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Minimizing Patient Migration: Enhancing Safety and Comfort for Patients and Caregivers in Bedridden Care

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MINIMIZING PATIENT MIGRATION: ENHANCING SAFETY AND COMFORT FOR PATIENTS AND CAREGIVERS IN BEDRIDDEN CARE

by
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A thesis submitted to the faculty of The University of Mississippi in partial fulfillment of the requirements of the Sally McDonnell Barksdale Honors College.

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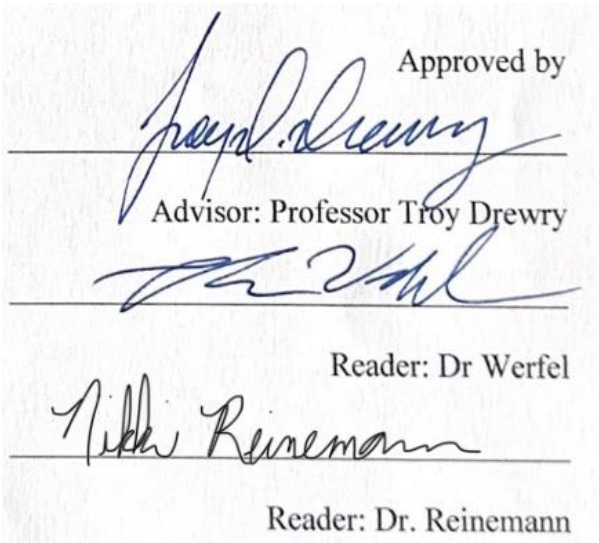

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DEDICATION

I would like to dedicate this thesis to my friends and family for their overwhelming love and support in all my endeavors, as well as to my professors whose guidance and encouragement have shaped me into the scholar I am today. This thesis stands as a testament to the collective support and encouragement of all those who have touched my life. Thank you for being a part of my journey.

ABSTRACT

Biomedical engineering seniors at the University of Mississippi embark on a senior project aimed at addressing an unmet clinical need. Our team, consisting of Kelsie Hand, Christian Miller, and Danielle Pasquini, identified a prevalent issue of bedridden patients slipping down in bed, leading to increased repositioning by caregivers. This not only impacts patient comfort but also poses risks of complications such as pressure ulcers and caregiver injuries. In our efforts to tackle the issue of patient slippage among bedridden individuals, our team introduced a novel solution comprising a non-slip vest for patients and a corresponding non-slip sheet attachment. This integrated system aims to enhance patient stability and comfort while significantly reducing the need for frequent repositioning. By addressing the underlying cause of slippage, our innovation not only emphasizes patient comfort but also mitigates the risk of musculoskeletal disorders for caregivers, thus enhancing their overall well-being. Future endeavors will focus on refining the design, conducting comprehensive testing, and pursuing regulatory approvals for clinical implementation.

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INTRODUCTION

In healthcare, the care of bedridden patients presents a significant challenge, particularly concerning the frequent need for repositioning by caregivers. This necessity arises not only from the discomfort experienced by patients but also from the potential development of pressure ulcers and other injuries if repositioning is neglected. Moreover, research indicates that the repetitive and strenuous nature of this task often leads to the development of musculoskeletal disorders among caregivers, posing a considerable risk to their health and well-being.

This thesis aims to shift the focus from simply addressing the challenges faced by caregivers in repositioning to tackling the root cause of the issue: preventing bedridden patients from slipping or requiring frequent repositioning altogether. Existing literature predominantly concentrates on enhancing the ease with which caregivers can reposition patients through the utilization of assistive devices such as hospital bed trapezes and draw/slip sheets. However, these interventions fail to address the core issue of patient slippage and the subsequent need for repositioning. By addressing this issue at its source, this research seeks to enhance both the safety and comfort of bedridden patients while simultaneously alleviating the physical burden placed on caregivers.

Literature Review

In addressing the unmet clinical need of patient migration in bed, our research team, consisting of myself, Kelsie Hand, and Christian Miller, undertook a thorough investigation into this phenomenon and its extensive impacts on both patients and caregivers. Patient migration, or the tendency for bedridden patients to gradually slip down the bed due to gravity and other factors, not only compromises patient comfort but also increases the workload for caregivers, necessitating frequent repositioning. This not only leads to physical strain but can also heighten the risk of developing musculoskeletal disorders among healthcare workers. Through our literature review, we discovered that existing solutions primarily focus on repositioning the patient after migration has occurred, rather than preventing it. Motivated by this gap in existing medical devices, we engaged in collaborative brainstorming and rigorous consultation with healthcare professionals, including interactions with the UMMC nursing school, to create a preventative solution. Our research and development efforts led to the innovative design of a non-slip vest, aimed at maintaining patient position and significantly reducing the need for caregiver intervention. This literature review will detail the process of identifying the issue, exploring its effects, and the creative journey toward our final product design.

What is patient migration?

Patient migration refers to the gradual movement of a patient's body downward in bed due to factors such as gravity, muscle weakness, or involuntary movements. This phenomenon often occurs in healthcare settings, particularly when patients are positioned with their head elevated, leading to a downward shift over time. Patient migration requires repositioning by a caregiver because it can result in several complications, including shearing

forces between the patient's skin and the bed surface, which increases the risk of pressure injuries. Repositioning is necessary to restore the patient to a safe and comfortable position, alleviate pressure points, and prevent the development of skin breakdown or other related complications. Additionally, frequent repositioning helps maintain proper alignment, enhances circulation, and promotes overall patient well-being, making it an essential aspect of quality patient care in healthcare settings.

Current Solutions

Current treatment options for patients experiencing migration in bed and those who cannot sit up independently involve a combination of manual and mechanical methods. Manual methods typically involve the assistance of caregivers who are trained to reposition patients using proper body mechanics and techniques. This may include lifting with the legs rather than the back, using draw sheets for assistance, and adjusting the patient's bed to reduce strain on the caregiver's back. These manual methods aim to prevent injuries, particularly musculoskeletal disorders among caregivers, while facilitating patient repositioning with relative ease and cost efficiency. However, these manual techniques may still pose risks of injury, require training to ensure proper execution, and are limited by the strength and availability of caregivers. On the other hand, mechanical methods such as hospital bed trapezes and adjustable beds equipped with features like Trendelenburg and reverse Trendelenburg positions offer alternative solutions. Hospital bed trapezes provide patients with something to grasp to reposition themselves, while adjustable beds allow caregivers to adjust the bed's position to prevent sliding and maintain proper elevation. These mechanical methods reduce physical strain on caregivers, increase efficiency, and provide added safety features like side rails to prevent falls. However, they come with drawbacks

such as high costs, maintenance requirements, and limited portability, which may restrict their accessibility and use in certain healthcare settings. Despite the availability of these treatment options, none of them fully prevent patient migration, highlighting the ongoing need for innovative solutions to comprehensively address this challenge.

Figure 1: Hospital Bed Trapeze Demonstration

Figure 1: Patient utilizing a hospital bed trapeze to assist in repositioning ("Help with Hospice")

The team's *Literature Review* document is shown in Appendix 1.

Prior Art Search

An essential aspect of designing solutions for patient migration is conducting a thorough examination of prior art to ensure innovation and differentiation from existing technologies. In our exploration, we have identified several examples of prior art relevant to the challenge of patient migration and repositioning within healthcare settings.

Prior Art Reference 1: Patient Position Device (US 9333139 B2)

Reference 1 presents a patent for a patient positioning device designed to aid in repositioning patients on hospital beds. Featuring flexible tracks along the sides of the bed and a sliding sheet propelled by a drive mechanism, this invention aims to enhance patient comfort and caregiver efficiency by facilitating smooth repositioning. The claims highlight features such as mattress adjustability and comprehensive repositioning methods, offering a versatile solution adaptable to various healthcare settings.

Figure 2: Prior Art Reference 1

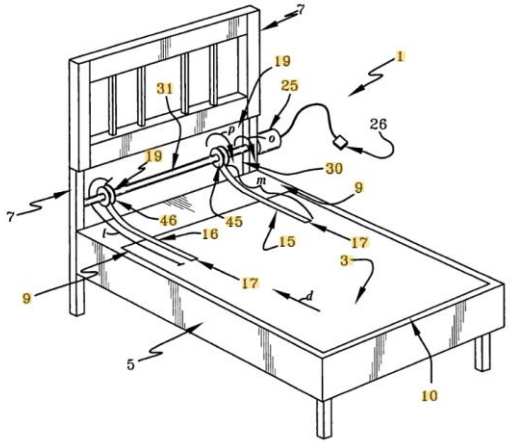

Figure 2: A device for translatably positioning a patient along a bed (U.S. Patent No. 7003819B2)

Prior Art Reference 2: Multi-position reclining bed (US8615828B2)

Reference 2 introduces a multi-position reclining bed that allows patients to transition from a fully reclined to a seated position. Unlike conventional hospital beds, this invention permits the leg section to drop below horizontal, redistributing weight from the buttocks and lower back to the lower thighs and feet. With claims emphasizing enhanced comfort during

prolonged sitting and improved patient independence, this bed seeks to promote patient well-being in healthcare environments.

Figure 3: Prior Art Reference 2

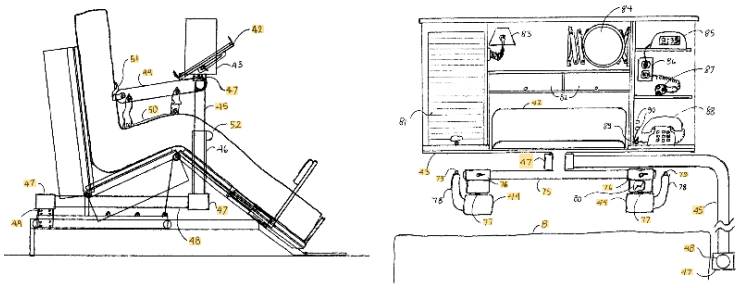

Figure 3: A reclining bed that provides the full ergonomic benefits of sitting up (U.S. Patent No. 8615828B2)

Prior Art Reference 3: Portable Medical Lift and Positioning Device (WO 2022/060610 A1)

Reference 3 addresses the challenges of repositioning and supporting bedridden patients with a portable medical lift and positioning device. Featuring a base, powered screw jack, radial adjustment head, and cushion cradle, this invention offers a versatile solution for caregivers. Its design enables customization for different body parts and sizes, promoting ease of use and patient comfort while reducing the risk of caregiver injuries. With claims highlighting its portability and cost-effectiveness, this device aims to enhance patient care in diverse healthcare settings.

