

# Engineering Strategies & Practice

**University of Toronto**  
**Faculty of Applied Science and Engineering**  
**APS112 & APS113**  
***Conceptual Design Specifications (CDS)***

Project #	172	Date	April 22 <sup>nd</sup> , 2021
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Project Title	Stimulus-Response Conditioning
Client	Adam Hahn, Jarett Leroux
Client Contact Person	Dominik Adamiak
Prepared By	Dominik Adamiak Christopher Jiang Crystal Jin Junandre Paul Somaita Tasnim

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## **Executive Summary**

Our clients, Adam Hahn and Jarett Leroux, want to leverage Team 172's technical background to build a device aimed at relieving a 6-year-old patient named Coal from pressure sores accrued from prolonged exposure to his bed and wheelchair. These skin injuries are commonplace for those with limited control of their limbs and are typically the result of blood flow obstruction near the area of the skin that is under pressure. The cost of treating ulcers is not sustainable for those with disabled dependents and ignoring the issue can lead to severe health defects. Our team identified the client need to be the gap in current solutions that simultaneously address sores caused by extended interactions with a bed and wheelchair.

The primary function of the device is to limit blood flow obstruction caused by prolonged pressure against the skin. For secondary functions, the device must: withstand the weight of the patient, accept operator input to initiate the procedure, reduce duration of fixed pressure against the skin, accept operator input to terminate the procedure. Affordability, comfort, and ease of use are high priority objectives due to the client's request for a device that is effective, easy to maintain, and near \$200. Lower priority goals include life expectancy, and portability which address the need for reliable solutions, that can be transferred between the bed and wheelchair with ease. Operability must not suffer from splashes and user weight up to 220lbs.

The team generated a list of 100 ideas using structured brainstorming, the SCAMPER method, and a morphological chart. We were then able reduce the number of ideas through two rounds of multi-voting and a graphical decision chart. We determined our three alternative designs to be the Modular Foam Pads, Transformable Alternating Pressure Mattress, and the Detachable/Extended Motorized Roller Pad.

The Modular Foam design consists of 30cm x 40cm pads made of pressure relieving foam where each pad can be connected by Velcro to be rearranged on beds and wheelchairs. The Transformable Alternating Pressure Mattress is composed of an air pump, 45 air cells, and valve system which inflate and deflate alternate cells to provide dynamic pressure relief on the user's body. There are gaps between every few air cells for foldability and the device can be powered by a cord or chargeable battery. The Detachable/Extendable Motorized Roller Pad is comprised of a motorized roller inside a pad with a top layer of foam, and each pad can be connected by a zipper. Ultimately, the team selected the Transformable Alternating Pressure Mattress due to its effectiveness on preventing pressure sores.

Moving forwards, the team will undergo prototyping and a series of testing such as load resistance, pressure redistribution, and battery discharge rate to determine the success of the design and report back to the clients.

## 1. Introduction

Our clients, Adam Hahn and Jarrett Leroux, students of St. Lawrence College has assigned our team to propose a design to prevent the development of pressure sores for a non-ambulatory patient. The team has identified the primary cause of pressure sores to be from prolonged pressure on the skin. This restricts the blood from circulating where the affected skin and underlying tissue gradually become damaged [1]. This report documents a detailed description of the identified problem, project requirements, the proposed conceptual design, and a proposed testing plan.

## 2. Problem Statement

Coal is a non-ambulatory 6-year-old boy that has limited control of his arms, no communication system, and requires constant care from his parents. As a result, he suffers from pressure sores. Pressure sores refer to various degrees of skin and tissue damage caused by restricted blood flow due to prolonged pressure against firm surfaces. These wounds can cause significant pain and lead to infections that extend to muscles, joints, and bones. It can be difficult to recover from pressure sores if left untreated, with complications sometimes leading to death [2].

The client seeks to prevent development of pressure sores without significantly altering household fixtures and furniture. Pre-emptive measures are preferred as they pose less health risks and are more sustainable than costly medical bills which can amount to \$3,600 per month for late-stage treatment in Canada [3]. Nearly 15.1% of Canadians in community care such as retirement centres or private homes suffer from pressure sores as they can develop quite quickly [4].

The traditional method of preventing pressure sores is to reposition the body every hour [2], which is a difficult practice to maintain for the user in focus. More modern approaches involve the use of specialized pressure relief mattresses such as the Drive Medical Alternating Pressure Low Air Loss Mattress System in Figure 1 and cushions like those manufactured by Sunrise Medical Kay Union for wheelchairs as shown in Figure 2. These solutions, though effective, are specialized for specific form factors. The client's need for a cost-effective solution that is transferable between Coal's bed and wheelchair highlights the gap that our design will address.



**Figure 1.** Example of existing pressure sore relief mattress [45]



**Figure 2.** Example of existing pressure sore relief wheelchair cushion [46].

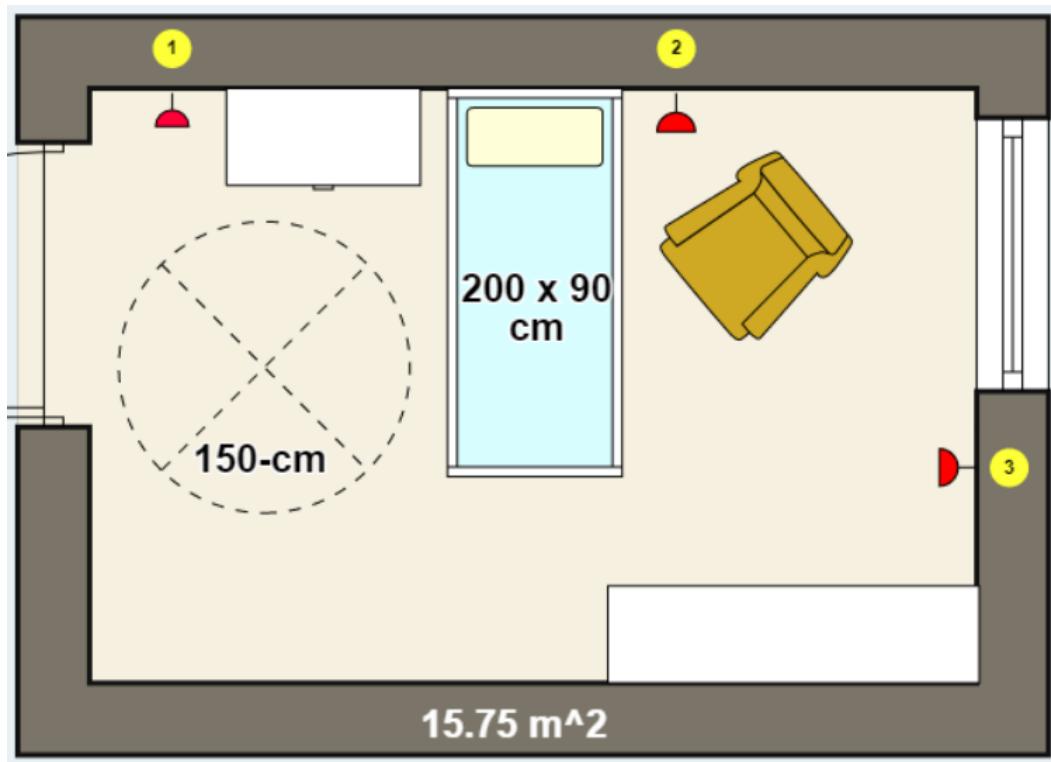
### 3. Service Environment

The service environment of this project is limited to the patient's bedroom and wheelchair. The immediate surrounding environment of the wheelchair when outside the house is unpredictable, and so was not considered. Information on the physical, virtual, and living environment was collected through the client or through alternative analysis when required (detailed in appendix D1). Figure 3 shows a conceptual floor plan for the patient's bedroom.

**Table 1.** Service environment specifics

Classification	Details
Physical Environment (see appendix D1 for more details)	<p>Room dimension: 4.5x3.5 m (14.5x11.5 ft) Room area: 15.75 m<sup>2</sup>(169 ft<sup>2</sup>)</p> <p>Bed dimensions: 200x90 cm</p> <p>Bed surface area: 1.8m<sup>2</sup> (19 ft<sup>2</sup>)</p> <p>Wheelchair dimensions, standard pediatric size [43]:</p> <ul style="list-style-type: none"> <li>• Seat width: 10-16 inches (avg. 33cm)</li> <li>• Seat depth: 8-16 inches (avg. 30cm)</li> <li>• Seat height: 8-20 inches (avg. 35cm)</li> </ul>
	<p>Approximately 20–25-degree Celsius room temperature, 30-60 % humidity, per ASHRAE [5]</p> <p>(Indoor extremes are 17-26 degrees Celsius (&lt;3 h/day) [6] and &lt;65% humidity [47])</p>
	<p>Other physical features in bedroom:</p> <ul style="list-style-type: none"> <li>• Window, curtained</li> <li>• Standard door</li> <li>• Caregiver area</li> <li>• Wheelchair area (150 cm diameter)</li> <li>• Centrally located bed</li> </ul>
Virtual Environment	<p>Wireless capabilities, bedroom: Wi-fi (2.4 &amp; 5 GHz), GSM, HSPA+, LTE, 5G, NFC, and Bluetooth.</p> <p>Other electrical devices, bedroom:</p> <ul style="list-style-type: none"> <li>• 3 standard 120V electrical power outlets.</li> <li>• 2 located adjacent to the head of the bed, one near the window.</li> </ul>

Living Things	Operator: The patient's parents/caregivers
	Malevolent being: The patient <ul style="list-style-type: none"> <li>Medical conditions experienced by patient pose a potential risk to device through inadvertent damage during sleep activities</li> </ul>
	No pets present in bedroom



**Figure 3.** Bedroom service environment mock-up, including 150-cm diameter wheelchair access circle, 200x90-cm single child bed, space for caregiver, and 3 outlets.

## 4. Stakeholders

The stakeholders in our project are the people and organisations that have varying types of interest in the development of this project. The final impact on the stakeholders, whether positive or negative, depends on how effectively this design accomplishes its treatment objectives in a manner consistent with the patient's needs and the various regulatory interests represented below.

**Table 2.** Stakeholders, and their interests

Stakeholder	Impact
Therapeutic Products Directorate (TPD)	<ul style="list-style-type: none"><li>TPD regulates and evaluates the “safety and effectiveness of diagnostic and therapeutic medical devices in Canada” [7]</li><li>Legal Interest: Protect population from unsafe medical treatments/devices.</li></ul> <p>See appendix E1-E4.</p>
Government of Ontario, Assistive Devices Program (ADP)	<ul style="list-style-type: none"><li>ADP program subsidizes 75% of the costs of medical devices for patients in Ontario with long term disabilities, including mobility aids such as “[wheelchair and bed] positioning devices (cushions, back and head supports...)” [8].</li><li>Financial/Legal interest: To ensure fair use of this program.</li></ul> <p>See appendix E5 for the process.</p>
Patient's physician/ physiotherapist	<ul style="list-style-type: none"><li>Family physician must be informed about device use on patient to ensure it does not interfere with current treatments.</li><li>They are also responsible with application of ADP.</li></ul> <p>See appendix E6</p>
St. Lawrence College, Centre for Behavioural Analysis (CBA)	<ul style="list-style-type: none"><li>Professional Interest: Need to ensure product as part of Coal's treatment follows all applicable ethical regulations in appendix E7 to maintain integrity of the program.</li></ul>

## **5. Detailed Requirements**

The following section provides a comprehensive description of the functions, objectives and constraints that define our design space. This helps to formulate the potential solutions that will prevent the development of pressure sores, which is the main problem the non-ambulatory patient currently faces.

### **5.1 Function**

The continuous pressure against rigid surfaces is the main cause of this problem. As a result, the primary and secondary functions listed below specify the distinct processes involved in preventing the development of pressure sores as well as the client's needs within the design boundaries.

#### **5.1.1 Primary Function:**

Limit blood flow obstruction caused by prolonged pressure against skin to prevent pressure sores for patient.

#### **5.1.2 Secondary Functions:**

To enable the primary function, the device must:

- withstand the weight of the patient.
- accept operator input to initiate the procedure.
- reduce duration of fixed pressure against the skin.
- accept operator input to terminate the procedure.

## **5.2 Objectives**

The objectives in Table 3 will be considered when creating a design to prevent pressure sores. The updated pairwise comparison chart used to prioritize this list can be seen in Appendix A.

**Table 3.** Design objectives in order of priority.

<b>Objective</b>	<b>Goal with metric</b>
Affordable	Should minimize design cost to less than \$200. (Appendix B1)
Comfort	Should cover surface dimension of bed fitting for a large adult: 137cm x 190cm. (Appendix B2)
Easy to Use	Should not require more than 1 operator.
Life Expectancy	Should maximize easily accessible parts. (Appendix B3)
	Should minimize number of moving parts. (Appendix B4)
Portable	Should minimize design weigh to not exceed 10 kg and a volume of 0.5 cubic meters, if foldable. (Appendix B5)

### **5.3 Constraints**

An overview of required design properties is shown in Table 4. Emphasis is placed on user/operator safety and ethical concerns.

**Table 4.** Design constraints.

<b>Category</b>	<b>Constraint</b>
Operational	Solutions with electrical components must have an ingress protection rating above 44. [10][11][12] (Appendix C1).
	Solutions supporting patient's weight must meet operational requirements under loads of 220lbs. (Appendix C2).
Safety and Regulations	Must not obstruct wheelchair control surfaces.
	Meet CCPSA anti-flammability requirements for bedding textile using the CAN/CGSB 4.2 N.27.5 testing standard. [13][14][15] (Appendix C3).
	Adhere to regulations under the Foods and Drugs Act targeting medical devices, and testing involving human subjects. [16][17] (Appendix C4).
	Must adhere to St Lawrence College's Ethical Research Involving Humans (CR501) policy. [18] (Appendix C4).
	Meet legal conditions required for patentability in North America. [19][20][21] (Appendix C5).

