

INTERNATIONAL STANDARD

ISO
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Third edition
1992-12-01

Hypodermic needles for single use — Colour coding for identification

*Aiguilles hypodermiques non réutilisables — Code de couleurs pour
l'identification*



Reference number
ISO 6009:1992(E)

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.

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.

International Standard ISO 6009 was prepared by Technical Committee ISO/TC 84, *Medical devices for injections*, Sub-Committee SC 1, *Syringes, needles and intravascular catheters for single use*.

This third edition cancels and replaces the second edition (ISO 6009:1988), of which it constitutes a technical revision. The major changes are that it covers a wider range of needle sizes, that translucent colours are included, that the colour zones previously used to specify opaque colours are now given only for information, and that mention is made of reference colour samples (i.e. sets of needle hubs of the appropriate colours).

Annexes A, B, C and D of this International Standard are for information only.

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Introduction

The intention of this International Standard is to specify colours to enable rapid visual identification of the outside diameter of single-use hypodermic needles. The presence of colour coding on a needle or package does not absolve the user of the responsibility to check the marked size of the needle.

The colours used to code needles may be applied in either opaque or transparent form, and the colour code is equally applicable to normal-walled, thin-walled and extra-thin-walled needles. The nominal outside diameters of needles listed in this International Standard for which colours are given are those specified in ISO 9626. This does not imply that hypodermic needles of all the listed nominal outside diameters are currently manufactured.

This International Standard establishes a colour code but does not specify that needles are to be colour-coded or to what portion of the needle and/or packaging the colour is to be applied. Such requirements may be given in the relevant product standards such as ISO 7864.

The Technical Committee responsible for the preparation of this International Standard has reviewed the use of instrumentally determined colour zones (chromaticity and luminance index) as used in previous editions to specify opaque colours, and has decided that instrumental measurement is not practicable. The measurement of the colour zone of an opaque colour, especially of an item of the size and shape of the hub of a needle, is a complex procedure requiring apparatus and expertise that is to be found in relatively few laboratories and test houses. It may therefore be inconvenient, difficult or impossible for a manufacturer or purchaser routinely to assess compliance of a product with colour zone values. Such difficulties are compounded in the case of translucent colours, which are being used increasingly by needle manufacturers to allow air bubbles inside the hub to be seen and eliminated before injection.

As a consequence, the colours in this International Standard are specified by name, accepting that this inevitably introduces a certain amount of subjectivity in the assessment of compliance. This subjectivity may be minimized by viewing the hubs under controlled lighting conditions (e.g. "daylight" (D_{65}) illumination at 1 000 lx to 1 500 lx) and by the use of assessors of medically-demonstrated correct colour vision. Visual comparison of the colour of a product with a reference colour sample is simple and quick, and is therefore a useful routine method of product assessment. Accordingly, reference colour samples have been made available. These take the form of sets of needle hubs of colours complying with this International Standard. Details are given in annex B and it should be noted that only those diameters of needle currently having coloured hubs are included (i.e. 0,3 mm to 1,2 mm nominal outside diameter). It is expected that the range of diameters included in the reference colour samples will be extended in due course.

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Hypodermic needles for single use — Colour coding for identification

1 Scope

This International Standard establishes a colour code for the identification of single-use hypodermic needles of nominal outside diameters in the range 0,3 mm to 3,4 mm. It applies to normal-walled, thin-walled and extra-thin-walled needles and to opaque and translucent colours.

2 Colour code

The colour shall indicate the nominal outside diameter of the tube of the needle, and shall be as given in table 1.

NOTES

1 Attention is drawn to the sets of reference hubs available as reference colour samples (see annex A).

2 The colour zones of opaque colours, and the nearest colour samples in a number of colour atlases are given for information in annexes B and C respectively.

Table 1 — Colour code

| Nominal outside diameter of needle mm | Colour |
|--|---------------|
| 0,3 | yellow |
| 0,33 | red |
| 0,36 | blue-green |
| 0,4 | medium grey |
| 0,45 | brown |
| 0,5 | orange |
| 0,55 | medium purple |
| 0,6 | deep blue |
| 0,7 | black |
| 0,8 | deep green |
| 0,9 | yellow |
| 1,1 | cream |
| 1,2 | pink |
| 1,4 | red-violet |
| 1,6 | white |
| 1,8 | blue-grey |
| 2,1 | pale green |
| 2,4 | purple |
| 2,7 | pale blue |
| 3 | green-yellow |
| 3,4 | olive brown |

Annex A
(informative)

Reference colour samples

The reference colour samples referred to in this International Standard are available by contacting:

Melab

Medizintechnik und Labor GmbH

Heimsheimer Weg 17

D-7259 Friolzheim

Germany

Tel: + 70 44 4 18 84

Fax: + 70 44 4 24 20

This information is given for the convenience of the users of this International Standard and does not constitute an endorsement by ISO of the reference colour samples.

