materials used in our design are available in India.

Patient and Caregiver Safety: Methods

In order to verify that our device is safe, the team performed a Failure Modes and Effects Analysis (FMEA) to assess the level of risk of any potential failure modes for our design. The FMEA produces a Risk Priority Number (RPN) for each of the potential failures identified. Our specification states that each potential failure must have an RPN of 300 or lower in order for our device to be considered safe. The team elected to use an FMEA to verify the safety of our device because we will be unable to submit the device to a regulatory body like the FDA or India's CDSCO to be formally evaluated and approved for commercial use this semester. Additionally, it would be unethical and potentially dangerous to evaluate the safety of the device by asking people to act as either patient or caregiver and simulate a full transfer with any significant load on the prototype build. While ideally more thorough steps would be taken to verify the safety of the device for both patient and caregiver, an FMEA is a method that was feasible for the team to implement this semester.

An FMEA analysis consists of four steps, listed below:

1. Identify potential failures and effects
2. Determine severity
3. Gauge likelihood of occurrence
4. Failure detection

(*How to Conduct a Failure Modes and Effects Analysis (FMEA)*, n.d.)

Step 1. involves identifying any potential failures of the device and anticipating the effects of those failures. Step 2. involves rating the seriousness of the consequences of each identified failure mode on a scale of 1-10, with 1 indicating that there are no dangerous effects and 10 indicating hazardous, disastrous effects. Step 3. consists of ranking the likelihood of each failure mode – how often the failure occurs. Similar products and processes to our inflatable cushion should be identified and the documented failure modes for these products should be assessed for this step. A ranking on a scale of 1 (unlikely/no documented failures) to 10 (very likely) is applied for each failure mode, similar to the ranking applied in step 2. Finally, the likelihood for a design flaw to be identified by testing is evaluated in step 4. Again, a ranking from 1-10 is applied for this step, with a score of 1 indicating that a failure will definitely be identified by testing, and a score of 10 indicating that a fault will not be noticed by a user of the device. (*How to Conduct a Failure Modes and Effects Analysis (FMEA)*, n.d.)

After these four steps were completed, the Risk Priority Number (RPN) was calculated by multiplying the three scores from steps two through four together (*How to Conduct a Failure Modes and Effects Analysis (FMEA)*, n.d.).

FMEA Results

The results of the FMEA are presented in Table 5 below.

Table 5. A Failure Modes and Effects Analysis was performed to determine how safe our current design is. The Risk Priority Numbers do not exceed 300 which indicates that our design is considered safe.

Potential Failures and Effects	Severity	Likelihood of Occurring	Failure Detection	Risk Priority Number
Cushion rupturing during inflation and patient falling	9	2	2	36
Unstable cushion causing patient to fall	9	2	1	18
Caregiver hurting lower back during lateral transfer of patient	7	2	2	28
Scissor link supports breaking resulting in user injury	9	2	1	18
Battery dying in air pump	5	2	1	10
Patient with poor trunk control falling during lateral transfer	9	2	1	18

As shown in Table 5 above, 7 different potential failures were identified. The Risk Priority Number was calculated for each of these failures and recorded in the column on the right. The failure with the highest RPN is “Cushion rupturing during inflation and patient falling”. This received a high RPN because the effects are very severe for patient safety and it might be difficult to identify this failure during testing. Despite this potential failure having the highest RPN, it is only a 36 which is well below the maximum RPN of 300 in our specification. Although the scoring process in an FMEA is subjective, we believe that this process has highlighted areas in our design that need improvement in order to make it safe for caregivers and patients. All of the failures identified above would most likely be identified by testing, so with further testing of our design after making necessary design changes, we believe our design meets patient and caregiver safety standards.

Poovanthi Spatial Dimensions

The device needs to be less than 1.22 meters wide and 2.03 meters tall in order to fit between the therapy beds and into the therapy hall doorways. This requirement will be evaluated through the use of engineering drawings and CAD models. Because the dimensions of our ME 450 prototype build differ slightly from the customer facing design, we cannot physically measure the prototype. The use of engineering drawings is the most accurate and best use of our time to determine whether the final customer facing design will meet the dimension requirements. In order to calculate the width of the design, the inflatable cushion width needs to be added to the width of the foldover armrest bridge. As shown in Figure 30 above, the width of the inflatable cushion is 17.79 in and the width of the foldover armrest bridge is 8.15 in. The

total width is equal to 25.94 in therefore it meets the width dimension requirement. The total height in the design comes from the height of the cushion and wheelchair sling which is 25.34 in. Because the inflatable cushion height is less than 2.03 meters, it meets the height requirement. The engineering drawings for the inflatable cushion and foldover armrest bridge confirm that the design is compatible with the Poovanthi Institute's spatial dimensions.

Ability to withstand Poovanthi Environment

The final design must be able to withstand temperatures up to 43°C and 100% humidity as well as enduring 12 uses per patient daily over a span of 5 years, amounting to a total of 21,900 uses throughout the product's lifecycle (Shibu, B., personal communication, November 7, 2023). Given the impracticality of conducting empirical tests on the prototype for such an extensive usage, we have determined that a fatigue analysis using SolidWorks is the most fitting approach, providing accurate results. The analysis was performed on the cushion assembly model. The model's bottom plate was securely fixed, and a pressure of 1.4 psi was applied to the insides of both the top and bottom plates, simulating the support provided by the inflatable cushion. A distributed load of 150kg was then applied to the top plate. These pressure and load scenarios were treated as distinct "events" in the study, specified as "zero-based" loads to account for the dynamic variation from zero to 150 kg. These pressure and force assumptions are appropriate in this case because there is no other way to model the support from the inflatable in the solidworks model. The number of cycles for the events was set to 21,900. We defined the fatigue data and used the S-N curves for the materials of the design which will be aluminum and plywood. Before running the analysis, we ensured that the fatigue calculations were run for the whole model. In order to analyze the results, the life plot was examined at different locations on the model. The life plot tells us the number of cycles that cause failure at a particular location. Meeting or surpassing the demanding benchmark of 21,900 cycles would confirm the design's resilience in the Poovanthi environment, demonstrating its capability to withstand 12 uses per patient daily for an extensive 5-year period. In order to test the design's ability to withstand temperatures of 43°C and 100% humidity, the properties of the materials composing the design were researched to ensure the device maintains the necessary strength at the specified temperature and humidity. It would be very difficult to re-create the environment in Poovanthi to test our prototype, so a theoretical analysis was used.

Ability to Withstand Poovanthi Environment - Results

The fatigue testing performed on solidworks demonstrated that not all points on the inflatable cushion model would endure 21,900 cycles of loading. The life plot from the simulation can be seen in Figure 42 below.

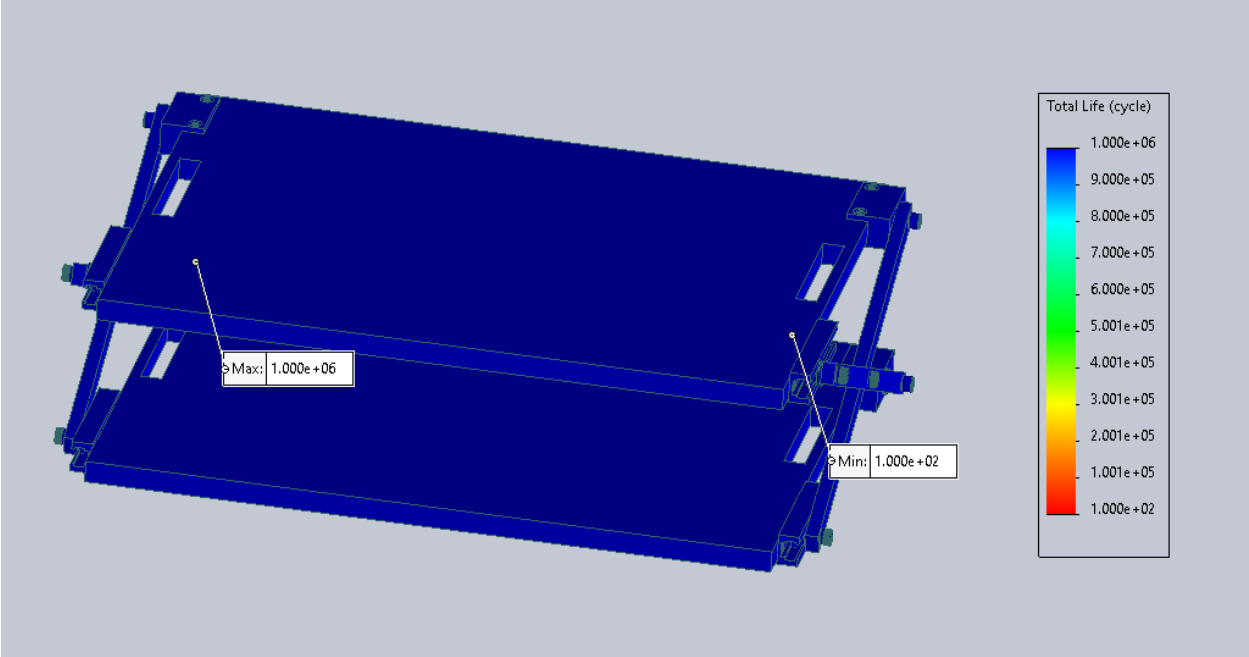


Figure 42. The fatigue testing performed on the inflatable cushion model in solidworks demonstrates that not all nodes in the design would ensure 21,900 lifecycles.

The lifecycle plot reports how many cycles each mesh node on the model can withstand. As shown in Figure 42, the mesh nodes on the outside of the model can all withstand up to 1,000,000 cycles which would meet our requirement. This is not the case for the whole model. The minimum number of cycles a mesh node could endure was 100 cycles which does not meet our requirement. This mesh node is located on the inside of the top plate. Because all points in the model cannot endure the specified number of cycles, the design does not meet this requirement. There is a possibility that only a few internal mesh nodes do not meet the number of cycles, but we cannot determine that from the results. If the majority of the mesh nodes on the model could withstand over 21,900 cycles, it is possible that the design would not fail in its expected lifetime. Further empirical testing would be necessary to confirm these simulation results, but with the time remaining and limited resources this is not possible.

The second specification in this requirement states that the materials in the design must be able to withstand the high temperatures and humidity in Poovanthi. The table below reports the material, whether it can withstand temperatures up to 43°C and 100% humidity, and the source.

Table 6. The results of our environment verification test. All of the materials used in the design can withstand the specified temperatures and humidity.

Material	Can the material withstand 43°C and 100% humidity?	Source

Plywood	Yes	(*Thermal Properties - Performance Panels*, n.d.)
Aluminum	Yes	("How Hot Is Too Hot For Aluminum?," 2023)
Polyester Fabric	Yes	(*Heat Press Time and Temperature Chart - Fabric & Uses*, n.d.)
Steel	Yes	(*Operating Temperature - an Overview | ScienceDirect Topics*, n.d.)
Brass	Yes	(Specialties,Inc, 2023)

Through examining the material properties of the materials used in the design, we determined that all materials would maintain their strength when being used in the high temperatures and humidity environment of Poovanthi. Although there is concern of corrosion and rusting of materials like aluminum and steel, the device will be used indoors and will not always be subject to moisture in the environment. Therefore we believe that this will not affect the function of the device over its lifecycle. Building on the insights from the material properties research, the design successfully aligns with the specified requirements, demonstrating its capacity to withstand conditions of 43°C and 100% humidity in Poovanthi.

Ability to Transfer a 150 kg Patient in Four Minutes: Methods

As mentioned on page 50, weight testing was performed on the cushion subsystem prototype. This testing was done to estimate the load-bearing capacity of the final design and to identify any weak components in the design to revise. This testing also allowed the team to evaluate the stability of the prototype under an applied load. Finally, the weight testing allowed the team to compare the theoretical time to inflate for Pump B, as shown in Fig. 27 (page 46), with measured inflation times obtained from testing. Empirical testing is ideal for verifying the design's ability to meet the requirements associated with these metrics due to the team's inability to simulate the inflatable using software (J. Luntz, personal communication, November 7, 2023).

The dimensions of the PVC inflatable cushion manufactured by Yivibe and incorporated in the ME 450 prototype do not match the dimensions of the proposed post-ME 450 inflatable design. The dimensions of the prototype inflatable (length x width x height) are 56 x 27 x 15 cm. This means that the total volume of the prototype inflatable is 22.68 L compared to the volume of 13.25 L from the SolidWorks model. Furthermore, the area of the top surface of the prototype inflatable (56 x 27 cm) is 234.36 in^2 compared to the 161.67 in^2 area of the modeled

inflatable. If the maximum allowable time required to inflate the modeled 13.25 L design is 2 minutes, then the time required to inflate the 22.68 L prototype under the same conditions is 2 minutes * (22.68 L/13.25 L) = 3.42 minutes. Additionally, to subject the prototype to the calculated 2.05 psi pressure, a weight of 2.05 psi * 234.36 in^2 = 480.44 lbs should be applied.

To conduct the test, weight was added to the deflated prototype in increments of 50 lbs, beginning at 0 lbs. To load the prototype, a crate was placed on the top plate of the prototype and two 25 lb iron plates were added to the crate for each 50 lb increment. When the height of the stacked weights surpassed the height of the crate, long metal supports were inserted in the corners of the crates to contain the weights. An aluminum rod was also inserted through the center holes of the weights for additional support. For each weight, the cushion was inflated and the time to inflate was recorded. The cushion was deflated before adding more weight. Only a single trial was conducted on the prototype for each tested weight. We recognize that it is best practice to perform multiple trials to acquire data, and it is worth noting that this may affect the reliability of our results. Images of the test setup are shown below in Figure 43.

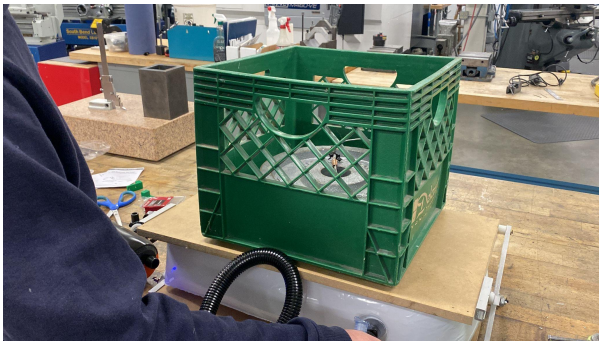


Figure 43a.

Figure 43b.

Figure 43. Shows the test setup for the timed dynamic weight testing. Figure 43a shows the fully-inflated prototype cushion with a load of 100 lbs in the green crate. Figure 43b shows the deflated cushion with 200 lbs of calibrated weights loaded in the crate. As seen in Figure 43b, the height of the stacked weights exceeds the crate height, and four long corner supports and a tube through the center of the weights were used to contain the weights.

The pump used for this prototype automatically shuts off once the inflating object reaches a pre-set pressure. This pressure setting can be adjusted in increments of 0.5 PSI from 0.0 to 20 PSI. As the cushion inflated, the pressure shown on the digital display of the pump would ramp up from 0.0 PSI. The team found that the calculated theoretical pressure of the fully-inflated inflatable was below the displayed pressure value on the pump in some cases. To avoid an auto-shutoff of the pump in the middle of a trial, the pump was set to reach an arbitrary pressure of 4.5 PSI, higher than was actually required, and manually shut off when the inflatable was fully inflated.

The stability of the prototype was visually assessed both while the cushion inflated and after testing had concluded by watching recordings and viewing pictures taken during testing.This approach allowed us to monitor if our prototype structure could withstand the stresses from the loading without large deflections.

After the overall prototype failed under this loading, the inflatable cushion component remained intact. Static weight testing was performed on just the inflatable cushion with the top and bottom plates but no supporting links. The cushion was inflated with no applied load and weight was added to the already filled inflatable. This allowed the team to obtain additional load-bearing data for the inflatable component of our design. Because of the lack of stabilizing structures after failure, the team deemed it unsafe to perform additional dynamic tests. This additional testing began at the failure load of 250 lbs and concluded once 385 lbs of weights were loaded onto the cushion. Initially, the team planned to load weight onto the cushion until the inflatable itself either leaked or ruptured. The whole setup was placed along a cabinet to prevent the weight from tipping backwards off of the cushion, but it was still unstable from side-to-side, and it was difficult to balance the weights on the cushion. Due to this instability, we judged that it was not safe to continue the test once we saw the cushion under loads close to the maximum tested load of 385 lbs. A photo from the static weight testing is shown in Figure 44.

Figure 44. Shows the test setup for the stationary testing without the stabilizing links. The circular weights for the trial depicted in the figure total 350 lbs.

As shown in Figure 44, the same crate and rods from dynamic testing were used to contain the weight in the static testing. The cabinet that the cushion and crate were propped up against supported some of the load, which mimicked the backrest on the wheelchair, which would also prevent the cushion from tipping backwards. For both the dynamic and stationary tests, the

weights of the crate and the long metal supports were considered to be negligible and are not accounted for in the data presented in this report.

Weight Testing Results

During the dynamic weight testing, the MDF boards split at the locations of the stationary ends of the links under a load of 250 lbs, which caused the screws holding those ends of the links to come loose. This was a critical failure, and the inflation testing could not continue after it had occurred. The prototype was able to fully inflate without failure under the 250 lb load, and the failure occurred almost immediately after the pump was turned off and the cushion began to deflate. Figure 45 shows the split in one of the MDF plates where a link was connected after the failure had occurred.

Figure 45. The split MDF at the location of the top plate where the stationary end of a link was screwed into. Similar material failures occurred in three of the four locations where a link was directly screwed into the MDF.

Of the four locations where the end of a link was screwed into MDF, the material failed at all but one after the pump was turned off when the prototype was under a load of 250 lbs. The one surviving connection was on the bottom plate. We have concluded that the reason for this failure was due to the way in which the links were connected to the plates at these locations. Notably, the MDF did not fail at any of the connections between the T-tracks and the boards. A likely explanation for this is that each T-track component was secured to a board at two locations with two screws. This means that any force transmitted through the track was distributed across a larger area than the loads experienced at the single-screw connections at the failure locations. Due to this difference, the failure locations experienced higher stresses than the T-track connections and thus failed first.

