



**Department of
Biomedical Engineering**
UNIVERSITY OF WISCONSIN-MADISON

Bed-Mounted Modular Training Surface

BME 400

Section 302

Preliminary Report

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Abstract

Clinical simulation programs are a resource that can be used by students to help develop their skills when it comes to clinical application. The main goal of these programs is to use task trainers and training models to develop skills and knowledge, while also elevating confidence when it comes to translation in a real-life setting. However, due to limited funding, many of the programs are neglected and not fully fledged, leading to many of these programs not having enough surface space to perform specific operations. Current designs to resolve these problems are reported to be too bulky and hard to store. With this, the team has tried to solve this problem by creating a design for the specific ProCuity beds used by the University of Wisconsin-Madison School of Public Health that can expand and retract depending on the patients' needs. This design will be easily stored in its retracted form and attached to the mattress when unfolded, matching the height and width of the mattress for use in any required training.

The goal of this design is to make a surface that can be attached to the bed and easily transferred between designs, can be used universally due to its lightweight, and be stable enough to facilitate the task trainers that will be operated on it.

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Introduction

Clinical simulation programs are dedicated training facilities that work to train healthcare students in practicing technical skills. There are over 400 simulation centers within the United States that vary in both size and operational environment [1]. A multidisciplinary group of students who participated in these programs was surveyed and reported that the program elevated their knowledge, skills, and confidence when it came to the application of the procedures. The team's client, Shannon DiMarco, operates the procedural training program at the School of Medicine and Public Health at the University of Wisconsin Madison. They primarily focus on using models and task trainers to train medical students in pediatric care, specifically line insertions, suturing, and laryngeal airway insertions. However, the client finds the space provided to be unsatisfactory due to the diverse equipment they need, leaving little room for the tables needed to perform the training.

The current solution for this dilemma is simple folding tables; however, the client finds these still too bulky and hard to store. The current spaces at the School of Medicine use ProCuity beds within their facility; with these taking up a large portion of the space, the client requested a simulation surface that fits onto the bed to provide a surface for the task trainers and, in addition, can be easily stored when needed. Due to simulation program investments being neglected because institutions that host these programs focus on physical equipment rather than faculty training, there are very few products on the market that fit the client's needs [2]. Products on the market are focused on record management and patient care, as opposed to providing a large and compactable surface that training operations can be performed on.

The client requests a workstation that is lightweight and secure to conduct procedural training. With the current solution lacking the ability to be hosted within the compact simulation rooms, they provide a hazard and limit space for training. The team will create a workstation that easily compacts for storage, attaches to the bed, and meets desired constraints for sanitation and safety.

Background

Clinical simulation programs aim to provide an environment in which practicing students can train skills to be applied to real procedures. Not only are the training robust and realistic, but they also prepare for actual patient care scenarios [3]. The main draw of these programs is the ability to immerse students in a real-time operating environment. Facilities will come equipped with scrub stations, operating rooms, trauma rooms, and many other set-ups that holistically assist in the development of knowledge as well as hard skills needed.

The school of medicine and public health mainly focuses on training residents on pediatric procedures. The training that the client provides includes line insertions, suturing, and laryngeal mask airway insertions. They are all very critical procedures, and with patient safety being

directly correlated to the professional's experience, this makes these procedural training highly important. One great example of the critical importance of simulations would be line insertions. Line insertions are very precise operations in which catheters are inserted into a large vein, usually the jugular vein or subclavian vein. This process comes with inherent risk, with the possibility of arterial puncture, catheter-associated bloodstream infection, and possible death [4]. All of these risks diminish when it comes to operator experience, further emphasizing the need for more procedural training.

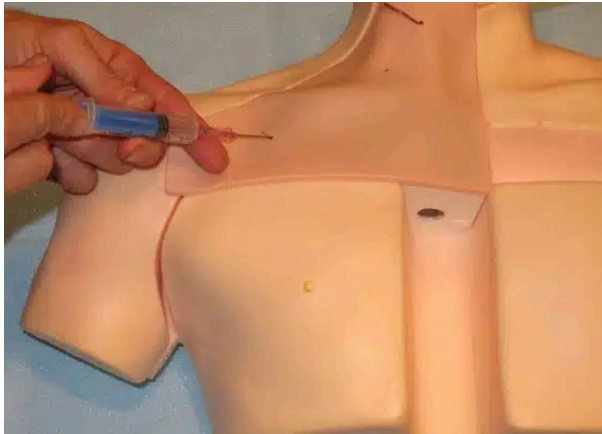


Figure 1: Line Insertion task trainer [5]

