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Spring 2021

## Tubing/Lines Entanglement Reduction in Healthcare Settings

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# *Tubing/Lines Entanglement Reduction in Healthcare Settings*

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**Abstract—** Intravenous (IV) lines used in various healthcare settings pose a risk to patients and their caretakers. A few common risks include IV lines becoming torn out and coming into contact with open wounds. We propose to solve this problem by designing a device that prevents IV and wire entanglement without obstructing patient care. Our objectives in identifying a solution include increasing patient comfort, mobility, and ease of transfer. By solving this issue, other potential benefits include reducing time spent on non-essential tasks and reducing the number of personnel needed to transport patients. We intend to validate our product with healthcare employees to ensure our solution creates a marketable product that is affordable, effective, and benefits patients and caregivers alike.

**Keywords—** Catheter, Intravenous, Healthcare, Tangle, Organization

## I. INTRODUCTION

The overall goal of this project is to design a medical device to prevent entangled wires and IV lines during patient care and transport that does not obstruct patient care. Ensuring the organization of wires and IV lines may decrease adverse outcomes such as entanglement of the patient, falls by both patients and health care providers, and connection errors or damage of medical equipment.. It's estimated that 18% of nursing care employee's injuries can be attributed to slipping, tripping, and falling [5]. Our objectives to solve this problem include increasing patient mobility, comfort and ease of transfer. After interviewing multiple health care providers, it was noted that every one of them mentioned the disorganization of IV lines and wires. The issue is especially prevalent in very ill patients, as they may need many IV drips or pumps. The disorganization of IV lines could lead to entanglement and difficulty transferring patients when time is critical to the patient's life. It could also lead to unsanitary conditions, as IV lines can drag across incisions and possibly introduce pathogens into the wounds.

Initial research on current products that address this issue was performed. The purpose of this research was to understand and gather inspiration from previous products, while also making sure that our design respected their

intellectual property. A handful of designs were found in this research. All with widely different attaching systems, collapsing methods, functionalities, materials, and prices. Some of the designs that closely resembled our ideal solution would later be used in our competitive technical assessment.

## II. USER NEEDS

The first gate's primary objective was to establish a list of stakeholder requirements. To do this, we began by reaching out to medical professionals for interviews. We received input from two critical care surgery specialists, a critical care registered nurse (CCRN), and a certified flight registered nurse (CFRN). These interviews helped us further solidify our design aspirations while also helping us understand the main features that would make our product successful. After looking over our interview notes, seven main points immediately jumped out. These formed the basis of our stakeholder requirements. The device should:

1. Prevent entanglement and tension from occurring
2. Be easy to use
3. Reduce the time it takes to transport patients by facilitating
4. Provide a more sterile environment
5. Provide clarity in organization of tubes/ wires
6. Be affordable/competitive financially
7. Not obstruct the doctors/ nurses from giving care

These newly established stakeholder requirements were then used to further analyze products on the current market. By doing this we could understand where previous designs before us had failed consumer expectations. Additionally, extensive patent research was conducted to ensure our initial design ideas did not violate patent law. This patent research also helped spark new ideas that could be used to address our stakeholder requirements.

## III. DESIGN INPUTS

During the design inputs stage of the design process, the engineering requirements were extracted and used in the first

phase of the Quality Function Deployment (QFD). The complete QFD is located in Table 9 in the Appendix. The first engineering requirement was the device must attach to the hospital bed with 15 lbf. This came from the customer requirement of preventing entanglement and tension from occurring. The best place to organize the wires and IV lines to prevent entanglement would be a location close to the patient. If the device was located on the IV pole further away from the patient, this could allow for easier entanglement of the lines. The second engineering requirement was to split the device into 6 sections. This requirement was derived from the user need of providing clarity in the organization of IV tubes and wires. The sectioning of the device lets the IV lines to be organized in a clear manner and they can be labeled and separated from each other. The third engineering requirement was that the device would be made of a plastic material and the material we chose was acrylonitrile butadiene styrene (ABS). This requirement satisfies the customer requirement of being affordable and competitive financially. The plastic material allows the device to be low cost, but also have a strong base that would not break. The fourth engineering requirement was the device would be adjustable. This requirement was derived from the user needs of easy to use and reduce the time it takes to transport patients. The adjustability of the device would allow the device to fit to different styles of hospital beds and attach to different places on the bed, so it could be easy for a caregiver to move the device. The last engineering requirement was that the size of the device would be under six inches. This requirement was made to satisfy the customer requirement to not obstruct the medical personnel from taking care of the patient.

A competitive technical assessment was conducted in the QFD comparing competitor's devices to the device that we think we could produce. This part of the QFD was performed to figure out what devices were already on the market and determine how those devices fell short of the customer requirements so we could make a device that better satisfied the requirements. The devices we ranked ours against are in the Appendix in Table 9. Each device was ranked on a scale 1-5 on how well they satisfied each customer requirement. From this assessment, we learned that low cost was an easy improvement to make to our device and would make our device better than the competitor's devices. We also learned that it is very important that the device does not get in the way of the doctors and nurses because it could introduce a new problem instead of fixing an existing one. We decided to seek a final design that incorporates elements from the competitor's portable IV stand design and the IV line separating design. From the preliminary risk assessment which is in Figure 8 in the Appendix, all the conceptual models presented low or moderate risk. The areas of moderate risks were that the user does not know how to operate/attach the device, the device falls off the bed, and the device impedes fluid flow. The design concepts that presented the lowest risk were concepts that allowed line slack for patient movement and allowed multiple IV lines and wires to be distinguished from each other. The recommended

actions from the risk assessment were to label the device clearly, create a clear and concise user manual, include a backup mechanism to prevent falls, and include a failsafe to avoid over compression of IV lines.

#### IV. DESIGN PROCESS

The third gate was the design process stage. At the beginning of this stage, we utilized brainstorming techniques to officially settle on our design. The methods utilized included Solution Searches and 6-3-5 Brainwriting modified to work with a group of four. As a group, we selected the most promising idea from each person and compared each using a phase two, step one QFD. The QFD enabled us to rate each design on a scale from 1 to 3 by its potential to satisfy our engineering and customer requirements. We settled on a design featuring a screw-in clamp mechanism for attaching to a bed side, a side protrusion that can hold an IV pole, and tapered slots on top to hold the medical lines. It would be superior to the competition by holding more lines, being more mobile, and having the capability to hold an IV pole..

