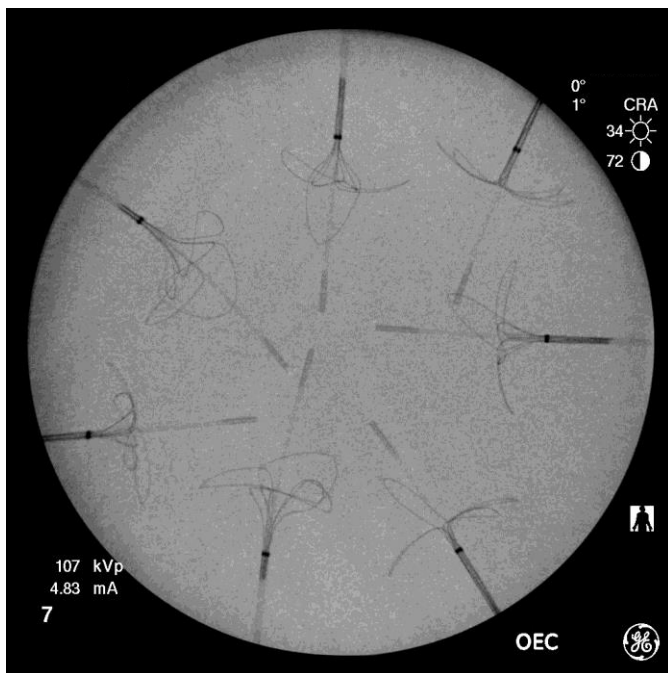


# Radiopacity

## Introduction

Radiopacity refers to the relative inability of electromagnetic radiation, specifically x-rays, to pass through a particular material. In more practical terms, it describes how visible a medical device will be during a procedure where x-rays are used. **Figure 1** shows devices arranged on a body mimic, or phantom, used to provide clinically relevant x-ray attenuation. Radiopacity is a critical parameter when the tracking, placement, or retrieval of the device can have significant effects on patient outcomes. The importance of radiopacity is most obvious when using fluoroscopy. Fluoroscopy is used for procedures in which it is necessary to see a device in motion within the body. It is commonly used in fields such as gastroenterology, cardiology, and orthopedic surgery, among many others [1].



**Figure 1.** Sample of image used in radiopacity evaluation.

## Qualitative vs. Quantitative

According to the current industry standards, there are generally two acceptable ways to measure and report the radiopacity of a medical device: qualitatively and quantitatively. ASTM F640-12

defines qualitative radiopacity testing as visually comparing radiographic images of a device to a user-defined standard [2]. One typically successful approach is to choose a standard that is already known to be radiopaque under clinical settings. While qualitatively comparing radiovisibility will still be subject to individual interpretation, having a well-understood reference provides a basis for justifications of radiovisibility with regulatory authorities. On the other hand, quantitative radiopacity testing calculates the difference in pixel intensity between the image of a device and the image of a user-defined standard, providing a more direct indication of radiovisibility. This method is recommended when comparing iterations in product design, or when comparing your device to a competitor's design (these could serve as the "user-defined standard"). Alternatively, some standards, such as ISO 5361 suggest the use of a 1x1x10 mm Al block as a reference standard [3]. In these cases, either qualitative or quantitative radiopacity can suffice depending on the standard and the purpose of the study. However, quantitative evaluation will always provide more definitive data. Ultimately, the recommended method will depend on the risk associated with the device or component being evaluated as well as the goal of the study.

## Product Development

Radiopacity evaluation can aid in understanding manufacturing process changes, comparing to benchmarks, and in many cases is an essential assessment of device safety and effectiveness. The location, size, shape, concentration, and other characteristics of the radiopaque features should be considered in the beginning stages of product development. An expensive animal study is a bad place to learn that your device isn't visible under fluoroscopy. For this reason, a benchtop evaluation of radiopacity using a clinically relevant body phantom can provide quick and easy verification that your device has adequate radiopacity. At MED

Institute, we can provide you with a realistic representation of your device's radiopacity to ensure it can be used safely to improve patient outcomes.

## Our Methods

Our lab is ISO/IEC 17025 accredited with respect to radiopacity testing. We offer both qualitative and quantitative testing in accordance with the ASTM standard, F640-12, and can accommodate other standards as needed for your device. Our lab also offers several clinically relevant body phantoms to produce images that best suit your needs and will provide you with a realistic portrayal of your device's visibility.

## Our Services

We have the tools and experience to help with your radiopacity evaluation needs. Contact us to work with you to make products and therapies that will improve patient outcomes.

If you have any questions or need any additional information, please contact:

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## References

[1] W.J. Davros, "Fluoroscopy: basic science, optimal use, and patient/operator protection.," *Techniques in Regional Anesthesia and Pain Management*, vol. 11, no. 2, pp. 44-54, 2007.

[2] ASTM F 640-12. Standard Test Method for Determining Radiopacity for Medical Use. 15 December 2012.

[3] ISO 5361. Anaesthetic and respiratory equipment – Tracheal tubes and connectors. 1 September 2016.