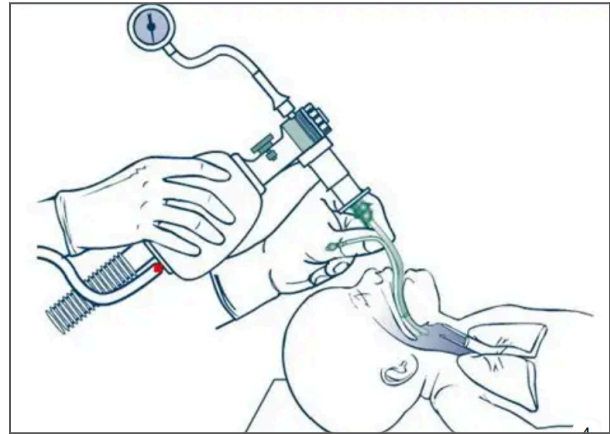


Figure 2: Laryngeal Mask Airway Insertion Model [6]

With such a diverse offering, one of the drawbacks of these programs is funding. The aim of the programs is to get trainees fully immersed in every aspect of a practicing health care professional. This leads to it being hard to host such a large operation with very finite funding that is available within the world of procedural training [7]. This leads to heavy burdens or downsizing in the facilities that host the clinics. The University of Wisconsin-Madison's clinical simulation program faces a problem, with Shanon Dimarco highlighting that the program is currently suffering due to the amount of space allotted for task trainer operations. Their proposed solution to the problem is a simple white folding table. However, they are still bulky, not easily stored, and are a tripping hazard.

The client has requested a simulation surface that acts as a simulation surface that can be used for operating on models and task trainers, be attached to the ProCuity beds that are used within the facility, be easily compatible and transferable between designs, as well as be easily used by both mentors and students. By optimizing the amount of space within the program, the hope is to maximize the amount of development accessible to students and allow for more hard skills when entering into a clinical setting.

Preliminary Designs

Trifold Corner Strap

The trifold corner strap features three equal-sized panels, attached by piano joints in alternating directions to fold into one neat stack. In order to prevent fluid leakage, a thin silicone sheet will be placed over the entire surface, which will easily fold and stretch with the panels. The method of securing the surface to the mattress will be done with 4 elastic straps, one on each corner.

These straps will easily slip under the corners of the mattress, preventing movement in all directions. This design will also feature a compact, retractable handle, allowing for briefcase-like carrying when in its folded state. Dimensions will be 36" (91.4cm) width, 80" (203cm) length, and ¼" (0.635cm) thickness.