With our concept selected we moved on to evaluating engineering approaches we could use for each component of the design. We examined existing products and patents to inform our method of holding the medical tubing. We also investigated manufacturing methods and materials that would best suit our product. Additionally, we researched testing methods to be used to verify our design components.

Next, we developed a QFD parts design matrix. Our engineering requirements were the inputs, and their relationships to the broken-out components of our design were evaluated. Relationships were defined as strong, weak, or negligible. From these relationships, specifications for each component were developed based on the research we conducted into engineering approaches and the criticality of the relationships. The final matrix is shown in Fig. 1 of the appendix.

For the final step of this stage, we created a design Failure Modes and Effects Analysis (FMEA) to improve our design by evaluating risks. We identified four functions of the design and broke each out into potential modes of failure and further into what these failures may cause. Each potential effect of the failures were assigned numerical ratings for severity, occurrence, and detectability. The product of these ratings is known as the Risk Priority Number (RPN). All potential causes of failures with high RPNs were assigned suggested actions to improve our design and reduce risk.

#### V. DESIGN OUTPUTS

The fourth gate was the design outputs stage. Our design underwent multiple iterations during this time. To begin, we updated the carabiner attachment mechanism of our initial CAD model and had it 3D printed through Bierce Library, shown in Fig. 2 in the appendix.

This alpha prototype was very useful when communicating our design to others and developing verification methods. We received feedback on the prototype from professors and technicians within the Biomedical

Engineering Department that led to further design development. We also added and edited design elements as a result of our design verification, including finite element analyses of simulated stresses. This all led to our more recent design that incorporates a Velcro fastening system and thumb slides to secure medical tubing. We had this model 3D printed as our second alpha prototype, shown in Fig. 3; see the appendix for all part and assembly drawings, Figs. 4 through 7.

As we added elements to our design, we specified them in our Bill of Materials (BOM). Decision matrices were utilized to compare parts and ultimately select the most favorable.

## VI. DESIGN VERIFICATION

Verification tests were completed to ensure that the design outputs met the initial engineering requirements. Test protocols were created for each test to include the objective of the test, the rationale, the materials needed, the test methods, and applicable drawings and test set-ups. The rationale was developed from research, keeping in mind the requirement for efficient, quality care in a healthcare setting. A summary of the verification results for each of the tests are listed below.

**Table 1:** A summary of the verification results for each verification test. The device met the minimum requirements to pass each verification test.

| Engineering Requirements   | Test Method              | Acceptance Criteria      | Pass? |
|--|--------------------------|--------------------------|-------|
| Device attaches to bed with 50 N of force                                    | Instron Tensile Test     | > 50 Newtons             | Yes   |
| Device securely holds wires of ID from 0.5mm to 5mm with 11 pounds of force. | Force Gauge Test         | > 11 lb-f                | Yes   |
| Device is no greater than 6"x6"x6"   | Tape Measure             | Less than 6 cubic inches | Yes   |
| Device can be deployed in under 1 minute                                     | User deploys device      | < 1 minute               | Yes   |
| Low cost and manufacturing complexity  | Time/Cost to manufacture | < \$25                   | Yes   |
| Flow rate is not restricted by device  | Flow Meter Test          | < 5% difference          | Yes   |

|   |                      |                                      |     |
|---|----------------------|--------------------------------------|-----|
| Device improves patient safety and minimizes tangling | Clinical Application | Improved results via clinical survey | Yes |
|---|----------------------|--------------------------------------|-----|

After implementing each verification test the device was found to receive a passing score each test, meeting the minimum requirements within each protocol.

## VII. MEDICAL DEVICE

Gate 5 is currently in progress and will be complete by April 26th. All the parts have been ordered and received for the prototype. We have started the Validation Testing discussed in section eight.

## VIII. VALIDATION TESTING

Validation tests were completed to ensure the medical device met the customer requirements. The tests were conducted using a prototype device in a clinical simulation. A picture of the device being utilized during validation can be seen in Figure 8 in the Appendix. Validation documents were made including the plan, procedure, and validation report. The validation plans for each customer requirement can be found in Table 7 located in the Appendix. The detailed procedure for each validation can also be found in the Appendix in Table 8. The validation report shows the outcome of each validation and can be found in Table 9 of the appendix. If a validation procedure failed to meet acceptance criteria, a comment was left with an explanation.

## IX. RISK MITIGATION PROCESS

During the design process, a conceptual Failure Modes and Effects Analysis was created during the second gate to evaluate potential functions of the device and their respective failure modes. This was done by first identifying a function of the device and how the device would fail to perform that function. The effects of the device failing by each mode could then be identified. To complete this, the impact of failure on many variables was investigated including on patients, hospital staff, and the device itself. A severity score (Table 4 in the Appendix) was then assigned to each effect of failure based on the result of the failure. This ranged from a score of 1, equating with inconvenience or minor discomfort, to 5, equating with patient death. Potential causes of each failure were then identified and assigned an occurrence score (Table 5 in the Appendix) based on how likely that cause was to happen. This ranged from an occurrence of 1 equating with a probability of less than  $10^{-6}$  to a score of 5 equating with a probability of  $\geq 10^{-3}$ . The severity and occurrence scores were used to assign a classification code to each risk, which can be found in Table 3. The risk priority number was assigned by multiplying severity, occurrence, and detection, to produce a value from 1 to 75.

After a concept was chosen for the device design, a design FMEA was created during gate 3 using the functions that were selected for the final prototype. The appropriate

failure modes, effects of failure, and mechanisms of failure were identified in a manner like that of the conceptual FMEA. The occurrence and severity scoring system were also the same. The key risks identified included the device harming the patient or healthcare staff, the sizing of the device being wrong so that it does not interface with the tubing or bed properly, the device is broken by the user, fluid flow is reduced, the holding mechanism fails, and the device does not interface with the IV pole properly.

