Designation: F640 – 20

Standard Test Methods for Determining Radiopacity for Medical Use[1]

This standard is issued under the fixed designation F640; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

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]

B209 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.

4. Summary of Test Methods

4.1 The test specimen is placed so it sits at or near the middle of the X-ray image area in the X-ray imaging system.

[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.

*A Summary of Changes section appears at the end of this standard

X-ray images are made at specified voltages, times, and currents that are typical of those used in the X-ray diagnosis of humans. Preferred settings are those appropriate for the product and for the particular area of body interest (for example, leg, heart, and so forth). The radiopacities of the test specimen and user-defined standard are evaluated in terms of the image background with or without the use of a body mimic. The radiopacity may be reported qualitatively or quantitatively.

5. Significance and Use

5.1 These methods are intended to determine whether a material, product, or part of a product has the degree of radiopacity desired for its application as a medical device in the human body. This method allows for comparison with or without the use of a body mimic. Comparisons without the use of a body mimic should be used with caution as the relative radiopacity can be affected when imaging through the human body.

5.2 These methods allow for both qualitative and quantitative evaluation in different comparative situations.

6. Apparatus

6.1 *X-Ray Imaging System.*

6.2 *X-Ray Film or Digital Image Acquisition System*—The film or digital imaging system shall be appropriate for the imaging conditions used. A grid may be used.

6.3 *Body Mimic (if used)*—See Appendix X2 for discussion of body mimics. (Note that this is not an all-inclusive list and other body mimics might be appropriate.)

6.3.1 *Animal*—An appropriate animal, or portion of appropriate animal, with which to perform the tests may be used.

6.3.2 *Cadaver*—A human body, or portion of human body, with which to perform the tests may be used.

6.3.3 *Metal, Plastic, or Composite*—A metal, plastic, or composite material of appropriate dimensions may be used. For example, a 5.0 mm, 10.0 mm, or 15.0 ± 0.15 mm thick aluminum sheet might be appropriate. The aluminum sheet shall be ≥99 % in purity, or type 1100 or purer, in accordance with Specification B209.

6.3.4 *Phantom*—An apparatus that mimics a portion of the body may be used; note that this apparatus may be as complex as a manufactured torso with appropriate densities representing all portions of the anatomy within the torso, or may be as simple as a defined thickness of water.

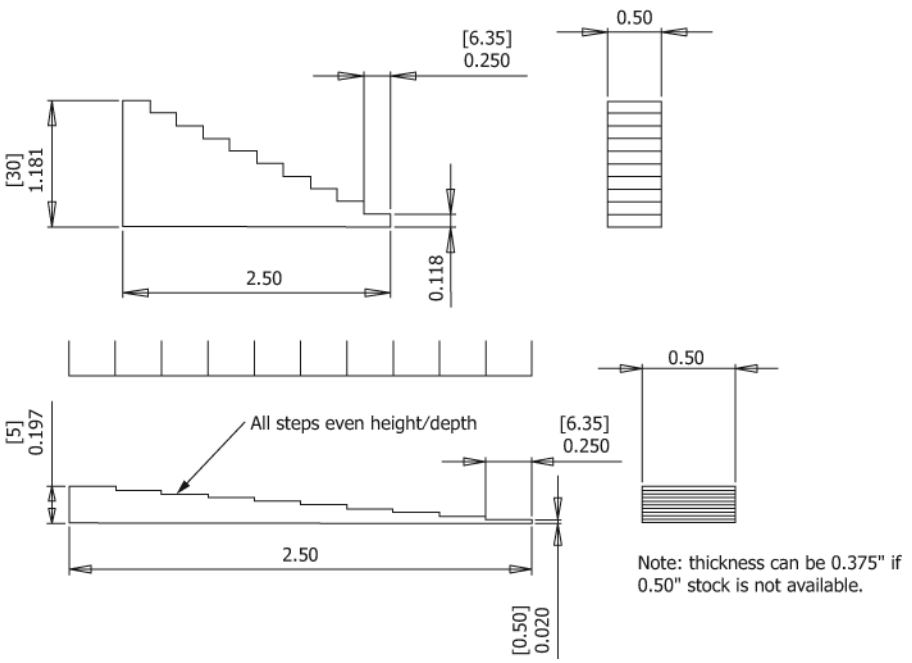
6.3.5 *Step Wedge*—A step wedge may be used as a user-defined standard, if it has the requisite thickness steps. 1100 aluminum shall be used to construct step wedges. Examples of step wedges are shown in Fig. 1. Users may use other step wedge dimensions as long as the step thickness is known.

6.4 *Rubber Blankets*—Blankets incorporating X-ray absorbers may be used to mask the image area not covered by the body mimic material (this prevents undercutting). Lead sheets may also be used for masking.

6.5 *Back-Scatter Protection,* as described in Guide E94/E94M, or as appropriate with the specific X-ray imaging system.

7. Test Specimens

7.1 *Material*—The material may be in any form. For comparing results between materials, best results will be obtained by utilizing the same form and dimensions for each material.



NOTE 1—The tolerance shall be ±0.005 in. Units are in inches [mm]. 1100 aluminum shall be used. Users may use other step wedge dimensions as long as the dimensions are known.

FIG. 1 Example Dimensions of Aluminum Step Wedges