

**STATEMENT ON CREATING LABELS OF PHARMACEUTICALS
FOR USE IN ANESTHESIOLOGY**

Committee of Origin: Equipment and Facilities

**(Approved by the ASA House of Delegates on October 27, 2004, and last amended on
October 28, 2015)**

Rationale:

The practice of anesthesiology requires administering a wide variety of potent medications. These medications are often given in high acuity situations and in environments with poor visibility and multiple distractions. Medications with widely differing actions, such as muscle relaxants, vasopressors, and vasodilators, are often used in the course of a single anesthetic, at times simultaneously. It has been recognized for some time that perioperative medication errors are a significant source of morbidity and, rarely, mortality.¹⁻⁴ Interest in medication errors has extended to regulatory agencies, the federal government, and the general public.

Medications are often selected based upon the location and visual features of the container/syringe. The recognition and identification of an object depends on shape, color, brightness, and contrast. As these elements become increasingly distinctive, identification of the object becomes faster and more accurate.⁵⁻⁷ Identification of the medication is verified by reading the label. Therefore, although multiple factors contribute to medication errors, consistency and clarity of pharmaceutical and syringe labeling, in accordance with human factors, are important elements in their prevention. ASTM has come out with their own standards regarding how best to label pharmaceutical containing syringes and vials.⁸⁻⁹ There are some minor differences in the standard colors as designated by ASTM and ISO. This Statement will provide the standards of each and highlight where differences exist.

References:

1. Currie M, Mackay P, Morgan C, Runciman WB, Russell WJ, Sellen A, Webb RK, Williamson JA. The “wrong drug” problem in anaesthesia: an analysis of 2000 incident reports. *Anaesthesia and Intensive Care*. 1993; 21:596-601.
2. Fasting S, Gisvold SE. Adverse drug errors in anesthesia, and the impact of coloured syringe labels. *Can J Anesth*. 2000; 47:1060-1067.
3. Merry AF, Webster CS. Labeling and drug administration error. *Anaesthesia*. 1996; 51:987-988.
4. ISO 26825:2008, Anaesthetic and respiratory equipment – User-applied labels for syringes containing drugs used during anaesthesia – Colour, design and performance.
5. Treisman A. Feature and objects in visual processing. *Scientific American*. November 1986; pp: 114-125.
6. Triesman A. Features and Objects. *Quarterly J of Exp Psychology*. 1988; 40A (vol 2) 201237.

7. Kosslyn SM. Aspects of a cognitive neuroscience of mental imagery. *Science*. 1988; 240:1621-1626.
8. ASTM Designation: D4774 – 11, Standard Specification for User Applied Drug Labels in Anesthesiology.
9. ASTM Designation: D6398 – 08 (Reapproved 2014), Standard Practice to Enhance Identification of Drug Names on Labels.

Statement:
















The primary consideration in the design of labels for syringes and drug infusion bags should be patient safety and the reduction of medication errors. This is particularly true for the potent medications used in the practice of anesthesiology. Therefore, the ASA supports the manufacture and use of labels meeting the following standards, which are consistent with those established by ASTM International (ASTM), the International Organization for Standardization (ISO), and the Institute for Safe Medication Practices (ISMP):

1. **Label Content:** The drug’s generic name and concentration for syringe labels, and the total volume or contents for an infusion bag should be the most prominent items displayed on the label of each syringe or infusion bag containing pharmaceuticals for use in the practice of anesthesiology.
2. **Font:** The text on the label should be designed to enhance the legibility, of the drug name and concentration as recommended in ASTM D4267, *Standard Specification for Labels for Small-Volume (100 ml or less) Parenteral Drug Containers* and D6398, *Standard Practice to Enhance Identification of Drug Names on Labels*, and ISO 26825:2008, *Anaesthetic and respiratory equipment – User-applied labels for syringes containing drugs used during anaesthesia – Colour, design and performance*. These standards include recommendations for font size, extra space for separation around the drug name, and use of additional emphasis for the initial syllable, or a distinctive syllable, of similar drug names.
3. **Contrasting Background:** Maximum contrast between the text and background should be provided by high-contrast color combinations as specified in Section 6.3.1 of ASTM D6398-08. This minimizes the impact of color blindness:

Text	Background
Black	White
Blue	Yellow
White	Blue
Blue	White

4. **Color:** Nine classes of drugs commonly used in the practice of anesthesiology have a standard background color established for user-applied syringe labels by ASTM D4774-

11, *Standard Specifications for User Applied Drug Labels in Anesthesiology* and ISO 26825:2008 (only eight, copper has not been added).

