	Minimizing Ambulatory Vibrations – Group 8	**Quality System Procedure Form**	
		Doc. No: 4	Rev. 7
		Date: 4/25/18	Status: Draft

Human Factors Evaluation

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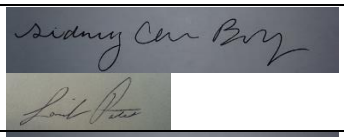
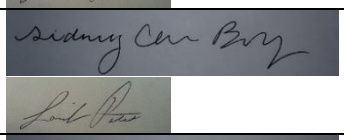
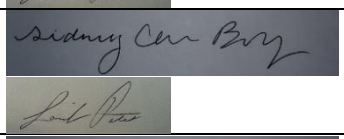
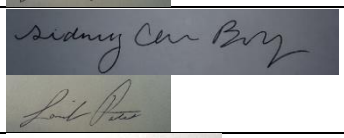
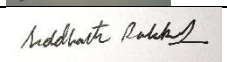
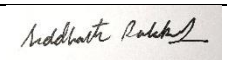
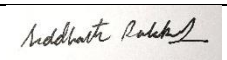
CHANGE RECORD:

Rev	Date	Description of Change	Authorization
1	10/19/17	Initial Draft	
2	11/24/17	Task Analysis, Anthropometric Measures redone	
3	12/09/17	Comments from last revision were addressed and document was set up to be made consistent with other documents.	
4	12/10/17	Introduction and the appendix was added and document was proofread	
5	4/4/18	Minor wording changes. Specific emphasis on creating a task analysis section that actually plans necessary tasks.	
6	4/15/18	Additional edits to the task analysis in effort to better clarify section	
7	4/25/18	Further proofreading and word changes.	

Introduction:

During emergency transportation situations, patients are exposed to consistent and often severe vibrations. While undesirable for all patients, this is particularly dangerous for newborn infants. Studies have shown that the vibrations transferred to infants during transport by emergency vehicles can cause serious complications. Despite extensive research characterizing these vibrations, no commercially viable product has been brought to market. Our solution aims to enhance the standard neonate transportation incubator using a cost-effective, accessible solution. More specifically, our product implements affordable passive vibration damping materials to minimize the forces transferred to the neonate during transportation.

This document lays out a plan of what we intend to do to ensure that our solutions will be usable in every aspect of their performance. From the clinical, maintenance, and user point of view, the answers to the questions we would like to ask will guide our design solution. The document is split into three sections to create a more simplified format.

Exploratory analysis:

Group to contact	Specific people in group to contact	Method of approaching	Specific Actions
Clinicians	Neonatal physicians, emergency medical personnel	Questionnaire, interviews	Questions: • What are some specific health considerations for infants? • How many infants do these health issues affect? How serious are the complications? • How are infants more susceptible to these health complications than adults are? • What is a common mistake made when transporting neonates? • What conditions commonly appear as a result of improper transport? • What specific considerations have to be

			made for infants in critical care? • How do vibrations affect infants more than adults? • Are possible complications due to amplified vibration different from the complications due to current vibration levels?
User (Transport nurses)	Michael (Children's hospital contact)	Asking questions, observing work, device assessments	Questions: • How is our product interacting with the patient? • What are the contact points between the patient and the apparatus? • Where are we able to intervene with the current setup? Where are we unable to intervene? • Can the incubator be lowered so it is closer to the stretcher base? • Do the stretchers come in various lengths and sizes? • What actions do you need to be able to do in the transport process that our device cannot interfere with? • How can we reproduce an ambulatory setting to mimic the setup you have? • How much time do you have between calls prepare the ambulance? • How long is the length of a typical call from infant pickup to infant drop-off? • How tall is the infant (ie. When the infant is laying on the mattress, how

			much height is there to raise the tray?) Observations: • Watch the TN put together incubator transporter • Note any current issues to be improved on or any particularly challenging parts that shouldn't be altered • Observe an actual transport to assess what considerations need to be made for the process (depending on regulations) Device Assessments: • Ask our TN for input through the design process • Ask for constructive feedback; what is good about our design and what is bad? • What would he specifically change and how would he recommend changing that?
Maintenance Personnel	Ambulance maintenance – who would be cleaning equipment	Interviews, observing work, device assessment	Questions: • What issues do you already encounter with the equipment that we should avoid making more difficult? • What complications do you foresee with our potential solutions? • Are there specific components that are more challenging to clean/maintain than others are? • How often do you replace components in the ambulance? Observations:

