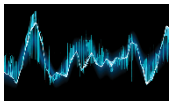
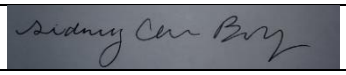
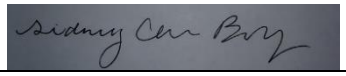
	Minimizing Ambulatory Vibrations – Group 8	**Quality System Procedure Form**	
		Doc. No: 9	Rev. 6
		Date: 4/21/18	Status: Draft

Verification Test Plan

Approved by:	**Date:**
Michael Adams	4/21/18
Sid Bala	4/21/18
Sidney Cannon-Bailey	4/21/18
Samik Patel	4/21/18
Neil Vinjamuri	4/21/18

CHANGE RECORD:

Rev	Date	Description of Change	Authorization
1	11/3/17	Initial Draft	
2	11/28/17	Formatted document to increase readability. Added mores specifics (timing of tests, resources need for tests, etc.) to provide more information. Developed additional specifications to verify. Noted necessary changes.	
3	12/1/17	Added more detail to specifications. Altered points highlighted in previous revision. Proofread.	
4	2/11/18	Added more detail, changed wording to make more clear	
5	4/13/18	Removed Fatigue Testing plan, added success criteria to all tests	
6	4/21/18	Updated all document numbers, tray height specification added	

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.

Design Specification 1: Tray and Mattress Size

- Purpose: This test will confirm that the designed tray and mattress will be the correct size for the incubator and the range of infant sizes possible.
- Success Criteria: The tray should be 24.2" by 11.8". The mattress must be at least 8.5" by 6" and no greater than 24" by 11.6".
- Timing: This test is simple enough to perform continually through the design process and should be considered throughout the design process.
- Potential Tests: Measure designed tray and area where infant lays and ensure they are within accepted dimensions.
- Test Protocol: Simply use a ruler to ensure the tray and mattress are at the acceptable size. See document #10 for full protocol.
- Resources: Ruler/measuring tape, new tray.
- Test Report: See document #20 for report.

Design Specification 2: Vibration Minimization

- Purpose: This test will measure and quantify the vibrations where the infant would be seated in the incubator. It will compare the vibrations that occur with a typical incubator setup (the control) and with an incubator setup including a potential solution. This test will also compare the vibrations experienced at the base of the incubator and the inside of the incubator to observe the transmissibility of the stretcher-incubator.
- Success Criteria: This test will be considered successful if the peak vibration magnitude is reduced by at least 30%.
- Timing: This test can be performed as often as new potential solutions are developed, but testing ability will depend mainly on ambulance availability.
- Testing Protocol: Using accelerometers, the vibrations in the ambulance will be recorded at various locations: inside the Plexiglass shell on either side of the incubator and either side of the incubator base (4 total accelerometer locations). The vibrations of the original setup and the proposed solution will then be compared to observe the damping efficiency. See document #11 for full protocol.
- Resources: In order to perform this test, access to an ambulance is required. Additionally, the incubator-stretcher configuration must be present to have realistic vibrations. Lastly, the accelerometers as well as people to collect and analyze the collected data must be available.
- Test Report: See document #21 for report.

Design Specification 3: Ability to Clean

- Purpose: This test will confirm whether the solution will be able to be cleaned by the materials used by the ambulance staff without compromising the damping properties of the apparatus.
- Success Criteria: The vibrations after cleaning the apparatus should remain within 5% of the original value.
- Timing: Should be performed after Design Specification 2, Vibration Minimization has been successfully verified
- Potential Tests: Vibration analysis before and after exposure to the cleaning agents.
- Test Protocol: Vibrations of the apparatus will be measured (as in the protocol for Vibration Minimization) before and after cleaning the apparatus with travel nurses' PDI disinfectant wipes. See document #12 for full protocol.
- Resources: PDI wipes, accelerometer.
- Test Report: See document #22 for report

Design Specification 4: Temperature limits

- Purpose: This test will compare the damping properties of the tray before and after being exposed to a heat source.
- Success Criteria: The vibrations after heat application to the apparatus should remain within 5% of the original value.
- Timing: This test can be performed upon fabrication of the tray. Tray fabrication will occur after a damping solution has been finalized and the test Vibration Minimization has been shown successful.
- Testing Protocol: Apparatus will be tested for vibrations before and after being exposed to a heat source above 37 degrees Celsius. See document #13 for full protocol.
- Resources: In order to perform this test, access to a heat source that controls heat outflow is required as well as a thermometer to record the temperature of the apparatus surface. Additionally an accelerometer is needed to measure vibrations
- Test Report: See document #23 for report.

Design Specification 5: Water Resistance

- Purpose: This test will confirm whether the solution will be able to withstand the possible weather effects of the environment this solution will be operating in.
- Success Criteria: The vibrations on the apparatus after water exposure should remain within 5% of the original value.
- Timing: Should be performed after successful Vibration Minimization testing.
- Potential Tests: Water exposure to the apparatus
- Test Protocol: Apparatus will be tested for vibrations before and after being exposed water. See document #14 for full protocol.
- Resources: Water, spray bottle, accelerometer
- Test Report: See document #24 for report

Design Specification 6: Tray Weight

- Purpose: This test will ensure the tray is not imposing an unsafe force on the damping materials
- Success Criteria: This test will be successful if the tray weighs less than 30 lbs
- Timing: This test is simple enough to perform continually through the design process and should be considered throughout the design process.
- Potential Tests: The tray can easily be weighed using any scale.
- Test Protocol: This test will be performed by setting the tray on a scale and recording the weight. See document #15 for full protocol
- Resources: Scale, apparatus
- Test Report: See document #25 for report

Design Specification 7: Tray Height

- Purpose: This test will ensure the tray is not exceeding a height that prevents the travel nurse access to the infant
- Success Criteria: This test will be successful if the tray is elevated less than 1.25” from the incubator.
- Timing: This test is simple enough to perform continually through the design process and should be considered throughout the design process.
- Potential Tests: Tray height can be easily measured using a ruler/tape measure.
- Test Protocol: This test will be performed by setting the tray within the incubator and determining elevation from the surface once the solution is interposed between the tray and incubator.
- Resources: Ruler
- Test Report: See document #26 for report