BME 301 (Biomedical Engineering Design) Spring 2009

Project #37: Heated Diagnostic Radiology Exam Table

FINAL REPORT

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Abstract

Clinical X-ray examinations sometimes require patients to remain still for over an hour. A common patient complaint is that X-ray examination tables are uncomfortable; specifically they are too hard and too cold. Patient discomfort is undesirable because an uncomfortable patient is more prone to moving during a long procedure. The objective of the client and our team is to create a device that can provide patient comfort while at the same time preserving patient safety and radiolucency. The focus of our work is to create a device to modify the current hard laminate surface of the X-ray table through the addition of a pad and heat. Our team designed and constructed an X-ray table heating pad composed of polyethylene padding, a particle board and polyethylene tubing conduit, and a heating element in series with a pump. Despite modeling the expected radiolucency, testing showed that our prototype did not adequately meet the radiolucency design criteria for a commercially viable product Therefore, future work entails researching alternatives to the polyethylene and particle board tubing conduit.

Problem Motivation

A common patient complaint is that X-ray examination tables are uncomfortable, i.e. they are too cold and hard. Patient discomfort is a problem because during long procedures a patient may be more prone to move if uncomfortable. Patient movement during imaging does not allow proper image acquisition, as movement will distort the image, making it difficult for effective and accurate diagnosis.

Background

Diagnostic Use of X-rays

X-rays are short wavelength electromagnetic waves produced when fast-moving electrons collide with substances in their path. X-rays are similar to visible light rays except that they have 1/10,000 the wavelength

(Tsai, 2004). The short wavelength of X-rays allows them to penetrate very dense substances to produce images, or conversely shadows, that can be recorded on photographic film (Tsai, 2004) or digitally. X-ray imaging is useful diagnostically because density differences between various body structures produce images of varying intensity, light and dark, on the X-ray film (Tsai, 2004). Dense structures appear white, and air-filled or low density areas of the body appear darker or black.

A simplified diagram of an X-ray system is shown below (Figure 1). Grids reject unwanted rays while phosphor screens emit many light photons for each X-ray photon, thus assisting in the contrast of the image and the darkening of the photographic film, respectively (Tsai, 2004). The X-rays are scattered in all directions from the source but, in order to prevent harm to the patient and technicians as well as increase resolution, they are directed by a collimator. The collimator directs the emission so that only the X-rays used to make the image are passed. Harmful low energy X-rays that are not capable of passing through a patient's body are stopped by an aluminum filter. Electrons are accelerated at +100 kV from the heated filament to the tungsten anode, consequently emitting X-rays (Tsai, 2004).



In medicine, X-rays have primarily been used to image the anatomy of the body. One of the most common uses of X-ray imaging is in the diagnosis of skeletal pathologies. According to our client, Lanee Maclean,

the duration of a procedure can last from mere minutes to more than an hour. To preserve the integrity of the image it is necessary for the patient to remain still during image acquisition.

Current X-ray Examination Table

The examination table we are working with is shown below in Figure 2.



The exam table is a generic, widely available model that is commonly used by many X-ray facilities. The table has a hard laminate surface where the patient lies during a procedure. Along the edges of the hard laminate surface are metal guide rails available for the attachment of medical instrumentation.

The top of the table is 2.2 m long and .8 m inches wide. The table top is capable of moving 1.14 m vertically and 0.25 m transversely. The height of the table top is adjustable from 0.55 m at its lowest to 0.84 m at its highest. The maximum patient weight as specified by the manufacturer is 158 kg. The standby heat load of the table is 844 kilojoules per hour.

X-ray Attenuation

Sources of X-ray attenuation are an important consideration in the design and construction of a heated radiological examination table because the attenuation of the materials within the path of the X-rays may affect the contrast of an X-ray image. However, for all practical purposes, the fluid flow and temperature will have little to no effect on X-ray attenuation and can therefore be ignored (Vetter, J. Personal interview. 3/2/09). This leaves the tubing, padding, and backboard as the only components of the design where the attenuation must be evaluated.

X-ray attenuation is characterized by the linear attenuation coefficient (μ) and relates to the radiolucency or radiopaqueness of a material. The linear attenuation coefficient is a property of the material. Generally, materials composed of atoms with high atomic numbers will attenuate more than materials composed of atoms with low atomic numbers. A material that attenuates less will produce an artifact of smaller magnitude in the resulting Xray image.

