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NEONATAL CHEST COMPRESSION DEVICE

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Abstract

The goal of the project was to design a neonatal chest compression device to be used in the NICU of the Monroe Carell Jr. Children’s Hospital at Vanderbilt during surgical procedures performed on the infant’s abdomen or chest. During these procedures the surgeons cannot stop to perform the chest compressions so another doctor or nurse is needed; however, due to size constraints, there is no room for another person to step in around the bed to perform the compressions. Therefore, the device must occupy minimal space around the operating area and be quick and easy to set-up. In order to be a success, the device must provide chest compressions as effective as or more effective than the traditional, manual method. It must maintain a rate of 80-100 compressions a minute and provide 11-12 pounds of force in order to compress the width of the infant’s chest by one third. The force value was obtained through a series of tests performed on Isabel, a SimNewB simulation baby housed in the NICU. Isabel was also used as the method of evaluation when testing the final prototype. The final design consisted of a compressed air actuated pneumatic cylinder placed directly above the infant’s chest. The compressed air was supplied by a portable, quiet air compressor and the air flow was controlled by a three-way solenoid valve and electronic timer. From testing, it was concluded that the device was successful in meeting the basic criteria, however further work should be done to implement important safety aspects including maximum force control and sterilization.
I. Introduction

1.1 Problem Statement

The purpose of this project was to design a neonatal chest compression device to be used in the NICU of the Monroe Carell Jr. Children’s Hospital at Vanderbilt. Infants in the NICU are 0-30 day olds and weigh from mere ounces to three pounds. These infants may undergo surgical procedures in the abdomen, chest, and/or neck regions. Common surgical procedures include the gastroschisis repair where the infant’s intestines and internal organs are placed back inside the infant’s abdomen\textsuperscript{1}, and the Kasai procedure to connect the liver to the small intestine for infants with biliary atresia\textsuperscript{2}. During these procedures, emergency chest compressions to restart the heart and get blood pumping may need to be performed. The surgeons cannot stop their surgeries to perform the chest compressions. Another doctor or nurse is needed to perform the chest compressions; however, due to the tiny size of the newborn, there is no room for another person to step in around the bed to perform the compressions.

Chest compressions are performed as seen in Figure 1. The doctor wraps both his hands around the infant’s chest. The thumbs press down on the center of the infant’s chest below the nipple line. The force of the thumbs should compress the width of the infant’s chest by one third or approximately two to three centimeters. The doctor needs to apply a steady rate of 80-100
compressions per minute. In the past year, Dr. Walsh has seen two such incidences occur, where an infant needed chest compressions but was unable to receive them due to the limited space.

1.2 Device Goals

Before designing the device, we came up with criteria and goals the device had to meet in order to be considered a success. Our overarching goal was for the device to ultimately be used in the Children’s Hospital at Vanderbilt and in other NICU’s. The device therefore needed to meet the requirements set by our advisor, Dr. Walsh.

The most important factor we considered was safety. When designing the device, safety needed to be our primary concern. Our first goal was to thus design a safe device with built in safeguards. The limited space in the NICU needed to be addressed with our device. Therefore, our second goal was to build a device that would take up little space and not intrude upon the surgeon’s space. The device also needed to be OR compatible. We needed to use materials that could be easily sterilized or covered in sterilized drapes.

In order to be a success, the device needed to provide chest compressions as effective as or more effective than the traditional, manual method. Thus, the device needed to provide 80-100 compressions a minute. The driving force of the device needed to reduce the width of the infant’s chest by one third. The depth of chest compression needed to be variable due to the varied size of infants in the NICU. For the device to be used in emergency surgical situations, it needed to be fast and easy to setup. If the device took minutes rather than seconds to setup, it would be worthless to Dr. Walsh, thus fast deployment was a necessary component to the device. In order to facilitate fast setup times, the device should be portable, easy to transport from NICU room to room.
1.3 Current Chest Compression Devices

To begin designing the device, we looked at four standard chest compression devices available in the market. Currently, there are no chest compression devices available for use on children or more specifically, small infants in the NICU. The American Heart Association Guidelines presently do not recommend performing automated mechanical chest compressions on infants\(^4\). In researching the Life-Stat, AutoPulse, LUCAS 2, and X-CPR, we aimed to scale down the adult chest compression device into a smaller neonate friendly design.

<table>
<thead>
<tr>
<th>Method of Actuation</th>
<th>Life-Stat</th>
<th>LUCAS II</th>
<th>X-CPR</th>
<th>AutoPulse</th>
</tr>
</thead>
<tbody>
<tr>
<td>Piston via compressed air (50-90 psi)</td>
<td>Piston via electricity</td>
<td>Piston via compressed air and constricting band</td>
<td>Load distributed band</td>
<td></td>
</tr>
<tr>
<td>Dimensions (length, width, height)</td>
<td>18.3 x 7.6 x 22.5 inches</td>
<td>12.6 x 9.1 x 25.2 inches</td>
<td>20.5 x 17.7 x 3.0 inches</td>
<td>32.5 x 18.2 x 3.3 inches</td>
</tr>
<tr>
<td>Weight</td>
<td>19 pounds</td>
<td>17.2 pounds</td>
<td>25.4 pounds</td>
<td>27.1 pounds</td>
</tr>
<tr>
<td>Compression Depth</td>
<td>0 – 3.2 inches</td>
<td>1.57 – 2 inches</td>
<td>0 – 2 inches</td>
<td></td>
</tr>
<tr>
<td>Rate of Compressions</td>
<td>100 per minute</td>
<td>100 per minute</td>
<td>100 per minute</td>
<td>80 per minute</td>
</tr>
<tr>
<td>Powered By</td>
<td>Battery</td>
<td>Battery or electrical outlet</td>
<td>Battery</td>
<td>Battery</td>
</tr>
</tbody>
</table>