	PMS ^a	ASTM ^b - RGB		ISO ^c - RGB
Induction Agents	Process Yellow C	255.255.0		255.255.0
Benzodiazepines and Tranquilizers	Orange 151	255.102.0		255.102.0
Benzodiazepine Antagonists	Orange 151 / White Diagonal Stripes	255.102.0		255.102.0
Muscle Relaxants	Florescent Red 805 ^d	255.114.118		
	Florescent Red 811 ^e			253.121.86
	Warm Red ^f			245.64.41
Muscle Relaxant Antagonists	Florescent Red / White Diagonal Stripes	255.114.118		253.121.86
Opioid/Narcotics	Blue 297	133.199.227		133.199.227
Opioid/Narcotic Antagonists	Blue 297 / White Diagonal Stripes	133.199.227		133.199.227
Major Tranquilizers and Anti-Emetics	Salmon 156	237.194.130		237.194.130
Vasopressors	Violet 256	222.191.217		222.191.217
Hypotensive Agents	Violet 256/White Diagonal Stripes	222.191.217		222.191.217
Local Anesthetics	Gray 401	194.184.171		194.184.171
Anticholinergic Agents	Green 367	163.217.99		163.217.99
Beta Blockers	Copper 876U	176.135.112		NA ^g
	White	255.255.255		255.255.255

a - Pantone Matching System

b - ASTM International; prior to 2001 it was the American Society for Testing and Materials

c - International Organization for Standardization

d - Designated by ASTM International

e - Designated by ISO

f - Designated by ISO as an alternative if Florescent Red cannot be printed

g - ISO has not designated a color for Beta Blockers

IMPORTANT — The colors represented in this electronic file are not intended to be used for color matching.

RGB (Red, Green, Blue) is used only for digital (computer based) designs. Any design created with an RGB color profile must be converted to CMYK (Cyan, Magenta, Yellow, black) or PMS color codes before printing. As a rule of thumb, you should only use RGB when designing for computer-based applications.

5. Label Enhancements to Reduce Drug Administration Errors:

- **Bar coding:** Essential information, including the drug's generic name and concentration could be bar coded at a location on the label which will not interfere with the label's legibility, as specified in Section 8 of ASTM D6398.
- **Label material** shall allow the user to write information on it using a ball-point pen or felt-tip marker without smudging or blurring as specified in Section 2.3 of ISO 26825:2008.
- **Printing:** All printing is in black bold type with the exception of succinylcholine and epinephrine which are printed against the background color as reverse plate letters within a black bar running from edge to edge of the label.
- **Tall Man Letters:** The FDA Office of Generic Drugs requested manufacturers of sixteen look-alike name pairs to voluntarily revise the appearance of their established names in

order to minimize medication errors resulting from look-alike confusion. Letters from the FDA encouraged manufacturers to revise labels and labeling that visually differentiated their established names with the use of "Tall Man" letters. The following are Tall Man drug names from lists of easily confused medications compiled by the FDA and the ISMP that may be administered by the anesthesia care team during a procedure.

ChlorproMAZINE	DiphenhydrAMINE	DOBUTamine	DOPamine
ePHEDrine	EPINEPHrine	fentaNYL	HydrALAZINE
HYDROmorphone	HydroOXYzine	NiCARDipine	SUFentanil

Useful Websites (last accessed May 2015):

For referenced ASTM International standards, visit the ASTM Website Reading Room at:

<http://www.astm.org/READINGLIBRARY/>

or, send an email to ASTM customer service at: service@astm.org

For referenced ISO standards, visit the ISO (International Organization for Standardization)

Website at: <http://www.iso.org/iso/home.html>

FDA Name Differentiation Project

<http://www.fda.gov/Drugs/DrugSafety/MedicationErrors/ucm164587.htm>

FDA/ISMP Tall Man Letters

<https://www.ismp.org/tools/tallmanletters.pdf>

Institute for Safe Medication Practices (ISMP) Syringe Label Guidelines

<http://www.ismp.org/tools/guidelines/labelFormats/Injectable.asp>

Error-prone abbreviations

<http://www.ismp.org/Tools/errorproneabbreviations.pdf>