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10. Appendix

10.1. Product Design Specifications

Development of an Upper Extremity Fracture Model (fracture_model)

Product Design Specifications

Kim Maciolek (Team Leader), Hope Marshall (Communicator),
Kevin Beene (BWIG), Gabe Bautista (BSAC)

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Function:

Currently residents learn casting techniques by trial and error on pediatric patients. Our client, Dr. Matthew Halanski, requires a forearm fracture model that teaches safe cast application and removal techniques. The design should incorporate sensors for temperature, pressure and contact (i.e. laceration) along the simulated limb to assess safe fracture reduction. The data obtained will be used to develop self-teaching modules in which persons using the model will be able to compare their casting techniques with those of the experts.

Client requirements:

Our client desires a device that:

- Is portable and reusable
- Clearly indicates successful fracture reduction
- Measures temperature and force applied to forearm
- Detects cast saw contact with skin surface

Design requirements:

1. Physical and Operational Characteristics

a. *Performance requirements*: The device should be reusable, easily sanitized, and teach safe placement and removal of a cast for a distal radius and ulna fracture. The device should be easily transportable for training purposes in various hospital environments. The device should indicate when fracture is properly reduced.

b. *Safety*: The device cannot harm training residents or doctors using the device as a teaching tool. Device should be stored safely including protection from all circuits or electronic components.

c. *Accuracy and Reliability*: The device should mimic common fracture conditions including the force necessary to immobilize the fracture. The device should be accurate enough to allow the same person to complete the casting procedure and achieve the same results.

d. *Life in Service*: Design must be reusable and last at least 10 years in a hospital setting.

e. *Shelf Life*: Device should be stored at room temperature and atmospheric pressure. Device may require battery changes.

f. *Operating Environment*: The device should be used at room temperature, atmospheric pressure, low humidity, in a dry environment with minimal dirt or dust. The device should be handled by healthcare professionals and students. The simulated limb should withstand forces necessary for standard casting procedures.

g. *Ergonomics*: The device must be easily used by one or multiple medical professionals at a time. A single user should be able to view pressure readings and thermal readings while using the device without the help of another user. The user should be notified when the simulated limb fracture has been correctly immobilized or when the cast saw is in close proximity to the skin without the help of another user. The device should be easily maneuverable by one person including transportation to and from various hospital environments.

h. *Size*: The model, in its entirety, should be no larger than 1 cubic meter.

i. *Weight*: The maximum weight of the device should be no more than 5 kg.

j. *Materials*: The device should be composed of materials that have similar properties to those of a human forearm. Materials should be durable to allow for repeated use.

k. *Aesthetics*, *Appearance, and Finish*: Model should be aesthetically pleasing to users and easy to identify as a forearm cast placement and removal training tool.

2. Production Characteristics

a. *Quantity*: One functional device is needed.

b. *Target Product Cost*: Total production cost should be less than $20,000.00.

3. Miscellaneous

a. *Standards and Specifications*: IRB approval required prior to testing.

b. *Customer*: Functionality and multi-faceted uses as an all-encompassing training model are the main priorities for the client. Client is especially concerned with measuring blade temperature, preventing accidental cutting of wires, and visually displaying if fracture is reduced correctly.

c. *Patient-related concerns*: Device should be easy to sterilize as it will be used in a hospital setting.

d. *Competition*: Currently, devices on the market only include only a few aspects of the desired device: simulated limb, pressure monitoring, thermal monitoring, user-friendly monitor and use as a teaching tool for application and removal of a cast. This device will be unique in its ability to combine all aspects.