*Table 1. Comparison of adult chest compression devices.*

The Life-Stat by Michigan Instruments provides chest compressions via compressed air at 50 – 90 psi. The Life-Stat is an updated version of the Thumper 1007 model and meets the requirements for chest compressions set out by the 2010 American Heart Association Guidelines\(^4\). The Life-Stat is composed of a backboard connected to a rigid stand containing the oxygen powered piston as seen in Figure 2. A key advantage of the Life-Stat is its ability to vary the depth of compression. The compression depth varies from 0 – 3.2 inches. This allows for the
device to be used on a variety of patients because the device will not be limited by patient size. The device also boasts the fastest setup time in comparison to other devices researched. According to Michigan Instruments, the Life-Stat takes approximately five seconds to setup as opposed to 30 for the AutoPulse and 20 for the LUCAS 2. It should also be noted that the Life-Stat as well as the X-CPR and LUCAS 2 have built in ventilators to be used in conjunction with the chest compressions. Our advisor, Dr. Walsh does not believe this feature is necessary for our neonatal chest compression device. Thus, the ventilation specifications of the devices are not compared in this paper. One of the main disadvantages of the Life-Stat is its bulky design. The device is 22.5 inches tall, 7.625 inches wide and 18.25 inches long. With the backboard included, the device weighs 19 lbs. Another disadvantage of the Life-Stat is the inability to vary the rate of compressions. The compression rate is set at 100 compressions per minute. The device provides some good design ideas, mainly the use of compressed air to power a piston. Pistons have been found to provide better chest compressions than the manual method of CPR. In a study using porcine models, the Thumper, the predecessor to the Life-Stat device, was found to increase coronary perfusion pressure and return of spontaneous circulation. The study authors attributed the increase in pressure and return of circulation to the rapid down stroke of the piston.

The LUCAS 2 by Jolife is similar to the Life-Stat; a suction cup like piston is actuated to provide compressions. The LUCAS 2 builds off of the original LUCAS device that used pneumatics to actuate a piston. Electrical power is used in the updated LUCAS device. Instead
of using a stand connected to a backboard like the Life-Stat, the LUCAS 2’s piston is held by two supporting legs which connect to a backboard as seen in Figure 3. The LUCAS 2 measures 12.6 inches by 25.2 inches by 9.1 inches and weighs 17.2 pounds\(^7\). Thus, the LUCAS 2 is slightly more lightweight than the Life-Stat. The advantages of the LUCAS 2 include: its ability to maintain correct chest compression position, it’s made of composite, non-conducting materials, and it runs off of a battery or if desired, electrical power. In a study using an artificial thorax from pigs, the LUCAS 2 provided enhanced pressure and blood flow in comparison to manual CPR\(^8\). The disadvantages of the LUCAS 2 are similar to those of the Life-Stat device and include the inability to vary compression rate and its bulky design. In order for the same chest encircling, piston supporting legs to be incorporated into the NICU chest compression device, the maximum width of the supporting legs would be limited to an inch as to not disrupt the work of the surgeons and take up too much space. Thus, this type of support structure would be difficult to adapt for our design.

The X-CPR by Humed Co., Ltd, has a similar design to the LUCAS 2. As seen in Figure 4, the device is composed of a band with a piston powered by compressed air. In addition to the action of the piston, the strap constricts the chest providing Simultaneous Sterno Thoracic Cardiopulmonary Resuscitation (SST-CPR), which is a combination of chest compression and

**Figure 3.** Picture of the LUCAS 2, which uses electric power to drive the device as opposed to compressed air\(^7\).

**Figure 4.** Picture of the X-CPR by Humed Co., Ltd, which uses a sterna piston and thoracic strap to provide SST-CPR\(^9\).
constriction. SST-CPR provided by the X-CPR has been shown in canine studies to improve the return of spontaneous circulation as compared to manual chest compressions. Another advantage of the X-CPR device is its ability to vary the depth of compressions from 0 – 5 cm. The device is limited in that the compression rate is fixed at 100 compressions per minute. The weight of the device is also a major disadvantage; it weighs 25.4 pounds, eight pounds more than the LUCAS 2.

The AutoPulse by Zoll takes a different approach to providing compressions. Instead of using a piston powered by compressed air, the device compresses the chest using a load distributed band. As Figure 5 shows, the device consists of rigid backboard connected to the constricting band. The advantages of the device include ease of use and automated ability to adjust to the patient’s chest size, shape, and resistance. The AutoPulse’s main disadvantages include its heavy weight, 27.1 pounds and its compression method, the chest constricting band. For the NICU device, Dr. Walsh desires a device that provides a point force in the center of the chest below the nipple line. Conflicting studies have come out on the effectiveness of the AutoPulse. A study comparing the AutoPulse to manual chest compressions on porcine models found that the AutoPulse had superior myocardial flow, aortic pressure, and coronary perfusion pressure. However, a study in the Journal of the American Medical Association found that the AutoPulse had worse neurological outcomes and a lower incidence of survival versus manual compressions on hospital patients. Zoll, the makers of the device, also have recently been targeted by the FDA for failure to disclose complaints about the AutoPulse. The AutoPulse is battery operated and according to the complaints, the device stopped working.
due to battery failure or power loss and prematurely ended chest compressions\textsuperscript{14}. While the load distributing band of the AutoPulse looks promising, its design is inferior to the other compression devices for our project. A band constricting the entire chest of neonate is not the best option for our NICU device. A piston driven device would be better suited for our project.

