



# 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.

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<sup>ε1</sup> NOTE—Figures 1-6 were corrected editorially in April 2012.

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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 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, Medical, and Child Resistant Packaging.

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<sup>2</sup> For referenced ASTM standards, visit the ASTM website, [www.astm.org](http://www.astm.org), or contact ASTM Customer Service at [service@astm.org](mailto: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).

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

DRUG CLASS <sup>A</sup>	EXAMPLES	PANTONE COLOR (unearned)	LABEL EXAMPLES
1 Induction Agents	Etomidate, Ketamine, Methohexital, Propofol, Thiамylal, Thiopental	YELLOW	PROPOfol _____ mg/mL Date _____ Time _____ Int _____
2 Benzodiazepines	Diazepam, Midazolam	ORANGE 151	MIDAZolam _____ mg/mL Date _____ Time _____ Int _____
3 Benzodiazepine Receptor Antagonist	Flumazenil	ORANGE 151 AND 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 Antagonist (Non-Depolarizer)	Endrophonium, Neostigmine, Pyridostigmine	FLUORESCENT RED 805 AND 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 AND 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 AND 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	LABETalol _____ 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**



**FIG. 2 Label for an Antagonist Drug**

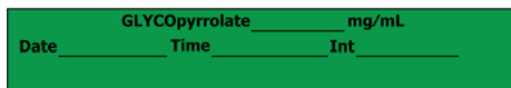
## 5. Significance and Use

5.1 The objective of this specification is to facilitate identification of drugs in syringes filled by the user. The use of

colors is intended only as an aid in identification of drug groups and does not absolve the user from the duty to read the label to correctly identify the drug prior to use.

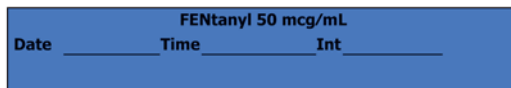


**FIG. 3 Reversed Plate Printing Used to Identify "SUCCINYLcholine," "EPINEPHrine," and Beta Blockers, "ESMOlol," "LABATolol," and "METOprolol"**

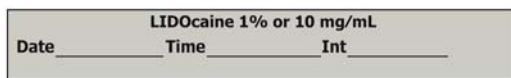


NOTE—Bold upper-case type is shown for first or first and second syllables of the drug name.

**FIG. 4 Optional Printing**



**FIG. 5 Drug Name and Dosage**



**FIG. 6 Alternative Label Showing Concentration in Percent and mg/mL**

5.2 The user may alternatively use black and white labels rather than these colored labels.

## 6. Type and Color Requirements

6.1 The type should be as large as possible (minimum 10-point) using bold type. Upper and lower case letters are preferred for better legibility. All printing shall be in black bold with the exception of "SUCCINYLCHOLINE", "EPINEPHRINE" and Beta Blockers "ESMOLOL", "METOPROLOL", "LABATOLOL" which shall be printed against the background color as bold reverse plate letters within a black bar (copper bar for Beta Blockers) running from edge to edge on the upper half of the label, the rest of which shall display the colored background (see Fig. 3).

6.1.1 The established (generic) name of the drug shall be used. The use of the proprietary (trade) name of the drug is optional. The initial syllable, or initial two syllables, of the drug name may be emphasized by being printed in a bold upper case type a minimum of 2 points larger than the remainder of the drug name, which is typed in lower case (see Fig. 4).

6.1.2 Except for antagonists, the name of the drug and concentration (for example, "mg/mL," "mcg/mL," or "mcg/mL"; see Fig. 3 and Fig. 5) should be printed on the upper half of the label to leave space below for entry of the date, time, and initials of user).

6.1.3 For induction agents and local anesthetics the concentration of the solution (as "%" or "mg/mL") and the date of preparation should appear on the label, as shown in Fig. 6.

6.1.4 For antagonists the name of the drug should be printed along the center line of the label to permit a sufficient width of diagonal stripes to appear above the name for easy recognition (see Fig. 2).

## 7. Keywords

7.1 anesthesiology; drug labels; label requirements

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