The team was also able to make conclusions regarding the effectiveness of the stabilizing X linkages. Overall, these results were encouraging. The links demonstrated the ability to stabilize the device, and minimal deflections were noticeable. One issue was identified with the link structures regarding their stabilizing effect. The hex head bolts that slid along the T-tracks were susceptible to binding. This binding would occur on only one side of the device at a time,

and could be mitigated by adjusting the location of the crate on the top plate. The binding would prevent one of the linkages from raising, leading to one side of the inflatable cushion rising more than the other. An example of this is shown in Figure 46.

Figure 46. One or more of the hex head bolts on the left side of the device is jammed, resulting in the right side of the inflatable being raised higher than the left.

Usually, the stuck bolt would break free from the bind without intervention, and when this occurred, the cushion would quickly level itself out. Despite this issue, the links still resulted in much greater stability and more symmetrical inflation than was observed when inflating the cushion with no supports in preliminary tests early in the semester at lower weights. The stabilizing links greatly reduced the wobble of the cushion during inflation. In cases where binding did not occur, the links rose at the same rate. Revisions to the design that would address the binding issue and the plates splitting are proposed in the Discussion section (page 81).

The inflation times recorded during the dynamic testing are plotted in Figure 47. below, along with a trendline and a plot of theoretical inflation times calculated from the analysis on pages 40-47.

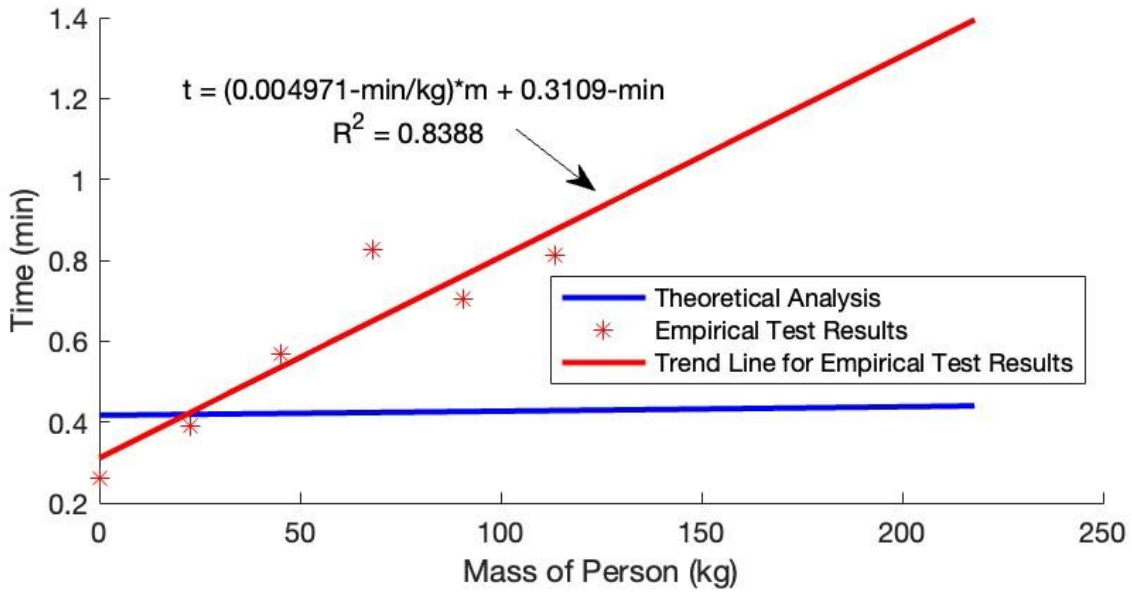


Figure 47. All of the inflation times for the loads tested, up to 250 lbs (113 kg), are under one minute, well below the maximum 3.42 minutes calculated from the dimensional analysis on page 69.

For all trials that were performed, the time to inflate the cushion was under 3.42 minutes — calculated from the analysis on page 69 — by a large margin. The longest inflation time was 49.5 seconds under the load of 150 lbs (68 kg). Based on the trendline, one would expect that the longest time to inflate would be at the maximum tested load of 250 lbs (113 kg). However, the actual recorded time when the prototype was under this load was 48.75 seconds. Because only one trial was performed at each load, human error has a greater effect on the data. Had multiple trials been performed at each load and the data at each load been averaged, the results would be more reliable and align more closely with the trendline of the plotted data. While it cannot be said with certainty that the time to inflate the prototype would be under the calculated 3.42 minutes under the maximum calculated load of 480.44 lbs or 217.92 kg determined from the dimensional analysis on page 69, the plotted data is encouraging, and if further testing were to be conducted at a later date, the team is confident that the design would pass the transfer time requirement.

For the static testing, a maximum load of 385 lbs was placed on the cushion. This means that for the prototype cushion's top surface area of 234.36 in^2, the maximum pressure of the cushion was around 1.64 PSI. Recall from the dimensional analysis (page 69) that a load of 480 lbs would need to be loaded onto the cushion in order for it to be under the required 2.05 PSI calculated pressure. For this reason, the results of this test are inconclusive, as we did not determine whether or not the cushion would be able to withstand a pressure of 2.05 PSI. Converting the applied 1.64 PSI to a weight on the post-ME 450 inflatable of top surface area 161.67 in^2, it can be concluded that the cushion could support loads up to 265.14 lbs or 120.26

kg. Conclusions cannot be made for loads higher than 120.26 kg because the prototype inflatable was not tested to failure.

In summary, if the binding issue is addressed, the linkage structures work very well to stabilize the cushion under loading. The connections between the links and boards need to be altered in order to meet the 150 kg loading requirement. It was not determined whether or not the inflatable cushion would be able to withstand the required 2.05 PSI, but it was confirmed that it would be ankle to withstand at least 1.64 PSI, which is 80% of the required maximum value. For the loads tested during dynamic testing, up to 250 lbs (113 kg), the time to inflate was well under the maximum allowable value, meaning that the transfer time specification is likely met, but it cannot be verified with absolute certainty for loads past the maximum tested weight.

Sanitation

We want our design to be easily cleaned with cleaning materials available at the Institute, specifically alcohol based disinfectants. The components that come in contact with the patients will remain in each of their individual wheelchairs and will only be used by one patient, but they will still get dirty overtime. In order to determine if our design meets this requirement, we have researched whether the materials of the components that come in contact with the patients are compatible with alcohol based disinfectants. These results are displayed in a table where there are rows for each material, whether it is compatible with each disinfectant, and a row for the sources stating whether or not it is compatible. In this case, we will assume that only the wheelchair sling and armrest bridge will come in contact with the patient. This assumption is valid because they will be seated in the sling so they won't come in direct contact with the inflatable cushion and also, the patient's do not use the air pump themselves. This analysis is appropriate because we do not have prototype builds on the wheelchair slings and armrest bridge to test with the disinfectant. Also, the build might not have the same material that will be in the customer facing design. There is a lot of research done from reliable sources that will tell us if a material is compatible with alcohol based disinfectants, so we are confident that this mode of analysis is appropriate. The effects of common chemicals used for sanitation on the materials composing our final design are listed in Table 7.

Table 7. Effects of common cleaning chemicals on the materials used in the final design

	Do Chemicals Corrode Listed Materials?					
Material	Alcohol	Chlorine	Formaldehyde	Hydrogen Peroxide	Iodophor	Peracetic Acid
Polyester Fabric	No	No	No	No	Inconclusive	No
Aluminum	No	Inconclusive	No	No	No	No
Steel	No	No	No	No	No	No

Brass	No	No	No	No	No	No
Sources	(*"New catalytic system for oxidation of isopropyl alcohol with thin film catalysts,"* 2014), *"Effect of certain sterilization methods on the quality of stomatological instruments,"* n.d.) *("Preparation of CO2 absorbing polyester fabric by treating it with titanium isopropyl alcohol,"* 2023)	(*"Chlorine and sulfur effects on copper-aluminum wire bond reliability," 2022)* *("Atmospheric corrosion of T2 copper and H62 brass exposed in an urban environment," 2023)* *("Industrial washing conditions as factor that influence the cellulose structure and mechanical strength of bed linens," 2023)* *("Corrosion resistance of commonly used plumbing materials for water distribution systems exposed to disinfection treatments," 2020)*	(*"Poly-thiourea formaldehyde based anticorrosion marine coatings on type 304 stainless steel*," 2020) *("Toward closed loop recycling of polyester fabric: Step 1. decolorization using sodium formaldehyde sulfoxylate," 2020)*	*("Effects of nitric acid passivation on the physicochemical properties of stainless steel 316 and its reactivity with highly concentrated hydrogen peroxide,"* 2022) (*"New development for combined bioscouring and bleaching of cotton-based fabrics,"* 2009) *("Phosphorus vacancy-rich FeP@Al2O3 catalyze hydrogen peroxide decomposition for wastewater purification: Catalytic mechanism and performance evaluation,"* n.d.) *("Corrosion resistance of commonly used plumbing materials for water distribution systems exposed to disinfection treatments," 2020)*	*("Effect of certain sterilization methods on the quality of stomatological instruments,"* n.d.)	(*"Corrosion Inhibition of Peracetic Acid-Based Disinfectants,"* 2022) *("New development for combined bioscouring and bleaching of cotton-based fabrics,"* 2009)

Cost Analysis

A cost analysis is necessary to determine whether our design meets the price requirement given to us by our stakeholders at Poovanthi. The stakeholders required that the solution must have a price less than $1,987. In order to determine the final price of the design, we will have to calculate the cost to make one unit. This is outlined in the BOM in Table 3. We will then use the cost model outlined in Appendix F. After inputting the BOM into the cost model, we have to determine the labor that needs to be performed and the cost per hour for this labor. To calculate the total labor cost per unit, we will divide the cost of labor per hour by the number of units manufactured per hour. Then we will have to calculate the shipping and distribution costs. We will assume that it will be manufactured in India so the shipping cost would come from the cost to drive the finished product from the manufacturer to Poovanthi. The cost model includes a cost consideration for sales, but because we are designing this for Poovanthi, we will assume that our sales cost will be $0 because there is no need for additional advertising. For the sake of our cost analysis that we will perform this semester, we will assume that overhead costs are also $0 because we have not considered IT, rent, supply chain, HR, finance, or utilities requirements for our design. Lastly, we need to calculate the manufacturing costs which includes the equipment and fixtures. Once we have these individual cost components, we will add them up to get a total cost. Because this cost is per unit which includes the inflatable cushion, wheelchair sling, and foldover armrest bridge, we need to multiply this cost by the number of patients that Poovanthi would purchase the device for. We will reach out to Dr. Shibu, CMO at Poovanthi to present our final design to him and determine how many units he would want to purchase. The final cost for the design will be equal to the price per unit multiplied by the number of units purchased added to the cost of 2 air pumps. We are assuming that the Institute will have one air pump per therapy hall because they are more expensive. Once this final cost is determined, we can compare it to the price limit to determine what price we should charge the institute to make a profit. If the total cost is greater than or equal to $1987, we have failed this price requirement because it did not meet their price request and we would not make a profit off of the product either. Because we make assumptions that there is no overhead cost and sales cost, the cost analysis might not be the most accurate, but it will provide us with a valuable estimate that will tell us whether or not we need to make certain materials or manufacturing processes cheaper in order to meet the design requirements.

Cost Analysis Results

The completed cost model can be seen in Appendix F. The final cost for our design would be $848.66 (₹70760.13 INR).which meets our price requirement. After reaching out to Dr. Shibu, we determined that the Institute would purchase 11 full sets of our design. The Institute also has

two therapy halls so two air pumps would be purchased for each hall. When completing the cost model, the cost of material per unit was calculated using the BOM. After calculating the material cost, we determined the average salary of a woodworker and mill operator in India. The average salary of a woodworker was ₹305.77 and the average salary of a mill operator was ₹309.9(Institute, n.d.). This is equivalent to $3.60 and $3.72 respectively. The time of operation was estimated in order to produce 11 units and the total cost of manufacturing was calculated to be $0.122. For distribution, the cost of the shipper box was added to the pack and ship labor cost. The cost for shipping was determined by the freight rate per kilometer multiplied by the distance in kilometers from the manufacturer. The chosen manufacturer, *Sri Vinayaga Engineering,* is located in Bhokar which is 217 km from Poovanthi. The total shipping cost for 11 units came out to be $9.93 (Ltd, n.d.). Because we are outsourcing the manufacturing to existing manufacturers in India, we would not have to consider the machine costs. The final cost to produce and ship 11 units added to the cost of two air pumps came out to be $848.66 (₹70760.13 INR). This is well below our maximum price of $1,987 (₹165708.94 INR) which allows the Institute to purchase additional units or air pumps if necessary.

Ease of Manufacturability

One of Dr. Shibu's requests was that our device should be easy to manufacture to reduce cost. To make manufacturing easier, our team intends to make the device entirely manufacturable within India, so as to make the device accessible to Poovanthi and other Indian healthcare institutions. On top of that, our aim is to keep the manufacturing plans for our parts relatively simple to reduce the labor required to manufacture and assemble the device. To verify this requirement, the team can research manufacturers within India to see if they can manufacture the parts of our device. The closer to Poovanthi, the better, so transport costs can be minimized. To verify that the manufacturing plans themselves are simple, the team can consult one of the X50 professors on the manufacturing plans of each of our individual parts.

Ease of Manufacturability Results

The manufacturing of our device includes cutting plywood, milling the links and tracks, and drilling holes in the plywood to attach the links and tracks. These three steps can be performed at many different manufacturing locations in India. Poovanthi is located in Madurai, so we focused on manufacturers located in the same state, Tamil Nadu. One of the closest options for manufacturing was *Sri Vinayaga Engineering* located 217 km from Poovanthi(*SRI VINAYAGA ENGINEERING - DRO MILLING JOB WORKS TAPPING RAF MILLING JOB WORKS*, n.d.). This manufacturer provides all the services we need and is located near Poovanthi, making it a viable option for the production of our device.

In addition to finding a manufacturer in India, we also needed to ensure that there were air pumps available in India that meet our pressure and flow rate requirements. To find pumps that would be available to the Poovanthi Institute, the team searched Amazon India. The paddle board pump used for our prototype, depicted in Figure 25b (page 43), was purchased from

Amazon, but the team was unable to find it on Amazon India. However, a similar pump intended for the same use scenarios as our prototype pump is available on Amazon India. This pump meets all flow rate and pressure requirements outlined on page 58, and would be a viable option for use at Poovanthi. A comparison between important specifications of the prototype pump and the pump available on Amazon India can be seen in Table 8.

Table 8. A comparison of the pump purchased from Amazon for the prototype cushion and a similar pump available on Amazon India.

	Prototype Pump	Amazon India Pump
	 (*Amazon.Com : 20PSI High Pressure SUP Air Pump - 6000mAh Rechargeable SUP Pump 12V Stand Up Paddle Board Electric Pump Inflator/Deflator - Portable Air Compressor for Inflatables Boats,Tent,Stand Up Paddle Boards : Sports & Outdoors*, n.d.)	 (*TONSIM Digital Electric Pump Sup AV220V/DC12V 110W Air Pump 2500mAh3 Rechargeable Stand-up Board Pump Max 20PSI Air Inflator for Stand Up Paddle Board Inflatable Tent Air Mattresses : Amazon.in: Car & Motorbike*, n.d.)
Price (USD/INR)	$120/₹10,011	$138/₹11,523
Batteries	1*6000mAh	3*2500mAh
Max. Flow Rate(s) (L/min)	350 or 70	70
Max. Pressure (PSI)	20	20

As shown in Table 8, while inflating, both pumps can provide a pressure of up to 20 PSI, which greatly exceeds the calculated minimum of 2.05 PSI (see page 58). Both pumps also supply a flow rate much higher than the calculated 6.63 L/min minimum (see page 58). Note that there are two distinct flow rates listed for the prototype pump. This is because that pump automatically switches between two stages. At higher pressures, it switches from the first stage to the second stage. The first stage corresponds to the higher flow rate (350 L/min) and the second stage corresponds to the lower flow rate (70 L/min). The Amazon India pump specifications only list a single maximum flow rate value of 70 L/min. It should also be noted that the prototype pump has

two openings, one for inflation and the other for deflation, while the Amazon India pump only has a single outlet for inflation. Both pumps can be charged with a USB-C charging cable. While the pump available on Amazon India is slightly more expensive than the prototype pump, it should be noted that the prices listed in Table 7 are subject to change, and cannot be assumed to be accurate past the submission date of December 12th, 2023 for this report. Despite differences between the two pumps, their specifications are similar enough to reasonably conclude that the difference in performance as it pertains to our design would be minimal.

Commercialization Potential

Our device needs to be commercially available in order for it to be sold to and used within Poovanthi. For the device to be commercially viable in India, it must comply with CDSCO regulations and not infringe on current patents. To ensure our device meets these regulations, our team would perform regulatory compliance testing. Our device is non-invasive, does not come into contact with injured skin, and does not channel or store substances. This means that our device would be considered a Class A device by the CDSCO. Regulatory compliance testing therefore would involve applying for manufacture, sale, or distribution of a Class A medical device. This is outside of the scope of our current semester timeline. To check if our device is not infringing other patents, we can inspect our device and compare it to current patented devices on the market within the same problem space of patient transfer. If our device is visually similar, uses similar movements, processes, or materials, that may be cause for concern, and will require further redesigning. However, from what we have explored so far, our design is distinct enough from current solutions to not be considered infringing on any patents.

As the team performed benchmarking and viewed current solutions throughout the semester, there were no current patents or designs that would come into conflict with the commercialization of our device in its current stage. The design both differs enough and executes the transfer uniquely enough that current market solutions are not infringed upon.

We were unable to contact relevant sources within the timeline of the semester to check the compatibility of the design with CDSCO Class A regulations for medical devices. Given more time, our team could hypothetically get in contact with the William Davidson Institute at the University of Michigan and request their expertise for analyzing the device in comparison to CDSCO regulations.

