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## **BSI Standards Publication**

# Dentistry — Guidance on colour measurement



#### **National foreword**

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# TECHNICAL REPORT

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## Dentistry — Guidance on colour measurement

Médecine bucco-dentaire — Directives relatives au mesurage de la couleur



## PD ISO/TR 28642:2016 **ISO/TR 28642:2016(E)**



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#### **Foreword**

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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 <a href="www.iso.org/directives">www.iso.org/directives</a>).

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For an explanation on 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 the following URL: <a href="www.iso.org/iso/foreword.html">www.iso.org/iso/foreword.html</a>.

The committee responsible for this document is ISO/TC 106, *Dentistry*, Subcommittee SC 2, *Prosthodontic materials*.

This second edition cancels and replaces the first edition (ISO/TR 28642:2011), which has been technically revised.

#### Introduction

The colour appearance of teeth and other dentistry-related tissues need to be matched and reproduced in order to achieve acceptable aesthetics in an efficient manner. Three major groups of issues, related to colour compatibility, colour stability and colour interactions, are identified and considered in this document. Interpretation of colour differences associated with these three groups through 50:50 % perceptibility and acceptability visual thresholds is suggested. Colour is a psychophysical phenomenon that is assessed by both visual and instrumental methods. Other elements of appearance, including gloss and translucency, affect aesthetics and may influence the characterization of colour appearance.

The International Commission on Illumination (CIE) colour difference formulae and resources, in particular CIE Pub No 15.3, were used in this document.

#### **Dentistry** — Guidance on colour measurement

#### 1 Scope

This document identifies three types of topics related to shade conformity and interconvertibility of monochromatic and polychromatic tissues and materials related to the discipline of dentistry; it describes visual and instrumental methods for assessment of these topics.

This document suggests interpretation of the findings through colour difference thresholds and provides guidelines for future standardization related to dental shade conformity and interconvertibility. It also includes guidelines related to colour vision of persons undertaking visual colour assessments and instructions for reporting of colour and colour difference assessments.

#### 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 11664-1, Colorimetry — Part 1: CIE standard colorimetric observers

#### 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:

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

#### 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  $E(\Delta E)$ .

Note 2 to entry: Two formulae for calculating  $\Delta E$  are recommended in this document: CIE 76 (denoted  $\Delta E^*_{ab}$ ) and CIEDE2000 (denoted  $\Delta E_{00}$ ).

#### 3.2

#### 50:50 % perceptibility threshold of colour difference

difference in colour that can be detected by 50 % of observers under controlled conditions, with the other 50 % of observers noticing no difference in colour between the compared objects

Note 1 to entry: A nearly perfect colour match in dentistry is a colour difference at or below the 50:50 % perceptibility threshold.

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#### 3.3

#### 50:50 % acceptability threshold of colour difference

#### AT

difference in colour that is considered acceptable by 50 % of observers under controlled conditions, with the other 50 % of observers replacing or correcting the restoration

Note 1 to entry: An acceptable colour match in dentistry is a colour difference at or below the 50:50~% acceptability threshold.

#### 3.4

#### colour standards in dentistry

sets of polychromatic or monochromatic samples (tabs, chips, or patches), most frequently made of dental ceramic or resin (tooth shade guides), or silicone elastomer (skin shade guides in maxillofacial prosthodontics)

Note 1 to entry: The polychromatic and monochromatic samples are fabricated for the purposes of colour matching hard and soft oral tissues, and human skin (see Reference [2]).

#### 3.5

#### coverage error

index that describes the mean of minimal colour differences ( $\Delta E^*_{min}$ ) between the specimens of one set (e.g. a shade guide) to each specimen of another set (e.g. natural teeth)

Note 1 to entry: The coverage error is calculated as the mean  $\Delta E^*_{\min}$  for all best matches as follows:

Coverage error = 
$$\frac{\sum \Delta E *_{\min}}{n}$$

where n is the number of best matches.

Note 2 to entry: The smaller the coverage error, the higher the chances of successful shade matching.