During gate 3 and gate 4, risk mitigation efforts were made to reduce the identified risks as stated below. It was determined that a backup mechanism was needed to prevent the device from falling on the floor or a patient, so a safety cable will be attached to the device to provide a backup holding mechanism if the Velcro fails. The device will also be made in an easily detectable color so it can be quickly recognized if it falls on the floor. All edges were filleted too, to prevent injury. A verification test was also required to ensure the flow difference at the entrance and exit of the device is no more than 5% different. A verification test was also done to ensure the strap can withstand a pulling force of at least 15 pounds. Steps were also taken during gate 5 to mitigate the risk of incorrect sizing. These included a quality review that will be performed after manufacturing before the device is released, labels that will be affixed for the diameters of tubing that is allowed, and a thorough instruction manual that will be included. To mitigate the risk of the device breaking, a thorough instruction manual will be included that provides detailed use instructions for the healthcare workers. To mitigate the risk of fluid flow being reduced, a thorough instruction manual and labeling will be included to give the maximum diameters of tubing permitted as well as proper instruction on how to use the device. To mitigate the risk of the Velcro failing, users are instructed to replace the Velcro strap after one year of use. To mitigate the risk of the device not interfacing with the IV pole correctly, instructions on how to attach the IV pole are included in the instruction manual. The dimensions of a standard IV pole were also used in creating the attachment point on the device. A detailed summary of the risks identified and the respective mitigation strategies can be found in the Risk Summary Table (Table 9 in the Appendix).

After conducting a risk-benefit analysis, it was determined that the benefits of the device clearly outweigh any residual risks. When properly used, the device can dramatically increase the quality of patient care. Reducing the entanglement of IV lines improves patient comfort, mobility, and ease of transportation. The device is also very likely to reduce patient injury as IV lines won't be torn out, or rub and contaminate wounds. The hospital staff will also be more efficient as the device is likely to reduce time spent on non-essential tasks and reduce personnel needed to monitor IV lines and transport patients. The risks to using the device are mostly minor and/or not very likely to happen. The device could be used incorrectly and not function properly, causing IV lines to hang free or the device to fall and pose a tripping hazard, but these events are not likely to happen due to the mitigation steps taken. The device could also restrict fluid flow but this is not very likely, and most

hospitals have monitors that warn staff if IV fluids are not flowing properly.

## X. MARKETING AND MANUFACTURING CONSIDERATIONS

### A. Market Size

If our product successfully solved the stakeholder problems that we set it is not unreasonable to assume any interested hospital would purchase one for each staffed bed. Currently, there are a total of 919,559 staffed hospital beds in the U.S [4]. Even on 0.1% of U.S hospital beds, we could see an initial market of 919 sold products.

### B. Expected Costs

Our current design consists of 3 distinct components. The plastic body, the velcro straps, and the rubber tube grips. The raw material cost of making one plastic body out of ABS was calculated using the following equation,

$$P_U = P_B \rho V \quad (1)$$

Where  $P_U$  is measured in U.S dollars per unit and represents the cost associated with one device,  $P_B$  is measured in U.S dollars per pound and represents the cost per pound of buying ABS in bulk,  $\rho$  is measured in  $\text{lb}/\text{in}^3$  and represents the density of ABS, and  $V$  is measured in  $\text{in}^3$  and represents the volume of one device.

We can estimate  $P_B$  at \$0.794/lb [1] and  $\rho$  at  $3.79\text{E}-2 \text{ lb}/\text{in}^3$  after a simple unit conversion. We can then break down our plastic body into a cross section, calculate the area of this cross section, multiply the cross section by the body's length, then add a generous 10% waste factor to this volume to estimate a total volume of  $36.7125 \text{ in}^3/\text{part}$ . When plugged into equation (1) we can estimate an ABS raw material cost of \$1.1055/part.

Our velcro straps are currently purchased off of amazon for \$5.77/part. After researching new suppliers or negotiating bulk pricing, securing a price below \$2.50/part would be a realistic price goal.

We need 42 sheets of food grade silicone rubber whose dimensions measure  $0.27 \times 1.25 \text{ in}$ . This can be calculated as  $15.5925 \text{ in}^2/\text{part}$  of rubber after a generous 10% waste factor. We can multiply this by its price per square inch and determine a final cost of rubber per part. Square inch prices were researched at \$0.058/ $\text{in}^2$  but could likely get as low as  $0.043/\text{in}^2$ . Using the later price, we can estimate a food grade silicone rubber cost of \$0.677/part.

Adding the three raw material prices together, we get a final raw material cost of \$4.285/part. We can use this number to estimate labor cost at \$4.285/part and an overhead of \$8.565/part. Taking a 60% margin on \$17.13 yields \$10.28 of profit per part and a final product cost of \$27.41.

### C. Competitive Assessment

When compared to other products on the market, a final price point of \$27.41 is extremely competitive. At a relatively expensive price point we could compare our device to that of Davinci Medicals, IV Guard IV Line Organizer [6]. This

device is similar to our design but has a more complicated attachment system, less reliable tube holding, and less functionality. This device is currently being sold for \$499.00. At a price point comparable to our own, we have the Beata Clasp [7]. This device has substantially less features than our device but is currently being sold for \$14.95. With a waste factor of less than 10% and better priced velcro straps, our device's price point could easily dip below \$27.41. This would allow it to be even more competitive with devices such as the Beata Clasp.

## XI. SUMMARY FEASIBILITY DISCUSSION

The need we initially identified was to reduce the entanglement of medical lines during patient care and transport. Having not fully completed the design process, we can only say we expect our design to satisfy this goal. We developed a design that will hold the medical lines in separate lanes and hold them there with light contact. Our team considers the current resultant product to be a prototype; it may not be made of the same materials or by the same methods that it would be in large scale manufacturing, but it accurately showcases all features we want our design to have. Furthermore, it can be used by stakeholders to test for requirements, which can further confirm that our design satisfies the need we initially identified.

## XII. DISCUSSION, LESSONS LEARNED, AND CONCLUSIONS

The biggest issue that was present during this design process was the restrictions we faced due to Covid-19. It was difficult to find a solution to a problem when we could not see the problem in the hospital setting. It would have been helpful to go to different hospitals and see the different styles of hospital beds and how they have equipment set up to make sure our device could be compatible with the different environments. Another issue that arose was that it took a long time to order and receive parts. As a result, the verification testing had to be performed later in the process. Moreover, we went through some changes and iterations later in the process due to new information and input given to help make the device perform better.

Something that could be done differently from the beginning was to keep the device simpler. The attachment of the first concept device to the bed was over-engineered and complicated, when there were more simple solutions that were not only easier to make, but easier for a caregiver to put in use. We could have focused more on making the device very easy for the caregiver to operate because if the device was too complicated it might not be worth purchasing.

Another thing we could have done differently is talk to more professors, engineers, and stakeholders about our device and how it works. The more people that we talked to about our device, the better our design concept became. Getting other's input really helped us come up with new ideas on how to make our device better and we went through a couple iterations because of it.

