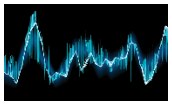
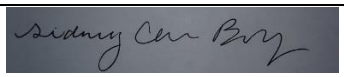
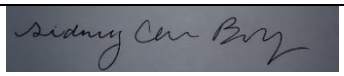
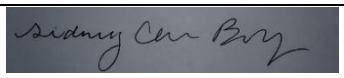
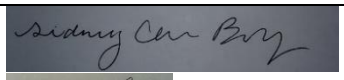
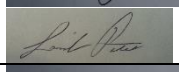
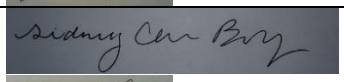
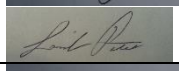
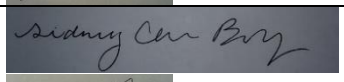
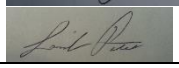
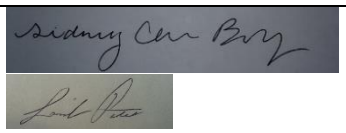
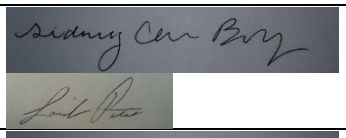
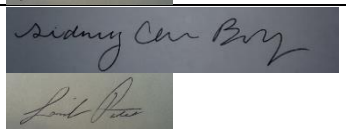
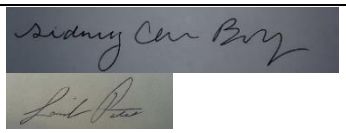
	Minimizing Ambulatory Vibrations – Group 8	**Quality System Procedure Form**	
		Doc. No: 7	Rev. 10
		Date: 4/15/18	Status: Draft

Product Design Specification

Approved by:	**Date:**
Michael Adams	4/15/18
Sid Bala	4/15/18
Sidney Cannon-Bailey	4/15/18
Samik Patel	4/15/18
Neil Vinjamuri	4/15/18

CHANGE RECORD:

Rev	**Date**	**Description of Change**	**Authorization**
1	10/19/17	Initial draft based on observation of the incubator and setup/conversation at Stat MedEvac location.	
2	11/25/17	Updated content based on quantification of vibrations within the ambulance.	
3	11/30/17	Updated content with further data analysis pertaining to power spectral density.	
4	12/03/17	Format for the document has been updated with greater justification for design specifications sought.	 
5	12/10/17	Introduction and appendix was added.	 
6	12/12/17	Added details for specifications. Tolerances were added. Removed notes from document to finalize.	 

7	1/16/18	Changed specification for Vibration Minimization section to reflect the more realistic standard established in the verification plan	
8	1/23/18	Fatigue constraint eliminated	
9	3/18/18	Altered infant height allowance based on conversation with travel nurse. Controller holes converted to incubator-tray attachment. Load rating/durometer added to material specification section based on preliminary verification tests	
10	4/15/18	Added additional material specification regarding polyester covering and sorbothane material. Added weight specification	

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 outlines the different specifications that need to be addressed by the solution that will be finally implemented to damp vibrations in this incubator system.

In the current setup, the tray holding the infant is bolted to a controller (See appendix for labeled diagram) that houses and delivers medical care for the infants (gas and temperature control) to ensure that the environment the infant is in is well mediated. The incubator houses the infant during travel and has a mattress on a tray that is secured to the incubator. The incubator also has a protective shield around the tray so the internal environment is isolated from the exterior. The current setup must be altered to accommodate our design and this document outlines the specifications of each anticipated change.

Note that the stretcher that carries the incubator is Stryker's Powered Ambulance Cot. It provides stability within the ambulance and a mode to transport the incubator from the

hospital to the ambulance and vice versa. However, the stretcher setup cannot be altered due to regulations.

Design Specifications

Vibration Damping:

- Solution must effectively damp vibrations in the 10-15 Hz peak frequency range
- Solution must damp vibrations in this range to the magnitude of the vibrations in the floor
    - Vibrations at the floor are –20 dB/Hz in a normalized power spectrum
    - The stretcher amplifies the vibrations from the floor, mainly at the 12 Hz (±3 Hz) frequency level
    - Goal is to minimize vibrations to 30% of their current value
    - Current peak vibrations at 12 Hz are approximately 0 dB/Hz when converted to Power Spectral Density. Therefore to minimize by 30%, the vibrations should be lowered to approximately -10 dB/Hz.