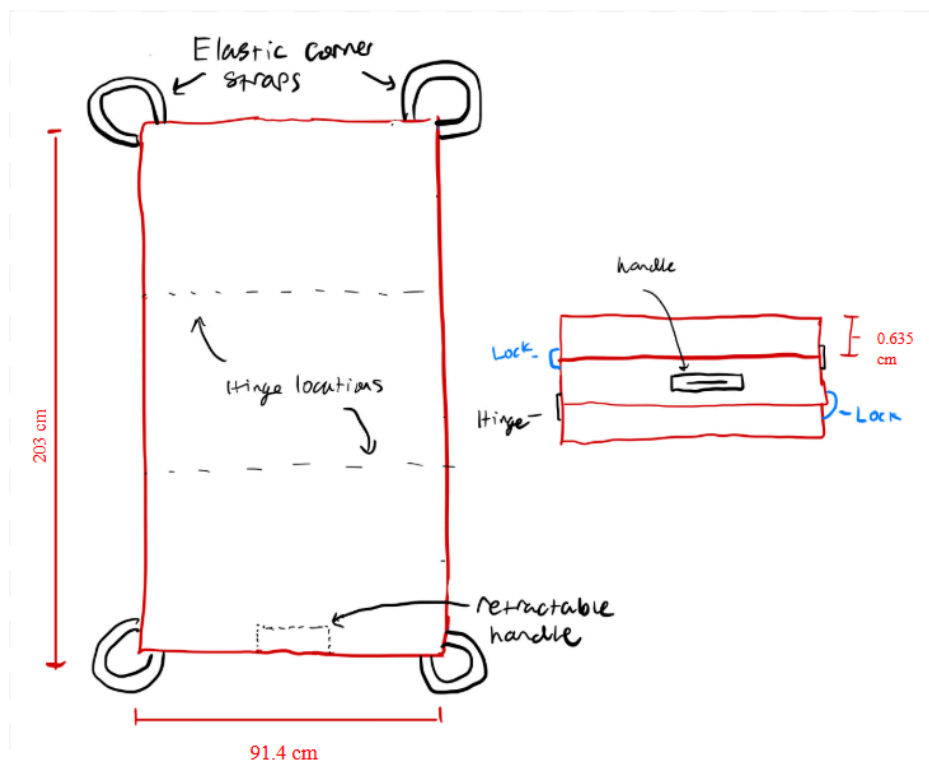


Figure 3: Trifold Corner Strap Sketch

Bifold Mattress Cover

The bifold mattress cover will prioritize the mattress in terms of attachment as well as security. It will feature a thin sheet that spans the length and width of the bed. The sheet will have a piano hinge at half the height, allowing for the simulation surface to be able to be compacted to half its length. Additionally, attached to the longer sides will be wings of the same thickness that will wrap around the mattress. By lifting the mattress, the simulation surface will be able to slide the length of the mattress, and when placed on the bed, provide a level and stable station in which procedural training can take place.

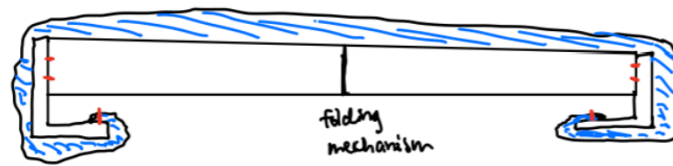


Figure 4: Bifold Mattress Cover Sketch

Buckle Bedframe

This design features three panels of 0.635cm thick polypropylene that are sewn into a sterilizable fabric. These panels will fold along internal panel hinges to allow for compact storage. When unfolded, the mat will lay flat over the length and width of the mattress to allow for maximum surface area. The mat features four buckle components along the corners, which will loop around and tighten to the bedframe. This will secure the mat to the bed, reducing any risk for slipping during use.

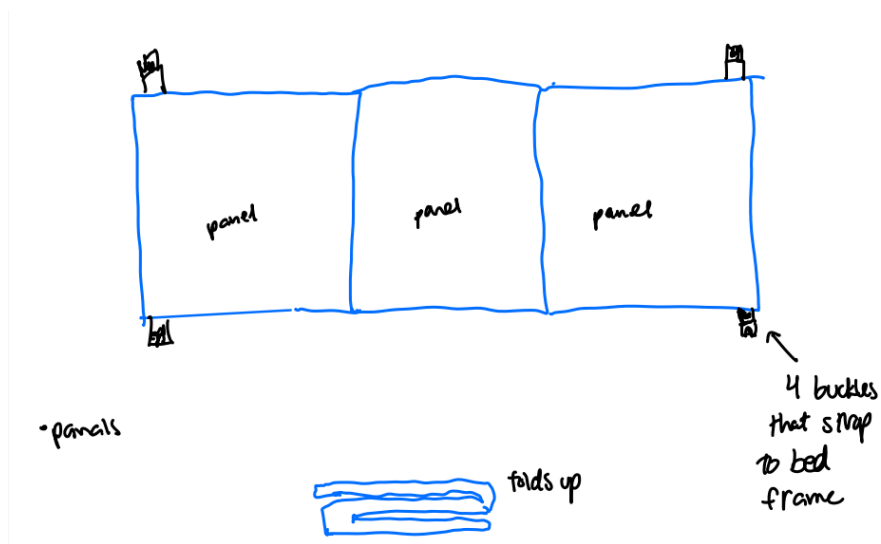


Figure 5: Buckle Bedframe sketch

Preliminary Design Evaluation

Surface Design Evaluation

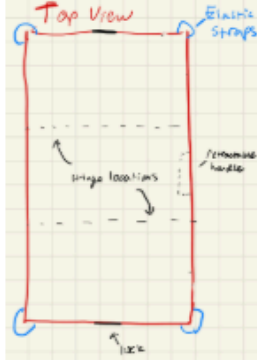
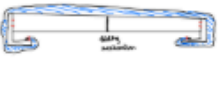
Criteria	Weight	Design 1 Trifold Corner Strap 		Design 2 Bifold Mattress Cover 		Design 3 Buckle Bedframe 	
		Score (5 max)	Weighted Score	Score (5 max)	Weighted Score	Score (5 max)	Weighted Score
Compactibility	30	5	30	3	18	5	30
Ease of Use	25	4	20	2	10	3	15
Secureness	20	3	12	5	20	3	12
Ease of Fabrication	15	3	9	3	9	4	12
Safety	10	5	10	5	10	5	10
Total	100	81		67		79	

Table 1: Preliminary design matrix

The simulation surface design matrix compares three different designs. These designs were then ranked according to set criteria by the team. The criteria are weighted (assigned out of 100) according to the client's priorities for usage within the program's space. The highest weighted score for each category is highlighted in green.

