Designation: F640 – 12

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 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.

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 at or near the middle of the X-ray image area in the X-ray imaging system. X-ray images are made at specified voltages, times, and

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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**

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 and user-defined standard is 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):* (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 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 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.

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, or as appropriate with the specific X-ray imaging system.

6.6 *Densitometer (if used)*—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,* 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. For example, each X-ray image is made at a specified voltage, current, time contrast and brightness, 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).

8.2 Imaging conditions shall be described in the test report.

9. Procedure

9.1 *Test Specimen Placement*—Place the test specimen(s) and the user-defined standard at or near the middle of the X-ray imaging area. If a body mimic is used, place the test specimen(s) and the user-defined standard as appropriate in, on, or under the body mimic. As appropriate, the effect of the clinical X-ray table shall also be included with use of an appropriate material of thickness similar to that used clinically.

9.2 *X-Ray Exposure*—Complete X-ray exposure using conditions typical of those used in the X-ray diagnosis of humans, the product, and for the particular area of interest.

9.2.1 If using film, the exposure shall be of such duration that an optical density of 0.8 to 1.2 is obtained for the background.

9.3 *Film Development (If Used)*—Develop the X-ray film in accordance with the manufacturer's instructions. If a digital analysis method will be used, convert the developed film image(s) to digital format using an appropriate digital scanning or photographic method.

9.4 *Qualitative Analysis*—Visually compare the image(s) of the test specimen and the user-defined standard to the background on the film or in the digital image (whether original or converted from film).

9.5 *Quantitative Analysis:*

9.5.1 *Measurement of Optical Density (Film):*

9.5.1.1 *Background*—Measure the background (includes body mimic, if used) optical density with a densitometer to determine whether it is within the specified range of 0.8 to 1.2.

9.5.1.2 *Test Specimen Image*—Measure the optical density of the image of the test specimen and the user-defined standard with a densitometer.

9.5.1.3 *Optical Density Difference*—Subtract the optical density of the test specimen and the user-defined standard from the optical density of the background.

9.5.2 *Measurement of Pixel Density (Digital):*

9.5.2.1 *Background*—Measure the background pixel intensity.

9.5.2.2 *Test Specimen*—Measure the pixel intensity of the test specimen and user-defined standard. Pixel intensity may be measured at multiple points and averaged or used to determine radiopacity at different points in the test specimen.

9.5.2.3 *Pixel Intensity Difference*—Subtract the pixel intensity of the test specimen and the user-defined standard from the pixel intensity of the background.

10. Report

10.1 The report shall include the following:

10.1.1 All test equipment, including source type, filter type, detector type, machine geometry, machine type and model numbers, and film type and resolution (if film is used) or imaging system resolution (if digital analysis is used).

10.1.2 All test conditions, including the specific values of kVp and mA·s, the source-to-detector distance, the object-to-detector distance, and, if film is used, the focus-film distance and film exposure settings.

10.1.3 If applicable, specification requirements, as listed in the requirements of the standard specification for the medical device and the number and title of the medical device specification (for example, Practice F647).

10.1.4 Test specimen description, including the manufacturer's name; the type of device or part; the dimensions, including diameter, wall thickness, and so forth; and the specific material(s), including elements or chemical formula(e), and the type of radiopaque additive (if any) and how it occurs in the part, such as a uniform dispersion, line of specific cross section, and so forth.

10.1.5 Body mimic description, if used : (*1*) for a phantom, include the manufacturer's name and model number, and the type of device, for example, "torso" or "knee," if applicable. Also include a description of the materials and dimensions. (*2*) for a cadaver, include the location and dimensions; (*3*) for an animal, include the location and dimensions.

10.1.6 If used, the material and thickness representing the X-ray table.

10.1.7 User-defined standard description, including materials and dimensions.

10.1.8 If applicable, test specimen and user-defined standard placement in comparison to the body mimic (that is, on top of, within, underneath, near, and so forth).

10.1.9 Optical and X-ray image(s) of the test specimen(s).

10.1.10 Optical density or pixel intensity readings for all measurements as described in 9.5.

11. Precision and Bias

11.1 The precision and bias of these test methods have not yet been established.

11.2 It is intended to develop data for the overall method and the measurement of density from a round-robin test.

12. Keywords

12.1 implants; radiopacity; surgical applications; surgical devices; surgical implants; test methods; X-ray

APPENDIX

(Nonmandatory Information)

X1. RATIONALE

X1.1 *General*—The initial development of this standard was based on the need to determine the location in the body of plastic parts of small diameter. This led to a proposed requirement for an optical density contrast measured on the medical device. However, radiopacity is a property of many types of medical devices and its required numerical level is influenced by many variables, some of the principal being: type of material, size, thickness, and configuration; part of body or circulatory system; and X-ray energy applied during the procedure.

X1.2 *Specification Values*—This standard does not have any requirements for minimum levels of radiopacity, nor is there a preferred test method (of the three described). The standard specification for the medical devices may specify materials and values for some parameters of the test method, such as for the body mimic and the X-ray test voltage

X1.3 *Background Density*—It has been proposed that, for many applications, an optical density contrast of 0.10 is satisfactory. For larger pieces and thin sections of the human body, a contrast of 0.05 optical density units may be adequate.

SUMMARY OF CHANGES

Committee F04 has identified the location of selected changes to this standard since the last issue (F640 – 07) that may impact the use of this standard. (Approved Dec. 15, 2012.)

(1) Method A was removed and methods B and C were combined.
(2) The location of the test specimen in the X-ray image was modified to allow it to sit at or near the middle versus only the middle.
(3) The following was added to the procedure: As appropriate, the effect of the clinical X-ray table shall also be included with use of an appropriate material of thickness similar to that used clinically.
(4) The calibration standard for the digital analysis (standard that creates a clear and completely opaque areas) was removed.
(5) The step wedge was identified as a user-defined standard.
(6) The X-ray exposure procedure was clarified to indicate completion of X-ray exposure using conditions typical of those used in the X-ray diagnosis of humans, the product and for the particular area of interest.
(7) A requirement to report the material and thickness representing the X-ray table, when used, was added.