February 21, 2021

Dr. Craig Scratchley
School of Engineering Science
Simon Fraser University
Burnaby, BC, V5A 1S6

Re: ENSC 405 Requirements Specification for Rise's Roll24

Dear Dr. Scratchley,

Please find attached to this letter the requirement specifications document for Rise's *Roll24*. This purpose of this document is to specify the requirements for *Roll24*, an automated solution for rotating a bedbound patient. *Roll24* will use machine learning to recognize a patient's posture and position on the bed and periodically rotate them using software and a microcontroller. This product is a low-cost solution to improve a patient's wellbeing.

This requirements specification document first introduces the product, then describes the high-level requirements, the software requirements, the hardware requirements, the mechanical requirements, the safety requirements, the sustainability requirements, and finally, describe the engineering standards that *Roll24* must comply with.

Our team consists of five senior engineering students in the SFU program – Jonathan Choy, Joon Kwon, Wilson Liu, Tyler Rasmussen, and Himson Chick. Our diverse team is made up of students in Computer Engineering, Systems Engineering and Electronics Engineering.

Thank you for reviewing this requirement specifications document. If you have any questions or concerns, please contact our Chief Communications Officer, Wilson Liu, through Canvas, Company 4's Gitlab, or through email at yla361@sfu.ca.

Sincerely,

Himson Chick
Chief Executive Officer
Rise


Requirements Specifications

For

*Roll24*


| | | |
|---|---|---|
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# Abstract

This document lists all of the software, hardware, and mechanical requirements for *Roll24* at each stage of the product design phase. *Roll24* will be made up of distinct parts as shown in Figure 1 below.

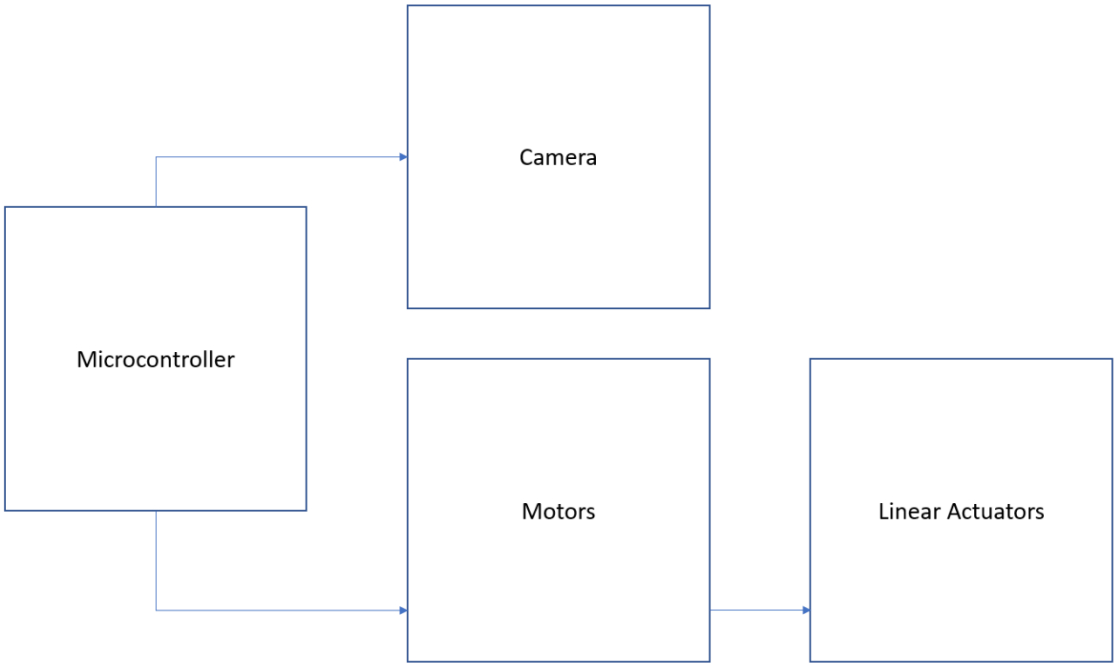


Figure 1. System Component Overview

The distinct parts are split into 2 major groups, hardware, and software. The microcontroller, motors, and linear actuators are to follow the hardware and mechanical requirements for the *Roll24*. The camera adheres to the software requirements outlined in the document regarding the patient monitoring system.