\textbf{II. Methods}

\textit{2.1 Initial Prototype Designs}

The design approach began by identifying multiple mechanisms by which force could be safely applied to an infant chest either manually or automatically. The first prototype design involved a contained air balloon placed directly above the chest that would expand with incoming air provided by either a hand or foot pump. This device would be manual, allowing the surgeon to control the rate at which the compressions are provided. However, the concern with this device was that the air would not enter and exit the balloon fast enough to provide a rate of 80-100 compressions per minute. The next approach was to somehow incorporate a belt around the chest that would be pulled downward towards a backboard to compress the chest. This could have been done manually with a pulley system or automatically with a step motor and controller to maintain a constant rate. The fear with this device was that it would not provide proper compressions because the force would not be concentrated directly in the center of the chest.
2.2 Final Prototype Design

Our final prototype design, the one that was eventually built and tested, involved a more sophisticated pneumatic system. The system consists of a stainless steel single-acting, spring return pneumatic cylinder actuated by compressed air from a mobile, quiet air compressor, shown in Figure 6. The air compressor incorporated was mounted on a cart. The air flow in this system is controlled by a three-way solenoid and electronic timer configured as shown in Figure 7. In the on-position, the solenoid valve takes in compressed air and feeds it to the pneumatic cylinder forcing the piston to thrust downward. In the off-position, the valve releases the air supply into the environment through an exhaust which allows the spring return on the cylinder to push the piston back into the rest position. Since the timer allows for cyclical switching of the valve between on and off, the piston is able to move up and down in a repetitive fashion. The timer was provided by JORC industrial and is able to accommodate valve opening and closing times from 0.1 seconds to 99 hours. The power source for the

**Figure 6.** The final device design incorporated an air compressor (left) and a pneumatic cylinder (right). The flow of air was controlled by a solenoid valve and electronic timer.

**Figure 7.** The 3-way solenoid connects directly to the electronic timer which connects directly to the power source. The inlets and outlets on the valve are also shown.
solenoid valve, timer, and air compressor is simply drawn from a typical wall outlet at 60 Hertz and 120 Volts.

Two ideas were generated for the design of the support structure. The first was to use a stand mount that sits under the infant and is anchored by its weight with an extending, adjustable arm that supports the cylinder directly over the baby’s chest. This was the design that was built and tested. The second idea is still a potential possibility for future improvement and involves incorporating a flexible arm that connects directly to the side of the bed. The bed used in the Vanderbilt NICU is the Giraffe OmniBed by General Electric, and there is a specific connection piece needed to mount accessories to the side of the bed. The piece has been acquired, but further design is needed to build the flexible arm support system.

2.3 Force Determination

In order to determine the specifications of the required pneumatic cylinder, it was necessary to evaluate the amount of force needed to compress a baby’s chest. This information was not readily available in any literature accessed so it was found experimentally via two methods. The first method was to use Isabel, the SimNewB simulation baby housed in the Vanderbilt NICU, and a bathroom scale. The scale was placed underneath Isabel’s back and was used to record measurements of force as traditional compressions were performed on her chest. From this data a range of acceptable forces was identified. To verify this range and that the scale itself was measuring correctly, a second method was used in which free weights were used to compress the chest.
2.4 Calculations

Once the force required was found, calculations were performed to determine the specifications. The following equation was taken from a guide on pneumatic cylinder mechanics:

\[ F = p A = p \pi d^2/4 \]

Where \( F \) = force exerted (N), \( p \) = gauge pressure \((N/m^2, \text{Pa})\), \( A \) = full bore area \((m^2)\), and \( d \) = full bore piston diameter \((m)\). From testing, the lower limit of acceptable force was found to be 12 pounds, or approximately 50 Newtons, and the air compressor acquired was able to provide a constant source of compressed air at 100 psi, or about 690 kilopascals. Using this information, the bore diameter of the pneumatic cylinder was found to be 10 mm, or about \(7/16\)th of an inch.

![Table 2](image)

The next calculation necessary was that of the time cycle. Since the device incorporated a timer with an on-time and off-time, the full cycle would be a sum of the two. In order to provide the correct rate, the device would need to cycle 80 to 100 times each minute meaning the full cycle time would need to be between 0.6 and 0.75 seconds. It was assumed that on-time would equal off-time and therefore each would be half of the full time. The range of cycle on and off times is shown in Table 2 and the calculations leading to this result are shown below:

\[ Cycle \text{ Length} = 1/Cycle \text{ Frequency} \]

\[ On/Off \text{ time} = Cycle \text{ Length}/2 \]

In order to accommodate the need to change the cycle time, the timer incorporated in the design was variable and the on/off time ranges were each 0.1 seconds to 99 hours.
2.5 Safety Considerations

The safety aspects of the device were evaluated using DesignSafe, included in Appendix B. DesignSafe allowed for the proper documentation of every possible safety concern as well as the risk level. Then possible ways to avoid risk were determined and risk levels incorporating safety features into the design were calculated. At the end, all but one had risk levels of low. The possibility of rupture due to an exorbitant amount of pressure in the system remained at a moderate risk level. Unfortunately, even with proper training, this is still a potential concern.

