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**Anaesthetic and respiratory equipment —
User-applied labels for syringes
containing drugs used during
anaesthesia — Colours, design and
performance**

*Matériel d'anesthésie et de réanimation respiratoire — Étiquettes
apposées par l'utilisateur sur les seringues contenant des médicaments
utilisés pendant l'anesthésie — Couleurs, aspect et propriétés*

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Foreword

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The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 26825 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 1, *Breathing attachments and anaesthetic machines*.

In this corrected version of ISO 26825:2008, the colour used for Figure 2 has been modified in order to match that of fluorescent red in Table 2.

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Anaesthetic and respiratory equipment — User-applied labels for syringes containing drugs used during anaesthesia — Colours, design and performance

IMPORTANT — The electronic file of this document contains colours which are considered to be useful for the correct understanding of the document. Users should therefore consider printing this document using a colour printer.

1 Scope

This International Standard gives requirements for labels which the user attaches to syringes so that the contents can be identified just before use during anaesthesia. It covers the colour, size, design and general properties of the label and the typographical characteristics of the wording for the drug name.

This International Standard does not give requirements for labels applied to a syringe or cartridge by the drug manufacturer.

NOTE National or regional regulations might require additional labelling, which can include bar coding. No requirements for this additional labelling are given.

CAUTION — The use of colours is intended only as an aid in the identification of drug groups and does not absolve the user from the duty of reading the label and correctly identifying the drug prior to use.

2 General

2.1 The label shall be self-adhesive and shall withstand the following test:

a) Apply the label to a 10 ml or 12 ml polyethylene syringe for at least 12 h at (23 ± 2) °C.

NOTE Polyethylene was chosen as the material of the test syringe because it has poor adhesion properties and represents the 'worst case'.

b) Immerse the syringe and label in a 50 % solution (volume fraction) of isopropanol in water for 5 min.

c) After immersion, remove the syringe from the liquid, hold vertically and allow it to air dry for 5 min.

d) The label shall not move, curl or lift at the edge when touched by hand.

2.2 If the labels are provided as a tape, the location where the tape shall be cut between labels shall be perforated or clearly marked. If there is backing material, the label shall be easily separable from it and from adjacent labels.

2.3 The material of the label shall be suitable for the user to write additional information upon it, e.g. the concentration of the drug, using a ball-point pen, without smudging or blurring.

2.4 The label package shall be marked with the number and date of this International Standard, i.e., ISO 26825:2008.

3 Colour, size and adhesive requirements for label

3.1 General

It is recommended that the colour, size and design of labels applied to a syringe or cartridge by the drug manufacturer and any labels designed to be transferred from the original medication container to a syringe, should be consistent with those specified in this International Standard.

3.2 Background colour and designs

3.2.1 The background colours and designs shall be as specified in Table 1. The background colour shall not be so dark as to interfere with the legibility of any additional information that is written on the label using a black ball-point pen.

3.2.2 To denote a drug of opposite action (including antagonists), 1 mm wide diagonal stripes of designated colour, alternating with 1 mm wide white stripes shall be used (see Table 1). The stripes shall run from the lower left to the upper right at an angle of $(45 \pm 5)^\circ$ to the long axis of the label. The striping shall be omitted behind and below the drug name (see 3.4.4 and Figure 1).

3.3 Size of label

Each label shall have a length of between 25 mm and 40 mm and a width of between 10 mm and 15 mm.

NOTE The size of the label was chosen so that it will fit most sizes of syringe without obscuring the graduation marks.

3.4 Colour, character size and positioning of drug name

3.4.1 The drug name shall be in accordance with the Pharmacopoeia of the country in which the label is to be sold.

3.4.2 The height of the letters used for the drug name shall be as large as possible and shall be not less than 2,5 mm in a plain (sans serif) font with approximately similar proportions of line and space in the letters (i.e. bold or semi-bold style). Either of the following forms of presentation shall be used:

- a) lower case letters with an initial upper case letter;
- b) lower case letters with the distinguishing parts of similar drug names in upper case letters (known as 'tall-man' lettering).

All-upper case lettering shall not be used.

NOTE See Clause 4 for non-Roman alphabets.

3.4.3 Except for drugs of opposite action (including antagonists), the name of the drug shall be printed on the upper half of the label to allow space for the drug concentration to be written.

