Product Design Specification

Reducing Whole-Body Vibrations in Neonatal Transport

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Function:

Critically ill neonates, as a result of birth defects or other disorders, require transport to neonatal intensive care units (NICU) where specialized medical professionals and equipment increase their chances of survival. Transport in ambulances or helicopters, while necessary, induces physiological stressors which adversely affect the health of the neonates. In particular, whole body vibration (WBV) and excessive sound levels can induce head bleeds, leading to subsequent neurodevelopmental impairment or death. Minimizing the effects of mechanical vibrations and rotational and translational motion could improve outcomes during transport. The current transport incubator has ventilators, monitoring equipment, and temperature control mechanisms, but no control of the physical stressors aforementioned. The client, Dr. Ryan McAdams, tasked the team with developing a novel transport bed to minimize these issues. The new bed must ensure the safety and security of the neonate while maintaining the functions of current incubators.

Client requirements:

1. The device must minimize the vibrational forces within the incubator so that a critical neonate does not sustain injury.
2. The device must minimize translational and rotational forces enough to prevent injury to critical neonates.
3. The device must either attach to current incubators or include all the associated functions including ventilators, monitoring equipment, and temperature control mechanisms.
4. The device must be small enough to fit within a standard ambulance and allow the movement of the transport team.
5. The data collection method must meet industry standards and provide appropriate support to justify the damper design´s effectiveness at reducing whole body vibrations.

Design requirements:

1) **Physical and Operational Characteristics**

a) Performance requirements

i) The product must decrease the amount of whole-body vibrations to be below 0.315 m/s^2 as suggested by ISO standard 2631 regarding human exposure to whole-body vibrations [1].

ii) The product should allow the infant to maintain proper vital signs in a range appropriate for its size, age, and condition:

(1) A heart rate between 100 and 160 beats per minute [2].

(2) A respiratory rate between 30 and 60 breaths per minute [2].

(3) Blood pressure of no less than 30 mmHg systolic [3].

(4) An oxygen saturation level between 85% and 95% [4].

iii) The sampling frequency of the testing mechanism should be at least 100 Hz in order to appropriately cover the range of frequencies experienced within the incubator while traveling in an ambulance or helicopter [5].

iv) The testing mechanism should be able to continuously collect and store data for at least 1 week.

b) Safety

i) The transport bed, and any alterations made to it, must not inhibit the delivery of continuous treatment to the neonate.

ii) The device should not interrupt the functioning of the incubator, ventilator, or monitoring equipment.

iii) Any potentially hazardous components of the device (e.g. sharp edges, long cords, or small pieces) should not be accessible to the neonate while in the incubator.

iv) The device should be able to be decontaminated with a U.S. Environmental Protection Agency (EPA)-registered hospital disinfectant without degradation for the 5 year lifetime of the ambulance [6].

c) Accuracy and Reliability

i) The device should be able to effectively reduce the amplitude of vibrations with a frequency in the human sensitivity range of 3-20 Hz [7].

ii) The root mean square vibration exposure should fall below the 0.315 m/s^2 comfort limit specified in ISO 2631 [1].

iii) The device should not lose function or require maintenance over the course of its lifespan.

iv) The device should be functional when supporting neonates from 2.5-4.5 kilograms [8].

d) Life in Service

i) On average, ambulances have a lifespan of around 5 years and travel around 300,000 miles, assuming proper maintenance and standard operating conditions. The device should be able to withstand these conditions [9].

ii) Incubators can last several years, but undergo significant stress due the vibrations and mechanical forces they withstand on a day-to-day basis and due to intense transportation (e.g., ambulance rides, cleaning, etc.). The device should be able to withstand similar mechanical stress to the incubator and last around a similar time frame [10].

iii) The device should not compromise the functionality or safety of the incubator throughout the lifespan of its use.

e) Shelf Life

i) If electrical components are involved in the design, the device should function for a minimum of 7 years [11].

ii) If no electrical components are included, the device should last for at least 12 years [11].

f) Operating Environment

i) The operating environment for both the dampening device and testing mechanism will be targeted for ground transport using an ambulance and the Voyager transport incubator by International Biomedical [12].

g) Ergonomics

i) No parts of the device will interfere with ambulance personnel or obstruct access to the neonate.

ii) For any electrical components, there will be a simple screen interface.