Criteria for Design Matrix

Compactability

Compactability is the ability for the simulation surface to go from an orientation that lays over the mattress to one that is easily able to take up much less space and be stored. The Clinical Simulation Program's main constraint to providing the most effective training is due to their limited space. Without room to host a table in their simulation spaces, the design must condense into a much smaller orientation in addition to providing a space to perform procedural training on models. This left compactability high on the team's list of priorities, with a weight of 30/100.

Ease of fabrication

The ease of fabrication refers to how easy the material can be processed in order to fabricate the design. The team has access to University of Wisconsin-Madison fabrication spaces, which include machinery that will be employed for fabrication of prototypes and final designs. With this, the team has to be cognizant of the resources that are available, and the fabrication process will be a lower priority of the design, with a weight of 15/100.

Ease of Use

Weight refers to the overall maneuverability and application of the simulation surface. Since transferring between a compact and fully extended design will be conducted by either the trainers or the students, the design must easily be picked up and moved. The Clinical Simulation team has requested that the design be no more than 11.34kg, allowing anyone within their team to apply or compact it easily. This places ease of use relatively high on our priorities, with a weight of 25/100.

Secureness

Secureness pertains to the ability of the design to fit securely over the bed. When the simulation surface is being used, it will be supporting training models for pediatric airway openings, suturing, and many others that will require the surface to be stable and level. Due to this, the design must contain a novel attachment method that securely attaches to the Procuity Lex and ZX beds the Clinical Simulation Program uses. Considering this, security will be one of our top priorities, ranking 20/100.

Safety

Safety describes the ability to operate the simulation surface going from its compact to full length design. With this, the surface must be able to fold relatively easily without risk or hurting the person operating the device, in addition to having an ergonomic design in which edges or sides can not maim the users while it is being converted between designs. With the scope of our project, relatively to the other criteria the safety is of low priority at 10/100.

Conclusion

The final design selected is the Trifold Corner Strap. This design was chosen because of its exceptional performance across the criteria outlined in the design matrix, giving it the highest

score of all three designs. After reviewing the designs, it was evident that a trifold design would allow it to be most compactable. Implementation of the trifold design allows to maximize the amount of space within the procedural training rooms and as a result be able to run trainings more efficiently. By dividing the surface sheet into three even sections, and the utilization of piano joints, the trifold corner design was ranked highest, as it would be able to fold into a third of its original size in addition to providing a portable surface that can be attached to the beds. Since both design one and three utilized this design, they were ranked highest. Design two was compactable, but it only halved the surface height, leading to it being ranked a little lower. Each design either used a strap to secure the simulation surface or utilized the mattress itself and the geometry of the design to secure it. Design one and three were not rated very highly as it was assumed that the straps could lead to the simulation surface moving if too much pressure was put on it depending on the training being conducted. Design two is geometrically secured by designing the shape around the mattress itself. This provides a very rigid attachment method and would be most stabilized once inserted onto the bed.

Material Evaluation

Criteria	Weight	<u>Material 1</u> HDPE		<u>Material 2</u> Polypropylene		<u>Material 3</u> Aluminum (6061-T6)	
		Score (5 max)	Weighted Score	Score (5 max)	Weighted Score	Score (5 max)	Weighted Score
Sterilizability	35	5	35	5	35	5	35
Weight	25	5	25	5	25	2	10
Durability	20	3	12	4	16	5	20
Cost	10	5	10	5	10	2	4
Ease of Fabrication	10	5	10	5	10	3	6
Total	100	92		96		75	

Table 3: Design Matrix of Materials

The material matrix compares three different materials. These designs were then ranked according to set criteria by the team. The criteria are weighted (assigned out of 100) according to the client's priorities for usage within the program's space. The highest weighted score for each category is highlighted in green.

Criteria for Design Matrix

Sterilizability:

Sterilizability refers to the cleaning of surfaces after training and procedural practices. The Clinical Simulation Program uses training models in which replicant bodily fluids are used. The simulation surface will never come in contact with bodily fluids, and because of this, FDA regulations for sanitization of medical devices do not have to be considered. Since the only sterilization will come from rudimentary cleaning, this is a relatively low priority,

Weight:

The weight refers to the weight of the material. The material being used in the design will go into the design. Regardless of the design, utilization of a material that is lightweight will assist in the goal of reducing the weight to be around 10 lbs. To make sure that the design is as universally usable as possible, this is a high priority, and given a weight of 25/100.

Durability:

Durability refers to the amount of weight the material can support. The operating service does not need to support much weight. Since the surface will be used to assist in training simulations, the client stated that the models and the pressure applied by training is negligible and do not have to be a concern. This makes this a low priority, ranking 20/100.

Cost:

The cost pertains to the cost of the material. Material cost will be used in the final design. With this, the Clinical Simulation Program provides \$2000. Considering the cost of all of the considered materials and large funding given, cost is ranked at a low weight of 10/100.