Figure 4: Prior Art Reference 3

Figure 4: A life and position device designed to aid attendants in moving and propping various selected body parts of a patient from atop a support surface (Patent No. 2022/060610 A1)

Prior Art Reference 4: Patient Repositioning Sheet and Sling (EP3614988B1)

Reference 4 presents a patent for a patient repositioning sheet and sling designed to facilitate safe and efficient movement of patients in bed. Featuring multiple handles and strap members, this invention allows caregivers to slide or reposition patients while minimizing friction and discomfort. The sheet's dual-surface design, with a high-friction upper surface and low-friction lower surface, offers both stability and ease of movement. With claims emphasizing versatility and patient comfort, this device provides a practical solution for patient handling in healthcare environments.

Figure 5: Prior Art Reference 4

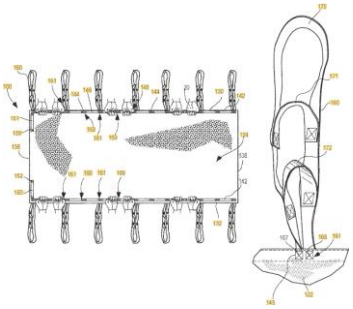

Figure 4: A patient repositioning apparatus doubles as a repositioning sheet and a sling (Patent No. EP3614988B1)

Prior Art Reference 5: Estimation and Monitoring of Patient Torso Angle (US 9836942 B2)

Reference 5 introduces a patent for a patient monitoring system designed to estimate and monitor the torso angle of patients in bed. Utilizing sensors embedded in the mattress, this system detects changes in patient position and activity level, providing real-time feedback to caregivers. With claims focusing on accuracy and reliability, this technology aims to enhance patient safety and prevent complications associated with improper positioning. By alerting caregivers to potential issues, such as patient migration, this system facilitates proactive intervention and improves overall patient care.

Figure 6: Prior Art Reference 5

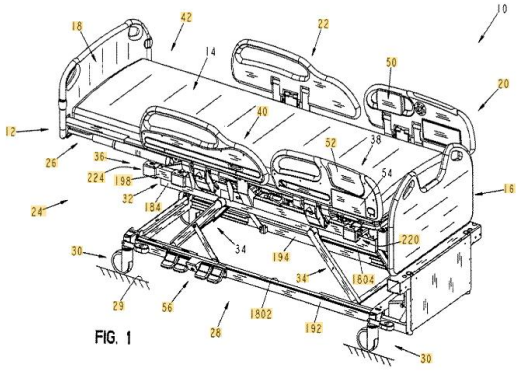

Figure 5: A bed with a patient monitoring system (Patent No. US 9836942 B2)

Prior Art Reference 6: Patient Monitoring System (US 8419660 B1)

Reference 6 describes a patent for a patient monitoring system that utilizes sensors attached to the mattress to detect changes in patient position and movement. Featuring a pressure-sensitive liquid component, this system alerts caregivers to deviations from predetermined thresholds, ensuring timely intervention and preventing adverse events. With claims emphasizing versatility and reliability, this technology offers a comprehensive solution for patient monitoring in healthcare settings. By providing continuous surveillance of patient movement, this system enhances patient safety and improves the quality of care.

The team's *Prior Art Search* document is shown in Appendix 2.

Clinical Need

Our project aims to devise a method to prevent patients from slipping down in bed, thereby diminishing the necessity for caregivers to frequently readjust patients and lowering the risk of injury to both caregivers and patients.

Brainstorming Process and Notes

Initial Brainstorming

In our initial brainstorming sessions, we focused on tackling the issue of patient migration in bed. Studies indicated that patient migration in bed can lead to discomfort, pressure ulcers, and increased caregiver strain (Smith et al.). Motivated by these findings, we set out to devise an innovative solution that would mitigate patient migration and enhance overall patient comfort and safety. After thorough exploration of existing solutions and consideration of various approaches, we converged on the concept of a dynamic positioning

system. Our original design concept involved an upper-body support bed attachment that would be strapped onto the bed frame, providing support under the patient's arms to prevent downward sliding while allowing for natural movement and comfort. A rough draft of our original design is shown in Figure 7.

Figure 7: Original Design

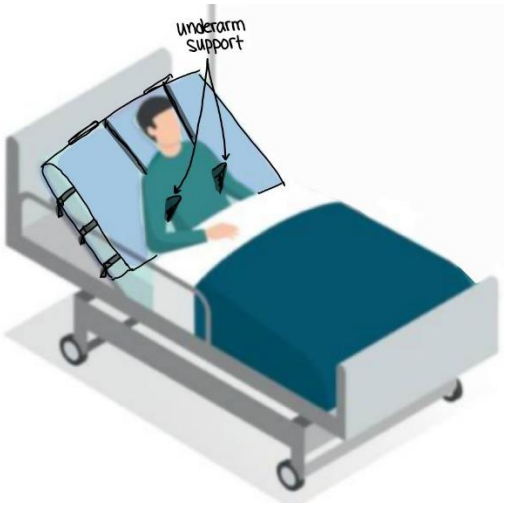

Figure 7: Rough sketch of the team's original idea to use underarm supports to prevent the patient from slipping down the bed.

However, after meeting with Ms. Jessica Hill, as well as 6 additional nurses at the University of Mississippi School of Nursing, our group decided to shift our design idea. While our primary goal remains focused on preventing patient migration, we decided to design a more user-friendly solution.

Final Design

After careful consideration and feedback from healthcare professionals, our final design comprises a non-slip vest paired with a non-slip sheet head-of-bed attachment. The

non-slip vest is worn by the patient and features adjustable Velcro straps to ensure a secure and customized fit, accommodating patients of various sizes. Made from neoprene, a comfortable yet durable fabric, the vest incorporates non-slip material along the back to prevent the patient from sliding downward on the bed. Additionally, the non-slip sheet attachment is affixed to the head of the bed using adjustable straps, providing a stable surface for the patient's upper body. This design was chosen for its simplicity, effectiveness, and ease of use, offering a practical solution to prevent patient migration and enhance safety in healthcare settings by creating more friction between the vest and bed surface. Figure 8 depicts the drawing detailing our final design.

Figure 8: Non-slip Vest Final Design

Figure 8: The neoprene vest is designed to prevent patient migration in hospitals. It's adjustable with Velcro straps and has non-slip material to keep patients secure on the bed.

Benefits of our final design:

1. Prevention of Patient Migration

a. Non-slip Vest: The neoprene vest, paired with a non-slip sheet head of bed attachment, creates increased friction between the patient and the bed, reducing the likelihood of the patient slipping down.
b. Velcro Straps: Adjustable Velcro straps ensure a secure fit, accommodating patients of various sizes and providing customizable support.
c. Ease of Removal: The vest features Velcro straps for quick and easy removal, allowing caregivers to swiftly adjust or remove the vest as needed without causing discomfort to the patient.

2. Enhanced Patient Comfort
    a. Neoprene Material: Made from neoprene, a biocompatible material that is not a common allergen, the vest ensures patient comfort during use, minimizing the risk of skin irritation or allergic reactions.
    b. Reduced Pressure Points: By preventing patients from sliding down the bed, the vest helps distribute pressure more evenly, reducing the risk of pressure ulcers and discomfort.
3. Increased Safety for Patients and Caregivers
    a. Prevents Injury: By stabilizing patients in bed, the vest helps prevent falls and injuries, reducing the risk of harm to both patients and caregivers.
    b. Secure Attachment: The non-slip sheet head of bed attachment ensures that the vest remains securely in place, providing reliable support without the risk of slippage or displacement.

Materials

We chose neoprene as the primary material for our vest. In selecting neoprene as the primary material for the non-slip vest, we prioritized both patient comfort and safety. Neoprene's soft and cushioned texture provides a gentle yet secure support system for patients, minimizing discomfort even during prolonged use. Its inherent flexibility allows the vest to adapt to various body shapes and sizes, ensuring a personalized and snug fit for each patient. Moreover, neoprene's biocompatibility and hypoallergenic properties make it an ideal choice for medical applications, as it reduces the risk of skin irritation or allergic reactions commonly associated with other materials. Additionally, neoprene's water-resistant nature adds to its durability, ensuring that the vest remains functional and hygienic over time, even in the presence of bodily fluids.

For the non-slip sheet head of bed attachment, we opted for a high-friction material specifically designed to enhance traction and stability. This material effectively prevents patients from sliding down the bed, reducing the need for frequent repositioning by caregivers and minimizing the risk of patient injury. By utilizing a material with superior non-slip properties, we ensure that the attachment remains securely in place, even during patient movement or adjustment. This reliability is crucial in maintaining patient safety and comfort, particularly for individuals with limited mobility or those at risk of falls.

We opted for a vest design with Velcro closures instead of zippers for several reasons. Firstly, Velcro closures allow for quick and easy removal in case of a medical emergency, providing caregivers with rapid access to the patient's body if needed. Moreover, Velcro eliminates the risk of snagging or tearing the patient's skin, unlike a zipper.

Additionally, the choice of a vest/wearable design was deliberate to ensure that the patient wouldn't feel restrained while still benefiting from the support and stability provided by the vest. This design approach prioritizes patient comfort and safety, allowing them to move freely while minimizing the risk of slipping down the bed.

Design Overview

Our design comprises a neoprene vest paired with a non-slip head of bed sheet. The vest is constructed using durable and biocompatible neoprene material, chosen for its flexibility, comfort, and resistance to allergens. It features Velcro straps for quick and easy adjustment, ensuring a secure and comfortable fit for patients of varying sizes. The vest design prioritizes patient safety and comfort, allowing for easy removal in case of medical emergencies while providing reliable support to prevent slipping down the bed.