The problem for bed-bound patients is that nurses and caretakers may not be able to help the patients 24/7. Our solution fills the gap throughout the day and night and would allow for patients to be repositioned consistently during short-staffed shifts. This product is currently designed for patients in care homes and individual homes but may be subject to change. There are other similar products in the market but are very expensive [1]. Our goal is to create an affordable, adaptable option that can work for many bedbound patients.

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# 1 Introduction

## 1.1 Background

Pressure ulcer (PU) is defined as a lesion or trauma to the skin and underlying tissue resulting from unrelieved pressure, shear, friction, moisture, or a combination of all these, usually appearing over a bony prominence [2]. Multiple research results show that the overall incidence of pressure ulcers various countries can range from 7.1% to 23.8%.[2] The pressure ulcers can prolong the hospital stay up to three times, introduce complications, and sometimes can even cause death.[2]

Bed sores are serious problems for elderly [3]. “Pressure injuries are listed as the direct cause of death in 7-8% of all patients with paraplegia. As many as one third of hospitalized patients with pressure injuries die during their hospitalization. More than half of those who develop a pressure injury in the hospital will die within the next 12 months.” [3].

## 1.2 Scope

This document specifies the functional requirements and the specifications for *Roll24*. The software, hardware, and mechanical requirements are required functionalities of the system at each stage of the design process. The final product must also be compliant with the various engineering standards and this document also considers the safety and sustainability of the product.

The appendix includes the list of requirements, stated as alpha phase, to be delivered for the proof-of-concept prototype and their Acceptance Test Procedure.

## 1.3 Intended Audience

The intended audience for this document is for all engineers responsible for the implementation and design of the *Roll24* product. The requirements listed in this document is intended to set the guidelines for all functionalities of the product at all development and testing phases and should be used as a reference. This process will ensure the intended design of the product will be used in the correct setting.

## 1.4 Requirements Classification

For this document, the following convention will be used to label the functional requirements:

**Req [Section].[Subsection].[Requirement Number]-[Design Stage]**

The different design stages are abbreviated as:

**AP –** Alpha Phase

**BP** – Beta Phase

**PP –** Production Phase

# 2 High Level Requirements

The high-level requirements listed below describe the general operation and other requirements that the device must meet as a working prototype and production ready product.

## 2.1 Operation Requirements

Table 2.1: Operation Requirements

| | |
|---|---|
| **[Req 2.1.1-BP]** | *Roll24* must be able to roll the patient onto their side |
| **[Req 2.1.2-BP]** | *Roll24* should be able to visually determine a patient's position |
| **[Req 2.1.3-BP]** | *Roll24* should be easy to assemble/disassemble |
| **[Req 2.1.4-BP]** | *Roll24* must run on North American AC power outlets |
| **[Req 2.1.5-BP]** | *Roll24* must attach to the ends of the bed frame |
| **[Req 2.1.6-BP]** | *Roll24* must have a switch to power the device on and off |

## 2.2 Other Requirements

Table 2.2: Other Requirements

| | |
|---|---|
| **[Req 2.2.1-PP]** | *Roll24* should be low maintenance and durable |
| **[Req 2.2.2-PP]** | *Roll24* should be easy to be cleaned |
| **[Req 2.2.3-PP]** | *Roll24* should be comparable in price to other long term care home beds |
| **[Req 2.2.4-PP]** | *Roll24* must all pass Appendix A: Acceptance Test Procedure and signed off by a certified Quality Check Personnel before shipment |
| **[Req 2.2.5-PP]** | Any component that does not pass Appendix A: Acceptance Test Procedure are to be reviewed, corrected, and retested |

# 3 Software Requirements

The *Roll24* will need to be able to function without any sort of manual intervention. This means that it will need to monitor the patient's positioning to avoid positions that may threaten the patient's health. Also, the process must be able to run itself periodically. This period should be variable and set manually by a caregiver.

## 3.1 Patient Monitor

Table 3.1: Patient Monitor Requirements

| | |
|---|---|
| **[Req 3.1.1-AP]** | The product must monitor the patient's positioning on the bed |
| **[Req 3.1.2-AP]** | The monitor must determine the boundary in which the patient can be repositioned |
| **[Req 3.1.3-AP]** | The monitor should not record information that would invade the patient's privacy |
| **[Req 3.1.4-BP]** | The monitor should send a notification to a caregiver if the patient is in an unsafe position |
| **[Req 3.1.5-BP]** | The product must monitor the patient's posture |
| **[Req 3.1.6-BP]** | The monitor must be able to recognize positions that could be dangerous for the patient |