The attenuation of a material is more often characterized as the mass attenuation coefficient (μ/ϱ), which is simply the linear attenuation coefficient (μ) divided by the density of the material (ϱ). An important aspect when examining the mass attenuation coefficient is noting that it is dependent on photon energy (Figure 3.). Also, a typical photon energy range for diagnostic X-ray imaging is between 12.4 and 124 keV (Links, 2005) which is indicated in Figure 3.



Upon examination of the mass attenuation vs. photon energy graphs in Figure 3, it becomes apparent that cortical bone has a discontinuity in its curve around 10^{-2} MeV. This discontinuity is often called the K-edge or absorption edge. The K-edge represents the photoelectric absorption of photons by the lead atom. This

phenomenon is essentially the photoelectric effect and explains why lead is used to block X-rays whereas X-rays readily pass through a medium such as air. In other words, the K-edge is responsible for the radiopaqueness of a material. Therefore, using materials that lack a K-edge is essential for the success of a heated radiologic examination table.

The materials being used for the heated radiologic examination table must not only lack a K-edge to prevent radiopaqueness, but also attenuate in such a way that produces a uniform loss in intensity of the incident X-ray beam across the entire image (Vetter, J. Personal interview. 3/2/09). A uniform loss in intensity prevents any of the materials used from appearing in the X-ray image due to differences in contrast.

The percent loss of intensity of the incident X-ray beam can be calculated using Equation 1. What is important to note from this equation is that the percent loss of intensity of the incident X-ray beam is dependent on three different factors; the mass attenuation coefficient, the thickness, and density of the material. Therefore, assuming different materials will be present within the imaging area of an X-ray, the densities and thicknesses of the various materials can be adjusted such that the percent loss of intensity of the incident X-ray beam is nearly uniform across the imaging area. This adjustment will thus eliminate any of the materials from appearing in the X-ray image due to differences in contrast.

$$\left[1 - \left(\frac{I}{I_o}\right)\right] \cdot 100 = e^{\left(-\left(\frac{\mu}{\rho}\right) * \Delta x \cdot \rho\right)}$$
Equation 1
(Links, 2005)

Where:

 $\begin{bmatrix} 1 - \left(\frac{I}{I_o}\right) \end{bmatrix} \cdot 100 = \text{Percent loss of intensity of the incident X-ray beam}$ $(\mu/\rho) = \text{Mass attenuation coefficient}$ $\Delta x = \text{Thickness of the material}$ $\rho = \text{Density of the material}$

Client's Requirements & Design Constraints

The application of our device for use in X-ray or radiology procedures creates several limitations on our design. Several requirements and design constraints have been developed by our client, in addition our team has developed several of its own, and these are listed below.

Radiolucency: The most important constraint on our design is radiolucency. Our device must be uniformly radiolucent. Contrast introduced into an image could render it useless in the diagnosis of certain pathologies, or possibly lead to the improper diagnosis of a certain disease state. When considering our design we must consider how specific materials, X-ray energies, and configurations will affect the image. The design and development of the device will largely depend on the radiolucency of materials available.

Patient Safety: Patient safety is very important. We must identify and eliminate the potential for patient burns or fluid leaks. We must make sure the surface that the patient will come into contact with is non-toxic and easily sanitized. Furthermore, this foam must not absorb any fluids with which it comes into contact. Ideally the padding used would be FDA approved for clinical use and sterilization.

Heated Examination Surface: Our device must provide a controllable, comfortable amount of heat to the patient. Ideally, the amount of heat transferred to the patient would vary between low, medium and high levels. The heat applied should not exceed a physiologically safe value and should not be capable of burning the patient under any circumstances. The technician should have control of the temperature through a variable temperature selector and a thermostat should be installed as a safety measure if time and resources allow.

Cushioned Examination Surface: The device must have lower rigidity than the current hard laminate surface. Specifically, it must deform at least 25 percent of its thickness when a stress between 68 and 103 kPa is applied. This value is consistent with specifications provided by manufacturers for firm to medium foams.

