SLOVENSKI STANDARD
oSIST prEN ISO 26825:2021

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Anestezijska in dihalna oprema - Nalepke za injekcijske brizge z zdravili, ki se uporabljajo pri anesteziji - Barve, oblika in lastnosti (ISO 26825:2020)

Anaesthetic and respiratory equipment - User-applied labels for syringes containing drugs used during anaesthesia - Colours, design and performance (ISO 26825:2020)

Anästhesie und Beatmungsgeräte - Aufkleber für Spritzen mit Arzneimitteln zur Anwendung bei der Anästhesie, die vom Anwender angebracht werden - Farben, Design und Leistung (ISO 26825:2020)

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 (ISO 26825:2020)

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ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment
11.040.25	Injekcijske brizge, igle in katetri	Syringes, needles an catheters

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INTERNATIONAL STANDARD

ISO 26825

Second edition
2020-10

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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Contents

Page

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

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

This second edition cancels and replaces the first edition (ISO 26825:2008), which has been technically revised. The main changes compared to the previous edition are as follows:

— change of the former requirement on the drug name into a recommendation in 5.4.1;

— revision of the labels for benzodiazepines, suxamethonium, muscle relaxant reversal drugs and adrenaline;

— addition of a requirement on the size of diagonal stripes on the label in 5.4.4;

— revision of the indication of the concentration of the drug on the label;

— addition of recommendations on labelling of ready mixed drugs;

— deletion of the colour fluorescent red;

— revision of Table 1 on background colour coding, Table 2 on representation of colours and Table A.1 on examples of alternative colour designations, and merging of the relevant information into one table (Table 1).

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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

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.

1 Scope

This document gives requirements for labels attached 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.

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

2 Normative references

There are no normative references in this document.

3 Terms and definitions

No terms and definitions are listed in this document.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

4 General

4.1 Adhesive requirements

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

a) Apply the label to a 10 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.

4.2 Labels provided as a tape

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.

Check conformity by visual inspection and functional testing.

4.3 Material

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.

Check conformity by functional testing.

4.4 Packaging

The label package shall be marked with a reference to this document, i.e. ISO 26825:2020.

Check conformity by visual inspection.

5 Colour, size and design requirements

5.1 General

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 document.

5.2 Background colour and designs

5.2.1 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.

Check conformity by visual inspection.

5.2.2 To denote a drug of opposite action (including antagonists), 1 mm wide diagonal white stripes, alternating with 1 mm wide stripes of designated colour, shall be used (see Table 1). The stripes shall run from the lower left to the upper right at an angle of (45 ± 5)° to the long axis of the label. The striping shall be omitted behind and below the drug name (see 5.4.4 and Table 1, Examples No. 4, 8, 11, 13 and 16).

Check conformity by visual inspection and functional testing.

5.3 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.

Check conformity by measurement.

5.4 Colour, character size and positioning of drug name

5.4.1 The drug name should be in accordance with the pharmacopoeia of the country in which the label is used.

5.4.2 The height of the letters used for the drug name should 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 1 When "tall-man" lettering is applied, see recommendations in Reference [1] and see Table 1, Example No. 12.

NOTE 2 See Clause 6 for non-Roman alphabets.

Different letter sizes can be used:

— for drug names with many letters (e. g. Calciumgluconate) in order to increase readability of more important parts of the name;

— for drugs that are used in different concentrations (e.g. SUFentanil 5 µg/ml and 25 µg/ml).

Check conformity by visual inspection and measurement.

5.4.3 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 or printed in the lower half.

Check conformity by visual inspection.

5.4.4 For drugs of opposite action (including antagonists), at least the upper 20 % of the width of the label shall be marked with diagonal stripes (see Table 1, Examples No. 4, 8, 11, 13 and 16). The diagonal stripes of each side of the drug name shall take up at least 15 % of the length of the label. The top of the drug name shall be separated from the diagonal stripes by at least 0,5 mm.

Relaxant reversal drugs should be made more discernible from all other drugs of opposite action and antagonists by the addition of a transverse black line below the drug name (see Table 1, Example No. 11). The black line should be 1 mm thick and limited to the width of the drug name.

Check conformity by visual inspection.

5.4.5 All letters shall be black except for

a) the labels for suxamethonium and adrenaline, which shall have bold white lettering for the drug name 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 Table 1, Examples No. 9 and 14);

b) the label for benzodiazepines, which shall have bold white lettering for the drug name alone (see Table 1, Example No. 3).

Check conformity by visual inspection.

5.4.6 Labels for heparin shall have a white background and a black border of width between 1 mm and 2 mm. Labels for protamine shall have a black background with white diagonal stripes as described in 5.2.2 and 5.4.4 (see Table 1, Examples No. 7 and 8).

Check conformity by visual inspection.

5.4.7 The unit of concentration should be pre-printed below the drug name to the right (see Table 1, Examples No. 3, 7 and 12) with the exception of drugs of opposite action or antagonists. In this case, the

unit of concentration should be printed below the drug name to the right-aligned with the drug name (see Table 1, Examples No. 11 and 13).

If the numerical value of the concentration is pre-printed it should be below the drug name preferably centrally (see Table 1, Examples No. 6 and 9).

5.4.8 For drugs that are ready mixed in the ampoule (e. g. neostigmine and glycopyrrolate), either two labels may be used or the background colour of a single label should reflect the action intended for the drug.

For neostigmine and glycopyrrolate, the intended action of the combination is muscle relaxant reversal. The label should be as for neostigmine with the name glycopyrrolate printed below.

6 Regional variations

The characteristics used to specify the presentation of the drug name (i.e. letter size, typeface and weight, case of lettering) in 5.4.2 are intended to confer good legibility in Roman alphabets. If conformity with 5.4.1 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.