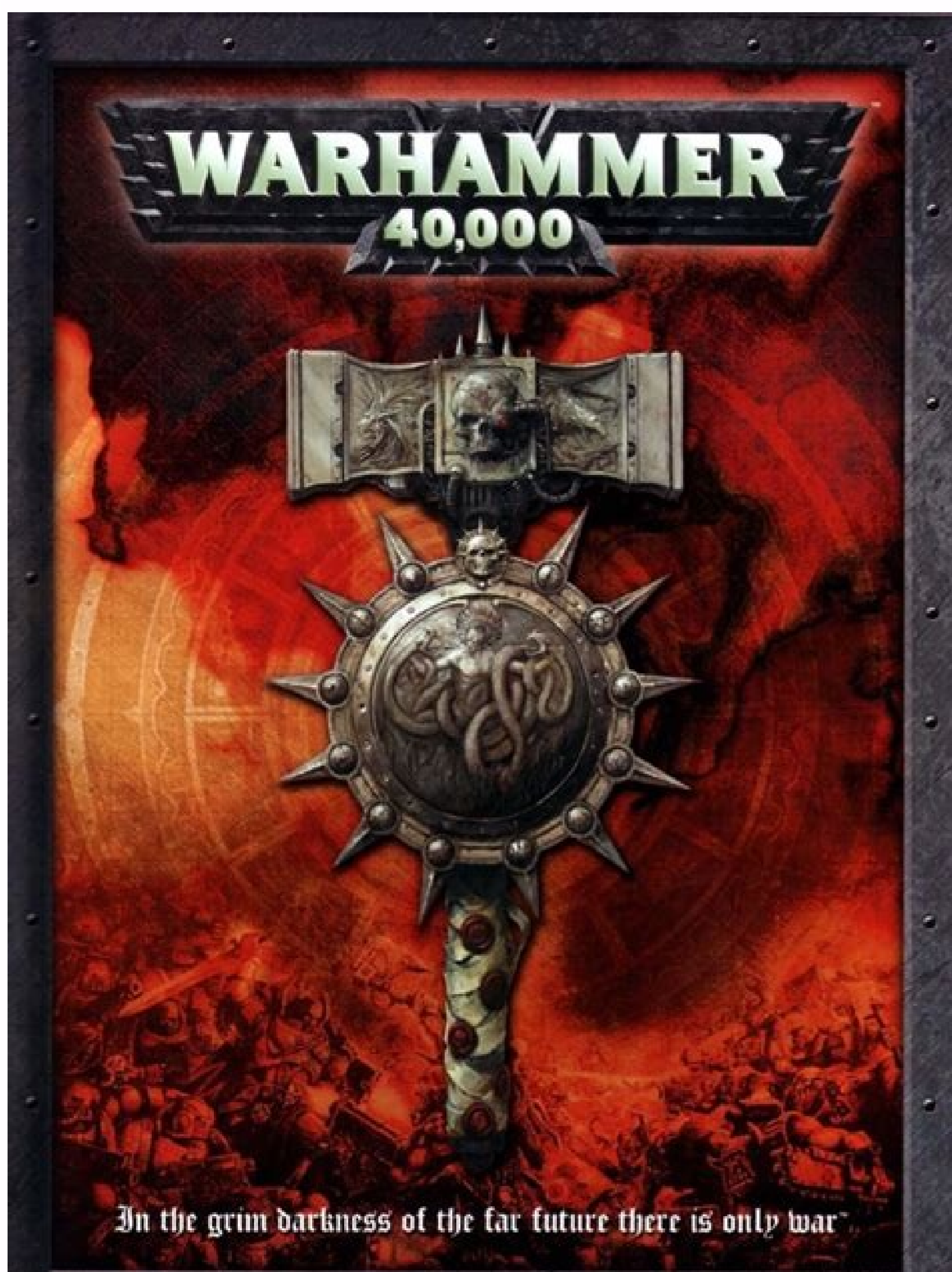
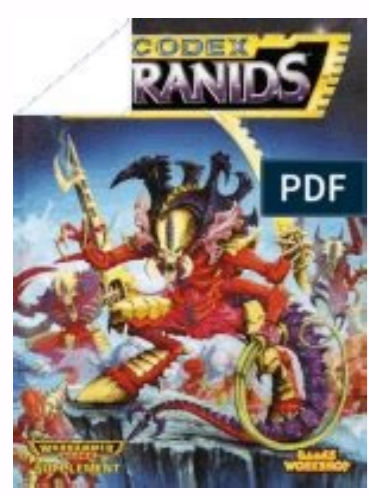


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Designation: F756 - 13

Standard Practice for Assessment of Hemolytic Properties of Materials¹

This standard is issued under the fixed designation F756; 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 approval. A superscripted epsilon (ϵ) indicates an editorial change since the last revision or approval.

1. Scope

1.1 This practice provides a protocol for the assessment of hemolytic properties of materials used in the fabrication of medical devices that will contact blood.

1.2 This practice is intended to evaluate the acute *in vitro* hemolytic properties of materials intended for use in contact with blood.

1.3 This practice consists of a protocol for a hemolysis test under static conditions with either an extract of the material or direct contact of the material with blood. It is recommended that both tests (extract and direct contact) be performed unless the material application or contact time justifies the exclusion of one of the tests.

1.4 This practice is one of several developed for the assessment of the biocompatibility of materials. Practice F748 may provide guidance for the selection of appropriate methods for testing materials for a specific application. Test Method E2524 provides a protocol using reduced test volumes to assess the hemolytic properties of blood-contacting nanoparticulate materials; this may include nanoparticles that become unbound from material surfaces.

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 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
 - E2524 Test Method for Analysis of Hemolytic Properties of Nanoparticles
 - F619 Practice for Extraction of Medical Plastics
 - F748 Practice for Selecting Generic Biological Test Methods for Materials and Devices

3. Terminology

- 3.1 *Definitions:*
- 3.1.1 *plasma hemoglobin*—amount of hemoglobin in the plasma.
 - 3.1.2 *% hemolysis*—free plasma hemoglobin concentration (mg/mL) divided by the total hemoglobin concentration (mg/mL) present multiplied by 100. This is synonymous with hemolytic index.
 - 3.1.3 *comparative hemolysis*—comparison of the hemolytic index produced by a test material with that produced by a standard reference material such as polyethylene under the same test conditions.
 - 3.1.4 *direct contact test*—test for hemolysis performed with the test material in direct contact with the blood.
 - 3.1.5 *extract test*—test for hemolysis performed with an isotonic extract of the test material, as described in Practice F619, in contact with the blood.
 - 3.1.6 *hemolysis*—destruction of erythrocytes resulting in the liberation of hemoglobin into the plasma or suspension medium.
 - 3.1.7 *negative control*—material, such as polyethylene, that produces little or no hemolysis (<2 % after subtraction of the

¹ This practice is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.16 on Biocompatibility 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.

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