SVENSK STANDARD
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Anestesi- och respiratorutrustning – Etiketter för injektionssprutor innehållande läkemedel som administreras vid anestesi, avsedda att appliceras av användaren – färg, utformning och funktion (ISO 26825:2008, IDT)

Anaesthetic and respiratory equipment – User-applied labels for syringes containing drugs used during anaesthesia – Colours, design and performance (ISO 26825:2008, IDT)

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Vill du veta mer om SIS eller hur standarder kan effektivisera din verksamhet är du välkommen in på www.sis.se eller ta kontakt med oss på tel 08-555 523 00.

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Den internationella standarden ISO 26825:2008 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av ISO 26825:2008.

The International Standard ISO 26825:2008 has the status of a Swedish Standard. This document contains the official English version of ISO 26825:2008.

Upplysningar om sakinnehållet i standarden lämnas av SIS, Swedish Standards Institute, telefon 08-555 520 00. Standarder kan beställas hos SIS Förlag AB som även lämnar allmänna upplysningar om svensk och utländsk standard.

Information about the content of the standard is available from the Swedish Standards Institute (SIS), telephone +46 8 555 520 00. Standards may be ordered from SIS Förlag AB, who can also provide general information about Swedish and foreign standards.

Denna standard är framtagen av kommittén för Anestesi- och respiratorutrustning, SIS/TK 329.

Har du synpunkter på innehållet i den här standarden, vill du delta i ett kommande revideringsarbete eller vara med och ta fram andra standarder inom området? Gå in på www.sis.se - där hittar du mer information.

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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

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*.

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 $(45 \pm 5)°$ 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).