## **6. Alternative Design Generation, Selection, and Description**

This section briefly dives into the processes and tools used to select three alternative designs from approximately 100 ideas generated to solve the client need. The selected designs and their performance against key objectives are described in detail. See appendix G for a more on the idea generation and selection process.

### **6.1 Idea Generation Process**

Early research suggested that it would be easy to diversify potential form factors but not the mechanism by which static pressure is reduced. The team decided to generate at least 80 ideas using three ideation tools to fully explore the design space. The process began with a structured brainstorming session; each member contributing approximately 12 ideas, with a brief description of material composition and operational process. *Substitute* and *Combine* from the SCAMPER method were then used for slightly more unique results. A Morphological chart helped to promote variations in the team's approach to addressing functional requirements in the final session. Members were tasked with identifying a unique mean for each secondary function.

99 ideas were compiled before the selection process. Solutions involving shelled fluids, and soft padding were common during early sessions.

## 6.2 Alternative Design Selection Process

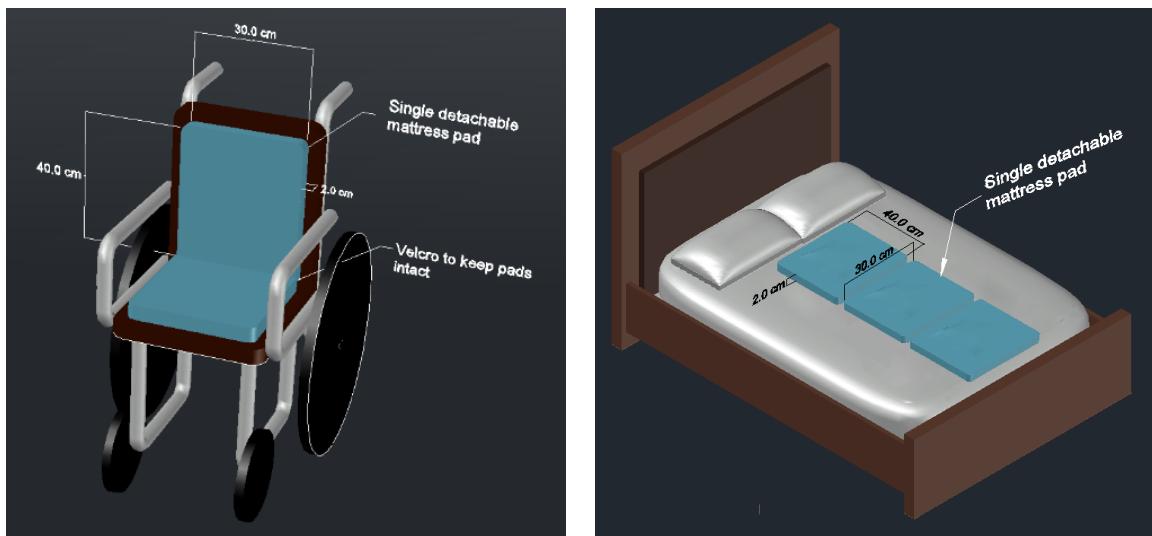
The team elected to use simpler decision-making models for early stages of the idea selection process. Multi-voting was used for the first two rounds of idea generation, the central goal being to quickly eliminate ideas with a high probability of underperforming on the project's requirements. With each member holding 17 votes, the team reduced the number of ideas under consideration to 45 in the first round. The second round resulted in a reduction to 16, with each member having 7 votes. Three final alternative designs were selected from this batch using a graphical decision chart that gauged potential performance against the two objectives with the highest priority: comfort and affordability. The selected alternatives were further optimized to improve their all-around performance.

## 6.3 Alternative Designs

This section describes the three proposed alternative designs, specifications of the designs, and how each design meets the objectives (see appendix F).

### 6.3.1 Modular Foam Pads (MFP)

This design consists of several pads that are made from pressure relieving foam. This foam features an open-cell composition which allows for even distribution of the patient's weight across the surface of the pad along with increased air flow within the pad [48]. This pressure-distribution reduces areas with higher pressure; as a result, decreasing the probability of developing pressure sores. Additional features of this design include a Velcro system to detach the foam pads to transfer the design from a bed to a wheelchair (see Figure 4 and Figure 5). Dimensions of a single pad is  $30\text{cm} \times 40\text{cm} \times 2\text{cm}$



**Figure 4.** CAD Drawing of Molecular Foam Pad on a Wheelchair

**Figure 5.** CAD Drawing of Molecular Foam on a Bed

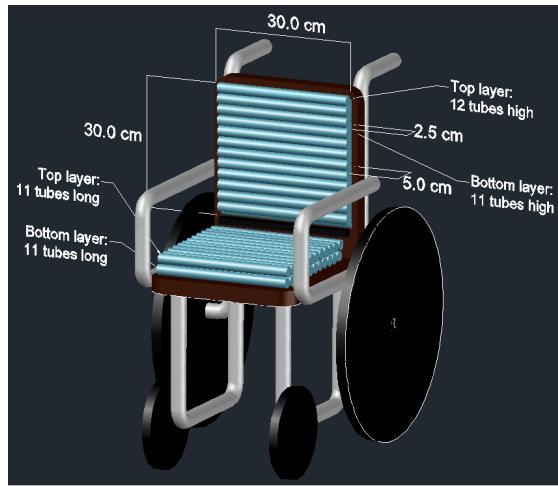
**Table 5.** Molecular Foam Pads Performance.

Objective	Weighted Score	Assessment
Affordable	24%	<ul style="list-style-type: none"> <li>• Approximately \$53 (Appendix F6)</li> </ul>
Comfort	18%	<ul style="list-style-type: none"> <li>• Support surface area: 0.36 m<sup>2</sup> (Appendix F7)</li> </ul>
Easy to Use	12%	<ul style="list-style-type: none"> <li>• All parts repairable/replaceable</li> <li>• Requires 1 operator.</li> </ul>
Life Expectancy	12%	<ul style="list-style-type: none"> <li>• 2 moving parts.</li> </ul>
Portable	8%	<ul style="list-style-type: none"> <li>• Volume: 0.0072m<sup>3</sup></li> <li>• Total weight: 0.576kg (Appendix F8)</li> </ul>

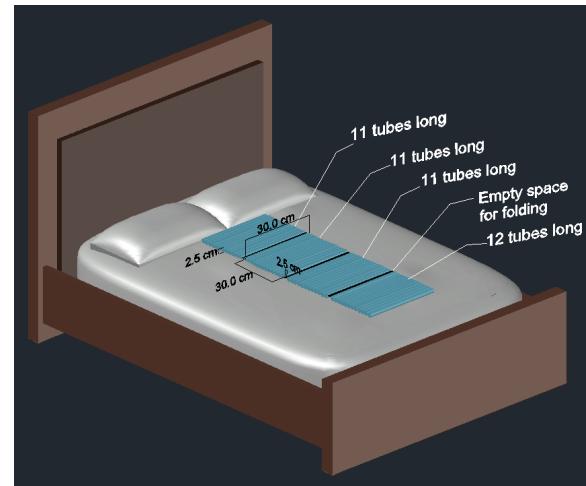
### 6.3.2: Transformable Alternating Pressure Mattress (TAP)

This design is an alternating pressure mattress that has the flexibility and transferability to be used on both the patient's wheelchair and bed. It consists of 45 air-cells arranged in parallel along the long axis of the design, connected to a portable air pump and valve system [Figure 8] that allows the inflation and deflation of alternate cells, providing alternating pressure relief on the patient's back. In contrast to existing AP mattress solutions, this proposed mattress will include several removed cells to allow for the required flexibility to transform from a horizontal bed orientation [Figure 7] to a semi vertical wheelchair orientation [Figure 6]. The design also consists of a portable chargeable battery which can power the device away from any electrical outlets.

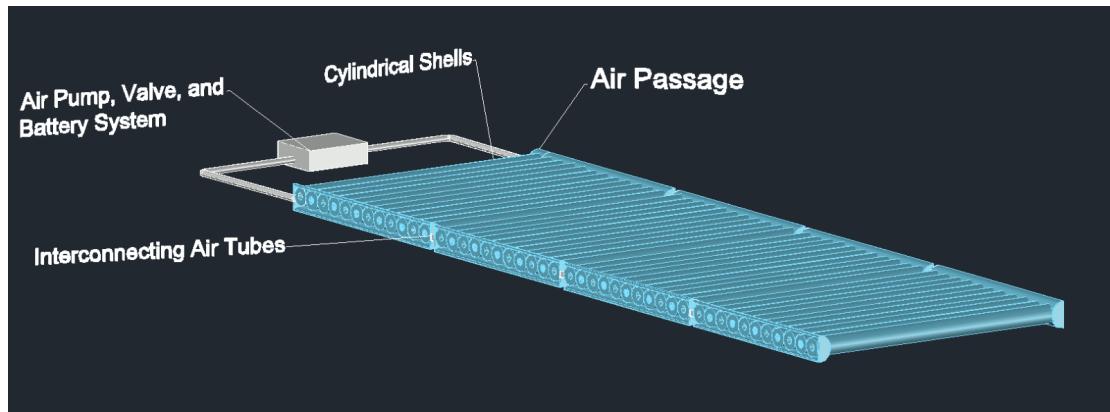
- Full length of design (long axis, horizontal position): 120 cm
- Length of one foldable section: 27.5-30 cm, 4 sections total
- Interior pressure (max): 0.4 psi
- Pump used: 6025SE Thomas Diaphragm Air Pump
- Battery used: Aluratek power pack.
- Tubing used: expandable sleeve plastic tubes.
- Valve used: 3-way ball valve.



**Figure 6.** CAD Drawing of Transformable Alternating Pressure Mattress Placement on a Wheelchair



**Figure 7.** CAD Drawing of Transformable Alternating Pressure Mattress Placement on a Bed



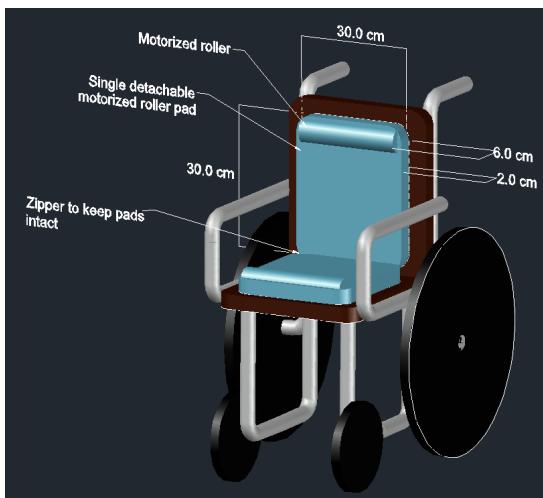
**Fig 8.** Close up CAD of the assembly in the horizontal position

**Table 6.** Transformable Alternating Pressure Mattress Design Performance.

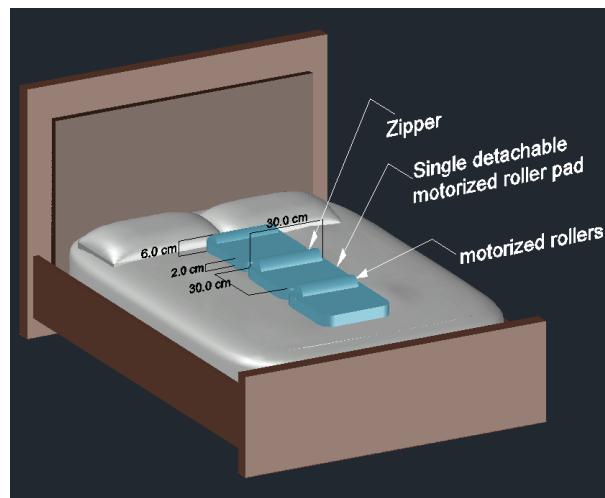
Objective	Weighted Score	Assessment
Affordable	18%	<ul style="list-style-type: none"> <li>• Approximately \$379</li> </ul>
Comfort	30%	<ul style="list-style-type: none"> <li>• Support surface area: <math>0.36 \text{ m}^2</math></li> </ul>
Easy to Use	9%	<ul style="list-style-type: none"> <li>• All parts repairable/replaceable</li> <li>• Requires 1 operator.</li> </ul>
Life Expectancy	9%	<ul style="list-style-type: none"> <li>• 5 moving parts.</li> </ul>
Portable	10%	<ul style="list-style-type: none"> <li>• Volume: <math>0.0072 \text{ m}^3</math></li> <li>• Total weight: 3.9 kg</li> </ul>

### 6.3.3 Detachable/Extendable Motorized Roller Pad (MRP)

This design embeds a motorized roller inside a pad covered with a thin piece of foam at the top layer. By using a controller, the roller can move back and forth along a set of rails and produce a wavelike motion along the surface of the pad. This will alternate the static pressure on the patient and prevents the formulation of pressure sores as a result [50]. The overall size of the pad is also adjustable. Each pad can be extended by attaching multiple pads together using zippers sewn onto each end. Dimensions of a single pad is  $30\text{cm} \times 30\text{cm} \times 6\text{cm}$  and width of foam is  $2\text{cm}$ .



**Figure 9.** CAD Drawing of Detachable/  
Extendable Motorized Roller Pad  
Placement on a Wheelchair



**Figure 10.** CAD Drawing of Detachable/  
Extendable Motorized Roller Pad  
Placement on a Bed

**Table 7.** Detachable/Extendable Motorized Roller Pad Performance.

Objective	Weighted Score	Assessment
Affordable	16%	<ul style="list-style-type: none"> <li>• Approximately \$419 (Appendix F1)</li> </ul>
Comfort	28%	<ul style="list-style-type: none"> <li>• Support surface area: <math>0.27\text{m}^2</math></li> </ul>
Easy to Use	12%	<ul style="list-style-type: none"> <li>• All parts repairable/replaceable.</li> <li>• Requires 1 operator.</li> </ul>
Life Expectancy	2%	<ul style="list-style-type: none"> <li>• 5 moving parts.</li> </ul>
Portable	12%	<ul style="list-style-type: none"> <li>• Volume: <math>0.0162\text{ m}^3</math></li> <li>• Total weight: 75.3 kg (Appendix F5)</li> </ul>

## **7. Proposed Conceptual Design**

The final recommended design selected is the Transformable Alternating Pressure Mattress (TAP). From the final 3 alternative designs, a weighted decision matrix employing the 5 main objectives was used, of which the TAP scored the overall highest, being most effective relative to alternative 1 in the comfort and portability, while being most effective relative to alternative 3 in affordability, comfort and life expectancy.

