Project Design Specification

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Problem Statement:
The ankle and foot are commonly scanned using Computed Tomography (CT) machines. There is currently no device for both positioning the feet and applying a measurable load on them during a CT scan. This team will design and build a foot holder for a GE CT scanner that contains no metal or radiopaque materials within the scanning field, allows the patient's feet to be held in a standardized neutral position, is easily cleaned and disinfected, and is lightweight for easy transportation around the facility. The foot holder must also be securely attached to the CT scanning table. Additionally, we will develop a method to use and measure a force against the feet so that the force simulates a weight-bearing image.

Client Requirements:
- Hold feet securely
- Apply measurable load to feet
- Must not obstruct CT imaging
- Easily moveable by one person

Design Requirements:
1. Physical and Operational Characteristics
a. Performance Requirements- The device must provide a measurable load on the feet of up to 50 pounds.

b. Safety- The device must comply with standards for medical devices established by the FDA. It must be CT compatible and cause no harm or discomfort to the patient.

c. Accuracy and Reliability- Results must be reproducible. The device must be accurate to within ± 0.5 lbs.

d. Shelf Life- The device must last 10-20 years and be stable enough for use numerous times per day.

e. Operating Environment- The device must not be corroded by the disinfecting solution and must be able to withstand X-ray bombardment.

d. Ergonomics- Must be able to support human feet comfortably.
Operation of the device should be easy to use, and not interfere with the standard CT procedures. It also should not significantly lengthen the duration of the scan. The handle should not require excessive torque and easily be within reach of the technician.

e. Size and Shape- Must fit within the CT scanner, a diameter of 70 cm. It should be sufficiently small to allow easy movement and storage. It should be able to fit a variety of different sized feet.

f. Weight- The device must be weigh less than 40 lbs and should be easily transported by a single technician.

g. Materials- Must have low X-ray attenuation. It should be sufficiently rigid and strong to prevent flexion and breakage.

f. Aesthetics - It should be smooth, elegant, and safe-looking.

2. Product Characteristics:

a. Quantity- Preferably three, but only one is required.

b. Target Product Cost- The device should stay within the client budget, ideally under $500 for a working prototype and under $1000 to manufacture.

3. Miscellaneous:

a. Standards and Specifications- The device should comply with the guidelines set up by the FDA for medical instruments. Further information is available online at the FDA's website. The device is subject to performance and safety standards, without exception, for its classification.

b. Customer- The customer will primarily use the device in CT scanners; therefore, its use should tailored for use in CT scanners.

c. Patient-related concerns- The device will have to be disinfected between uses.

d. Competition- Similar devices exist for holding the feet, however none provide a measurable load on the feet.