Summary
This application note describes the method of measuring the radiopacity of materials using ASTM F640.

Background
For positioning and tracking of permanent and temporary medical devices such as hip and knee replacements, catheters, stents, dental components, and screws, X-ray and fluoroscopy is commonly used to visualize the device. To visualize the component, the electron density of the component has to be greater than the surround tissue, be it soft tissue (skin, muscle, organs), or hard tissue (bone).

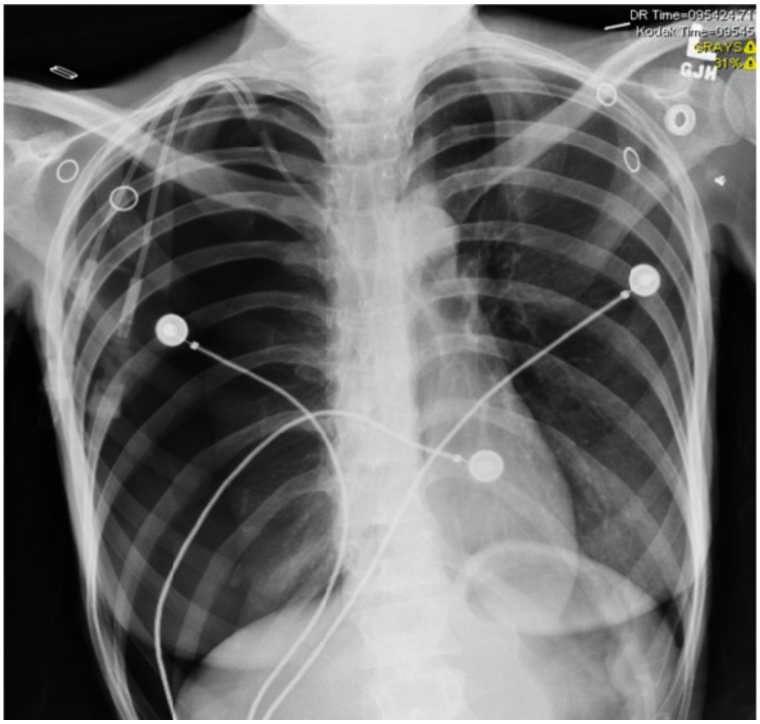

Figure 1: X-ray image of external electrodes on patient.

Medical devices often incorporate a material or construct that will partially or totally block the transmission of electromagnetic radiation in the form of X-rays through the device. These materials are often terms *radiopacifiers*, or are radiopaque, as opposed to radiolucent materials that freely allow the passage of X-rays. On an analog X-ray film, a radiopaque material will appear white, while on a digital X-ray, it will appear dark gray or black, as the two styles of X-ray are usually inverted in terms of black and white.

Most metals show high electron density, and therefore are naturally radiopaque. Often, strands or beads made out of tantalum are incorporated into devices to permit the radiologist, surgeon, or X-ray technician to visualize the position of the device, as well as tracking its movement. Minerals such as barium sulfate, zirconium oxide, and bisthmuth are often incorporated into medical devices as well, such as plastics and cements.

When designing new devices, quantitative measurements of the radiopacity of the material can aid in design characteristics and regulatory approval, as well as product differentiation. ASTM F640 "Standard Test Methods for Determining Radiopacity for Medical Use" is a commonly used technique for quantifying the radiopacity of medical devices, as well as non-medical devices.

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Procedure
In ASTM F640, a device is placed in the viewing window of an X-ray system. Included in the viewing window is an aluminum step wedge of known, precisely machined thickness from a particular alloy, as it is known that different alloys have differing radiopacities.[1] The X-ray image is collected at clinically relevant doses. A layer of material can be laid over the samples to simulate the tissue layer that would be over the device when in use, such as vascularly, skin, and muscle tissue for a catheter used in the arm or leg, or bone tissue for devices used in the chest or pelvis. This layer is called a 'body mimic', and can either be a material designed to have a similar radiopacity to the tissue in question, could be cadaveric or animal tissue, or, another simulant. Often, researchers will just use 5 or 10 mm aluminum plate as a body mimic.