Ability to Transfer Disabled Patients/Can be Operated by One Caregiver

The team has performed a formative usability test with occupational therapist Danny Shin to demonstrate the prototype and verify that the design meets the needs of transferring a disabled patient and being operated by only one caregiver (D. Shin, personal communication, November 17, 2023). The results of the test are as follows. When asked about how convenient the device is compared to other solutions on the market, Danny responded that it would depend on the time to fully inflate the cushion. He mentioned it was a better solution than the Hoyer lift and slide sheet, and would definitely use it for the earlier stages of therapy. He would especially use it if there

was assistance from an incline while moving the patient horizontally. When asked about safety concerns surrounding the addition of scissor links to stabilize the patient and support the cushion, he said that if the cushion is on the wheelchair, it might be difficult to slide the patient onto the cushion. He suggested that the sling be able to attach to the cushion to provide more protection against patients falling. When asked if the transfer process seemed easy enough for untrained family caregivers to perform the transfer with the device, he replied that he did believe untrained caregivers could easily use the device. He added that it felt intuitive that the cushion raises to bed height. When asked if he believed caregivers would use this device over their own strength, he responded that he believed they would, since the main physical stressor — vertically lifting the patient — is tiring over time. Since our device relieves caregivers of needing to use their own strength for that portion of the transfer process, he believes using the device would be the preferable option. For final thoughts and suggestions, Danny said we should consider tilting the cushion slightly downward to work with gravity during the horizontal transfer.

Another formative usability test was performed with Coleman Bray (C. Bray, personal communication, December 9, 2023). The results are as follows. She stated that concerns centering the patient she had with the current design iteration are: patient safety and stability opposite of the bed-facing side in case they accidentally lean off, and bigger sling sizes to properly fit larger patients. Concerns centering the caregiver are: manually moving the sling will cause back pain due to bending over, especially with the position of the handles.

Based on the results of the usability testing, design recommendations have been made to address these issues. Table 9 organizes the aforementioned concerns and their matching recommendations.

Table 9. Usability issues from verification testing and the successive design recommendations

Usability Issue	Design Recommendation
A stakeholder was concerned with how to sanitize the sling.	Use material that can be put in the wash.
Both stakeholders suggested the sling being detached from the cushion would be a safety issue.	Add cutouts to plates to secure sling to the cushion with straps.
A stakeholder noticed that patients may catch their skin on extruding screws from the armrest bridge.	Recess screws further into the armrest connector to prevent any possible injury from extrusions.
Both stakeholders expressed thoughts that sliding the patient from wheelchair to bed after inflating would be difficult on the caregiver, especially their back.	Move the sling handles higher up on the sling.

Validation Plan

Though it is outside of our semester time frame, our team has outlined a potential summative usability test to address the previously mentioned requirements. The objective of this usability test would be to address concerns of both ease of use and intuitiveness of the transfer process.

The summative test would involve a small group of relevant stakeholders (caregivers, OTs), and rather than surveying and asking questions, we would have them perform the transfer with a lightweight stand-in for a patient, such as a mannequin. Other than briefly explaining how the transfer process would work, interaction with the participant would be limited. The selected tasks that would be performed by participants are: position the patient next to the bed, turn on the pump, keep the patient stabilized as the cushion inflates, stop the pump at the appropriate time, unfold the armrest bridge, slide the patient across to the bed, slide the patient back over the wheelchair, deflate the cushion while keeping the patient stable, fold up the armrest bridge, and charge the battery of the pump.

The testing environment would mirror the setting of intended use for the device: a therapy hall with similarly spaced beds in Southern India. The data we would collect is the time it takes to perform the full transfer, and completion rates for the transfer, use errors and the frequency with which they occur, and qualitative feedback from participants. Design recommendations would be suggested based on use errors noted or feedback. These design recommendations would be used to make design edits for an improved device that hopefully would address any usability issues, similar to Table 9.

Discussion

Overall, the team is satisfied with the progress made this semester toward developing an assistive device for patient transfers in low-resource settings. For the limited time and resources available, the problem was thoroughly explored and the design process implemented throughout the semester led to a strong, unique design that satisfied a majority of the requirements and specifications. These requirements and specifications were determined through independent research and stakeholder consultations. However, there were challenges encountered and mistakes made at points along the process, and not every aspect of the problem was a major focus for the team. Additionally, though most specifications were met by the design, not all of them were. This section details the aspects of the problem that could be more thoroughly explored, proposed improvements to address weaknesses or failures in the design, the challenges and risks encountered by the team, and potential risks to end-users of the transfer device.

Problem Definition

The patient transfer problem facing caregivers, patients, and therapists at the Poovanthi Institute was explored to the best of the team's ability. We received imperative insight into the specifics of the problem from conversations with stakeholders directly involved with Poovanthi

or with relevant healthcare experience in the US, benchmarking against existing transfer devices, and academic research into the broader patient transfer problem faced in India and globally. Still, some limitations prevented the team from further exploring the problem.

The primary obstacle in researching the problem was the location of the Poovanthi Institute. The time zone difference between Tamil Nadu and Michigan made it challenging to schedule virtual meetings between Dr. Shibu and our team. Dr. Shibu provided the team with imperative details for our requirements throughout the semester, but meetings were brief and infrequent as a result of the time zone difference. Additionally, because of the Institute's location, information about the Institute's environment that aided our design process was limited to the experience of Dr. Shibu and Lucy, individuals closely connected to Poovanthi. Because of this, we were unable to observe the caregivers and patients at Poovanthi firsthand and did not have access to personal information or data related to the patients and caregivers at the Institute. Therefore, knowledge gaps had to be filled through independent research and consultations with proxy stakeholders in the United States.

If the team had more time and resources to circumvent this obstacle, the problem could be more thoroughly defined to suit Poovanthi's exact needs. A major consideration during the design process was the willingness of the caregivers, therapists, and patients at Poovanthi to utilize the design. Even if a design were to pass every quantifiable metric that verified our requirements and specifications,, if caregivers deemed the design to be extremely inconvenient or complicated, or if patients felt uncomfortable using it, our design would fail their needs. With direct access to the Institute and the patients, caregivers, and therapists residing there, interviews and usability testing would be performed with the individuals the team was designing for. Therefore, design decisions would be directly informed by the opinions and experiences of the people closest to the problem we attempted to solve this semester. If granted access, personal data would also be collected to refine our requirements and specifications, including information on patient weights and mobility, caregiver strength, and average transfer times. This information would inform our requirements and specifications.

With more time and an expanded budget, the questions related to transfer times, load-bearing capacity, and stability for our design that we attempted to address with the weight testing described on page 68 could be further explored. For the tests that were conducted, only one trial was performed at each weight on only one prototype. Ideally, multiple trials would be performed for each weight, and testing would be performed on multiple prototypes. This testing method would allow for the identification of trends and outliers in the data and would minimize error in the data. Furthermore, prototypes with the design changes described in the design critique below could be constructed and tested using this test method to assess how well the design changes solve the issues identified with the first prototype that was constructed.

Design Critique

After the completion of the engineering analysis and verification tests, we are satisfied with the performance of the design verifying the design requirements, but there are several

imperative improvements to address. These improvements are explained below and derive from completed empirical testing and conversations with stakeholders through the formative usability test.

1.) Aluminum Brackets to Secure Link Attachments

When performing the empirical weight testing, the supports for the inflatable cushion failed at 250 lbs. We determined that the stationary end of the links attached to the top and bottom plates failed: the screw that was used to attach the link split the wood at all of the connections except for one, as shown in Figure 45. Ideally, the top and bottom plates would be aluminum to strengthen this connection, but this would potentially increase the price of our design and exceed Poovanthi's price threshold. In order to increase the material strength at the connection points and keep the price under Poovanthi's price threshold, we implemented aluminum brackets in the design, as seen in Figure 48. Here, the bracket would slip over the side of the board and then attach on the top by two wood screws. Thus, the stationary side of the link is attached to aluminum instead of wood.

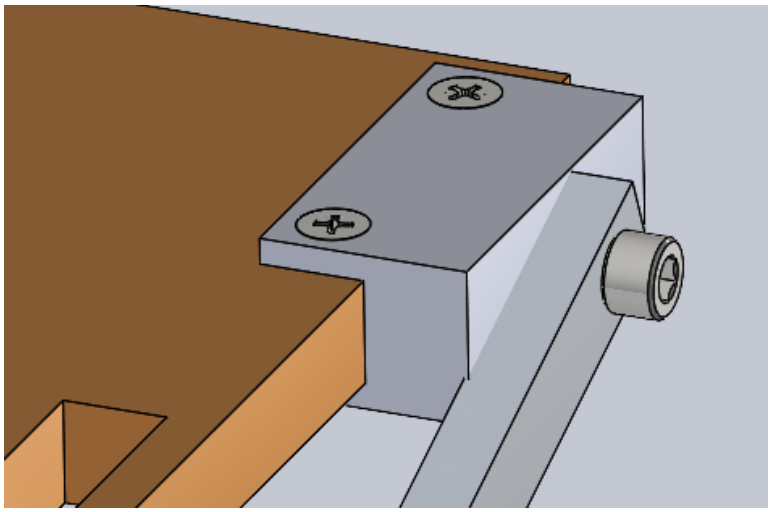


Figure 48. The addition of an aluminum bracket on the side will prevent the early failure of the scissor link supports during weight testing.

2.) Recessing the Screws on the Armrest Bridge

Following discussions with Danny Shin during usability tests of the inflatable cushion design, he voiced concerns for the hardware on the armrest bridge (D. Shin, personal communication, November 17, 2023). He cautioned that both the wheelchair sling and the patient's skin could potentially catch onto the protruding screw heads when sliding across the armrest bridge (D. Shin, personal communication, November 17, 2023). To mitigate this issue, the design was enhanced by recessing the screw heads into the armrest tube connector, eliminating any extrusion. Figure 49 below illustrates this improvement.

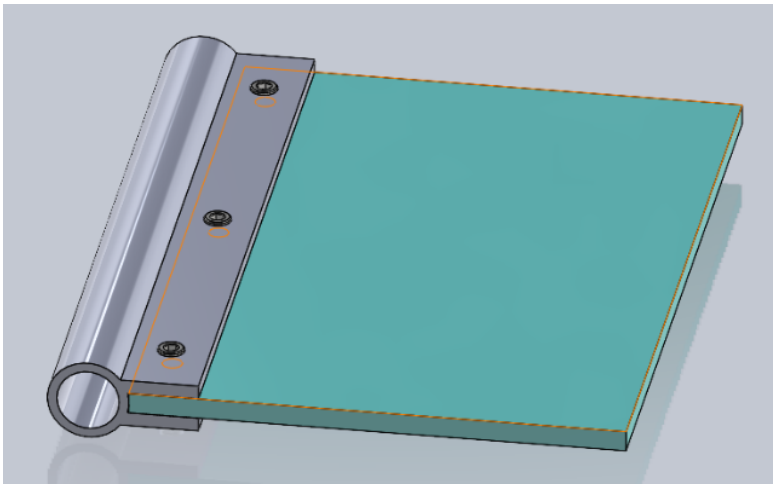


Figure 49. The screw heads were recessed into the armrest connector in order to prevent the wheelchair sling or patient from getting caught.

3.) Use of T-Slot Bolts Instead of Hex Head

The initial design employed hex head bolts to connect the sliding end of each link to the track. While the hex head allowed lateral movement during cushion inflation, we observed that the bolt caught in the track, and there was excessive space between the link and the track with this configuration. To address these issues, we explored alternative fasteners and identified that t-slot bolts aligned effectively with our current track dimensions, as illustrated in Figure 50. The adoption of t-slot bolts promotes smoother sliding of the link in the track, eliminating an undesired wiggle at the connection point. Additionally, we plan to incorporate a suitable lubricant to easily facilitate movement for the links if necessary.

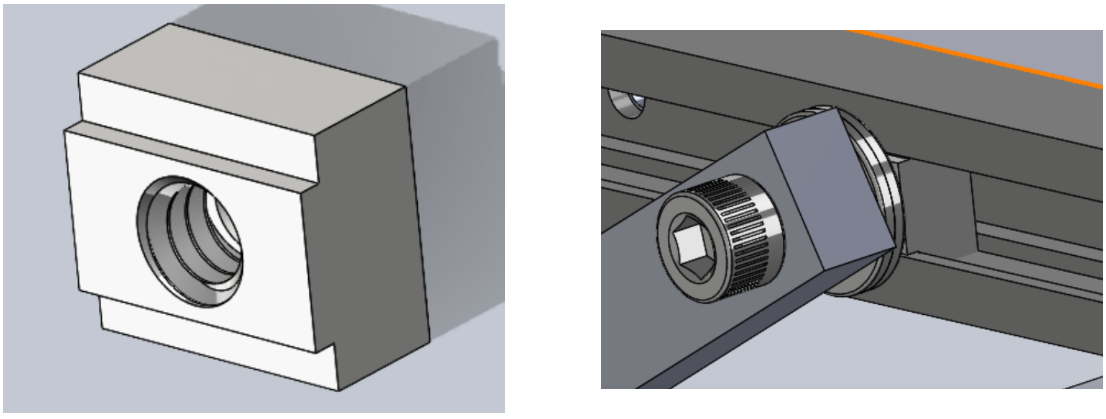


Figure 50. The t-slot nut (left) fits in the track (right) and allows a secure connection with the link that moves smoothly in the track.

4.) Holes to Secure Wheelchair Sling

Two other concerns expressed by Danny were the absence of a mechanism attaching the patient's wheelchair sling to the cushion and an unsecure connection between the bottom plate and the wheelchair structure (D. Shin, personal communication, November 17, 2023). To address these concerns, we incorporated strategic cutouts in both the top and bottom plates. The numerous straps on the wheelchair sling would conveniently clip into these cutouts when the patient is not undergoing transfer. Similarly, straps will be employed to fasten the bottom plate securely to the wheelchair structure. This design enhancement not only facilitates an easy installation of the cushion but allows for straightforward replacement when needed. Refer to Figure 51 for a visual depiction of the cutouts in the top and bottom plates.

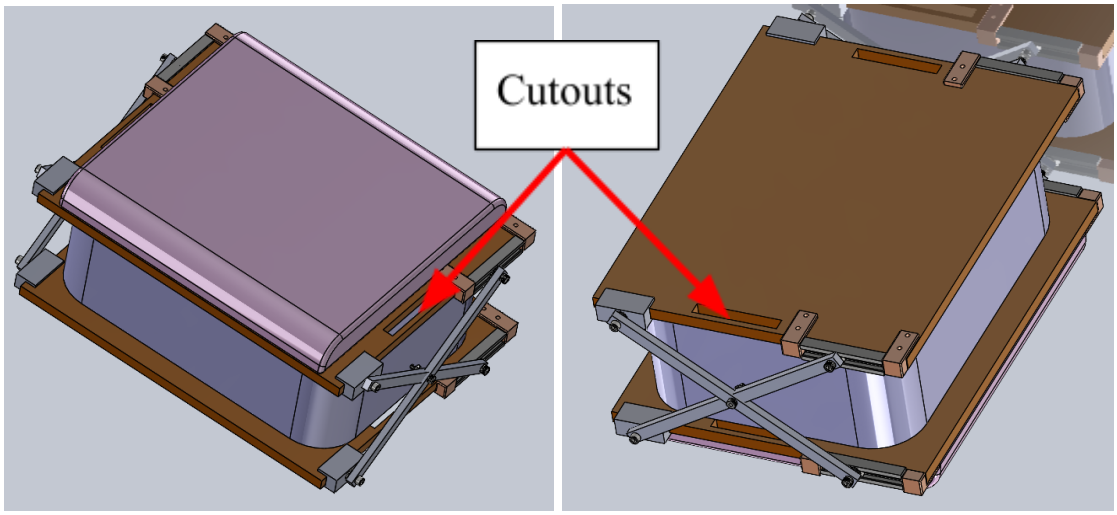


Figure 51. The cutouts in the top and bottom plate provide a method of securing the wheelchair sling to the top plate and the bottom plate to the wheelchair.

5.) Improvements to Inflatable Design

The ME 450 prototype build of our design uses an off-the-shelf inflatable whose dimensions do not match our actual CAD design. With more time and resources for this project, we would construct our own inflatable. In order to address the possible rupture of the inflatable, we spoke with Dr. Luntz about implementing internal structures that prevent the cushion from completely collapsing in the case of rupture (J. Luntz, personal communication, October 16, 2023). Figure 52 below illustrates the internal structures.

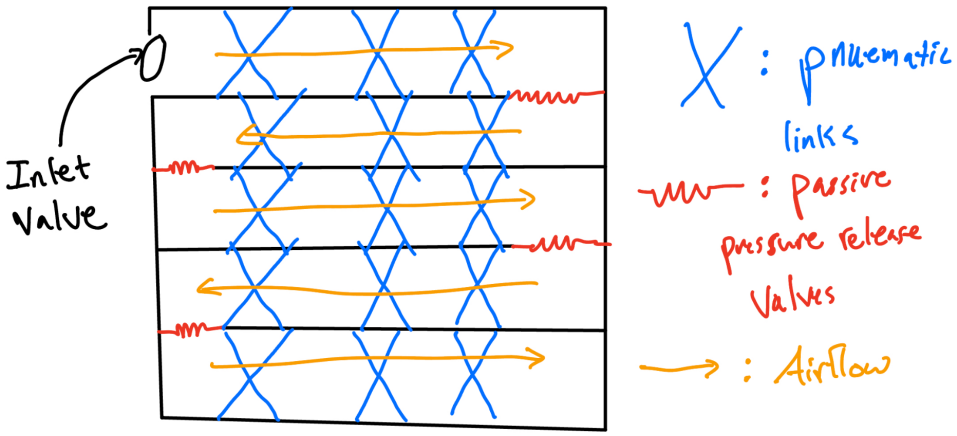


Figure 52. The internal structures of the inflatable would act as a safeguard in the case of rupture. Pneumatic links shown in blue start elastic when the cushion is not inflated and end rigid when the layer they are in is fully compressed with air. Passive pressure release valves shown in red are actuated when the preceding layer reaches the pressure corresponding to the patient's mass.

The internal structures would create different levels within the inflatable that are all connected by passive pressure release valves on each alternating side as shown in Figure 52. When an internal structure is fully inflated with compressed air, the pneumatic links would become rigid and hold that layer intact. This would additionally aid in the stability of the cushion because each layer would be treated as a solid foundation with the fully expanded pneumatic links Therefore, the air would inflate the cushion level by level as demonstrated by the orange arrows in the figure. If a rupture occurs, the air would first leak from the level the rupture occurs at and slowly leak from the other levels sequentially when the pressure corresponding to the mass of the person exceeds the pressure difference of the passive pressure release valves. If this intuition is effective, the concept would slowly lower the patient down instead of falling rapidly and risking injury. As a disclaimer, the materials and individual designs for the pneumatic links, pressure release valves, and the inflatable walls are unknown: these concepts are currently intuitive and need to be researched and developed to apply to this design.