## XIII. FUTURE WORK

At the conclusion of this project, it was recognized that some changes could still be made to more precisely fulfill the

needs of the customer. While many features of the device satisfied the initial customer requirements per verification and validation testing, other concepts and designs exist that could also satisfy these requirements. A key requirement was that the device prevents entanglement and tension of IV tubes and other wires. While our multiple slotted design approach does separate tubes, it does not fully address the tension that can be put on these tubes. Perhaps a new design could incorporate a second device with a quick-release mechanism that is activated upon exceeding a specified amount of tension. Another requirement was that the device is easy to use. While the device is simple in structure and function, it does require multiple steps to attach the device to the bed. The device could be designed negating the Velcro strap in favor of an attachment mechanism that only uses one step such as, for example, a claw-like backing that is flexible enough to encompass the bed but then sturdy enough to close around the rail and cannot be easily removed. The Failure Modes and Effects Analysis can give further insight on future opportunities to reduce risk. The weight of the device was not a serious consideration in the initial design so more research could also be done into lightweight materials that are cost efficient to manufacture.

## XIV. INDIVIDUAL ROLES AND RESPONSIBILITIES

### A. Amy Beskitt

Amy Beskitt was responsible for management, Quality Engineer, and Analyst roles. She conducted stakeholder interviews with Dr. Thompson and took part in developing the stakeholder requirements and problem statement from the interviews. She also completed the phase 1 Quality Function Deployment in Gate 2 and helped to complete the Design FMEA in Gate 3. During Gate 4, she completed the engineering analysis by conducting a Finite Element Analysis on the prototype and made a Gantt chart to plan the major task and milestones for Gate 5 and distribute the workload. She also developed some of the validation plans and procedures for Gate 5.

### B. Abigail Kraft

Abigail had responsibilities in administrative, quality, and testing engineering roles. She conducted background research and found existing products to address customer needs. She also conducted an interview and aided in testing the device at Akron Children's Hospital. Abigail played a main role in developing the conceptual Failure Modes and Effects Analysis and doing a risk analysis for many potential device functions. Abigail developed protocols and executed a majority of the verification testing, gathering data to support the functionality of the device. Abigail also helped to develop feasible validation testing ideas. She authored the Design Verification, Risk Mitigation Process, Future Work, and Professional and Ethical Responsibilities sections of the Honors Final Report.

### C. Grace Elerick

Grace Elerick was responsible for a mixture of administrative, regulatory, management, and associated tasks

in the Quality Engineer role. She held one stakeholder interview and contributed to developing stakeholder requirements from all interviews. She took part in creating the Failure Mode and Effects Analysis and multiple QFDs, including the parts design matrix. Grace was responsible for all 3D modeling, assemblies, and drawings. She has also completed work on validating the device and will continue to do so through the completion of the medical device stage.

#### D. Zachery Steck

Zach holds responsibilities for the Marketing Research and Quality Engineer roles. For the first gate review of the design process Zach was responsible for conducting patent research for products that met our user needs. In addition to this, he interviewed a registered flight nurse to learn more about the needs of critical care patients when confined to the limited space of a helicopter or ambulance. During the second gate review of the design process, Zach was partially responsible for the QFD. He focused on specific competitor research and ranking against our user requirements. In the third and fourth gates, Zach was responsible for FMEA updates, performing all activities related to purchasing, and market evaluation. He also assisted in validation protocol writing. Zach authored the academic introduction, user needs, and marketing and manufacturing considerations sections of our final paper.

#### XV. PROFESSIONAL AND ETHICAL RESPONSIBILITIES

The design of this device was created with many ethical considerations in mind. On a large scale, this device is intended to improve patient care by reducing wire entanglement without obstructing patient care. Our device was designed to increase patient comfort, mobility, and ease of transfer. Thus, the device furthers the humanitarian goals of technology within healthcare. The device also has a positive economic impact on society in various ways. The device reduces time spent on non-essential tasks and reduces the number of personnel needed to transport patients. In this way, it improves the efficiency of hospitals and healthcare centers while not sacrificing quality of care. If this device were produced on a large scale, it should be manufactured to

last at least 5 years. In this way, it is an environmentally friendly device that will be reused many times and can be recycled when the lifespan of the device has been reached. Overall, this device was designed to have a positive global impact on patients and healthcare workers, fulfilling the ethical responsibilities of a biomedical engineer.

#### XVI. ACKNOWLEDGEMENTS

We thank Steve Paterson and Dr. Alhalawani for their assistance with testing and design recommendations. We thank Dr. Keszenheimer for his guidance.

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Fig. 3. Second alpha prototype.

Fig. 4 - 7. Drawings of second alpha prototype.

