Product Design Specifications: Neonatal Transport Unit

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BME 300/200

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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). The quality of that transport heavily influences survival or morbidity [1]. Transport in ambulances or helicopters, while necessary, induces physiological stressors including vibration, translational inertia forces, and rotational inertia moments [2]. These environmental exposures are associated with intraventricular hemorrhage (IVH) in transferred neonates, leading to subsequent neurodevelopmental impairment or death [3]. The current transport incubator has ventilators, monitoring equipment, and temperature control mechanisms, but no control of the physical stressors aforementioned. The natural frequencies of the incubator (12-16 Hz) accentuates the ambulance's natural frequencies (2.5-15 Hz), resulting in amplified vibration felt by the neonate [4]. The proposed device will oppose the mechanical forces transmitted through the transport vehicle or undergo purposeful motion which acts to absorb such forces. The device will improve neonatal transport outcomes by mitigating the effects of vibration and motion, improving the safety of the critical neonate, and simplifying the required care by the medical transport team.

Client Requirements:

1. The device must minimize vibrational forces such 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 mitigate sound levels experienced by the neonate in order to eliminate stress and injury (maximum accepted level of 45 dB) [5].
4. The device must either attach to current incubators or include all the associated functions including ventilators, monitoring equipment, and temperature control mechanisms.
5. The device must be small enough to fit within a standard ambulance and allow the movement of the transport team.

Design Requirements:

1. Physical and Operational Characteristics:

a. Performance Requirements:

- The product must decrease the amount of whole-body vibrations to be below 0.87 m/s^2 as recommended by the ACGIH for the exposure of adults [2].
- The product should be capable of reducing the volume of excessive sound levels to be below 45 decibels in order to prevent permanent hearing damage while riding in the transport vehicle [6] .

- The product should allow the infant to maintain proper vital signs in a range appropriate for its size, age, and condition:
    - A heart rate between 100 and 160 beats per minute [7].
    - A respiratory rate between 30 and 60 breaths per minute [7].
    - Blood pressure of no less than 30mmHg systolic [8].
    - An oxygen saturation level between 85 and 95% [9].

b. Safety:

- The transport bed must allow for continuous treatment and should not disrupt the incubator, mechanical ventilator, or monitoring equipment.
- The device should be sterilizable and resistant to degradation that can be caused by common sterilization chemicals such as ethylene oxide [10].
- The device must not have any sharp edges or long cords that the neonate could interact with.

c. Accuracy and Reliability:

- The device should require no maintenance during its lifetime, but should be easy to remove or replace if any malfunctions occur.
- The device should be functional for neonates ranging from 0.66 to 12 pounds [11].

d. Life in Service:

- The service life of a device should allow for 5,000 lifetime transports, or an estimated 5 years of operation, assuming that all ideal practices and operating conditions are followed.

e. Shelf Life:

- The device should last for a minimum of 7 years if any electrical components are involved in the design or a minimum of 12 years if no electrical components are included [12].

f. Operating Environment:

- The operating environment of the device will be ground transport using an ambulance with an incubator [13].

g. Ergonomics:

- The device should have a simple screen interface to control any electrical components.

- The entire device will be designed such that it causes no interference to ambulance personnel when installed and functional.

h. Size:

- The device should be able to fit inside the Voyager transport incubator by International Biomedical, which has dimensions of 53cm H x 48cm W x 99cm L [14].
    - The device could also be created to fit inside the ambulance under the incubator.

i. Weight:

- The device should be no more than 10lb which is equivalent to 5% of the incubator's weight when empty [15].

k. Materials:

- The materials should be safe to use in a medical environment and be in compliance with all federal EMS regulations. [13].

l. Aesthetics, Appearance, and Finish:

- The device should be entirely white or gray to make it easy to identify when cleaning is required [16].
- The device should be distinguishable enough from the incubator that it is not a challenge to locate and remove.
- Aesthetics should not impede the functionality of the device.

2. Product Characteristics:

a. Quantity:

- One functional prototype should be developed by the end of the semester.
- Once refined, the prototype will be mass produced for the general market.

b. Target Product Cost:

- The device will cost no more than $500 to fabricate and test.

3. Miscellaneous:

a. Standards and Specifications :

- The device must be compatible with a sterilization process in accordance with ISO 14937 [17].

- The product will be a Class II medical device according to FDA standards due to moving components that pose some risk to the patient and measurement capabilities [18].
    - FDA approval will be required for commercial use of the device.
- The device must comply with ISO 2631 which sets acceptable frequencies of whole body vibration, established to minimize health risk and discomfort [19].
    - Specifies that for health and comfort, vibrations should not exceed 0.5-80Hz.
    - Specifies that for patients that are motion sick, vibrations should not exceed 0.1-0.5Hz.
- IEC 60601-2-20 sets standards for the basic safety and essential performance of neonatal transport incubators [20]. This standard has been recognized by the FDA under Sec. 880.5410.

b. Customer:

- The target customer for our product is a hospital; specifically, the department within the hospital that manages neonatal transport and/or a Neonatal Intensive Care Unit (NICU).
- The device should be easily compatible with the equipment already used by the hospital, including incubators, transport carts, ambulances, and any accessory equipment used to treat patients during transport.

c. Patient-Related Concerns:

- The device should not pose additional risks to the patient during transport.
- Thorough testing must be completed to ensure the device does not decrease comfortability for the patient.

d. Competition:

- One category of competing designs involves the use of passive vibration isolation systems such as the use of a quasi-zero-stiffness (QZS) isolator placed beneath the infant compartment. This design has a high ability to attenuate low frequency vibrations [21].
- Magnetorheological (MR) dampers address variations in the international roughness index and the curve radius of roads in order to reduce vibrations within the vehicle. The pneumatic suspension system can be toggled between a compliant and stiff setting while the MR damper has an adjustable continuous range of viscosities that allow it to work in tandem with the pneumatic suspensions to reduce vibrations [22].
- A plate mounted to the incubator and another to the stretcher with a gap in between. Between the parallel plates springs are attached, “preferably gas springs, with a range and a damping effect” [23]. The spring reduces vibrations transmitted to the infant during transport.

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