Two other problems that were identified by stakeholders and weight testing on our prototype were the need to hold the pump nozzle in the inflatable inlet and the need to quickly plug the inlet once the cushion was fully inflated to prevent a significant amount of air from escaping. Additionally, the caregiver should ideally have both hands available for the majority of the process to keep the patient as comfortable and safe as possible. Another issue with the inlet valve on the prototype inflatable is that without firmly pressing the pump nozzle into the valve, air could escape while the cushion inflates due to the imperfect seal between the pump nozzle and cushion inlet valve. An example of the style of valve on the prototype inflatable is shown in Figure 53.

Figure 53. The inlet valve on the prototype inflatable is difficult to quickly and securely plug before a significant amount of air is lost when the cushion is loaded with weight.

The valve in Figure 53 contains an inner flap and an outer plug. The inner flap covers up the inlet hole and is pushed out of the way by the pump nozzle. When the pump nozzle is removed, the flap moves back into place. This flap is meant to prevent leakages from the inflatable before the plug is pushed in to completely seal it. This design works well when there is no external load applied while the cushion inflates, but during weight testing on the prototype, it was found that the load on the cushion would force air out despite the flap.

A redesign of the inlet valve should be able to hold the pump nozzle in position to free both hands of the caregiver and be able to be easily and quickly sealed once the cushion is fully inflated. Two potential solutions the team identified were the use of a schrader valve, the style of valve used for tires, or the use of a sports ball valve, seen on basketballs, footballs, soccer balls, and other similar objects. These valves are self-sealing and do well at holding the pump needle in place during inflation. However, because the inlet hole on the inflatable and outlet hole on the pump needle are so small, using one of these styles of valves would greatly reduce the volumetric flow rate into the cushion, consequently increasing the transfer time. This effect would be exacerbated by the baffle structures in the cushion. Additionally, we have designed for the cushion to be compatible with commercially available paddle board pumps. An adapter for certain paddle board pumps could be designed to be used with one of these valve types, but the possibility of replacing the pump at any point causes an issue. The same model of pump may no longer be available when it needs to be replaced, and another pump that meets the specifications required for the device would replace it. In this scenario, a new adapter would be needed. To avoid this, any valve would ideally be compatible with any pump that the Institute would elect to use.

We believe the style of twist seal used in some reusable water bottles would address all of the issues identified with the existing prototype valve. An example of such a seal is depicted in Figure 54 below.

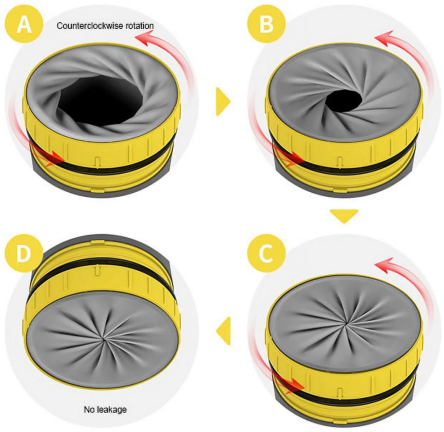


Figure 54. Depicts the twist seal technology used on some tumbler lids. This style of seal allows for the lid to wrap around straws and prevents water leakages when fully closed. (*French Coverless Twist Cup Tumbler Straw Sippy Water Bottles Portable for Children Adults New*, n.d.)

When used on tumbler lids, this twist seal style of a valve can wrap tightly around a straw to hold it in place. Similarly, if used on our inflatable design, this style of seal would be able to tighten around a wide variety of pump nozzles, allowing for a high degree of flexibility and adjustability for pump and nozzle choices. The seal would hold the pump in place, and give the caregiver freedom to stabilize the patient instead.. Finally, while usability tests would be required to confirm this, the team's initial impressions are that the caregiver would be able to easily and quickly twist and seal this style of seal when compared to forcefully plugging up the hole on the current valve type. With only this style of seal, air could still quickly rush out of the inflatable once the pump is removed. For this reason, the internal flap would still be used in conjunction with this new twist seal. The twist seal would only replace the plug component on the current valve, not the flap. As stated previously, the baffle structures in the redesigned cushion would also slow the escaping air between pump removal and sealing the inflatable. Further prototyping and testing is needed to assess the validity of this style of seal if work on this project is to continue after this semester.

Despite these areas of improvement, we are very satisfied with the performance of our design. When tested against our top five requirements identified by stakeholders, the prototype we built satisfied four out of the five. The four top requirements met include: price, patient and caregiver safety, ability to be operated by one caregiver, and ability to transfer patient from wheelchair to therapy bed and vice versa in 4 minutes or less. The only specification for a top

requirement not met was the ability for the design to support a weight up to 150 kg. The supports failed at 250 lbs (113 kg), but the inflatable itself was able to support 385 lbs (175 kg). With the implementation of these design improvements, we believe the inflatable cushion design would be able to meet this requirement.

Risks

During our design process, challenges were encountered that had to be overcome. One of these challenges, as discussed in the Problem Definition section (page 81), was the inability to speak directly with caregivers, patients, and therapists at Poovanthi. Because of this, there was a real risk of designing a device that did not address the needs of these individuals. There was a possibility that the list of requirements and specifications that we defined could be incomplete or inadequate for solving the needs of these stakeholders. To minimize this risk, the team consulted with individuals with experiences analogous to the therapists and caregivers at Poovanthi. Specifically, nurses and occupational therapists in the United States were interviewed and surveyed to obtain the perspectives of people similar to the prospective users of our device. While every individual is different, and there are significant cultural differences between the US and India, the healthcare professionals we spoke with all have experience with patient transfers and identified many limitations and issues associated with existing transfer methods and devices for the team. Their perspectives were invaluable and provided insights that reading studies alone could not. These individuals helped us understand the emotions and thought processes of patients and caregivers in transfer situations.

Another challenge experienced by the team was our lack of in-depth knowledge about inflatables. Early in the design process when the team elected to incorporate an inflatable cushion in our design, several concerns arose. Our design necessitated that the inflatable cushion was compact when deflated, but could also withstand large weights. The team was unsure if an affordable inflatable was feasible to accomplish these tasks. The stability of the inflatable while it inflated was another area of concern. Finally, finding a pump that was powerful enough to quickly inflate the cushion with the weight of a person on it was another challenge associated with our design. Our lack of experience with inflatables could have greatly hindered our ability to make meaningful and informed design decisions. To address this risk, the team met with Dr. Jonathan Luntz, a researcher who runs an inflatables lab at the University of Michigan. Dr. Luntz advised the team on important aspects of the design process. He influenced decisions regarding the geometry of the inflatable in our design, the use of external stabilizing supports, and the tests and analyses that were performed to assess the effectiveness of the design. Another source we consulted was Professor Aaron Towne, a fluid mechanics professor at the University of Michigan. Along with Dr. Luntz, Professor Towne helped the team to determine equations to use for determining the pump specifications required for our design to be successful.

In addition to the risks and challenges faced by the team during our design process, there are some risks that we have identified that could impact end-users of our device. There is a pinching risk for patients and caregivers when using our device. If a patient or caregiver's fingers

or arm were to be positioned between two of the stabilizing links on the sides of the cushion as it deflated, the limb or fingers could be pinched, resulting in a significant injury to the individual. For this reason, the caregiver should be alert and aware of the patient's positioning during transfers and to be mindful to keep their own arms clear of any pinching hazards. While our design is meant to assist the caregiver, it does not replace the caregiver, and it is the role of the caregiver to safely and properly use any transfer device.

The risk of a puncture or rupture of the inflatable while it is in use is also present. This could occur from wear over time, a sharp object puncturing the inflatable, or if the cushion is over-inflated. While this risk is present, the consequences of this risk to the caregiver and the patient are not likely to be severe if the internal structures shown in Figure 52 (page 86) are incorporated into the design. These structures would prevent a fast, violent drop of the cushion and instead cause it to slowly deflate, giving the caregiver and patient time to react and prevent injury. Such an event would be an inconvenience to the users of the device, and the transfer would be delayed, but the risk of serious harm is low. Similarly, if the battery of the pump used to inflate the cushion were to fully drain before the transfer was complete, the transfer would have to be completed through other means or the caregiver would have to either charge the pump or use another pump.

Reflection

From the engineering learning blocks assigned to our coursework for this project and course, to the insight received from our stakeholders, our team has learned to apply core principles of engineering to our design project under the implications of global and local impacts. Our initial considerations for these impacts were opaque. We set a foundation to solve our real-world problem: to improve Poovanthi's current standard practices of transferring disabled patients from wheelchair/stretcher to therapy bed and vice versa. However, our understanding of FDA, ISO, and CDSCO regulations, patient treatment assessments, user requirement and specification guidelines versus verification/validation testings, and sustainability considerations were unknown or incoherent.

Public health, safety, and welfare impacts

We knew that both healthcare and welfare regulations exist to prevent illness, injury, and financial burdens regarding the development of medical devices. FDA, ISO, and CDSCO are examples of healthcare regulations that locally impact our project. Market cost limitations (e.g. purchase cost of a product in the market) for our sponsor and consumer are examples of welfare regulations that locally impact our project. However, we needed to research the exact details of how these regulations must be met. FDA, ISO, and CDSCO all have different approval methods to grant permission for a product to be used in the market. And, Poovanthi's current patient transfer methods needed to be benchmarked to understand their health limitations for the caregiver and patient, and the availability of their product components. Dr. Shibu's $1,987 cost limit was a realization for our team when we benchmarked Poovanthi's current patient transfer

methods. We also realized that they do not have technicians staffed to fix the hydraulic lifts imported from Norway (L. Spicher, personal communication, October 9, 2023). These hydraulic lifts were primarily used as their most convenient transfer process for lifting patients. Because of this lack of staffed technicians, we focused on making our design simple and easy to repair or replace if necessary.

Design usage in a global marketplace

If our final design reaches the global marketplace in the future, we foresee an imperative and simple improvement in the current patient transfer methods that we benchmarked. Our design would not only require a maximum exertion of 35 lbs from a single caregiver, which reduces lower back injury among caregivers, as opposed to the mechanisms that we benchmarked in Fig. 1-5, the product would also be cheaper than a hydraulic lift. This provides the same lifting requirements needed to complete the vertical phase of the hydraulic lift transfer.

Characterizing potential societal impacts of our design

Even though Lucy is our sponsor and Poovanthi/Dr. Shibu is our primary consumer, we learned from the engineering learning blocks of this course that they are not the only stakeholders that have power in the evolution of our design project. The engineering learning blocks suggested we create a stakeholder bullseye to target each stakeholder and their level of power within our design project, as shown in Fig. 6. We realized that stakeholders can be proxy bystanders of the design with similar attributes as Dr. Shibu, competitors of the status quo that are satisfied with their current transfer processes, and public health and safety regulators to ensure that our product is safe to sell on the market. Proxy bystanders, such as Dr. Danny Shin (OT), Coleman Bray (RN), Dr. Megan Godell (OT), and Thomas Rooney (RN), provided us with imperative advice on daily activities within the healthcare industry: patient treatment assessments (Functional Balance Grades, Missouri.edu) and realistic transfer processes for convenience. We realized that products on the market that were approved by public health regulators does not guarantee the effectiveness of the product. Some transfer processes are seen as extremely complicated to conveniently perform, and therefore, these proxy bystanders confessed that in reality, if they feel comfortable performing the process without aid, they would do it. With all of this said, we needed to strategically develop a design that passes the Patient Transfer CTPP preferred by Lucy Spicher (ME450 FA23 Patient Transfer CTPP, Google Doc), and validate usability with healthcare providers for the ease and effectiveness of our design. This strategy would confirm the effectiveness of our design to be used as the new status quo.

Social and economic impacts associated with manufacturing, usage, and disposal of our design

The social and economic impacts associated with manufacturing, usage, and disposal of our design are limited because our current commercialized objective is not for mass production. Our project's current goal is to satisfy the consumer needs of Poovanthi: 11 units of our design with two market air pumps. However, we do realize that our design and the air pumps can have

faults, such as wear and tear and inflatable cushion ruptures. This can cause a need for buying multiple sets of 11 units and two pumps. Though producing thousands of units for mass production is not our primary commercialization goal, we understand that we would be liable for intended uses that malfunction from improper builds. With this said, we expect to have CDSCO and ISO evaluations completed to decrease this liability risk. For disposing of the design after expected wear and tear and rupturing faults, our final design attempts to consider sustainability efforts that align with eliminating the climate crisis, despite sustainability not being a user requirement. Leading up to this report, our prototype tests conclude that more testing is needed before finalizing a marketable product. With this in mind, the materials we intend to use have the chance to change. If we find that elastically compostable material for the inflatable cushion and rigid compostable material for the scissor links, boards, and fasteners are effective in complying with our user requirements and specifications for our design, we will choose compostable materials over recyclable and nonrecyclable materials.

Cultural, privilege, identity, and stylistic intra-connections within our design project

Overall, the connections between each team member were stable and did not infringe on the project's progress. The only major differences that aided in the project were Kate's strong computer-aided design skills, James' strong manufacturing skills, Karl's fluid mechanics abilities, and both Karl's and Sean's strong written communication skills. Kate quickly developed CAD models which saved the team time during numerous design changes. James' manufacturing skills helped aid in the understanding of effective manufacturing processes and fasteners to quickly develop the prototype from the CAD models. Karl's ability to find an approximated theoretical model for the inflation process, with guidance from Professor Towne and Dr. Luntz, University of Michigan faculty, helped confirm the needed air pump and geometry for the inflatable to achieve the required inflation transfer time.

Cultural, privilege, identity, and stylistic connections and power differences with our design project's sponsor and primary consumer

Overall, the connections between us, Lucy, and Dr. Shibu were stable and did not infringe on the project's progress. Though, both power and cultural differences were present between the team and Lucy/Dr. Shibu. Lucy had the ability to experience the Poovanthi environment and share with us her requirements, critiques, and guidance for our design concepts. This power difference benefited our team because Lucy's experience is credible and shared an imperative insight of the healthcare habits and environment at Poovanthi. Dr. Shibu lives in a different culture in India than us in the US. Therefore, his experiences with understanding and quantifying patient treatment assessments are different in India than they are in the US. For example, assessments that address comfort levels can be different between India and the US (e.g. Indian citizens experience high amounts of humidity and temperatures that are not common in the US). This limitation was difficult to address in our design process because we have not lived in India to experience its culture and environment.

Inclusion and Equity

As mentioned in the previous subsections, the power dynamics between us and stakeholders were informative and professional. We considered their advice and requirements to conceptualize designs that met their needs. If we disagreed with their advice or their advice was unclear, we compromised agreements to address both theirs and our concerns. In the event that we could not include stakeholder advice within our design, we accounted for this with logical justifications as to why their advice may not be appropriate within the context of our design problem. For example, we originally considered advice from a healthcare bystander regarding a patient assessment evaluation for quantifying patient mobility. However, we realized that this assessment was not preferred by our sponsor, and therefore, would be inapplicable for the regular assessments that Poovanthi provides.

In the case of our experiences, we understood that our bias toward having no chronic immobility can intuitively disregard any possible disadvantage of those with chronic immobility relevant to the transfer process. Therefore, we approached this design project by seeking advice from experienced end-users of these transfer processes, rather than assuming what is intuitively appropriate. In the event that we as a team must decide upon whether or not to include information within our findings that is more relevant to our experiences, we chose to abide by our formal team agreement of having a majority rule.

Ethics

Our greatest ethical dilemma we faced was time consumption. Attempting to complete this project within one semester and having other class and extracurricular commitments was difficult. We managed time consumption by completing the necessary tasks at hand while knowing that our final design does not have to be finalized by the end of the semester. As a team, we had to make difficult decisions for what to include in our design reviews, what analytical approximations were appropriate, and what stakeholder advice is preferred by Poovanthi and Lucy. If we had more time to process all of these decisions, we would feel more confident with the ethical contexts associated with our final design. If our current design were to enter the marketplace, these ethical contexts that would need more time consumption are safety and liability, financial costs associated with potential mass manufacturing plans, such as labor and natural resource consumption, and sustainability impacts to combat the climate crisis.

Most of our personal ethics align with the University of Michigan: safety and liability, financial costs, and sustainability impacts. The only dilemma would be that time consumption is extremely limited with each semester. This is potentially the same for future employers because each employer has its own time constraints to complete tasks. We understand that the University of Michigan is an extremely competitive institution, and to compete with others requires time constraints due to the intellectual similarities between each individual. Therefore, similar to the philosophical nature of ethics, the dilemma to effectively complete a task within a time constraint

is expected and should be practiced with mindfulness to avoid ineffective final designs and mental fatigue.

Recommendations

From our experiences with this project, we have several recommendations for our project sponsor, Lucy Spicher, and for any future ME 450 teams who may continue work on the design outlined in this report.

The first important recommendation is to perform analyses and tests related to the design changes in the design critique section beginning on page 82. The recommended changes are as follows: (1)Adding aluminum brackets to connect the stabilizing linkage structures to the top and bottom plates to increase the load-bearing capacity of the design, (2) recessing the screws on the armrest bridge design to avoid snagging and discomfort on the bridge during transfer, (3) replacing the hex-head bolts that slide along the T-tracks with lubricated sliders fit to the dimensions of the tracks to reduce the binding of the linkages during inflation, (4) adding cutouts to the top plate to secure the wheelchair sling to the plate while the cushion inflates, (5) adding baffle structures to slow the deflation of the cushion in the event of a puncture or rupture, (6) replacing the valve on the inflatable with a twist seal. For more details on each of these changes, review the design critique section on page 82.

Of these proposed design changes, analyses and testing is likely not needed for (2). It is clear that leaving screw heads poking out on the armrest bridge could lead to comfort and functionality issues with the device that are easily avoided by recessing the screw heads. For the other changes, there is a need for engineering analysis and verification and validation.

