

# Product Design Specification for BME 402, Group 38: Heated Diagnostic Radiology Exam Table

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## 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 with 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 contrast can be introduced
- No anatomical distortion
- No obstruction of technician workspace
- Uniform heating
- No introduction of artifacts

## 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. The device will not be mechanical but of solid state design.
- 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 ~54 C). The device will be well insulated to prevent electrical shock. Voltage and currents will be kept at a safe level to avoid patient harm in the event of insulation failure. There must not be a magnetic field created by the device that could interfere with surrounding equipment or patient implants i.e. pacemakers/defibrillators. Regulations and guidelines for high voltage will be taken into high consideration. FDA certification may be required. We may have to submit a Section 2 - 510(k) Summary and Certification.

- c. *Accuracy and Reliability:* Device must maintain a constant temperature whenever turned on (+/- 3 degrees farhenheit) , as well as remain permanently radiolucent. The device will heat uniformly. The temperature of the device will be under patient control.
- d. *Life in Service:* The device must have a life span of greater than 10 years. The need to replace the heating element or matting is acceptable assuming the cost of doing so is reasonable relative to the time needed between replacements (i.e. ~50\$ per year in service).
- e. *Shelf Life:* The device must have a shelf life of greater than 20 years.
- f. *Operating Environment:* The device must operate at a temp of 22°C and standard pressure. The device must not degrade in the presence of x ray radiation.
- g. *Ergonomics:* The device fit on the top of a standard x-ray table, and should not have any rough edges.
- h. *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.
- i. *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.
- j. *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. Testing has shown that tubing is not an acceptable material to use, the level of contrast introduced is too high. A uniform material is necessary with uniform heating capabilities. 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.
- k. *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**

- a. *Quantity:* Eventually, large scale production of the product may be needed to provide for hospitals.
- b. *Target Product Cost:* The cost of the prototype must not exceed 1000 USD. The cost of the final manufactured heated examination pad would ideally not be more than 800 USD.

## **3. Miscellaneous**

- a. *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.
- b. *Customers:* Primarily the client, but can be potentially extended to any radiologist that looks to improve patient comfort during x-ray exams. Pediatric radiologists are prospective users of this device.
- c. *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. Electrical safety will be taken into high concern.
- d. *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.