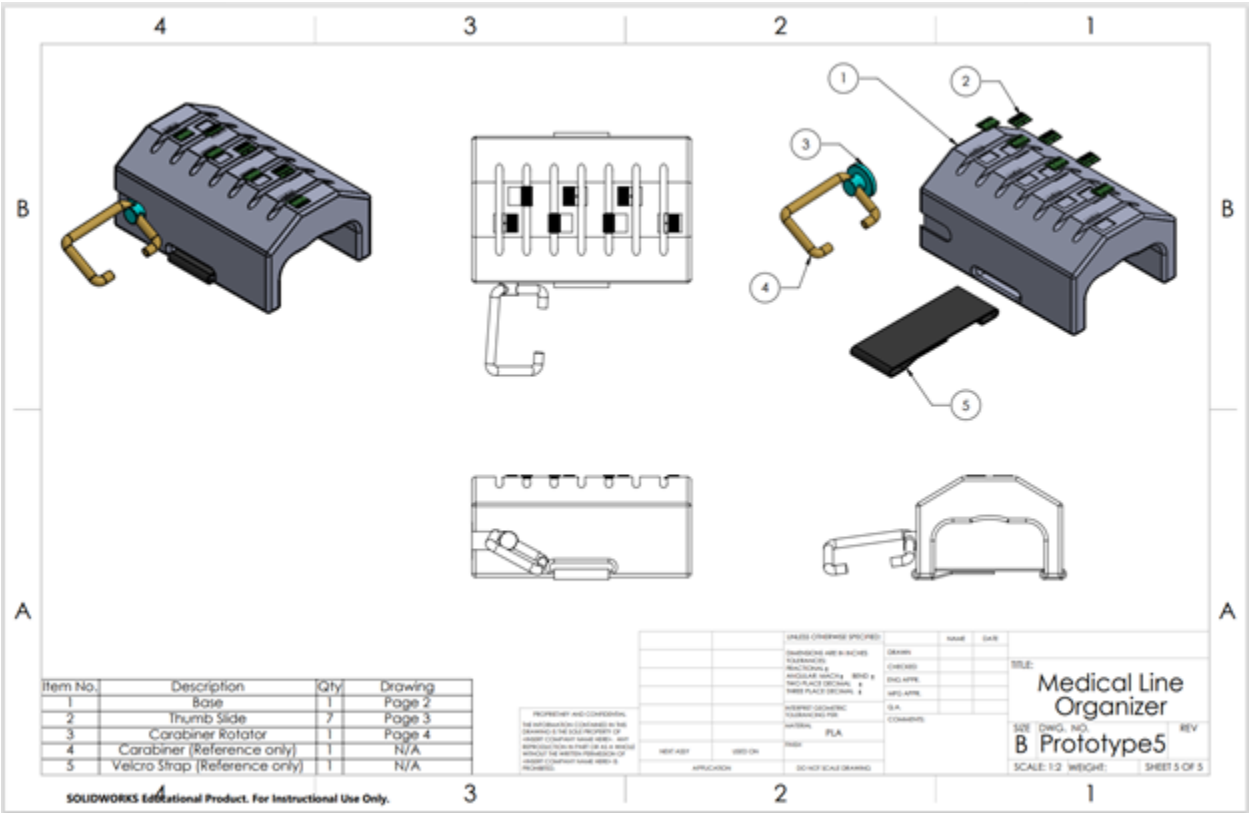


Fig. 4. Prototype Assembly.

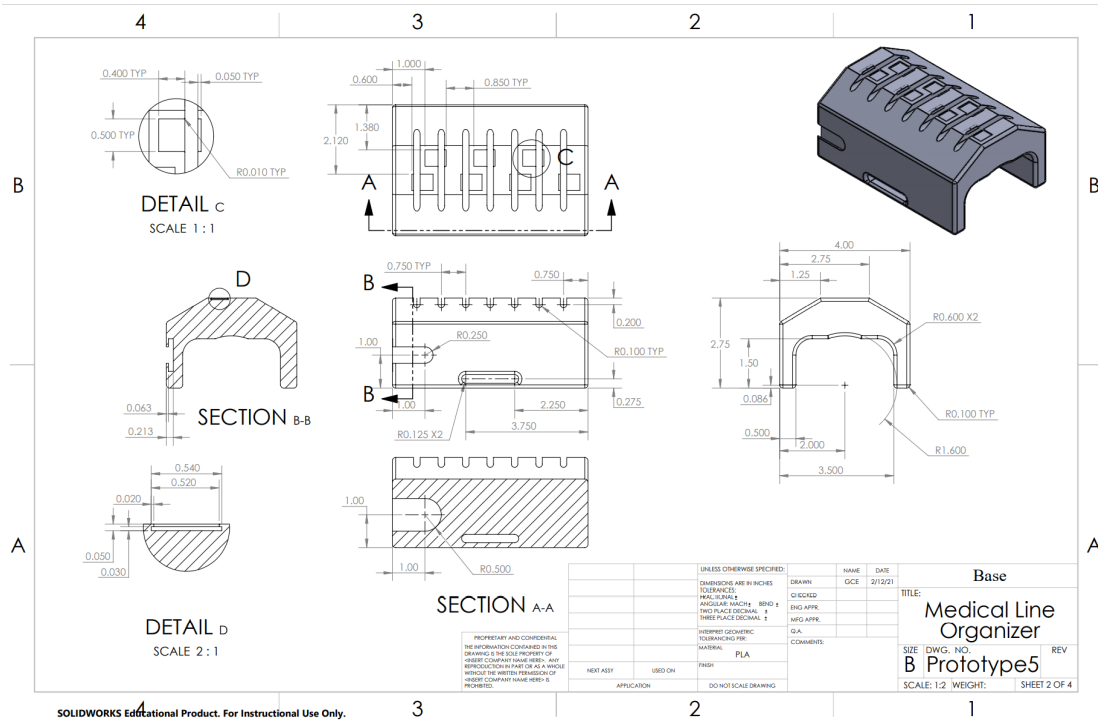


Fig. 5. Prototype base.