The client's primary want was to eliminate the patient's bedsore induced crying behaviour. The TAP's 4-section foldable design bridges the gap that exists currently by allowing the same device to operate on both wheelchair and bed, where the patient developed bedsores, while addressing the need to eliminate the pressure sores. Pressure sores develop when blood capillaries are squeezed shut through applied pressure, and while there are biological and antibacterial treatments to address already-developed wounds, the best way to stop bedsore development at its root is to reduce the pressure applied while the patient is lying down. Static means such as alternative 1, are helpful in reducing the intensity of the pressure, but bedsores are likely to continue developing over long time periods. Periodic repositioning of the patient may be required to for this alternative to be completely effective. In situations where the patient is non-ambulatory and cannot be repositioned easily, a dynamic approach is preferred [80], where parts of the patient's body periodically lose contact with the mattress surface, such as during an inflation/deflation cycle of alternating air cells found in this design. Studies have shown that similar alternating pressure designs are 3 times more effective than the closest comparable solutions in treating pressure sores [81]. All factors under consideration point to supporting the recommendation of the TAP as the final design.

## **8. Measures of Success**

This section of the document outlines a series of tests that will measure the proposed design's ability to deliver on key requirements. These examinations will assess the solution's ability to withstand various loads, average pressure against skin, and battery's discharge rate. AutoCAD renderings will be made prior to developing the prototype, to improve on team's understanding of dimensional constraints, material use, and build time. Testing will take place at UoT facilities, from which tooling and other testing articles will be sourced. Cost of material is expected to fall near the project's budget.

Materials to be used in each test include:

Prototype mat (30cm x 40cm)

Thomas 6025E electric air compressor (3 amps, 4psi)

Dead weight (60kg, 80kg, 100kg)

Air flow/pressure gauge

### **8.1 Load resistance**

This test measures the downward force the solution can sustain over time. The solution will undergo various 24-hour tests while tubes are pressurized (4psi) with the compressor powered by the average 120volt outlet.

#### Additional material

Flatness Gauge

#### Procedure

1. Air pressure gauge will be placed along the air path, between the pump, and mat to gauge pressure reading.
2. Air compressor will be switched on with valves closed for 24hours
3. Weight will be placed on top of mat for duration of test
4. Flatness gauge will be placed on top of weight
5. Repeat with higher rated weight.

#### Data collection and interpretation

The solution's ability to maintain form, and air pressure are the primary metrics to use for this test. The team will monitor the flatness gauge for indications of unexpected weight distribution during operation and pressure gauge for potential leaks or pump faults. Variance of less than 3% on flatness gauge and psi rating above 3.8 will be considered a success. See table 8 for an example of a table to be used for data collection.

**Table 8.** Example load resistance test data collection

Test #	Weight	Balance variance over 24h (%)	Pressure deviations
1			
2			
3			

### **8.2 Pressure redistribution**

This test focuses on measuring pressure redistribution effects of alternating air pressure tubes. The solution will execute its normal sequence of operation over a period of 5 hours using the average 120volt wall outlet.

#### Additional material

4 Small force sensors (2.5cm diameter)

Digital data recorder device

Wood board measuring 30cm x 40cm x 3cm

#### Procedure

1. Air pressure gauge will be placed along the air path, between the pump, and mat to gauge pressure reading.
2. Air compressor will be switched on with valves operating normally for 30 minutes.
3. Force sensor pressure will be placed directly above various tubes and board.
4. 100kg weight will be placed on board.
5. Repeat 3 times with sensors positioned on different tubes.

#### Data collection and interpretation

The force sensors will be used to gauge complete inflation and deflation of various alternate tubes. Pressure ratings will be monitored by the team using the recording device to measure pressure at tubes in focus every 10 minutes. Complete deflation, and inflation of alternate tubes indicates a success. Failure to redistribute air is an indication that the device may not be successful in redistributing pressure against skin. See table 9 for an example of a table to be used for this test.

**Table 9.** Example pressure redistribution test data collection (cut short).

Test #	Tube ID	Pressure at 10min interval	Pressure at 20min interval	Pressure at 30min interval
1				
2				

#### **8.3 Battery discharge rate**

The aim of this test is to measure the solution's ability to power the pump through the day using only the integrated battery. The team expects the user will reproduce the average of 13 hours spent out of bed [79].

#### Additional material

Lithium-Ion battery (16000 mAh)

#### Procedure

1. Air pressure gauge will be placed along the air path, between the pump, and mat to gauge pressure reading.
2. Dead weight will be placed on mat (long axis on a horizontal surface).
3. Air compressor switched on for 16 hours.
4. Repeat with higher rated weight.

#### Data collection and interpretation

Metrics to be used for this test are the battery's ability to continuously provide power, with the air compressor delivering a constant 4psi to the mat through the test. Tests will be considered positive if the prototype meets both expectations. Large variations in air pressure without power loss may indicate a pump issue, and will be investigated for faults. A low battery indication, leading to shutdown before end time will be considered as failure. Example of a table to be used for data collection is shown in Table 10.

**Table 10.** Example load resistance test data collection

Test #	Weight	Battery life at 16h (mAh)	Power for duration of test (yes/no)	Pressure deviations.
1				
2				
3				

## 9. Conclusion

In summary, the requirements derived from the client statement show the problem to be largely physiological in nature. The central aim is to reduce the probability of developing pressure sores from prolonged periods in bed, and wheelchair. Three alternate solutions were generated using various idea generation and selection tools. The Transformable Alternating Pressure Mattress was selected as the conceptual design to propose to the client. Moving forward, the team will prototype and conduct tests around the design a deeper analysis.

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## Appendices

### Appendix A

The pairwise comparison chart displayed in Table 5 was used in order evaluate the relative significance of each objective. This method compared each of the objectives individually against all the other objectives and was given a score of either 0 or 1, depending on whether that objective was of more or less importance compared to the other objective. Finally, the objective with the highest score was deemed most important while the objective with the least total score was concluded to be of least importance.

**Table 10.** Pairwise Comparison of the Objectives

Objective Name (Number)	No. 1	No. 2	No. 3	No. 4	No. 5	Points
Affordable (1)	-	1	1	1	1	4
Comfort (2)	0	-	1	1	1	3
Easy to Use (3)	0	0	-	1	1	2
Portable (4)	0	0	0	-	0	0
Life Expectancy (5)	0	0	0	1	-	1

Rank of the objectives from most important to least important

First: Affordable

Second: Comfort

Third: Easy to Use

Fourth: Life Expectancy

Fifth: Portable

## **Appendix B**

### **Appendix B1: Cost Considerations**

There are many pre-existing measures to prevent pressure sores including, pressure mattresses, sheepskin mattress pads, and orthopedic cushions [22]. However, the issue with these pre-existing solutions is that they can be expensive and may not prevent pressure sores as effectively [44]. The cost of an average pressure mattress can range from \$200 to \$3,000 [23] depending on the quality and type of material used. The price of sheepskin mattress pads often varies in cost between \$250 to \$500 [24] depending on the size of the material. Other measures such as orthopedic cushions can also be expensive and cost between \$100 to \$400 [25]. The problem with pre-existing designs is that they are expensive or may not be effective on the entire body. Thus, this design is intended to be affordable; the pricing of the design should be lower than the minimum cost of pressure mattresses and sheepskin mattress pads.

### **Appendix B2: Design Versatility and Comfort**

We expect the patient will grow and require larger bed sizes during the service life of the device. Solutions must be applicable to various bed dimensions to account for this. The design should be effective on mattresses with dimensions up to 137 cm x 190 cm or “Full Bed Size” according to US standard bed dimensions [9]. This size allows for a male adult of average height (175.4 cm) and build to sleep comfortably [34]. The extra width objective adds to the flexibility of our solution.

### **Appendix B3: Easy Use Properties of the Design**

When distributing a product that has many components, making easily accessible parts becomes an advantage to the consumers as it allows the design to be easily replaced and repaired. Parents of special needs children require designs that are less complex as they ensure quick replacement and minimal design surface area as they are easy clean; this becomes a necessity when these products are used regularly [26]. The benefit of a simple design that they are easy to clean and inexpensive since designs with easily accessible parts costs less during the manufacturing process [27].

### **Appendix B4: Expected Life Expectancy**

The average life expectancy of pre-existing products that prevent pressure sores vary according to the type of product. Pressure mattresses used to prevent pressure sores have a life span between 7-10 years [28], while Orthopedic pillows relatively last up to 5 years [29] and sheepskin mattress pads can perform for at least 4 years [30]. For the design to achieve a higher life expectancy than pre-existing products, it will be designed to minimize the number of moving

parts in the design to prevent rusting and deterioration of moving parts; this will allow the design to last for several years.

### **Appendix B5: Design Transportation**

The portability of the design should be taken into consideration as the parents may require the use of the design on another bed or a wheelchair. On average, pre-existing solutions to preventing pressure sores can vary depending on the size. Non portable pressure mattresses are one of many preventive measures used for pressure sores as they weigh approximately 32-63 kg [31] and come in volumes ranging between 1.2 cubic meters to 0.5 cubic meters [32][33] depending on the size of the mattress. Other preventive measures include sheepskin mattress pads which are often portable as they come in small, compact sizes, weighing between 6-14 kg [30] and ranging in volumes between 0.3 cubic meters to 0.15 cubic meters [32][30], while orthopedic cushions are made with light material for easy transportation and portability. Taking the pre-existing solutions into account, the design should not weigh more than the average weight of sheepskin mattress pads and exceed the volume of a twin sized pressure mattress for easy transportation.

## **Appendix C**

### **Appendix C1: Ingress Protection Standards**

The Canadian Standards Association's CAN/CSA-C22.2 No. 60529:16 is a Canadian adaptation of the International Electrotechnical Commission's IEC 60529 standard for metrics and testing methodology for enclosure protection against ingress from solids and liquids. An ingress protection of 11 or IP11 provides the minimum protection against foreign bodies while the highest rating of IP68 prevents dust particles and pressured liquid from traveling through an encasing [10][11][12]. In the interest of user/operator safety and extending service life, an IP rating of 44 is set for solutions with electrical components. This prevents the patient, a malevolent being, from accessing internal modules and keeps the solution operational when exposed to spills.

### **Appendix C2: Average Weight of North American Male**

Solutions that support the user's weight must be able to carry slightly more than the average weight of a male adult in North America. US males tend to have a higher average weight with a mean of 89.7 kg or 198 lbs according to latest CDC surveys [34]. We're setting a goal of 220lbs to provide some safety margin.

### **Appendix C3: Minimum Flammability Requirements**

Solutions must satisfy minimum flammability requirements using the 45° angle cigarette test as outlined by the Canadian Standards Board's CAN/CGSB 4.2 No. 27.5 standard for textile flame retardance testing methods in order to match flame spread requirements for mattresses and other bedding textile under the Canada Consumer Product Safety Act [13][14][15]. We expect the user will sleep on the solution, and with their disability in mind, see value in extending mattress attributes geared towards user safety.

### **Appendix C4: Regulations and Guidelines for Medical Devices, and Human Testing**

Solutions must meet requirements listed in part 2 of the consolidated Medical Devices Regulations (SOR/98-282) aimed at low volume production, custom-made medical devices for *special access* [16][17]. Design must also adhere to SOR/43.11 under the Foods and Drugs Act alongside St. Lawrence College's Ethical Research Involving Humans (CR501) policies which seek to protect the user from harm & malpractice during development, and production stages [18].

### **Appendix C5: Patentability Requirements**

Solution must meet Patentability requirements as expressed by the World Intellectual Property Organization, Canadian Intellectual Property Office, and United States Patent and Trademark Office [19][20][21].

## Appendix D

In lieu of missing information, parts of the service environment were derived from an analysis based on the initial project description PDF and current physical standards/averages.

### Appendix D1: Bed and Wheelchair Size Considerations, Bedroom Size Estimate

Since the patient is a six-year-old child, a *size single* bed was assumed, which has a maximum size of approximately 90 x 200 cm [35]

(NOTE: this is just the current bed size, not the maximum bed size our design aims to be adaptable to, see appendix B2)

From [36], several types of pediatric wheelchairs body designs where surveyed, with specific attention paid to the maximum dimensions of roughly 25.5 inches (65 cm) overall width (this is the seat dimension + the frame dimensions, for seat exclusive see [43]), and a slightly larger maximum length (> 65 cm). Considering the space needed for the patient's caregiver behind the wheelchair, and the extra margin of space needed to maneuver the wheelchair (such as rotating it, placing the patient inside etc.), a circular space of diameter 150-cm was assumed to be reserved for the wheelchair, located between the bed and door.

The remaining room was structured to allow for the main elements of the bed and wheelchair area to fit comfortably, and to allow for space on the other side of the bed for a caregiver/parent to be present. The room layout visual was conceptualised using the “*floorplancreator.net*” program.

Assumption was made with regards to location and number of standard Canadian 120V power outlets, and presence of wireless signals.

### Appendix D2: Environmental Considerations

The temperature and humidity ranges for an interior bedroom service environment were taken from ASHRAE (American Society of Heating, Refrigeration, Air-conditioning Engineers), seen in the figure below:

The American Society of Heating, Refrigerating, and Air Conditioning Engineers, Inc (ASHRAE) provides guidelines that are intended to satisfy the majority of building occupants wearing a normal amount of clothing while working at a desk. The ASHRAE guidelines recommend 68 F to 74 F in the winter and 72 F to 80 F in the summer. The ASHRAE guidelines recommend a relative humidity (RH) of 30 to 60 percent.

