

# Table of Contents

<b>Abstract .....</b>	<b>1</b>
<b>Problem Statement .....</b>	<b>1</b>
<b>Background .....</b>	<b>1</b>
Computed Tomography.....	1
Materials.....	4
<b>Client Requirements .....</b>	<b>6</b>
<b>Preliminary Designs.....</b>	<b>7</b>
Cable Design .....	7
Screw Design.....	9
Pneumatic Design.....	10
<b>Preliminary Design Evaluations .....</b>	<b>12</b>
<b>Final Design.....</b>	<b>14</b>
Overview .....	14
<b>Conclusion .....</b>	<b>17</b>
Future Work .....	17
Ethical Considerations.....	20
<b>References.....</b>	<b>22</b>
<b>Appendix.....</b>	<b>23</b>
Product Design Specifications.....	23
NP843 material data sheet.....	25

## **Abstract**

A CT scan can be used to find anatomic subtleties in the feet and ankles that are not seen in a radiograph. However, a radiograph is taken with the patient bearing weight whereas the CT scan is not, resulting in inconsistent images. There is currently no standard device used with CT imaging to ensure the feet and ankles are held in a consistent, standard position as well as simulate the patient bearing weight during the scan. For this reason, a device was constructed for use with a General Electric CT scanner that would simulate weight-bearing conditions – to match the conditions of a radiograph – and have the feet set together in an upright position. Continued work with the prototype includes modifying the device so that it is more appealing and adapting it for use with MRI.

## **Problem Statement**

While nearly all feet radiographs are shot with the patient bearing weight, computed tomography (CT) scans of the feet and ankles are done in non-weight bearing conditions. A device that applies a load to the feet during a CT scan, thus better simulating the anatomic alignment of the bones and tissues under physiologic loading, is needed. The device must also secure the feet upright and together, in order to establish a standard position for CT imaging of the feet and ankles.

## **Background**

### **Computed Tomography**

Computed tomography is an X-ray-based medical imaging modality. The basis of X-ray imaging is that different materials or tissues have different X-ray attenuation—the fraction of a beam that gets scattered or absorbed by the material per unit thickness. As a

material's attenuation coefficient increases, the amount of energy that can pass through the material decreases. Bones have a much higher coefficient of attenuation than soft tissues, creating contrast between bone and soft tissue in X-ray images. The CT scanner takes projections from many angles and builds the output using a reconstruction algorithm. The intensity of the resulting image is a map of attenuation. CT provides both 2D cross-sectional images and 3D renderings, which can allow for easier human interpretation of complex anatomical geometries.

The CT scanner our client uses is a GE Lightspeed 64-slice model, as seen in Figure 1. The patient lies down on the table and a technician secures the patient with padded straps before the scan is conducted. During the scan, the table moves at a constant velocity through the hole in the gantry while technicians monitor everything through an adjacent control room. According to our client, typical scans are completed in 20 seconds or less.



**Figure 1**

This is a picture of the CT scanner our client uses. The device is located near the gantry at the end of the table.

Our client is specifically interested in CT imaging of the feet and ankles. Generally, patients that have chronic, unexplainable foot pain, the source of which was not found using other imaging modalities such as X-ray radiographs, resort to CT. It is not known specifically how the images will differ in loaded vs. unloaded conditions but it is hypothesized that there will be anatomic subtleties only visible when the feet are imaged under a load. For example, our client has observed that some feet have a high arch when unloaded flatten out when a load is applied. Such observations support this hypothesis. This hypothesis will be tested in a research study with this device, as

discussed in the future work section of this report. Areas of specific interest to our client include the Lisfranc joint (tarsal-metatarsal joint [2]) and the posterior tibial tendon (connects calf muscle to the navicular bone, which contributes to the arch of the foot [4]).