The non-slip head of bed sheet is designed to create increased friction between the patient's body and the bed surface, effectively reducing the likelihood of the patient sliding down. Crafted from high-quality, non-slip material, this sheet is tailored to fit securely over the head of the bed, providing a stable surface for the patient. Its design aims to maintain patient autonomy and comfort by offering a non-restrictive solution to prevent migration, ensuring that patients can adjust their position without feeling constrained.

Together, the neoprene vest and non-slip head of bed sheet form a comprehensive solution to address patient migration in healthcare settings. By combining the benefits of support and stability with ease of use and comfort, our design aims to enhance patient care and reduce caregiver strain associated with frequent repositioning tasks.

Design and Development Plan Summary

After a collaborative session with nurses at the University of Mississippi School of Nursing on March 8, 2024, our team opted to make a substantial alteration to our product design. The initial concept of a bed attachment was replaced with a neoprene vest design to address the issue of patient slippage in bed. The nursing school team provided valuable insights and guidance, leading to a more efficient and user-friendly solution.

After the meeting, the design and development plan was revised to reflect this pivotal change. The new strategy focused on the development of a neoprene vest with non-slip fabric for upper body support, aiming to reduce patient slippage and enhance comfort. The product is intended for use by weak bedridden individuals, with materials such as neoprene, non-slip fabric, and Velcro being key components of the design. Moving forward, the project timeline, which can be found in Appendix 3, outlines key milestones such as prototype testing at Baptist Memorial Hospital and the completion of the non-slip sheet prototype.

We have determined eight user needs:

1. Patient comfort
    a. Lack of patient comfort can lead to discomfort, agitation, and potential skin irritation, affecting the overall well-being of the patient and potentially hindering the effectiveness of treatment.
2. Caregiver safety
    a. Inadequate measures to ensure patient stability and prevent slippage can increase the risk of musculoskeletal injuries, strain, and accidents for

caregivers during patient repositioning, impacting their well-being and ability to provide care.

3. User-friendly design
    a. A complex or unintuitive design can result in difficulty in product use, leading to potential errors, inefficiencies, and user dissatisfaction, ultimately affecting the product's usability and effectiveness.
4. Durability
    a. Poor durability can result in premature wear and tear, product malfunction, and potential safety hazards, compromising the product's longevity, reliability, and overall performance.
5. Time-saving features
    a. Lack of time-saving features can lead to inefficiencies, increased workload for caregivers, and delayed patient care, affecting operational efficiency, quality of care delivery, and overall patient outcomes.
6. Reusability
    a. A lack of reusability can result in increased resource consumption, environmental impact, and higher costs associated with frequent replacement or disposal of the product, posing sustainability challenges and economic implications.
7. Proper fit
    a. Poor fit can lead to discomfort, reduced effectiveness of the product, and potential safety risks for the user, impacting user experience, treatment outcomes, and overall product performance.

8. Biocompatibility and allergen-free materials
    a. Inadequate consideration of biocompatibility and allergen-free materials can result in allergic reactions, skin sensitivities, and adverse health effects for users, compromising patient safety, compliance, and treatment efficacy.

Our revised *Design and Development Plan Summary* is shown in Appendix 3.

Design Summary Matrix

We've outlined the design inputs, outputs, essential requirements, and verification and validation activities for each of the identified user needs in the design summary matrix.

User Need 1: Patient comfort will be addressed by incorporating neoprene material for the vest construction to ensure comfort and minimize the risk of skin irritation or tearing. Mechanical testing will be conducted to assess effectiveness, followed by validation through clinical evaluation.

User Need 2: Caregiver safety will be addressed … focuses on maximizing friction between the vest and sheet to prevent patient slippage and enhance caregiver safety. We'll undergo rigorous mechanical testing to ensure optimal friction levels and further validate through comprehensive clinical evaluations.

User Need 3: User-friendly design will be addressed … focuses on providing detailed instructions for ease of use. We'll thoroughly test the instruction manual and perform meticulous visual inspections and quality control checks for validation.

User Need 4: Durability will be addressed … underscores the significance of using durable materials for long-term use. Mechanical testing will rigorously verify durability, while clinical evaluation will provide validation for this aspect.

User Need 5: Time-saving features will be addressed … incorporates Velcro straps for swift and effortless removal. Mechanical testing, followed by clinical evaluations, will ensure the effectiveness of this feature.

User Need 6: Reusability will be addressed… emphasizes material and construction that allow for cleaning and reuse. Verification through mechanical testing will be followed by validation through comprehensive clinical evaluations.

User Need 7: Proper fit will be addressed … necessitates an adjustable design to accommodate individuals of varying sizes. Mechanical testing will ensure effectiveness, with subsequent clinical evaluations providing further validation.

User Need 8: Biocompatibility and allergen-free materials will be addressed… highlights the importance of using biocompatible materials free of most allergens. Material certification will rigorously verify this aspect, and clinical evaluation will provide validation for its biocompatibility.

The team's *Design Summary Matrix* is shown in Appendix 4.

Risk Management Plan Summary:

The Risk Management Plan for the vest and non-slip sheet design aims to address potential hazards associated with preventing patient migration in bedridden individuals. While there are not many inherent risks with our product, misuse could decrease its effectiveness. This plan outlines risk management activities throughout the lifecycle of the products, from initial development to post-market surveillance.

To address the inherent risks associated with our product, we have devised several essential measures and protocols aimed at averting potential product failures.

1. **Identifying Intended Use and Potential Misuse Scenarios:**

The vest and non-slip sheet are meticulously designed to mitigate slip-down incidents among bedridden individuals. Potential scenarios of misuse involve utilizing the vest without the accompanying head of bed sheet attachment or overlooking the necessity for periodic patient readjustment.

2. **Product Maintenance and Sterilization**

The product consists of a vest constructed from grippy/non-slip material, strategically engineered for optimal effectiveness when paired with the non-slip head of bed sheet attachment. Both components are designed for routine sterilization and cleaning by users, ensuring maintenance of hygiene standards and longevity of use.

3. **Risk Assessment and Mitigation:**

Proactive measures are taken to minimize potential user errors, including the provision of comprehensive instruction manuals for proper usage. These manuals aim to mitigate risks associated with user interface design features, accommodate special user needs, and ensure the portability of the device.

4. **Quality Control:**

To ensure safety and reliability, we'll implement strict quality control for our non-slip vest and sheet. Through thorough inspections and tests, we'll verify that each product meets our high standards. By maintaining these standards, we aim to reduce the risk of defects or malfunctions that could decrease the effectiveness of the product. This proactive approach not only ensures adherence to regulations but also builds trust in our product among healthcare professionals and patients, thereby improving the overall effectiveness and reliability of our solution.

By adhering to this Risk Management Plan, we aim to minimize risks associated with the vest and non-slip sheet design, ensuring the safety and effectiveness of these devices in preventing patient migration and enhancing patient care.

The team's *Risk Management Plan Form* is shown in Appendix 5.

Failure Modes and Effects Analysis (FMEA) Summary

1. Friction Reduction:
    a. Failure Mode: Decrease in non-slip properties of vest material.

        i. Effect: Increased risk of patient sliding, leading to discomfort and potential injuries.
    b. Failure Mode: Wear and tear of non-slip sheet attachment.
        i. Effect: Loss of stability, impacting safety and comfort.
2. Incorrect Usage:
    a. Failure Mode: Misalignment of Velcro straps on the vest.
        i. Effect: Inadequate fit, compromising effectiveness.
    b. Failure Mode: Improper attachment of sheet to bed frame.
        i. Effect: Reduced stability, increased risk of slippage.
3. Material Integrity:
    a. Failure Mode: Deterioration of neoprene material.
        i. Effect: Structural compromise, potential failure.
    b. Failure Mode: Degradation of non-slip properties.
        i. Effect: Diminished effectiveness, safety impact.
4. Sizing Issues:
    a. Failure Mode: Inaccurate sizing for different body types.
        i. Effect: Poor fit, reduced support.
    b. Failure Mode: Non-adherence to strap adjustments.
        i. Effect: Uneven support, increased risk of displacement.

Addressing these failure modes with risk management strategies will enhance product safety and effectiveness in preventing patient migration.

Table 1: Severity Rating Table

Severity (SEV)		
Ranking	Definition	Effect
5	Catastrophic	Device failure or defect may cause death or permanent injury with or without warning of failure
4	Severe	Device failure or defect will cause severe injury which would necessitate revision surgery
3	Moderate	Failure renders device useless or will result in a minor injury of a non-permanent nature
2	Minor	Failure will result in no loss of product performance but may create some annoyance to user
1	None	No effect

Table 1 illustrates ratings for various levels of device failure severity. A low rating suggests minimal impact on product performance, whereas a high rating may pose a significant risk to a patient using the product. These ratings play a crucial role in determining the Risk Index of a device failure, as shown in Table 3. This table has been supplied by Troy Drewry.

Table 2: Occurrence Rate Table

Occurrence (OCC)		
Ranking	Definition	Frequency
5	Extremely High	Failure almost inevitable
4	High	Repeated failure
3	Likely	Occasional failure
2	Rare	Failure unlikely
1	Remote	Remote chance of failure

Table 2 displays the occurrence rates and their associated definitions for device failures. A low occurrence rate signifies a minimal likelihood of device failure, whereas a high occurrence rate indicates a high probability of failure in that specific area. These rates are essential in determining the Risk Index of a device failure, as illustrated in Table 3. This table has been supplied by Troy Drewry.

Table 3: Risk Index Table

Risk Index Table							
			Hazard Severity Level (S)				
			None	Minor	Moderate	Severe	Catastrophic
			1	2	3	4	5
Occurrence	Extremely High	5	5	10	15	20	25
	High	4	4	8	12	16	20
	Likely	3	3	6	9	12	15
	Rare	2	2	4	6	8	10
	Remote	1	1	2	3	4	5

Table 3 illustrates the Risk Indices of different device failures in relation to their severity level and occurrence rate. This table is utilized to assess the overall risk associated with a device failure. Provided by Troy Drewry.

