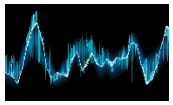
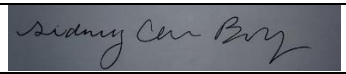
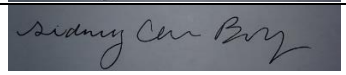
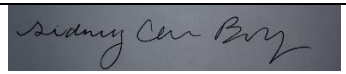
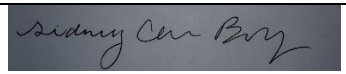
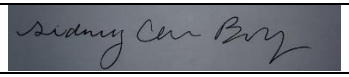
	Minimizing Ambulatory Vibrations – Group 8	**Quality System Procedure Form**	
		Doc. No: 6	Rev. 5
		Date: 4/3/18	Status: Draft

Failure Mode and Effects Analysis

Approved by:	**Date:**
Michael Adams	4/3/18
Sid Bala	4/3/18
Sidney Cannon-Bailey	4/3/18
Samik Patel	4/3/18
Neil Vinjamuri	4/3/18

CHANGE RECORD:

Rev	Date	Description of Change	Authorization
1	10/27/17	Initial Draft	
2	11/27/17	Added risk classification scheme, altered risk classification index and added more component level failures.	
3	11/29/17	Updated FMEA table based on changes to IHA and Risk Summary documents.	
4	12/10/17	Added introduction and appendix sections. Proofread the document.	

5	4/3/18	Minor wording 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.

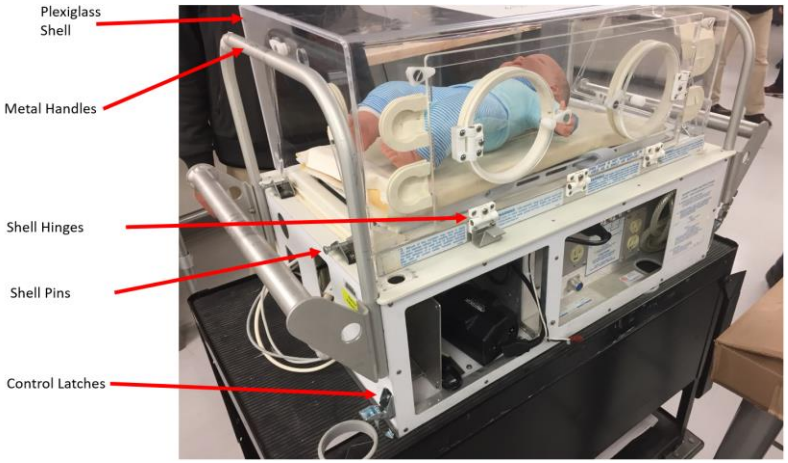
This documents analyzes the different components, their failure modes and the effects on the overall function of the device. It also assesses the associated risks that may be imposed on the users of the device in the event of such failures.

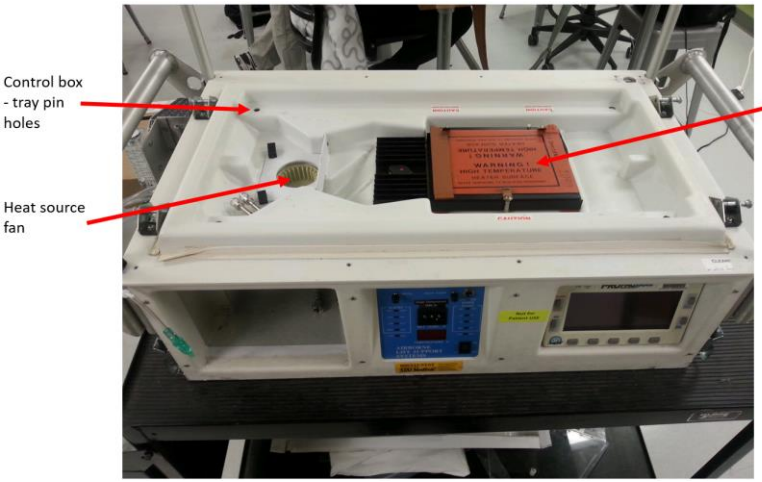
Function or Component (see below Appendix for designated parts)	Failure Mode	Effect on System	Possible Hazards	Risk Index	User Detection Means	Applicable Control(s)
Velcro anchor (connects velcro strap to plastic tray)	Depending on final material properties and how the strength compares to current tray, plastic tray could break at location of velcro anchor.	Velcro no longer attached to tray, no longer holding infant down	Infant would no longer be strapped to the tray and would experience more vibrations due to this loss of control	4	Velcro will not be attached to tray. Visual or audible cracking of tray will alert user. Infant no longer secured	Testing the bed extensively ahead of time; calculating the strength of the material used and ensuring it can withstand the stresses that could occur during transport
Velcro Safety Harness	Velcro breaks due to velcro tray anchor strength and rigidity	Velcro no longer holding infant down	Infant would no longer be strapped to the tray and would experience more vibrations due to this loss of control	2	User would visually identify that the velcro is broken and infant is no longer secured	Testing the material ahead of time; calculating the strength of both the tray anchors and velcro straps to ensure they can withstand the maximum stresses during ambulatory transport
Tray pins, connect the tray to the incubator	Tray dislodges from incubator and directly disturbs the infant laying on the tray	Could amplify vibrations felt by infant as the pins are no longer holding the tray in place and no longer limits vertical and lateral displacement	Infant would be shaken more and this would have a negative effect on the infant's health	4	User would visually identify that the tray is out of the control box	Testing the pins for strength to ensure they securely hold the tray down