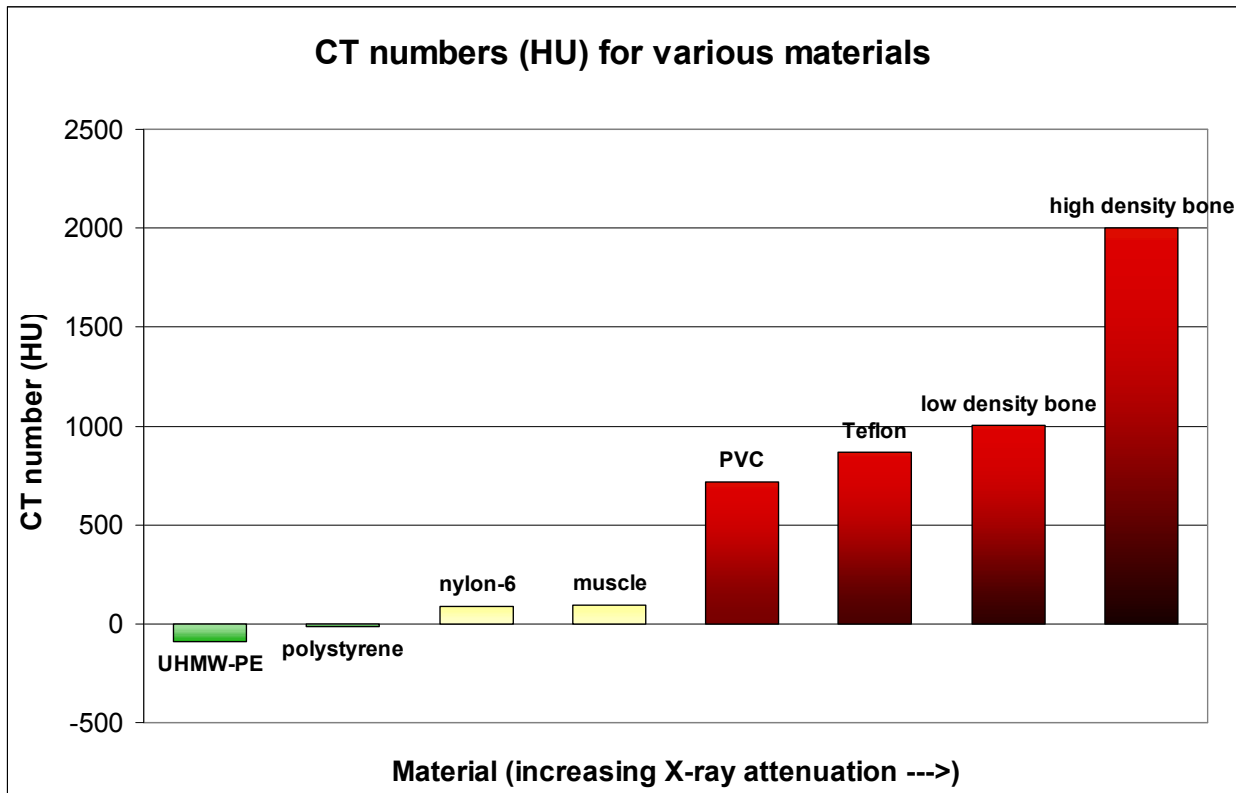
There is currently no standard position for CT imaging of the feet and ankles, making comparisons between different images difficult or impossible. This device would help to establish a standard position: the feet together and upright, or perpendicular to the legs.

## **Materials**

Several criteria were considered when selecting materials for the device:

1. **X-ray attenuation:** any material in the scanning field had to be radiolucent to avoid interfering with CT imaging.
2. **Strength:** had to withstand reaction forces from load on feet.
3. **Weight:** lightweight materials were required to improve portability.
4. **Cost:** low cost materials were preferred.

A material's X-ray attenuation varies with the energy of the X-rays passing through it [6]. Dr. Schreibman conducts his ankle CT exams at 120-140 keV and 100-400 mA. For these energy levels, the Hounsfield scale (unit: HU) quantifies the radiodensity, or relative transparency of a material to X-rays [1]. The standard defines air at -1000 HU and water at 0 HU. A material's HU value is also often referred to as its CT number. Figure 2 displays the CT numbers for various materials [5]:



**Figure 2**

Graph of the CT numbers obtained from Schneider *et al* [5]. This is a measure of each material's attenuation. The values are relative to water, with a CT number of zero.

As seen in Figure 2, polyethylene has a very low CT number of -89—the lowest out of the other common thermoplastics on the graph. Once it was known that polyethylene has exceptionally low X-ray attenuation, its other properties were investigated.

Specifications for polyethylene were obtained online from McMaster-Carr [3], a large supplier of hardware and raw materials. They offered several varieties of polyethylene—low density, high density, and ultra high molecular weight (UHMW). All three varieties of polyethylene have a similar density so it was assumed that all three had a CT number approximately equal to that given for polyethylene [5]. Since all three were

lightweight, the decision was based on the tensile and impact strengths. The UHMW variety provided exceptional tensile strength (3050 psi) and was unbreakable by a notched Izod impact test. According to McMaster's product description, standard grade UHMW is "ideal for applications that require chemical, friction, and impact resistance" [3]. UHMW polyethylene was selected as the material for several fabricated components of the final design prototype.

Two large plates of a phenolic-paper composite material (called NP843) were donated by Norplex-Micarta. According to the company, this material is extensively used in the medical industry for X-ray tabletops, as it is strong and radiolucent. This material will be implemented in a future prototype as described in the future work section of this report. A data sheet for NP843 is available in the Appendix.

## **Client Requirements**

Our client's requirements for the foot holder are listed below:

1. **Low X-ray attenuation:** all materials in the scanning field, defined from the ankle to the bottom of the foot, had to be radiolucent in order to avoid interfering with or creating artifacts in CT images.
2. **Apply load to feet:** the device had to be able to apply an adjustable load of up to 50 lbs. to the feet.
3. **Measure the load:** the device had to be able to measure the load with an accuracy of  $\pm 1$  lb.
4. **Hold the feet:** the feet had to be held securely for the duration of the scan (usually under 30 seconds according to our client). They should be positioned together and upright, with the feet perpendicular to the legs.

5. **Portable:** the device had to be lightweight and easily movable by one technician.
6. **Cleanable:** the portions of the device that come in contact with the patient had to be resistant to common disinfectant chemicals that are used for cleaning after each scan.

For a more detailed description of the design requirements, please see the Product Design Specification in the Appendix.

