



Designation: D4774 – 24

Standard Specification for User Applied Drug Labels in Anesthesiology¹

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1. Scope

1.1 This specification covers the size, color, pattern, and type used on labels applied to unlabeled syringes filled by the users or their agents to identify the drug content. This specification is not intended to cover labels applied by the drug manufacturer.

1.2 The values stated in SI units are to be regarded as the recommended values. The use of inch-pound system values, not being exact equivalents, may result in nonconformance with the standard.

1.3 *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.*

1.4 *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:*²

D996 Terminology of Packaging and Distribution Environments

2.2 *Other Standard:*

Pantone Matching System³

¹ This specification is under the jurisdiction of ASTM Committee F02 on Primary Barrier Packaging and is the direct responsibility of Subcommittee F02.50 on Package Design and Development.

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² 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.

³ Available from Pantone, Inc., 509 Commerce Boulevard, Carlstadt, NJ 07072–3098.

3. Terminology

3.1 *Definitions*—General definitions for packaging and distribution environments are found in Terminology D996.

4. Significance and Use

4.1 *Risk of Medication Errors*—There is an inherent risk of medication errors related to the possible selection and administration of a wrong drug.

4.1.1 *Objective of Specification*—The objective of this specification is to reduce the risk of medication errors by facilitating the correct identification of drugs in syringes filled by users.

4.1.2 *Use of Colors*—The use of colors is intended only as an aid in identification of drug classes and does not absolve the user from the duty to read the label to identify correctly a drug before use. (1)⁴

4.2 *Alternative Use of Black and White Labels*—The user may alternatively use white labels with black printing rather than these colored labels (see Fig. 1).

5. Size and Background Color Requirements

5.1 *Label Size*—The labels shall have a nominal length of 25 mm to 35 mm and a width of 10 mm to 13 mm.

5.2 *Label Background Color*—The colors and patterns given in Fig. 1 shall be used to distinguish these groups of drugs. The background color shall not interfere with the ability of the user to write information on the label.

5.2.1 *Antagonists*—To denote an antagonist, 1-mm wide diagonal stripes of the agonist color alternating with a 1-mm wide white stripe shall be used. The stripes shall run from the lower left to the upper right at an angle of approximately 45° to the long axis of the label. The name of an antagonist drug shall appear in the center of the label and the striping shall be omitted behind and below the name (see Fig. 2).

⁴ The boldface numbers in parentheses refer to a list of references at the end of this standard.