Transfusion Device: Product Design Specifications

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Problem Statement

A double volume exchange transfusion is a procedure in which a baby's entire blood volume is exchanged twice in order to clear the blood of bilirubin and prevent brain damage in newborn babies. Since the procedure is not done frequently due to the increase of phototherapy treatments, neonatologists are thereby less experienced with this procedure. The goal is to improve the safety of the transfusion by designing a device that can eliminate incorrect use of stopcock, count the waste taken from the baby, and differentiate between the stopcock connections.

Client Requirements

- Device that ensures accurate use
- Easily identifiable tubing connections for both the 3-way and 4-way stopcock
- If not disposable, must be able to be autoclaved
- Portable and needs to be placed near baby

Design Requirements

1. Physical and Operational Characteristics
    a. *Performance requirements:* Device must enhance and make the transfusion process more efficient. Should be easy to use and intuitive despite infrequent usage (once every 3 to 5 years). Can be used during the procedure as well as during training.
    b. *Safety*: Must be safe to use in a clinical environment and should decrease the morbidity and mortality of the exchange transfusion.
    c. *Accuracy and reliability:* Should allow the user to only turn the stopcock one direction and count the number of revolutions accurately.
    d. *Life in Service/Shelf Life:* Should last the duration of the transfusion (2 to 4 hours). If not disposable, the device would ideally last for 10 transfusions.
    e. *Operating Environment:* Indoor clinic, hospital, or laboratory. Operated between 20-25°C. Pressure and moisture should not affect operation.
    f. *Ergonomics:* Should be comfortable for the user and easy to handle. Force exerted by user should be less than 10 N.
    g. *Size:* Needs to be portable and small enough to be handheld or placed near baby. Should be no bigger than 500 cm^3.
    h. *Weight:* 1 kg or less.
    i. *Materials:* The device will incorporate the stopcock, syringe, and IV tubing. Material needs to be able to be sterilized.
    j. *Aesthetics, appearance, and finish:* Should be presentable in a hospital setting.

2. Production Characteristics
    a. *Quantity:* One prototype as a proof of concept.
    b. *Target Product Cost:* System less than $500.

3. Miscellaneous
    a. *Standards and Specifications:* Meets FDA standards for a Class II medical device.
    b. *Customer:* To be used at Meriter Hospital as a teaching tool and for clinical practice.
    c. *Patient-related concerns:* Apart from general transfusion safety requirements, there are no special considerations for the device.
    d. *Competition:* There are no similar devices in the market and no foreseeable competition due to infrequency of the procedure