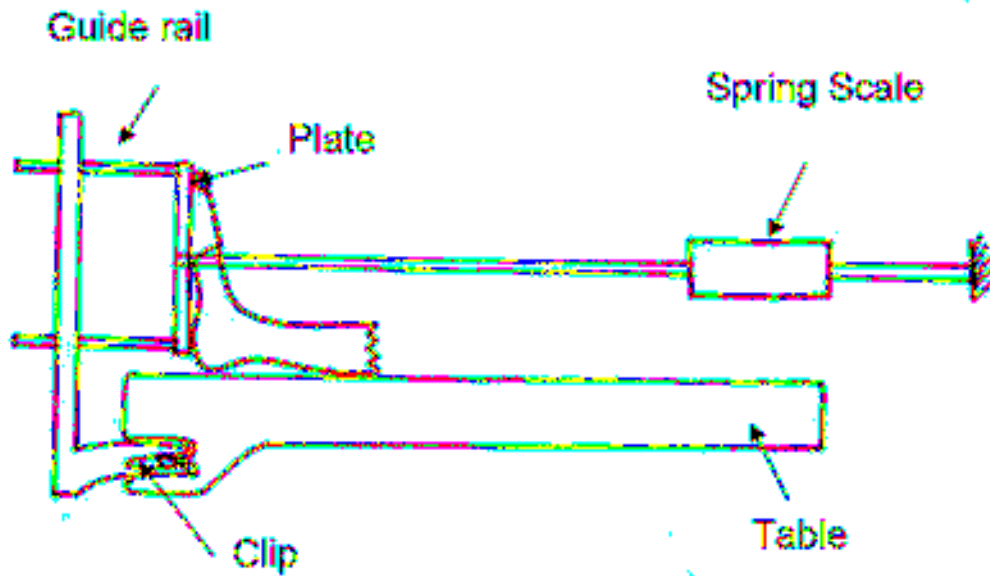
## **Preliminary Designs**

This section presents each of the preliminary designs that were brainstormed early on in the project. The reasoning used in this section also reflects the thought process that occurred at that stage of the project.

### **Cable Design**

The cable design, shown in Figure 3, pulls the feet to apply a force via two cables attached to either side of a plate against which the feet rest. As the technician tightens the cables, they pull the plate, thereby applying a force to the feet. The cables are attached to a shoulder piece, not shown in the diagram below and held down by the weight of the patient. The force will be measured using a spring scale on each cable. This will let the technician know whether or not the tensions in the cables are equal, so an equal force will be acting on the feet.





**Figure 3**

Side view drawing of the cable design. The cable pulls on the plate to apply a load to the feet. This load is measured by the inline spring scale.

#### **Advantages**

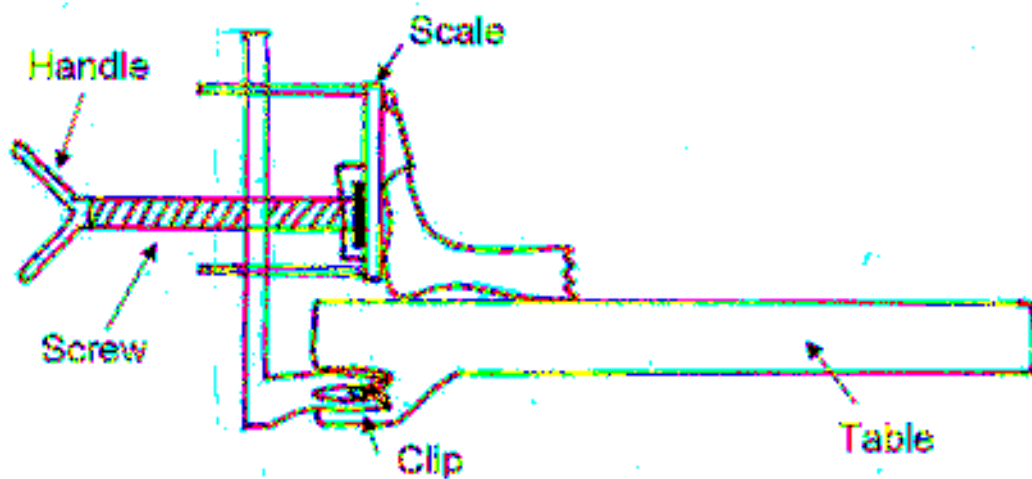
- metal free
- accurate force measurement
- easy to adjust force

#### **Disadvantages**

- takes up a lot of space
- imposing to patient
- time consuming to position patient
- more parts to clean

## Screw Design

Figure 4 displays the screw design, named for its use of a screw to drive a plate against the patient's feet. The screw is a large threaded rod with 1"-8 threads. A rod with a 1" diameter was chosen to ensure that it would be able to withstand the reaction forces from the load plate. The rod is driven by a long handle distal to the load plate. It was desirable to have a long handle to allow the operator to generate greater torque.



**Figure 4**

Side view drawing of the screw design. The force is applied by rotating the screw that drives the plate into the feet. The load would be measured by a scale or load cell based system

## Advantages

1. *Safety* – the technician has immediate manual control of the load on the feet. If the patient experiences pain, the handle can be quickly reversed to remove the load.
2. *Portable* – the entire assembly is estimated to weigh less than 10 lbs.
3. *Durability* – all parts are wear-resistant and the UHMW-PE parts have high impact strength, minimizing damage to the device if dropped.

