
Dentistry — Colour tabs for intraoral tooth colour determination

*Médecine bucco-dentaire — Plaquettes de teinte pour la
détermination de la teinte dentaire intra-buccale*

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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 106, *Dentistry*, Subcommittee SC 2, *Prosthetic materials*.

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.

Introduction

In dentistry, colour matching, colour communication among dentist and dental technician (indirect restorations) and colour reproduction and verification are essential elements for a successful aesthetic restoration. Other important appearance attributes include translucency/opacity, gloss, opalescence and fluorescence.

Questions regarding the principles of chromatics and the individual colour perception have been controversially discussed for years between those involved. Today, various systems are available for the purpose of objectivizing tooth colour perception. The most common method is the colour comparison using reference colours being supplied in the form of shade guides consisting of tooth shaped colour tabs made of ceramic, for a dental colour system. The objective of this document is to specify test methods for such colour tabs. This document does not cover colour samples, which are produced by each manufacturer to demonstrate colour effects usually of all components of a given individually designed assortment. These colour samples are not used to determine the colour *in vivo* and are not provided in a tooth-shaped form.

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Dentistry — Colour tabs for intraoral tooth colour determination

1 Scope

This document specifies requirements for tooth-like colour representations made of ceramic materials used to determine the tooth colour in the patient's mouth or to check the colour of dental prosthesis, which are referred to as colour tabs in this document.

The colour coordinates of colour tabs are left to the manufacturers' discretion.

Resources for visualizing the colours of ceramic and other masses, e.g. mass shade guides and colour patterns for certain ceramic and other masses, do not fall into the scope of this document. They can be manufactured from any materials and serve solely to illustrate the colour effect; they do not serve to determine colour inside the mouth.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 1942, *Dentistry — Vocabulary*

ISO 8601-1, *Date and time — Representations for information interchange — Part 1: Basic rules*

ISO 8601-2, *Date and time — Representations for information interchange — Part 2: Extensions*

ISO 11664-2, *Colorimetry — Part 2: CIE standard illuminants*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO/TR 28642, *Dentistry — Guidance on colour measurement*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942 and the following apply.

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

- ISO Online browsing platform: available at <http://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

3.1

colour difference

single number or metric expressing the distance from complete match in colour or shade

Note 1 to entry: A colour distance metric defined by the International Commission on Illumination (CIE) is called delta E (ΔE).

Note 2 to entry: Two formulae for calculating ΔE are recommended in this document: CIELAB or CIE 76 (denoted ΔE^*_{ab}) and CIEDE2000 (denoted ΔE_{00}). CIEDE2000 formula is currently the most advanced one and is recommended by CIE as it exhibits better correlation with visual findings compared with CIELAB.

3.2

colour coordinate

set of three independent colour components required for the unique description of any colour in a defined colour coordinate system

EXAMPLE CIE-Lab ($L^*a^*b^*$), CIE LCH*, CIEDE2000 (L^*C^*h').

3.3

colour sample

colour representation, corresponding as exactly as possible to a discrete colour of a *tooth colour* (3.6) system

Note 1 to entry: A colour sample can be manufactured from any material and serves solely to illustrate the colour effect; it is not to be used for colour determination inside the mouth.

3.4

colour tab

body similar in shape and colour to a tooth, which is manufactured from at least two layers of ceramic materials and represents as exactly as possible a discrete colour of a tooth colour system

Note 1 to entry: The colour tab is usually fixed to a holding pin intended to enable positioning of the colour tab close to the patient's tooth without major occlusions.

3.5

shade guide

arrangement of *colour tabs* (3.4) representing in their entirety a manufacturer-specific tooth colour system and serving for the visual (intraoral) determination of the patient's tooth colour by means of comparing the latter with the colour tabs of the shade guide.

Note 1 to entry: Usually, the colour tabs are set in (a) joint holder/s, with colour tabs being removable from the holder.

3.6

tooth colour

(true) value of the measurand tooth colour

Note 1 to entry: This definition is adapted for the context of this document and according to JCGM 100:2008 (Joint Committee for Guides in Metrology).

3.7

countershape

surround that accommodates a *colour tab* (3.4)

Note 1 to entry: Also known as "mould".

4 Requirements

4.1 Materials and processing

Colour tabs shall be manufactured from at least two layers of ceramic materials.

NOTE The exact structure of the colour tab as well as the composition and the processing of the materials are at the manufacturers' discretion.

4.2 Appearance

Colour tabs used to intraorally match the shades of natural teeth shall provide toothlike shapes.

Note 1 to entry This is to provide a shape the user is familiar with. Many years of clinical experience show that tooth shaped tabs lead to an intuitive handling of the tabs.

4.3 Uniformity

The measured colour coordinates of the colour tab shall match the colour coordinates of the tooth colour system within certain tolerances that are subject to the manufacturer's definition.

In the absence of any manufacturer's definition, the perceptibility threshold defined in ISO/TR 28642:2016 ($\Delta E^*p = 1,2$) shall be used as the tolerance.

4.4 Cleaning and disinfection

Manufacturer's instructions for use must describe the methods and agents for cleaning, disinfection or sterilization. The given procedures, cleaners and disinfectants shall not affect the colour stability of the colour tab.