Ease of Fabrication

The criteria for the ease of fabrication portion of the material refers to how easily the material will be to work with. The team's final design will require the material to be cut and formed into a foldable mattress cover which can accurately act as an operating table for pediatric airway procedural training. Given the complexity of the design is relatively low, the team does not expect the materials to undergo significant alterations. For this reason, the ease of fabrication was weighed with a score of 10/100.

Conclusion:

The three material options that the team considered were high density polyethylene (HDPE), polypropylene, and 6061-T6 aluminum. HDPE is a strong, chemically resistant thermoplastic made from polymerized ethylene. Polypropylene is a lightweight, semi-rigid thermoplastic, with high toughness, chemical resistance, and heat resistance. Aluminum is a lightweight metal used in construction, transportation, and everyday products due to its high strength, corrosion resistance, and ductile properties.

After evaluating material considerations alongside client specifications and requirements, the team has determined that polypropylene is the most suitable material for the base of the design. Polypropylene scored highly across all categories. This final design will act as an operating table for students in the clinical lab simulation. For that reason, durability in the form of stiffness and strength is important. Polypropylene has a tensile strength of 30-50MPa [1], while HDPE has a tensile strength of 31.7Mpa [2]. Lastly, aluminum has a tensile strength of 310MPa [3]. While all of the materials possess substantial tensile strength, aluminum has a density of 2.7g/cm³, which would yield a final design weight of 70.2lbs. That is significantly outside of the specifications. Additionally, the cost of aluminum is far greater than the two thermoplastics, making it less accessible and compelling as a material selection. The density of HDPE and polypropylene are 0.95g/cm³ and 0.9g/cm³ respectively. While these densities will both yield a design within the weight range, polypropylene's stiffness and creep resistance properties are slightly more advantageous for the team's design. Sterilizability is another important factor in the team's design. All three materials are chemically resistant, and therefore scored similar in that section.

Fabrication

Materials

The materials selected for the design were chosen to ensure functionality and durability, while remaining within budget and weight specification. The entire device must weigh less than 11.34kg and withstand repeated transportation from its compact storage configuration to extended deployment as per Appendix I. Polypropylene panels will be used for the base component of the device. This material was selected for its light weight, high strength, and resistance to creep. It can be specially ordered with the necessary dimensions. Piano hinges will be installed along the width of each panel, secured using a through bolt. This will provide the mechanism for alternating folding of the panels. A thin silicone sheet will be attached to the base of the model to prevent leakage of simulated fluids while not inhibiting the folding mechanism. Adjustable fabric straps will be secured to each corner of the surface when extended, which will wrap around the corners of the mattress, similar to a fitted bedsheet. For a detailed materials list see Appendix II.

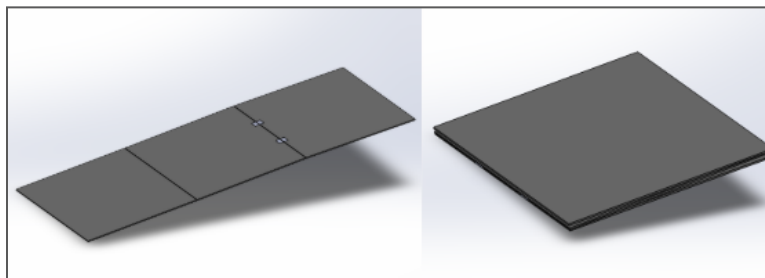


Figure 6: SolidWorks Drawing of Final Design

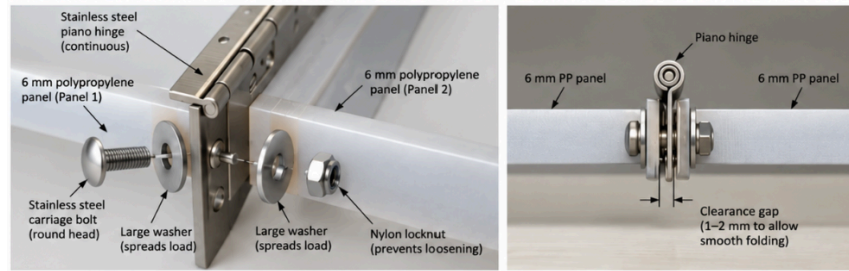


Figure 7: Image generated using ChatGPT depicting piano hinge mechanism for attachment using through-bolt