**Figure 4.** Expert from ASHRAE document on standard interior temperature and humidity ranges [6]

## Appendix E

A mattress augmentation device being constructed by this team will have a unique status in the eyes of the TPD that will determine what regulations (from *medical devices regulations*, [7]) it must follow and what licence it must apply in order to be used/sold in Canada, detailed below.

### Appendix E1: Legal status of current engineering team and the proposed product:

The tasks Team 172 is responsible for means the legal status of the team in this project is the *Manufacturer* (fig. 5), since we fulfill the requirements of “designing, manufacturing, assembling, processing, labelling …” the product.

- **Importer** – a person in Canada, other than the manufacturer of a medical device, who is responsible for the medical device being brought into Canada for sale.
- **Distributor** – a person, other than a manufacturer, importer or retailer, who sells a medical device in Canada for resale or use, other than for personal use. A person outside of Canada selling medical devices into Canada is also considered a distributor.
- **Manufacturer** (as defined in section 1 of the Medical Devices Regulations) – a person who sells a medical device under their own name, or under a trademark, design, trade name or other name or mark owned or controlled by the person, and who is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the device, or for assigning to it a purpose, whether those tasks are performed by that person or on their behalf.

**Figure 5.** The 3 main activities/roles as defined in the TPD compliance document [37]

Per the *Health Canada TPD* guidelines, a potential mattress augmentation device would fall under the category of a Class II product, which translates to a low-medium risk device, seen in figures 6-7 below.

#### Classes of Health Canada Certified Products

The *Medical Devices Regulations* (Regulations) utilize a risk-based approach to regulating products within its scope. The safety and effectiveness evidence required to support a medical device licence application is proportional to the risk of the device, which is determined by applying the Classification Rules for Medical Devices detailed in Schedule 1 of the Regulations.

The Medical Devices Regulations separate medical devices into the following 4 risk categories:

1. Class I: Low risk devices such as wound care and non-surgically invasive devices.
2. Class II: Low-to-medium risk devices including contact lenses and the majority of surgically invasive devices (e.g., surgical gloves, needles, magnetic resonance imaging equipment).
3. Class III: Medium-to-high risk devices such as hip implants, glucose monitors, ultrasound diagnostic imaging equipment, and surgically invasive devices that are intended to be absorbed into the body or that are intended to remain in the body for at least 30 consecutive days.
4. Class IV: High-risk devices such as pacemakers and surgically invasive devices that diagnose, control, or correct a defect in the central cardiovascular system. The device manufacturer, importer, or distributor is responsible for classifying the device.

Nearly all medical devices retailed by HMEDA members generally fall into class I. For most HMEDA members, the only class II devices they are likely to sell will be air flotation and/or alternating pressure mattresses. When a retailer sells a device to an end-user, that retailer will not require a MDEL. When a manufacturer or distributor sells a Class I device to a retailer, that manufacturer or distributor must have a MDEL.

**Figure 6.** Classification of various products into risk classes I-IV [37]

- Class 2 medical devices examples
  - Mattress, air flotation, alternating pressure

**Figure 7.** Classification of various products into risk classes I-IV [37]

## Appendix E2: Required licence required under the TPD for manufacturers of class II medical devices in Canada

A *Medical Device Licence* (MDL) is required for manufacturing class II products, from the table in figure 8 below:

MDL: Medical device licence		
Activity type	Description	Licence required
Importing	I am in Canada. I buy medical devices from a manufacturer and/or supplier (distributor) <b>outside</b> of Canada and sell them <b>in</b> Canada. The foreign manufacturer or distributor already has an MDEL.	MDEL
Importing	I am in Canada. I buy medical devices from a manufacturer and/or supplier (distributor) <b>outside</b> of Canada and sell them <b>in</b> Canada. The foreign manufacturer or distributor <b>may not</b> have an MDEL.	MDEL
Distributing	I am in Canada. I buy medical devices from a manufacturer and/or supplier (importer or distributor) <b>in</b> Canada and sell them <b>in</b> Canada.	MDEL
Distributing	I am outside Canada. I sell medical devices <b>exclusively</b> to an MDEL holder in Canada. My name is <b>not</b> on the label.	No licence required
Distributing	I am outside Canada. I sell medical devices <b>exclusively</b> to healthcare facilities or retailers in Canada. My name is <b>not</b> on the label.	MDEL
Distributing	I am outside Canada. I sell medical devices to importers as well as healthcare facilities and/or retailers in Canada. My name is <b>not</b> on the label.	MDEL
Manufacturing	I am in or outside Canada; I sell <b>Class II, III or IV</b> medical devices in Canada that only have <b>my name</b> on the label as the manufacturer. I do not sell Class I medical devices in Canada.	MDL

**Figure 8.** Licence requirements for various activity types and descriptions [37]

## Appendix E3: Requirements for Class II MDL licence applications from the Medical Devices Regulations (MDR)

The legal health and safety stakes of TPD in this project are detailed in the relevant sections of the MDR for class II products in figures 9-11:

**Item 6: Attestations**

**Class II Licence Applications**

**Attestation of Compliance with the Applicable Requirements of sections 10 to 20**

Manufacturers of Class II medical devices must attest that they have objective evidence establishing that they are compliant with section 10, subsections 11(1) and 12(1) and sections 13 to 20 of the MDR.

In the case of decorative contact lenses, manufacturers must attest that they have objective evidence establishing that they meet section 10, subsections 11(2) and 12(2) and sections 13 to 17 of the MDR.

**Figure 9.** Required sections for compliance in the MDR for class II products [38]

**10** A medical device shall be designed and manufactured to be safe, and to this end the manufacturer shall, in particular, take reasonable measures to

- (a) identify the risks inherent in the device;
- (b) if the risks can be eliminated, eliminate them;
- (c) if the risks cannot be eliminated,
  - (i) reduce the risks to the extent possible,
  - (ii) provide for protection appropriate to those risks, including the provision of alarms, and
  - (iii) provide, with the device, information relative to the risks that remain; and
- (d) minimize the hazard from potential failures during the projected useful life of the device.

**11 (1)** A medical device other than a decorative contact lens shall not, when used for the medical conditions, purposes or uses for which it is manufactured, sold or represented, adversely affect the health or safety of a patient, user or other person, except to the extent that a possible adverse effect of the device constitutes an acceptable risk when weighed against the benefits to the patient and the risk is compatible with a high level of protection of health and safety.

**(2)** A decorative contact lens shall not adversely affect the health or safety of a user, except to the extent that a possible adverse effect of the device constitutes a risk that is compatible with a high level of protection of health and safety.

SOR/2015-193, s. 2.

[Previous Version](#)

**12 (1)** A medical device other than a decorative contact lens shall perform as intended by the manufacturer and shall be effective for the medical conditions, purposes and uses for which it is manufactured, sold or represented.

**(2)** A decorative contact lens shall perform as intended by the manufacturer.

**Figure 10.** Relevant compliance sections 10, 11.1, 12.1, 13 - 20 in the actual MDR [38]

- 13** During the projected useful life of a medical device, its characteristics and performance shall not deteriorate under normal use to such a degree that the health or safety of a patient, user or other person is adversely affected.
- 14** The characteristics and performance of a medical device shall not be adversely affected by transport or conditions of storage, taking into account the manufacturer's instructions and information for transport and storage.
- 15** Reasonable measures shall be taken to ensure that every material used in the manufacture of a medical device shall be compatible with every other material with which it interacts and with material that may come into contact with it in normal use, and shall not pose any undue risk to a patient, user or other person.
- 16** The design, manufacture and packaging of a medical device shall minimize any risk to a patient, user or other person from reasonably foreseeable hazards, including
- (a)** flammability or explosion;
  - (b)** presence of a contaminant or chemical or microbial residue;
  - (c)** radiation;
  - (d)** electrical, mechanical or thermal hazards; and
  - (e)** fluid leaking from or entering into the device.
- 17** A medical device that is to be sold in a sterile condition shall be manufactured and sterilized under appropriately controlled conditions, and the sterilization method used shall be validated.
- 18** A medical device that is part of a system shall be compatible with every other component or part of the system with which it interacts and shall not adversely affect the performance of that system.
- 19** A medical device that performs a measuring function shall be designed to perform that function within tolerance limits that are appropriate for the medical conditions, purposes and uses for which the device is manufactured, sold or represented.
- 20** If a medical device consists of or contains software, the software shall be designed to perform as intended by the manufacturer, and the performance of the software shall be validated.

**Figure 11.** Relevant compliance sections 10, 11.1, 12.1, 13 - 20 in the actual MDR [38]

## Appendix E4: First page of Class II product MDL application form

The full document can be found at [39], the first page is shown for reference in figure 12 below.



### New Class II Medical Device Licence Application Form

(disponible en français)

Before completing this form, you must consult the document Guidance Document – How to Complete the Application for a New Medical Device Licence (available on the website).

**1. Name of the Device (as it appears on the label)**

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**2. Manufacturer Information (as it appears on the label and the quality management system certificate)**

Contact Name and Title:	Company ID (if known):		
Company Name:			
Telephone:	Facsimile:	E-mail:	
Telephone (international):		Facsimile (international):	
Street:	Suite:	P.O. Box:	City:
Province/State:	Country:		Postal/Zip Code:

**3. Regulatory Correspondent Information**

Same as Manufacturer

Other (specify below)

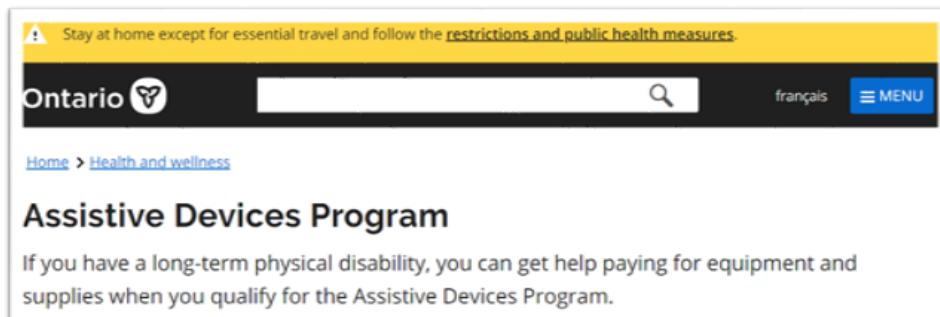
Contact Name and Title:	Company ID (if known):		
Company Name:			
Telephone:	Facsimile:	E-mail:	
Telephone (international):		Facsimile (international):	
Street:	Suite:	P.O. Box:	City:
Province/State:	Country:		Postal/Zip Code:

**Canada**

**Figure 12.** Page 1/7 of CII MDL application form under Health Canada TPD [39]

## Appendix E5: Establishing basic eligibility of patient for ADP funding

The ADP program includes funding for *mobility aids* (Figure 14), which includes similar devices to the scope of this project, such as *positioning devices (cushions, back, head supports...)* (figures 13-15).



**Figure 13.** Overview of ADP [8]

## How to apply

Find out more about how to qualify, apply and find a vendor for these types of equipment and supplies:

- mobility aids
- hearing aids and other devices
- communication aids
- visual aids
- diabetic equipment and supplies
- respiratory equipment and supplies
- home oxygen therapy
- artificial eyes and facial prosthetics
- custom orthotic braces, compression garments and lymphedema pumps
- prosthetic breasts or limbs
- enteral-feeding pumps and ostomy supplies

**Figure 14.** Types of disabilities covered under the ADP. [8]

## Types of mobility aids covered

Through the Assistive Devices Program (ADP), we help cover the costs of:

- manual wheelchairs, power wheelchairs and power scooters
- power add-ons (devices added to a manual wheelchair if you don't need a power wheelchair)
- positioning devices (e.g. cushions, back and head supports, power tilt and recline)
- forearm-crutches
- wheeled walkers for adults
- pediatric walkers, standers and strollers

**Figure 15.** Types of devices covered under the mobility disability under ADP. [8]

## Appendix E6: Further patient-specific application details, including those found in the ADP application form

The application for the ADP funding requires the approval of a registered physiotherapist (see figure 17) to confirm the patient's illnesses and current medical needs. In this case, if the patient's family has already benefited from ADP funding for medical devices relating to the patient's non-ambulatory ailments, such as a wheelchair, then (Figure 16):

the reason for application would be given as,

(2) *Another type of device required in addition to previously ADP funded devices,*

And the cause of the need for the replacement device would be due too:

(4) *Special circumstances- attach letter of rational.*

[The patient's medical practitioner would need to attach a letter explaining the patient's case of bedsores requires addition passive medical support both in his bed and wheelchair.]

The medical practitioner would also need to specifically prescribe our mattress design solution since it is not a natively ADP-funded device (currently our team is not an approved vendor with the government of Ontario for the ADP).

The financial stake of 75% monetary coverage by the ADP for medical devices necessitates the rigorous application process our device must pass, which includes the patient's family doctor to

confirm and recommend the usage of our final device as a treatment of the exact mobility issues that are applicable for ADP funding.