Table 3 displays the risk indices of failures based on their occurrence rate and severity level. The severity rate of a device failure, as depicted in Table 1, determines the overall severity or danger posed by a specific failure. The severity scale ranges from 1, indicating "no effect," to 5, indicating an effect that "may cause death or permanent injury without warning of failure." Similarly, the occurrence rate of a particular failure is detailed in Table 2, with the scale ranging from 1, signifying a "remote chance of failure," to 5, suggesting that failure is "almost inevitable." When multiplied together, these values define the risk index of a specific device failure. Risk indices below 5 are considered relatively safe, while those exceeding 10 are deemed extremely hazardous and detrimental. Our product's failure points have been assessed using Table 1.

- Fit:
    - If the vest is not appropriately sized for the patient, its effectiveness is likely to be compromised, which could result in discomfort and diminished functionality. This issue is particularly pertinent if the patient's body size falls outside the range of the pre-designed adjustable vest sizes, which can affect the product's overall performance. Recognizing the importance of a proper fit for the vest to function as intended, a risk index of 4 has been assigned. This level of risk has led us to consider offering our vests in multiple sizes and/or with enhanced adjustability features to meet the varying needs and body types of patients, ensuring that every individual can benefit from the optimal performance of our product.
- Biocompatibility:
    - The biocompatibility of our product is vital for maintaining patient safety and comfort. The potential risk of allergic reactions to materials in the vest emphasizes the importance of biocompatibility in medical devices to prevent patient discomfort and adverse reactions. Allergic reactions stemming from non-biocompatible materials can result in health complications, jeopardizing the safety and efficacy of the product. To mitigate this risk, we are taking preventative measures by using neoprene, a material that is not a common allergen, in the construction of the vest. This proactive approach aims to safeguard patient safety and comfort while minimizing the risk index to 4.
- Weight limit:

    - The impact of product effectiveness for heavier patients emphasizes the need for considerations regarding weight limits to ensure optimal functionality and patient comfort. Heavier patients experiencing sliding down the bed more frequently due to their weight poses a risk of discomfort and potential safety issues, underscoring the importance of addressing weight-related factors in product design. To mitigate this risk, larger vests with larger grippy surface areas are advised to provide adequate support and prevent sliding for heavier patients, reducing the risk index to 4 and improving overall patient care and product effectiveness.
- Life cycle:
    - The life cycle of our product designed to prevent patient migration involves addressing long-term functionality challenges. Continuous use and wear of the grippy material may reduce the product's effectiveness in preventing patient slippage, necessitating proactive maintenance measures. To maintain optimal performance and patient safety, it is essential to monitor product performance and replace it when necessary. Implementing a replacement protocol based on performance or a specified timeframe is recommended to address longevity issues and uphold device efficacy. Proactive maintenance strategies are crucial, with a risk index of 4 emphasizing the importance of timely replacements to ensure the product's effectiveness in preventing patient migration.
- Skin irritation:

- The risk of skin tearing or irritation under the arms where the vest sits underscores the importance of preventive measures to maintain skin integrity and prevent discomfort. Friction from the vest on underarm skin could lead to irritation, highlighting the necessity of addressing contact-related skin issues in the product design. To mitigate this risk, incorporating soft material on the underarms of the vest is recommended to provide a cushioning layer and reduce skin irritation, ultimately improving patient comfort and safety. With a risk index of 6 emphasizing the significance of addressing skin-related concerns, proactive steps in product design are crucial to ensure optimal comfort and safety for patients.

- Quick removal:
  - Efficient vest removal is crucial in urgent situations to ensure timely patient care and prevent potential complications. The inadequacy of vest removal speed, particularly during emergencies like coding, underscores the importance of incorporating user-friendly design features for effective product usage. Challenges faced by nurses and caregivers in swiftly removing the vest can lead to delayed patient response and compromised care quality, highlighting the need for streamlined removal mechanisms in emergency scenarios. To address this issue, our design incorporates easily removable vests with Velcro closures to enable fast and efficient removal, promoting quick response times and reducing patient risk. With a risk index of 6 emphasizing the critical nature of timely intervention and removal capabilities

in patient care scenarios, prioritizing quick removal features is essential for enhancing patient outcomes and optimizing care delivery.

- Sanitation:
    - While not posing a high risk, inadequate sanitation protocols can still lead to health complications like infections, underscoring the importance of upholding high cleanliness standards. Even with a low-risk index of 2, It is crucial to implement regular and proper sanitation techniques to minimize infection risks and ensure the well-being of patients.

The team's original FMEA Form can be found in Appendix 6.

Verification and Validation Plan Summary

The Verification and Validation Plan for our product includes the following activities:

Verification Plans:

1. Mechanical Testing:
    a. Conduct mechanical testing to ensure the product withstands necessary forces to prevent slippage.
    b. Account for user needs related to patient safety and caregiver comfort.
2. Instruction Manual Testing:
    a. Verify the clarity and effectiveness of the instruction manual for ease of use.
    b. Ensure user needs for product understanding are met.
3. Material Certification:
    a. Certification testing to confirm biocompatibility and the absence of allergens in materials.

b. Address user needs for product safety and compatibility.

Validation Plans:

1. Clinical Evaluation:
    a. Conduct clinical evaluations to validate product usability and effectiveness in real-world scenarios.
    b. Address user needs related to durability, time-saving, fit, and biocompatibility.
2. Visual Inspections/Quality Checks:
    a. Regular inspections and quality checks to ensure product adherence to specifications.
    b. Address user needs related to ease of use, time-saving, and reuse.

By executing these verification and validation activities, our project aims to ensure the product meets essential requirements, functions correctly and is safe for users.

Regulatory Pathway for Reimbursement

The regulatory pathway for reimbursement outlines the necessary steps to ensure that the medical device not only meets regulatory approvals but also qualifies for coverage by insurance providers, such as Medicare and private insurers. This process is crucial for the adoption and accessibility of medical innovations in clinical settings, as it ensures that patients can afford the necessary treatments and devices. For our non-slip vest, designed to prevent patient migration in bedridden patients, the following points highlight the essential components of the reimbursement pathway:

Identify Appropriate Reimbursement Codes:

- Determine relevant HCPCS and CPT codes that apply to the vest, crucial for billing Medicare and other health insurers.

Medicare Coverage as Durable Medical Equipment:

- Classify the vest under Medicare Part B, which covers Durable Medical Equipment, ensuring it fits the criteria for reimbursement.

Evidence of Clinical Efficacy and Cost-Efficiency:

- Conduct clinical trials and economic analyses to demonstrate the vest's effectiveness in reducing the need for frequent patient repositioning and its potential to lower related healthcare costs.

Prepare Comprehensive Reimbursement Documentation:

- Compile a comprehensive portfolio including clinical data, economic studies, and real-world usage evidence to support the vest's effectiveness and necessity.

By carefully navigating these steps, we aim to secure the necessary reimbursement approvals, enhancing the vest's accessibility and utility in healthcare settings.

Gillespie Business Plan Competition Summary

The team entered the Gillespie business competition on April 12, 2024, under the team and company name "SwiftShift MedTech" as part of the senior design project with the following logo:

Figure 9: SwiftShift MedTech Logo

Figure 9: SwiftShift MedTech Logo, designed by Danielle Pasquini.

SwiftShift MedTech is dedicated to addressing the significant challenge of patient migration in bedridden individuals with our innovative non-slip vest. Our company is committed to enhancing both patient safety and caregiver ease, alleviating the need for frequent repositioning. As we finalize our proof of concept, we are also in the process of securing a patent to protect this unique innovation. Our business plan involves initially targeting local hospitals and nursing homes, establishing a strong foundation before expanding our reach. By introducing the vest into these settings, we aim to demonstrate its effectiveness and ease of use directly to healthcare professionals who handle patient care daily. This strategic market entry is supported by competitive pricing, positioning SwiftShift MedTech's non-slip vest as a cost-effective solution designed to improve patient care and reduce healthcare costs.

Future Works

In our future work plans, we are focused on further enhancing the effectiveness and usability of our product. One key aspect of our strategy involves conducting clinical testing to validate the product's ability to prevent patient slippage in bed. By engaging in comprehensive clinical evaluations, we aim to gather crucial insights into the product's performance in real-world scenarios and its impact on patient safety and caregiver comfort.

Through this process, we will be able to refine and optimize our design to ensure that it meets the highest standards of functionality and effectiveness.

Another important objective in our future work plans is to expand the size range of our product to accommodate individuals of all sizes. Recognizing the diverse needs of our user base, we are committed to ensuring that our product can provide a comfortable and secure fit for a wide range of patients. By incorporating adjustments and enhancements to accommodate varying body types and sizes, we strive to enhance the overall user experience and accessibility of our product. This expansion of our size range underscores our dedication to inclusivity and our goal to cater to the diverse needs of our target market.

Through these initiatives, we are poised to strengthen the performance, usability, and inclusivity of our product, setting the stage for continued innovation and growth in the healthcare industry. By prioritizing clinical testing and size range expansion, we are taking proactive steps to ensure that our product not only meets but exceeds the expectations and requirements of our users, ultimately contributing to improved patient outcomes and enhanced caregiver experiences.

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Appendix 1

BACKGROUND

- **Summary:**

Provide a summary (supported by 3 – 5 literature references) that states your area of focus and/or disease state, historical/evolution of treatment modalities, and current state of the art.

Area of focus: Bedridden patients frequently experience difficulties maintaining their position when sitting up in bed, requiring assistance from caregivers to prevent sliding. This issue not only compromises patient comfort but also poses risks for complications, including the development of pressure ulcers in patients and injuries to caregivers. The need for frequent readjustment disrupts patient care and can lead to inefficiencies in healthcare delivery. Developing effective solutions to mitigate this challenge is crucial for improving patient outcomes and enhancing caregiver efficiency.

Historical/evolution of treatment: Throughout history, caregivers have employed various techniques to assist bedridden patients in maintaining their position while sitting up. Traditional methods often involve manual repositioning by caregivers, which can be physically demanding and uncomfortable for both the patient and the caregiver. While devices like the hospital bed trapeze and draw/slide sheets have been introduced to provide assistance, they may not fully address the issue of patient sliding and still require significant effort from caregivers and/or patients. As the healthcare landscape evolves, there is a growing recognition of the need for innovative solutions to enhance patient comfort and reduce caregiver burden in managing bedridden patients.