			• Watch how the maintenance personnel take apart/clean equipment • Pay attention to any difficulties they encounter and be sure to avoid these in our potential solutions
Guardians	Parents of neonatals	Asking questions, Interviews	Questions: • What are some of your concerns when transporting infants? • What would you recommend to someone who has little to no experience with infants?

Task analysis:

Analyzing the tasks related to maintaining and implementing the damper in a helicopter or ambulance is key to ensuring that the design is feasible and can suit the intended user, which includes an infant as well as the maintenance personnel and attending travel nurse who interact with the system.

Task 1: Optimal Space for Treatment on Infant

It is important to consider the available space within the incubator for the transport nurse. Changing of the dimensions of the mattress and tray could possibly lessen the area available for the transport nurse to treat the patient within the incubator. In order to understand the available space in the incubator, we must interact with the incubator first hand. By placing an infant sized object where the neonate would be laying and attempting to interact with the object, we can determine how much room is available to raise the tray height or add damping material.

Task 2: Electrical Maintenance

Electrical malfunction may be an issue if actuators or related sensors are implemented; a skilled technician must maintain these components of the product periodically. This is a discussion to have between both a skilled technician and a nurse. It is necessary to ask a technician how the sensors should be maintained and then perform these actions ourselves. From this, we can determine the simplicity level, especially when these actions must be performed by someone who does not have a technical background (ex. Nurses).

Task 3: Cleaning

Specific tasks that must be accomplished for the product to work properly include routine cleaning and testing of equipment. Vibration padding will likely need to be removed and checked thoroughly for infectious agents. In order to design a product that can be cleaned by maintenance personnel, we must observe and experience how to clean the apparatus. This will involve us wiping down the current incubator using the wipes that the travel nurse personnel typically use.

Task 4: Optimal Space for Infant Comfort

To ensure that the infant will still have ample space in the chamber, the thickness of the vibration padding and any additional tray height must be minimal enough so that the space may still fit an individual with the anthropometry data described below. Determining infant movements due to vibrations and its own passive/active movements is essential in determining the viable space necessary for the infant.

Task 5: Loading/Unloading Stretcher from Ambulance

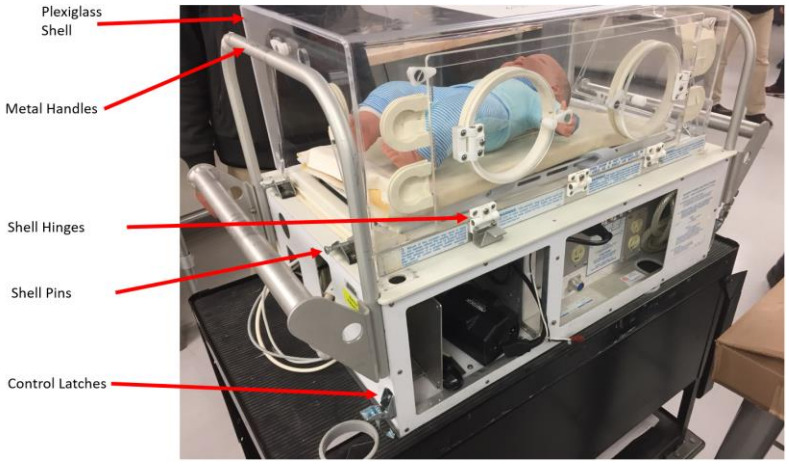
Perform loading/unloading of stretcher onto ambulance bed. Locking of the stretcher onto the ambulance will place an increased force on the stretcher. Understanding the effects of the force on the implemented prototype will allow for a device less likely to be displaced upon placing the stretcher into/out of the ambulance.