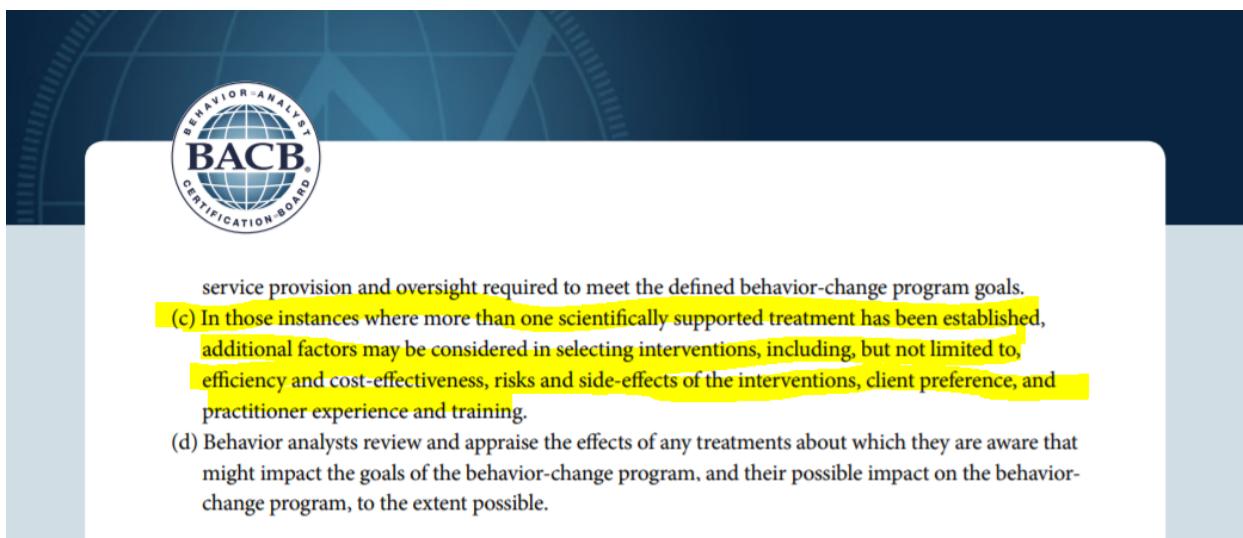
Conforming the usage and design of our device to the specific definitions outlined in the ADP and receiving the funding will also accomplish the goal of affordability with respect to the patient's parents.

<b>Reason for Application (check one)</b>		
<input type="checkbox"/> First access for Mobility Devices		
<input type="checkbox"/> Another type of device required in addition to Previously ADP Funded Device(s)		
<input type="checkbox"/> Modifications to Non ADP Funded Device(s)		
<input type="checkbox"/> Replacement of Previously ADP Funded Device(s) no longer in use		
<input type="checkbox"/> Modifications/Adjustments /Additional Components to Previously ADP Funded Device(s) currently in use		
<b>Replacement Device(s) and/or Modifications Required Due To: (check as appropriate)</b>		
<input type="checkbox"/> Change in applicant's mobility status - previously ADP funded equipment no longer meeting basic mobility needs as defined by ADP for funding purposes		
<input type="checkbox"/> Change in applicant's body size - previously ADP funded equipment is either too large or too small.		
<input type="checkbox"/> Previously ADP funded equipment is worn out		
<input type="checkbox"/> Special circumstances - none of the above - attach letter of rationale.		
<b>Confirmation of Applicant's Eligibility for a Positioning Devices – Seating (answer required for each statement)</b>		
1. <input type="checkbox"/> Applicant requires the seating components to provide postural support and/or pressure relief during mobility. Applicant can maintain a functional posture during mobility with the seating components prescribed.		
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A		
2. Applicant requires the tray prescribed to provide postural support during mobility and/or to support an ADP approved communication aid required during mobility.		
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A		
<b>Non ADP Funded Options Prescribed (Optional)</b>		
<input type="checkbox"/>		
<input type="checkbox"/>		
<input type="checkbox"/>		

**Figure 16.** Relevant section from pg.10 from the APD mobility disability device application form [40]

## **Appendix E7: St. Lawrence Collage, Centre of Behavioral Analysis Information- Further Information**

The clients of this project (who will act as distributors of the device to the patient) are affiliated with St. Lawrence's Centre for Behavioral Analysis, whose ethical guidelines for associated practitioners' states that "*all staff must follow the Behavior Analyst Certification Board Professional and Ethical Compliance Code*" [41]. In addition, any treatment on behalf of the centre must abide by the full list of legislative actions detailed in fig. 18. While most of the specific ethical codes in the BACB and legislative acts deal with the conduct between client and patient (not relevant to our design), there also exists provisions that detail the responsibility of the clients to the patients regarding the technology being used in the treatment (i.e. Team 172's design). The PR review by the client will be the first part of insuring that the relevant treatment standards at St. Lawrence Collage are met, such as those highlighted in fig 17 (which would be considered during the actual treatment), maintaining the safety of the patients and upholding the standards of the behavioral program at St. Lawrence Collage.



**Figure 17.** Expert from the BACB code of ethics (indirectly St. Lawrence CBA code of ethics)

[41]

- Regulated Health Professions Act
- Personal Information Protection and Electronic Documents Act
- Personal Health Information Protection Act
- Child and Family Services Act
- Mental Health Act
- Health Care Consent Act
- Substitute Decisions Act
- Human Rights Code
- Occupational Health and Safety Act
- Accessibility for Ontarians with Disabilities Act
- Health Protection and Promotion Act

**Figure 18.** Relevant legislative acts that define St. Lawrence Collage's CEA guidelines [42]

## Appendix F

### Appendix F1: Cost Calculation for Detachable/Extendable Motorized Roller Pad

The calculation of the cost of this design was done by summing the prices of each individual part of the product together. Each of the prices was obtained from research. The following is the complete calculation of the design.

Price for Roller:

$$\begin{aligned} \text{Volume of Roller} &= \pi r^2 h = \pi(3\text{cm})^2(30\text{cm}) \approx 850\text{cm}^3 \\ \text{Volume of Roller (Online)} &= \pi r^2 h = \pi(1.745\text{cm})^2(58.42\text{cm}) \approx 559\text{cm}^3 \end{aligned}$$

Now we find the ratio between the two and use this ratio to calculate the price.

$$\text{Ratio} = \frac{850\text{cm}^3}{559\text{cm}^3} \approx 1.52$$

$$\text{Price of Roller} \approx \text{Price of Roller (Online)} \times \text{Ratio} \approx \$29.4$$

The price of roller taken from online is \$19.25 [55].

Next, we find the price of a fabric. This time instead of calculating the volume, we'll need to calculate the surface area of this design and use the value of \$4.99/1.15m<sup>2</sup> [56] for a broadcloth, which is a fabric that would be good for the design to find its price.

$$\begin{aligned} \text{Total Surface Area} &= 4 \times \text{sides} + 2 \times \text{ends} = 4 \times (0.06m)(0.3m) + 2(0.3m)(0.3m) \\ &= 0.252m^2 \end{aligned}$$

$$\text{Total Price of Fabric} = \text{Total surface area} \times 4.99 \text{ CAD/m}^2 = 1.26 \text{ CAD}$$

Now, we need to find the price of the foam padding. This can be done using the same method used to calculate the cost of rollers.

$$\begin{aligned} \text{Volume of Foam} &= bhl = (30cm)(6cm)(30cm) \approx 5400cm^3 \\ \text{Volume of Foam (Online)} &= bhl = (40cm)(2.5cm)(40cm) \approx 4000cm^3 \end{aligned}$$

Now we find the ratio between the two and use this ratio to calculate the price.

$$\text{Ratio} = \frac{5400cm^3}{4000cm^3} = 1.35$$

$$\text{Price of Foam} \approx \text{Price of Foam (Online)} \times \text{Ratio} \approx \$33.7$$

Price of foam taken from online has a cost of \$24.99 [57]. This foam was chosen, because it is used in sofas, which will provide comfort.

Next, we need to find the price of the rails. We can use the weight and the price per kg for aluminum, which is the material used for each rail, to calculate the price. The price/kg for aluminum which is \$1.79/kg [58]

The weight of the rails can be calculated using the density of the material (aluminum), which is 2.7 g/cm<sup>3</sup>. (See Figure for dimensions of the rail) [59]

$$\begin{aligned} \text{Weight of both Rail} &= 2 \times \text{Volume} \times \text{Density} \\ &= 2 \times \left( (2.38cm) \times (0.79cm - 0.47cm) + \pi \left( \frac{0.47cm}{2} \right)^2 \right) \times (30cm) \\ &\times 0.0027 \text{ kg/cm}^3 \approx 0.151\text{kg} \\ \text{Price of Rails} &= 0.151\text{kg} \times \$1.79/\text{kg} \approx \$0.27 \end{aligned}$$

We also need the price of an 800 N motor. We chose to use an 800N motor since the average mass of an adult is about 80kg and therefore their weight is approximately 800N [53].

The price of an 800N motor is generally around \$69.01 from research [54].

There are 4 zippers, one on each end of the pad and the price of each is \$1.18 [60]. Therefore, the price of 4 zippers will be \$4.72.

With the cost of each component identified, we can sum up their prices to find the total cost.

$$\text{Total Cost of 1 pad} = \text{Summation of prices of all components} \approx \$139.62$$

### **Appendix F2: Comfort Calculation for Detachable/Extendable Motorized Roller Pad**

This calculation is done using the dimensions of a pad. Since the design is extendable, we can construct it in such away that it satisfies the metrics for the comfort objective. The following calculation shows one configuration that satisfies the comfortability objective.

$$\text{Width} = 30\text{cm} \times 5 \text{ pads} = 150\text{cm}$$

$$\text{Length} = 30\text{cm} \times 7 \text{ pads} = 210\text{cm}$$

### **Appendix F3: Surface Area of Detachable/Extendable Motorized Roller Pad**

This calculation is done using the predetermined dimensions of the design.

$$\begin{aligned}\text{Total Surface Area} &= 4 \times \text{sides} + 2 \times \text{ends} = 4 \times (0.06\text{m})(0.3\text{m}) + 2(0.3\text{m})(0.3\text{m}) \\ &= 0.252\text{m}^2\end{aligned}$$

### **Appendix F4: Life Expectancy of Detachable/Extendable Motorized Roller Pad**

The life expectancy of this design is determined by comparing the life expectancy of each components in the design.

**Table 11.** Life Expectancy of each Component in Detachable/Extendable Motorized Roller Pad

Component	Life Expectancy
Fabric	1-3 years [61]
Foam	6-7 years [62]
Steel (Roller)	11-52 years [63]
Aluminum (rails)	40-80 years [64]
Motor (800N)	7 – 9 years This is calculated based on the assumption the motor is used for 12 hrs a day [65]

Based on this table, we can see that clearly the fabric will have worn out first before other components and therefore, the life expectancy of this design will be 1-3 years.

### **Appendix F5: Calculation of the portability of Detachable/Extendable Motorized Roller Pad**

This calculation on the volume of the design was done using the dimensions of the design.

Here is the full calculation of the volume of the Detachable/Extendable Motorized Roller Pad.

$$Volume = bhl = (0.3m)(0.06m)(0.3m) = 0.0054m^3$$

However, some assumptions were made while calculating the overall weight of the design.

Assumption: The weight of the foam, fabric and zippers are neglected since they are insignificant compared to the weight of the roller. The weight of the motor will not be counted as well, as it can be detached upon transferring from the bed to wheelchair.

Here is the full calculation of the portability of the Detachable/Extendable Motorized Roller Pad.

$$Volume \text{ of } Roller = \pi r^2 h = \pi(3cm)^2(30cm) \approx 850cm^3$$

$$Volume \text{ of } Roller \text{ (Online)} = \pi r^2 h = \pi(1.745cm)^2(58.42cm) \approx 559cm^3$$

The dimension of the roller found online has a radius of 1.745cm and length of 58.42cm [55].

Now, we find the ratio between the two and use this ratio to calculate the weight.

$$Ratio = \frac{850cm^3}{559cm^3} \approx 1.52$$

$$Weight \text{ of } Roller \approx Weight \text{ of } Roller \text{ (Online)} \times Ratio = 24.9 \text{ kg}$$

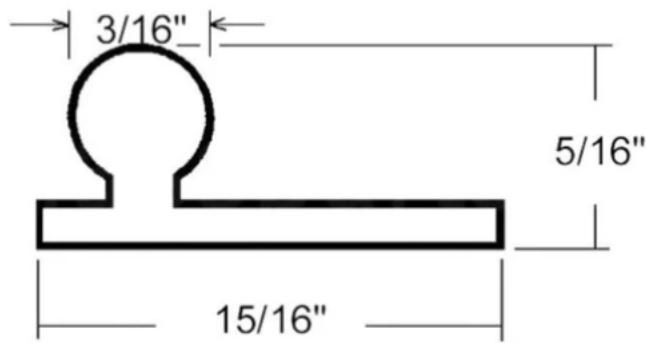
The weight of the rails can be calculated using the density of the material (aluminum), which is 2.7 g/cm<sup>3</sup>. (See Figure 19 for dimensions of the rail) [59]

$$Weight \text{ of both Rail} = 2 \times Volume \times Density$$

$$= 2 \times \left( (2.38cm) \times (0.79cm - 0.47cm) + \pi \left( \frac{0.47cm}{2} \right)^2 \right) \times (30cm)$$

$$\times 0.0027 \text{ kg/cm}^3 \approx 0.151\text{kg}$$

Therefore, the overall weight is equal to approximately 25.1 kg.



**Figure 19.** Diagram of Sliding Screen [66]

### Appendix F6: Cost Calculation for Modular Foam Pads

The calculation of the cost of this design was done by determining the volume of each pad and multiplying it per  $\text{cm}^3$ . The price was obtained from research. The following is the complete calculation of the design.

$$\text{Volume of one pad} = (30\text{cm}) \times (40\text{cm}) \times (2\text{cm}) = 2400\text{cm}^3$$

The price of memory foam with a 20-year life expectancy is \$4.65 USD per board foot. [49]

1 board foot is  $2359.74\text{cm}^3$  and for simplicity we can round that as 1 board foot =  $2400\text{ cm}^3$

With Coal's current dimensions, he requires three pads, so we find the cost to be:

$$\text{Cost of 3 pads} = (2400\text{cm}^3) \times \left( \$4.65 / 2400\text{cm}^3 \right) = \$13.95 \text{ USD}$$

We convert to CAD to get \$17.56.