State of the art: Current strategies for addressing the challenge of patients sliding down in bed when sitting up emphasize the development of assistive devices and ergonomic solutions. One notable advancement in aiding patients to sit up in bed is the hospital bed trapeze. Functioning as a pulley system positioned above the bed, the trapeze enables patients to exert force and elevate themselves with greater ease. Its design, aimed at providing reliable assistance for moving, raising, and lowering the body while in bed, signifies a significant improvement in patient mobility and independence. By pursuing comprehensive prevention measures and integrating innovative solutions like the hospital bed trapeze, we can significantly enhance the quality of care for bedridden patients and alleviate the strain on caregivers. Additionally, standard innovations like adjustable bed rails and draw/slide sheets make readjusting patients easier for caregivers and save time.

- **Search Terms:**

Provide all search terms used to generate your literature references.

"How to help a patient move up in bed"
"Head of bed elevation"
"How to prevent patients from slipping down their bed"

"Pulley for hospital beds"

- **References:**

List all references used for your summary (3 – 5 references required – more if needed).

Hospital Bed Trapezes | Trapeze Bars | Bed Trapezes | Overhead Trapeze | Medical Trapeze
The sliding patient: How to respond to and prevent migration in bed - https://med.libretexts.org/Bookshelves/Allied_Health/Foundations_for_Assisting_in_Home_Care(McLain_O'Hara-Leslie_and_Wade)/12%3A_Personal_Care/12.08%3A_Unit_G-_Assisting_with_Transfers_Turning_and_Positioning_and_Body_Mechanics/12.8.07%3A_Procedure-_Transfer_to_the_Sitting_Position_in_Bed

CURRENT TREATMENT OPTIONS

- **Summary:**

Provide a summary (supported by 3 – 5 literature references) that states the current treatment options for your area of focus and/or disease state and the pros and cons of each.

Consider value, safety, effectiveness, and cost.

Treatment options for patients who have slipped down in bed and cannot reposition themselves involve a combination of manual and mechanical methods. Currently, treatment options focus mainly on training caregivers how to properly assist a patient without potentially hurting themselves, or the patient, while doing so. A few of these methods include lifting with your legs rather than your back, adjusting the patient's bed in a position that reduces strain on your back, and placing draw sheets underneath the patient and positioning yourself behind the head of the bed, grabbing the draw sheet on each side of the patient and gently pulling the drawsheet toward you. Some pros to following these methods are that they help prevent injuries (especially musculoskeletal disorders), they allow caregivers to reposition patients with greater ease, and they are extremely cost-efficient (they do not cost a lot of money if any at all). Some cons, however, are that these methods still do not 100% prevent the possibility of injury, training is required to ensure proper techniques are being used, and manpower/strength is required which limits who can reposition the patient (an example would be that most elderly spouses/family members will not be able to reposition their loved ones if needed). There are also some mechanical methods/devices that are used to reposition a patient without injuring the caregiver and/or the patient. A couple of mechanical methods/devices that can be used are mechanical lifts and adjustable beds with features (like Trendelenburg and reverse Trendelenburg) that can move the bed into positions that help prevent sliding and maintain good HOB elevation. A few pros of using these methods are that

hospital beds are highly adjustable which helps caregivers put the patient in a position that will make it easier to slide them up the bed, hospital beds often have safety features such as side rails that prevent patients from falling out of the bed when they are being repositioned and locks that keep the bed steady when pulling the patient up, they both reduce physical strain on the caregiver, and they are much more efficient than manual methods. Cons of using these methods are that they are very expensive, require regular maintenance (specifically mechanical lifts), and have limited portability.

- **Search Terms:**

Provide all search terms used to generate your literature references.

"Current treatment options for head of bed elevation to prevent risk of musculoskeletal disorders in healthcare workers"
"Current treatment options to help bedridden patients when they have shifted down their bed"
"Motorized assist devices to help patients who have slipped down their beds"
"Trendelenburg bed position"

- **References:**

List all references used for your summary (3 – 5 references required – more if needed).

Pulling a patient up in bed Information | Mount Sinai - New York
Preventing Musculoskeletal Injuries | Facilities Management
Assistive Technology for Positioning - Physiopedia
https://www.ngcare.com/archives/learn-to-safely-reposition-your-bed/

IDENTIFY USER NEEDS

- **Summary:**

Provide a summary (supported by 3 – 5 literature references) that states the user needs for your area of focus and/or disease state.

Head-of-bed (HOB) elevation commonly causes patients to gradually shift downward in their beds due to the force of gravity. This downward movement can lead to shearing forces between the patient's skin and the bed surface, increasing the risk of pressure injuries and causing the patient unnecessary pain. Patient migration poses challenges, not only for the patients themselves but also for healthcare providers. When patients slide down in bed, nurses are required to readjust them toward the head of the bed by pulling the patient up. Repositioning patients can become a repetitive task, with sources saying patients should be repositioned every 2 hours. This frequent patient repositioning is not only time-consuming, but it puts a lot of strain on the caregiver's back and contributes to a significant risk of musculoskeletal disorders (MSD) among healthcare workers. According to the National

Library of Medicine, "Nursing is ranked as the top occupation among all the professions that have the potential to develop MSDs, with the highest prevalence rate of MSDs in the world." To try and help with these problems, the American Nursing Association has recently introduced standards for safe patient handling and mobility with the goal of reducing manual patient handling to create safer working environments for its members while providing patients with proper care. Finding a way to minimize the need for nurses to pull patients up in bed/reposition them would be very beneficial for both patients and caregivers, helping them both prevent unnecessary injuries that could have been easily avoided with the right equipment and/or methods.

- **Search Terms:**

Provide all search terms used to generate your literature references.

"Patient migration in bed"
"Complications with lifting patients who have migrated down the bed and cannot lift themselves"
"Complications with motorized assist lifts for patients sliding down hospital beds"
"How often do bedridden patients need repositioned"
"What profession has the most injuries due to musculoskeletal disorder"

- **References:**

List all references used for your summary (3 – 5 references required – more if needed).

Role of Bed Design and Head-of-Bed Articulation on Patient Migration - PMC
How patient migration in bed affects the sacral soft tissue loading and thereby the risk for a hospital-acquired pressure injury
The sliding patient: How to respond to and prevent migration in bed -
Turning patients over in bed: MedlinePlus Medical Encyclopedia.
How Often Should Bed Bound Residents Be Repositioned *(2023)*
Prevalence of Work-Related Musculoskeletal Disorders: Psychological and Physical Risk Factors - PMC.

MARKET RESEARCH

- **Summary:**

Provide a summary (supported by 3 – 5 literature references) that illustrates the market potential for your area of focus and/or disease state.

The market potential in this field is substantial, with research revealing that patient migration poses challenges not only for patients but also for caregivers, necessitating

frequent repositioning by nurses. Solutions in this area can cater to a wide range of patients, from those in ICU settings to bariatric patients in everyday hospitals. Moreover, the market includes nurses and caregivers seeking assistance with patient care solutions, offering diverse opportunities for innovation. Despite the existence of some solutions, they remain limited and unevenly distributed among different groups. As highlighted in various references, the target market encompasses working nurses and patients dealing with patient migration. For example, a study from 1995 found that nurses pulled patients up in bed an average of 9.9 times per shift, indicating persistent challenges despite existing solutions. Considering approximately 5.2 million nurses and 34 million hospital admissions annually, there is significant market potential, given the varying degrees of patient movement and nurse involvement. Additionally, the market may extend to at-home applications for family caregivers, further expanding the customer base.

- **Search Terms:**

Provide all search terms used to generate your literature references.

"Patient Migration"
"Bed Migration"
"Patient Migration Bed"
"Sliding Patients in Bed"

- **References:**

List all references used for your summary (3 – 5 references required – more if needed).

Role of Bed Design and Head-of-Bed Articulation on Patient Migration - PMC
How patient migration in bed affects the sacral soft tissue loading and thereby the risk for a hospital-acquired pressure injury - PMC
The sliding patient: How to respond to and prevent migration in bed -
Prepare to care for patients of size
https://www.sciencedirect.com/science/article/pii/S0169814122000439
Nursing Workforce Fact Sheet.
Fast Facts on U.S. Hospitals, 2024 | AHA
How to prevent elderly from sliding down and lift them back up

COMPETITIVE LANDSCAPE

- **Summary:**

Provide a summary (supported by 3 – 5 literature references) that discusses the providers/companies with current treatment options for your area of focus and/or disease state and the pros and cons of each.

One commonly utilized solution for addressing the challenge of weak patients unable to sit up in bed is the overhead trapeze bars. As described by Preferred Health Choice, these triangular-shaped bars provide patients with a graspable support for repositioning themselves. While effective for patients with sufficient upper body strength to lift themselves using the pulley system, this solution proves ineffective for weaker patients unable to manage the pulley. Another approach involves caregivers physically lifting the patient back up in bed, often achieved by gently pulling the bedsheets to reposition the patient. Additionally, using pillows or wedges under the knees can help mitigate sliding, with specialized foam pillows tailored for such applications. Registered nurse Angela Morrow outlines the steps for this method, emphasizing proper positioning and support to prevent discomfort and skin sores. However, both of these solutions are temporary, as patients often revert to their original uncomfortable position after readjustment. Moreover, relying on caregivers to lift patients repeatedly can lead to caregiver strain and discomfort over time.

- **Search Terms:**

Provide all search terms used to generate your literature references.

"Hospital bed trapeze"
"How to prop a patient up in bed"
"How to keep a patient from sliding down in bed"

- **References:**

List all references used for your summary (3 – 5 references required – more if needed).

https://www.phc-online.com/Hospital-Bed-Trapeze-s/76.htm
How to Properly Position Bed Bound Patients
How to prevent elderly from sliding down and lift them back up

Appendix 2

I would like a minimum of two (2) prior art references to be from international sources – i.e., outside the US Patent Office and from international journals or sources.