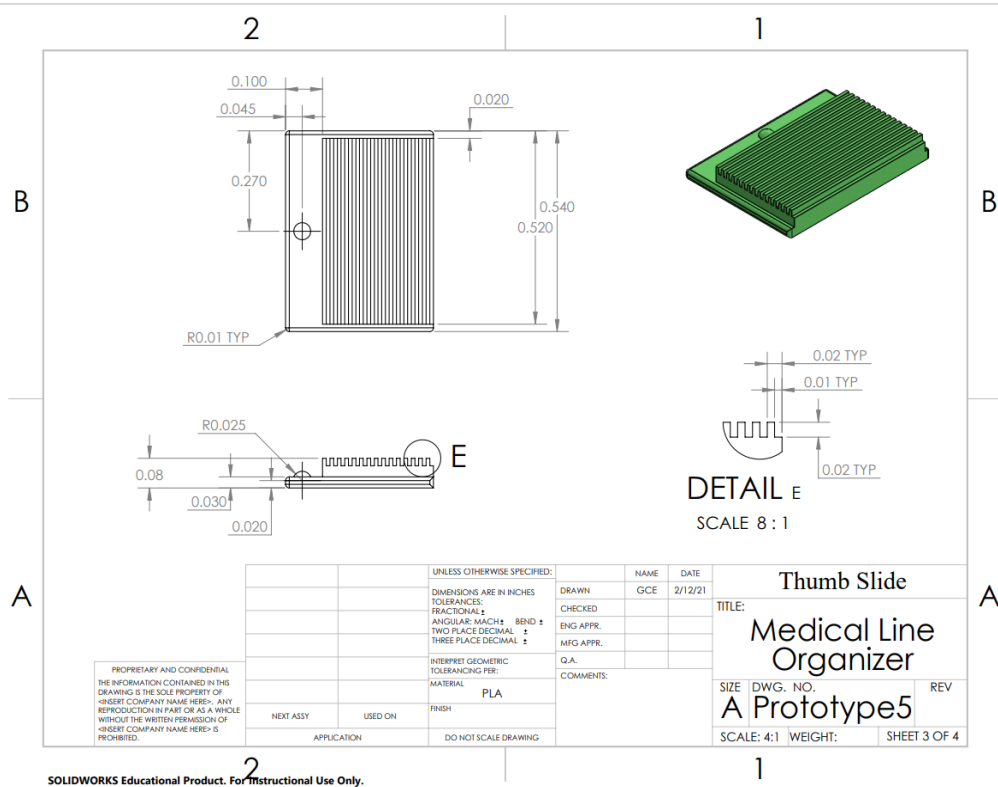
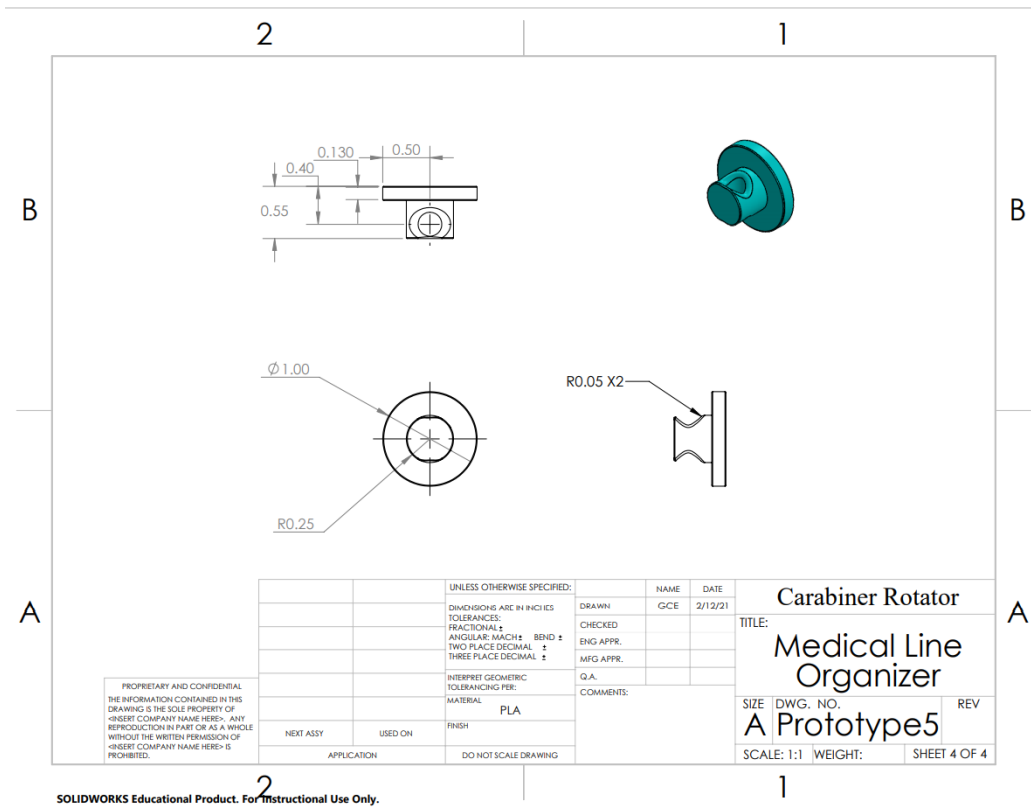


Fig. 6. Prototype Thumb Slide.



SOLIDWORKS Educational Product. For Instructional Use Only.

Fig. 7. Prototype Carabiner Rotator.



Fig. 8. Device during validation.

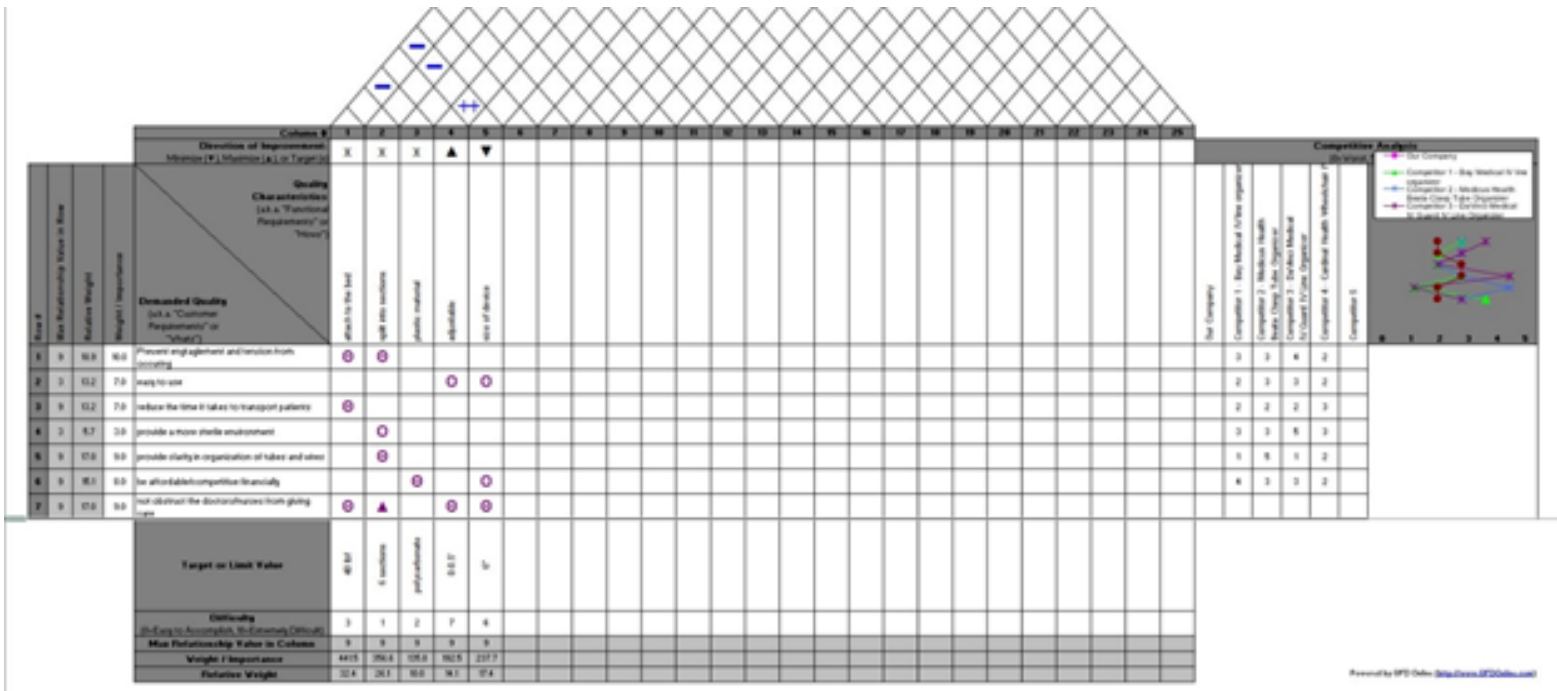


Fig. 9: The Overall Quality Function Deployment Diagram

## Tables

Table 2: The risk table shown below was used to assign a risk classification to each failure cause and effect. A severity score was assigned to the effect of failure and an occurrence score was assigned to the mechanism of failure.