### Appendix F7: Comfort Calculation for Modular Foam Pads

This calculation is done using the dimensions of a pad. Since the design is extendable, we can construct it in such a way that it satisfies the metrics for the comfort objective. The following calculation shows one configuration that satisfies the comfortability objective.

$$\text{Width} = (30\text{cm}) \times 5 \text{ pads} = 150\text{cm}$$

$$\text{Length} = (40\text{cm}) \times 5 \text{ pads} = 200\text{cm}$$

## **Appendix F8: Volume and Weight of Molecular Foam Pads**

The calculations of the volume are determined from the given dimensions from section 6.3.1. Where the length = 30cm, width = 40cm, and height = 2cm.

$$Volume = l \times w \times h = (0.3m)(0.4m)(0.02m) = 0.0024m^3$$

The volume of a single foam pad is determined to be  $0.0024m^3$

$$Volume\ of\ Three\ Pads = 3 \times l \times w \times h = 3(0.3m)(0.4m)(0.02m) = 0.0072m^3$$

The volume of three foam pads is  $0.0072m^3$

To calculate the weight of the molecular foam pads the density of pressure relief foam must be found.

Pressure relief foam density ranges from  $3lb/ft^3$  to  $5lb/ft^3$  [67]. For this calculation we will consider the density of  $5lb/ft^3$

First, we must convert  $lb/ft^3$  to  $kg/m^3$ . In doing so, we find the density of pressure relief foam to be approximately  $80kg/m^3$ .

$$Weight\ of\ a\ Single\ Pad = Volume \times Density = (0.0024m^3) \left( \frac{80kg}{m^3} \right) = 0.192kg$$

$$Total\ Weight\ three\ Pads = 3 \times 0.192kg = 0.576kg$$

Finally, we can calculate the mass of three molecular foam pads. We get that three pads weigh approximately  $0.576kg$ .

## **Appendix 0: Outlining the general geometry for the mattress pad device.**

*Case I.*

The mattress must support the patient in a horizontal lying down position.

*General form (side view):*

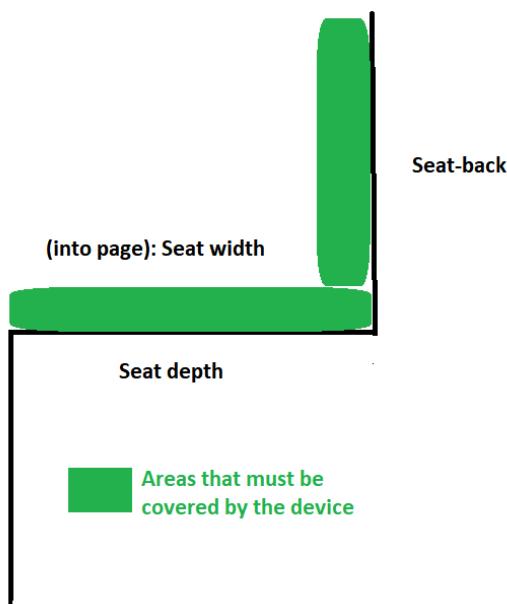


**Figure 20.** Side View of Mattress Pad

*Case II.*

The mattress must support the patient in a sitting down position while in the wheelchair. The areas that must be covered are the entirety of the seat depth, and the entirety of the seat back height. Overflow outside the seat dimensions is undesirable. In addition, the mattress width must not exceed the wheelchair width.

*General form (side view):*



**Figure 21.** Side View of Mattress Pad Positioned on a Wheelchair

In order to facilitate the change from a fully horizontal position to the upright position, the mattress will be composed of several identical sections, each separated by a small gap connected by a minimal amount of connective material to facilitate folding. More specific information about these dimensions can be found in appendix I.

*Main Requirement:*

The design must provide pressure relief to the patient while in either position. This will be accomplished through the current state of the art in bedsore treatment, alternating pressure. Each section of the mattress pad will therefore be composed of several parallel cylinders that are connected to two side tubes, connected at the ends to the air pump/valve system.

### **Appendix I: Calculating required dimensions for general design.**

A key requirement for our design is that it must be usable on both a bed and a wheelchair. This imposes several size constraints that are limited primarily by the size of the wheelchair, since it is the smaller of the 2 service environments. From our PR, the dimensions of the wheelchair we are designing this device for are:

- Seat width: 10-16 inches (avg. 33 cm)
- Seat depth: 8-16 inches (avg. 30 cm)
- Seat height: 8-20 inches (avg. 35 cm)

This means that the width of the mattress pad device must be limited to no more than 33 cm. In order to provide a margin of error (since the device will not be foldable in the horizontal direction, see VII), we have set the width to 30 cm. According to the following graph from [68],

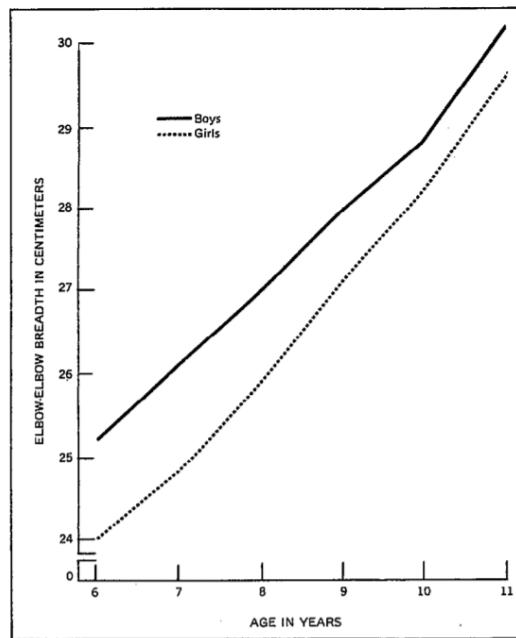


Figure 16. Mean elbow-elbow breadth of U.S. children by age and sex.

**Figure 22.** Mean Elbow-Elbow Breadth of Children

This will allow the patient to not outgrow the mattress in width until at least age 10, giving it a lifespan in that regard of 4 years.

For the length of the device (long axis), we have chosen a length of 120 cm [average height of a 6-year-old], split into 4 sections of 30 cm each by small gaps containing no air cells with only minimal fabric connectors + 2 small air tubes, in order to the sections to be allowed to fold in on themselves. This is critical since as per the previously mentioned wheelchair dimensions, and a PR constraint to not obstruct the wheelchair's control surfaces, each section length must not exceed the seat depth (30 cm) and height (35 cm). To maintain uniformity among section dimensions, the 30 cm length was chosen for each section length. The small 5-cm gap at the top of the seat height is not a concern, as the geometry outlined in appendix 0 means that the vertically oriented sections will already be lying on top of 2\*2.5 cm layers, which means the 5 cm gap is perfectly filled.

## **Appendix II: Calculating the pressure each cylindrical cell needs to be inflated too.**

The force that this mattress pad device must support is the weight of a 220 lb [100 kg = 980N] body, as detailed in the PR. In practice, the actual weight of the 6-year-old child will be much lower, but this is a safety and effectiveness factor that is built in. In the horizontal position, the surface area of the mattress device is

$$0.3m \times 1.2m = 0.36m^2$$

Using the formula for pressure, we can see that the pressure experienced by the mattress surface is

$$\frac{980N}{0.36m^2} = 2722 Pa$$

which is according to the conversion formula = 0.4 psi.

This means that we must inflate the interior cells to at least 0.4 psi in order to maintain support for the maximum weight force.

## **Appendix III: Calculating the required pump needed to inflate the device.**

The following pump model was selected: 6025SE Thomas Diaphragm Air Pump [71].

This is an air pump that is meant for medical applications including *hospital beds* and *air mattresses* and includes a DC model which can be charged via a portable battery. The DC option also includes a controller to manage the parameters of the pump's operation. It has a weight of 3.3 kg, and has a quiet operating cycle, making it ideal for use in the context of our patient's needs. The pump is rated for 4 psi, which is a factor of 10 greater than the 0.4 psi this mattress requires. The airflow rate is 42.5 L per minute, and since the volume of our device is given by:

$$45 \text{ cylinders} \times \pi \left( \frac{2.5\text{cm}}{2} \right)^2 \times 30 = 6626.8 \text{ cc} = 6.62 \text{ L} [45 \text{ cylinders of diameter } 2.5\text{cm}]$$

The pump can comfortably fill the interior volume within 10 seconds, although the actual operating cycle will be derived from current medical state of the art and battery power constraints.

The pump will be attached to the 2 main transverse air tubes that will provide the air to alternating cylinders through a 3-way ball valve [78], in order to allow for one set of alternating cylinders to be inflating while the other set is deflating, giving us the necessary alternating pressure.

Cost= \$254

#### **Appendix IV: Calculating the Power requirements for our device.**

The Thomas valve draws 1.5 A. If we utilise a portable [69] Aluratek power-bank battery which is rated for 16 A-h, and can deliver up to 3 Amps, it can power the Thomas pump/valve for up to 24 hours on a single charge. This will allow us to use the medically accepted inflate/deflate cycle of 10 minutes [70] throughout any period that the patient is in the wheelchair, only requiring the power bank to be charged overnight as the pump is plugged into the outlet in the patient's bedroom. When in the bed position, the pump system will be connected to the end of the mattress at the patient's feet, to minimise disturbances while sleeping, and when in the wheelchair position, the power bank and pump will be stored in a hangable container on the back of the wheelchair's seat, with the air tubes looping over the top of the seat rest to reach the mattress.

Cost: \$65

#### **Appendix V: Finding out what material to construct the device out of**

The material used to construct the main mattress device must satisfy several requirements:

- It must be fire retardant (PR constraint)
- It must be affordable (PR objective)
- It must have a long-life expectancy (PR objective)
- It must be comfortable to a patient with pressure sores (PR objective)
- It must be able to withstand the necessary pressures discussed in appendix II.

The material that satisfied all these properties to a high degree of effectiveness is known as *Polypropylene fabric*.

- Meets/exceeds FMRC's testing requirements for flame retardation, no smoke generation upon burning, no significant charring/burn through [72]
- Polypropylene fabric has a relatively low-moderate cost in textile industry applications [73]
- 20–30-year lifespan for polypropylene
- Current state of the art solutions in bedsore prevention fabrics involve the use of polypropylene due to its desirable moisture and low-friction properties [74], [75]
- Polypropylene can be sourced in thicknesses from 2-12 mm [75]. It also has a tensile strength of approximately 4800 psi [76]. If we assume our cylindrical compartments approximate the geometry of a pipe, we can use *Barlow's formula* for ultimate burst pressure:

$$(Burst\ Pressure, \text{psi}) = 2 \times \frac{(tensile\ strength\ material, \text{psi})(thickness\ material, \text{mm})}{(Diameter\ "pipe", \text{mm})}$$

$$Burst\ Pressure = 2 \times \frac{(4800\ psi)(2\ mm)}{25mm} = 768\ psi$$

Significantly higher than our maximum pressure of 0.4 psi.

In addition, polypropylene is also highly weldable [75], allowing the intra-sectional tubes to be attached to openings in the fabric.

Cost estimate for material and construction = \$60

## **Appendix VI: Air tube design required.**

The air tubes are small physical tubes that will facilitate the transfer of air from one section of the design to another. Since there is a desire to reduce the width of the sections to as much as

degree as possible while in the horizontal position, but also the need to have sufficient clearance so that the folding mechanism will not be compromised, expandable sleeving tubes will be used [77]:



**Figure 23.** Expandable Sleeving Tube

This will allow them to be in a contracted position while horizontal, and to be expanded and stretched when the device needs to fold over to the wheelchair configuration.

## Appendix G: Idea Generation and Selection Process

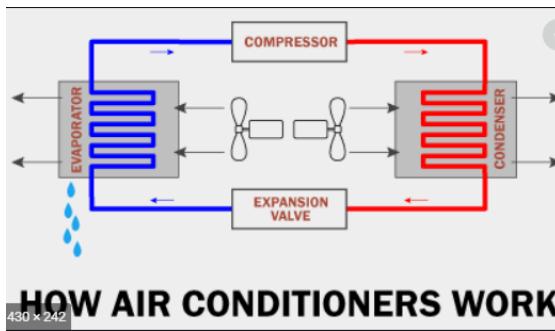
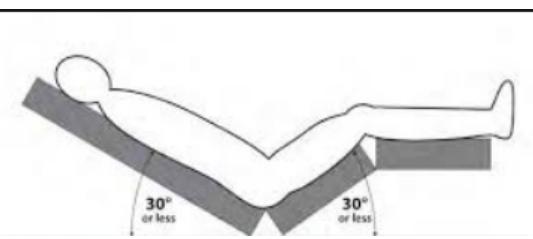
**Table 12.** Ideas generated using Structured Brainstorming, SCAMPER Method, Morphological chart; and two voting rounds to select 16 ideas from 99.