Prior Art Reference #1 (US 9333139 B2, Patient Position Device)

- **Search Terms:**
  Provide all search terms used to generate your prior art reference.

"Head of bed elevation"
"Patient reposition device"

- **Summary:**
  Provide a brief summary of the invention – remember to pay close attention to the Abstract, Background of the Invention, Summary of the Disclosure, and Claims.

The patient positioning device is designed to restore patients to a desired position on a hospital bed. The device consists of a flexible track along each side of the bed, spanning its entire length, and a sheet with beaded edges that slide along these tracks. A drive mechanism near the head end of the bed pulls the sheet upward towards the head, facilitating patient repositioning (like a conveyor belt). The claims describe features like a mattress allowing vertical and angular repositioning, the drive mechanism collecting and wrapping repositioned sheet portions around a roller within the mattress, and the first end of the mattress having an open space for sheet storage. It aims to enhance patient comfort and repositioning efficiency, with potential applications in adjustable beds and healthcare settings. The background highlights the relevance of patient movement devices in hospital beds. The examples provide different options for how tracks are incorporated, the flexibility of materials used, and methods for installation. Overall, the invention addresses practical challenges in patient repositioning on hospital beds with a comprehensive and flexible system.

- **Source:**
  US Patent & Trademark Office (https://www.uspto.gov)
  Google Patents (https://patents.google.com)
  Lens.org (https://www.lens.org)
  other https://www.lens.org/lens/patent/197-946-240-478-612/frontpage?l=en

https://www.lens.org/lens/patent/197-946-240-478-612/frontpage?l=en

Prior Art Reference #2 (US8615828B2, Multi-position reclining bed)

- **Search Terms:**
  Provide all search terms used to generate your prior art reference.

"sitting up in hospital bed"
"patient repositioning"

- **Summary:**
  Provide a brief summary of the invention – remember to pay close attention to the Abstract, Background of the Invention, Summary of the Disclosure, and Claims.

The multi-position reclining bed can adjust from a full sitting-up position to the typical supine position; the leg section of this bed can drop below horizontal, unlike most conventional hospital beds. The goal of this invention is to provide more comfort for the patient by shifting some of the weight off of the butt and lower back when in the seated position. The butt and lower back are typically subjected to carrying the weight of the head and shoulders when lying down with the head elevated, so these areas can become uncomfortable quickly. The erect positioning of this bed, with the feet allowed to go below horizontal, shifts the body weight to the lower thighs and feet. This invention allows for long-term sitting without back or butt discomfort. Additionally, the buttocks section of this bed has a tilt that prevents forward sliding when the back section is inclined. It is claimed that the bed can be used for "...hospitalization purposes as well as everyday office work, or any variation or combination of use." Overall, the bed is intended to enhance the comfort of those confined to bed for long periods of time as it utilizes power-adjusted positions that can shift the body weight to various areas; it also allows such individuals to become more independent in regards to positioning in bed.

- **Source:**
  US Patent & Trademark Office (https://www.uspto.gov)
  Google Patents (https://patents.google.com)
  Lens.org (https://www.lens.org)
  other

Prior Art Reference #3 (WO 2022/060610 A1, Portable Medical Lift And Positioning Device)

- **Search Terms:**
  Provide all search terms used to generate your prior art reference.

"A device to enable a bedridden patient to adjust their position in a bed without additional aid"

- **Summary:**

Provide a brief summary of the invention – remember to pay close attention to the Abstract, Background of the Invention, Summary of the Disclosure, and Claims.

The portable medical lift and positioning device is designed to assist attendants in repositioning and supporting patients in bed or other support surfaces. The device includes a base for stability, a separately powered screw jack, a radial adjustment head, a cushion cradle, and fitted cushions that are designed to raise and lower specific body parts. The lift attachment points on the front base connect to a lift with adjustable telescoping components and a lever arm, enabling the device to be customized for various body parts. The mount joint, which connects the cushion cradle to the lift, allows for angle adjustment. The device aims to address the challenges faced by attendants dealing with immobile, obese, or incapacitated patients. It is portable, easy to assemble, and has the ability to provide a lightweight, compact, and maneuverable solution for lifting, propping, securing, and turning bedridden patients. It also claims benefits such as preventing caregiver injuries, aiding in patient comfort, and offering a cost-effective alternative to existing patient lifting systems. The device's versatility is highlighted by its capability to support different-sized patients and accommodate various body parts, promoting ease of use and disinfection.

- **Source:**

  US Patent & Trademark Office (https://www.uspto.gov)
  Google Patents (https://patents.google.com)
  Lens.org (https://www.lens.org)
  other

Prior Art Reference #4 (EP3614988B1, "Patient repositioning sheet and sling")

- **Search Terms:**

  Provide all search terms used to generate your prior art reference.

"bed repositioning"

- **Summary:**

  Provide a brief summary of the invention – remember to pay close attention to the Abstract, Background of the Invention, Summary of the Disclosure, and Claims.

This device was invented as a way to reduce the difficulty and danger placed on caregivers who need to move or reposition patients in bed. The apparatus can serve as both a patient repositioning sheet and a patient sling. The invention includes a sheet with multiple handles and strap members, where the sheet itself has upper and lower surfaces composed of different materials. The handles of the sheet are fastened along both long sides of the sheet, and the strap members, which can be used to secure the sheet to a lifting device, are found along the short edges of the sheet. This device can be utilized to move or slide the patient into their desired resting position using the handles lined along the sheets. The lower surface of the sheet is formed from a low-friction material in comparison to the upper surface. In general, higher friction materials are typically more comfortable for the patient, as these include materials like textiles, cloths, and microfibers. This is one of the reasons the

upper surface of the sheet is made out of high-friction material. The other added benefit of this high friction upper surface is that it prevents unwanted sliding of the patient. Additionally, the low friction lower surface of the sheet allows for easier repositioning or sliding of the sheet in bed. The sheet can be created to fit any shape or size, making it a versatile invention for the repositioning of patients in bed.

- **Source:**
  US Patent & Trademark Office (https://www.uspto.gov)
  Google Patents (https://patents.google.com)
  Lens.org (https://www.lens.org)
  other

Prior Art Reference #5 (US 9836942 B2, "Estimation and monitoring of patient torso angle")

- **Search Terms:**
  Provide all search terms used to generate your prior art reference.

"Patient Migration"

- **Summary:**
  Provide a brief summary of the invention – remember to pay close attention to the Abstract, Background of the Invention, Summary of the Disclosure, and Claims.

The invention is a device that uses sensors that can tell if the patient moves or changes their position in bed. The background goes into describing devices in hospitals or homes that help move the head/upper body of the patient to laying-down or seated positions while the support apparatus keeps track of how the patient's body is positioned and then uses sensors to monitor the position relative to the body position to detect migration. The summary of disclosure goes on to describe this technology for monitoring the position and movement of a person in a hospital bed relative to the bed. The sensors in use can determine if a person is sliding down, rolling, or falling off along with the patient's activity level. Finally, this patent has 18 claims including a method for monitoring a person's body position using sensors on both the person and bed to track their position, calculating the angle of a person's upper body/head section, and lateral rotation.

- **Source:**
  US Patent & Trademark Office (https://www.uspto.gov)
  Google Patents (https://patents.google.com)
  https://patents.google.com/patent/US9836942B2/en?q=(%22patient+migration%22)&oq=%22patient+migration%22

  Lens.org (https://www.lens.org)
  other

Prior Art Reference #6 (US 8419660 B1, "Patient Monitoring System")

- **Search Terms:**

  Provide all search terms used to generate your prior art reference.

"Patient Migration"

- **Summary:**

  Provide a brief summary of the invention – remember to pay close attention to the Abstract, Background of the Invention, Summary of the Disclosure, and Claims.

  This invention is a sensor that is attached to the mattress of the patient's bed that has a squishy part and a pressure sensor that alerts the caregiver if pressure changes in a certain way. The background section describes previous methods to alert caregivers of patients moving beyond the allowed range including strings and alarms or sensors. The summary of the invention/disclosure describes the migration sensor attached to the mattress. The liquid part that contains the pressure sensor is monitored by a computer that reads pressure and if outside of the threshold, alerts the caregiver. The invention in another iteration used multipole sensors that monitored each other as well as the patient. Finally, the patent has 2 claims including a system keeping an eye on patients lying on a mattress that alerts nurses when the patient moves, uses multiple sensors that reset the stored data to zero if both notice movement at the same time, sensors on both sides of the mattress to detect side to side.

- **Source:**

  US Patent & Trademark Office (https://www.uspto.gov)
  Google Patents (https://patents.google.com)
  Lens.org (https://www.lens.org)
  https://www.lens.org/lens/patent/191-359-610-446-438/fulltext

  other

Project Name: SwiftShift MedTech	DHF # 1	D&D Plan Revision: B

Appendix 3

Description of Product

Executive Summary	SwiftShift MedTech presents an innovative approach in the healthcare industry to revolutionize the issue of patient slip in bed. Our product aims to reduce the migration of patients in bed to prevent the risks and injuries that follow the patient migration.
Description of the Problem to be Solved	Bedridden patients propped up in bed for long periods of time slide down causing discomfort and the need to be readjusted by caregivers, causing potential discomfort and pain for the caregivers.
Needs Statement	A more affordable and accessible alternative to repositioning bedridden patients in order to increase patient comfort, minimize pressure injuries in patients, and prevent musculoskeletal disorders amongst caregivers.
Literature Review	Our area of focus is centered around helping weak patients sit themselves up in bed and/or prevent them from sliding down in bed when sitting up. A solution to this issue would be beneficial in increasing the comfortability of patients, as well as some related medical problems. “A 2013 study found that patients in traditional hospital-bed designs migrated about 13 cm (5″) when the HOB was raised to 45 degrees. Both bed movement and gravity cause patients to slide down in bed over time if the HOB [head of bed] is kept elevated. Such migration presumably causes friction and shear forces between the mattress and skin as the patient slides against the bed surface.” Both friction and forces between the mattress and skin are known to be linked to pressure ulcers. Wiggerman also mentions the high risk of caregiver injury when assisting a weak patient up in bed. Historically, patients who are unable to sit themselves up in bed require the assistance of one or two other people to do so. Some of the steps for this technique: “Place one arm (the arm closest to the patient) behind the patient’s shoulders. If it is a particularly frail patient or one who cannot control their neck or head, rest your forearm and hand behind their head. This prevents their head from rolling back. Place your other arm underneath the patient’s thighs. Use a gentle rocking motion to assist the patient to propel forward and up into a sitting position…On the count of 3 (count aloud so the patient knows when they will be moving), help to move the patient to the sitting position by slowly pushing them up. Rock forward and then backward, keeping your back aligned, and shifting your weight from your front to your rear leg. This provides a firm base of support and balance while assisting the patient into a sitting position.” This