Anatomical Distortion: It is important that our device does not alter the normal anatomical orientation of the patient. X-rays are commonly used in imaging body anatomy, and as such altering the spatial orientation

could render the X-ray procedure useless for its intended purpose. Our design team must consider the anatomy of all patients that may possibly use the device and ensure that the rigidity (or lack thereof) of the padding does not change the patient alignment to a point where the X-ray is unusable for diagnostic purposes.

Obstruction of Technician's Workspace: The size of the device must be limited, in that it must not obstruct with the workspace of the X-ray technician.

Cost: The cost of the final design should be under \$200. Our client has a rather tight budget, and furthermore, this device is not necessary to X-ray imaging so high costs may deter clinics from purchasing it.

Proposed Design Schematic

Initial brainstorming developed several options. These options included heating the exam table through an exothermic chemical reaction, an amorphous sac of heated fluid, and a tubing conduit. After further consideration of cost, ease of manufacture, and availability of materials the tubing conduit design was chosen. To predict the radiolucency of the design, a MatLab program was created (Figures 4 & 5). The MatLab simulations showed that the thickness of the various materials used in the tubing conduit design could be adjusted such X-ray absorption across the surface of the tubing conduit design is relatively consistent.

Using the simulation, a schematic of the major components required for creating a heated radiologic









examination table attachment was developed (Figure 6.). It was determined that the exam table attachment

should include four major components: a cushioned pad, an electric heater, a pump, and tubing.



Figure 6: Proposed Design Schematic

The cushioned pad is placed on top of the examination table and will provide the needed comfort to the patient. Embedded within the cushioned pad will be a network of tubing that will carry a fluid across the length of the table (Figure 7.). The network of tubing converges into one tube at the ends of the table. Connected in series to the tubing is an electric pump and heater. The electric heater provides a comfortable temperature to the patient and the electric pump circulates the fluid through the system.

Padding

To address the patient complaint regarding the hard surface of the exam table, we will incorporate a foam pad into our design. In order to decide which material was most suitable, a design matrix was constructed (Table 1). This pad must meet several criteria.



First, it must be radiolucent. Since the X-ray quality cannot be sacrificed, the material itself must have a low coefficient of attenuation. Usually this can be achieved by choosing thin, low density materials like polymer-based foams. As such, we focused our search on these types of materials.

Second, the pad cannot be too soft so as to cause a change in normal bone and organ alignment within the patient, yet also it must be comfortable enough to address the patients' concerns regarding table hardness. A target firmness of was selected. This parameter was based on the desire to have a normal, 35 kg, child sink no more than 1 mm into the pad when lying flat on his or her back. Since the pad we used was 1.5 mm thick – due to heat transfer considerations – a deformation of 1 mm was deemed to be a sufficient amount of compliance.

Third, the pad must be sanitary since it is to be used in a clinical setting. This includes a smooth nonabsorptive coating to resist any bodily fluids that may come into contact with the pad. This pad coating must not degrade in the presence of a sterilizing spray containing bleach.

Finally, cost will have to be taken into consideration since we only have a budget of about \$200. Since we cannot fabricate the pad ourselves we must take care to find a supplier that can provide us the material we select at the cheapest price possible. From initial research, we anticipate the cost of the pad to run as high as 60 - a full 30 percent of our budget.

PETa

The first material we examined was fine-cell polyethylene (PET) foam. Our calculations indicate that that this material will only deform about 0.3 cm under the weight of a standard child. Also, through testing we have shown that this material is very radiolucent, making it an ideal candidate for this design. Furthermore, there is a coating on both sides of the materials that is liquid resistant, providing an ideal surface for sterilization. Lastly, it is FDA approved, making it convenient if our client decides to seek approval for clinical testing.

PETb

A second material investigated was coarse-cell polyethylene foam. Our calculations indicate that that this material will only deform 0.2 cm under the weight of a standard child. Also, through testing we showed that this material is even more radiolucent than the fine-cell PET foam. However, the surface of the materials is very porous and as such not conducive to sterilization or resistant to any liquids or bodily fluids that it may come into contact with.

In order to use this device in our design we would have to use some kind of coating to seal the surface and make it suitable for sterilization. Introducing another component to the mat design would bring about many new complications, such as how coating would react with the foam, whether or not it would be radiolucent enough, and whether or not it would be able to tolerate the frequent heating/cooling cycles and repeated flexing of the mat.