Annex B (informative)

Colour zones for opaque colours

B.1 Conditions of colour measurement

The chromaticity (x , y) and luminance index Y ($\beta = 10^{-2}Y$) are determined with a spectrophotometer by the equidistant wavelengths method ($\Delta\lambda = 10$ nm) under the following conditions:

- a) **Lighting and examination condition:** (O/d), in accordance with CIE Publication No. 15.2, specular brilliant excluded;
- b) **Reference colorimetric observer:** 2°, in accordance with CIE Publication No. 15.2;

c) **Illuminant:** C source in accordance with CIE Publication No. 15.2;

d) **Reference white:** perfect reflecting diffuser, approximated by a barium sulfate plate.

B.2 Colour zones

The colour zones for opaque colours are given in table B.1.

Table B.1 — Colour zones for opaque colours

| Nominal outside diameter of needle mm | Colour | Colour zone | |
|--|-------------|--|---|
| 0,3 | yellow | $x = 0,448$ $y = 0,468$ $x = 0,488$ $y = 0,511$ | $x = 0,507$ $y = 0,492$ $x = 0,468$ $y = 0,456$ $\beta > 0,40$ |
| 0,33 | red | $x = 0,540$ $y = 0,326$ $x = 0,500$ $y = 0,289$ | $x = 0,560$ $y = 0,280$ $x = 0,610$ $y = 0,330$ $0,10 < \beta < 0,20$ |
| 0,36 | blue-green | $x = 0,203$ $y = 0,300$ $x = 0,246$ $y = 0,306$ | $x = 0,267$ $y = 0,347$ $x = 0,234$ $y = 0,370$ $0,30 < \beta < 0,50$ |
| 0,4 | medium grey | $x = 0,302$ $y = 0,314$ $x = 0,313$ $y = 0,324$ | $x = 0,323$ $y = 0,315$ $x = 0,303$ $y = 0,302$ $0,20 < \beta < 0,65$ |

| Nominal outside diameter of needle mm | Colour | Colour zone | |
|--|---------------|--|---|
| 0,45 | brown | $x = 0,360$ $y = 0,332$ $x = 0,440$ $y = 0,356$ | $x = 0,452$ $y = 0,338$ $x = 0,367$ $y = 0,325$ $0,04 < \beta < 0,15$ |
| 0,5 | orange | $x = 0,482$ $y = 0,394$ $x = 0,542$ $y = 0,421$ | $x = 0,561$ $y = 0,394$ $x = 0,498$ $y = 0,375$ $0,22 < \beta < 0,40$ |
| 0,55 | medium purple | $x = 0,258$ $y = 0,193$ $x = 0,274$ $y = 0,237$ | $x = 0,294$ $y = 0,243$ $x = 0,285$ $y = 0,201$ $0,07 < \beta < 0,20$ |
| 0,6 | deep blue | $x = 0,151$ $y = 0,178$ $x = 0,197$ $y = 0,218$ | $x = 0,203$ $y = 0,182$ $x = 0,164$ $y = 0,132$ $0,05 < \beta < 0,10$ |
| 0,7 | black | $x = 0,296$ $y = 0,313$ $x = 0,315$ $y = 0,338$ | $x = 0,350$ $y = 0,319$ $x = 0,290$ $y = 0,273$ $\beta < 0,05$ |
| 0,8 | deep green | $x = 0,013$ $y = 0,745$ $x = 0,310$ $y = 0,685$ | $x = 0,310$ $y = 0,441$ $x = 0,254$ $y = 0,397$ $0,09 < \beta < 0,20$ |
| 0,9 | yellow | $x = 0,448$ $y = 0,468$ $x = 0,488$ $y = 0,511$ | $x = 0,507$ $y = 0,492$ $x = 0,468$ $y = 0,456$ $\beta > 0,40$ |

| Nominal outside diameter of needle mm | Colour | Colour zone | |
|--|------------|--|---|
| 1,1 | cream | $x = 0,331$ $y = 0,341$ $x = 0,356$ $y = 0,372$ | $x = 0,377$ $y = 0,364$ $x = 0,341$ $y = 0,337$ $0,65 < \beta < 0,80$ |
| 1,2 | pink | $x = 0,328$ $y = 0,308$ $x = 0,332$ $y = 0,321$ | $x = 0,407$ $y = 0,338$ $x = 0,373$ $y = 0,282$ $0,40 < \beta < 0,60$ |
| 1,4 | red-violet | $x = 0,300$ $y = 0,287$ $x = 0,288$ $y = 0,254$ | $x = 0,320$ $y = 0,270$ $x = 0,316$ $y = 0,293$ $0,40 < \beta < 0,65$ |
| 1,6 | white | $x = 0,297$ $y = 0,308$ $x = 0,310$ $y = 0,326$ | $x = 0,330$ $y = 0,318$ $x = 0,303$ $y = 0,295$ $\beta > 0,80$ |
| 1,8 | blue-grey | $x = 0,250$ $y = 0,267$ $x = 0,262$ $y = 0,309$ | $x = 0,295$ $y = 0,314$ $x = 0,290$ $y = 0,299$ $0,10 < \beta < 0,20$ |
| 2,1 | pale green | $x = 0,302$ $y = 0,367$ $x = 0,337$ $y = 0,376$ | $x = 0,320$ $y = 0,339$ $x = 0,307$ $y = 0,336$ $0,45 < \beta < 0,65$ |
| 2,4 | purple | $x = 0,329$ $y = 0,233$ $x = 0,338$ $y = 0,194$ | $x = 0,411$ $y = 0,241$ $x = 0,376$ $y = 0,267$ $0,10 < \beta < 0,20$ |