3.4.4 For drugs of opposite action (including antagonists), at least the upper 20 % of the height of the label shall be marked with diagonal stripes (see Figure 1). The top of the drug name shall be separated from the diagonal stripes by at least 0,5 mm.

3.4.5 All letters shall be black except for the labels for suxamethonium and adrenaline which shall be printed against the background colour as bold reverse plate letters within a black bar running from edge to edge of the upper half of the label, the rest of which shall display the coloured background (see Figure 2).

3.4.6 Labels for heparin and protamine shall have a black border of width between 1 mm and 2 mm (see Figures 3 and 4).

3.4.7 The unit of concentration can be pre-printed at the bottom right hand corner of the label (see Figure 5).

4 Regional variations

The characteristics used to specify the presentation of the drug name (i.e. letter size, typeface and weight, case of lettering) in 3.4.2 are intended to confer good legibility in Roman alphabets. If compliance with 3.4.1 necessitates the use of non-Roman alphabets, some of these characteristics, notably case and absence of serifs, might not be available. Also, for a fixed character height, the ratio of character height to width and the presence of long ascenders and/or descenders can affect legibility. In such instances, analogous principles of legibility for the appropriate alphabet should be used.



Figure 1 — Example of a label for a drug of opposite action (including antagonists)



Figure 2 — Example of reverse printing to identify suxamethonium (and adrenaline)

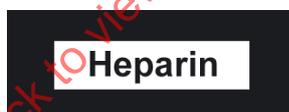


Figure 3 — Example of label for heparin



Figure 4 — Example of label for protamine



Figure 5 — Example of label with drug name and unit of concentration

Table 1 — Background colours for user-applied labels for use on syringes containing drugs used during anaesthesia

Drug class	RGB colour ^a	Examples of drugs
Induction agents	Yellow 255.255.0	Thiopentone, methohexitone, propofol, ketamine
Benzodiazepines	Orange 255.102.0	Diazepam, midazolam
Benzodiazepine antagonists	Orange 255.102.0 with white diagonal stripes	Flumazenil
Muscle relaxants	Fluorescent red ^b 253.121.86 or warm red 245.64.41	Suxamethonium ^c , d-tubocurare, pancuronium, atracurium, vecuronium
Relaxant reversal agents	Fluorescent red ^b 253.121.86 or warm red 245.64.41 with white diagonal stripes	Neostigmine, edrophonium, pyridostigmine
Opioids	Blue 133.199.227	Morphine, fentanyl, pethidine
Opioid antagonists	Blue 133.199.227 with white diagonal stripes	Naloxone
Vasopressors	Violet 222.191.217	Adrenaline ^c , ephedrine, phenylephrine, metaraminol
Hypotensive agents	Violet 222.191.217 with white diagonal stripes	Nitroprusside, nitroglycerine, phentolamine, hydralazine
Local anaesthetics	Grey 194.184.171	Procaine, lignocaine, bupivacaine, ropivacaine
Anticholinergic agents	Green 163.217.99	Atropine, glycopyrolate
Anti-emetics	Salmon 237.194.130	Droperidol, metoclopramide, tropisetron
Miscellaneous drugs	White 255.255.255	Oxytocin, heparin, protamine, potassium chloride, tetrahydroaminacrin (THA), antibiotics, non-steroidals

NOTE See Table 2 for representations of colours and Annex A for alternative colour designations.

^a A tolerance of ± 10 % is permitted for each non-zero component.

^b Warm red can be used if the printing of fluorescent red presents insurmountable difficulties.

^c All printing is in black with the exception of suxamethonium and adrenaline which are printed against the background colour as reverse plate letters within a black bar running from edge to edge of the label (see 3.4.5).

Table 2 — Representations of colours^{a, b}

 Yellow RGB 255.255.0	 Orange RGB 255.102.0	 Fluorescent red RGB 253.121.86	 Warm red RGB 245.64.41	 Blue RGB 133.199.227
 Violet RGB 222.191.217	 Grey RGB 194.184.171	 Green RGB 163.217.99	 Salmon RGB 237.194.130	 White RGB 255.255.255

^a **IMPORTANT** — The colours represented in the electronic file of ISO 26825 are not intended to be used for colour matching.

^b Examples of alternative colour designations are given for information in Annex A.