For (1), the team recommends empirical weight testing similar to the testing outlined on page 68 to assess the effectiveness of the aluminum brackets. Initial testing should be conducted using a prototype constructed with mostly materials leftover from the construction of the prototype that was constructed this semester. This would allow for a preliminary assessment of the bracket components at little additional costs incurred. Several trials at each tested load should be performed. Design change (3) can be tested during the same tests. The effectiveness of the sliding bolts can be assessed qualitatively, as the effects of significant binding in the tracks will be visually apparent. Trials should be repeated for different amounts and types of lubricants on the sliders to identify an effective solution.

For design change (4), the team recommends creating cutouts of various shapes and sizes in boards, strapping the wheelchair sling to the boards using these cutouts, and performing usability tests with patients and caregivers in the US by allowing them to feel how much the sling can slide for each configuration. Based on feedback from these stakeholders, refinements can be made and a practical, secure design can be selected.

Design change (5), the addition of internal baffle structures in the inflatable, is the most challenging to implement and analyze. The team recommends contacting Dr. Jonathan Luntz for advice on any testing or changes made to the inflatable. Additionally, from our previous discussions with Dr. Luntz, we know that it is difficult to simulate inflatable structures with software. Instead, we recommend the construction of a non-load bearing prototype inflatable. For the construction of this prototype, an off-the-shelf inflatable could be purchased, cut into sections of the correct sizes and geometries, and sealed with glue. Dr. Luntz has mentioned to us that there are methods to seal the seams on self-constructed inflatables, and he should be consulted for the best approach for the construction of this prototype. Once the new prototype inflatable is constructed, the effects of the baffles on inflation time when unloaded should be tested by performing timed, unloaded trials on the cushion with baffles and comparing the results to timed, unloaded trials on a cushion with no baffles. After obtaining these results, if they are promising, more involved research and development should be done on this design to assess its ability to bear load. We recommend that, if it is allowed, the resources in Dr. Luntz's inflatables lab be utilized for this process.

For design change (6), we recommend usability testing comparing the original prototype inflatable valve and the twist seal lid from a tumbler similar to the one shown in Figure 54 (page 88). Several individuals should be asked to plug the original valve and to seal the twist lid and rank the two seals based on which was easier to use. The individuals should be timed and the time it takes for each seal type should be recorded. If these results indicate that the twist seal design is indeed superior to the plug design, a smaller twist seal should be developed and tested to determine whether or not it would be effective at containing the air in the inflatable at pressures of up to 2.05 PSI, the pressure calculated on page 58.

If the testing described for any of the design changes identifies failures in the changes, the changes should be iterated upon. We also encourage any teams who may continue work on our design to explore the design space and generate alternative concepts for solving the issues in the design that the proposed changes attempt to address. It is possible that better solutions to these issues were overlooked that could be identified by other teams.

We also recommend that stakeholders should be consulted about the pinching risk presented by the stabilizing X linkages. For a more detailed explanation of this risk, review pages 89-90. During our meetings with stakeholders throughout the semester, this pinching risk was not pointed out by any stakeholders. Because of this, it was overlooked and the team this semester failed to account for it in our verification and validation testing. We recommend that stakeholders should be explicitly asked about this risk and whether or not it would be simple and straightforward to prevent. The stakeholders who should be consulted, if available, would include occupational therapists, nurses, caregivers, and stroke or spinal cord injury patients.

Conclusion

This design project focuses on addressing a critical need at the Poovanthi Institute of Rehabilitation and Elder Care in India: safe and efficient transfer of patients between

wheelchairs, stretchers, and beds. With millions of people worldwide suffering from strokes and spinal cord injuries annually, the demand for effective patient transfer solutions is evident and would greatly ease the burden and challenges faced by both patients and caretakers. The cultural and socioeconomic context in India amplifies the need for an accessible and affordable solution. Current patient transfer devices used in healthcare settings were analyzed, revealing gaps in the solutions. A set of engineering requirements were formed based on understanding the needs of stakeholders and the problem as a whole. These requirements and specifications prioritize low price, ease of use, compatibility with facility dimensions, patient transport capabilities, safety, sanitation, commercialization. With ethical considerations, inclusivity and cultural factors in mind, we utilized design heuristics to generate concepts that meet the engineering requirements. Our final design utilizes an inflatable wheelchair seat cushion and a market air pump that will vertically raise the patient to the height of the bed, and a foldover arm rest component and wheelchair sling that will provide extra support for the patient when the caregiver is transferring them laterally onto the therapy bed. We built and tested a prototype of the inflatable cushion that verifies the engineering analysis performed to confirm the inflatable cushion's stability, caregiver safety, and ability to lift 250 lbs (113 kg) and perform a transfer in less than 4 minutes, despite failing to satisfy our 150 kg user specification. Due to the time restrictions of this semester, we unfortunately failed to provide our sponsor with a prototype that meets all of the user requirements and specifications. With this said, we explained in our *Recommendations* and *Design Critique* sections that there is room for additional prototype modifications to be designed and tested after the semester. Thus, we are satisfied with our design project's overall progress in attempting to develop an innovative solution for our sponsor Lucy Spicher and primary consumer Poovanthi using our engineering design process and first principles learned.

Acknowledgments

We would like to thank the following people for all of their support throughout the semester:

- Dr. B. Shibu, CMO of Poovanthi Institute of Rehabilitation and Elder Care, India (Sponsor and Primary Consumer)
- Lucy Spicher, Mechanical Engineering Ph.D candidate at the University of Michigan (Sponsor)
- Professor Kathleen Sienko, Mechanical Engineering Professor at the University of Michigan (ME 450 Instructor)
- Dr. Danny Shin, Ph.D, Mechanical Engineering Post-doctoral researcher at the University of Michigan (Proxy bystander stakeholder)
- Professor Aaron Towne, Mechanical Engineering Professor at the University of Michigan (Proxy bystander stakeholder)
- Dr. Jonathan Luntz, Ph.D, Mechanical Engineering researcher at the University of Michigan (Proxy bystander stakeholder)
- Thomas Rooney, RN (Proxy bystander stakeholder)
- Coleman Bray, RN (Proxy bystander stakeholder)

- Dr. Megan Godell, Certified and Licensed Occupational Therapist Assistant in Michigan (Proxy bystander stakeholder)

Team Bios

Kate Bray

Hello! I'm Kate, and I am from Severna Park, MD. My passion for the medical device industry has been a constant throughout my journey. Over the past four summers, I've been fortunate to intern in this field and gain invaluable insights. While I initially pursued a biomedical engineering major, it was during my first internship that I discovered my true calling in the mechanical engineering aspect of healthcare innovation. In my most recent role with Stryker Spine's New Product Development team, I had the privilege of contributing to the design of instruments and implants for lumbar interbody fusion procedures. This experience has deepened my appreciation for the powerful intersection of engineering and healthcare, which I'm excited to bring to our project. After my upcoming December graduation, I would like to join a rotational program at a medical device company to further develop as an engineer. Beyond academics and work, I thrive outdoors and embrace an active lifestyle, culminating in the completion of four triathlons. My goal is to eventually complete an Ironman 70.3.

James Johnston

Hello, my name is James and I live in Cincinnati, OH. I have been working through the engineering curriculum at the University of Michigan for the past four years. It has been an enjoyable and rewarding opportunity to get to have the opportunity to work with the university to learn about mechanical engineering. The instructional staff has been incredibly supportive and my fellow students have been a source of collaboration. I have gotten to experience the design process two times before with the previous manufacturing and design classes, giving me a chance to work with CAD software, a manufacturing lab, and mechatronics. I will be graduating in the spring of 2024, and looking ahead I would like to take part in a rotational program within automotive engineering to gain exposure to different possible positions. As for outside of work, I am currently a writer for the Michigan Daily, and enjoy practicing the piano and learning about music and music theory. I enjoy playing jazz and the improvisational aspect that comes with it.

Sean Rooney

Hi, I’m Sean. I’m from Clinton Township, MI. I will be graduating in May of 2024. I chose to pursue engineering because I enjoyed the physics and calculus classes that I took in high school, and wanted to continue to expand my knowledge in these topics and other related topics. I chose mechanical engineering specifically because I wanted to be able to physically interact with and observe the things that I help to design. I have internship experience in test engineering in the automotive industry, and I hope to work in the automotive industry after graduation. Outside of school and work, I enjoy keeping fish and maintaining aquariums. There are so many interesting and different ways to experience that hobby. I have had to give it up while in school because my apartment does not allow pets, but I am excited to get back into it after graduation. I am excited

to see what designs the team comes up with this semester and hope that I can help in some way to solve a problem that I think is very important to address.

Karl Vostal

Hello, my name is Karl. I reside in Farmington Hills, MI. I will graduate with my degree in Bachelor of Science in Engineering, Mechanical Engineering with a specific program in Sustainable Engineering in May of 2024. Starting as early as elementary school, math, science, and music has always been my passion of excitement. When I took advanced placement courses in physics and calculus in high school, I enjoyed learning about mechanical principles such as Newton's Laws of Motion, and applying the mathematical concepts from calculus to those principles. With music, I started playing tuba in elementary school and gained enough experience to participate in the high school's prestigious symphony band as a junior and senior. As a tubist, applying math and physics concepts greatly inspired me both emotionally and mentally. During senior year, I originally desired to be a mechanical engineer that designs roller coasters at amusement parks. I even chose to analyze the dynamics of a toy roller coaster for the final project of my high school physics course. Unfortunately, by the time I reached college, I realized that the roller coaster industry is limited. Reflecting on career choices, pursuing engineering and music became my goal. Therefore, as a graduating senior in college, I plan to use mechanical engineering as a foundation for understanding technical components of loudspeakers and other acoustic devices that are found in the music industry. As a fun fact, because of my emotional inspiration for music, I have decided to pursue a masters in music technology/sound engineering and a PhD in neuroscience. My career aspiration is to be an electronic music producer and disc jockey, with the benefit of understanding how to manipulate sound from engineering to provide acoustic therapy for patients and immerse concertgoers in a surreal music environment.

APPENDIX A

NIOSH Lifting Equation

The NIOSH Lifting Equation can be calculated using the Recommended Weight Limit (RWL) and Lifting Index (LI). These equations are defined below:

$$RWL = LC \times HM \times VM \times DM \times AM \times FM \times CM$$

Where:

- LC = Load Constant
- HM = Horizontal Multiplier
- VM = Vertical Multiplier
- DM = Distance Multiplier
- AM = Asymmetric Multiplier
- FM = Frequency Multiplier
- CM = Coupling Multiplier

The level of physical stress is estimated using the Lifting Index which can be calculated using the equation below:

$$LI = \frac{Load\ Weights}{Recommended\ Weight\ Limit\ (RWL)}$$

If the LI is less than or equal to 1.0, it complies with OSHA lifting standards.

APPENDIX B

Concept categorization during concept generation process

Figure B.1 shows the four different categories we placed our narrowed down concepts into. The categories are: Board (yellow), Lift (green), Sit-to-stand (blue), and Other (pink). Using this organization and the requirements filters, we were able to reach our top four concepts. Sketches of some of these concepts are shown below the color-coded categories.

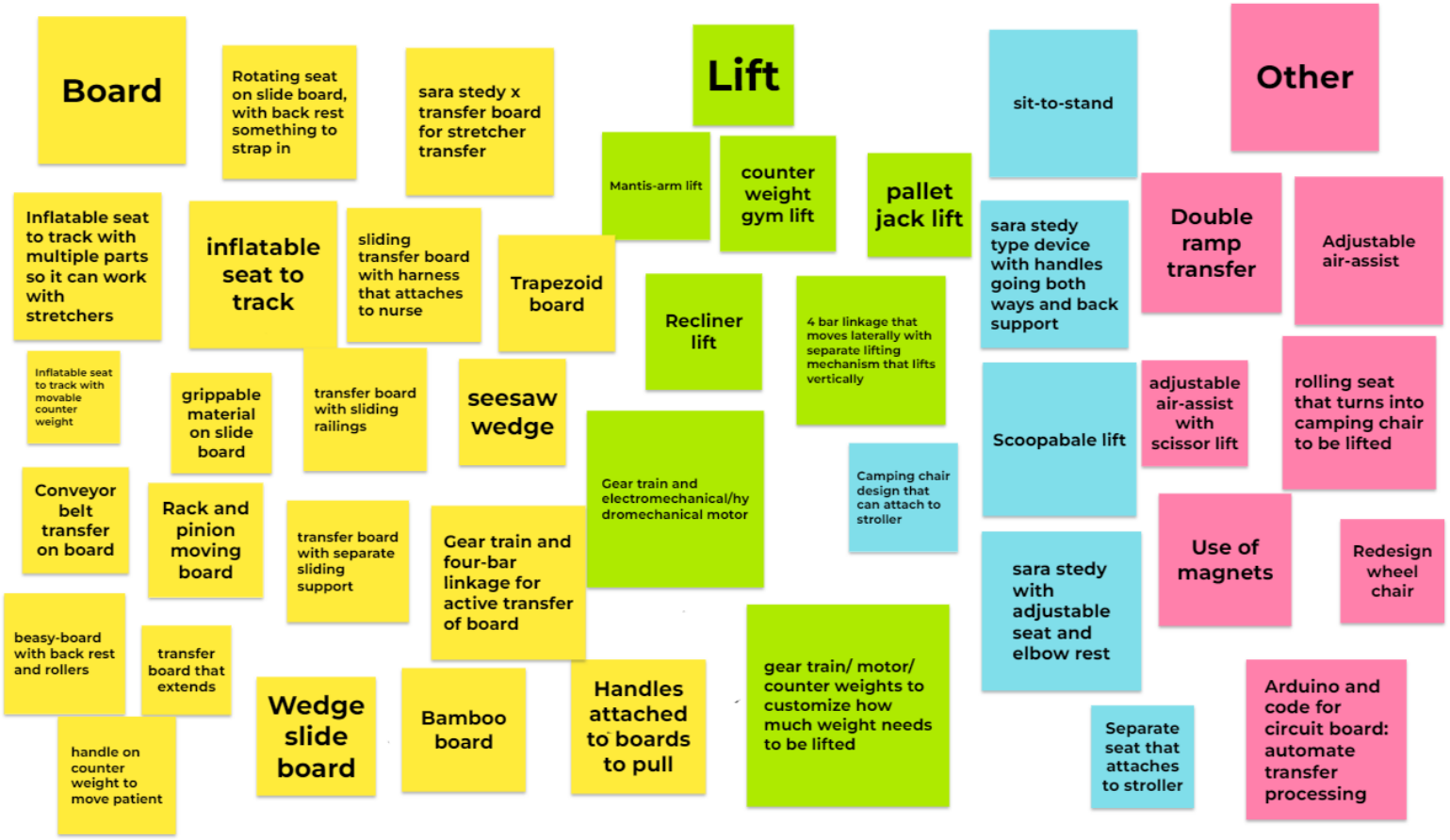


Figure B.1. Color-coded categories for generated design concepts.

Examples of several design concepts generated independently by the team are shown below in Figures B.2 through B.9.