	technique seems to be difficult for both the patient and the person involved in assisting, so some better devices and techniques have been created to solve this problem. One of the current state-of-the-art solutions for assisting patients in sitting up in bed is a hospital bed trapeze, which is essentially a pulley above the bed for the patients to pull themselves up with. The hospital bed trapeze is "Designed to offer reliable assistance for moving, raising and lowering the body while in bed."
Prior Art Search, Assessment, & Patentability	<u>Description of patents found:</u> ● Patient Repositioning Device: ○ This system incorporates flexible tracks along each side of the bed and a sliding sheet with beaded edges. A drive mechanism near the head of the bed facilitates the movement of the sheet, similar to a conveyor belt, making repositioning smoother and more efficient. ● Multi-Position Reclining Bed: ○ This bed design allows the leg section to drop below horizontal, redistributing body weight to alleviate discomfort in the buttocks and lower back areas. Additionally, the bed's design includes a tilt mechanism in the buttocks section to prevent forward sliding when the back section is inclined. ● Portable Medical Lift and Positioning Device: ○ This device has a stable base, powered screw jack, radial adjustment head, and cushion cradle with fitted cushions, offering comprehensive support. Its lift attachment points and mount joint allow for adjustable positioning. ● Patient Repositioning Sheet and Sling Apparatus: ○ Serves as both a sheet and a sling for moving patients. Its upper surface is made from high-friction material to prevent sliding while the lower surface is made of low-friction material to allow for smooth repositioning It has multiple handles/straps to assist caregivers in pulling up the sheet. ● Migration Sensor for Patient Bed: ○ A sensor system designed to detect and alert caregivers of patient movement on the mattress. Pressure sensors monitor pressure changes and send alerts if the patient moves excessively.
Competition & Differentiation	Our solution faces its primary competition from the patient repositioning sheet. However, given the substantial differentiation

	between our product and the repositioning sheet, concerns regarding patent infringement are unwarranted.
Value Proposition & Differentiation	In contrast to our main competitor, the patient repositioning sheet, which relies on one to two caregivers exerting physical strength to move the patient, our product eliminates the need for such exertion. By preventing slippage entirely, it significantly reduces the risk of caregivers developing musculoskeletal disorders during patient repositioning.
Anticipated Regulatory Pathway	FDA Class I
Reimbursement Strategy	Hospitals and OTC
Estimated Manufacturing Cost	With approximately $15 allocated for materials and labor per unit, our estimated manufacturing cost reaches around $17 per unit when factoring in one-time expenses like sewing machines.
Potential Market & Global Impact	Our target market encompasses hospitals, hospice care organizations, and any setting where individuals are bedridden. Globally, our solution could benefit bedridden individuals worldwide.
Intended Use / Indications for Use	Reduce patient slip when propped up in bed
Patient Population	Weak bedridden individuals
Materials	Neoprene, non-slip fabric, velcro, twin xl sheets, fastening straps
Features	Upper body support, non-slip materials
Components	1. Neoprene vest with non-slip fabric on the back 2. Sheet with non-slip fabric and fastening straps

Project Name: SwiftShift MedTech	DHF # 1	D&D Plan Revision: B

Add Rows as needed

User Needs

Transfer User Need # and Design Input to QD0006F02, Design Summary Matrix.

If a user's need will not be fulfilled, provide a rationale for not fulfilling the need.

User Needs #	**Description (User request)**	**Design Input or Rationale for Not Fulfilling Need**
U1	Patient comfort	Vest made out of neoprene to ensure comfort and avoid uncomfortable rubbing against the skin
U2	Caregiver safety	Non-slip material reduces patient slippage, in turn significantly reducing the need for readjustment of patient
U3	User friendly	Easy to use with instructions for use
U4	Durability	Designed for long-term use and functionality
U5	Time-saving	Time between patient readjustments is greater, saving time for caregivers
U6	Reusable	Product can be cleaned and reused for an extended period of time
U7	Fit	Design is adjustable
U8	Biocompatible and allergen-free	Materials are biocompatible and free of most common allergens

Add Rows as needed

Part Number

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Part Number	Description	UDI[1]
1	Neoprene vest with non-slip fabric attached to the back	
2	Sheet with non-slip material attached and straps to ensure stable attachment to the mattress	

[1] Document UDI if UDI needs to be included on the CAD and/or etched on the physical part.

Add Rows as needed or attach Excel list.

Timeline

Attach a project timeline that defines at a minimum the project tasks, the name of the responsible team member, milestones, the start date, and the due dates. The project timeline should be updated throughout the project and a copy of the current timeline should be reviewed during design review meetings. It is acceptable to use Excel, Project, or other project management tools.

Date	Event
9/25/2023	Decision to focus on the unmet clinical need of bedridden patient slippage
10/16/2023	Prior Art Search Done
12/06/2024	New Literature Review Done
03/8/2024	Meeting with UMMC Nursing School leads to pivot in product design/switched from bed attachment to vest design
03/11/2024	Design and Development Plan Updated/Revised to reflect pivot
03/28/2024	Meeting with CIE for Gillespie Competition Information and Prep
03/28/2024	Risk Management Report finished
04/02/2024	Prototype materials received
04/10/2024	Gillespie Business Plan submitted
04/11/2024	Reserved sewing machines in the IDEA Lab and sewed vest prototype
04/12/2024	Gillespie Competition

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Future Goals:

APR 2024 - Finish non-slip sheet prototype

APR 2024 - Test prototype at Baptist Memorial Hospital

APR 2024 - Finish testing, prepare presentation and complete written portion

MAY 2024 - Present thesis/Senior design project

Project Team

Function Required	**Name**
Product Development	Kelsie Hand
Quality Assurance	Danielle Pasquini
Regulatory Affairs	Christian Miller
Independent Reviewer	Troy Drewry
Additional Functions As Needed	
Manufacturing	Kelsie Hand
Sterilization	Danielle Pasquini
Packaging	Christian Miller

Add Rows as needed

Approvals			
Title	Name	Signature	Date
Product Development	Kelsie Hand		11 MAR 2024
Quality Assurance	Danielle Pasquini		11 MAR 2024
Regulatory Affairs	Christian Miller		11 MAR 2024

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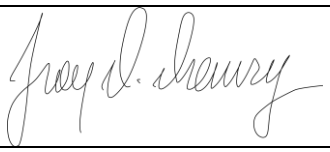
Independent Reviewer	Troy Drewry		11 MAR 2024

Description of Design and Development Plan revisions.

Revision	Effective Date	Author	Description of Change
B	11 MAR 2024	Hand, Pasquini, Miller	Revised Development Plan

Revision History (Form)

Version	**CR number**	**Approval Date**
A		6 DEC 2023
B		11 MAR 2024

Project Name SwiftShift MedTech	DHF # 1	Matrix Revision: B

Appendix 4

User Need #[1]	Design Input[2]	Design Output[3]	Essential Req[4] (Yes/No)	Verification Activity[5]	Validation Activity[6]
U1	The vest does not hinder patient comfort	Neoprene ensures the vest remains comfortable and minimizes the risk of skin irritation or tearing for the patient.	No	Mechanical testing	Clinical evaluation
U2	Prevent patient slippage to promote caregiver safety	Ensure friction is maximized between vest and sheet to eliminate the need for patient readjustment	No	Mechanical testing	Clinical evaluation
U3	Ease of Use	Detailed instructions provided	No	Instruction manual testing	Visual Inspections/Quality Control
U4	Durability	Use of materials designed for long-term use and durability	No	Mechanical testing	Clinical evaluation
U5	Time-saving	Velcro straps ensure the vest can be swiftly and easily removed	No	Mechanical testing	Clinical evaluation

Project Name SwiftShift MedTech	DHF # 1	Matrix Revision: B

U6	Reusable	The product can be cleaned and reused	No	Mechanical testing	Clinical evaluation
U7	Fit	The product is adjustable to accommodate individuals of varying sizes	No	Mechanical testing	Clinical evaluation
U8	Biocompatibility	Materials are biocompatible and free of most allergens	No	Material certification	Clinical evaluation

Add rows as needed.

[1]Need # from QD006F01, Design and Development Plan

[2]Design Inputs are to be reviewed by the team to ensure they are complete, not ambiguous, and do not conflict.

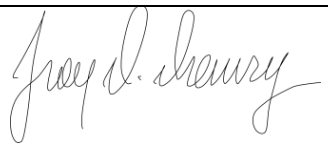
[3]Design outputs should include catalog numbers, drawings/specifications, material specifications, sterilization, packaging, labeling, features/components of the device, etc.

[4]Essential design requirements include those that if they are not met the product could cause harm to a patient or the device could malfunction. The essential design requirements are the features of the design that are deemed critical for function of the component. For these features, validation of the final parts should be performed or alternatively, 100% inspection of the essential design output requirement features may be performed.

[5] Verification activities could include mechanical testing, animal testing, review of drawings/specifications, tolerance stack-ups, labeling reviews, packaging, etc. List applicable document numbers and document names.

[6] Validation activities could include animal testing, clinical studies, saw bone labs, cadaver studies, visual inspection of product, etc. List applicable document numbers and document name

Project Name SwiftShift MedTech	DHF # 1	Matrix Revision: B

Approvals			
Title	Name	Signature	Date
Product Development	Kelsie Hand		11 MAR 2024
Quality Assurance	Danielle Pasquini		11 MAR 2024
Regulatory Affairs	Christian Miller		11 MAR 2024
Independent Reviewer	Troy Drewry		11 MAR 2024

Add Rows as needed

Description of matrix revisions.