Material Specification:

- Sorbothane rubber utilized
- Sorbothane durometer for material underneath tray lip should be lower than 60 with a load rating greater than 10 lb
- Sorbothane durometer for material between tray and incubator should be lower than 70 with a load rating greater than 5 lb
- Sorbothane rubber of mass less than 15 lb when summed
- Sorbothane covered in polyester material to ensure ease of cleaning

Temperature:

- Solution must effectively function in a temperature range from 17°C - 38.9°C [1]
    - Can increase in 0.1°C increments [1]
    - Our clients (STAT MedEvac, Pittsburgh, PA) operate the incubator at 34°C
    - Solution must effectively function in this temperature range without material degradation
    - Solution must not interfere with the temperature setting knob function
- Solution must not alter the heat absorption by the current tray

Infant Height Allowance:

- Allowable elevated height for the tray is 1.25" (±.1") compared to the location of the current tray
    - Determined based on amount of space available for a neonate when placed in the incubator and the space necessary to access the neonate through hand holes in the shell [2]
    - The maximum dimension for a neonate that can be supported by the incubator is 8.27" x 5.91"
    - Limiting the elevation of the tray to about 0.687 ± .1" will not only ensure that infant will have enough space in the incubator but also allow for the nurse to still perform necessary clinical procedures. [2]
        - Hand holes in plexiglass shield are 3.25" from bottom of the shield to the bottom of the hand holes and 8.75" from bottom of the shield to the top of the hand holes [3]

Tray Dimensions:

- The current tray dimensions are 24" x 11.75" x 1.5", and thickness of 0.105". [3]
    - The length and width of a new tray must be identical to the current tray
- While the length and width of the final tray should be the same dimensions as the original to fit in the incubator, the mattress supporting the infant only needs to accommodate the largest possible infant
    - Based on feedback from multiple travel nurses as well as anthropometric research, the largest patient size we should account for is approximately 8.5" long and 6" wide. [3]
- The incubator system that is used to develop is the Voyager Infant Transport System by Airborne Life Support Systems.
- These dimensions were also physically measured since we have access to the incubator (provided to us by Stat MedEvac).

Tray Weight:

- The tray must be able to be supported by the Voyager Infant Transport System and also usable for travel nurses
- Based on talking to multiple nurses, a weight below 30 pounds would be easily manageable during their setup and transport time
- Therefore, a limit of 30 pounds should be applied to the tray and corresponding damping materials
- Maximum weight of incubator/design unit should be less than 120 lbs

- Data obtained from stretcher mechanical analysis as provided by Stryker

Controller Dimensions:

- Our solution must fit within the length and width of the controller as our solution will sit in the incubator hole [3]
- Controller dimensions are 30.5" x 15" x 9.5" and can accommodate a tray of 1" depth [3]
- Tray lip is supported by the controller lip, both of which have different dimensions
  - Controller lip varies from 1" to 1.5" wide, but is primarily 1" during contact with the tray (because tray lip width is 1"). [3]

Incubator-Tray Attachment:

- Must have a screw less than .33 ± .05" diameter that fits through the holes in the incubator [3]
- Our solution should account for the location of the holes in the incubator: .74" x .67" from the incubator lip wall as our solution must implement a threaded portion fitting through the hole at this location [3]
- Prototype must not move once attached to the incubator

Cleaning:

- Our solution's mechanical function must not be affected by the sterility techniques utilized by the nurses
  - Use PDI wipes consisting of ~45% isopropanol and .25% benzyl ammonium chlorides [4]
- The implementation of our solution must abide by the current process of tray cleaning and not alter protocol utilized by the nurses
  - The solution must be easily sterilized and easily detachable from the incubator

Water Resistance:

- Solution will interact with weather such as rain and snow
- The solution should be water resistant to the point that water/sun exposure does not affect the function and effectiveness of our solution.
  - Assuming the raindrop delivers pressure of 72 Pa (7.34 mmH_2O) , it should be able to solidly resist this. A water-resistant device must be able to withstand 200 mmH_2O [2], well above the pressure exerted by raindrops. Therefore, it is sufficient that our design be water resistant rather than waterproof.

