



Designation: F640 – 23

Standard Test Methods for Determining Radiopacity for Medical Use¹

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1. Scope*

1.1 These test methods cover the determination of the radiopacity of materials and products utilizing X-ray based techniques, including fluoroscopy, angiography, CT (computed tomography), and DEXA (dual energy X-ray absorptiometry), also known as DXA. The results of these measurements are an indication of the likelihood of locating the product within the human body.

1.2 Radiopacity is determined by (a) qualitatively comparing image(s) of a test specimen and a user-defined standard, with or without the use of a body mimic; or (b) quantitatively determining the specific difference in optical density or pixel intensity between the image of a test specimen and the image of a user-defined standard, with or without the use of a body mimic.

1.3 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.4 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.5 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 ASTM Standards:²

D209/B209M Specification for Aluminum and Aluminum-

Alloy Sheet and Plate

D3182 Practice for Rubber—Materials, Equipment, and Procedures for Mixing Standard Compounds and Preparing Standard Vulcanized Sheets

E94/E94M Guide for Radiographic Examination Using Industrial Radiographic Film

E1316 Terminology for Nondestructive Examinations

F647 Practice for Evaluating and Specifying Implantable Shunt Assemblies for Neurosurgical Application

3. Terminology

3.1 *Definitions*—For definitions of terms relating to X-ray procedures, refer to Terminology **E1316**.

3.2 Descriptions of Terms:

3.2.1 *body mimic, n*—a piece of material, a phantom, a cadaver, or an animal utilized to mimic the appropriate X-ray attenuation through a particular part of the human body.

3.2.2 *digital resolution, n*—the number of pixels per inch in a digital image.

3.2.2.1 *Discussion*—This may be different in the *x* and *y* directions.

3.2.3 *grayscale range, n*—the number of levels in pixel intensity resolved in the digital image.

3.2.3.1 *Discussion*—This range is normally 256 levels in an 8-bit grayscale image, but 16-bit grayscale images can also be used.

3.2.4 *pixel intensity, n*—the grayscale level of a pixel between 0 and 255, as determined by the digital analysis program.

3.2.5 *pixel intensity difference, n*—the difference in grayscale level between two regions or objects in an image, reported to within the significance capability of the digital analysis program.

3.2.6 *user-defined standard, n*—a comparison standard selected by the user. This standard could be a reference material or a predicate device.

3.2.6.1 *Discussion*—This standard may be an existing medical product or a material in a particular form, it may be a commercially available standard, or it may be one developed by the user.

¹ These test methods are under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and are the direct responsibility of Subcommittee F04.15 on Material Test Methods.

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² For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.