Revision	Effective Date	Author	Description of Change
A	6 DEC 2023	Hand, Pasquini, Miller	Revisions from design review meeting 1
B	11 MAR 2024	Hand, Pasquini, Miller	Pivot to non-slip vest after meeting with UMMC Nursing School

Project Name SwiftShift MedTech	DHF # 1	Matrix Revision: B

Revision History (Form)

Version	**CR number**	**Approval Date**
A		6 DEC 2023
B		11 MAR 2024

Appendix 5

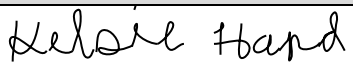
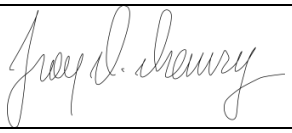
Project Name: Non-slip Vest and Sheet Attachment for Bedridden Patient Stability

1. Purpose of Revision

■ Risk Management Plan (initial) ☐ Risk Management Report

☐ Modification to Risk Management Plan ☐ Modification to Risk Management Report

2. Plan and Report Approvals

Revision	Team Member Function	Team Member Name (printed)	Team Member Approval Signature	Date
A	Product Development	Kelsie Hand		28 MAR 2024
	Quality Assurance	Danielle Pasquini		28 MAR 2024
	Regulatory Affairs	Christian Miller		28 MAR 2024
	Executive Management	Troy Drewry		28 MAR 2024
	Other			

3. Risk Management Details

Risk Management Plan: This Risk Management Plan outlines Risk Management activities for the lifecycle of the products listed in Table 1-3 from the initial product development through post-market surveillance. Post-market surveillance will be performed as needed, but at a minimum, an annual review is required for each product, as outlined in QD006, Design and Development.

Table 1: Part Number

Part Number	**Description**
	Vest to prevent bedridden individuals from slipping down an elevated bed
	Non-slip sheet bed attachment to be paired with the vest

Add rows as needed or attach a list.

Table 2: Indications for Use

Indications for Use	Prevent slip down the bed in bedridden individuals
Foreseeable Misuse (In what way(s) might the medical device be deliberately misused?)	Vest is not used in conjunction with head of bed sheet attachment; Vest is used with intent to neglect or not occasionally readjust patient

Table 3: Description of the Product

Risk Item	Description
Materials and/or components	Vest, grippy/non-slip material, head of bed sheet, adjustable clasps on sheet
Energy delivered to and/or extracted	No energy is delivered to and/or extracted from
Substances delivered to and/or extracted from the patient	No
Duration of Use	~5 years
What is the lifetime of the device?	We approximate the lifetime to be roughly 5 years
Biological materials processed by the device for subsequent re-use	No

Risk Item	Description
Supplied sterile or intended to be sterilized by users	Intended to be sterilized by users
Intended to be routinely cleaned and disinfected by the user	Yes
Intended to modify the patient environment?	No
Measurements?	Yes
Is the device interpretative?	No
Intended for use in conjunction with medicines or other medical technologies?	No
Unwanted outputs of energy or substances?	No
Is the device susceptible to environmental factors?	No
Essential consumables or accessories associated with the device?	Yes, a non-slip head of bed sheet attachment
Routine maintenance and/or calibration?	No
Software?	No
Restricted “shelf life”?	No

Risk Item	Description
Is the device subject to mechanical forces?	Yes
Is the device intended for single use?	No
Is safe disposal of the medical device necessary?	No
Is installation or special training required?	No
How will information for safe use be provided?	Each vest will come with a comprehensive instruction manual detailing how to wear the vest effectively to maximize its benefits. Additionally, the manual will provide clear guidance on safely and swiftly removing the vest in the event of a medical emergency.
Can the user interface design features contribute to user error?	Yes, improper use of the vest, such as incorrect wearing or failure to utilize the non-slip sheet, can result in the user not fully maximizing the benefits of the product.
Is the medical device used in an environment where distractions can cause use error?	No
Will new manufacturing processes be established or introduced?	No
Is device critically dependent on human factors such as user interface?	No

Risk Item	Description
Does device have connecting parts or accessories?	Yes, a non-slip head of bed sheet
Does device have control interface?	No
Does device display information?	No
Is device controlled by menu?	No
Will the medical device be used by persons with special needs?	Yes
Can the user interface be used to initiate user actions?	No
Does the medical device use an alarm system?	No
Does the medical device hold data critical to patient care?	No
Is device intended to be mobile or portable?	Yes
Does the user of the medical device depend on essential performance?	No

Add Rows as needed

3.1. For each risk area, mitigation activities actions are defined that are typically examined as part of risk management. For each action, the appropriate evidence consists of several different items. The evidence

documents (physical copies or references) are placed in the Design History File and/or Risk Management File.

3.2. The following documents, at a minimum, should be included in the Risk Management File for each product:

3.2.1. *Complaint Review*

3.2.2. *Clinical / Literature Review*

3.2.3. *Risk Analysis*

3.2.4. *Trending related to product complaints, CAPAs, Non-Conforming Reports (NCR)*

4. Risk Management Report

4.1. At the completion of the project, this document becomes the cover sheet for the Risk Management Report. Documents are compiled and approved to verify that risk mitigation evidence is complete or a rationale has been written to justify why the activity was not necessary. Any key assumptions should be included in the objective evidence or rationale. Mark the items included in the report. For items not included a rationale to justify why the activity is not necessary must be attached.

☐ Complaint Review

■ Clinical / Literature Review

■ Risk Analysis

☐ Trending related to product specific complaints, CAPAs and/or NCRs

For items not included provide a rationale to justify why activity was not necessary:

Comments: ■ n/a

5. Risk Acceptance Criteria

5.1. Risk acceptance is defined in QD006, Design and Development and QD009F01, FMEA and documented in the risk analysis.

6. Risk / Benefit Summary

6.1. Document an assessment of overall residual risk, if applicable.

6.2. Address the following questions:

6.2.1. *Is the risk level acceptable?* ■ *Yes* ☐ *No*

6.2.2. *Do the benefits outweigh the potential risks?* ■ *Yes* ☐ *No*

If the risk level is not acceptable, document how the benefits outweigh the potential risk.

Comments: ■ n/a

7. Post Market Surveillance

7.1. Post-market surveillance will consist of periodic review and update, as needed, of applicable risk management documents, but at a minimum an annual review is required for each product, as outlined in QD006, Design and Development.

7.2. Specific post-market surveillance activities will typically include complaint and adverse event analyses and review/update of appropriate risk analysis documents (i.e., FMEA).

8. Dates

8.1. Anticipated Launch Date: _____04/12/24_____

8.2. Next Risk Management Review (Month/Year): ____TBD_____

Revision History (Form)

Version	**CR number**	**Approval Date**
A		03/28/2024

Failure Modes and Effects Analysis (FMEA)

Process or Product Name:	UpLift Support Vest
Responsible:	Kelsie Hand, Danielle Pasquini, Christian Miller

Prepared by: Kelsie Hand, Danielle Pasquini, Christian Miller

FMEA Date (Orig): 3/28/24 (Rev:) 1 CR

Risk #	Feature / Function	Potential Failure Mode	Effects of Failure	SEV	Potential Causes	OCC	Current Controls	Risk Index	Recommended Actions (if needed)	Responsible Person(s)	Actions Taken	SEV	OCC	Risk Index
#	What is the feature/function under investigation?	In what ways does the key input go wrong?	What is the impact on the key output variables (customer requirements) or internal requirements?	How severe is the effect to the customer?	What causes the key feature/function to go wrong?	How often does cause or failure mode occur?	What are the existing controls that prevent either the cause or the failure mode?	Severity x Occurrence	What are the actions for reducing the RPN. Should have actions only on high RPN's or easy fixes.	Who is responsible for the recommended action?	What actions have been taken and date completed?			
1	Fit	If the vest does not properly fit the patient, the product will likely not be effective	Patient is uncomfortable	2	Patient is too large/too small for predesigned adjustable vest sizes	2	Different size options	4	Production of multiple/adjustable sizes	Manufacturer	One adjustable size for prototype	2	2	4
2	Biocompatibility	Potential allergic reactions	Patient has an allergic reaction	2	Use of materials like latex that have common allergies	2	All materials in product are biocompatible	4	Utilize solely biocompatible materials	Manufacturer	All materials are considered biocompatible	2	2	4
3	Weight limit	Product could be less effective for heavier patients	Patient needs to be readjusted more often	2	Heavier patients may be more likely to experience slide down the bed more often due to their weight	2	Larger vests with larger grippy surface area help to prevent slide of heavier patients	4	N/A	Manufacturer	N/A	2	2	4
4	Life cycle	Long term use of the product could wear down the grippy material, making the product less effective	The product will not be effective and prevent slip	2	Use of product over multiple years	2	Protocol to replace the product when decreased function is noticed or after 5 years	4	N/A	Nurses / caregivers	N/A	2	2	4
5	Skin irritation	Risk of underarm skin tearing or irritation where vest sits	Patient is uncomfortable/in pain and does not want to wear the vest	3	Possible slide down the bed can cause the vest to rub more on the underarms	2	Soft material attached to area where the vest will sit on the underarms	6	Attach soft material to underarms of vest	Manufacturer	None at this time	3	2	6
6	Quick removal	If vest cannot be removed quick enough for instances such as coding, could lead to complications	Patient at risk for inadequate care	3	Nurses/caregivers are unable to remove vest quickly	2	Velcro on vest has easy access	6	Use easily removable vest	Nurses / caregivers	Purchased vest with velcro closures for easy and quick removal. (Completed on 28 Mar 2024)	4	2	6
7	Sanitation	If product is not able to be properly sanitized, could lead to health complications such as infection	Patient at risk for infection	2	Vest is not sanitized properly / as often as necessary	1	Protocols to ensure frequent sanitation and proper sanitation techniques	2	N/A	Nurses / caregivers	N/A	2	1	2