



Designation: D4774 – 11

## Standard Specification for User Applied Drug Labels in Anesthesiology<sup>1</sup>

This standard is issued under the fixed designation D4774; 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 ( $\epsilon$ ) indicates an editorial change since the last revision or reapproval.

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

### 2. Referenced Documents

#### 2.1 ASTM Standards:<sup>2</sup>

<sup>1</sup> This specification is under the jurisdiction of ASTM Committee D10 on Packaging and is the direct responsibility of Subcommittee D10.32 on Consumer, Pharmaceutical and Medical Packaging.

Current edition approved April 1, 2011. Published May 2011. Originally approved in 1988. Last previous edition approved in 2006 as D4774 – 06. DOI: 10.1520/D4774-11.

<sup>2</sup> 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.

#### D996 Terminology of Packaging and Distribution Environments

#### 2.2 Other Standard:

Pantone Matching System<sup>3</sup>

### 3. Terminology

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

### 4. Size and Background Color Requirements

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

4.2 *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.

4.2.1 *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).

<sup>3</sup> Available from Pantone, Inc., 509 Commerce Boulevard, Carlstadt, NJ 07072–3098.

	DRUG CLASS	EXAMPLES	PANTONE COLOR (uncoated)	LABEL EXAMPLES
1	Induction Agents	Etomidate, Ketamine, Methohexital, Propofol, Thiамylal, Thiopental	YELLOW	PROPofol _____ mg/mL Date _____ Time _____ Int _____
2	Benzodiazopines	Diazepam, Midazolam	ORANGE 151	MIDAZolam _____ mg/mL Date _____ Time _____ Int _____
3	Benzodiazopine Receptor Antagonist	Flumazenil	ORANGE 151 & WHITE DIAGONAL STRIPES	FLUMAZenil _____ mg/mL Date _____ Time _____ Int _____
4a	Muscle Relaxants (Depolarizer)	Succinylcholine <sup>B</sup>	FLUORESCENT RED 805	SUCCINYLcholine _____ mg/mL Date _____ Time _____ Int _____
4b	(Non-Depolarizer)	Atracurium, Cisatracurium, Mivacurium, Pancuronium, Rocuronium, Vecuronium	FLUORESCENT RED 805	ROCUronium _____ mg/mL Date _____ Time _____ Int _____
5	Relaxant Agonist (Non-Depolarize)s	Endrophonium, Neostigmine, Pyridostigmine	FLUORESCENT RED 805 & WHITE DIAGONAL STRIPES	NEOstigmine _____ mg/mL Date _____ Time _____ Int _____
6	Narcotics	Alfentanil, Fentanyl, Hydromorphone Meperidine, Morphine, Sufentanil Remifentanil	BLUE 297	FENTanyl _____ mcg/mL Date _____ Time _____ Int _____
7	Narcotic Antagonists	Levallorphan, Naloxone	BLUE 297 & WHITE DIAGONAL STRIPES	NARcan _____ mg/mL Date _____ Time _____ Int _____
8	Major Tranquilizers	Chlorpromazine, Droperidol	Salmon 156	DROperidol _____ mg/mL Date _____ Time _____ Int _____
9a	Vasopressors	Ephedrine, Norepinephrine, Phenylephrine	Violet 256	EPHEDrine _____ mg/mL Date _____ Time _____ Int _____
9b	Vasopressors	Epinephrine <sup>B</sup>	Violet 256	EPINEPHrine _____ mcg/mL Date _____ Time _____ Int _____
10	Hypotensive Agents	Hydralazine, Nitroglycerine, Nitroprusside, Phentolamine, Trimethaphan	Violet 256 & White Diagonal Stripes	NITROglycerine _____ mg/mL Date _____ Time _____ Int _____
11	Local Anesthetics	Bupivacaine, Chlorprocaine, Lidocaine, Mepivacaine, Procaine, Ropivacaine, Tetracaine	Gray 401	LIDOcaine _____ mg/mL Date _____ Time _____ Int _____
12	Anticholinergic Agents	Atropine, Glycopyrrolate, Scopolamine	Green 367	GLYCOpyrrolate _____ mg/mL Date _____ Time _____ Int _____
13	Beta Blockers	Esmolol <sup>B</sup> , Labetolol <sup>B</sup> , Metoprolol <sup>B</sup>	Copper 876U	LABETolol _____ mg/mL Date _____ Time _____ Int _____

<sup>A</sup> Drugs that do not fit into the above classes should be labeled with black printing on a white background. The examples shown are representative, not restrictive.

<sup>B</sup> All printing is to be in black boldtype, with the exception that "succinylcholine" and "epinephrine" shall be printed against the background color as reversed plate letters within a black bar running from edge to edge of the label.

FIG. 1 Standard Background Colors for User Applied Syringe Drug Labels