2.6 Evaluation

Finally, in order to evaluate the prototype, it was tested on Isabel under similar conditions as in the NICU, meaning that the same amount of space and appropriate equipment was present. Isabel’s monitor was able to identify proper compressions by measuring blood flow rate. Figure 8 illustrates the initial evaluation of the device on Isabel from which one can see the limited amount of space around the baby and the bed, as well as proper placement and positioning of the device.

Figure 8. The proper placement of the device is in the center of the chest directly below the nipples. The device takes up minimal space around the infant as there is very little room to begin with.
III. Results

3.1 Force and Pressure Data

The force data collected using Isabel determined that proper chest compressions performed on an infant of that size requires no less than 11 pounds of force. Unfortunately, Isabel’s blood flow monitor was not able to tell us if the force was too great, only if it was too low. Therefore, for safety reasons, the device was designed to only provide force between 11 and 12 pounds. However, the provided force can be increased or decreased by changing the gauge pressure on the compressed air source. Figure 9 displays the force data collected, as well as a corresponding graph that illustrates the necessary pressure provided by the air compressor. These pressure values were determined using the experimental force data and the equations illustrated in the Methods. Theoretically, a minimum of 72 psi is required to provide proper compressions. However, when tested on Isabel, anything below 100 psi was insufficient.

Figure 9. After performing a series of tests on Isabel, we were able to determine a minimum baseline for effective compressions (top). From those results, the force data was translated into input pressure to identify a theoretical minimum for the air compressor setting (bottom).
3.2 Addressing Adjustability and Safety

The final design that we ended up building proved to be a great advance in engineering an automatic device able to perform chest compressions on an infant. The device also included several adjustable components so that it would be useful in multiple situations and on different size infants. These include the ability to change the height and position of the air cylinder so that it can be properly placed just above the infant’s chest, as well as the ability to adjust the output force by varying the gauge pressure on the air compressor and the cycle time by changing the on/off time on the timer. The application of adjustability also addresses specific safety concerns. For example, by setting the gauge pressure on the air compressor to reach a maximum of 100 psi, it ensures that the compressor will not provide a force great enough to do any harm to the baby. For smaller infants, this maximum setting can be adjusted downward. Another issue of safety addressed was sterilization. Since only the rubber stopper at the end of the piston actually comes into contact with the baby, it is the only component that is a real concern. The proposed solution would be to use disposable plastic covers that envelope the stopper and can be thrown out and replaced for the next patient.

3.3 Economics

In terms of overall cost, the project ended up being very inexpensive with respect to the current adult compression devices on the market, which range from $5,000 to $14,000. The cost of materials alone was under $500. A cost analysis using only material cost is shown in Table 3, factoring in the cost of development of two engineers at $15 per hour for 400 hours results in an additional $12,000.
The market for this type of device is fairly large, but not sustainable. Since the problem has been observed here at Vanderbilt multiple times, it is not unrealistic to assume that it has occurred in other NICUs as well. Therefore, it is thought that each NICU would be interested in purchasing at least one device. There are over 1500 NICU units in the US alone, however once each unit has obtained a device the market demand drops substantially. Looking at the market, a viable entry price may be between $1000 and $3000 per unit. It is assumed that to save multiple infant lives per year that this cost would be well worth it to any reputable NICU.

The device does however have a lifecycle in which certain parts will need to be maintained and replaced. If this device were to be manufactured and distributed by a company that company could supplement device sales with the sale and maintenance of parts. It is recommended, with the way the device is built at the moment that the air cylinder is replaced at least once per year and the solenoid valve every five years. These are the manufacturers’ recommendations, but one way to avoid this would be to use higher quality parts in the original device. The air compressor will need to be maintained by oil lubrication and the hoses and fittings should be checked often for leaks.

In order to legally market and sell the device it will first need to be successfully approved by the FDA as a biomedical device. A suggested approach to obtaining approval is discussed further in Recommendations.

<table>
<thead>
<tr>
<th>Material</th>
<th>Cost per Unit</th>
</tr>
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<tbody>
<tr>
<td>Air Cylinder</td>
<td>$15</td>
</tr>
<tr>
<td>3-Way Solenoid Valve</td>
<td>$109</td>
</tr>
<tr>
<td>Electronic Timer</td>
<td>$80</td>
</tr>
<tr>
<td>Coiled Air Hose</td>
<td>$33</td>
</tr>
<tr>
<td>25’ Tubing</td>
<td>$12</td>
</tr>
<tr>
<td>Air Compressor</td>
<td>$200</td>
</tr>
<tr>
<td>Wall Plug</td>
<td>$7</td>
</tr>
<tr>
<td><strong>TOTAL UNIT COST:</strong></td>
<td><strong>$456</strong></td>
</tr>
</tbody>
</table>

Table 3. Excluding the cost of labor for development, the per unit cost of the devices comes in just under $500.
IV. Conclusions

The goal of the project was to create a device capable of performing chest compressions on a small infant 0-30 days old. The criteria stated that it must be quick and easy to set up, take up minimal space around the operating area, provide approximately 11-12 pounds of force, maintain a constant rate of 80-100 compressions per minute, and be safe and sterilized such that no harm comes to the infant or operator. We were able to meet every criterion for the most part. However, there is still work to be done on the safety features and sterilization. Also, the device set-up is less efficient than hoped for so there is definitely room for improvement there. Another possible problem identified during testing was that the force provided is not always consistent and is dependent on the air compressor quality. To make this device the best it can be it is important to make sure the compressor used has no problem supplying a constant gauge pressure of 100 psi or more. Overall, the project was successful. We were able to build a device that can be considered a great starting point and has definite potential for future improvement.