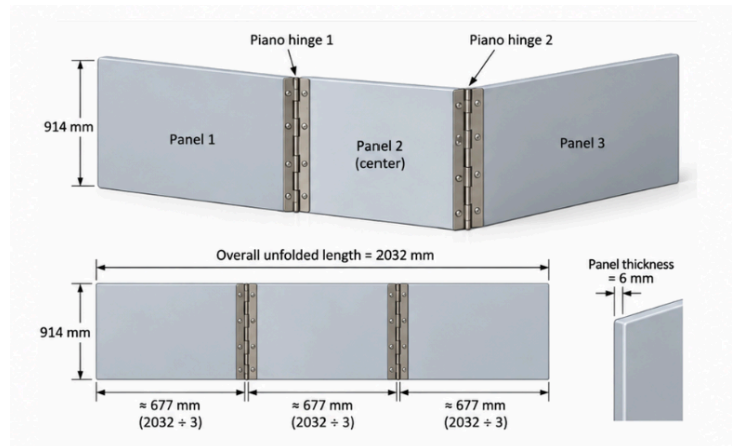


Figure 8: Image generated using ChatGPT Featuring the Dimensions of the Final Design

Methods

The fabrication of the polypropylene base will be very straightforward. After the team purchases the polypropylene panels, piano hinges, and through-bolts to secure the hinges to the panels, the parts will be assembled. Once the base has been successfully fabricated to compact $\frac{1}{3}$ of its length (as per Appendix I), the team will secure the protective silicone sheet. The mechanism for securing the silicone sheet to the panels has not yet been determined, and will likely require guidance from the Design Innovation Lab. Finally, the adjustable straps will be ordered and secured to the corners of the base when extended.

Testing and Results

Testing

Testing for the Trifold Corner Strap will begin before final fabrication of the device is completed, as well as after. The testing will serve as a way to gauge the stability and durability of the device's securement components, as well as a way to evaluate the ease of use or effectiveness of the surface. Tensile testing will be performed on the adjustable straps prior to their fixing to the

surface. This test will provide the team with a Young's Modulus graph where the yield strength can be determined, as well as the elongation. The team expects the straps to maintain elasticity and withstand a tensile force significantly greater than the force it is expected to undergo while in use. It is important to note that while maintaining elasticity is important, because the straps are adjustable, they will be able to tighten around the corner of the mattress securely, despite any plastic deformation. After the initial fabrication of the device, the team will conduct a comprehensive survey from students in the Clinical Simulation program to assess the ease of use in deployment of the device, as well as effectiveness in acting as a clinically adjacent operating surface.

Testing Protocol



Figure 9: Image of MTS Criterion 43.504 to be used for Tensile Testing [11]

- I. *Tensile Testing using MTS Criterion 43.504*
 - A. Cut fabric strap specimen to the required dimensions and record its width, thickness, and gauge length. Inspect specimen for fraying, cuts, or other defects before testing.
 - B. Turn on the MTS Criterion 43.504 and open the appropriate tensile-test method in MTS TestSuite. Confirm that the selected load cell and grips are suitable for the expected strap strength.
 - C. Clamp the fabric strap securely between the upper and lower grips, keeping the specimen centered and aligned with the loading axis, with $\frac{1}{4}$ inch space between the top and bottom grip surfaces and the specimen. Ensure sufficient grip length to prevent slipping during the test.
 - D. Attach the MTS axial extensometer within the gauge section of the specimen and verify that it is aligned with the loading direction. Zero the load and strain channels before beginning the test.

- E. Start the tensile test; the specimen will be loaded in tension. Continuously record force, crosshead displacement, and extensometer strain throughout the test.
- F. If the software indicates the extensometer strain has been maxed, remove it before continuing the test to failure.
- G. Continue loading until the fabric strap ruptures or another specified failure criterion is reached. Record the maximum tensile force and the observed failure location and mode, including rupture, tearing, grip failure, or slippage.
- H. Use the recorded force and specimen dimensions to determine tensile stress,

$$\sigma = \frac{F}{A_0},$$

and use extensometer data to determine strain,

$$\epsilon = \frac{\Delta L}{L_0}.$$

- I. Report the maximum load, tensile yield strength, strain at failure where reliably measured, and any failure modes.

II. *Usability and Satisfaction Testing*

- A. Using a student test subject from the clinical simulation lab, have the subject deploy the prototype from its compact position, and set the surface up on the hospital bed.
- B. Once the test subject has set the prototype into place, have them perform a clinical simulation procedure which requires the use of simulated fluids.
- C. Finally, have the test subject clean the surface using chemical disinfectant wipes, and close the surface back into its compact configuration.
- D. After the test subject has had the chance to test the surface, offer a comprehensive survey regarding effectiveness of the device during the simulation procedure, and ease of use during the deployment and storing.
- E. Repeat steps A-D with different test subjects until you have 5-10 data entries to document. Ensure all test subjects are students of the clinical simulation lab and have used the previously implemented simulation surface (folding table). Include data regarding the prior clinical simulation experience of each subject.