#	Ideas generated using <i>Structured Brainstorming</i>	Round 1 votes	Round 2 votes
1	Curved rocker that attaches to the person and rotates them.	CH1	
2	Two balls in a pad that's extendable that move back and forth.	CY6	
3	Small square pads that can be placed wherever that spring up periodically.		
4	A rectangle pad that's split into two. Air blows up one side at a time.	S7	
5	A rectangle pad that splits into two. A spring lifts up one side at a time.		
6	A cushion with cylindrical sections that have different air pressures.		
7	A pulley system with bands that lifts one side of the body at a time.	CH2	
8	Massage cushion (similar to those massage chairs) that shake.	CH3	

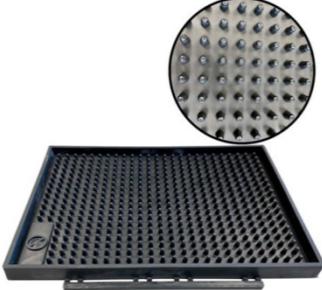
9	Harness with Straps that lock into different positions.		
10	Variations of different position molds.		
11	Bouncy Ball material (kinda like a yoga ball) which will bounce up and down and circular motion.		
12	Motorized foot rollers (but softer material).	J1 CY5	J1 CY1 S1
13	Vibration Pad		
14	<p>Robotic Cushion</p> <ul style="list-style-type: none"> <li>• With the command to initiate a pressure relieving process, the cushion folds in a way that will flip the patient onto their side and therefore change the positioning of the patient and relieve the pressure built up from being one position for a long period of time.</li> <li>• With the command to terminate the process, the cushion will fold in a way that will flip the patient back to their original position.</li> <li>• A similar sort of technology can also be applied to wheelchairs, except in this case with the command to initiate the pressure relieving process, the cushion will start to move in a wave-like motion (like a massage chair) that will help to massage the patient and therefore relieve the pressure built up from sitting in the wheelchair for too long.</li> </ul>	J2 CY4	CH1
15	<p>Human Massage (Maybe not work because parents may go to work?)</p> <ul style="list-style-type: none"> <li>• A set of things that maybe we will provide for the parents to do that will help to relieve the pressure points on the patient.</li> <li>• For example, massaging the points that exhibit some redness.</li> <li>• From repeating this procedure, for a certain number of times, every day can maybe relieve the pressure points on patients and therefore prevent bedsores.</li> </ul>		
16	<p>Medication (Maybe not work, will cause complications along with other prescribed medication?)</p> <ul style="list-style-type: none"> <li>• Since from research we know that staying in a position for a long period of time will obstruct blood flow and therefore lead to bedsores.</li> <li>• With this medication, we can perhaps widen blood vessels to promote blood circulation (to provide nutrients to nearby cells) so even with long term pressure points the patient will still not</li> </ul>		

	develop bedsores.		
17	<p>Microscopic robots</p> <ul style="list-style-type: none"> <li>With the command to initiate the pressure relieving process, the microscopic robots will gather and will reposition the patient. Which will help to relieve the pressure built up from being in the same position.</li> <li>With the command to terminate the pressure relieving process, the microscopic robots will gather and put the patient back into its original patient.</li> <li>The same technology can apply in a wheelchair except that the relieving process will involve helping the patient with repositioning specific parts of the body. (We cannot really do what we did in a bed because there is very limit space in a wheelchair)</li> </ul>		
18	<p>Injectable microscopic robots</p> <ul style="list-style-type: none"> <li>Upon injection the microscopic robots will travel along with blood circulation eventually to the site with blood obstruction. With the command to initiate the process, they will expand the blood vessel to relieve the pressure and increase blood flow (provide nutrients to nearby cells)</li> <li>Upon the command to terminate the process, they will leave the site with circulation obstruction and eventually leave the human body through an excretory system. (Perhaps the urinary system?)</li> </ul>		
19	<p>Robotic Water Pad (similar to a waterbed) (Repeating ideas)</p> <ul style="list-style-type: none"> <li>Works in the same principle as a waterbed, except when you activate to try to relieve pressure some sort of machine embedded in the bed will start to generate waves and try to create something similar to that of a massage chair.</li> <li>When the operator terminates the pressure relieving process, the machine will stop the generation of waves.</li> <li>This same technology can be applied to a wheelchair as well. <ul style="list-style-type: none"> <li>We should choose to use water since it does happen to reduce the development of bedsores.</li> <li><a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4566317/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4566317/</a></li> </ul> </li> </ul>	J3, S9 CY2, CH4	J2 CY2 D5
20	<p>Heating Pad (cover the whole mattress and wheelchair)</p> <ul style="list-style-type: none"> <li>By activating the procedure to relieve pressure, the pad will</li> </ul>	S8, D1	

	<p>start to heat up and warm up the patient. This will help to relieve the pressure built up from sitting in one position for a long period of time.</p> <ul style="list-style-type: none"> <li>• By terminating the procedure to relieve pressure points, the pad will stop heating up and eventually cool down after a period of time.</li> <li>• Same thing can be applied to a wheelchair, where we have a pad on top of the seat of a wheelchair and the pressure relieving procedure will work in the same way as described above.</li> </ul>		
21	<p>Swing</p> <ul style="list-style-type: none"> <li>• There will be a frame attached to the bed (having similar dimensions) and the patient will rest in it as he/she would in a regular bed.</li> <li>• When we activate the procedure to relieve pressure the machine will start to swing sideways which will move the patient from side to side and act the same time moving the patient from a position that he/she has stayed in.</li> <li>• When we terminate the procedure to relieve pressure the machine stops the swinging.</li> <li>• This same technology could be applied to a wheelchair, except at a smaller scale. The pressure relieving process will work in the same way as described above.</li> </ul>	CY3, CH5	CY3
22	<p>Robotic arm</p> <ul style="list-style-type: none"> <li>• There are several robotic arms attached across the frame of the bed.</li> <li>• Upon the command to initiate the pressure relieving process, the robotic arms will be able to reposition the patient and massage their body at the same time to relieve the pressure from being in the same spot over a long period of time.</li> <li>• Upon command to terminate the pressure relieving process, the robotic arms will return to their original position. <ul style="list-style-type: none"> <li>○ This same technology can be applied to robotic arms as well. The pressure relieving process will be the same as the one described above.</li> </ul> </li> </ul>		
23	<p>Trained Squirrels</p> <ul style="list-style-type: none"> <li>• The patient will acquire a family of trained squirrels, upon command they will line up together and massage the patient and will help to relieve the pressure points on the patient.</li> </ul>		

	<ul style="list-style-type: none"> <li>Upon another whistle, they will stop and return to their daily life.             <ul style="list-style-type: none"> <li>This same method of reducing pressure applies with wheelchairs as well.</li> </ul> </li> </ul>		
24	A protective “cocoon” that the patient can wear while on bed/wheelchair	CH6, D2	CH2
25	Water mattress with alternating current that can be controlled based on pressure needs		
	 <p><b>HOW AIR CONDITIONERS WORK</b> 430 x 242</p>		
26	Water mattress with “wave” feature (similar to 21 but ‘mattress’)		
27	Pressure relief folding device- certain positions, like the one shown below, are shown in the literature to reduce points of pressure to the body when compared to a fully horizontal position. A pressure relief folding device would transform the patients resting position into a similar shape as shown below at specific points for a certain time period to reduce the pressure.	S1, J4 CY7, CH7, D3	CY4, S2, D1,CH 3
			
28	Beanbag cushion (Similar to others but using “cushion”)		
29	Roller device that can be automatically controlled during night		
30	Pressure sensor device. This is just something that can augment other design ideas by providing a way for the product to sense if the patient’s body is in hard/prolonged contact with a part of the device. Once this information is obtained, then the device can use the pressure sensor data to decide when to start/stop its treatment if we do include an automatic operational aspect.	D4	
31	Mattress pads that can be assembled into a longer mattress or disassembled into a smaller pad cushion for wheelchairs – this will be	J5, S9	

	achieved by Velcro flaps that can combine single pads into larger/longer mattresses pads. (These pads can be made up of any type of material that helps prevent pressure sore – examples include standard foam, fiber filled, etc.)		
32	Thin mattress pads that can be folded into a thicker and smaller sized pad for wheelchairs or can be unfolded to be a thin long pad that is placed on top of the bed - (will have grooves for folding) made with materials such as standard foam, fiber filled, etc.)	S17, CH8 D5	D6
33	Rolling rods installed under the bed (bed sheet/thick cover will be placed on top of the rollers) - will have a built-in button to start rotating the rods for 5-10 minutes, then will automatically turn off. (Rod size can be adjusted for wheelchair)		
34	Many small beads placed on the rod with built-in button to start rotating the beads for 5-10 minutes, then will automatically turn off. (In this design the large beads will be moving under the bed) - the beads can be removed and placed onto the wheelchair.	J6	
35	Large spherical rollers underneath the bed (will have thick bed cover over the rollers for comfort). Once again will have a start button to automatically roll the rollers for 5-10 minutes. (Similar to 33, small difference in procedure.)	J7, S10 CY8	
36	Make mattress pads using polystyrene beans (material used in bean bag chairs) and apply a similar idea of the Velcro or foldable mattress pads.	D6	
37	A type of vibrating blanket/bedcover placed under the patient to allow their body to move for at least 5-10 minutes, then will turn off automatically.		
38	Pad/pillows made with gel (or any type of liquid material) – will have a built-in function that will keep the gel in motion for a couple minutes and will then turn off automatically.	J8 CY9, CH9, D7	J3 CY5
39	Bedsheets and pillow covers that relieve pressure (can be folded to be used on a wheelchair) - will be made with material that does not absorb moisture, keeping skin dry. (will be like a cooling bedsheets)		
40	Fabric above bed/wheelchair seat that occasionally slides left and right to “pivot” body.  • Similar to Chris & Crystal: Swing system.		
41	Rollers integrated inside fabric that create uneven pressure areas.	J9 CY10	
42	Expanding on roller idea: Device that actively inflates and deflates for inconsistent pressure against the body.	S11	J4 CY6 S3, D1

43	Bed/wheelchair w/ rollers that move the patient (Areas between the rollers have no normal pressure.)		
44	Fabric w/ self-compressing springs inside, springs change their state between compressed and extended to carry the user's w/o applying constant pressure on any individual part for more than 2 hours.	CH10, D8	
45	Magic idea Air Blower-like devices are pushed at the side of the body & bed/wheelchair surface; Air is occasionally forced between the contact surfaces to briefly reduce pressure. Similar to human exhaust while sitting.		
46	Stretchable fabric w/ antenna like mechanisms inside that expand to lift different parts of the patient's body.	J10 CY11	
47	Magic idea: Bed & wheelchair are basically miniaturized wind tunnels within small frames.		
48	Similar idea to a floor mat but used for a bed or wheelchair. This mat will be small in size such that it can fit on the wheelchair. In terms of the bed, several mats can be lined up to fit the size of the patient's bed. Generally, this mat will have a spike like texture which is good for increasing blood flow (will be comfortable enough to lay on).	CH11	
			
49	Portable pressure bed: This is similar to the idea of a yoga mat in terms of the way they can be stored. It should be a type of mat that can drape over a wheelchair and can be used on top of the patient's bed. This can also have a built-in massage setting, so when the patient requires body movement, they can turn on the massage setting to allow the body to move for 5-10 minutes.	S12, J11 CY12, D9	J5 CY7 S4, D2, CH4

			
50	Similar idea to compression socks: This is like adding onto Dom's idea for creating something the patient can wear. Basically, compression socks are made with elastic fibers that apply pressure on the skin to increase blood flow (can have a zipping feature for patient to wear easily).	S13, CH12	
51	Materials for wearable design (addition to Dom's idea): The design can be made with materials used for sports fabrics as they are good for thermal insulation, so if the patient is sweating this material helps with cooling down the body. Other feature includes vapor transmission (waterproofing material), so when the patient sweats the material will allow the moisture to escape as vapors.		
52	Mattress pad/ bed mat made with Celliant fiber: This material is often used to increase blood flow in the body. Maybe find a way to incorporate this material into the other designs (not really a single idea but a sub idea to add onto other ideas)		
53	Analogy (automatic response to pain, like having your hand too close to a fire): Like Dominik's idea, where there is a cocoon, there is some sort of sensor within the clothing, when there is excessive pressure, the clothing will react (putting air inside the clothing and then releasing) and reposition the patient. When in a wheelchair, when the sensor senses that there is excessive pressure will employ alternating air bubble to reduce the pressure.	J12 CY13	CH5
54	Robotic Suit: Magic Solution: Attached to the patient and will lift different parts of the body. This is related to the pulley system and can be applied to a wheelchair as well.		
55	Analogy (automatic response to pain): Whenever the patient is in a position for too long, the design will deliver an unpleasant stimulus (not harmful to the health of the patient in any way) that will force the patient to voice their concerns before a pressure sore could develop. This will get the attention of the caretaker for them to reposition the patient. This same technology could be applied to a wheelchair as well.		
56	Timer: After certain period of time, the caretaker will be alerted that	D10	

	the patient has been in a position for a long period of time and need to be repositioned. This could be done by placing pad with pressure sensors). The same technology can be applied to wheelchair, where a pad with pressure sensors is placed on top of the seat of the wheelchair and when there is an excessive amount of pressure applied, will send out an alert to the caretaker to be positioned.		
57	Mattress: Build with a material that will melt with temperature, upon command to reduce pressure, the mattress will heat up and melt the material within, at the same time becoming softer like (water) and heats up the patient's body to reduce pressure. Upon command to terminate the procedure, the temperature will decrease, and the material will solidify (not all the way to the degree of a regular mattress's softness). Applies to wheelchair as well, except the mattress will be a thick pad on the seat of the wheelchair instead.		
<b>Ideas generated using the SCAMPER method</b>			
58	Pressure Relief Folding Device with padding made of Celliant fiber (similar to others. Difference: "folding device").	S14, CH13	
59	Pressure Relief Folding Device with heating instead of regular padding.		
60	Replacing the unpleasant stimulus with an automatic response to mold cushion into comfortable and pressure relieving position.	S3 J13 CY1, CH14	
61	Combining rollers that are integrated within the mattress padding with mattress that vibrates.	D11	
62	Portable Rollers made with similar materials made for the mat in idea #48. Can be put below the patient as it automatically rolls and vibrates.	J14	
63	Vibrating Blanket made of cooling and pressure relieving material.		
64	Vibrating Blanket that also heats/warms the patient.		
65	Pressure Sensor Device when activated will target and vibrate the area.		
66	Yoga Ball material that can lift the patient into different positions (Kinda like a bouncy ball but certain areas can stay lifted).		
67	Protective wearable cocoon with rollers inside. (Think of a puffer jacket but instead of down there are rollers).	J15 CY14	
68	Wearable cocoon filled with water.		
69	The motion of the folding device that reduces critical "pressure points" by placing the patient in a more relaxed non-horizontal position will be activated once embedded pressure sensors detect the existence of such points for a certain time period. (Similar to idea 29.	D12	