h) Size

i) The device will fit inside or under the Voyager transport incubator by International Biomedical with dimensions of 53 cm H x 48 cm W x 99 cm L [13].

i) Weight

i) The dampening device should be no more than 4 kg which is equivalent to 10% of the incubator's weight when empty [13].

ii) The testing mechanism should contribute less than 2 kg to the incubator system so that its weight will have a minimal effect on the vibrations experienced by the neonate [14].

j) Materials

i) The materials should be safe to use in a medical environment and be in compliance with federal EMS regulations [12].

ii) The damping device and testing mechanism should avoid using heavy metals or latex materials on portions of the device that may come into contact with a patient [15].

k) Aesthetics, Appearance, and Finish

i) The device should appear as a part of the incubator, but with distinguishing characteristics, such as color or material, that set it apart from the incubator as a whole. This will assist in removal, isolation, and cleaning of the device if needed.

ii) The color of the device should be either white, green, or blue, which all symbolize cleanliness. Color selection is important to provide confidence to the client and user that the product was professionally developed and is functional [16].

iii) Appearance and material considerations and choices should not ultimately affect the functionality of the device. FDA regulations surrounding material and color choices need to be carefully considered.

2) Production Characteristics

a) Quantity

i) A single functional prototype should be developed by the conclusion of the semester.

ii) A single testing device must be acquired to perform repeat testing on both the initial prototype and future developments.

iii) Design should be able to be mass produced for commercial use in the future.

b) Target Product Cost

i) The design should cost no more than $500 for preliminary development and testing.

3) Miscellaneous

a) Standards and Specifications

i) The dampening prototype can be considered a Class I or Class II device depending on the modifications that accompany the design. Either class will require compliance with sections 513(a)(1)(A)- general controls, 513(a)(1)(B)- special controls and specific risks, and potentially 510(k)- premarket notification [17].

(1) If the device modifies the incubator and replaces any components that are present in International Biomedical's Voyager, then it will require FDA approval and must meet requirements for a class II medical device

(2) If the device does not alter the incubator setup and presents a minimal risk to the patient, then it may meet the requirements described for class I devices.

ii) To ensure safety and efficacy, the device must follow the requirements under 21 CFR Part 820- Quality System Regulation [18].

iii) The device must comply with sterilization standards described in ISO 14937 [19].

iv) If the device directly alters the isolette, it must meet the standards in IEC 60601-2-20, which outlines safety and performance requirements for transport incubators [20].

b) Customer

i) The hospital requesting the device requires that the device is compatible with their preexisting transport setup.

(1) Alternatively, the design should include all the associated functions of a transport incubator including temperature control, ventilators, and monitoring systems.

ii) The design should fit within a standard ambulance and not hinder the mobility of transport teams.

(1) The maximum area for device implementation, as detailed for Type III Transport Ambulances, is 173 cm interior headroom and 124 cm aisle width [21]. It is important to note these are maximum size constraints while the functional design area may be limited further within this space for mobility and accessibility.

iii) The design must improve transport outcomes by reducing vibrations with no additional adverse effects on patient health.

c) Patient-related concerns

i) During use and transport, the device should not introduce any additional threats or risks to the neonate.

ii) The product should not come in contact with the patient in case of allergic reaction to the material.

iii) Thorough testing must be completed before testing on patients can occur to ensure comfortability, safety, and effectiveness. All risk management procedures must be fully and carefully analyzed.

d) Competition

i) The Quasi-Zero-Stiffness (QZS) Isolator is a proposed design which targets low-frequency vibrations via modifications made to the incubator control box [22]. The design primarily utilizes concentric magnets and coil springs to mitigate vibrations. However, the design requires extensive modifications to the preexisting setup and has not been experimentally proven.

ii) The isolation device for shock reduction is another proposed design which utilizes gas springs between the isolette and stretcher deck [23]. The design features variable pressures in the springs as a way to target various frequency ranges. The proposed design makes considerable modifications to the preexisting setup while failing to acknowledge the presence of monitoring systems.

iii) Magnetorheological (MR) dampers help stop vibrations in vehicles when driving on roads that have changes in smoothness and shape. The pneumatic suspension system can be set to be soft or firm, and the MR damper can be adjusted to

different levels of firmness to work with the pneumatic suspension and reduce vibrations [24].

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