References

[1] Incubator Service Manual (http://int-bio.com/wp-content/uploads/2016/06/Voyager-Service-Manual-English-Rev-C.pdf)

[2] Emergency travel nurses

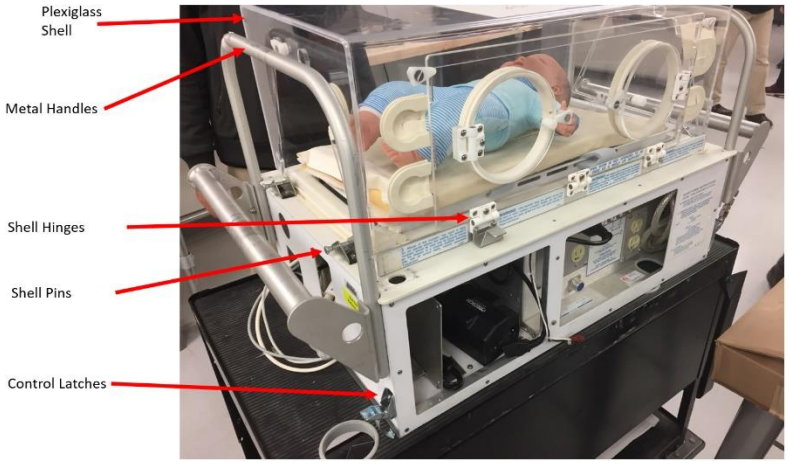
[3] Airborne Specification Brochure (https://www.anandic.com/bausteine.net/f/11394/AirborneBrochure_EN.pdf?fd=2)

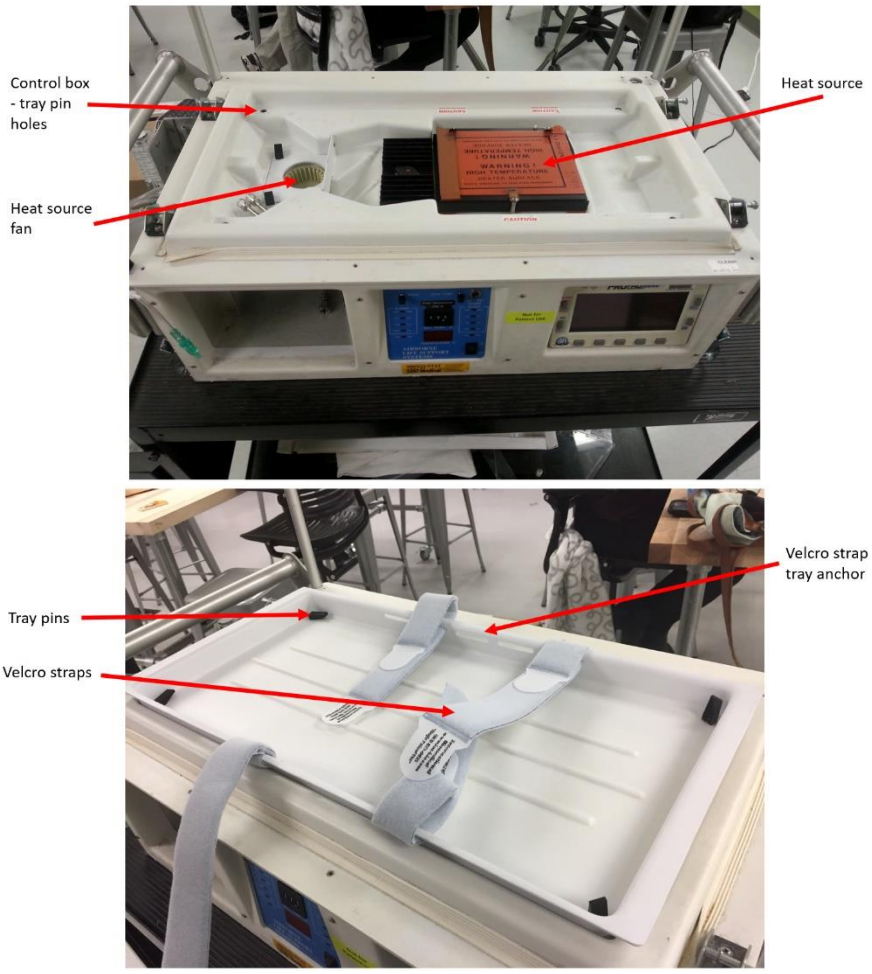
[4] PDI Wipes Specification Sheet (https://store.acplus.com/images/msds/PDI%20Super%20Sani-Cloth%20Germicidal%20Disposable%20Wipes%20MSDS%207-15-2009.pdf)

[5]Water Surface Tension (http://www.engineeringarchives.com/prb_fm_surfacetensionraindrop.html)

[6] Water Resistance (https://www.livestrong.com/article/528427-hard-vs-soft-soles-in-hiking-boots/)

Appendix




Control box - tray pin holes
Heat source
Heat source fan
Tray pins
Velcro straps
Velcro strap tray anchor