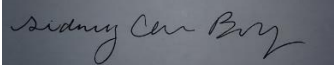
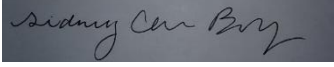
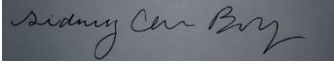
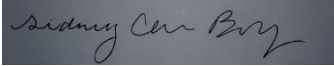
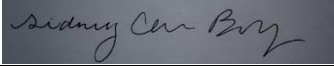
	Minimizing Ambulatory Vibrations – Group 8	Quality System Procedure Form	
		Doc. No: 2	Rev. 5
		Date: 4/16/18	Status: Draft

Initial Hazard Analysis

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CHANGE RECORD:

Rev	Date	Description of Change	Authorization
1	10/20/17	Initial Draft	
2	10/25/17	Updated hazards associated with the incubator and the solution implemented	
3	11/28/17	Added more relevant hazards and formatted the hazards in a table. Also noted other sections to include.	
4	12/10/17	Added section to include and proofread the document.	
5	4/16/18	Minor wording changes. Added severity scale	

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 focuses on some of the potential hazards associated with operating the incubator. It also assesses the causes of these hazards and severity in terms of its impacts on the neonate while being transported.

Potential Hazard	Cause	Severity
Vibrations are amplified rather than minimized	If we use a passive vibration damping material with the wrong spring or damping constant, this could theoretically result in our product amplifying vibrations instead of reducing/eliminating them.	High
Velcro straps could break due to amplified stress from increased vibrations	Refer to cause associated with vibration amplification.	High
Tray could break due to amplified force from increased vibrations	Refer to cause associated with vibration amplification.	High
Solution Environment Severity	Our solution is necessitated by the fact that emergency transportation is often turbulent, and our solution will be subjected to the same potentially harsh environment. If the material or hardware of our solution is damaged or worn down by the forces imparted during travel, it would not perform as expected. This would ultimately be caused by vibration amplification.	High
Malfunction of medical delivery from control box due to amplified force from increased vibrations	Refer to cause associated with vibration amplification.	High
Extreme wear on mattress and solution components from amplified force due to increased vibrations	Refer to cause associated with vibration amplification.	Medium
Incubator becomes dislodged from controller; incubator pins fail due to amplified force from increased vibrations	Refer to cause associated with vibration amplification.	Medium
Tray pins dislodge due to amplified force from increased vibrations	Refer to cause associated with vibration amplification.	Medium
Vibrations are not damped/isolated	In a passive vibration damping system, if the material doesn't have an appropriate spring constant, or is altered or installed improperly, the system	Medium

	would not minimize vibrations. While this would not necessarily amplify the vibrations, it would maintain the harmful vibrations affecting the infants.	
Latch Mechanism Alterations	One potential solution we are considering involves adding a damping solution to the latch that connects the incubator-control mass to the stretcher. Adding any sort of mechanism to these latches could result in adverse effects. For example, the latch could potentially fail and fall off the stretcher, potentially harming the infant and any nearby emergency workers.	Medium
Heat Loss	To reduce vibrations transferred to the infant in our system, our solution adds vibration damping materials between the incubator and tray which increases the space between the two. If the heat is not sufficiently transferred from the heating element to the tray, the neonate's body temperature may be kept lower than the medical personnel intended.	Low
Bed Holding Pin Not Rigidly Supported	A potential solution involves placing a material between the bed/heater/pin interface to damp vibrations between the heater and the plastic covering. Damping vibrations at this interface could lead to no longer maintaining the rigid body nature of the bed/heater/pin interface.	Low

Severity Scale:

- 1) Low: minimal injury to the neonatal infant due to malfunction
- 2) Medium: injury amplification and increased discomfort on neonatal infant
- 3) High: potential for injury significantly increased or another separate unrelated injury

Appendix:

