Designation: F640 – 07

StandardTest 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.

This standard has been approved for use by agencies of the Department of Defense.

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, also known as DXA, (dual energy X-ray absorptiometry). The results of these measurements are an indication of the likelihood of locating the product within the human body.

1.2 *Types of Tests*—There are three methods of tests described, differing in the method of determining radiopacity.

1.2.1 *Method A*—Radiopacity is (*1*) qualitatively determined by viewing image(s) of a test sample and the image background, with or without the use of a body mimic, or (*2*) quantitatively determined as a specific difference in optical density or pixel intensity between the image of a test sample and the image background, with or without the use of a body mimic.

1.2.2 *Method B*—Radiopacity is determined by (*1*) qualitatively comparing image(s) of a test sample and a user-defined standard without the use of a body mimic, or (*2*) quantitatively determining the specific difference in optical density or pixel intensity between the image of a test sample and the image of a user-defined standard without the use of a body mimic.

1.2.3 *Method C*—Radiopacity is determined by (*1*) qualitatively comparing image(s) of a test sample and a user-defined standard with the use of body mimic or (*2*) quantitatively determining the specific difference in optical density or pixel intensity between the image of a test sample and the image of a user-defined standard with the use of a body mimic.

1.3 The values stated in SI units are to be regarded as the 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 and health practices and determine the applicability of regulatory limitations prior to use.*

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 Guide for Radiographic Examination

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 is normally 256 levels in an 8-bit grayscale image

3.2.4 *optical density, n*—the range of values of optical density as measured by a densitometer; in this test method the expected range is 0.50 to 1.50.

3.2.5 *optical density difference, n*—the difference in optical density units between two regions or objects in an image, reported to at least two digits to the right of the decimal point.

[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.

Current edition approved March 1, 2007. Published March 2007. Originally approved in 1979. Last previous edition approved in 2000 as F640 – 79 (2000). DOI: 10.1520/F0640-07.

[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**

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

3.2.7 *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.

3.2.8 *user-defined standard, n*—a comparison standard selected by the user.

3.2.8.1 *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 in the middle of the X-ray image area in the X-ray imaging system. 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 radiopacity of the test specimen is evaluated in terms of the criteria described for the test method selected.

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.

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 must be appropriate for the imaging conditions used. A grid may be used.

6.3 *Body Mimic for Methods A and C (not all-inclusive):*

6.3.1 *Aluminum Sheet*—A 10.0 ± 0.15-mm thick aluminum sheet may be used. If so specified in the standard for the medical device, a 15.0 ± 0.15-mm thick sheet may be used. The aluminum sheet shall be ≥99 % in purity, or type 1100 or purer, in accordance with Specification B209.

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

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

6.3.4 *Calibration Standard*—For digital analysis, a standard that creates a completely clear area and a completely opaque area in the image to allow setting of the full range of 256 grayscale levels.

6.3.5 *Metal, Plastic, or Composite*—A metal, plastic, or composite material of appropriate dimensions may be used.

6.3.6 *Phantom*—A device that mimics a portion of the body may be used; this device 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 tub of water.

6.3.7 *Step Wedge*—A step wedge may be used if it has the requisite thickness steps.

6.4 *Rubber Blankets*—Blankets incorporating X-ray absorbers may be used to mask areas outside that 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, or as appropriate with the specific X-ray imaging system.

6.6 *Densitometer*—The densitometer shall be capable of measuring the optical density over the range of 0.0 to 3.0 optical density units, minimum. It shall have a measuring accuracy of ±0.02 optical density units or better. The densitometer shall have been calibrated within six months previously by a method and calibration standard traceable to the National Institute of Standards and Technology. This is not required if digital analysis is used.

6.7 *Step Tablet,* [3] for calibrating densitometers. This is not required if digital analysis is used.

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.

7.2 *Product*—The product or specific part or section of the product may be utilized in any desired configuration.

NOTE 1—For plastics, a 2.0-mm thick sheet of material is often molded especially for testing. For example, see the description of sample in Practice D3182.

8. Imaging Conditions

8.1 The test shall be performed at appropriate conditions for the imaging system, the product or material, and the area of the body within which the product is intended for use.

8.2 Imaging conditions shall be described in the test report.

9. Procedure—Method A

9.1 *Test Specimen Placement*—Place the test specimen(s) in the middle of the X-ray imaging area. If a body mimic is used, place the test specimen(s) as appropriate in, on, or under the body mimic and ensure that the test specimen(s) are in the middle of the X-ray imaging area. If digital analysis will be used, place the calibration standard within the image so that it does not interfere with the desired imaging of the test specimen(s) and body mimic.

9.2 *X-Ray Exposure*—As necessary for the imaging system, the product or material, and the area of the body within which the product is intended for use.

9.2.1 If using film and a body mimic, the exposure shall be of such duration that an optical density of 0.8 to 1.2 is obtained for the background or through the body mimic, if one is used.

[3] SRM 1001 has been found suitable for this purpose. The sole source of supply of the apparatus known to the committee at this time is National Institute of Standards and Technology (NIST), 100 Bureau Dr., Stop 1070, Gaithersburg, MD 20899-1070, https://srmors.nist.gov. If you are aware of alternative suppliers, please provide this information to ASTM International Headquarters. Your comments will receive careful consideration at a meeting of the responsible technical committee,[1] which you may attend.