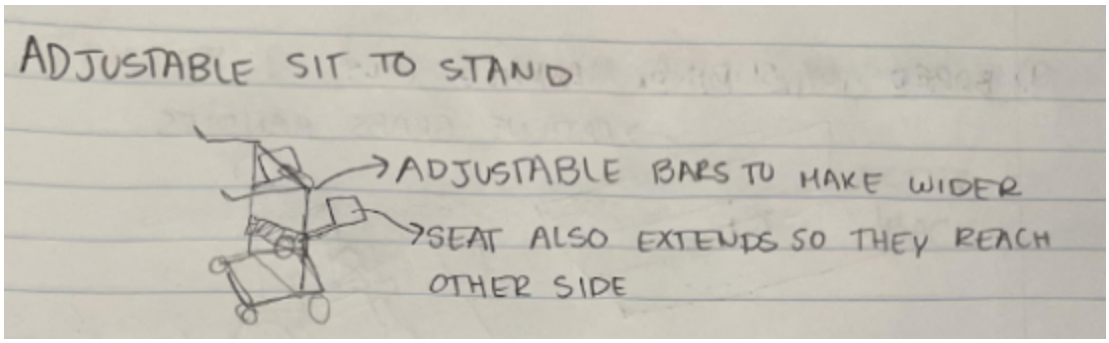


Figure B.2. Sit-to-stand device with adjustable seat and elbow rest

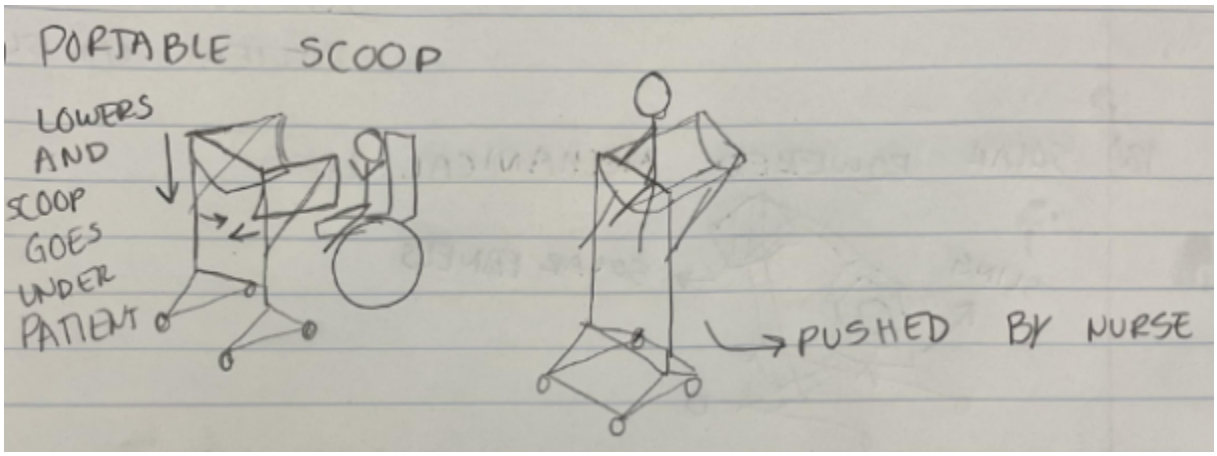


Figure B.3. Scoopable lift

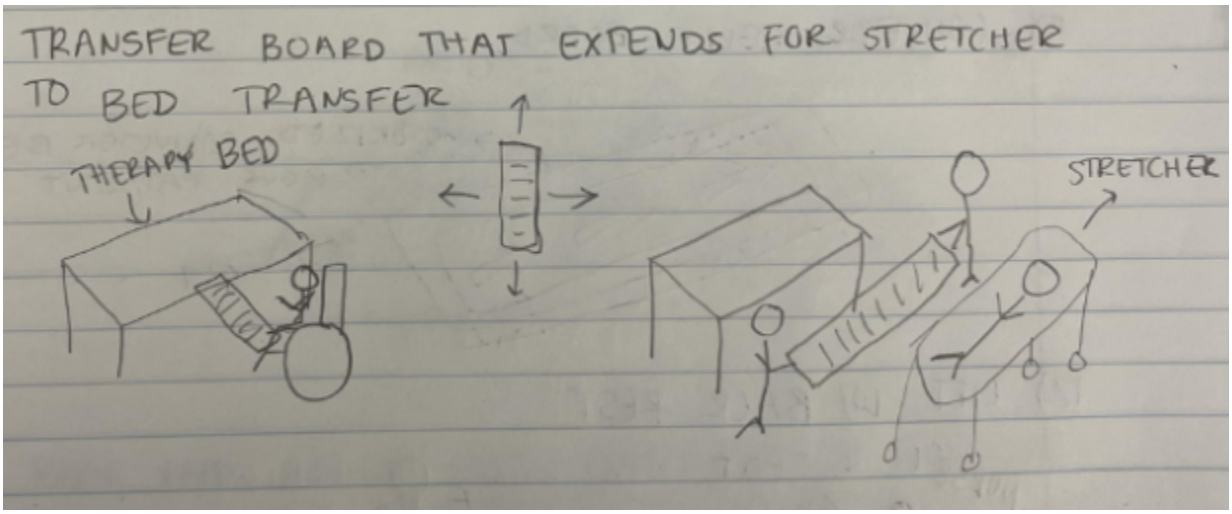


Figure B.4. Transfer board that extends to stretcher transfer board

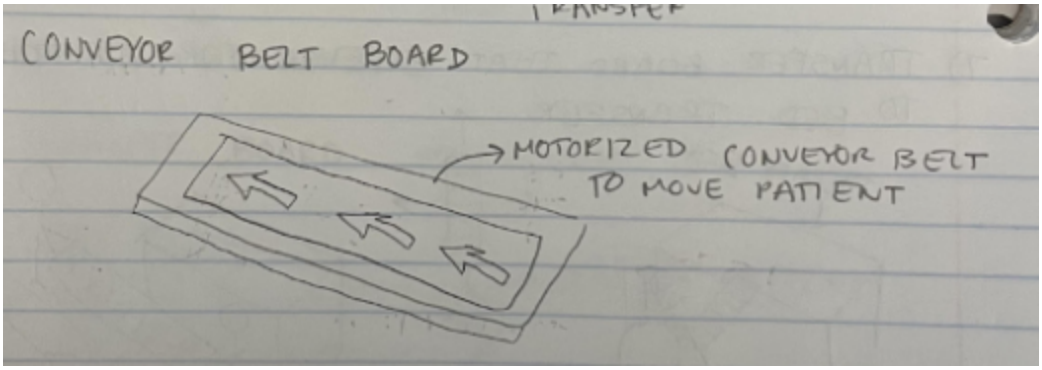


Figure B.5. Conveyor belt transfer board

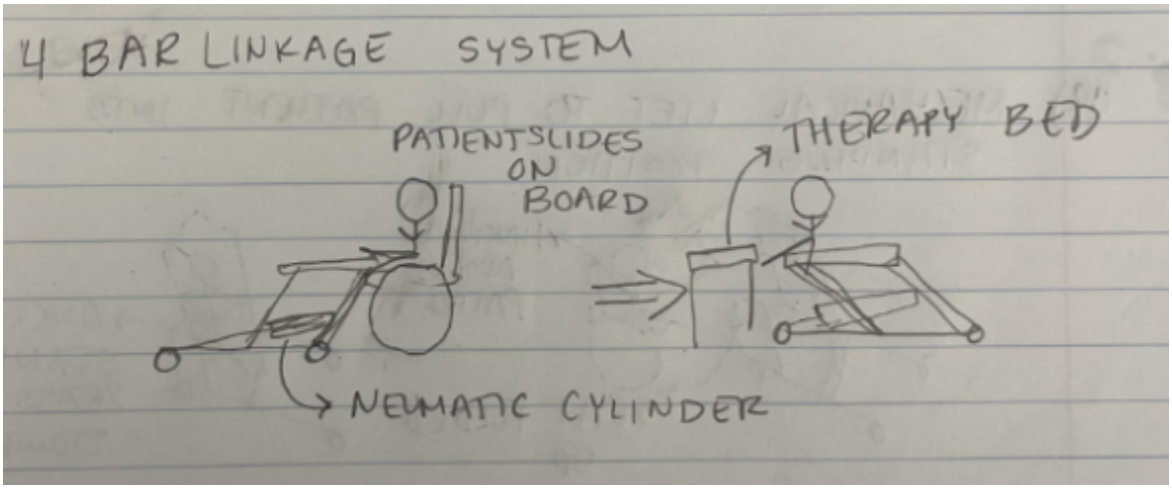


Figure B.6. Four-bar linkage with pneumatic cylinders

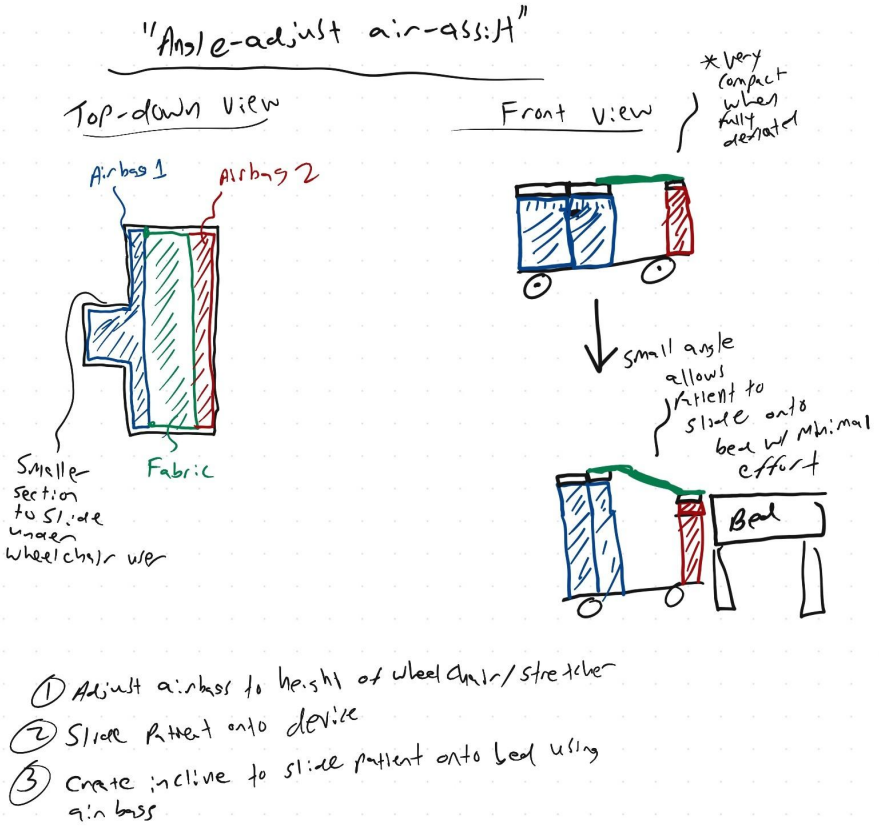


Figure B.7. Air-assisted angle adjust

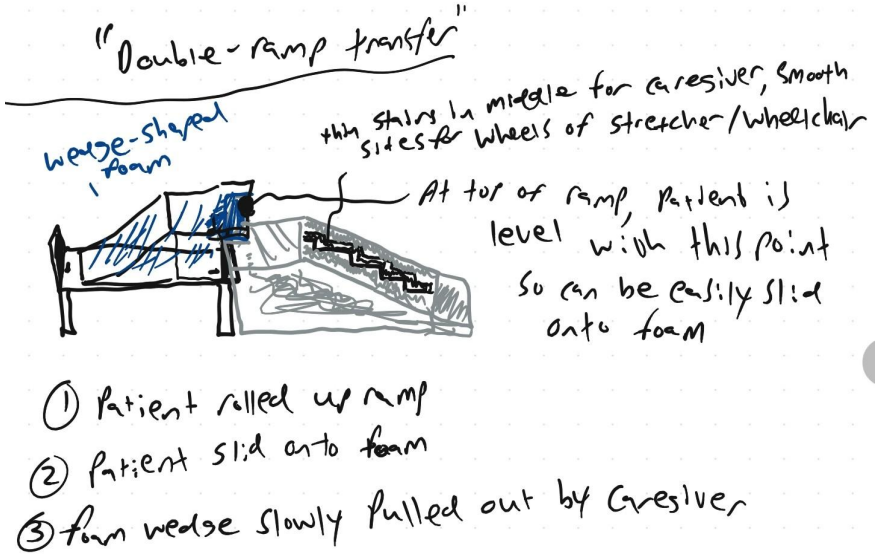


Figure B.8. Double ramp transfer device

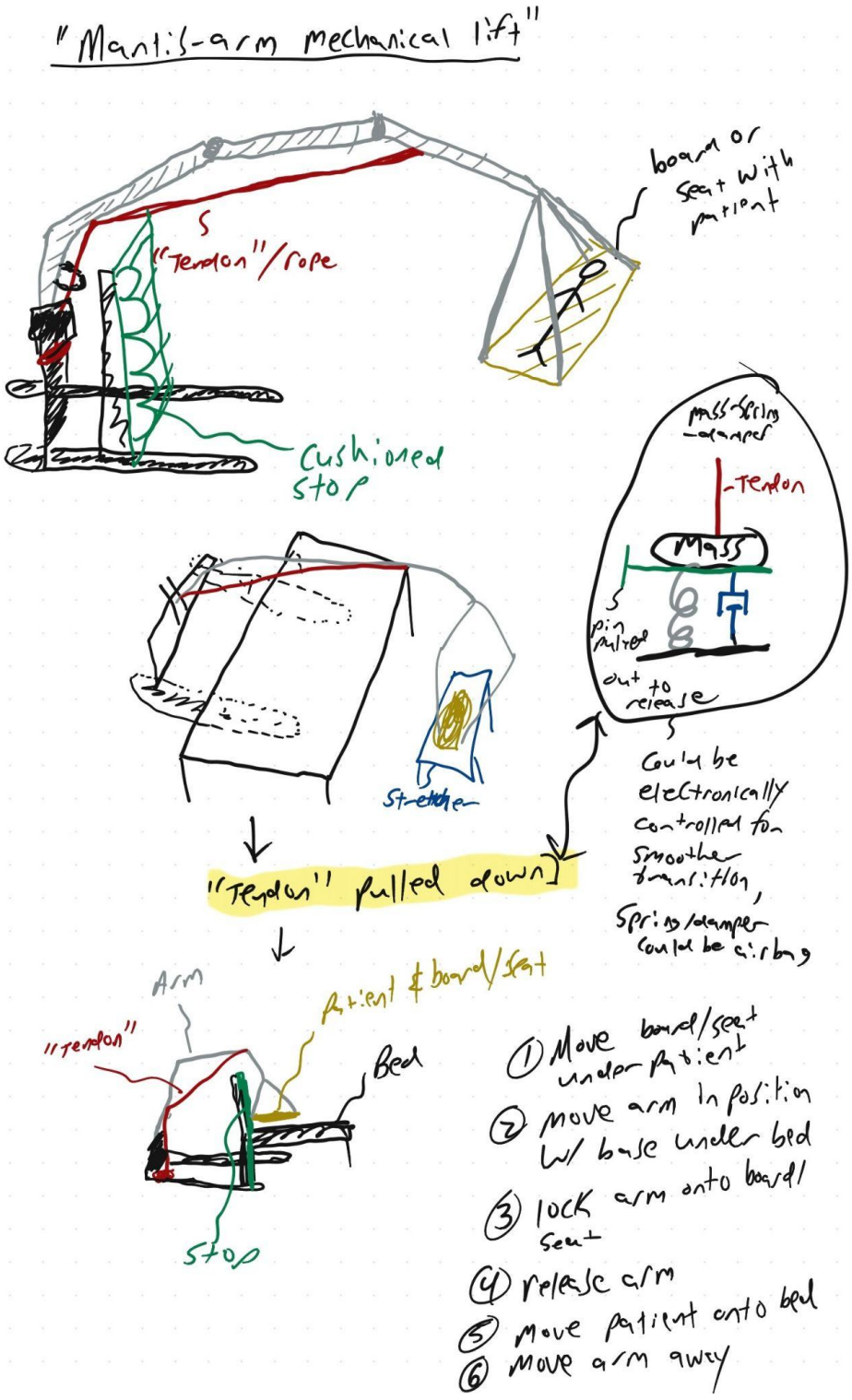


Figure B.9. Mantis-arm mechanical lift

APPENDIX C

Derivation and calculation of the centroid locations for the inner and outer rails of the curved track

A derivation of the centroid location for a quarter-circular arc of radius *R* is shown in Figure C.1

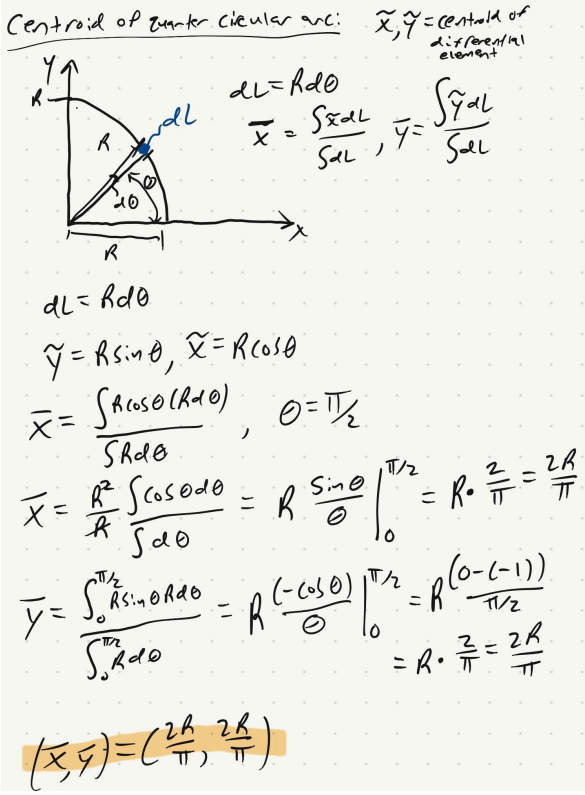


Figure C.1. The centroid of a quarter-circular arc of radius *R* using the (x,y) coordinate system shown in the figure is located at ($2R/\pi$, $2R/\pi$).

An expression for the y coordinate of the centroid location for the geometry of a single rail shape in the design presented in this report is derived in Figure C.2.

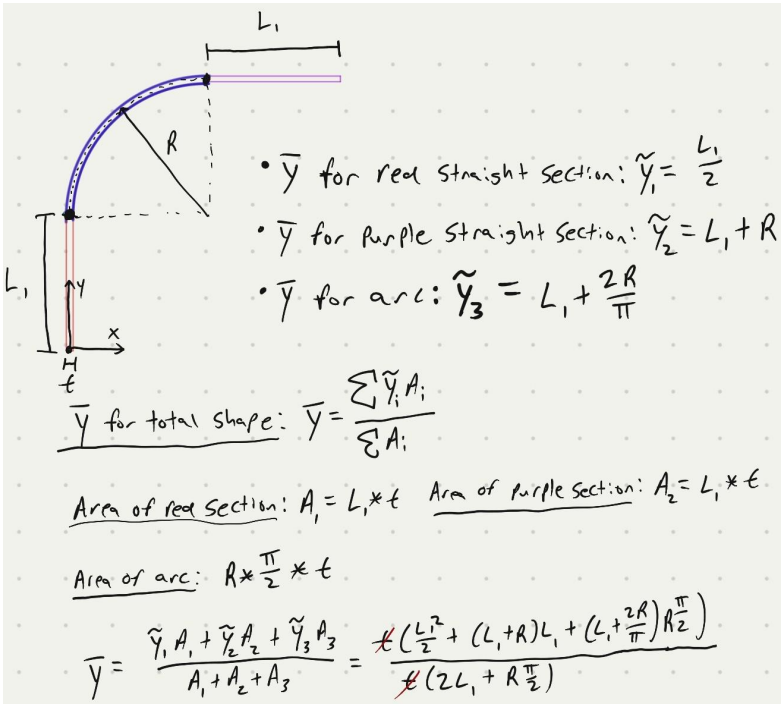


Figure C.2. The y-coordinate of the centroid for the geometry of a single rail of the dual-rail track system is given by the expression for $\bar{y}$ at the bottom of the figure.

For both the outer rail and the inner rail, the length L_1 of the straight parts of the track is equal to 20 inches. The radius R of the curved arc portion of the rail is equal to 20.75 inches for the inner rail and 33.25 inches for the outer rail. Substituting these values into the expression for $\bar{y}$ shown in Figure C.2 provides a value of $\bar{y} = 28.89$ inches for the inner rail and $\bar{y} = 37.03$ inches for the outer rail. These values were used in Equation 1 (page 38) to determine the minimum length of the horizontal component of the track legs, H.

APPENDIX D

"Design Priority Evaluation" survey results

The survey results for ranking our requirements in the pugh chart are shown in the figures below.

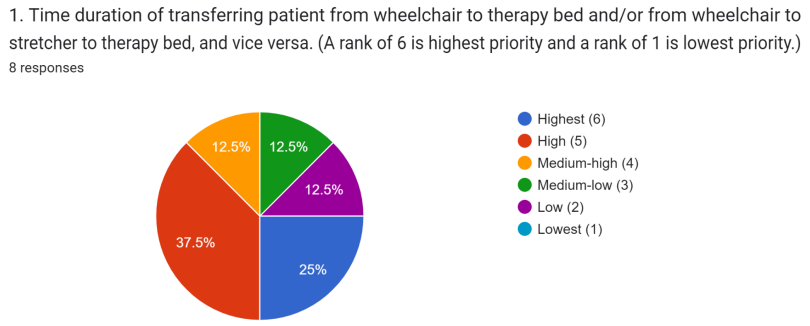


Figure D.1. Charts depicting the ranking results of patient transfer time duration.