## 3.2 Process Automation

Table 3.2: Process Automation Requirements

| | |
|---|---|
| **[Req 3.2.1-AP]** | The repositioning process must halt if the patient monitor sends a signal that it detects danger and/or the patient has moved out of the boundary determined by the monitor |
| **[Req 3.2.2-AP]** | The patient repositioning process should run periodically |
| **[Req 3.2.3-BP]** | The automation should keep the support risers aligned despite varying weight distribution |
| **[Req 3.2.4-BP]** | There must be an interface to set the period length manually |

# 4 Hardware Requirements

Our device's system is based on controlling stepper motors to move the frames vertically and horizontally to rotate bed bound patients.

Currently in preliminary design phase, the *Roll24's* hardware specifications and electronic components are still under development and not finalized. An overview of the requirements that it must meet are outlined below and are subject to change.

## 4.1 Motor

Table 4.1: Motor Requirement

| | |
|---|---|
| **[Req 4.1.1-AP]** | Motor must be National Electrical Manufacturers Association (NEMA) compliant |
| **[Req 4.1.2-AP]** | Motor must move more than 13.5kg vertically and horizontally |
| **[Req 4.1.3-BP]** | Motor must be securely mounted to chassis |

## 4.2 Microcontroller

Table 4.2: Microcontroller Requirement

| | |
|---|---|
| **[Req 4.2.1-AP]** | The microcontroller must transmit/receive signals from stepper driver in real-time |
| [**Req 4.2.2-BP]** | The microcontroller must stop transmitting signals to stepper driver when failsafe switch is pressed, or abnormal conditions are present |
| **[Req 4.2.3-BP]** | The microcontroller must limit motor operation to the frames dimension |

## 4.3 Electronics

Table 4.3: Electronics Requirement

| | |
|---|---|
| **[Req 4.3.1-AP]** | Device must have an easily accessible and simple to use control panel to operate |
| **[Req 4.3.2-BP]** | Device must use power derived from 120V 60Hz wall outlet |
| **[Req 4.3.3-BP]** | Electronic components and wires must be enclosed in a chassis |
| **[Req 4.3.4-BP]** | Device must have a mechanical failsafe switch to quickly and easily shutdown device [4] |
| **[Req 4.3.5-PP]** | Device must have efficient voltage conversion |

# 5 Mechanical Requirements

The *Roll24* will need to be designed in a way to be lightweight and highly modular so that can be customized to fit any bed size. At this stage of development, the design will be for single size bed frame and can be scaled to fit other sizes in the future. A commercial sling for repositioning patients, will be attached to the moving part as part of the module. With our design and selection in material, we hope to keep the bulk and weight of the entire chassis low.

## 5.1 Chassis and Sling

Table 5.1: Chassis and Sling Requirement

| | |
|---|---|
| **[Req 5.1.1-AP]** | Chassis must not bend or distort when a patient (up to 250lb) is using it |
| **[Req 5.1.2-AP]** | Chassis should mount to ends of a single size bed frame |
| **[Req 5.1.3-AP]** | The sling must support the patient weight (up to 250lb) |
| **[Req 5.1.4-AP]** | The sling should be detachable and washable |
| **[Req 5.1.5-BP]** | Chassis must include mechanism to prevent patient from falling off the bed |
| **[Req 5.1.6-BP]** | Chassis must shield the moving mechanical components to prevent body parts catch in the machine |
| **[Req 5.1.7-BP]** | Chassis must not have exposed electronic components or wires |
| **[Req 5.1.8-PP]** | Chassis should be lightweight and adjustable dimensions for various sizes of bed |
| **[Req 5.1.9-PP]** | Chassis should be easily installed |

# 6 Safety Requirements

The safety standards that the *Roll24* must follow for its design and intended use are outlined below. As it directly interacts with the patient, their safety is our top priority when defining hazards and selecting components to ensure that they are not harmed when using the *Roll24*.