Despite the radiolucency and firmness of this foam ranking better than the fine-cell PET and the polyvinyl rubber materials (PVR), the difficulties presented by sterilizing the material render it impractical for use in our design.

PVR

The third material we explored was PVR foam. Like the fine-cell PET, this material was coated on both sides with a smooth, liquid-resistant surface that would have made sterilization quite simple.

Unfortunately, this material had several drawbacks. The foam firmness was similar to that of a memory foam mattress and raised concerns about whether such a surface would alter the alignment of the patient's body during imaging. Such distortion would be unacceptable and the material was deemed too soft since it deformed 0.5 cm under the weight of a standard child – more than twice the deformation of the fine-cell PET. Testing revealed that this was the least radiolucent of the three materials tested, confirming our decision to exclude this material from consideration.

Category	Weight	РЕТа	PETb	PVR
Radiolucency	50	47	40	34
Cost	20	10	14	10
Firmness	20	14	16	10
Sterilization	10	9	4	7
Total	100	80	74	61

Design Matrix for Padding

Table 1: Design Matrix for Padding

Tubing

Flow through a tube can be described by the Hagen-Pisoulle equation (Equation 2). By setting the inner diameter of the tubing at 0.3175 cm, we can calculate the pressure necessary to push the fluid through the system. We neglected the corners in our preliminary analysis, but will remodel the system using more advanced techniques before we begin construction on our prototype. Using these assumptions and taking the viscosity of water at 60 °C to be $u = 0.467 \text{ mN} \cdot \text{s} / \text{m}^2$ we calculated that the pump must supply a pressure of about 16.1 psi. Similarly, the tubing must be able to withstand fluid being pumped through at that pressure as well.



Equation 2: Hagen-Pisoulle equation for flow in a tube. This is an approximation of our system and a more rigorous analysis must be conducted before we purchase our pump

In addition to being strong enough to withstand a pressure of 16.1 psi and elevated temperature, the tubing must be radiolucent. Thought it does not need to be completely transparent, its coefficient of attenuation must closely match that of the padding so there is minimal contrast between the two materials in the X-ray image.

Though our budget is of utmost importance throughout the design of our prototype, it is of little consequence when selecting our tubing. First, plastic polymer tubing is a cheap and accessible component of our design. Since no special requirements are placed upon it, stock PET, Vinyl, Nylon or PVC will do well. Second, through the family of a team member, we will be able to procure our tubing materials at the manufacturers cost, rather than buying them through at third party retailer such as McMaster-Carr.

Finally, since heat must be conducted through the tubing to the patient padding interface, it is desirable that the materials selected for the tubing be poor insulators. Unfortunately, all plastic materials are fairly good thermal insulators, but the walls will be thin enough, and the tubing close enough to the patient that this will not present any serious complications. Nevertheless, it is still desirable that heat be able to move as freely as possible into and out of the tubing.

We were able to test our tubing options Mar. 4, but the results were inconclusive. After consulting with Dr. John Vetter of the Medical Physics department, we determined that it was necessary to use a phantom (a device which mimics tissue of the human body) during imaging.

PET

We anticipate this material to the most radiolucent of the tubing based on the testing results of the PET padding. It is rated at up to 150 psi and will thus be able to withstand the considerably lower pressures we will be applying. Finally, it has the highest thermal conductivity of any of the materials being considered (between 0.42 and 0.51). Our second round of testing confirmed that we will be using this tubing in our final design.

Vinyl

Based on earlier testing, we anticipate the vinyl tubing to be more radiopaque than the other samples, and therefore do not anticipate using this material in our design, especially considering its low thermal conductivity (0.25).

Nylon

Initially we considered the use of nylon tubing; however, the availability of nylon tubing of dimensions and quantities for our purposes is low. We have consequently decided not use this tubing material.

PVC

This material was the strongest rated tubing, able to withstand up to 250 psi. Unfortunately, that also made it the least practical. The large outer diameter would make construction of the tubing matrix to be inlaid into the padding difficult and could even necessitate a thicker pad, which would adversely affect the firmness and radiolucency of our design. Also, the thermal conductivity coefficient of 0.19 was low even for a plastic. For these reasons, PVC tubing is impractical for our prototype.