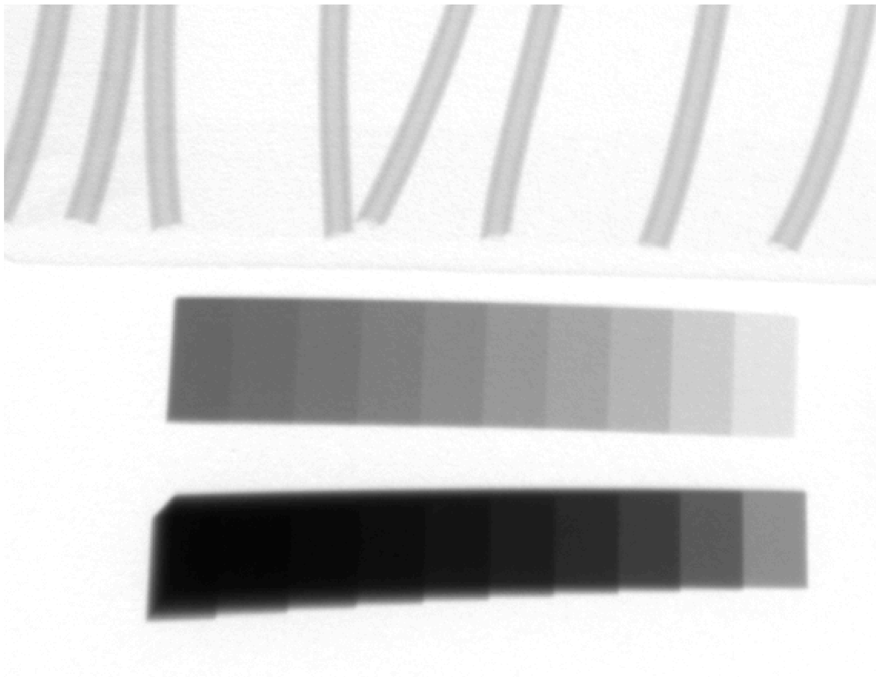

Figure 2: X-ray image shown two step wedges (bottom) of different thickness ranges, and tubing samples for analysis (top).

After the X-ray is obtained, the image is run through an analysis program that computes the pixel intensity of the step wedge as a function of wedge thickness, as shown in Figure 3. The thickness the step wedge, the darker the image, and the greater the pixel intensity. The results in Figure 3 show the calibration curve for images collected with and without a body mimic, and show the attenuating effects of the body mimic.

The sample is then analyzed, measuring the pixel intensity with the same program, and converting this intensity into an equivalent aluminum thickness. In the tubing samples in Figure 2, the equivalent aluminum thickness was 0.95 mm. With this approach, different X-ray systems will produce comparable radiopacity measurements.

[1] Watts, D.C., McCabe, J.F., Aluminum radiopacity standards for dentistry: an international survey, J. Dent., vol 27(1), 73-78 (1999).

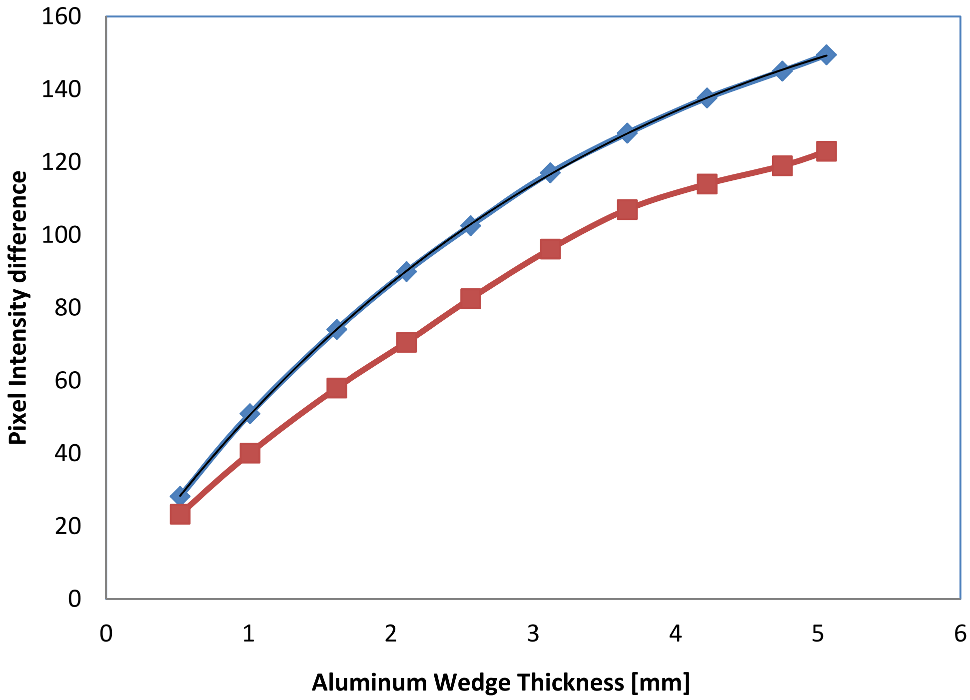

Figure 3: Pixel intensity calculation for aluminum wedge calibration. The blue diamonds are obtained without a body mimic. The red squares incorporate a body mimic.