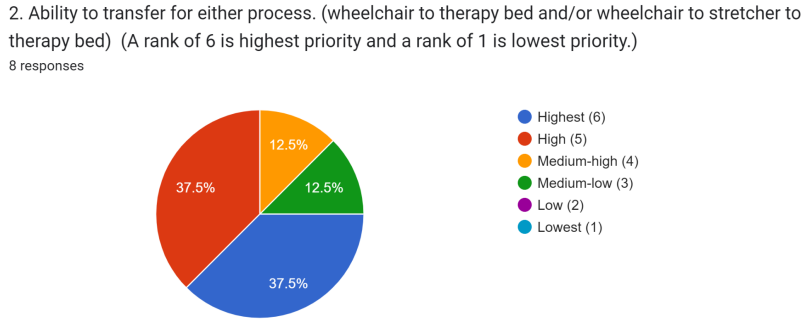


Figure D.2. Charts depicting the ranking results of ability to transfer between both wheelchair and stretcher to bed.

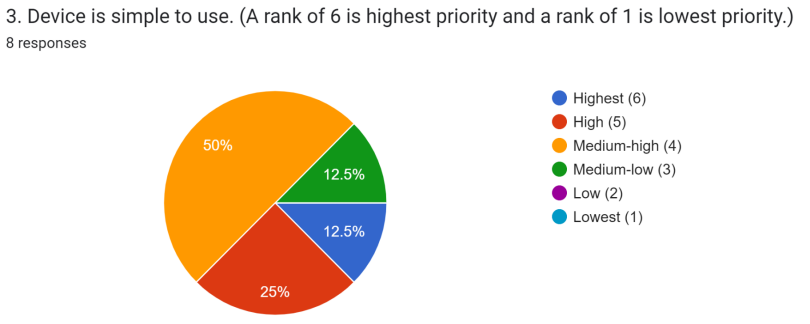


Figure D.3. Chart depicting the ranking results of simplicity of using the device.

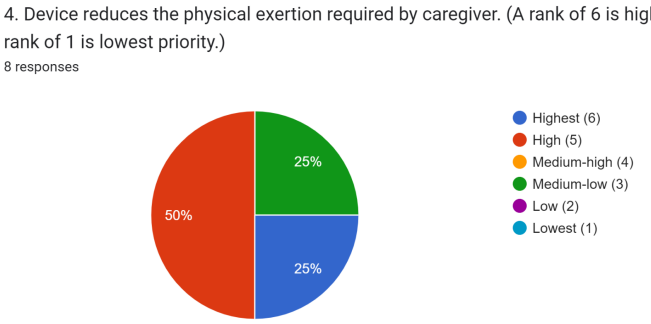


Figure D.4. Chart depicting the ranking results of reducing caregiver exertion.

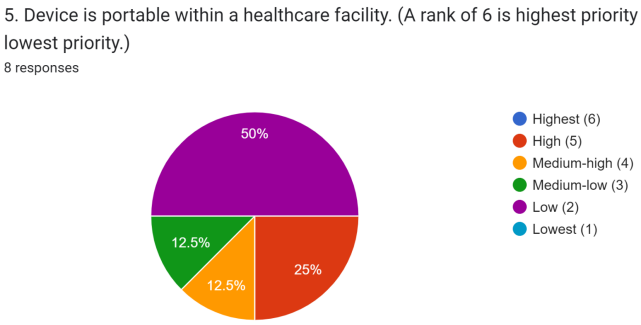


Figure D.5. Chart depicting the ranking results of portability of the device inside the facility.

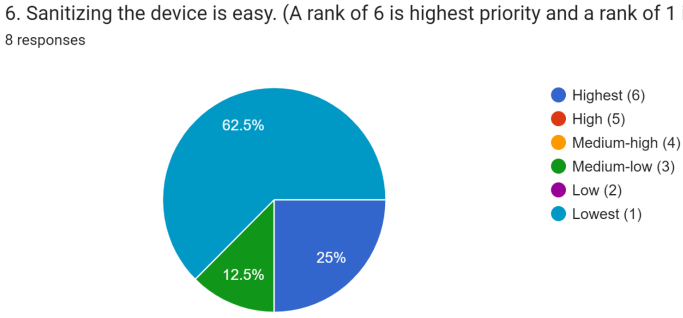
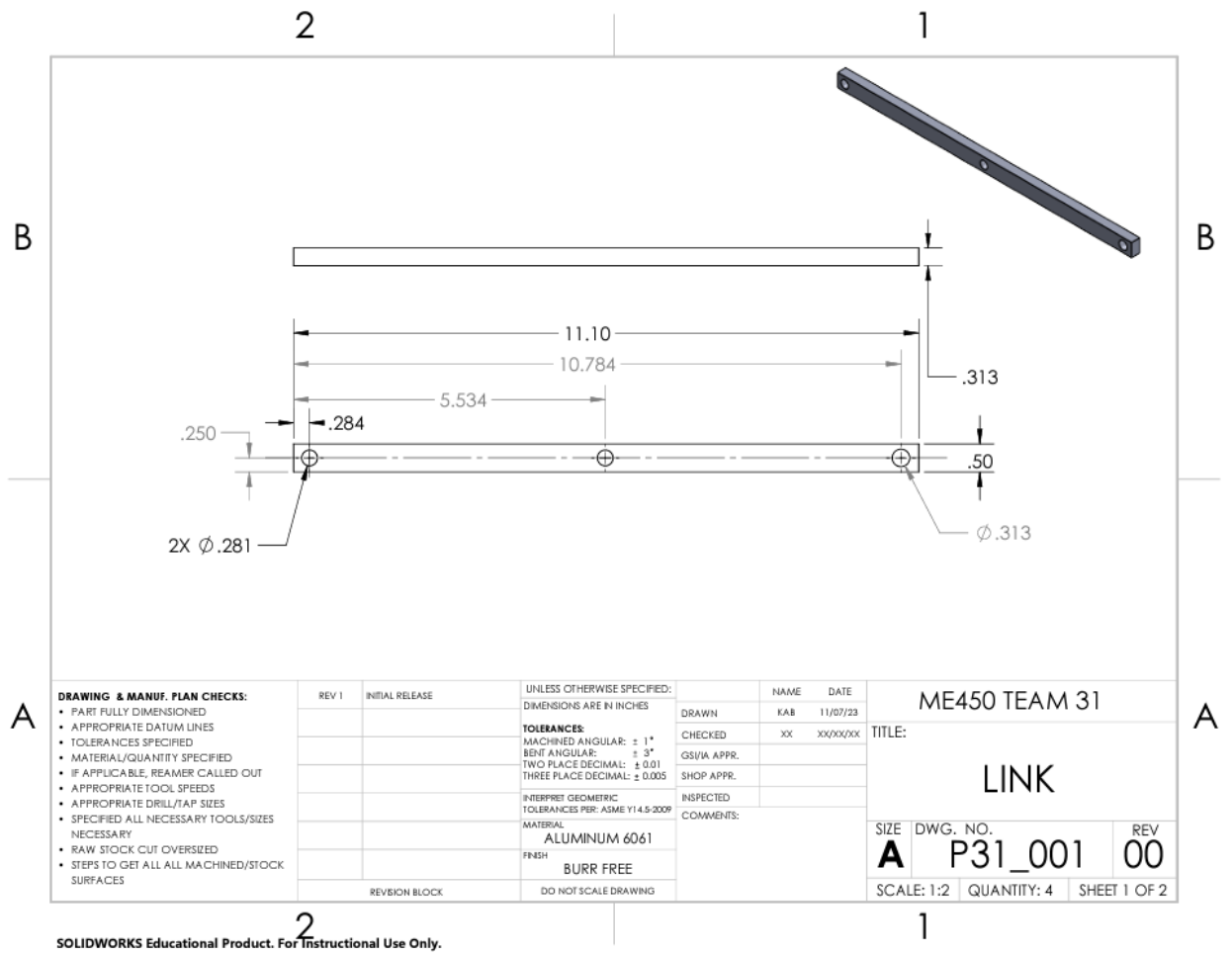


Figure D.6. Chart depicting the ranking results of ease of sanitization.

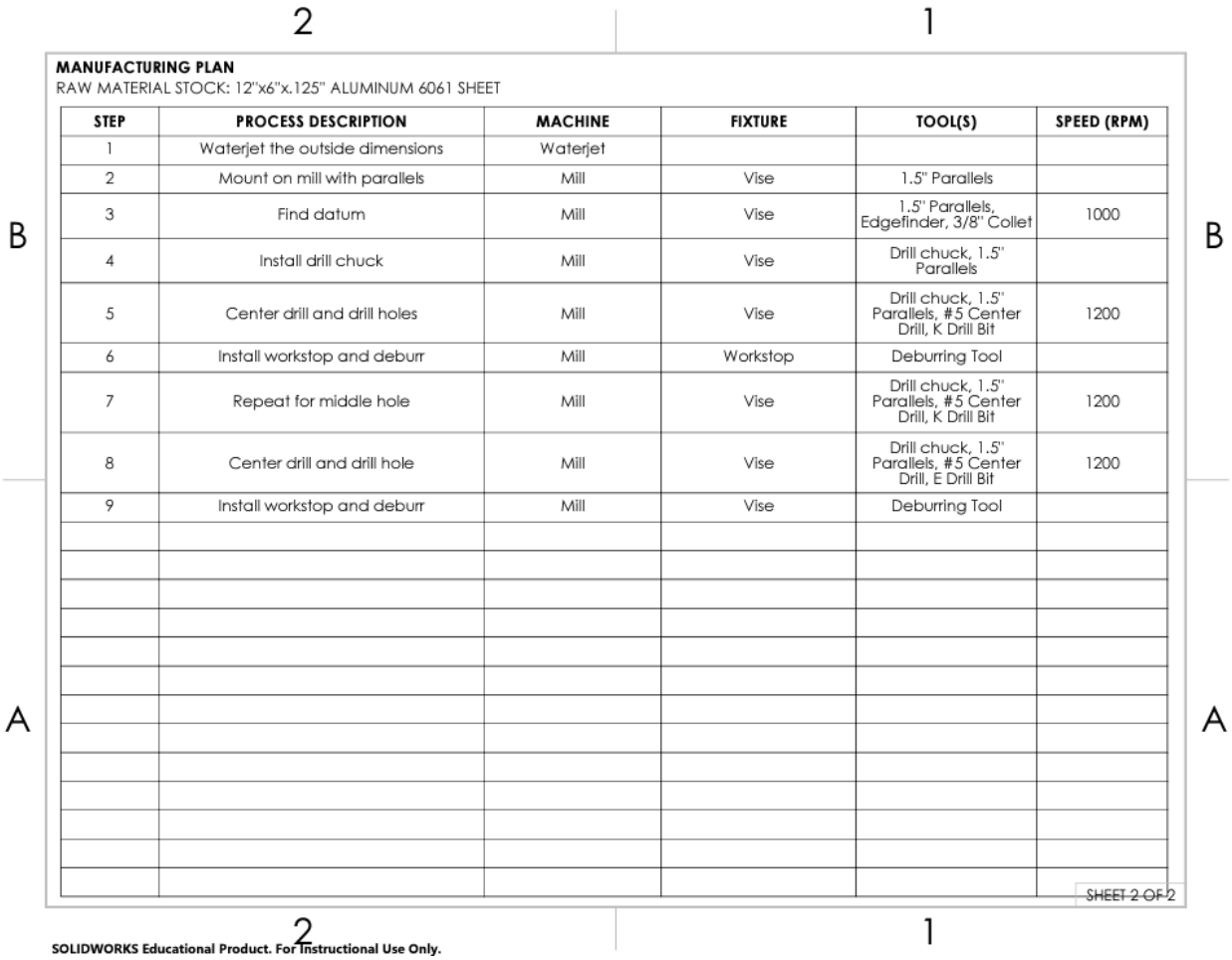
APPENDIX E

Engineering Drawings and Manufacturing Plan

The engineering drawings for the links, top and bottom plates, and track are shown below.



(a)



MANUFACTURING PLAN

RAW MATERIAL STOCK: 12"x6"x.125" ALUMINUM 6061 SHEET

STEP	PROCESS DESCRIPTION	MACHINE	FIXTURE	TOOL(S)	SPEED (RPM)
1	Waterjet the outside dimensions	Waterjet			
2	Mount on mill with parallels	Mill	Vise	1.5" Parallels	
3	Find datum	Mill	Vise	1.5" Parallels, Edgefinder, 3/8" Collet	1000
4	Install drill chuck	Mill	Vise	Drill chuck, 1.5" Parallels	
5	Center drill and drill holes	Mill	Vise	Drill chuck, 1.5" Parallels, #5 Center Drill, K Drill Bit	1200
6	Install workstop and deburr	Mill	Workstop	Deburring Tool	
7	Repeat for middle hole	Mill	Vise	Drill chuck, 1.5" Parallels, #5 Center Drill, K Drill Bit	1200
8	Center drill and drill hole	Mill	Vise	Drill chuck, 1.5" Parallels, #5 Center Drill, E Drill Bit	1200
9	Install workstop and deburr	Mill	Vise	Deburring Tool	

(b)

Figure 1E. Engineering drawing (a) and manufacturing plan (b) for the scissor link in the inflatable cushion assembly.