V. Recommendations

5.1 Future Work

A few modifications to the current prototype will need to be made in order to have a complete, lasting device. The current support structure is a ring stand borrowed from the Chemistry Department, which needs to be returned. A new stand should not be bought because the ring stand base would have to be modified to fit the device needs. The current base is too thick and not wide enough. The base needs to provide enough surface area to support the infant, and the current stand is not large enough to do so. A potential second support structure could be
built around the brackets, provided by Kent Meeks of GE, which fit into the GE Giraffe OmniBed. A flexible arm could be constructed to hold the pneumatic cylinder and connect to the brackets of the bed.

The effectiveness of the device versus traditional methods should be evaluated. In order for the device to be used, the chest compressions provided by it must be as effective as or more effective than the current methods. A study similar to the one performed with the LUCAS 2 using thoraxes from pigs could be developed to test the neonatal chest compression device. The study will allow for the operator to determine the optimum settings of the device, for example the psi of compressed air applied and how high off the chest the device should rest. The psi and device rest position depends on the size of the infant requiring chest compressions. This will allow for safer and more effective compressions based off of the individual patient receiving them.

With modifications to the structural support and concrete evidence of the effectiveness of the device, gaining FDA approval is the next step. The device is similar to the Life-Stat, Thumper 1007, and LUCAS devices in terms of actuating the compressions using compressed air. Thus, the NICU device could try for 510(k) clearance. In order for the device to be approved by the FDA, the current American Heart Association guidelines need to be altered and more testing will need to be done. The current guidelines do not suggest the use of automated mechanic chest compressions on children or infants. The study showing the effectiveness of the device versus the manual compression method will help in seeking approval from AHA to then have approval from the FDA.
5.2 Safety Concerns

The main concern of the device is safety. In order to improve the safety issues associated with the device, a couple of the DesignSafe suggestions need to be implemented. First, an instruction manual needs to be created. The instruction manual, along with proper training, will help decrease the safety risk associated with user error involved with properly setting up, starting and turning off the device, correctly adjusting maximum pressure, and knowing when to replace specific parts.

The device will be further modified to become safer. A feedback loop with strain gauges will be incorporated into the device. The strain gauges will determine the force applied by the piston. If the force applied is too great the feedback loop will alert the device operator to change the device settings or if the force is deemed more than too high but harmful, the device will automatically shut off. The feedback loop and strain gauges will increase the safety of the device.

Lastly, to decrease the spread of infections, sterilized drapes and coverings need to be bought and tested with the device. The sterilized covering of the rubber ending on the piston should not interfere with the compression action of the piston, but this should be evaluated in case the problem arises.
References


<http://content.onlinejacc.org/cgi/content/full/44/11/2214#FIG2>.


Ideation Process

Project Initiation
Neonatal Chest Compression Device
October 2010 to May 2011
Courtney Gallagher and Jillian Zeber: katherine.c.gallagher@vanderbilt.edu, jillian.m.zeber@vanderbilt.edu

1. Project objectives
To provide life sustaining chest compressions.

2. Importance of the Situation
When an infant is undergoing neck or abdominal surgery, it is difficult for the physician to get his hands around the baby without interfering. Therefore, there is a critical need for a device to provide chest compressions while occupying minimal space.

Innovation Situation Questionnaire

1. Brief description of the situation
When an infant is undergoing neck or abdominal surgery, it is difficult for the physician to get his hands around the baby without interfering. Therefore, there is a critical need for a device to provide chest compressions while occupying minimal space.

2. Detailed description of the situation

2.1. Supersystem - System - Subsystems

2.1.1. System name
Neonatal Chest Compression Device

2.1.2. System structure
An air cylinder connected to a timer, solenoid valve, and air compressor provides chest compressions.

2.1.3. Supersystems and environment
Operating room equipment.

2.1.4. Systems with similar problems
There are adult chest compression devices.

2.2. Input - Process - Output

2.2.1. Functioning of the system
Air cylinder piston is actuated by internal air pressure provided by compressor, which pushes down on a concentrated area of the chest.

2.2.2. System inputs
A force will be applied to the chest mechanically.

2.2.3. System outputs
The piston compresses the chest.

2.3. Cause - Problem - Effect
2.3.1. Problem to be resolved
   How to provide the force.
2.3.2. Mechanism causing the problem
   There is limited space in which to apply the force.
2.3.3. Undesirable consequences if the problem is not resolved
   If the problem is not resolved, the device will not meet the standards applicable for clinical use.
2.3.4. Other problems to be solved
   How to measure the force required to provide chest compressions on an infant, and how to make the force variable.