| Nominal outside diameter of needle mm | Colour | Colour zone | |
|--|--------------|--|---|
| 2,7 | pale blue | $x = 0,197$ $y = 0,197$ $x = 0,200$ $y = 0,260$ | $x = 0,291$ $y = 0,306$ $x = 0,289$ $y = 0,294$ $0,20 < \beta < 0,65$ |
| 3 | green-yellow | $x = 0,350$ $y = 0,525$ $x = 0,336$ $y = 0,450$ | $x = 0,380$ $y = 0,450$ $x = 0,420$ $y = 0,525$ $0,30 < \beta < 0,50$ |
| 3,4 | olive brown | $x = 0,402$ $y = 0,443$ $x = 0,362$ $y = 0,386$ | $x = 0,392$ $y = 0,372$ $x = 0,454$ $y = 0,415$ $0,10 < \beta < 0,25$ |

Annex C
(informative)

Colour samples for opaque colours

The nearest colour samples to the colours given in this International Standard are given in table C.1.

Table C.1 — Colour samples for opaque colours

| Nominal outside diameter of needle mm | Colour samples | | | |
|---|----------------|----------------|------------|-------------|
| | Munsell atlas | Fed. Std. 595a | RAL 840 HR | NF X 08-002 |
| 0,3 | 3,75 Y 8/14 | 23 655 | 1 021 | 1 330 |
| 0,33 | — | — | — | — |
| 0,36 | 7,5 BG 5/8 | — | — | — |
| 0,4 | N7 | 26 231 | 7 035 | 3 630 |
| 0,45 | 10 R 4/4 | 10 075 | 8 017 | 2 020 |
| 0,5 | 3,75 YR 6/12 | 12 473 | 2 003 | 1 130 |
| 0,55 | 2,5 P 4/8 | 27 144 | 4 005 | 2 710 |
| 0,6 | 2,5 PB 3/8 | 15 090 | 5 010 | 1 540 |
| 0,7 | N 2,0 | 27 038 | 9 005 | 2 603 |
| 0,8 | 2,5 G 4/8 | 14 090 | 6 001 | 2 455 |
| 0,9 | 3,75 Y 8/14 | 23 655 | 1 021 | 1 330 |
| 1,1 | 10 YR 9/2 | 27 769 | 1 015 | 2 225 |
| 1,2 | 2,5 R 7/6 | 11 630 | 3 015 | 2 870 |
| 1,6 | N 9,5 | 27 875 | 9 010 | 2 665 |
| 1,8 | 5,0 B 4/2 | 35 189 | 7 031 | 3 520 |
| 2,1 | 10 GY 8/2 | 24 504 | 6 019 | 3 470 |
| 2,4 | — | — | — | — |
| 2,7 | 2,5 PB 7/8 | 35 190 | 5 012 | 2 590 |
| 3 | — | — | — | — |
| 3,4 | — | — | — | — |

Annex D
(informative)

Bibliography

- [1] ISO 7864:1988, *Sterile hypodermic needles for single use.*
- [2] ISO 9626:1991, *Stainless steel needle tubing for the manufacture of medical devices.*
- [3] CIE Publication No. 15.2:1986, *Colorimetry.*¹⁾
- [4] Munsell Book of Color.²⁾
- [5] USA Federal Standard 595a, *Colors-Vol.1.*³⁾
- [6] German Standard RAL 840, *HR Farbreger (Colour register).*⁴⁾
- [7] French Standard NFX 08-002, *Collection réduite des couleurs — Désignation et catalogue des couleurs CCR — Étalons secondaires (Limited collection of colours — Designation and catalogue of CCR colours — Secondary Standards).*⁵⁾

1) Available from the Honorary Librarian (National Illumination Committee of Great Britain), c/o The Library, Thorn Lighting Ltd., 146 Lincoln Road, Enfield, Middlesex EN1 1SB, UK.

2) Available from Munsell Color, 2441 N. Calvert Street, Baltimore, MD 21218, USA.

3) Available from Superintendent of Documents, US Government Printing Office, Washington DC 20402, USA.

4) Available from RAL Deutsches Institut für Gütesicherung und Kennzeichnung eV, Bornheimer Strasse 180, 5300 Bonn 1, Germany.

5) Available from AFNOR, Tour Europe, Cedex 7, 92080 Paris La Défense, France.

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Descriptors: medical equipment, hypodermic needles, identification methods, colour marking, colour codes.

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