

# Neonatal 22-23-Week Premature Infant Simulation Manikin - PDS

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## **Function:**

There are currently no affordable neonatal manikins on the market made to resemble infants that are born at 22-23 weeks of gestation. Consequently, the first time many physicians, residents, or fellows use resuscitation skills needed to save an infant born extremely premature is during a real-life scenario. To provide a softer learning curve and to ultimately raise the rate of success of the resuscitation of premature infants, physicians are in need of a neonatal simulation manikin. The manikin must resemble an infant born at 22-23 weeks of gestation in size, appearance, weight, and mechanical function of skin while also having the capacity to be intubated, have IV access, and support central umbilical line placement. Ideally, the manikin would also have a ribcage and chest cavity to allow physicians to practice the techniques needed for thoracentesis and pericardiocentesis procedures.

## **Client requirements:**

- I. The manikin should:
  - A. Have the ability to be intubated, have IV access, and support central umbilical line placement.
  - B. Have a ribcage and chest cavity to allow users to train thoracentesis and pericardiocentesis procedures.
  - C. should resemble an infant born at 22-23 weeks of gestation in size, weight, appearance, and feel.
    1. Manikin should be no more than 30.48 cm in length and should not weigh more than 400 g to 500 g (weight can be adjusted if electronics were to be added).
    2. The skin of the manikin should resemble that of a true premature neonate in texture, thickness, and pigmentation.

## Design requirements:

### **1. Physical and Operational Characteristics**

#### *a. Performance requirements*

- i. The manikin should be able to support training in several different care processes including:
  1. IV application (for thoracentesis and pericardiocentesis), central umbilical line placement, intubation
  2. Users should be able to practice these procedures between 3 to 5 times before using skin replacements.
- ii. The manikin would likely be used several days of the week by different people in a training setting.
  1. As the skin of a 22-23-week premature infant is very thin and easily torn, the manikin will need skin replacements on areas of tearing, should they occur. This will allow for an accurate representation of neonatal infant skin.

#### *b. Safety*

- i. The team will consider several different materials in an attempt to best replicate premature neonatal skin. Use of these materials may require labeling, standards, and warnings depending on their chemical and physical properties..
- ii. Electrical components in the body cavities, for example, sensors to monitor compressions during resuscitation practice, will require proper safety labeling. This is currently beyond the goal of this semester, and will be considered in the future.

#### *c. Accuracy and Reliability*

- i. The chest cavity should always visibly rise when intubation and rescue breathing is properly performed.
- ii. The skin should tear 90% of the time from adhesive tape being placed on the skin and peeled off.
  1. This percentage is permitted to be lowered for the purpose of increasing durability, though the manikin will primarily prioritize accuracy over durability.
- iii. The weight of the model alone should be between 300g and 500g to allow for additional electronics and anatomical structures to be integrated into the design.
- iv. The overall height from head to toe of the manikin should be within  $\pm 10\%$  of 30.48 cm.

#### *d. Life in Service*

- i. The manikin should be usable for at least two years with use of skin

replacements.

1. The skin of the manikin is expected to tear with use as users train with the model and get experience. As such, skin replacements will be used to fix where tears occur, and should be sufficient for the life of the manikin to be at least two years..
  - ii. During training for residents, fellows, and physicians, the model should support use for multiple hours a day, all days of the week.
- e. *Shelf Life:*
  - i. When not in use, the manikin should be stored at room temperature: 20°C to 25°C with 20% - 60% humidity [1].
  - ii. The materials of the manikin must not lose realistic texture or physical properties and internal components must not lose functionality while in storage for up to two years.
  - iii. Batteries and electronics must be accessible for replacement as needed or last the duration of the manikin's shelf-life.
- f. *Operating Environment:*
  - i. The manikin will be handled in a clinical setting as a training simulator for medical personnel.
  - ii. The manikin will be operating and stored at room temperature: 20°C to 25°C with 20% - 60% humidity [1].
  - iii. The manikin will be exposed to pressure in the thoracic cavity required to depress the chest cavity one-third of the diameter of the chest wall during resuscitation attempts [2].
- g. *Ergonomics:*
  - i. The manikin should be used in a clinical, teaching setting, and should be handled with care as a premature neonatal infant would be handled. It should not be used beyond typical neonatal care procedure practices.
  - ii. The skin is extremely delicate, and can tear easily.
    1. Tears are expected to occur as medical students learn and get experience with handling newborns.
  - iii. Applied forces include those stated in *f. Operating Environment*, iv.
- h. *Size:*
  - i. The manikin should be approximately 30.48 cm in length from head to toe.
  - ii. The manikin's throat cavity should allow for intubation using a 2.0 mm to 2.5 mm diameter breathing tube.
  - iii. The manikin should include a zipper along the length of the back access point for internal maintenance.