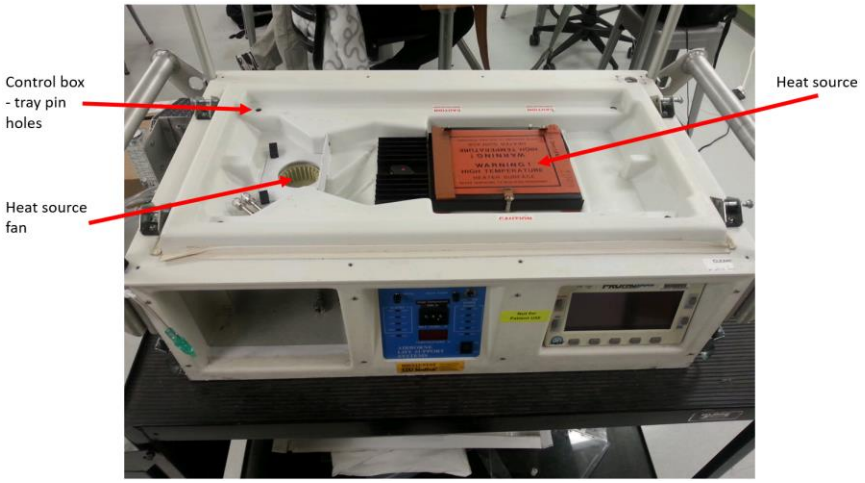
Anthropometry:

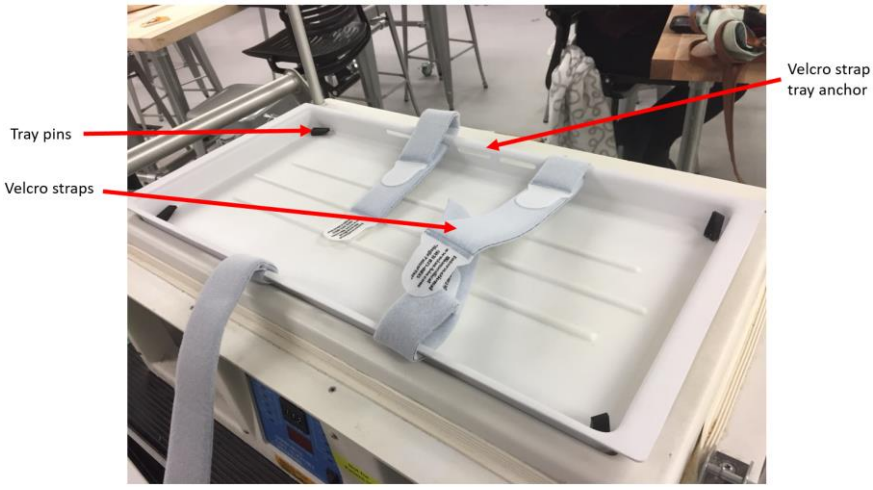
Normal range of neonatal infants at birth is 45.7 cm to 60 cm. A largescale anthropometric study of neonatal infants found the average length of 115 neonates to be 49.7 ± 2.1 cm (Mean ± SD). This is important because mattress configuration should allow for the height of the infant as well as a tolerance in case of infant movement within the incubator. The average head circumference of a neonatal infant based on this study is 34.5 ± 1.5 cm and the average abdominal circumference is 32.4 ± 2.1 cm. The mattress should allow for enough room for the infant in the event that the infant is not centered within the incubator on the mattress.

It is necessary to take into account that our solution will likely need to fit in this incubator. Assuming there is a 2-inch margin around the proposed mat solution, our workspace is roughly 15 inches x 35.2 inches x 20.9 inches.

Appendix:


Plexiglass Shell
Metal Handles
Shell Hinges
Shell Pins
Control Latches


Control box - tray pin holes
Heat source fan
Heat source


Tray pins
Velcro straps
Velcro strap tray anchor