4. *Accuracy* – the load is directly measurable at high accuracy and precision by either a strain gauge-based device or a simple scale.
5. *Simple mechanics* – it has no complex parts and should be relatively easy to manufacture and clean.
6. *Cost* – the total estimated manufacturing cost of this design is less than \$100.

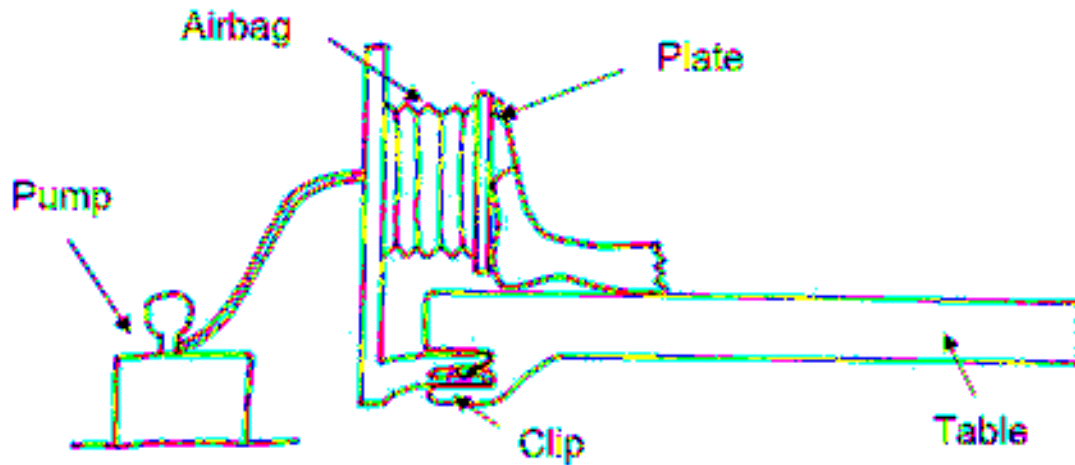
### **Disadvantages**

1. *Ease of use* –
  - a. The handle is manually operated and may require excessive force to use. Quantification of the operating force requires testing.
  - b. The amount of rotation necessary to apply a 50 lb. load on the feet is unknown but likely small. If the rotation is very small, such as 45 degrees or less, gearing may be required to allow for finer adjustment.
  - c. Space is also a concern, as the handle may not be easy to reach due to the proximity of the CT scanner.

### **Pneumatic Design**

This design consists of the same framework as the screw design, but uses an inflatable air bag and a pump, either manual or electric, to produce the force on the plate and feet, shown in Figure 5. The air bag will be attached between frame and the movable plate, with a tube running from the air bag, through the frame, and connecting to the pump. To make use of this design, the patient will lie on the table with his or her feet strapped against the plate, and the technician will use the pump to inflate the air bag, which will then push the plate against the feet, thereby applying a force to the feet.

Manual air pumps cost approximately eight dollars. One such pump, the Small Bellows Foot Pump, model 204IB, is 1.5 lbs, 3 liters, 9.25 in x 6.5 in, and 5.5 psi.



**Figure 5**

Side view drawing of the pneumatic design. The load is applied via an airbag in-between the two plates. The force is to be measured in relation to the amount of pressure in the airbag or by a scale or load cell based mechanism.

**Advantages:**

- metal free
- minimal strength required to operate design
- lightweight
- relatively easy to adjust force
- accurate force measurement
- manual pump – relatively cost effective
- electric pump – easy to inflate air bag

**Disadvantages:**

- air bag may be slow to deflate
- manual pump – takes a while to inflate air bag
- electric pump – less cost effective, consumes electrical power

## Preliminary Design Evaluations

The three preliminary designs were compared early on in the project based on several weighted criteria. The criteria were discussed, defined, and weighted by the team before creating the matrix and are described in Figure 6.

Criteria	Weight	Definition
Patient Safety	20	Patient safety was weighted the highest without question. A safe device would allow the load to be adjusted or removed quickly if the patient experiences pain.
Portability	20	Our client stressed that it was very important that the device be easily movable by one technician. It should be lightweight and easy to carry to another CT table.
Ease of use	15	The device must be easy to operate by one technician. It should not require excessive force or much effort to timely reach the desired load.
Accuracy	15	The load must be able to be accurately measured to within $\pm 1$ lbs. (arbitrary goal)
Durability	10	The device must be wear and impact resistant in order to have 10+ year shelf life.
Comfort	10	The device should not be imposing (e.g., claustrophobic or frightening in appearance) to the impatient or create any additional discomfort.
Cost	5	Cost of all components should be minimized. Less than \$300 is required.
Complexity	5	A less complex design is one with fewer parts and is estimated to be easier to manufacture.

**Figure 6**

This figure describes the criteria from which the comparison matrix was constructed.

Each team member individually generated a comparison matrix using the established criteria and the averages were used to create the final matrix shown in Figure 7.