Category	Weight	PET	Vinyl	Nylon	<u>PVC</u>
Radiolucency	50	25	20	20	18
Thermal Conductivity	30	24	12	12	9
Cost	10	9	9	9	9
<u>Strength</u>	10	10	10	10	10
Total	100	68	51	51	46

Design Matrix for Tubing

 Table 2: Design Matrix for Tubing

Heating

The patient will be heated by thermal energy conducted from hot water passing through the inlaid tubing system. There are two heat transfer interfaces, the first being from the heater to the carrier fluid and the second being from the carrier fluid to the patient. The water flowing through the inlaid tubing system heats the tube surface using convective thermal transfer. This is accomplished through the current formed by the fluid flowing through the tube. The patient, as well as the pad, is heated by conductive thermal transfer. This is simply the transfer of energy from molecule to molecule, starting at the tube outer surface and ending with the patient's skin. The heat that the patient feels is governed by a form of Newtons Law of Cooling (Equation 3)

		Equation 3:
O k	$t \rightarrow \wedge \cdot T$	Q = heat flow across tube wall
± tuba	tuba	T = Temperature (Kelvin)
$\underline{uve} \equiv $	iuoe	A = Cross-sectional area of tube
Δ	$2 \cdot \mathbf{R}$	K = Thermal conductivity of tube
<u>л</u>	ΔM	material
tube	tube	R = Radius of tube

This equation relates the change in temperature to the heat flow per unit area. The desired temperature outside the tube is 40° C, or roughly the temperature of a standard hot tub. Using commonly accepted values for the thermal conductivity and heat flow per unit area of polyethylene, the necessary water temperature was calculated

to be approximately 46.1° C. At steady state the heat transferred radially from the tubing conduit will be negligible compared to the total heat contained within the system, minimizing any potential gradient.

Coiled Wire

One solution for water heating is to use coiled wires wrapped around a metal tube. The coiled wires, after being subjected to an electric current, will generate heat, which will be transferred to the metal tube. The water, while en-route to the tubing inlaid in the pad, will pass through the metal tube and become hotter. The thermal energy of the water will then be radiated away as the water passes through the tubing inlaid in the particle board. The amount of current being supplied to the coiled wires will be regulated with a potentiometer, and the entire system would be enclosed and located on the ground next to the diagnostic table.

Heating Element

Another method of heating the water would be to build a scaled down version of tank water-heater, and use a standard heating element to heat the water. This method would allow a large volume of water to be heated to a high temperature, and stored for future use. Within the tank, the water could only be heated to one temperature, corresponding to the injected voltage. However, outside the tank the water could be cooled while traveling through the tubing using alternate means. The tank would sit on the floor, connected on one side to the water pump, and on the other side to a conduit leading to the tubing inlaid in the pad.

Commercial Heater

A commercially available water heater could be used to heat the water to the desired temperature. Specifically, a tankless water heater would be used. A tankless water heater heats water as it passes by a heating element, and thus does not require a storage tank to hold water. This method of heating the water would allow for a very accurate means of controlling water temperature, as nearly all commercially available water heater come equipped with a thermostat. The heater would also sit on the floor, and be connected in series to the pump and tubing conduits.

Design Matrix for Heating

The three heating components were analyzed using two distinct categories, cost and control (Table 3). Cost, weighted at 70%, represents the total cost of buying, installing, and using the specified component. Control, weighted at 30%, represents the degree of control that the element provides over the water temperature. The commercial water heater, being equipped with a thermostat, was ranked highest in the control category, but lowest in the cost category. The standard water tank heater element, while extremely cost effective, causes the temperature of the water to be high. The coiled wire method, consisting of a wire heated by a flowing current, was determined to be the best design.

Category	Weight	Coiled wire	Heater element	Commercial heater
Cost	70	56	56	14
Control	30	18	12	30
TOTAL	100	74	68	44

 Table 3: Design Matrix for Heating

Proposed Solution

After completing the component matrices, polyethylene (PET) padding and tubing, as well as a coiled wire element for heating, were determined to be the best solutions. The PET pad and tubing show little attenuation compared, to the human body, under diagnostic X-ray imaging. This makes them ideal components for the final design. Lastly, the coiled wire heating element, being cost effective and easy to control, will be used to heat the

water. After compiling all this information, the final schematic for the design was created (Figure 8).