## 6.1 Operational Safety Hazard

Table 6.1: Operational Safety Hazard

| | |
|---|---|
| **[Req 6.1.1-AP]** | The product must not have moving parts that can harm the patient |
| **[Req 6.1.2-AP]** | The product must not have sharp edges |
| **[Req 6.1.3-BP]** | The product must prevent patient from falling |
| **[Req 6.1.4-BP]** | The product should have an emergency stop button |
| **[Req 6.1.5-PP]** | The product should have a reset mechanism in case of power loss |

## 6.2 Electronic Safety Hazard

Table 6.2: Electronic Safety Hazard Requirement

| | |
|---|---|
| **[Req 6.2.1-BP]** | The electronic components and wires must be secured and shielded |
| **[Req 6.2.2-BP]** | The device must be compatible with 120V 60Hz outlets |
| **[Req 6.2.3-PP]** | The electronics must be properly grounded and protected from EMI/EMR |

## 6.3 Material Safety Hazard

Table 6.3: Material Safety Hazard

| | |
|---|---|
| **[Req 6.3.1-AP]** | The product must not have any strong magnetic components that will interfere with other medical devices |
| **[Req 6.3.2-PP]** | The product must not use any toxic materials where it contacts patient |
| **[Req 6.3.3-PP]** | The product should be water resistive |

# 7 Sustainability Requirements

The sustainability requirements of *Roll24* mentioned in the tables below dictate how Rise intends to lessen the environmental impact, product usability, and the expected lifetime of the product.

## 7.1 Efficiency

Table 7.1: Efficiency Requirements

| | |
|---|---|
| **[Req 7.1.1-AP]** | The product requires a standard North American AC power socket |

## 7.2 Durability and Maintenance

Table 7.2: Durability and Maintenance Requirements

| | |
|---|---|
| **[Req 7.2.1-PP]** | The product must work at regular temperatures, 10 to 40 °C |
| **[Req 7.2.2-PP]** | The sling must be reusable and washable up to 2000 wash cycles |

## 7.3 Environmental Considerations

Table 7.3: Environmental Requirements

| | |
|---|---|
| **[Req 7.3.1-PP]** | The product must have minimalistic packaging made out of recycled materials to reduce environmental impact |

# 8 Engineering Standards Requirements

The engineering standards requirements define the specific public standards that *Roll24* will follow. They will be used to be compliant with certified public standards and to protect the user from harm. These requirements must be met before the product can be available on the market.

## 8.1 General Engineering Standards

Table 8.1: General Engineering Standards

| | |
|---|---|
| **[Req 8.1.1-PP]** | The product must be compliant with CSA C22.2 NO. 0:20, the Canadian Electrical Code General Requirements set by Canadian Standard Association (CSA) Group [5] |
| **[Req 8.1.2-PP]** | The product must be compliant with CISPR 11/ ICES-001 Emissions [6] |
| **[Req 8.1.3-PP]** | The product must pass Class A emissions for an industrial setting [7] |
| **[Req 8.1.4-PP]** | The product must pass Class B emissions for a residential setting [7] |

## 8.2 Medical Engineering Standards

Table 8.2 Medical Engineering Standards

| | |
|---|---|
| **[Req 8.2.3-PP]** | The product must be compliant with the medical ISO/IEC/CAN standards |
| **[Req 8.2.4-PP]** | The product must be compliant with the IEC 60601 Standard for Medical electrical equipment [8] |

## 8.3 Software Engineering Standards

Table 8.3 Software Engineering Standards

| | |
|---|---|
| **[Req 8.3.1-BP]** | The monitoring software must follow the IEEE/ISO/IEC 12207-2017 standard for the software lifecycle [9] |
| **[Req 8.3.2-BP]** | Coding standards and conventions in the monitoring software must follow the Google Python style for better maintainability and readability [10] |

## 8.4 Electrical Engineering Standards

Table 8.4: Electrical Engineering Standards

| | |
|---|---|
| **[Req 8.4.1-BP]** | Unleaded solder must be used to meet RoHS directive to avoid the use of toxic and hazardous materials [11] |

| | |
|---|---|
| **[Req 8.4.2-PP]** | The electrical components must be compliant with the RoHS directive, to ensure that hazardous or toxic materials are not used in the manufacturing of our device [11] |
| **[Req 8.4.3-PP]** | The device electronics must conform to IEC 60204-1 Safety of machinery – Electrical equipment of machines – Part 1: General requirements [12] |
| **[Req 8.4.4-PP]** | The electronic wiring must conform to C22.2 NO. 127-18 – Equipment and lead wires set by Canadian Standard Association (CSA) Group [13] |
| **[Req 8.4.5-PP]** | The device power converter must conform to C22.2 NO. 107.1-16 – Power conversion equipment set by Canadian Standard Association (CSA) Group [14] |

# 9 Conclusion

With the rise of the aging demographic, pressure injury has become more prevalent in the elderly population. Bed sores are serious problems for elderly patients in both home and long-term care home environment. The problem for bed-bound patients is that nurses and care providers may not be able to help the patients 24/7. Current solutions require beds that cost upwards of $72,000 [15] or involve a nurse or caretaker that must attend to the patient to roll them onto their sides even throughout the night.