2.4. Past - Present - Future

2.4.1. History of the problem
   Currently, neonatal chest compressions are performed manually by a physician wrapping his hands around the baby’s chest. The problem was discovered in a surgical situation in which there was not enough space for chest compressions and the surgical procedure to occur simultaneously. A device for neonatal chest compressions has not been previously attempted to our knowledge.
2.4.2. Pre-process time
   We cannot avoid the baby needing chest compressions, and we cannot make space around the chest for the device.
2.4.3. Post-process time
   Once the chest compressions have been applied, the device is no longer needed. Therefore, carrying out a system function after the process is finished will do no good.

3. Resources, constraints and limitations

3.1. Available resources
   Adult chest compression devices that are available. Simulation baby that can be used to evaluate the device.
3.2. Allowable changes to the system
   The force, rate, and point at which the force is applied must all remain the same. However, the mechanism by which the force is applied should be changed.
3.3. Constraints and limitations
   The force, rate, and point at which the force is applied must all remain the same. The device must take up minimal space.
3.4. Criteria for selecting solution concepts
   The device needs to provide adequate chest compressions at rate of 80-100 compressions per minute. The compressions need to be correctly applied to the chest below the nipples. The compressions need to reduce the width of the chest by one third. The compressions need to be safe.

Problem Formulation and Brainstorming

Neonatal Chest Compression Device
1. Find an alternative way to obtain *Plunger is applied to the chest* that offers the following: provides or enhances *Force is applied to the chest*. does not cause *Forced applied to incorrect region*.

2. Resolve the contradiction: *Plunger is applied to the chest* should be provided to produce *Force is applied to the chest*. and shouldn't be provided to avoid *Forced applied to incorrect region*.

3. Find an alternative way to obtain *Force is applied to the chest*. that offers the following: provides or enhances *Chest is compressed*. does not cause *Too much force is applied*. and *Inadequate force* does not require *Plunger is applied to the chest*.

4. Resolve the contradiction: *Force is applied to the chest*. should be provided to produce *Chest is compressed*. and shouldn't be provided to avoid *Too much force is applied*. and *Inadequate force*.

5. Find an alternative way to obtain *Chest is compressed*. that offers the following: provides or enhances *Heart function is restored*. does not require *Force is applied to the chest*.

6. Find an alternative way to obtain *Plunger goes back to rest position*. that offers the following: provides or enhances *Chest expands*. does not cause *Plunger is not released fast enough*. 
7. Resolve the contradiction: Plunger goes back to rest position. should be provided to produce Chest expands. and shouldn’t be provided to avoid Plunger is not released fast enough.

8. Find an alternative way to obtain Chest expands. that does not require Plunger goes back to rest position.

9. Find a way to eliminate, reduce, or prevent Inadequate force in order to avoid Heart is not stimulated. under the conditions of Force is applied to the chest.

10. Find a way to eliminate, reduce, or prevent Too much force is applied. in order to avoid Break the baby's rib cage or other bodily harm. under the conditions of Force is applied to the chest.

11. Find a way to eliminate, reduce, or prevent Heart is not stimulated. under the conditions of Inadequate force.

12. Find a way to eliminate, reduce, or prevent Break the baby's rib cage or other bodily harm. under the conditions of Too much force is applied.

13. Find an alternative way to obtain Heart function is restored. that does not require Chest is compressed.

14. Find a way to eliminate, reduce, or prevent Forced applied to incorrect region. under the conditions of Plunger is applied to the chest.

15. Find a way to eliminate, reduce, or prevent Plunger is not released fast enough. in order to avoid Cuts off blood supply. under the conditions of Plunger goes back to rest position.

16. Find a way to eliminate, reduce, or prevent Cuts off blood supply. under the conditions of Plunger is not released fast enough.

Prioritize Directions

1. Directions selected for further consideration

First Priority

6. Find an alternative way to obtain Plunger goes back to rest position. that offers the following: provides or enhances Chest expands. does not cause Plunger is not released fast enough.

7. Resolve the contradiction: Plunger goes back to rest position. should be provided to produce Chest expands. and shouldn’t be provided to avoid Plunger is not released fast enough.
9. Find a way to eliminate, reduce, or prevent *Inadequate force* in order to avoid *Heart is not stimulated.* under the conditions of *Force is applied to the chest.*

10. Find a way to eliminate, reduce, or prevent *Too much force is applied.* in order to avoid *Break the baby's rib cage or other bodily harm.* under the conditions of *Force is applied to the chest.*

14. Find a way to eliminate, reduce, or prevent *Forced applied to incorrect region.* under the conditions of *Plunger is applied to the chest.*

15. Find a way to eliminate, reduce, or prevent *Plunger is not released fast enough.* in order to avoid *Cuts off blood supply.* under the conditions of *Plunger goes back to rest position.*

16. Find a way to eliminate, reduce, or prevent *Cuts off blood supply.* under the conditions of *Plunger is not released fast enough.*

**Long Term**

1. Find an alternative way to obtain *Plunger is applied to the chest* that offers the following: provides or enhances *Force is applied to the chest.* does not cause *Forced applied to incorrect region.*

2. Resolve the contradiction: *Plunger is applied to the chest should be provided to produce Force is applied to the chest.* and shouldn't be provided to avoid *Forced applied to incorrect region.*

11. Find a way to eliminate, reduce, or prevent *Heart is not stimulated.* under the conditions of *Inadequate force.*

12. Find a way to eliminate, reduce, or prevent *Break the baby's rib cage or other bodily harm.* under the conditions of *Too much force is applied.*

**Out of Scope**

3. Find an alternative way to obtain *Force is applied to the chest.* that offers the following: provides or enhances *Chest is compressed.* does not cause *Too much force is applied.* and *Inadequate force* does not require *Plunger is applied to the chest.*

4. Resolve the contradiction: *Force is applied to the chest. should be provided to produce Chest is compressed.* and shouldn't be provided to avoid *Too much force is applied.* and *Inadequate force.*

5. Find an alternative way to obtain *Chest is compressed.* that offers the following: provides or enhances *Heart function is restored.* does not require *Force is applied to the*
8. Find an alternative way to obtain *Chest expands* that does not require *Plunger goes back to rest position*.