<b>Criteria</b>	<b>Weight</b>	<b>Screw</b>	<b>Pneumatic</b>	<b>Cable</b>
<b>Patient Safety</b>	20	19.25	17.75	15.5
<b>Portability</b>	20	19	14.5	11.75
<b>Ease of use</b>	15	12	12.25	9.5
<b>Accuracy</b>	15	14	14	14
<b>Durability</b>	10	9	9	8.25
<b>Comfort</b>	10	9	9	3.25
<b>Cost</b>	5	4.75	3.5	3.5
<b>Complexity</b>	5	4.75	3.25	2.75
<b>Total</b>	<b>100</b>	<b>91.75</b>	<b>83.25</b>	<b>68.5</b>

**Figure 7**

The comparison matrix. This was used to help select the final design using the criteria explained in Figure 6.

As seen in the matrix, the screw design scored highest and was selected as the final design. With its simple manual control, patient safety was rated the highest. It was also estimated to weigh less than 10 lbs., so should be easy to carry from table to table. It scored high in all categories, with the only concern being ease of use. The pneumatic design scored high as well and was continually developed as a backup to the screw design. The cable design had several significant disadvantages that contributed to its low score and was no longer considered.

Both the screw and pneumatic designs were presented to our client shortly after the preliminary designs were evaluated. Our client liked the screw designed but was especially enthusiastic about the pneumatic design. He suggested that it would be easy to allow the patient to operate the pump and therefore allow them to increase the load until pain or discomfort was experienced. This was a significant advantage that had not been

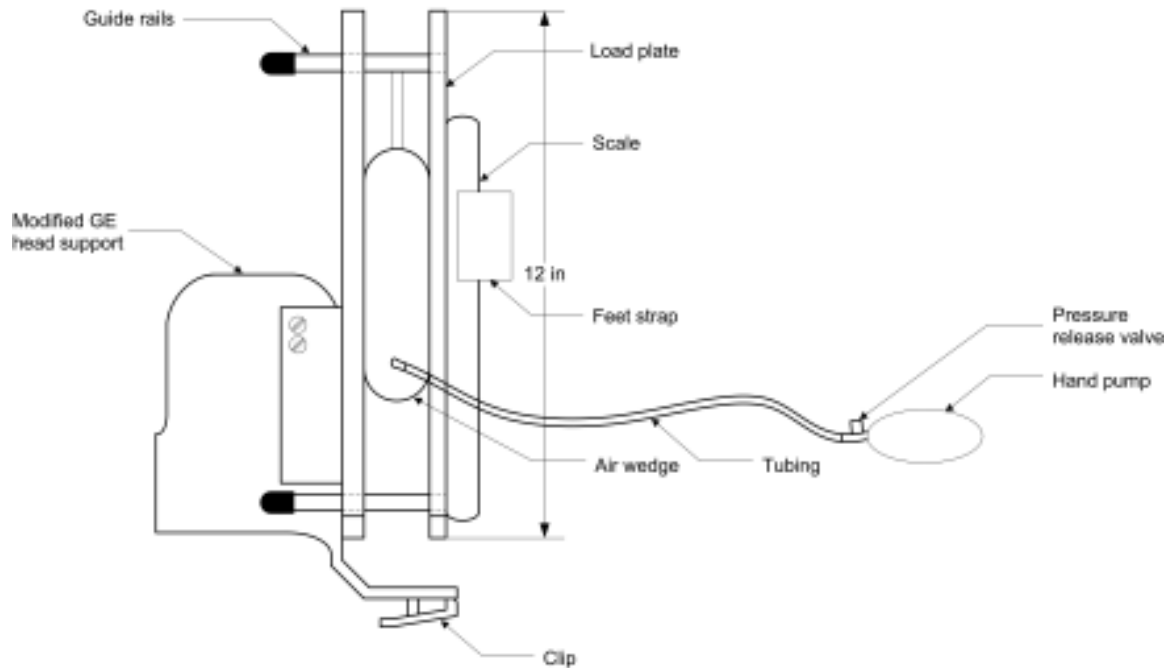
considered in the preliminary evaluation. It was found to be possible to allow the patient to operate the screw design as well but only if it were operated by a motor, which would add significant weight, cost, and complexity to the device. Thus the pneumatic design replaced the screw design for the final prototype.

## **Final Design**

### **Overview**

A side view drawing of the final design can be seen in Figure 8. Every GE Healthcare CT table is equipped with a standard connection port for table accessories and the final design made use of this. A GE Healthcare CT head holder was cut and used to connect the device to the table. The head holder was made out of a carbon fiber composite. Attached to the head holder is a 12"x12"x0.5" stationary plate made of UHMW polyethylene. Two blocks, each 4"x1.5"x1.5", made of the same polyethylene material were welded to the back of the stationary plate. Two 3/8" diameter holes were then drilled through each of the two blocks and through the head holder. Two 3/8" diameter rods were placed through the drilled holes on each side of the head holder, effectively fastening the stationary plate to the head holder. An inflatable air wedge was placed between the stationary plate and a free-sliding 12"x12"x3/8" plate—called the "load plate". The airbag is inflated via a manual hand pump and release valve. The pump would ideally be operated by the patient but could also be operated by the technician if the patient was incapable of doing it. There is a 6' long vinyl hose that connects the airbag to the hand pump. To ensure the load plate did not rotate, four 4" long x 3/8" diameter UHMW polyethylene guide rails were implemented. A mechanical scale was connected to the load plate via Velcro straps to measure the load. Also after

placing the device in the actual CT scanner some minor adjustments were needed. These include the length of the tube and more importantly since the GE table has a curved top, both the bottom of the stationary plate and the bottom of the load plate needed to be cut to the same curvature. The components of the final prototype are summarized in Figure 9. Pictures of the final prototype in the actual CT scanner can be viewed in Figure 10.