| Occurrence   |      | Severity |     |          |      |           |
|--|------|----------|-----|----------|------|-----------|
|  |      | None     | Low | Moderate | High | Very High |
|  |      | 1        | 2   | 3        | 4    | 5         |
| Occ.   | Sev. |          |     |          |      |           |
| Remote: Failure is unlikely, Improbable                                | 1    | AO       | AO  | AO       | AO   | AO        |
| Low: Relatively few failures   | 2    | AO       | AO  | AO       | AO   | SC        |
| Moderate: Occasional failures  | 3    | AO       | AO  | KC       | KC   | SC        |
| High: Repeated/Frequent failures                                       | 4    | AO       | KC  | KC       | KC   | SC        |
| Very High: Failure is almost inevitable, Frequent, Persistent failures | 5    | AO       | KC  | KC       | KC   | SC        |

Table 3: A classification code was assigned based on the severity and occurrence scores for each risk.

| Classification |                                       |  |
|----------------|---------------------------------------|--|
| Code           | To indicate                           | Criteria   |
| SC             | A potential safety characteristic     | Severity = 5 and occurrence = 2 to 5   |
| KC             | A potential key design characteristic | Severity = 4 and occurrence = 3 to 5<br>Severity = 3 and occurrence = 3 to 5<br>Severity = 2 and occurrence = 4 to 5 |
| AO             | Action is optional                    | Not SC nor KC  |

Table 4: The severity scores used to assess the potential effects of failure.

| Severity Scores | Possible Description  |
|-----------------|---|
| 5               | Results in Patient Death                                    |
| 4               | Results in permanent patient injury                         |
| 3               | Results in injury or requiring medical attention            |
| 2               | Results in temporary injury not requiring medical attention |
| 1               | Inconvenience or minor discomfort                           |

Table 5: The occurrence scores used to to assess the probability a mechanism of failure could occur.

| Occurrence Rating | Probability Range              |
|-------------------|--------------------------------|
| 5                 | $\geq 10^{-3}$                 |
| 4                 | $< 10^{-3}$ and $\geq 10^{-4}$ |
| 3                 | $< 10^{-4}$ and $\geq 10^{-5}$ |
| 2                 | $< 10^{-5}$ and $\geq 10^{-6}$ |
| 1                 | $< 10^{-6}$                    |

Table 6: Full list of the Engineering Requirements

| No. | Engineering Requirement | Target Value |
|-----|-------------------------|--------------|
| 1   | Attach to bed           | 15 lb force  |
| 2   | Split into sections     | 6 sections   |
| 3   | Plastic material        | PLA          |
| 4   | Adjustable              | 0-0.5 feet   |
| 5   | Size of device          | 6 inches     |

Table 7: Validation Plans

| Customer Requirement No. | Customer Requirement                             | Validation Method | Validation Procedure No. |
|--------------------------|--|-------------------|--------------------------|
| 1                        | Prevent entanglement and tension from occurring  | Demonstration     | VP-1                     |
| 2                        | Easy to use                                      | Demonstration     | VP-2                     |
| 3                        | Reduce the time it takes to transport patients   | Demonstration     | VP-3                     |
| 4                        | Provide a more sterile environment               | Demonstration     | VP-4                     |
| 5                        | Provide clarity in organization of tubes/wires   | Inspection        | VP-5                     |
|                          |  | Demonstration     | VP-6                     |
| 6                        | Be affordable/competitive financially            | Market analysis   | VP-7                     |
| 7                        | Not obstruct the doctors/nurses from giving care | Demonstration     | VP-8                     |

Table 8: Procedure for each validation

| Validation Procedure No. | Validation Procedure  |
|--------------------------|---|
| VP-1                     | <p><b>Summary:</b> Simulated use test in which the amount of entanglement with and without the device in use will be measured.</p> <p><b>Set-up:</b><br/> Equipment required: Simulated hospital bed, tubing, IV pole and camera<br/> Configuration: A simulated patient sits in the bed and is attached to tubing without the device and with the device in use.</p> <p><b>Procedure:</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Verify set-up is complete and correct without the device in use</li> <li><input type="checkbox"/> Ask the patient to complete a series of movements without the use of device</li> <li><input type="checkbox"/> Record and take pictures of the degree of entanglement that occurs</li> <li><input type="checkbox"/> Repeat the steps when the device is in use</li> </ul> <p><b>Acceptance Criteria:</b> The lines do not become tangled or are significantly less tangled with the device in use.</p>  |
| VP-2                     | <p><b>Summary:</b> Simulated use test in which the device's ease of use will be measured.</p> <p><b>Set-up:</b><br/> Equipment required: Simulated hospital bed, tubing, IV pole, and tape.<br/> Configuration: A hospital bed sits on one side of a room. On the opposite side, a zone designated with tape will be established. An IV pole and table with line management device is stationed next to the bed.</p> <p><b>Procedure:</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Verify set-up is complete and correct without the device in use</li> <li><input type="checkbox"/> Ask the medical volunteer to complete a series of actions.</li> <li><input type="checkbox"/> Ask the medical volunteer to fill out a questionnaire.</li> </ul> <p><b>Acceptance Criteria:</b> The average score on the given questionnaire is equal to or above a 4/5</p>   |
| VP-3                     | <p><b>Summary:</b> Simulated use test in which the caregiver will be timed moving a patient to another bed without the device in use and with the device in use.</p> <p><b>Set-up:</b><br/> Equipment required: Simulated hospital bed, tubing, IV pole and stopwatch<br/> Configuration: A simulated patient sits in the bed and is attached to tubing without the device and with the device in use. The same series of movements will be used to artificially tangle the lines with and without the device in use.</p> <p><b>Procedure:</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Verify set-up is complete and correct without the device in use</li> <li><input type="checkbox"/> Complete the series of movements to potentially create the artificial tangle</li> <li><input type="checkbox"/> Ask the caregiver to begin transferring the patient to another bed and start the timer</li> <li><input type="checkbox"/> End the timer after the caregiver is done transferring the patient</li> <li><input type="checkbox"/> Record the results and repeat the steps when the device is in use</li> </ul> <p><b>Acceptance Criteria:</b> The time it takes to move the patient with the device in use is less than the time it takes to move the patient with the device in use.</p> |