Figure 8: Final Proposed Design Schematic Polyethylene will be used for the pad and tubing material. A coiled wire heating system and pump will heat and move the water, respectively.

Final Design

Our final design consists of 3 components: a mat, a heating element and pump, and a tubing conduit.

Padding

A polyethylene mat is located on top of the particle board. This mat, which is of uniform thickness, provides enough cushioning for patient comfort, without causing anatomical distortion from too much bending. This mat is also FDA approved, resists chemical degradation, and is easily sterilized.

Heating Element and Pump

To heat the patient, a 300 watt heating coil was wrapped around a copper tube (Figure 9). As the water flows through the copper tube, heat is transferred to it from the coil. The power supplied to the heating element is controlled by an AC dimmer switch. After the



water flows out of the copper tube, it flows through the tubing conduit. Heat is then transferred radially from the tubes through the mat, to the patient. This relationship is modeled by Newton's Law of Cooling (Equation 3). A pump is placed in series with the heating element and tubing conduit to act as the driving force of fluid flow.

Tubing Conduit



In order to heat the patient, heated water was passed through a tubing conduit underneath the mat. The tubing conduit consists of ten polyethylene tubes inlaid in particle board (Figure 10). The tubes are connected to the particle board through the use of the adhesive Liquid Nails. The combination of tubing and particle board creates a

uniform radiolucent surface, and the adhesive minimizes the effect of sharp edges on the image.

Testing

Heating

To test the heating capabilities of our prototype the temperatures of the water within the tubing conduit were measured using a digital thermostat. Also, the temperature of the surface of the tubing conduit was recorded. When the heating element was at maximum power, the two temperatures were 49°C and 38°C

respectively. Therefore, the heating element proved to be capable of providing an adequate amount of heat to the patient.

Radiolucency

Before building our prototype, we tested our simulated designs and found some problems. Vertical faces caused artifacts not accounted for in the MatLab program. To compensate for this, we came up with a wide variety of different designs and constructed sever small arrays to test them. Square cut channels were originally tested, and back-cuts of varying depth were added to further compensate for the radio opacity of the tubing. These back-cuts, however, introduced further artifacts into the image and were discarded from consideration as a result.

Next, rounded and square-cut channels were tested. The rounded channels fit the tubing well, but testing revealed a less than ideal board-interface image. The square-cut channels were tested with water-based wood glue and the results were promising.

However, water based glue contracts upon drying and form air bubbles. These air bubbles introduce further artifacts into the image, and though the image at the wood-tissue is improved, the air bubbles make such a filler impractical. To correct this problem, a wide variety of non water-based adhesives (including Si and acrylic caulks,



plastic wood, epoxy and liquid nails, among others) were tested (Figure 11). The results were analyzed by our client (an X-ray technician) as well as Dr. Wally Peppler of the UW Department of Medical Physics and liquid nails was deemed to be most effective material for muting the difference in X-ray attenuation at the wood-tubing interface. The resulting image is much improved, especially under a tissue-equivalent phantom (Figure 12). However, even though the image is acceptable for diagnostic purposes, it is not desirable, and it is highly unlikely that our product would be commercially viable.

Though the MatLab simulation showed the back cut design (Figure 5) produces a lower difference in beam intensity loss, testing showed the vertical faces produced artifacts and thus the original design shown in Figure 4 was chosen.

Ergonomic Considerations

Human ergonomics is an important consideration when designing a heated radiologic exam table. A heated radiologic exam table should be constructed in a way such that any individual should be capable of understanding how it should be used. This requires the instructions to consist of figures and illustrations explaining the controls rather then the use of text. Also, not only should the design accommodate for individual differences in the users ability to understand how the design should be used, it should also accommodate for differences in the users physical ability. Any knobs or controls on the device should be large enough so that any user, regardless of physical ability, can navigate the controls.