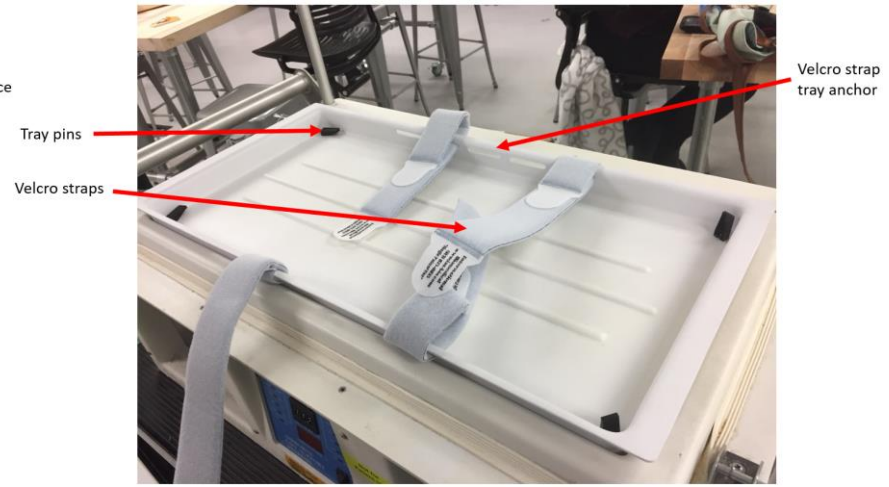
Function or Component (see below Appendix for designated parts)	Failure Mode	Effect on System	Possible Hazards	Risk Index	User Detection Means	Applicable Control(s)
Incubator Pins	Vibration of incubator increases, leading to the shell dislodging from the controller	Shell will dislodge from system. Thermodynanic seal will no longer be maintained	Infant will not receive the appropriate concentrations of oxygen and temperature will not be regualted	3	Shell is no longer held down by the pins and is visibly moving	Ensure that the solution does not interfere with incubator pin-incubator interface
Latches holding down the controller	Controller box is no longer rigidly attached to the rest of the system	If control box is dislodged from system, it will contribute to increased vibrations	Increased vibrations could worsen infant symptoms This could also cause more imminent danger to the infant if the control box were to move or fall off the stretcher	3	Visually identify controller system is moving around and latch(es) are not appropriately connected	Ensure that solution does not interfere with current latch setup; if necessary, add additional supports to hold the controller box down
Extreme wear on mattress due to amplification of force	Dissipation of mattress cushioning properties during fatigue loading due to vibration amplification	Mattress will no longer support infant comfort wise and will do less to damp vibrations	This mattress is a supplementary component and while the degradation is not ideal, it would only slightly increase vibrations	3	The user should make sure to check the mattress after use to maintain that it is in good condition and useable	Making sure the mattress is of high quality is important. Measuring the amount of deformation would provide an estimate on when to replace the mattress, but in general the best control is a user vigilantly ensuring the mattress is in good condition

Function or Component (see below Appendix for designated parts)	Failure Mode	Effect on System	Possible Hazards	Risk Index	User Detection Means	Applicable Control(s)
Damping material (sorbothane under tray edge and/or cylindrical mounts under tray)	Designed solution does not work (incorrect spring and/or damping constants)	Instead of damping vibrations, the vibrations are amplified	Vibration amplification can cause a number of system failures. It could cause vibrations that the control box and/or stretcher were not designed to handle. This could cause failure of the tray, velcro straps, mattress, incubator, and/or controller.	5	This should be visible relatively quickly by the attending nurse. It will be clear if there are dangerous vibrations compared to the normal case.	The solutions should be extensively tested in a variety of situations to ensure they are dependable wherever the ambulance may be.

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