#### 3.6

#### tooth whitening

change in tooth colour caused by bleaching or stain-removal agents and manifested by the increase in the value of lightness and the decrease of chroma

#### 3.7

#### colour shifting

change in perceived colour that is a sum of a blending effect and an effect of physical translucency

#### 3.7.1

#### colour shifting due to blending

change in perceived colour of a material due to a change in surroundings

Note 1 to entry: Colour shifting due to blending is a psycho-physical phenomenon and is not modelled by the current CIELAB mathematical model; it is an optical illusion, visually perceptible, but not quantifiable or measurable by any instrument.

#### 3.7.2

#### colour shifting due to physical translucency

change in colour of translucent dental restorations caused by surroundings and background (underlying layers of hard dental tissues or other restorative materials)

#### 3.8

#### opacity

measure of the ability of a material to block the passage of light

Note 1 to entry: A material with high opacity is one with low translucency/transparency.

#### 3.9

#### transparency

physical property of allowing the transmission of light through a material

Note 1 to entry: A material with high transparency is one with low opacity.

Note 2 to entry: Transparency is the extreme value of high translucency.

Note 3 to entry: A transparent material allows light to pass through undiminished, while a negligible portion of the transmitted light is scattered.

#### 3.10

#### translucency

ability of a material to allow light to pass through it

Note 1 to entry: A material with high translucency is one with low opacity.

Note 2 to entry: Translucent materials allow light to pass through only diffusely (they cannot be seen through clearly).

#### 3.11

#### gloss

capacity of a surface to reflect more light in some directions than in others

#### 3.12

#### specular gloss

ratio of flux reflected in the specular direction to incident flux (i.e. the angle of the reflected light is equal and opposite to the angle of the incident beam) for a specified angle of incidence, source, and receptor angular aperture

Note 1 to entry: These reflections normally have the highest reflectances (see References [2] and [3]).

#### 4 Visual and instrumental colour assessment

#### 4.1 Devices

Frequently used devices for visual and instrumental colour assessment in dentistry are spectrophotometers, spectroradiometers, colourimeters, imaging systems for traditional digital imaging and spectral imaging, viewing booths, and different types of hand-held shade matching lights.

Spectral measurement is performed using a spectrophotometer, a device designed to measure spectral transmittance and spectral reflectance of objects. Compared to colourimetric measurements, spectral measurements enable more flexible measurements to calculate colour differences under arbitrary illuminants and observers.

Spectrometer parameters relevant for dentistry include wavelength range, wavelength resolution, integration time and spectral sensitivity. In addition to these parameters, method of measurement, technology and geometry have to be taken in account when selecting the equipment or designing a system to measure spectra.

Spectral measurement accuracy can be measured in terms of root mean square error (rms) or degree of correlation between spectral data, and other weighted spectral measurements that emphasize the wavelength that are more relevant for human vision. Having spectral measurements of both reference and test samples, it is possible to calculate how robust is the pair of samples to changes in illumination and observers by means of index of metamerism.

#### 4.2 Setting

Colour assessment requires careful control of factors that affect colour perception and/or measurement. The following aspects of the test conditions should be specified in reporting visual assessments of colour appearance.

#### 4.2.1 Illuminant

The characteristics of the light source or sources that illuminate the object of a colour measurement as specified preferably by the spectral power distribution (SPD) and correlated colour temperature (CCT) specified according to ISO 11644-2. CIE standard illuminant D65 (representing noon daylight, CCT of 6500 K) with a Colour Rendering Index (CRI) of 90 or greater is recommended for visual colour measurements in dentistry.

#### 4.2.2 Standard observer

The 2° 1931 standard observer as defined in ISO 11664-1 should be used for teeth and dental restorations. The 10° 1964 supplementary standard observer, also defined in ISO 11664-1, should be used for larger measurement areas, such as oral soft tissues and skin.