Future Work

The current design satisfies all criteria though not to a degree that would make it a commercially viable product. In addition, our design will attenuate differently at different energy levels due to the potpourri of materials used in fabricating the prototype. Therefore, future work will focus on creating a more radiolucent prototype. This work entails researching alternatives to the polyethylene and particle board tubing conduit. Water equivalent materials, like *Solid Water*[®] and *Plastic Water*[®], would be ideal. However, these materials are expensive, limited in size, and would require complex machining. As a result, acrylic or non-expanded polystyrene may be the most appropriate choice. Both materials are excellent water equivalents for diagnostic X-ray energies, relatively cheap compared to *Solid Water*[®] and *Plastic Water*[®], and come in the appropriate size. Unfortunately, creating the channels and threads into the material would still require complex machining. Also, the described materials would exceed our current budget. These issues would need to be addressed for a fully functional prototype to be constructed.

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Appendix: Product Design Specifications

PROJECT TITLE:

Heated Diagnostic Radiology Exam Table (Project Number: 37 / Project Code: exam_table)

FUNCTION:

Our team will develop a device to facilitate in X-ray imaging. A frequent patient complaint is that current X-ray tables are hard and cold. The device we create will supplement existing tables by increasing comfort through cushioning and heating. Any material or design used in the construction of our prototype must not interfere will the quality of images obtained when using the device.

CLIENT REQUIREMENTS

Heated examination surface Softer/cushioned examination surface Must incorporate patient control All materials must be radiolucent No anatomical distortion No obstruction of technician workspace Cost less than \$200

DESIGN REQUIREMENTS:

1. PHYSICAL AND OPERATIONAL CHARACTERISTICS

Performance requirements: The device must be able to withstand continued use for up to ten hours at a time. The device must heat table surface to within +/- 5 C of 37 C. The device must be found comfortable by patients. The device must not interfere with X-ray imaging.

Safety: Care will have to be taken to make sure the patient is not at risk for burns, the table temperature may not exceed 50 C (skin burns at \sim 54 C). FDA certification may be required. We may have to submit a Section 2 - 510(k) Summary and Certification.

Accuracy and Reliability: Device must maintain a constant temperature whenever turned on, as well as remain permanently radiolucent.

Life in Service: The device must have a life-span of several years.

Shelf Life. The device must have a shelf life of several years.

Operating Environment: The device must operate at a temp of 22°C and standard pressure. *Ergonomics*: The device fit on the top of a standard X-ray table, and should not have any rough edges.

Size: The device should fit within the table top dimensions of 87" X 31-3/4" (2.2 m X 8.8 m). Additionally, the device should be capable of allowing 45" (1.14 m) of longitudinal and 10" (.25 m) of transverse table movement. The device should work properly at a vertical position of 22" (.55 m) to 33" (.84 m). The size of the section of the device not on the exam table is not limited but should be minimized keep from obstructing the technicians work environment.

Weight: As stated in the user's manual, the maximum patient weight safely supported by the examination table is 350 lbs (158 kg). The device and the patient combined should not weigh more than this amount.

Materials: It is important that the materials used be radiolucent or transparent to X-ray. Inconsistency in the layout or depth of material may create unwanted attenuation/contrast to the X-ray. The surface of the device should be easily disinfected with mild bleach or ethanol solution to allow for many uses. Soft or awkward materials that may obscure or disorientate the body part being imaged are not acceptable.

Aesthetics, Appearance, and Finish: The goal of the product is to increase patient comfort; therefore, the appearance of the product should not be intimidating or provoke any fear or nervousness in the patient.

2. PRODUCTION CHARACTERISTICS

Quantity: Eventually, large scale production of the product may be needed to provide for hospitals.

Target Product Cost: The cost of the prototype must not exceed 200 USD. The cost of the final manufactured heated examination pad would ideally not be more than 100 USD.

3. MISCELLANEOUS

Standards and Specifications: The design and construction of the device must comply with the standards set by the client including the use of radiolucent materials.

Customers: Primarily the client, but can be potentially extended to any radiologist that looks to improve patient comfort during X-ray exams.

Patient-Related *Concerns*: The device must be sterilized before use with a different patient. It should not pose any burn related risks to the patients.

Competition: Current products do exist that increase patient comfort during medical exams but are limited by their price and functionality. Relatively inexpensive examination table pads exist but lack the potential to control the pad's temperature. On the other hand, multiple companies produce heated examination tables. However, these products are largely limited by their high price and X-ray compatibility.