|      |  |
|------|--|
| VP-4 | <p><b>Summary:</b> Simulated use test in which the free movement of the tubing will be recorded</p> <p><b>Set-up:</b></p> <p>Equipment required: Simulated hospital bed, tubing, IV pole, 2 bed sheets, camera and paint</p> <p>Configuration: The tubes will be covered in paint in specified positions. The tubing will be pushed around to simulate the degree of movement. The markings of paint on the bedsheet will record how freely the tubes move with and without the device in use.</p> <p><b>Procedure:</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Verify set-up is complete and correct without the device in use</li> <li><input type="checkbox"/> A volunteer will complete a series of movements to push the tubing around and simulate the degree of movement that can occur</li> <li><input type="checkbox"/> Record and take pictures of the placement of paint that gets on the bed sheet</li> <li><input type="checkbox"/> Repaint the tubes and replace the bedsheet</li> <li><input type="checkbox"/> Repeat the steps when the device is in use</li> </ul> <p><b>Acceptance Criteria:</b> The movement of the lines with the device in use must be less than the movement of the lines without the device in use.</p> |
| VP-5 | <p><b>Summary:</b> Simulated use test in which a caregiver will use the device in a simulated environment and answer questions about the device's clarity.</p> <p><b>Set-up:</b></p> <p>Equipment Required: simulated hospital bed and tubing.</p> <p>Configuration: a simulated patient sits in the bed and is attached to the tubing.</p> <p><b>Procedure:</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Verify set-up is completed and correct.</li> <li><input type="checkbox"/> Ask the caregiver to place the tubes in the device.</li> <li><input type="checkbox"/> Ask the caregiver to work around the equipment as they would for an average check-up.</li> <li><input type="checkbox"/> Give the caregiver a questionnaire regarding the clarity provided by the device.</li> </ul> <p><b>Acceptance Criteria:</b> The caregiver must be able to complete the tasks and rate the device favorably on the questionnaire.</p>   |
| VP-6 | <p><b>Summary:</b> Visual inspection to confirm the product includes the correct labels.</p> <p><b>Set-up:</b></p> <p>Equipment Required: none.</p> <p>Configuration: N/A.</p> <p><b>Procedure:</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Train a visual inspector on the correct locations and types of labels.</li> <li><input type="checkbox"/> Have the visual inspector examine the device to locate the labels.</li> <li><input type="checkbox"/> Have the visual inspector record their findings</li> </ul> <p><b>Acceptance Criteria:</b> The inspector must find and report all labels. All labels must be correct.</p>   |
| VP-7 | <p><b>Summary:</b> Market analysis to compare our device to similar devices.</p> <p><b>Set-up:</b></p> <p>Equipment Required: Excel.</p> <p>Configuration: Decision matrix.</p> <p><b>Procedure:</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Verify correct software is utilized.</li> <li><input type="checkbox"/> Verify the matrix includes sections for Manufacturing Costs, Material Costs, and Shipping Costs.</li> <li><input type="checkbox"/> Enter details of our device into the matrix.</li> <li><input type="checkbox"/> Enter details of 2 competitor's products into the matrix.</li> <li><input type="checkbox"/> Record the results.</li> </ul> <p><b>Acceptance Criteria:</b> Our device must be the same or better than the competitors' devices.</p>   |
| VP-8 | <p><b>Summary:</b> Simulated use test in which a caregiver will use the device in a simulated environment and answer questions about the device's obstruction.</p> <p><b>Set-up:</b></p> <p>Equipment Required: simulated hospital bed and tubing.</p> <p>Configuration: a simulated patient sits in the bed and is attached to the tubing.</p> <p><b>Procedure:</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Verify set-up is completed and correct.</li> <li><input type="checkbox"/> Ask the caregiver to place the tubes in the device.</li> <li><input type="checkbox"/> Ask the caregiver to work around the equipment as they would for an average check-up.</li> <li><input type="checkbox"/> Give the caregiver a questionnaire regarding the level of obstruction caused by the device.</li> </ul> <p><b>Acceptance Criteria:</b> The caregiver must be able to complete the tasks and rate the device favorably on the questionnaire.</p>  |



Table 9: Validation Report

| Validation Procedure No. | Validation Name | Passed | Failed | Comments   |
|--------------------------|-----------------|--------|--------|--|
| VP-1                     | Simulation1     | X      |        | N/A  |
| VP-2                     | Simulation2     | X      |        | N/A  |
| VP-3                     | Simulation3     | X      |        | N/A  |
| VP-4                     | Simulation4     | X      |        | N/A  |
| VP-5                     | Inspection      | X      |        | N/A  |
| VP-6                     | Simulation5     | X      |        | N/A  |
| VP-7                     | Market Analysis | X      |        | N/A  |
| VP-8                     | Simulation6     |        | X      | Device was rated 3/5, not meeting the 4/5 requirement. |

Table 10: The Risk Summary Table gives an overview of the key risks and how they were mitigated. This includes the name of risk, risk priority number (RPN), potential risks, risk level, and how risks were mitigated.

| Name of Risk  | Summary of Risk  | RPN | Risk Level | Risk Mitigation   |
|---|--|-----|------------|---|
| Patient/staff trips on device                         | Device falls on floor and patient/staff trips on device                          | 18  | AO         | Make second safety cable, device made in orange color             |
| Patient/staff receives minor injury from using device | Fixation or use of device causes injury to patient or staff                      | 18  | AO         | Device is low-weight with filleted edges, attaches with velcro    |
| IV tube holding mechanism fails                       | IV tubes fall out of slots and pose a tripping hazard or pull at insertion sites | 12  | AO         | Include instruction manual, label for max/min diameter of tubes   |
| Device size does not match the bed size               | Device does not fit properly to bed and injures patient/staff                    | 9   | AO         | Adjustable Velcro and device width accommodates various bed sizes |
| Device restricts fluid flow                           | Too tight on IV lines and slows fluids   | 6   | AO         | Label and instructions for max/min diameter tubing allowed        |

|  |   |   |    |  |
|--|---|---|----|--|
| Device attachment mechanism on bed fails | Device falls or patient knocks device off bed and tangles tubing, poses a tripping hazard and tugs at insertion sites | 4 | AO | Device is manufactured with low weight, edges filleted |
| Device is broken by user                 | Device does not function properly- device falls, does not hold tubes injuring staff/patient                           | 4 | AO | Detailed instruction manual included                   |