13. Find an alternative way to obtain *Heart function is restored* that does not require *Chest is compressed*.

**Develop Concepts**

1. **Categorize preliminary ideas**
   Belt or band around the baby's chest, which will contract to provide chest compressions. Use of a motor to contract the belt or manual mechanism to input force. There must be a backboard to support the back in compressions.

2. **Combine ideas into concepts**
   How to apply the force to the chest.
   - Idea 1: Use a stepping motor to contract a belt around the baby's chest.
     Shortcomings: Loss of control on the chest compressions.
   - Idea 2: Manual compressions using a pulley or a pump.
     Shortcomings: Long set up time. Difficult to provide enough force at an adequate rate.
   - Idea 3: Pneumatic device consisting of an air cylinder, solenoid valve, microtimer, and compressed air source.

**Evaluate Results**

1. **Meet criteria for evaluating Concepts**
   - Idea 1: will apply enough force at a set rate, thin belt can be used, small and easy to set up
   - Idea 2: physician has control over force applied and rate at which it is applied, may use a thin belt
   - Idea 3: will apply force dependent on pressure, rate can be controlled via microtimer

2. **Reveal and prevent potential failures**
   - Idea 1: may apply too much force, loss of physician control
   - Idea 2: may not apply enough force or fast enough, long set up time, may require constriction of the whole chest (pump)
   - Idea 3: air source is inadequate, which requires proper testing to ensure a valid range for air pressure

3. **Apply Patterns/Lines of Evolution**

   **Increasing ideality**
   Added variability in that you can control the psi applied by the air compressor and change the rate of compressions applied.

   **Dynamization**
   The device could become a more portable system operating off of a battery instead of a wall outlet.

   **Increasing controllability**
Negative feedback could be incorporated into the device by adding force sensitive resistors.

4. **Plan the implementation**
   - Once we obtain a pneumatic cylinder and compressor, we can run tests to verify force output at specific psi's.
   - Build a complete device with time varying solenoid valve to test the rate of release and functionality as a whole
**designsafe Report**

**Application:** Group 15 Neonatal Chest Compression Device

**Description:** A pneumatic device that provides a downward force onto a neonate's chest in order to facilitate blood pumping.

**Analyst Name(s):** Courtney Gallagher, Jillian Zeber

**Company:** Group 15 VUSE

**Facility Location:** Monroe Carrell Jr. Children's Hospital at Vanderbilt

**Product Identifier:**

**Assessment Type:** Detailed

**Limits:** Detailed Assessment to look at all of the risks posed with using the neonatal chest compression device.

**Sources:** Senior Design Project

Guide sentence: When doing [task], the [user] could be injured by the [hazard] due to the [failure mode].