1. The skin material is not expected to be present where the zipper is, and should be durable enough to not tear when the zipper is opened and the internal components are handled.

*i. Weight:*

- i. The weight of the manikin should be between 300 g and 500 g.

*j. Materials*

- i. No soluble materials should be used for the outer skin layer.
- ii. The skin should resemble premature neonatal skin as accurately as possible.
  1. Initial factors to consider will be thickness, texture, and strength (should tear 90% of the time when adhesive tape is applied and removed). Future work will take pigmentation into account.
  2. Young's Modulus of adult skin is between 4.6 MPa and 20 MPa [3].
    - a. Outer skin layer will be estimated at 4.6 MPa since the skin of a newborn is much more fragile than adult skin.
    - b. Inner material should be minimally degradable and be within the 4 MPa to 20 MPa range, but it is not necessary that this material is fragile.
  3. Accuracy will be assessed through expert opinions via the client and possibly the client's colleagues.

*k. Aesthetics, Appearance, and Finish:*

- i. The finished manikin should resemble a 22-23-week premature infant as closely as possible in shape, form, and texture.
  1. The manikin should have the same flexibility of skin and tissue as a premature newborn, exhibiting similar softness in the body.
  2. The model's skin should resemble that of a true 22-23-week neonate.
    - a. This texture has been described as thin and wrinkled by experts [4].
    - b. The skin pigmentation should resemble that of a premature infant which is characterized by reddish, transparent skin [4].
      - i. The team recognizes the limitations to the portion of the population that can be accurately represented by one skin pigmentation. This will be taken into account, and the team will work to include as much diversity in the model as possible.
      - ii. In future work, when pigmentation is incorporated into the skin material, it is worthwhile to mention that IV insertion could prove to be more difficult with darker pigmentation.

## 2. Production Characteristics

### a. Quantity:

- i. The client currently requires a single prototype. With successful creation of one prototype, more can be produced at a later time.

### b. Target Product Cost:

- i. The target production cost has some flexibility and ranges from \$500-\$2000.
  1. Manufacturing costs would include materials and fabrication.
- ii. The team's goal is to produce a low-cost manikin that is less expensive than competing models on the market (\$2,000 to \$7,000).

## 3. Miscellaneous

### a. Standards and Specifications:

- i. ISO 13485: This standard states that the organization must ensure quality medical devices from design to distribution. This is achieved through ethical design considerations that put the customer and patient first, adherence to standards, and adequate documentation [5].
- ii. ISO 14971: This standard states that the design team must implement risk management to their process. This includes assessing risk associated with biocompatibility, electronics, moving parts, and usability, and controlling for these variables [6].
- iii. OSHA Standard 1910.1000: This standard sets regulation requirements for indoor office temperature and humidity levels: temperature must remain between 20°C and 25°C, and humidity levels must remain between 20% and 60% [1].

### b. Customer:

- i. The customer is a professor in the department of neonatology and newborn nursery at the University of Wisconsin-Madison. The customer understands that the project is highly theoretical, as there is little literature available on 22-23-week premature neonates. With little engineering background, the customer has also entrusted the team to accurately assess the feasibility of requests. The customer has communicated a preference for accuracy on the manikin's skin texture and thickness.

### c. Patient-related concerns:

- i. Not applicable.

### d. Competition:

- i. There are many neonatal manikins on the market. The three premature infant manikins most similar to this project include the following:
  1. Laerdal Medical's Premature Anne [7]
    - a. This manikin represents a premature newborn at 25 weeks of gestation.
    - b. The price of Premature Anne is between \$3,000 and \$6,900

depending on what training features are included.

- c. The skin is durable but not realistic.
2. Laerdal Medical's PremieNatalie [8]
    - a. PremieNatalie is meant for nursing mothers to practice breastfeeding.
    - b. The manikin is not realistic in the limbs or trunk, and does not have the skin texture of a premature newborn.
  3. Lifecast Body Simulation's Micro-Premie Manikin [9]
    - a. This manikin represents a neonate born at 22-23 weeks of gestation.
    - b. There is no information regarding the price, and it is not currently available on the market.
    - c. This manikin does not have IV access.

## References

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

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