Product Design Specification
Arm Holder for Cardiac CT Scans

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PURPOSE & DEVICE FUNCTION:

In computed tomography (CT) scanning, digital geometry processing is used to generate 3D images. The digital data is collected by a series of x-ray plates that rotate around the patient at high speeds, allowing the device to complete a chest scan within 15 seconds. However, to produce the best quality images using the CT scanner, the patient must be restrained to minimize movements. Respiration, cardiac motion, and patient restlessness produce blurring, doubling, and distortion artifacts in the reconstructed images and may lead to misdiagnosis (Dhanantwari et al, 2001). In one study, images of anesthetized patients still resulted in a 0.1mm error and 0.6-1.4mm error for non-anesthetized patients (Lemieux et al, 1994). For cardio and respiratory applications of CT scanning, beta blockers are given to the patient to help keep his or her heart rate below 60 beats per minute. A low heart rate prevents the patient's internal organs from excessive motion that can cause blurring in the final image.

To help maintain the patient's low heart rate and to restrict body movement, the arms must be comfortably secure out of the scanning area (the patient's chest) during the fifteen minute procedure. Since the scanning bed does not have a way of accomplishing this arm support, our client would like a device that can comfortably support and restrict movement of the patient's arms throughout the procedure. To prevent IV pinching, the inner elbow must remain unbent and accessible. Most of the patients are between 40 and 80 years of age and the device must accommodate individuals with restricted shoulder rotary motion. The device should be adjustable to accommodate all body sizes. The device must remain stable on the scanner table, have customizable height, grip angle adjustments, and provide support to the patient's forearms.

CLIENT REQUIREMENTS:

- Must withstand a fall of approximately four feet and daily wear-and-tear
- Device should have minimal movement once it is attached to the scanning table. Future testing with the device will determine the allowable variance.
- Should withstand hospital disinfectants
- Must provide comfortable arm support for 15-20 minute procedure
- Keep arms out of the scanning field (the chest area)
- Compatible with General Electric's 64-Slice VCT Scanner as well as Siemens, Toshiba, and Phillips scanners.

DESIGN REQUIREMENTS:

1. Physical and Operational Characteristics
    a. Performance Requirements
        i. Reusable. The CT scanners at the UW Hospital in Madison, WI are used approximately 5-10 times per day. The entire device should be able to withstand

this usage frequency without frequent maintenance or replacement (i.e., annual or more often).
ii. Withstands chemical disinfectant sprays and ethanol
iii. Sturdy; cannot shift on scanning table as a slight movement will distort or blur the image. The device should have minimal movement once it is attached to the scanning table. Future testing with the device will determine the allowable variance.
iv. Should withstand the weight of the patient's arms without tipping, bending, or deforming (see b.ii below)

b. Safety
i. Non-toxic, non-absorbing, and non-allergenic materials
ii. The device should withstand the weight of the patient's forearms, which is approximately 10% of one's body weight (Wuelker, 1996). For an American, this means that the device should support an average of 14-20 pounds without breaking, bending, or tipping (Halls, 2000).
iii. No sharp edges. Edges should be rounded to prevent any cuts or scrapes from being incurred by the patient or the medical professional setting up the device.

c. Shelf Life: The device should last for at least 6-8 years.

d. Operating Environment
i. Clean hospital environment. The CT scanning room is cleaned at least once daily with ethanol and disinfectant sprays.
ii. Standard room temperature ($20 \pm 5^{o}C$)

e. Ergonomics
i. Comfortable for 15-20 minutes. Device should not induce pain, cramping, or severe discomfort of the patient's arms.
ii. Supports forearms and wrists without discomforting the shoulders
iii. Adjustable to accommodate patients ages 40 to 80.

f. Size
i. Must fit in General Electric's 64-Slice VCT Scanner. Measurements of the scanning gantry will be taken at the next client meeting.
ii. Portable such that a nurse or doctor can lift the device and transfer it easily to and from the scanning bed.
iii. Device should be easy to store and should be small enough to fit in a cabinet of the CT scanning room or light and unobtrusive enough to hang up on a common coat hook (should not protrude more than two feet from the wall).

g. Weight
i. The device should weigh less than 30 pounds so that when not in use it can be removed from the scanning bed without inducing excessive stress on the nurse or doctor's arm and back muscles.

2. Production Characteristics
a. Quantity: 2 units
b. Target Product Cost: under $500

3. Miscellaneous
a. Standards and Specifications
i. If the device moves on to manufacturing and commercial stages, the device must meet hospital cleanliness standards (FDA)

b. Customer/Patient Related Concerns

i. Easy to use and set up. The device should not require a lengthy assembly time, preferably less than 3 minutes.
ii. Minimal training needed. Device should not require anything more complicated than lifting it onto the scanning bed, securing it, and making height and grip angle adjustments.
iii. Reasonable cost. The device should not cost more than $500.
iv. Safe. The device should not hurt or harm the patient or medical professionals in any way.

c. Competition

i. Dr. Jon Keevil's Version 1- Angled grip handle constructed of PVC tubing that provides arm stability during chest CT scans (Figure 1). The device is attached to the scanning table by a Velcro strap. Pillows are used in conjunction with the device to support the forearms. None of the components are adjustable.

Figure 1: Version 1 as demonstrated by team member.

ii. Dr. Jon Keevil's Version 2- This device is an alteration of the previously mentioned device with a straight handle (Figure 2).

Figure 2: Version 2 as demonstrated by team member.

REFERENCES

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