**Figure 8**

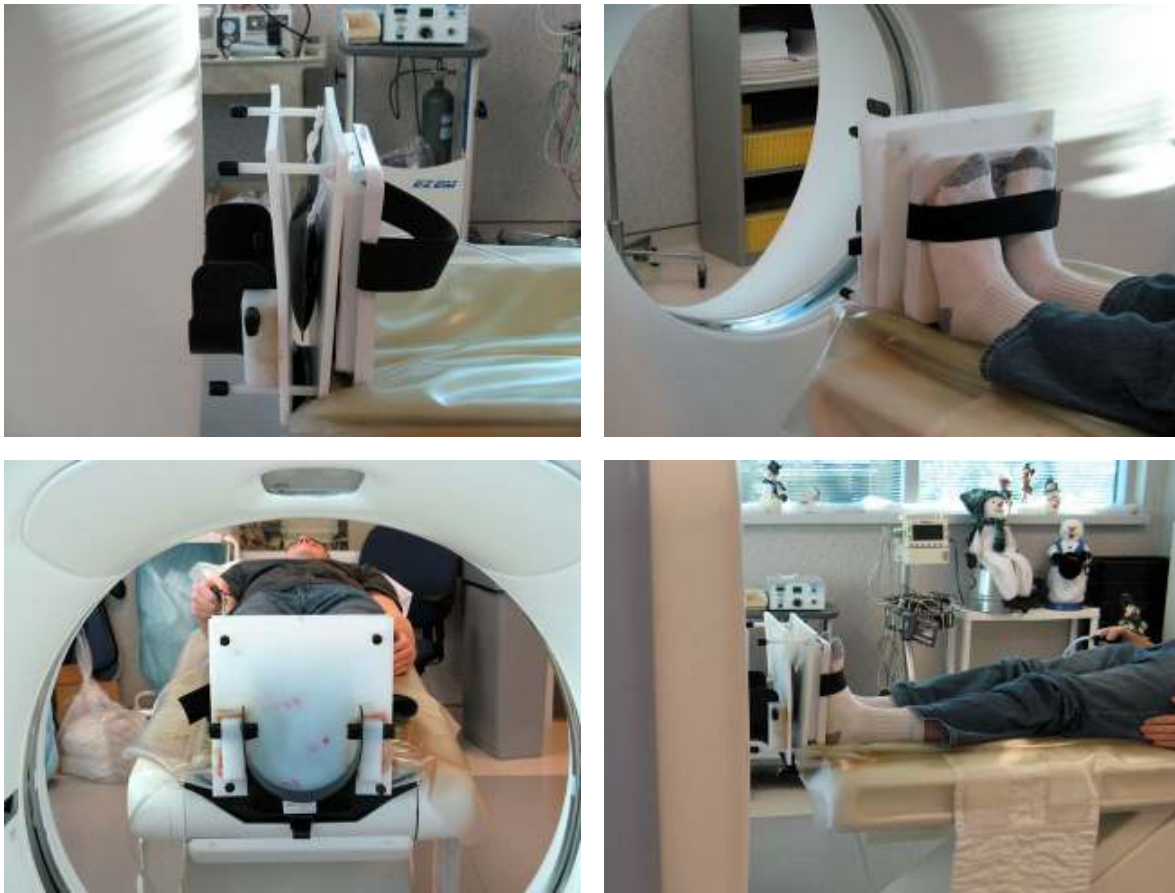
Side view computer aided drawing of the final prototype. The force is generated by an inflatable air-wedge located in between the two plates. The air-wedge is inflated via a hand pump operated by the patient. The load is temporarily measured by a scale underneath the patient's feet. The head holder is used to have the correct connection between the device and the standard GE table.



<b>Component</b>	<b>Description</b>	<b>Price</b>
Inflatable vinyl air wedge	Generates the load on feet; includes pump and valve	\$34.22
12x12x1/2" UHMW sheet	Rear plate, mounted to head support	\$10.94
12x12x3/8" UHMW sheet	Load plate	\$8.48
1'x1.5"x1.5" UHMW bar	Connects rear plate to head support	\$8.15
Strap	Secures feet in upright position	\$6.99
Velcro	Fastens the strap	\$5.99
Mechanical scale	Temporary force measurement mechanism	\$5.97
10 ft long vinyl tubing	Allows patient to operate pump	\$3.99
5'x3/8" diameter UHMW rod	Guide rails to prevent load plate torsion	\$3.80
Shoe lace	Used to hang air wedge from top guide rails	\$1.99
Electrical tape	Temporary nuts on guide rails	\$1.99
GE carbon fiber head support*	Fits CT table with proprietary clip mechanism	\$0.00
<b>Total cost:</b>		<b>\$92.51</b>

**Figure 9**

A summary table of the final prototype components with description of function and cost.