Our goal at Rise with the *Roll24* is to create an affordable solution that can be easily assembled and makes use of existing beds frames to relieve bed bound patients of bedsores. By doing so, we hope to relieve bed bound patients of bed sores throughout the day and night with minimal interaction from nurses and caretakers, thereby reducing the percentage of death caused by bed sores. The software, hardware, and mechanical requirements stated in this document are the functional requirements for the different phases in the design and production process. In the final production phase, the product will also be required to meet the safety and sustainability standards as well as to comply with the certified and required engineering standards to be marketable.

# 10 References


[1] "Lateral Rotation Medical Beds by ProBed Medical." https://www.pro-bed.com/ [Accessed Feb. 21, 2021].

[2] "Dressing interventions to heal pressure ulcers: A protocol for an overview of systematic reviews and meta-analysis." *Medicine, 99, e22699*. Geng, Jie, Zhao, Yali, Wang, Zheyuan, Wang, Mancai & Wei, Zhihong. (2020). https://doi.org/10.1097/MD.0000000000022699 [Accessed Feb 20, 2021].

[3] "What is the mortality rate for pressure injuries (pressure ulcers)?" https://www.medscape.com/answers/190115-82434/what-is-the-mortality-rate-for-pressure-injuries-pressure-ulcers [Accessed Feb. 21, 2021].

[4] "IEEE/ANSI C37.17-1997 - American National Standard for Trip Devices for AC and General Purpose DC Low Voltage Power Circuit Breakers." https://standards.ieee.org/standard/C37_17-1997.html [Accessed Feb. 21, 2021].

[5] "CSA C22.2 No. 0:20," *Standards Council of Canada - Conseil canadien des normes*. https://www.scc.ca/en/standardsdb/standards/30464 [Accessed Feb. 21, 2021].

[6] I. Government of Canada, "ICES-001 — Industrial, Scientific and Medical (ISM) Equipment," Jul. 23, 2020. https://www.ic.gc.ca/eic/site/smt-gst.nsf/eng/sf00018.html [Accessed Feb. 21, 2021].

[7] "ICES-Gen — General Requirements for Compliance of Interference-Causing Equipment - Spectrum management and telecommunications", *Ic.gc.ca*, 2018. [Online]. Available: https://www.ic.gc.ca/eic/site/smt-gst.nsf/eng/sf11413.html. [Accessed: 21- Feb- 2021].

[8] H. Canada, "List of Recognized Standards for Medical Devices," *aem*, Feb. 27, 2019. https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/standards/list-recognized-standards-medical-devices-guidance.html#s1-1 [Accessed Feb. 21, 2021].

[9] "IEEE/ISO/IEC 12207-2017 - ISO/IEC/IEEE International Standard - Systems and software engineering -- Software life cycle processes." https://standards.ieee.org/standard/12207-2017.html [Accessed Feb. 21, 2021].

[10] "styleguide," *styleguide*. https://google.github.io/styleguide/pyguide.html [Accessed Feb. 21, 2021].

[11] "RoHS 2 vs RoHS 3 (EU 2015/863)." https://www.rohsguide.com/rohs3.htm [Accessed Feb. 21, 2021].

[12] "IEC 60204-1:2016 | IEC Webstore." https://webstore.iec.ch/publication/26037 [Accessed Feb. 21, 2021].

[13] “CSA C22.2 No. 127-15,” *Standards Council of Canada - Conseil canadien des normes*. https://www.scc.ca/en/standardsdb/standards/28242 [Accessed Feb. 21, 2021].

[14] “CSA C22.2 No. 107.1-16,” *Standards Council of Canada - Conseil canadien des normes*. https://www.scc.ca/en/standardsdb/standards/28508 [Accessed Feb. 21, 2021].

[15] "Cost vs. Benefits Of The Freedom Bed™ By ProBed Medical", *Pro-bed.com*, 2019. [Online]. Available: https://www.pro-bed.com/cost-vs-benefits. [Accessed: 22- Feb- 2021].