4.5 Colour stability

If the cleaning instructions given by the manufacturer are complied with and unless no other information is given by the manufacturer, the maximum colour difference declared by the manufacturer shall apply for a period of at least 5 years from the date of manufacture. If the manufacturer did not specify a maximum colour difference, the perceptibility threshold defined in ISO/TR 28642: ($\Delta E^*p = 1,2$) shall be used as the maximum acceptable difference.

5 Test method for colour measurement

5.1 Test devices and test equipment

5.1.1 Spectrophotometers

5.1.1.1 Spectrophotometer with Ulbricht sphere to the following specifications:

Measurement geometry	d/8° sphere geometry
Repeatability	below 0,02 ΔE (r.m.s.) on a specified surface
Compliance of device with reference device	below 0,15 ΔE (r.m.s.) on a specified surface
Spectral range	Max. lower limit of spectral range: 400 nm Min. upper limit of spectral range: 700 nm
Spectral resolution	10 nm
Photometric range	0,0 % to 200 % reflection
Photometric resolution	below 0,01 %

5.1.1.2 Other spectrophotometers (e.g. spectroradiometer)

Measurement geometry	45°/d optical geometry (unidirectional, bidirectional or circumferential),
Background	with or without
Spectral resolution	1 nm–5 nm

The other specifications should be the same or similar as listed in [5.1.1.1](#).

5.1.2 Colour tab

All colour tabs of each shade guide shall be measured.

5.1.3 Countershape

The design shall ensure that the measuring spot is positioned normal to the observation direction of the spectrophotometer. To minimize the mould's influence on the colour measurement, the mould should be matte finished with black colour or the mould provides a cavity of at least the diameter of the measurement spot.

5.2 Procedure

5.2.1 Positioning of the colour tab

For the measurements insert the colour tab into the countershape (5.1.3). Position the surface of the tab in the measuring spot normal to the observation direction of the spectrophotometer. Parameters of the colour measurement deviating from this shall be declared separately by the manufacturer of the colour tab.

5.2.2 Measurement parameters to be set

Carry out the colour measurement of the colour tab using a spectrophotometer with Ulbricht sphere (5.1.1.1). Alternatively use a spectroradiometer as defined in 5.1.1.2.

The relevant parameters to be selected for the colour measurements are:

Measurement with proportion of reflection. Specular component and UV included.

Illumination spectrum: D65 (standard illuminant D at 6 500 K daylight) in accordance with ISO 11664-2.

Angle of illumination (visual field/visus): Either use 2°- or 10°- observer.

Diameter of measuring spot: The diameter shall be chosen according to the size of the colour tab. A value between 2 mm and 4 mm is recommended. When the diameter of the spot is set, a tolerance of +/-0,2 mm shall apply.

Distance measuring spot-border of colour tab: At least 1 mm in all directions.

NOTE Since colour tabs have curved surfaces, the specified spot size is an optimum giving a satisfactory average for the tab while maintaining measurement geometry within specifications.

5.2.3 Number of measurements

Four measurements shall be performed in the centre of the colour tab, with the tooth-shaped tab being rotated by 90° around the centre of the measuring spot following each measurement.

5.3 Expression of results

For each colour coordinate, the mean values are calculated from the four measurements. The mean values are the results of the measurement.

NOTE Colour coordinates can be obtained by using software associated with the measuring device.

6 Information and instructions

6.1 Information

The manufacturer shall make available the following information.

- a) The maximum permissible colour difference ΔE^*_{ab} of the colour tabs from the colour coordinates on which the shade guide is based. In the absence of further information, the declared value is valid for all colour tabs of the shade guide.
- b) In the case of a measurement method deviating from the test methods described in [Clause 5](#) being applied, information regarding the measurement method used and all the relevant parameters shall be given as well.
- c) Influence of any cleaning agents or procedures used in dentistry that might affect the colour of the colour tabs or any other aspect of the shade guide tabs or other components of the shade guide. Unless the manufacturer states otherwise, all cleaning agents and procedures used in dentistry are deemed permissible.
- d) Information regarding the permissible cleaning in commercially available autoclaves, either on the shade guide or on the packaging or in the instructions for use. This information comprises the permissible settings for cleaning and the statement to which components this information applies. Unless the manufacturer states otherwise, all parts of the shade guide are deemed autoclavable without restrictions.

6.2 Instructions

Each shade guide shall be accompanied by instructions for use. The instructions for use shall include at least the following information:

- a) name and address of the manufacturer of the shade guide;
- b) designation of the shade guide;
- c) maximum permissible colour deviation of the colour tabs (ΔE^*_{ab} , from the colour coordinates that the shade guide is based upon);
- d) all information regarding any potential deviations from the requirements defined in this document;
- e) methods and agents for cleaning, disinfection or sterilization.

Further information given by the manufacturer, e.g. regarding improper handling of the shade guide, is desirable.

When the graphic symbols described in ISO 15223-1 are used, they shall be in accordance ISO 15223-1.

7 Marking

The shade guide shall be marked with at least the following information:

- a) manufacturer's brand;
- b) date of manufacture in accordance with ISO 8601-1 and ISO 8601-2 (year, month, if relevant).

In addition, all colour tabs of the shade guide or their holding pins, respectively, shall be marked with the designation of the represented colour.