	Minimizing Ambulatory Vibrations – Group 8	**Quality System Procedure Form**	
		Doc. No: 8	Rev. 6
		Date: 04/18/18	Status: Draft

Validation Test Plan

Approved by:	**Date:**
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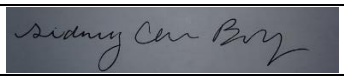
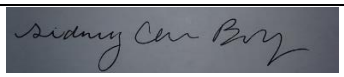
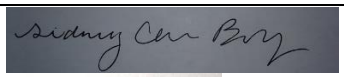
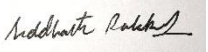
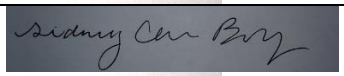
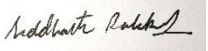
CHANGE RECORD:

Rev	**Date**	**Description of Change**	**Authorization**
1	11/02/17	Initial Draft	
2	11/28/17	Updated information based on on-field testing. Revised format of the document so it is more intuitive to a reader. Indicated missing information to fill in at a later date.	
3	12/02/17	Elaborated on specification purposes and minimized test protocol information, instead pointing to additional document for full protocol. Noted some additional sections to be clarified.	
4	12/10/17	Added introduction and appendix sections. Proofread document.	
5	04/17/18	Added success criteria and changed some minor details. Excluded storage validation test.	 
6	04/18/18	Added references to additional documents	 

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.

In the design specification process, a set of measurements were identified that aim to quantify our system's behavior. As discussed in the Verification Test Plan, a thorough quantitative analysis of the system will be conducted to ensure it performs as expected before proceeding to a full-scale implementation of the solution. After verifying that the system functions properly from an engineering standpoint, the solution will be implemented in its intended use environment. To validate that the design meets the expectations of the end-user, we intend to collect feedback regarding the user experience. Our solution targets emergency transport environments, specifically ambulances and potentially helicopters. Therefore, the primary end-users of our solution are the travel nurses and paramedics in the field.

Design Validation Specification 1: Cleaning

- Purpose: This test will ensure that the implemented solution can easily be cleaned periodically to prevent the build-up of harmful material. This will prevent further harm toward the infant being transported. Most ambulances use basic PDI wet wipes to clean all components of the incubator. Our solution must be compatible with their current cleaning routine. Our solution will utilize materials that can be cleaned by the 45% isopropanol and .25% benzyl ammonium chloride solution of the PDI wipes; as such, the purpose of this experiment to assess ease of cleaning.
- Success Criteria: The apparatus should have a minimum rating of 3.5 out of 5 for clinician satisfaction and all parts of the prototype should be cleanable by the clinicians
- Timing: This test should be performed by April 1, 2018 and should be tested by at least 5 clinicians
- Potential Tests: The ideal test for this is to recruit actual paramedics and EMTs to rate the ease of cleaning for us, since this is our exact customer who will be using the incubator.
- Test Protocol: We will collect feedback on ease of use and general impression of the cleaning process from the point of view of a travel nurse. See document #17 for full protocol.
- Resources: Paramedics and EMTs, PDI cleaning wipes
- Report: See document #27 for test report

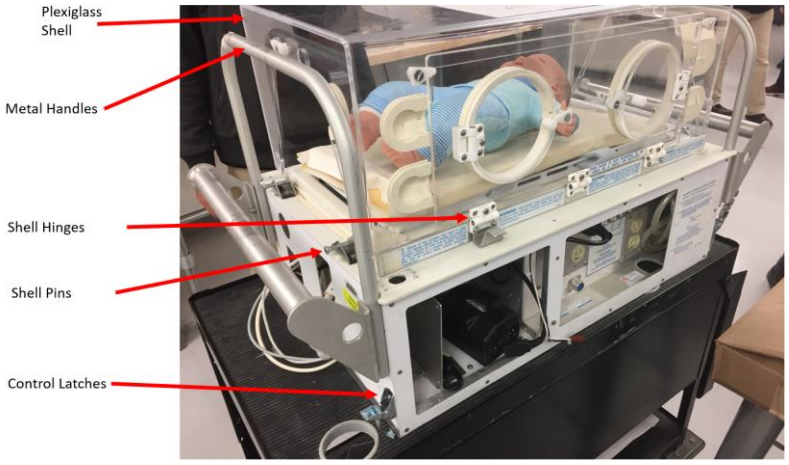
Design Validation Specification 2: Ease of Use

