Designation: F3044 – 26

Standard Test Method for Evaluating the Potential for Galvanic Corrosion for Medical Implants[1]

This standard is issued under the fixed designation F3044; 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 This test method covers conducting galvanic corrosion tests to characterize the behavior of two dissimilar metals in electrical contact that are to be used in the human body as medical implants or as component parts to medical implants. Examples of the types of devices that might be assessed include overlapping stents of different alloys, stent and stent marker combinations, orthopedic plates and screws where one or more of the screws are of a different alloy than the rest of the device, and multi-part constructs where two or more alloys are used for the various component parts. Devices which are to be partially implanted but in long-term contact within the body (such as external fixation devices) may also be evaluated using this method.

1.2 This test method covers the selection of specimens, specimen preparation, test environment, method of exposure, and method for evaluating the results to characterize the behavior of galvanic couples in an electrolyte.

1.3 Devices and device components are intended to be tested in their finished condition, as would be implanted (that is, the metallurgical and surface condition of the sample should be in or as close as possible to the same condition as in the finished device).

1.4 This test method does not address other types of corrosion and degradation damage that may occur in a device such as fretting, crevices, or the effect of any galvanically induced potentials on stress corrosion and corrosion fatigue. Surface modifications, such as from scratches (possibly introduced during implantation) or effects of welding (during manufacture), are also not addressed. These mechanisms are outside of the scope of this test method.

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

1.6 **Warning—**Mercury has been designated by many regulatory agencies as a hazardous substance that can cause serious medical issues. Mercury, or its vapor, has been demonstrated to be hazardous to health and corrosive to materials. Use caution when handling mercury and mercury-containing products. See the applicable product Safety Data Sheet (SDS) for additional information. The potential exists that selling mercury or mercury-containing products, or both, is prohibited by local or national law. Users must determine legality of sales in their location.

1.7 *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.*

NOTE 1—Additional information on galvanic corrosion testing and examples of the conduct and evaluation of galvanic corrosion tests in electrolytes are given.[2]

1.8 *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:*[3]

D1193 Specification for Reagent Water

E177 Practice for Use of the Terms Precision and Bias in ASTM Test Methods

E691 Practice for Conducting an Interlaboratory Study to Determine the Precision of a Test Method

F2129 Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices

[1] This test method is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.15 on Material Test Methods.

Current edition approved Feb. 1, 2026. Published February 2026. Originally approved in 2014. Last previous edition approved in 2020 as F3044 – 20. DOI: 10.1520/F3044-26.

[2] Marek, M., "Corrosion Testing of Implantable Medical Devices," *Handbook of Materials for Medical Devices*, Vol 23, ASM International, 2012.

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

G1 Practice for Preparing, Cleaning, and Evaluating Corrosion Test Specimens
G3 Practice for Conventions Applicable to Electrochemical Measurements in Corrosion Testing
G5 Reference Test Method for Making Potentiodynamic Anodic Polarization Measurements
G15 Terminology Relating to Corrosion and Corrosion Testing (Withdrawn 2010)[4]
G16 Guide for Applying Statistics to Analysis of Corrosion Data
G31 Guide for Laboratory Immersion Corrosion Testing of Metals
G46 Guide for Examination and Evaluation of Pitting Corrosion
G59 Test Method for Conducting Potentiodynamic Polarization Resistance Measurements
G71 Guide for Conducting and Evaluating Galvanic Corrosion Tests in Electrolytes
G82 Guide for Development and Use of a Galvanic Series for Predicting Galvanic Corrosion Performance
G102 Practice for Calculation of Corrosion Rates and Related Information from Electrochemical Measurements
G215 Guide for Electrode Potential Measurement

3. Significance and Use

3.1 Implantable medical devices can be made of dissimilar metals or come into electrical contact with dissimilar metals leading to the potential for galvanic corrosion, which may result in the release of corrosion products with harmful biological consequences or a compromise of structural integrity of the device. Therefore, it is important to determine the susceptibility of these types of devices to galvanic corrosion.