Results

Once the testing is conducted, the results will be recorded and organized in the charts below. Additionally, from the first testing method, a Young's Modulus graph will be provided with labels identifying the yield strength and elongation.

Survey Data Collection:

Average Ease of Use During Deployment and Storage of the Device (on a scale out of 10)	Average Satisfaction during Simulation Procedure (on a scale out of 10)

Table 3: Collection and analysis of survey data from students in simulation program

Discussion

Considering this design will have multiple points of connection, all points must be secure and meet their desired function. The design must be secured flush to the hospital bed during use, and simple enough to remove following use. Additionally, the straps used to secure the design must maintain their form and material properties throughout multiple uses without compromising their connection to the rest of the design or ability to secure the design. This design will ultimately be used to train procedures, and it will be of utmost importance that the design can be easily sanitized between usage intervals and does not induce difficulties during demonstration.

Conclusions

The simulation center is relatively small, and developing a stable workstation that maximizes floor space available will be crucial to demonstrate immersive procedures. Current methods being used for simulation are too bulky and difficult to store, leaving minimal space for accessing any components needed for simulation. In order to resolve this issue, the team is tasked with forming a design that will lay against the surface of their hospital bed; remaining fully secure throughout the duration of their simulation. The surface will be constructed from polypropylene to maintain a lightweight, rigid structure that can withstand routine chemical sanitation. Upcoming testing conducted will be used for analyzing the corner straps elasticity and deformation resistance, as well as usability testing. These tests will be important in collectively determining if any adjustments need to be made in order for the design to meet the requirement of 5 years in service without user difficulty. In addition to the base of the structure, the team will also be adding an electrical component to the device that will connect an outlet from the wall to the workstation. Also, it would be ideal for this feature to include spill-resistant outlets and USB-C ports for applications involving task trainers, tablets, or small cameras.

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Appendix

Appendix I: Product Design Specifications

Function:

The team's client, Shannon DiMarco from the Clinical Simulation Program at UW School of Medicine and Public Health, requests that a specialized, bed-mounted workstation that temporarily converts a standard hospital bed into a stable, ergonomic procedural platform be prototyped. Clinical simulation centers rely heavily on hands-on procedural training to prepare for real-world patient care. Specialized simulation suites often replicate acute care environments however, they frequently face severe spatial constraints, leaving insufficient room for dedicated, freestanding procedural tables alongside the patient bed. Current solutions like standard folding tables or rolling utility carts are poorly suited for this environment. They lack structural stability, take up valuable floor space, and do not securely interface with clinical equipment. The goal of this project is to create a device that can securely attach to existing bed architecture without damaging hospital equipment, which will allow healthcare trainees to perform procedures such as line insertions, suturing, and airway management in the constrained environment. The device must support static and dynamic loads of medical task trainers, withstand routine chemical sanitation, and feature a mechanism for rapid deployment and compact in-room storage.

Client requirements:

- The product should attach securely to a standard hospital bed, creating a hard surface for procedural learning.
- The product should be made of a material that will resist simulated fluids (fake blood and lubricants), as well as sanitization chemicals.
- The product must be light, easily transportable, and contain a folding component for compact storage.

Design requirements:

1. Physical and Operational Characteristics

a. Performance requirements

The bed-mounted modular procedural surface (sim-surface) will be used by UW-Madison's clinical simulation students. Pediatric procedural training will be performed on the surface, using anatomical models. The surface should be able to bear the weight of the tools used throughout the simulation, which should not exceed 4.5kg. [12] The design must securely attach to a standard hospital mattress, and remain securely attached and static once installed. The final design must store in the limited space available to the simulation room, compacting to 1/3 of its

length (27inches), and must withstand frequent transportation between storage and training sessions.

b. Safety

The final design must not include any sharp edges that can cause harm to the user who is practicing on the sim-surface. Furthermore, it must securely attach to the mattress and remain static during use, thereby minimizing the risk of injury if the surface were to move during training. Additionally, the material that is utilized for the surface must abide by applicable FDA regulations.

c. Accuracy and Reliability

The final design must span the full width and length of the bed, and contain a mechanism for attaching to the bottom of the mattress. The final design must contain a feature that allows for compact storage, but does not pose any risk for leakage of liquids onto the mattress. Additionally, this device should improve the working conditions for the students performing the procedural training.

d. Life in Service

The client wants the simulation training surface to be durable and to last for many years through numerous clinical simulations. The device is not expected to experience a large load, and therefore should not be subject to significant fatigue. The target life in service is 5 years.

e. Shelf Life:

When not in use, the training surface should be able to switch to a compact design that will be stored within the limited space of the procedural training room. The final design must be able to withstand room temperature conditions and must be able to stay in storage for the entirety of its life in service.

f. Operating Environment:

The training surface should be directly attached to the bed over the mattress, establishing a stable workstation in which different pediatric training models can be used. The training surface will have simulations that will expose it to liquids and exudates that resemble bodily fluids. The average person should be easily able to switch between the full-size and compact design while easily applying it to the surface.

g. Ergonomics

The surface must be able to fold and compact in a way that facilitates easy transport by a single person. This will involve the surface folding to a size that is not awkward to maneuver, as well as giving the individual moving the surface a clear and easy way to hold it.

h. Size

While unfolded, the surface must completely span the top of a standard hospital bed mattress. Most hospitals use mattresses that are 36" wide and 80" long. When compact, the surface should be able to be stored easily in a confined space, likely a storage closet. It should compact to 1/3 of its length, or approximately 27". [13]

i. Weight

The client has specified that the surface should weigh no more than 11.34kg in order to facilitate easy transportation.

j. Materials

The surface is intended to be used for a variety of medical simulations involving fake blood and other fluids. Taking this into consideration, the material should be relatively water-resistant and easy to clean and reuse over the course of its lifespan. The material should also be lightweight in order to comply with the 11.34kg weight limit.

k. Aesthetics, Appearance, and Finish

This surface will be used in professional medical settings and should reflect that in its appearance. A neutral, static color would be best, especially one that easily contrasts with the simulation dummies and fluids that will be used on it.

2. Production Characteristics

a. Quantity:

The client expects one operating surface that transitions between a full table design and a compact stored design. In addition, the client is providing the bed to which our device will need to attach.

b. Target Product Cost:

The client has given \$2000 to work with. These expenses will go toward the purchasing of materials for our prototype and final design. The finalized cost of the product will depend on the materials selected for the official design, and if the scope of our project shifts to max the operating service more intricate to facilitate procedural training that requires an electrical component.

3. Miscellaneous

a. Standards and Specifications

When considering the expectation of the product, the client requested a procedural training workstation that can be mounted to the mattress. On the workstation, students will learn how to do suturing, line insertions, and airway management, specifically for pediatric care. Considering that the operating surface we are crafting will host training models and is purely used for

educational purposes. It does not meet the following requirements to be considered a medical device per Section 201(h)(1) which states a medical device is:

An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

- (A) recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
- (B) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- (C) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The term "device" does not include software functions excluded pursuant to section 520(o). [14]

Due to this, our product will not have to adhere to medical device specifications designated by the FDA.

b. Customer

The workstation must be reusable as it is intended for multiple training simulations over extended periods of time. It should be easy to transport and set up, as well as easy to store away after use. The station will be designed to maximize space by stationing directly over the hospital bed. It is crucial for the design to be both stable and easily sterilized to remove any adverse effects during each test simulation.

c. Patient-related concerns

Training will be conducted using simulated fluids including fake blood and lubricants. Intensive sterilization such as the use of an autoclave will not be necessary for the design. Sanitization wipes and other regular cleaning materials will be satisfactory for cleaning and will be used between each simulation.

d. Competition

Per the client description of the project, the team is forced to create a training surface that will attach to the mattress of a bed to maximize space efficiency. Due to the novelty of this request, there is very little within the world of procedural training that meets the client's needs. However, the clients themselves have been trying alternative methods to accomplish these tasks.

The main method tried by the client was simple folding tables. These tables had a compact alternative design for storage and were cost-effective for limited budgets. However, the clients did not like them for multiple reasons. First and foremost, it was not stable enough for the procedural training they were conducting. In addition, even though the table did have a compact design, they believed it did not fully maximize their space.

In addition, there are workstations developed specifically for a medical space. For example, Capsa Healthcare has developed a wall-mounted workstation. This product has been actively used in patient rooms, medical and surgery departments, ICU, and many diverse healthcare environments. In addition to having flexible mounting arms and maximizing floor space, this design is ergonomic and assists in both patient and caretaker ease. However, this design fails in a few different ways. [15]

Appendix II: Materials Expense Sheet

Item	Description	Manufacturer	Date	#	Cost Each	Total	Link
Polypropylene	Material for base of simulation surface.		Have not purchased	N/A	N/A	\$0.00	N/A
Silicone Sheet	Material for chemically resistance barrier.		Have not purchased		N/A	\$0.00	
Piano Hinges	Mechanism for compaction		Have not purchased	4	N/A	\$0.00	
Adjustable Fabric Straps	Material for securing surface to mattress		Have not purchased				
					TOTAL:	\$0.00	