#### 4.2.3 Geometric conditions

The optical geometry of a measurement is defined by the angle of illumination and the angle of viewing relative to the surface of the object. It is expressed as illumination geometry/viewing geometry. CIE recommends different types of optical geometries in reflection, including  $0^{\circ}/45^{\circ}$ ,  $45^{\circ}/0^{\circ}$ ,  $d/0^{\circ}$  and  $0^{\circ}/d$ -based geometries that are most suitable for visual colour assessments in dentistry (where d denotes diffuse). Optical geometries that are associated with the use of integrating sphere are related solely to instrumental measurements.

#### 4.2.4 Illuminance

The total luminous flux incident on a surface is a measure of the intensity of the incident light (lumens/area). Illuminance is measured in lux (lx). The foot-candle is a non-metric unit of illuminance (used in photography).

NOTE An Illuminance of 1 000 lux is considered optimal for visual colour assessments[4].

#### 4.2.5 Visual angle of subtense

The visual angle of subtense (2 $\theta$ ) is calculated from the size of the object, r, and its distance, d, from the observer as:  $2\theta = 2 \arctan(r/d)^{[4]}$ .

In visual assessment, larger visual angle of subtense increase visual precision. A visual angle of subtense should not be less than  $2^{\circ}$ .

#### 4.2.6 Background

The background is defined as the surface upon which samples are placed; the environment of the stimulus, extending for about 10° from the edge of the stimulus in all, or most, directions.

#### 4.2.7 Surround

The surround is defined as the field outside the background. In practical situations, the surround can be considered to be the entire environment in which the stimuli are viewed<sup>[5]</sup>. The surround should be matte and neutral (light grey).

#### 4.2.8 Additional/other considerations

See Reference [1] for the additional consideration on the topics mentioned in this clause and on other related topics, such as spectral measurements and calculation algorithms, specular component, metamerism, whiteness index, and yellowness index.

#### 5 Observers

## 5.1 Evaluation of colour competency of candidate for observer in studies on acceptability or perceptibility in dentistry

#### 5.1.1 Ishihara colour blindness test

The Ishihara Colour Blindness Test<sup>[6]</sup> is a test for red-green colour deficiencies. It consists of a number of coloured plates, each of which contains a circle made of many different sized dots of slightly different colours, spread in a seemingly random manner. Within the dot pattern, and differentiated only by colour, is a number. The full test consists of thirty-eight plates, but the existence of a deficiency is usually clear after several plates.

#### 5.1.2 Farnsworth-Munsell 100 hue test

The Farnsworth Munsell 100 Hue Test<sup>[Z]</sup> has been used for many years as a definitive standard for testing colour discrimination, the ability to discriminate between various shades of a given colour. The test will determine if the observer is superior, average or poor at discriminating colour.

#### 5.1.3 Test for colour discrimination competency in dentistry

Test subjects should match pairs of shade tabs from two shade guides. One set of tabs should have original markings on tab holders (such as A1, B1, 1M2, 2M2, or similar) while the original markings of the other set of tabs should be covered with custom letters, numbers or symbols (such as M, N, 1, 2, or similar). VITA Classical  $^{\circledR 1}$  is an example of appropriate shade guide for this test. Visual comparisons should be made under the D65 illuminant of a viewing booth (the overhead lights should be turned off), at the distance of 25 cm to 33 cm, using  $0^{\circ}/45^{\circ}$  or  $45^{\circ}/0^{\circ}$  optical geometry. Tabs should be removed from joint tab holders, placed on the floor of the viewing booth and mixed. After a period of adaptation by observing the walls of the viewing booth, the observers should begin tab arrangement. At least twelve pairs of tabs should be used for this test and one point should be assigned for each correctly matched pair. The test can be repeated with at least seven-day intervals between the tests, in which case the higher of the two scores will be counted.

## 5.2 Guidelines for observer selection for acceptability or perceptibility evaluation in dentistry

#### 5.2.1 General tests

All potential observers should be evaluated by either the Ishihara test (the results should demonstrate normal colour vision) or the Farnsworth-Munsell 100 hue test (the results should demonstrate superior or average colour discrimination).