	Components and procedure slightly different.)		
70	A roller device that will have the rollers inside a gel filled mattress, in order to provide some relief between the patients back and the edges of the rollers (no pinching), while still allowing for the desired motion.	D13	D7
71	A bean-bag mattress that can adjust its shape periodically in order to eliminate developing pressure points through “shaking up” the beans using an embedded vibration pad.	D14	
72	A protective cocoon that also features thermally conductive “wires” which means that in addition to reducing pressure points using cushion relief, the variable thermal relief discussed in other ideas is also provided. Example:	S2, J16 CY15, CH15 D15	S5, D3, CH6
			
73	Spherical rollers that are controlled/operated by being placed in water that flows in a current via pressure difference. This reduces the complexity of any roller system (esp. Spherical rollers) that needs to be operated via mechanical means.		
74	Modular mattress with sections made up water-pads able to individually generate waves.		
75	Replace water in pad with air. Air will have various pressure levels to create wavelike effect.		
76	Wearable fabric that eliminates static pressure with integrated rolling rods.		
77	Wearable fabric with numerous expandable air tubes that can individually increase/decrease air pressure to limit static pressure.	S4	
78	Cushion that can vary pressure of static airflow intake by	S5	

	increasing/decreasing air travel space at various areas.		
79	Wearable protective “cocoon” made with sports fabric.		
80	Wearable protective “cocoon” that can be controlled through a sensory device and is made from elastic fibers (helps to release pressure)		
81	Pressure relief folding device that is made from Celliant fiber.		
82	Pressure relief folding device that molds into the patient's body.		
83	Portable pressure bed that will alert caretakers to turn on vibrating blanket/bedcover. (will turn on automatically).		
84	Massage cushions that can be assembled and disassembled into longer or shorter cushions using Velcro and will alert caretakers to turn on the device.	S6, J17 CY16	J7 S7

**Ideas generated using *Morphological Chart***

85	With the press of a petal the device will change the shape of a cushion that is made from fabric to reduce static pressure, and it will return to its original shape using a controller.		
86	A spring and water wave mattress that is activated with a crank handle and is stopped using a keyboard to type in a specific password.		
87	A elastic band that carries the weight of specific body parts of the patient that is activated by a pressure sensor. At the same time the device will have alternating air pressure within the mattress that will also help to reduce static pressure. This whole process will be terminated using voice control.		
88	A spring that is activated by cranking a handle and will change positions which can be stopped using voice control.		
89	A thick pad filled with gel and pressure sensors that will automatically turn on and the device to move the gel into different positions. The device will stop after a designated time period.		
90	A foam pad which turns on with a button and will stop after a certain time period.		
91	A spring-mattress system which has pressure sensors that can activate the compression/relaxation of the springs to change the shape of the mattress in order to reduce pressure points, automatically stopping after some time has elapsed.	S15	D4 CH7
92	A foam mattress that activates airflow for alternating air pressure through the depression of a pedal in order reduce pressure points, stops automatically after a certain time period.	CH16	
93	A gel/water bed which actives based on commands from an external	S16 CY17	

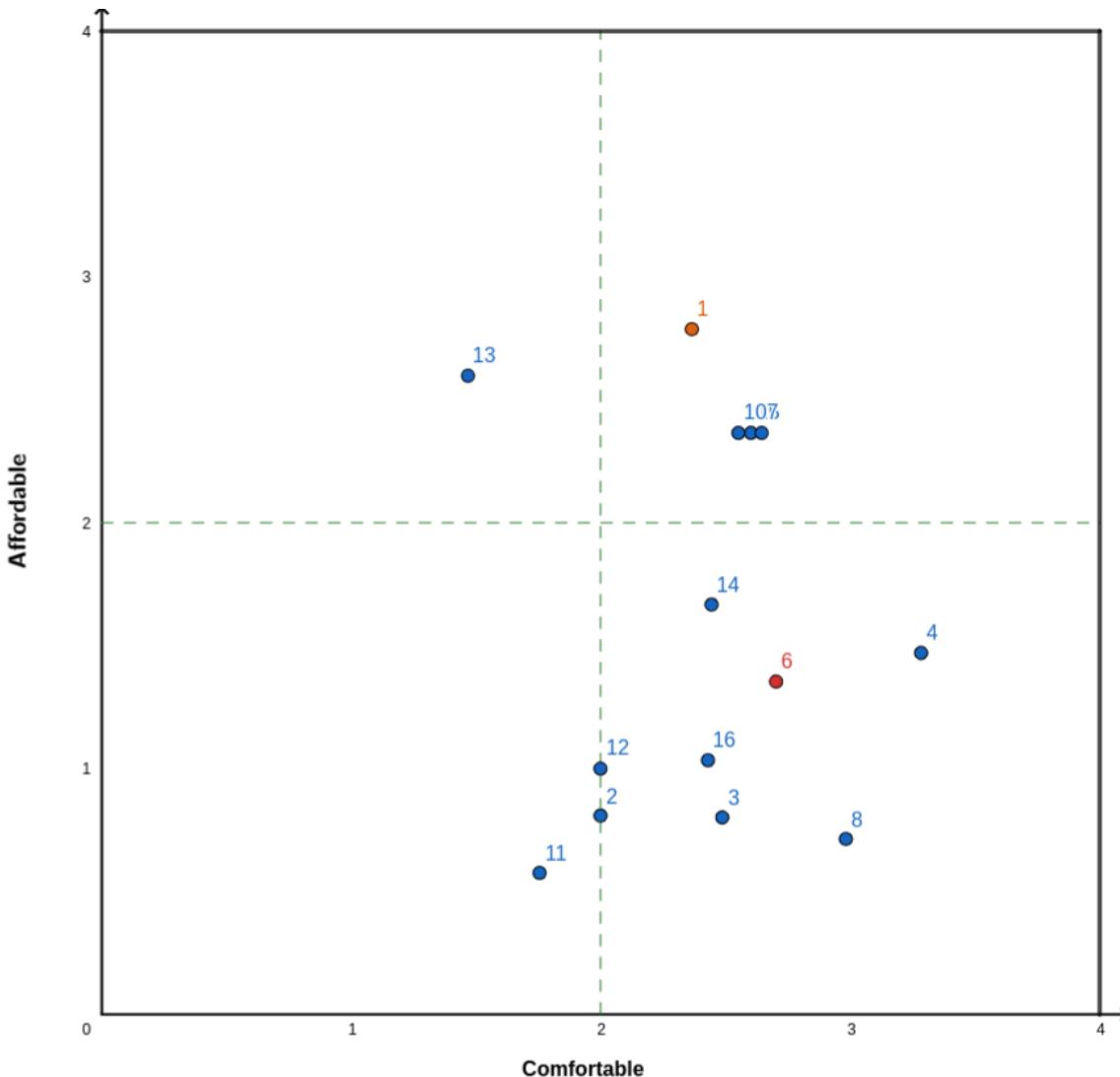
	controller/mobile application used by the parents (operators).		
94	Air filled foam device that can passively increase/decrease pressure at different sections with a crank or a handle. A timer is automatically set to terminate the process.		
95	Pad mechanism that shifts thick gel to rock user's body. Procedure starts by depressing a petal linked to the unit. Password protected deactivation via a keypad prevents accidental termination if caregivers aren't in close proximity.		
96	Fabric supporting the user is attached arms at its side that expand and compress to stretch and relax the material in order to reduce static pressure. Process starts by pushing an activation button on the device. Microphones and voice recognition software allow for deactivation by stating a programmed word or phrase out loud.	D16	
97	A gel-filled mattress/pad that produces water like motion within the mattress/pad and can be controlled by a controller/phone.		
98	A mattress/pad made from foam like material that has a heating system within the mattress which has a built-in pressure sensor that begins once the patient is in bed and will have a voice command system to turn the heating off within the bed.		
99	A mattress/pad made from springs that can physically change the position of the patient (idea #29) which can be controlled by a start button and turn off automatically after a certain time.	CH17 D1	

**Table 10.** Multi-voting results used for the Graphical Decision Chart to select the alternative design solutions.

#	Ideas
1	<del>Motorized foot rollers (but softer material) / inside fabric.</del>
2	<p>Robotic Cushion</p> <ul style="list-style-type: none"> <li>• With the command to initiate a pressure relieving process, the cushion folds in a way that will flip the patient onto their side and therefore change the positioning of the patient and relieve the pressure built up from being one position for a long period of time.</li> <li>• With the command to terminate the process, the cushion will fold in a way that will flip the patient back to their original position.</li> <li>• A similar sort of technology can also be applied to wheelchairs, except in this case with the command to initiate the pressure relieving process, the cushion will start to move in a wave-like motion (like a massage chair) that will help to massage the patient and therefore relieve the pressure built up from sitting in the</li> </ul>

	wheelchair for too long.
3	<p>Robotic Water Pad (similar to a waterbed) (Repeating ideas)</p> <ul style="list-style-type: none"> <li>• Works in the same principle as a waterbed, except when you activate to try to relieve pressure some sort of machine embedded in the bed will start to generate waves and try to create something similar to that of a massage chair.</li> <li>• When the operator terminates the pressure relieving process, the machine will stop the generation of waves.</li> <li>• This same technology can be applied to a wheelchair as well. <ul style="list-style-type: none"> <li>◦ We should choose to use water since it does happen to reduce the development of bedsores.</li> </ul> </li> </ul>
4	<p>Swing</p> <ul style="list-style-type: none"> <li>• There will be a frame attached to the bed (having similar dimensions) and the patient will rest in it as he/she would in a regular bed.</li> <li>• When we activate the procedure to relieve pressure the machine will start to swing sideways which will move the patient from side to side and act the same time moving the patient from a position that he/she has stayed in.</li> <li>• When we terminate the procedure to relieve pressure the machine stops the swinging.</li> <li>• This same technology could be applied to a wheelchair, except at a smaller scale. The pressure relieving process will work in the same way as described above.</li> </ul>
5	<del>A protective “cocoon” that the patient can wear while on bed/wheelchair</del>
6	Pressure relief folding device- certain positions, like the one shown below, are shown in the literature to reduce points of pressure to the body when compared to a fully horizontal position. A pressure relief folding device would transform the patients resting position into a similar shape as shown below at specific points for a certain time period to reduce the pressure. (Ex: Zero G bed.)
7	Thin mattress pads that can be folded into a thicker and smaller sized pad for wheelchairs or can be unfolded to be a thin long pad that is placed on top of the bed - (will have grooves for folding) made with materials such as standard foam, fiber filled, etc.) + Temp? Research effect of heat on sores.
8	Pad/pillows made with gel (or any type of liquid material) – will have a built-in function that will keep the gel in motion for a couple minutes and will then turn off automatically.
9	<del>Expanding on roller idea: Device that actively inflates and deflates for inconsistent pressure against the body.</del>
10	Portable pressure bed: This is similar to the idea of a yoga mat in terms of the way they

	can be stored. It should be a type of mat that can drape over a wheelchair and can be used on top of the patient's bed. This can also have a built-in massage setting, so when the patient requires body movement, they can turn on the massage setting to allow the body to move for 5-10 minutes
11	Analogy (automatic response to pain, like having your hand too close to a fire): Like Dominik's idea, where there is a cocoon, there is some sort of sensor within the clothing, when there is excessive pressure, the clothing will react (putting air inside the clothing and then releasing) and reposition the patient. When in a wheelchair, when the sensor senses that there is excessive pressure will employ alternating air bubble to reduce the pressure.
12	A roller device that will have the rollers inside a gel filled mattress, in order to provide some relief between the patients back and the edges of the rollers (no pinching), while still allowing for the desired motion.
13	A protective cocoon that also features thermally conductive "wires" which means that in addition to reducing pressure points using cushion relief, the variable thermal relief discussed in other ideas is also provided.
14	Wearable fabric with numerous expandable air tubes that can individually increase/decrease air pressure to limit static pressure.
15	Massage cushions that can be assembled and disassembled into longer or shorter cushions using Velcro and will alert caretakers to turn on the device.
16	A spring-mattress system which has pressure sensors that can activate the compression/relaxation of the springs to change the shape of the mattress in order to reduce pressure points, automatically stopping after some time has elapsed.



**Figure 24.** Graphical decision chart used to select 3 alternative design solutions.

**Table 13.** Objectives used for the graphical decision chart.

Objective	Goal with metric
Affordable	Should minimize design cost to less than \$200. (Appendix B1)
Comfort	Should cover surface dimension of bed fitting for a large adult: 137cm x 190cm. (Appendix B2)

**Table 14.** Updated alternative design solutions.

#	Idea
1	3( or 2) pads made of pressure reliving foam a. Can be folded into the shape of a wheelchair (groves for folding)
2	Tubed fabric: pump, valves, central computer. -> update #10

	<ul style="list-style-type: none"> <li>a. Plug in at night</li> <li>b. Battery during the day</li> </ul>
3	<p>3 (or 2) massage pads that can be connected</p> <ul style="list-style-type: none"> <li>a. In each pad there is a frame, one roller, one axle, one motor</li> <li>b. The roller will move up and down the rails</li> <li>c. The pad is covered by a thin piece of foam</li> </ul>

**Table 15.** Weighted decision matrix used to select proposed conceptual design.

Obj #	Obj weight	Alternative #1	Alternative #2	Alternative #3
1	30%	$30\% * 80\% = 0.24$	$30\% * 60\% = 0.18$	$30\% * 60\% = .18$
2	30%	$30\% * 60\% = 0.18$	$30\% * 100\% = 0.3$	$30\% * 60\% = .18$
3	15%	$15\% * 80\% = 0.12$	$15\% * 60\% = 0.09$	$15\% * 60\% = .09$
4	15%	$15\% * 80\% = 0.12$	$15\% * 60\% = 0.09$	$15\% * 40\% = .06$
5	10%	$10\% * 80\% = 0.08$	$10\% * 100\% = 0.1$	$10\% * 80\% = 0.08$
<b>Total</b>	<b>100%</b>	<b>0.74</b>	<b>0.76</b>	<b>0.59</b>