



Standard Test Method for Performing Behind-the-Knee (BTK) Test for Evaluating Skin Irritation Response to Products and Materials That Come Into Repeated or Extended Contact with Skin¹

This standard is issued under the fixed designation F2808; 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 The Behind-the-Knee (BTK) method, using the popliteal fossa of human volunteers as a test site, simultaneously evaluates the inherent chemical irritation, and the potential for mechanical irritation of substrates and products that are designed to come into repeated or extended close contact with the skin (see validation references **1-7**).² This is a bilateral test comparing a test material to a reference material with a known safety profile.

1.2 This test method shall be used by qualified health care professionals experienced in good clinical practice (GCP) procedures.

1.3 This test method can be performed using human subjects on either intact or compromised skin. Testing should be performed on intact skin for test substrates or products expected to have contact with normal, intact skin, or for direct comparison to products with a known skin irritation profile. Testing can be performed on compromised skin for test substrates or products that may commonly come into contact with damaged skin (for example, skin with diaper rash, or chapped skin) or skin that is expected to be hydrated.

1.4 Visual scoring of erythema and dryness is performed by a trained skin grader on a pre-defined scale.

1.5 Prior to use in this test, materials shall undergo overall favorable biocompatibility testing consistent with the approach outlined in protocol Practice **F748** or ISO 10993-1:2009. As a part of this series of testing, irritation per Practice **F719** or ISO 10993-10 shall be conducted.

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

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 and health practices and determine the applicability of regulatory limitations prior to use.

2. Referenced Documents

2.1 ASTM Standards:³

D6355 Test Method for Human Repeat Insult Patch Testing of Medical Gloves

F719 Practice for Testing Biomaterials in Rabbits for Primary Skin Irritation

F748 Practice for Selecting Generic Biological Test Methods for Materials and Devices

2.2 ISO Standards:⁴

ISO 10993-1:2009 Biological Evaluation of Medical Devices—Part 1: Evaluation and Testing Within a Risk Management Process

ISO 10993-10 Biological Evaluation of Medical Devices—Part 10: Tests for Irritation and Delayed-type Hypersensitivity

3. Terminology

3.1 Definitions:

3.1.1 *chemical irritation, n*—irritation caused by a physiological response to the chemical nature of a material. Such physiological responses may include: oxidation or reduction reactions, dehydration, disruption of the keratin ultra-structure or direct injury to cellular macromolecules or organelles.

3.1.2 *compromised skin, n*—skin that is treated with repeated application of surgical tape prior to the first sample application.

3.1.3 *edema, n*—observable swelling from abnormal accumulation of fluid in connective tissue.

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 **F04.16** on Biocompatibility Test Methods.

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² The boldface numbers in parentheses refer to the list of references at the end of this standard.

³ 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.

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