**Figure 10**

Pictures of the device in the CT scanner. The picture in the top left is a side view of the device. The picture in the bottom left is a picture of the bottom of the prototype through the gantry. The picture in the top right is an angled view from the patient's perspective. The bottom right picture shows a wider view from the side.

## **Conclusion**

### **Future Work**

The device has been successfully connected to a CT table but has not yet been tested under load while connected to the table. The next step would be to run the device through an active CT scan with a phantom—an object that mimics the X-ray attenuation properties of a patient. This would determine whether or not the materials interfere with

CT imaging. There is more work to be done to improve the load measurement accuracy, stability, and portability of the final design, as listed below:

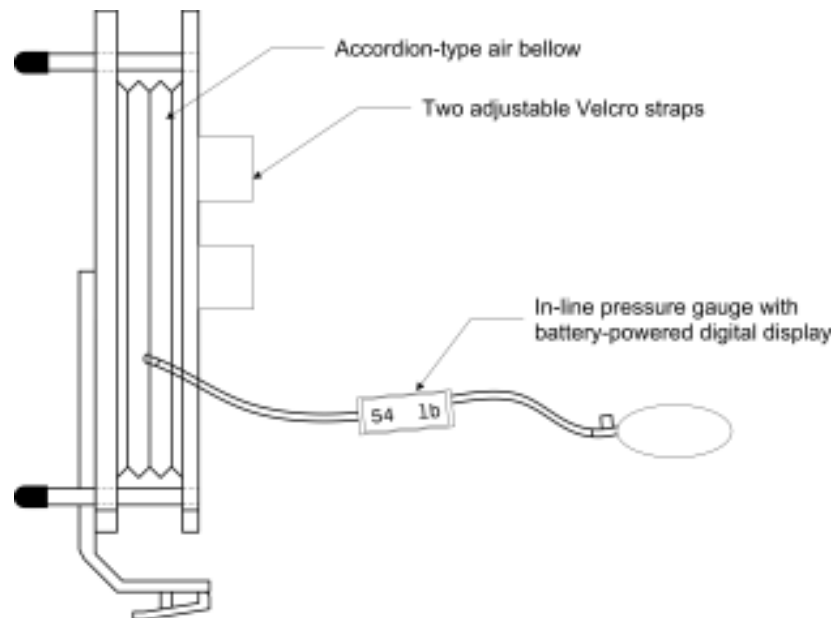
- **Load generation:** replace air wedge with larger accordion-type air bellow for uniform pressure distribution and increased stability. The air wedge expands by bulging out at the center while an accordion-type bellow would expand in more uniform linear motion.
- **Load measurement:** implement an in-line electronic pressure gauge connected to a battery-powered LCD display for more accurate load measurement. The accordion-style air bellow would provide us with a known surface area. A simple electronic circuit could be implemented to compute the force using the following equation:

$$\text{Force} = \text{Pressure} * \text{Area}$$

The circuitry would output the force data to an LCD display. The CT technician would then be able to record the load from the LCD and somehow associate that value with the image data for the scan. This would presumably be significantly more accurate for measuring the load than the mechanical bathroom scale and would also mean that there would be no radiopaque materials near the feat, removing any obvious possibility of the device interfering with the scan. Testing would be required to determine how the load varies with time for the duration of the scan. It is hypothesized that it will be fairly constant.

- Table connection:** replace modified head support with an assembly that takes up less space yet maintains clip mechanism for easy attachment and alignment to the table. The current head support and rear plate could be replaced by two pieces (or possibly one) made out of the phenolic-paper resin material (NP843) that we received from Norplex-Micarta. This material is empirically much stronger and has a higher rigidity than the UHMW polyethylene currently in use. The clip mechanism could be cut from the head support and fastened to the phenolic-paper plates. Testing is required to determine if the clip mechanism can withstand the normal loads subjected to the feet (plus a safety factor). It is hypothesized that the clip mechanism will need to be reinforced, possibly with a clamping mechanism.

These improvements are depicted in Figure 11.



**Figure 11**

Side view computer aided drawing of the future prototype. The force is generated by an accordion-type air bellow located in between the two plates. The air bellow is inflated via a hand pump operated by the patient. The load is measured indirectly by an inline pressure gauge.

To improve stability further, the cylindrical guide rails could be replaced with a different geometry that prevents the load plate from rotating about the y-axis (relative to the normal X-Y coordinate system depicted in Figure 11). The guide rails should also be constructed of a more rigid material than UHMW polyethylene, as they currently bend with relatively little effort.

The current straps are fairly crude and not adjustable enough for a wide variety of feet sizes. Two straps (or a single, thicker strap) would provide a more secure hold, which is beneficial since any movement of the feet during the scan could cause motion artifacts in the image. The straps would need to be connected to the load plate in a way that allows them to be slid up or down to accommodate a wide variety of feet sizes. They should use Velcro fasteners for ease-of-use purposes.

