



Standard Test Method for Extracting Residue from Metallic Medical Components and Quantifying via Gravimetric Analysis¹

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1. Scope

1.1 This test method covers the quantitative assessment of the amount of residue obtained from metallic medical components when extracted with aqueous or organic solvents.

1.2 This test method does not advocate an acceptable level of cleanliness. It identifies one technique to quantify extractable residue on metallic medical components. In addition, it is recognized that this test method may not be the only method to determine and quantify extractables.

1.3 Although these methods may give the investigator a means to compare the relative levels of component cleanliness, it is recognized that some forms of component residue may not be accounted for by these methods.

1.4 The applicability of these general gravimetric methods have been demonstrated by many literature reports; however, the specific suitability for applications to all-metal medical components will be validated by an Interlaboratory Study (ILS) conducted according to Practice E691.

1.5 This test method is not intended to evaluate the residue level in medical components that have been cleaned for reuse. This test method is also not intended to extract residue for use in biocompatibility testing.

NOTE 1—For extraction of samples intended for the biological evaluation of devices or materials, refer to ISO 10993–12.

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

1.7 *This standard may involve hazardous or environmentally-restricted materials, operations, and equipment. 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

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

G121 Practice for Preparation of Contaminated Test Coupons for the Evaluation of Cleaning Agents

G131 Practice for Cleaning of Materials and Components by Ultrasonic Techniques

G136 Practice for Determination of Soluble Residual Contaminants in Materials by Ultrasonic Extraction

2.2 ISO Standard:³

ISO 10993–12 Biological Evaluation—Sample Preparation and Reference Materials

3. Terminology

3.1 Definitions:

3.1.1 *ionic compounds/water soluble residue*—residue that is soluble in water, including surfactants and salts.

3.1.2 *non-soluble debris*—residue including metals, organic solids, inorganic solids, and ceramics.

3.1.3 *non-water soluble residue*—residue soluble in solvents other than water. Inclusive in this are oils, greases, hydrocarbons, and low molecular weight polymers. Typical solvents used to dissolve these residues include chlorinated or fluorinated solvents, or low molecular weight hydrocarbons.

3.1.4 *reflux system*—an apparatus containing an extraction vessel and a solvent return system. It is designed to allow boiling of the solvent in the extraction vessel and to return any vaporized solvent to the extraction vessel.

3.1.5 *reuse*—the repeated or multiple use of any medical component (whether labeled SUD or reusable) with reprocessing (cleaning, disinfection, or sterilization, or combination thereof) between patient uses.

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.

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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.

³ Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, <http://www.ansi.org>.