# Appendix A: Acceptance Test Procedure

Functional System Acceptance Test Procedure

| Tester Name: | | Date: | |
|---|---|---|---|
| FUNCTIONAL SYSTEM TEST | | | |
| Patient Monitor Requirements | | | |
| Relevant Requirement(s) | Procedure | Result | Comments |
| Req 3.1.1 | Monitor recognize a person on the bed. | ❑ Pass<br>❑ Fail | |
| Req 3.1.2 | Monitor determines the coordinate of the boundary on the bed. | ❑ Pass<br>❑ Fail | |
| Req 3.1.3 | Monitor does not save video of | ❑ Pass<br>❑ Fail | |
| Process Automation Requirements | | | |
| Req 3.2.1 | A signal can be sent to halt the repositioning. | ❑ Pass<br>❑ Fail | |
| Req 3.2.2 | Repositioning is activated following a period. | ❑ Pass<br>❑ Fail | |
| Motor Requirements | | | |
| Req 4.1.1 | Measure dimensions and ratings and compare to NEMA standards | ❑ Pass<br>❑ Fail | |
| Req 4.1.2 | Place more than 13.5 kg of weights on linear actuator and run the motor | ❑ Pass<br>❑ Fail | |
| Microcontroller Requirements | | | |
| Req 4.2.1 | Verify input/output at each register and measure pinouts for change in voltage using multimeter | ❑ Pass<br>❑ Fail | |
| Electronics Requirements | | | |
| Req 4.3.1 | Use controller to adjust motor speed and position one at a time ensuring full range | ❑ Pass<br>❑ Fail | |
| Chassis and Sling Requirements | | | |
| Req 5.1.1 | Chassis has no visible structure bending or distortion with real person lay on it | ❑ Pass<br>❑ Fail | |

| | | | |
|---|---|---|---|
| Req 5.1.2 | Chassis is mounted to the end of the testing bed | ❑ Pass<br>❑ Fail | |
| Req 5.1.3 | Sling can support a patient weight up to 250 lb | ❑ Pass<br>❑ Fail | |
| Req 5.1.4 | Sling is detachable and washable | ❑ Pass<br>❑ Fail | |
| Operational Safety Requirements | | | |
| Req 6.1.1 | Verify that moving parts do not touch patient when in use | ❑ Pass<br>❑ Fail | |
| Req 6.1.2 | Verify edges of moving parts are covered or rounded | ❑ Pass<br>❑ Fail | |
| Material Safety Hazard | | | |
| Req 6.3.1 | Verify that electronic components are sealed or covered in an enclosure | ❑ Pass<br>❑ Fail | |
| Efficiency | | | |
| Req 7.1.1 | Verify circuit schematic and visually inspect power adapter | ❑ Pass<br>❑ Fail | |

# Appendix B: Proof-Of-Concept Requirements

Table 10.1: Electrical Engineering Standards

| | |
|---|---|
| **[Req 3.1.1-AP]** | The product must monitor the patient's positioning on the bed |
| **[Req 3.1.2-AP]** | The monitor must determine the boundary in which the patient can be repositioned |
| **[Req 3.1.3-AP]** | The monitor should not record information that would invade the patient's privacy |
| **[Req 3.2.1-AP]** | The repositioning process must halt if the patient monitor sends a signal that it detects danger and/or the patient has moved out of the boundary determined by the monitor |
| **[Req 3.2.2-AP]** | The patient repositioning process should run periodically |
| **[Req 4.1.1-AP]** | Motor must be National Electrical Manufacturers Association (NEMA) compliant |
| **[Req 4.1.2-AP]** | Motor must move more than 13.5kg vertically and horizontally |
| **[Req 4.2.1-AP]** | The microcontroller must transmit/receive signals from stepper driver in real-time |
| **[Req 4.3.1-AP]** | Device must have an easily accessible and simple to use control panel to operate |
| **[Req 5.1.1-AP]** | Chassis must not bend or distort when a patient (up to 250lb) is using it |
| **[Req 5.1.2-AP]** | Chassis should mount to ends of a single size bed frame |
| **[Req 5.1.3-AP]** | The sling must support the patient weight (up to 250lb) |
| **[Req 5.1.4-AP]** | The sling should be detachable and washable |
| **[Req 6.1.1-AP]** | The product must not have moving parts that can harm patient |
| **[Req 6.1.2-AP]** | The product must not have sharp edges |
| **[Req 6.3.1-AP]** | The product must not have any magnetic components that will interfere with other medical devices |
| **[Req 7.1.1-AP]** | The product requires a standard North American AC power socket |