Our client would like to conduct a human-subject research study to test the hypothesis that imaging under a load is more beneficial than unloaded. This would require Institutional Review Board (IRB) approval. Our project advisor would also like us to adapt the device for magnetic resonance imaging (MRI) tables, where it could be used to indirectly load the knee. This would require a modified table connection mechanism to accommodate MRI tables and the removal of all metallic materials.

## **Ethical Considerations**

When designing the feet loader, we considered the autonomy and safety of both the patient and the technician. The final design allows the patient to have autonomy and a safe environment. The air wedge itself provides safety in two different aspects. First, the patient pumps air into the air wedge and therefore controls the amount of pressure applied to the feet. This avoids a situation in which the technician pumps excessive

amounts of air and causes pain or injury. Second, the air bag deflates quickly, so if the patient feels excessive pressure, he or she can release air in a timely manner to avoid injury. In the case that the patient cannot generate air pressure because of impairment, he or she should find a means to communicate the optimal amount of force to be applied to the feet. Also, the entire feet loader is made of non-toxic materials.

By using the feet loader, the patient may receive a better diagnosis for his or her ailment and can receive the proper treatment. There is a possibility that scanning the feet without loading them may lead to misdiagnosis, which could cause the patient to incur further injury. This device has the potential to keep the patient safe as well as improve his or her physical condition.

In addition, the feet loader is designed to ensure the technician's safety and ease of use. It is lightweight and compact, so the technician can easily carry the loader. If the technician drops the feet loader, he or she should not sustain permanent injury. However, the safety of the technician will improve if the design is developed further as stated in the future work. As the feet loader becomes lighter and more streamlined, it will become safer for the technician to use.

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# Appendix

## Product Design Specifications

December 13, 2006

**Team Members:** Ben Schoepke, Arin Ellingson, Anika Lohrentz, Alice Tang.

### **Problem Statement:**

While nearly all feet radiographs are shot with the patient bearing weight, computed tomography (CT) scans of the feet and ankles are done in non-weight bearing conditions. A device is needed that applies a load to the feet during a CT scan, thus better simulating the anatomic alignment of the bones and tissues under physiologic loading. The device must also secure the feet upright and together in order to establish a standard position for CT imaging of the feet and ankles.

### **Client Requirements:**

- Hold feet securely in a standardized position: upright and together.
- 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, adjustable load 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. It should not lengthen the time of radiation exposure.

*c. Accuracy and Reliability-* Results must be reproducible. The device must be accurate to within  $\pm 1$  lbs.

*d. Shelf Life-* As long as the device is properly stored, at room temperature in a mildly humid environment, there should be no concerns for shelf life.

*e. Operating Environment-* Must not be corroded by the disinfecting chemicals that are applied after every use. The device must be able to withstand X-ray bombardment.

*d. Ergonomics-* Must be able to comfortably hold human feet. Device should be easy to operate and should not interfere with CT protocols. The pump should be easy to use and its operation easy to understand.



*e. Size and Shape-* Must fit within a GE Lightspeed CT scanner, which has a gantry diameter of 70 cm. It should be sufficiently small for improved portability and storage. It should be able to securely hold a wide range of feet sizes.

*f. Weight-* Should be easily movable by one technician. A total weight of less than 20 lbs. should be sufficient.

*g. Materials-* All materials within the scanning field must be radiolucent (low X-ray attenuation). The load plate material should be sufficiently rigid and strong to prevent flexion and failure.

*f. Aesthetics-* It should look elegant and non-imposing to the patient.

## **2. Product Characteristics:**

*a. Quantity-* One device is required.

*b. Target Product Cost-* The budget for the prototype is \$300.

## **3. Miscellaneous:**

*a. Standards and Specifications-* The device should comply with the guidelines setup 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 for its classification.

*b. Customer-* The customer will primarily use the device in GE Lightspeed CT scanners.

*c. Patient-related concerns-* The device will have to be disinfected with common cleaning chemicals between uses.

*d. Competition-* Devices exist for holding the feet. However, none are capable of providing a measurable load on the feet.

# NP843 material data sheet



## NP843

### TECHNICAL DATA BULLETIN

GRADE: NP843      RESIN GRADE: ---      U. L. LISTED: M

DESCRIPTION: Paper reinforced phenolic grade with controlled conductivity. NP843 has mechanical strength similar to NP811. It has conductive surfaces only.

THICKNESS TESTED: 0.062", 0.125", and 0.500"

#### TYPICAL PROPERTIES

GENERAL PHYSICAL PROPERTIES	UNITS	VALUE
Specific Gravity	-	1.40
Rockwell Hardness (.062")	IR Scale	100
Moisture Absorption (.062", .125", .500")	%	2.3, 1.4, .4
Flexural Strength (.062" LW)	psi	25,000
CW		21,600
Flexural Modulus (.062" LW)	ksi	2,140
CW		1,400
Tensile Strength (.125" LW)	psi	22,000
CW		15,000
Izod Impact Strength E-49/50 (.500") LW	ft-lb/in	.70
CW		.50
Compressive Strength (isovisa (.500"))	psi	44,000
Bond Strength (.500")	lb	1,000
Shear Strength (perpendicular) (.062")	psi	11,500