Neonatal 22-23-Week Premature Infant Simulation Mannequin: PDS

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Function:

The simulation mannequin must be representative of a premature infant born at 22-23 weeks of gestation. The mannequin must be able to be intubated, which means that a breathing tube must be able to be placed into the mannequin's trachea. Additionally, the chest cavity and rib cage must be created so as to include further procedural training for medical professionals in thoracentesis and pericardiocentesis. As there is a lack of simulation mannequins for infants born this premature, it is critical to develop one that allows for medical personnel to be able to practice resuscitation techniques. Using a simulation mannequin with similar characteristics and technology that makes it seem more lifelike allows the medical professionals to practice in a less chaotic and stressful environment. It is essential for medical personnel to have access to a training mannequin such as this as it will allow neonatology to further advance and resuscitation to be possible for infants born at even younger gestational times.

Client requirements:

I. Length should be less than 30.5 cm
II. Improve skin texture of previous models
III. Ability to put synthetic breathing tube (2.00 -2.50 mm diameter) in mouth of mannequin, to attach a synthetic umbilical cord, and to be able to practice vital signs
IV. Base has to be able to handle breathing mask and bag practice, therefore pressure resistant
V. Weight around 400-500 grams
VI. Expandable lungs that replicate neonatal breathing
VII. The more prototypes the better

Design requirements:

1. Physical and Operational Characteristics

a. *Performance requirements*:

I. The mannequin must be able to last between 3-5 years and production cost must remain low to maintain reproducibility. It should also maintain similar characteristics to a real infant born at 22-23 weeks of gestation and include anatomically relevant structures.

b. *Safety*:

I. *User Safety* - Any electronics included in the mannequin must be enclosed and remain at a temperature low enough to ensure that the user is not experiencing any discomfort.

c. *Accuracy and Reliability*:

I. The skin that is included on the mannequin must be lifelike and resemble that of an extremely premature infant.

II. The mannequin should be an accurate anatomical representation of an infant born at 22-23 weeks of gestation.

d. *Life in Service*:

I. Typical use for simulation mannequins is between 3 to 5 years of frequent usage.

e. *Shelf Life*:

I. Batteries and electronics within the mannequin must be able to last for the full lifetime of the model.

f. *Operating Environment*:

I. The mannequin will be used as a training model in hospitals and teaching facilities.

g. *Ergonomics*:

I. The medical personnel using the simulation mannequin must be able to perform resuscitation procedures without hindrance.

II. The mannequin should be easy to use without exceedingly complicated electronic components that must be manipulated by the user.

h. *Size*:

I. The length of the mannequin should be roughly 1 foot when measuring from the "head" of the mannequin to the opposite side.

i. *Weight*:

I. The mannequin should be between 400 and 500 grams which does not include added electrical components.

j. *Materials*:

I. The mannequin must involve a skin-like material on the external surface. Electronic components should also be encased within this material.

k. *Aesthetics*, *Appearance, and Finish:*

I. The mannequin must look similar to an infant born between 22-23 weeks of gestation in both size and shape.

II. Additional aesthetics should not add any adverse effects to the experience nor add any extra weight.

2. Production Characteristics

a. *Quantity*:

I. The client requires a single prototype. With successful creation of one prototype, more will be needed.

b. *Target Product Cost*:

I. Cost should be low enough to be reproducible, and be created within a couple thousand

dollars.

3. Miscellaneous

a. *Standards and Specifications*

I. ISO 13485: This standard states that the organization must ensure quality medical devices from design to manufacturing and so on. This is achieved through ethical design that puts the customer and patient first, following standards, having adequate documentation, and so on[1].

II. ISO 14971: This standard states that risk management and design with risk considerations must be conducted by the design team. This involves risk evaluation and the implementation of risk control by the design team[2].

b. *Customer*:

I. The customer base for this product is medical schools that wish to educate their students on the intubation of neonatal infants. The students and medical professionals using the product would prefer if the mannequin is easy to handle but at the same time reflect the higher difficulties in resuscitation for premature infants of 22-23 weeks of gestational age.

c. *Patient-related concerns*:

I. The patients that this mannikin is supposed to simulate, the neonatal infant, would best benefit from this device if it is quite comparable to their likeness. Therefore, the patient-related concern is that the neonatal infant mannikin does not incorrectly train medical students in how to intubate the neonatal infant patient.

d. *Competition*:

I. There are many other neonatal intubation mannequins on the market today. These include, but are not limited to, models from Universal Medical Inc.[4], Laerdal Company[3], and Trucorp[5].

References

any quantitative information without references came directly from the client, Dr. Elgin

[1] B. Karthika and A. R. Vijayakumar, “ISO 13485: Medical Devices – Quality Management Systems, Requirements for Regulatory Purposes,” in *Medical Device Guidelines and Regulations Handbook*, P. S. Timiri Shanmugam, P. Thangaraju, N. Palani, and T. Sampath, Eds. Cham: Springer International Publishing, 2022, pp. 19–29. doi: 10.1007/978-3-030-91855-2_2.

[2] T. Sampath, S. Thamizharasan, K. Vijay Kumar Shetty, and P. S. Timiri Shanmugam, “ISO 14971 and ISO 24971: Medical Device Risk Management,” in *Medical Device Guidelines and Regulations Handbook*, P. S. Timiri Shanmugam, P. Thangaraju, N. Palani, and T. Sampath, Eds. Cham: Springer International Publishing, 2022, pp. 31–56. doi: 10.1007/978-3-030-91855-2_3.

[3] “Premature Anne,” *Laerdal Medical*. https://laerdal.com/us/products/simulation-training/obstetrics-pediatrics/premature-anne/ (accessed Sep. 23, 2022).

[4] “CPR Simulators | CPR Training Manikin.” https://www.universalmedicalinc.com/all-products/education/anatomical-models/medical-training-models/cpr-simulators.html (accessed Sep. 23, 2022).

[5] “TruBaby X | Infant CPR Manikin | Pediatric Manikin,” *Trucorp*. https://trucorp.com/product/trubabyx/ (accessed Sep. 23, 2022).