3.2 Use of this test method is intended to provide information on the possible galvanic component of corrosion of two dissimilar metals in contact with one another. The dissimilar metals in contact may be on the same implantable medical device or as component parts of individual medical implant devices.

3.3 This test method has been designed to accommodate a wide variety of device shapes and sizes encountered by allowing the use of a variety of holding devices.

3.4 This standard is presented as a test method for conducting galvanic corrosion tests in a simulated physiological environment. Adherence to this test method should aid in avoiding some of the inherent difficulties in such testing. Other standards such as Guide G71 are general and, while they provide valuable background information, do not provide the necessary details or specificity for testing medical device implants.

4. Apparatus

4.1 *Potentiostat,* verified in accordance with Reference Test Method G5. Other means of verifying the accuracy and reliability of the potentiostat may be used, so long as this is adequately documented. For this test method, the potentiostat should be a high impedance instrument configured as a zero resistance ammeter (ZRA). Alternatively, a setup consisting of a dedicated ZRA, an electrometer, and a two-channel recorder for recording the galvanic current and galvanic potential with time can be used. The currents measured during the test are likely in the nA range (or lower). The instrument used should be capable of reliably measuring such currents.

4.2 *The Tested Samples,* prepared as individual electrodes of the galvanic couple. The configuration of each electrode and holder will depend on the type of specimen being tested, as described in 5.2. The sample holder can be of various configurations, provided it allows for good electrical connection to the sample, provides a method of electrical connection outside of the test cell, ensures that the sample sits fully below the liquid level line in the test cell, does not come into physical contact with any other element of the cell or apparatus, and allows for masking of the sample at the point of connection.

4.3 *Reference Electrode*—A standard reference electrode should be used in the test. Examples of standard electrodes are provided in Guide G215, along with a table showing conversions between electrodes. The reference electrode used in the test shall be identified along with the conversion used, if necessary. Individual electrochemical potentials such as E_b and E_r should be reported relative to the saturated calomel electrode (SCE). (For example, the saturated Ag/AgCl electrode is 45 mV electronegative to SCE. A reading of 0 mV versus Sat'd. Ag/AgCl would be equivalent to a reading of –45 mV versus SCE. Therefore, to convert potentials measured using a Sat'd. Ag/AgCl electrode to the SCE scale, 45 mV should be subtracted.) When plotting curves, potentials may be plotted using raw data, that is, to the scale of the reference electrode used during the test and this shall be clearly shown on the axis label (for example, "Potential versus SCE (mV)" or "Potential versus Sat'd. Ag/AgCl (mV)").

NOTE 2—Due to the presence of mercury in the saturated calomel electrode (SCE) and the increasing regulation around the use of equipment and materials that contain mercury, there may be decreased availability of SCE as a reference electrode. When choosing a reference electrode for testing, users of this standard should also take note of any regulations relevant to their region.

4.4 *Salt Bridge,* such as a Luggin probe, may be used between the working and reference electrode, such as the type shown in Reference Test Method G5.

4.5 *Suitable Polarization Cell,* with a volume of at least 500 cm^3, equivalent to or similar to that recommended in Reference Test Method G5. The volume of the cell may be greater than 500 cm^3 if needed to accommodate a larger sample.

4.6 *Water Bath,* or other heating appliance capable of maintaining the test solution temperature at 37 ± 1 °C. Note that use of a hot plate to heat and/or agitate the solution (for example, using a magnetic stir bar) can cause excessive noise and interfere with the electrochemical data.

4.7 *Gas Bubbler,* to provide aeration and agitation, capable of delivering aeration at a rate of 150 cm^3/min.

4.8 *Thermometer,* with an accuracy for measurement within ±1 °C.

[4] The last approved version of this historical standard is referenced on www.astm.org.