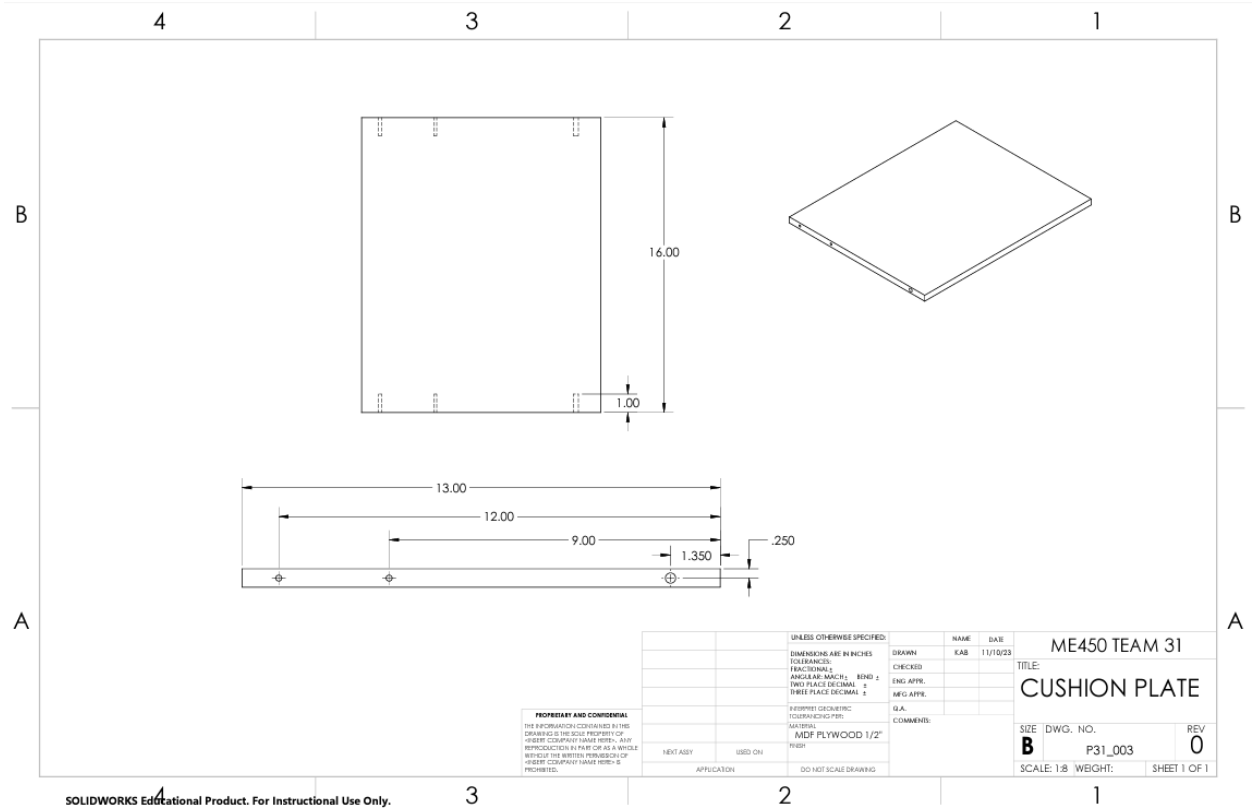
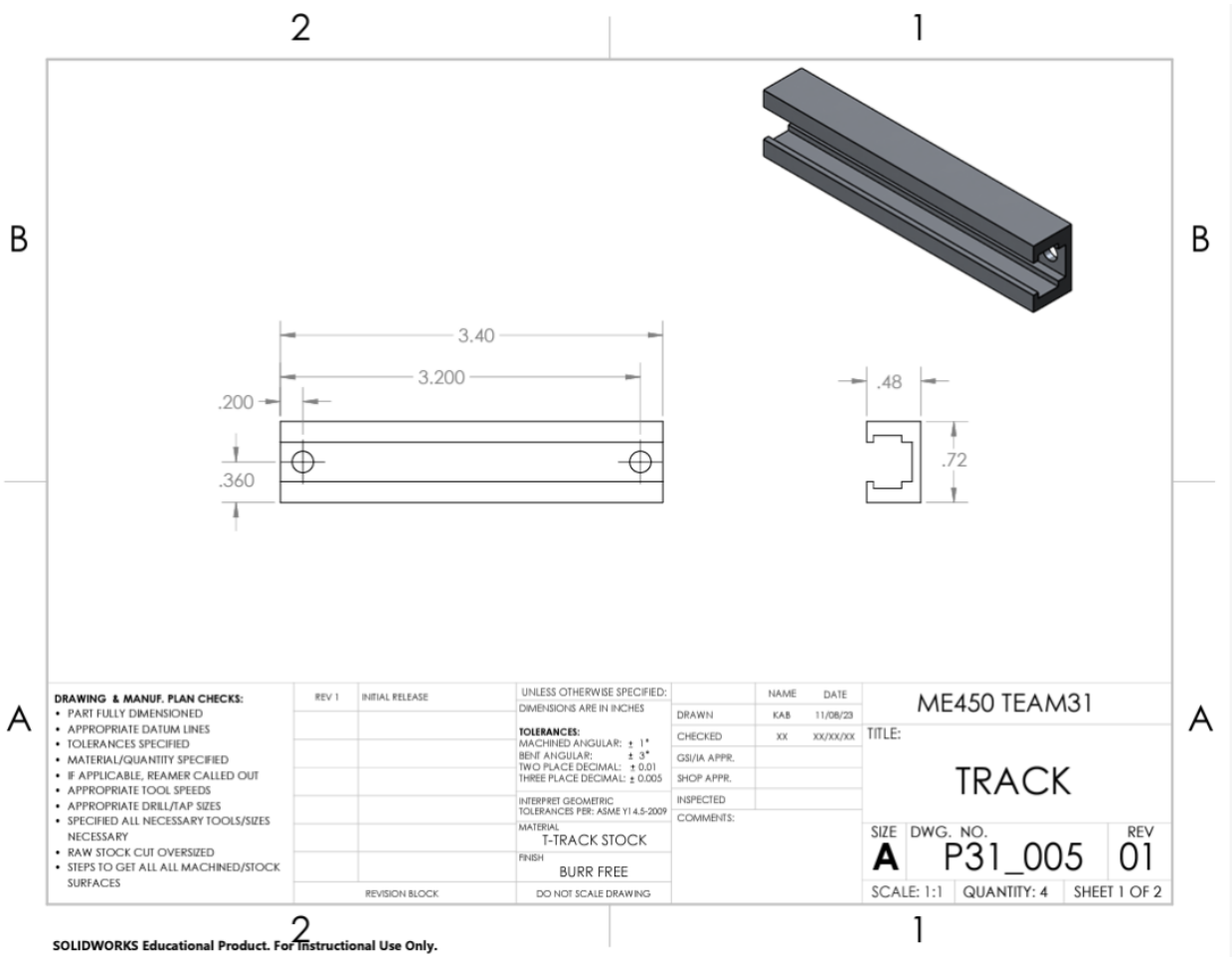
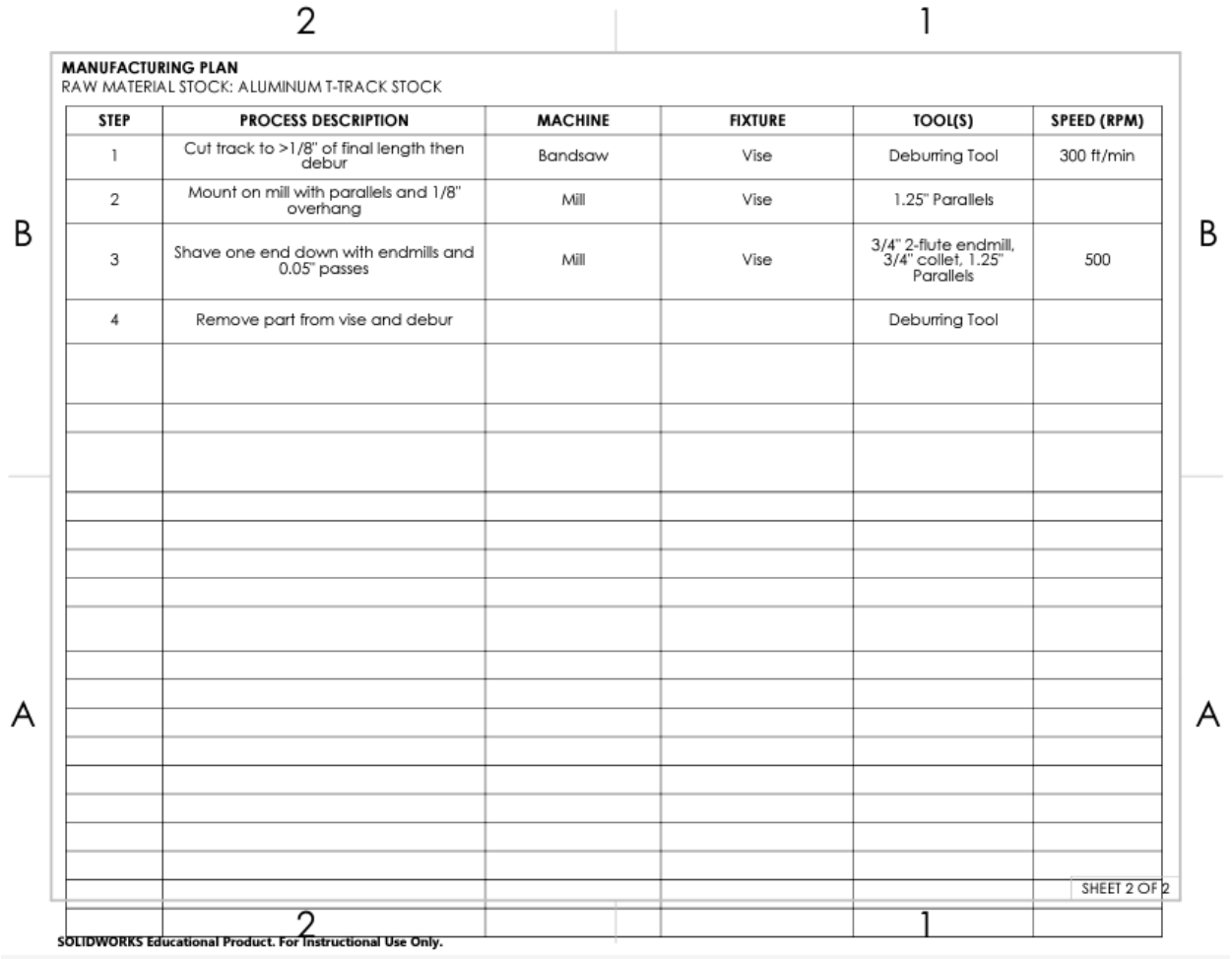


Figure 2E. Engineering drawing for the top and bottom plate in the inflatable cushion assembly.


2
1
B
B
3.40
3.200
.200
.360
.48
.72
A
A
DRAWING & MANUF. PLAN CHECKS:
• PART FULLY DIMENSIONED
• APPROPRIATE DATUM LINES
• TOLERANCES SPECIFIED
• MATERIAL/QUANTITY SPECIFIED
• IF APPLICABLE, REAMER CALLED OUT
• APPROPRIATE TOOL SPEEDS
• APPROPRIATE DRILL/TAP SIZES
• SPECIFIED ALL NECESSARY TOOLS/SIZES NECESSARY
• RAW STOCK CUT OVERSIZED
• STEPS TO GET ALL ALL MACHINED/STOCK SURFACES
REV 1
INITIAL RELEASE
REVISION BLOCK
UNLESS OTHERWISE SPECIFIED:
DIMENSIONS ARE IN INCHES
TOLERANCES:
MACHINED ANGULAR: ± 1°
BEVEL ANGULAR: ± 3°
TWO PLACE DECIMAL: ± 0.01
THREE PLACE DECIMAL: ± 0.005
INTERPRET GEOMETRIC TOLERANCES PER: ASME Y14.5-2009
MATERIAL
T-TRACK STOCK
FINISH
BURR FREE
DO NOT SCALE DRAWING
NAME
DATE
DRAWN
KAB
11/08/23
CHECKED
XX
XX/XX/XX
GSI/IA APPR.
SHOP APPR.
INSPECTED
COMMENTS:
ME450 TEAM31
TITLE:
TRACK
SIZE
A
DWG. NO.
P31_005
REV
01
SCALE: 1:1
QUANTITY: 4
SHEET 1 OF 2
2
1
SOLIDWORKS Educational Product. For Instructional Use Only.

(a)

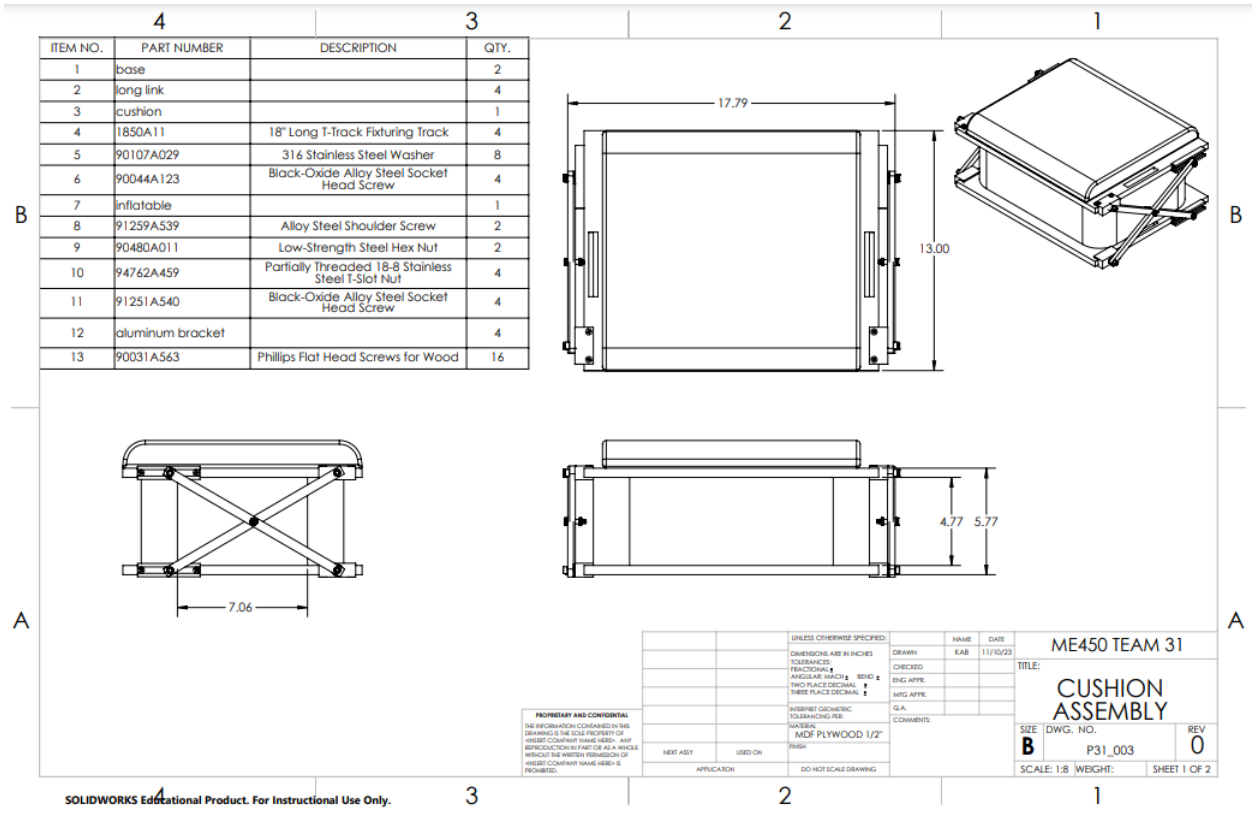


MANUFACTURING PLAN
RAW MATERIAL STOCK: ALUMINUM T-TRACK STOCK

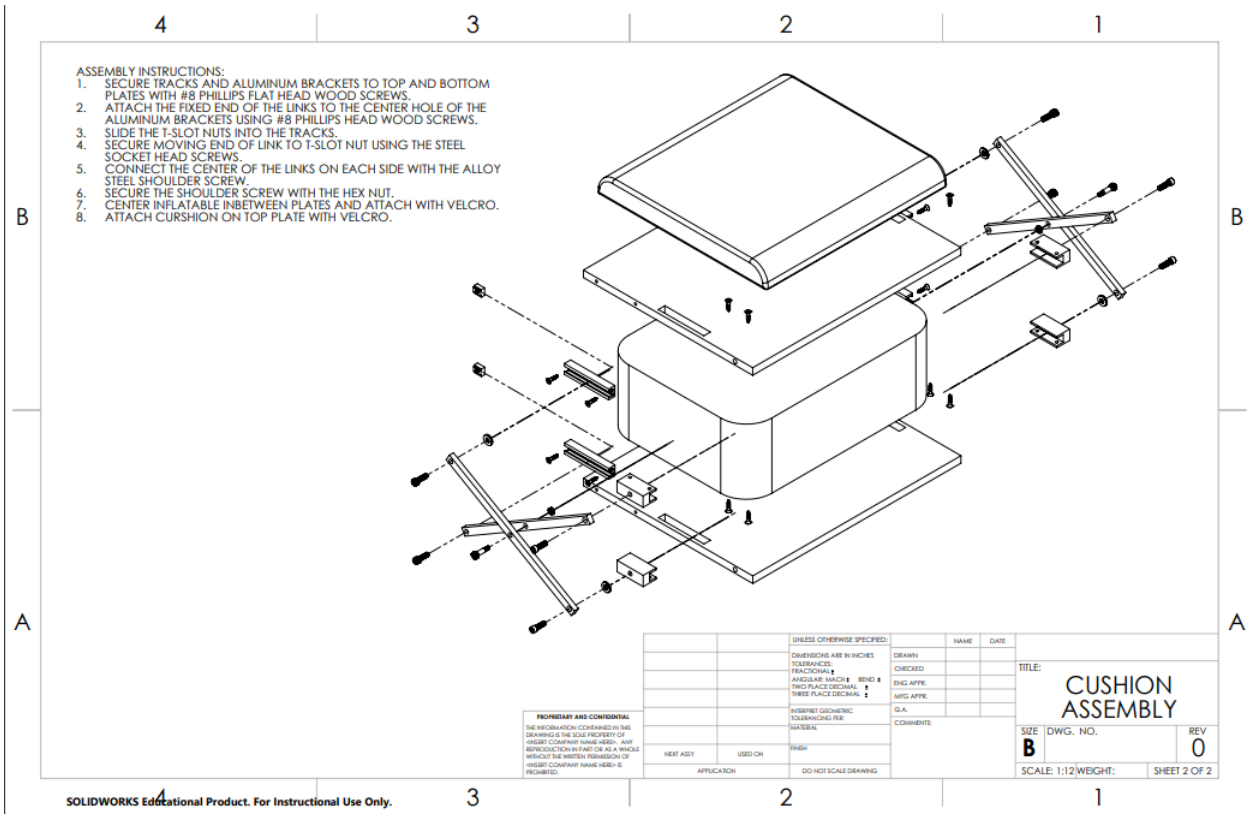
STEP	PROCESS DESCRIPTION	MACHINE	FIXTURE	TOOL(S)	SPEED (RPM)
1	Cut track to >1/8" of final length then debur	Bandsaw	Vise	Deburring Tool	300 ft/min
2	Mount on mill with parallels and 1/8" overhang	Mill	Vise	1.25" Parallels	
3	Shave one end down with endmills and 0.05" passes	Mill	Vise	3/4" 2-flute endmill, 3/4" collet, 1.25" Parallels	500
4	Remove part from vise and debur			Deburring Tool	

(b)

Figure 3E. The engineering drawing (a) and manufacturing plan (b) for the track component of the inflatable cushion design.



ITEM NO.	PART NUMBER	DESCRIPTION	QTY.
1	base		2
2	long link		4
3	cushion		1
4	1850A11	18" Long T-Track Fixturing Track	4
5	90107A029	316 Stainless Steel Washer	8
6	90044A123	Black-Oxide Alloy Steel Socket Head Screw	4
7	inflatable		1
8	91259A539	Alloy Steel Shoulder Screw	2
9	90480A011	Low-Strength Steel Hex Nut	2
10	94762A459	Partially Threaded 18-8 Stainless Steel T-Slot Nut	4
11	91251A540	Black-Oxide Alloy Steel Socket Head Screw	4
12	aluminum bracket		4
13	90031A563	Phillips Flat Head Screws for Wood	16



ASSEMBLY INSTRUCTIONS:
1. SECURE TRACKS AND ALUMINUM BRACKETS TO TOP AND BOTTOM PLATES WITH #8 PHILLIPS FLAT HEAD WOOD SCREWS.
2. ATTACH THE FIXED END OF THE LINKS TO THE CENTER HOLE OF THE ALUMINUM BRACKETS USING #8 PHILLIPS HEAD WOOD SCREWS.
3. SLIDE THE T-SLOT NUTS INTO THE TRACKS.
4. SECURE MOVING END OF LINK TO T-SLOT NUT USING THE STEEL SOCKET HEAD SCREWS.
5. CONNECT THE CENTER OF THE LINKS ON EACH SIDE WITH THE ALLOY STEEL SHOULDER SCREW.
6. SECURE THE SHOULDER SCREW WITH THE HEX NUT.
7. CENTER INFLATABLE INBETWEEN PLATES AND ATTACH WITH VELCRO.
8. ATTACH CURSHION ON TOP PLATE WITH VELCRO.

Figure 4E. The BOM and assembly instructions for the inflatable cushion design.

Appendix F

Cost Model

The cost model below will be filled out with our BOM and manufacturing costs in order to determine the final price of our design (Schwemmin, 2023).

VARIABLE COSTS									
		Cost Per Unit							
BOM	Plywood	1.3							
	Aluminum	5.82							
	Hardware	10.59							
	Inflatable	9.99							
	velcro	0.79							
	PLA	1.2							
	T track	8.74							
	Wheelchair sling	16							
	TOTAL	54.430							
			Run Time (h)	Batch Size (kg)	Operators / batch	Units / kg	Labor Rate ($)	Units / hr	Setup Time (h)
LABOR	Cutting Plywood	0.034	0.333	80.92	1	0.4325	3.6	105	0.08
	Milling Tracks and Lin	0.053146046	0.5	80.92	1	0.4325	3.72	105	0.08
	Drilling Holes in Plyw	0.034	0.33	80.92	1	0.4325	3.6	105	0.08
	TOTAL	0.122							
			Units per	Cost per	Labor Rate (/km)	Kilometers			
DISTRIBUTION	Shipper Box	0.602	0.602						
	Pack and Ship Labor	119.411			0.043	2777			
	Total	120.013							
			Capital Cost	Lifespan	Units / year				
MANUFACTURING	Equipment	0	0	0	0				
	Fixtures and Tooling	0	0	5	0				
	Total	0.000							
	Price per unit	$ 54.430							
	Total Units	$ 598.73							
	Shipping	$ 120.01							
	Cost of 2 air pumps	$ 240.00							
	Total	$ 958.74							

Figure 1F. The cost model outline that we will use to determine the final cost of our design.

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