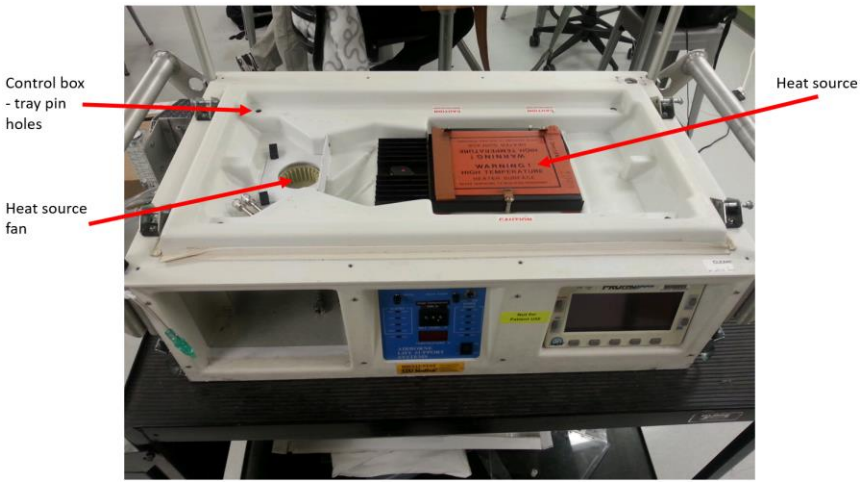
- Purpose: Due to the time constraints often faced by emergency paramedics/nurses on days with multiple patient cases, our product must not take too much time out of a nurse's schedule to set up and use. This test will ensure that the process of setting up the developed solution takes no more than 5 minutes.
- Success Criteria: The apparatus should take nor more than 5 minutes to set up and should have a minimum rating of 3.5 out of 5 for clinician satisfaction
- Timing: This test must be performed by March 1, 2018 and should be tested by at least 5 clinicians
- Potential Tests: The time it takes for travel nurses to set up our solution will be recorded. We will also ask for qualitative feedback of specific comments on what was most/least challenging.
- Test Protocol: This test will be accomplished by loading the incubation bed onto an emergency ambulance and observing and timing the paramedic/EMT to set up the solution. See document #18 for full protocol.
- Resources: Access to an ambulance, travel nurses, stopwatch
- Report: See document #28 for test report

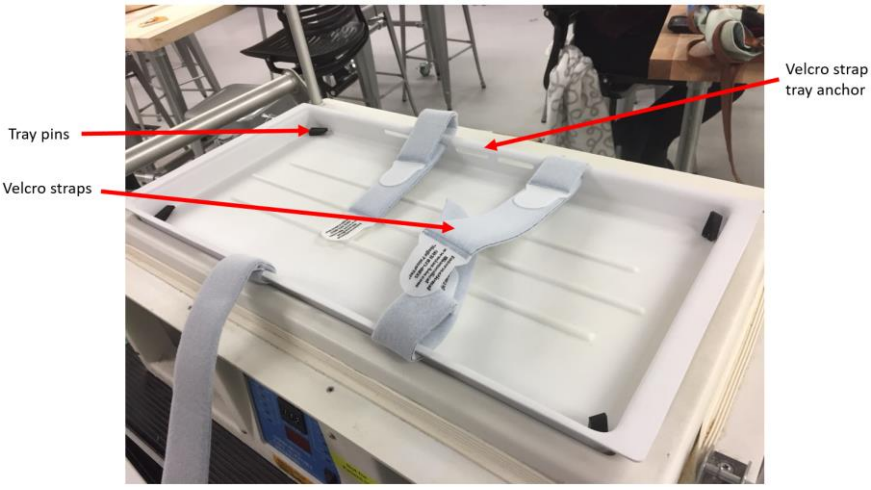
Design Validation Specification 3: Neonate Accessibility

- Purpose: Our solution causes the tray that the infant is resting on to be higher than in the current setup. This test will ensure that the baby is still accessible to nurses and can still be monitored with the new height.
- Success Criteria: The apparatus should have a minimum rating of 3.5 out of 5 for clinician satisfaction and all aspects of the infant must be accessible to the clinician
- Timing: This test must be performed by March 15, 2018 and should be tested by at least 5 clinicians
- Potential Tests: The nurses will be given a realistic situation in which a large neonate is placed on our new solution incubator and they will be asked to perform regular tasks (such as delivering oxygen or placing the infant in the incubator) and comment on if this is still possible with the new infant height.
- Test Protocol: To fully validate our design, we intend to have the emergency transport nurses test the system to ensure that none of the in-transport procedures would be affected by this change. See document #19 for full protocol.
- Resources: Travel nurses
- Report: See document #29 for test report

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