<table>
<thead>
<tr>
<th>User / Task</th>
<th>Hazard / Failure Mode</th>
<th>Initial Assessment</th>
<th>Final Assessment</th>
<th>Risk Reduction Methods /Comments</th>
<th>Final Assessment</th>
<th>Status / Responsible /Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infant Receive Chest Compressions</td>
<td>mechanical : crushing Too much force is applied to the infant's chest.</td>
<td>Serious Remote Unlikely Moderate</td>
<td>other design change: maximal force set at 12lbs, maximal psi of 100, both variable</td>
<td>Serious Remote Negligible Low</td>
<td>Complete [3/31/2011] Any user</td>
<td></td>
</tr>
<tr>
<td>Surgeon Chest Compressions</td>
<td>mechanical : unexpected start If a component of the device is left on without the user being aware and they turn on one component and the whole device turns on, you would have an unexpected start.</td>
<td>Slight Remote Unlikely Low</td>
<td>warning label(s), instruction manuals, standard procedures</td>
<td>Slight Remote Negligible Low</td>
<td>In-process Any user</td>
<td></td>
</tr>
<tr>
<td>Surgeon Chest Compressions</td>
<td>mechanical : fatigue After multiple uses, the cylinder or solenoid valve wear down.</td>
<td>Serious Occasional Possible High</td>
<td>standard procedures, instruction manuals</td>
<td>Slight Remote Unlikely Low</td>
<td>On-going [Daily] Surgeon</td>
<td></td>
</tr>
<tr>
<td>Surgeon Chest Compressions</td>
<td>mechanical : head bump on overhead objects The surgeon hits the support arm and bumps his head.</td>
<td>Slight Remote Unlikely Low</td>
<td>on-the-job training (OJT)</td>
<td>Slight Remote Negligible Low</td>
<td>In-process Surgeon</td>
<td></td>
</tr>
<tr>
<td>Surgeon Chest Compressions</td>
<td>mechanical : break up during operation The support holding the arm breaks with the force applied.</td>
<td>Serious Remote Unlikely Moderate</td>
<td>special tools or fixtures, build in a support structure</td>
<td>Serious Remote Negligible Low</td>
<td>TBD Engineer</td>
<td></td>
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<tr>
<td>Surgeon Chest Compressions</td>
<td>mechanical : magnetic attraction / movement The device is made out of metal and other objects might attract it.</td>
<td>Minimal Remote Negligible Low</td>
<td>Minimal Remote Negligible</td>
<td>Low</td>
<td>Any user</td>
<td></td>
</tr>
<tr>
<td>Surgeon Chest Compressions</td>
<td>mechanical : collapse If the movable arm is not mounted properly, the device will collapse.</td>
<td>Serious Remote Unlikely Moderate</td>
<td>Serious Remote Negligible</td>
<td>Low</td>
<td>On-going [Daily] Any user</td>
<td></td>
</tr>
<tr>
<td>Surgeon Chest Compressions</td>
<td>electrical / electronic : shorts / arcing / sparking If the electrical pump components become exposed and interact in a way they should not, sparks might fly.</td>
<td>Serious Remote Unlikely Moderate</td>
<td>Serious Remote Negligible</td>
<td>Low</td>
<td>On-going [Daily] Surgical assistant</td>
<td></td>
</tr>
<tr>
<td>Surgeon Chest Compressions</td>
<td>electrical / electronic : overloading The electrical outlet gets overloaded.</td>
<td>Serious Remote Negligible Low</td>
<td>Serious Remote Negligible</td>
<td>Low</td>
<td>In-process Any user</td>
<td></td>
</tr>
<tr>
<td>Surgeon Chest Compressions</td>
<td>electrical / electronic : water / wet locations If the electrical components get exposed to water or the cylinder gerts filled with water, the device will fail.</td>
<td>Serious Remote Negligible Low</td>
<td>Serious Remote Negligible</td>
<td>Low</td>
<td>TBD Any user</td>
<td></td>
</tr>
<tr>
<td>Surgeon Chest Compressions</td>
<td>electrical / electronic : overvoltage /overcurrent The device is plugged into the wall so overvoltage or overcurrent could occur or if a stronger power supply is used.</td>
<td>Serious Remote Unlikely Moderate</td>
<td>Serious Remote Negligible</td>
<td>Low</td>
<td>TBD Any user</td>
<td></td>
</tr>
<tr>
<td>Surgeon Chest Compressions</td>
<td>electrical / electronic : power supply interruption If someone trips over a cord and rips the cord out of the socket or accidently hits the switch. Both would be user errors.</td>
<td>Serious Remote Negligible Low</td>
<td>Serious Remote Negligible</td>
<td>Low</td>
<td>On-going [Daily] Any user</td>
<td></td>
</tr>
<tr>
<td>Surgeon Chest Compressions</td>
<td>slips / trips / falls : trip Accidentally tripping over the device.</td>
<td>Serious Remote Unlikely Moderate</td>
<td>on-the-job training (OJT), warning sign(s)</td>
<td>Low</td>
<td>On-going [Daily] Any user</td>
<td></td>
</tr>
<tr>
<td>User / Task</td>
<td>Hazard / Failure Mode</td>
<td>Initial Assessment Severity Exposure Probability</td>
<td>Risk Level</td>
<td>Risk Reduction Methods /Comments</td>
<td>Final Assessment Severity Exposure Probability</td>
<td>Risk Level</td>
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<tr>
<td>Surgeon Chest Compressions</td>
<td>noise / vibration : noise / sound levels &gt; 80 dBA The solenoid valve makes a loud clicking sound.</td>
<td>Slight Frequent Probable</td>
<td>High</td>
<td>other design change: insulation</td>
<td>Slight Remote Unlikely</td>
<td>Low</td>
</tr>
<tr>
<td>Surgeon Chest Compressions</td>
<td>confined spaces : confined spaces There is minimal space around the work area.</td>
<td>Slight Occasional Possible</td>
<td>Moderate</td>
<td>on-the-job training (OJT)</td>
<td>Slight Remote Unlikely</td>
<td>Low</td>
</tr>
<tr>
<td>Surgeon Chest Compressions</td>
<td>biological / health : unsanitary conditions If the plunger is exposed and not properly cleaned, infections could be spread.</td>
<td>Serious Remote Unlikely</td>
<td>Moderate</td>
<td>other design change: plastic coverlet</td>
<td>Serious Remote Unlikely</td>
<td>Low</td>
</tr>
<tr>
<td>Surgeon Chest Compressions</td>
<td>fluid / pressure : high pressure air Using compressed air or if the hose became unattached.</td>
<td>Slight Remote Unlikely</td>
<td>Low</td>
<td>on-the-job training (OJT)</td>
<td>Slight Remote Unlikely</td>
<td>Low</td>
</tr>
<tr>
<td>Surgeon Chest Compressions</td>
<td>fluid / pressure : pneumatics rupture If there is a pressure build up in any of the components between the compressor and cylinder, the device could rupture.</td>
<td>Catastrophic Remote Unlikely</td>
<td>Moderate</td>
<td>instruction manual: learn how to change the maximal pressure</td>
<td>Catastrophic Remote Unlikely</td>
<td>Moderate</td>
</tr>
</tbody>
</table>