#### 5.2.2 Test for colour discrimination competency in dentistry

As an alternative to general tests and in order to be considered competent for colour matching in dentistry, an observer should have correctly assigned at least 60 %, 75 % and 85 % of the sample pairs presented in the test (see 5.1.3) for poor-, average-, and superior colour discrimination competency,

<sup>1)</sup> Vita Classical ® is a trade name of Vita Zahnfabrik, H Rauter GmbH & Co KG, Postfach 1338, D-79704 Bad Sackingen, Germany. This information is given for the convenience of the users of this International Standard and does not constitute an endorsement of this system by ISO.

respectively. At least 20 observers with superior- and average colour discrimination competency should participate in evaluation of perceptibility and acceptability visual judgments in dentistry, including at least 50 % of dental professionals. Quality control and other visual colour evaluations should be performed by at least three observers qualified as having superior colour discrimination competency according to 5.1.2 and 5.1.3.

#### 5.2.3 Testing intervals for qualified observers

The time interval between passing the tests for colour discrimination as described above and the observation activity should not exceed twelve months.

#### 6 Testing of acceptability and perceptibility thresholds

Visual assessments of perceptibility and acceptability are performed for research, quality control and related purposes. Perceptibility judgment studies typically consist of subjects answering the question "Can I see a difference in colour?" These judgments are associated with detecting just-perceptible differences and they do not involve any interpretation of their importance<sup>[4]</sup>. These differences are usually small compared to what would be considered acceptable colour difference in a given industry. The colour difference acceptability can be determined by asking an additional question "Is this difference in colour acceptable?" Therefore, colour tolerance for a certain product is the just-perceptible difference increased by a commercial or aesthetic factor<sup>[4]</sup>.

Both visual and instrumental evaluations are necessary to determine colour difference thresholds in dentistry and they should be performed in compatible settings. Perceptibility and acceptability visual judgments should be performed under both in-vitro conditions and in clinical conditions.

#### 6.1 Tissues and materials to be tested for perceptibility and acceptability thresholds

Hard dental tissues, gingiva and skin, and corresponding dental restorative materials should be tested in order to determine perceptibility and acceptability thresholds.

#### 6.2 Test methods

#### 6.2.1 Visual judgments

Devices and settings described in <u>Clause 4</u> should be used. Visual comparisons should be made in a viewing booth with non-booth lighting turned off, in (simulated) clinical setting, or both, depending on the goal of the study.

#### 6.2.2 Instrumental evaluation

Devices and settings described in <u>Clause 4</u> should be used.

#### 7 Application and interpretation

Interpretation of the results is based on the research performed under defined and controlled conditions and methods. The colour difference thresholds for tooth coloured restorative materials, established in a prospective multi-centre research project (research sites: USA, Spain, Japan, Germany, Brazil, Hungary and Saudi Arabia), should be used: 50:50 % perceptibility threshold (PT) of  $\Delta E^*_{ab} = 1,2$  and 50:50 % acceptability threshold (AT) of  $\Delta E^*_{ab} = 2,7$ [8]. These thresholds can be applied to all issues related to quality of tooth colour matching in dentistry.

#### 7.1 Colour compatibility

#### 7.1.1 Colour compatibility between dental material and human tissues

If the colour difference is at or below  $\Delta E^*_{ab}$  = 1,2, it represents a very good match; if this difference is between  $\Delta E^*_{ab}$  = 1,2 and  $\Delta E^*_{ab}$  = 2,7, it represents an acceptable match; if this difference is above  $\Delta E^*_{ab}$  = 2,7, it represents an unacceptable match.

#### 7.1.2 Colour compatibility between dental materials

If a colour difference between nominally equivalent shades of similar dental materials/shade tabs made by the same or a different manufacturer is at or below  $\Delta E^*_{ab} = 1,2$ , it represents a very good colour compatibility; if it is between  $\Delta E^*_{ab} = 1,2$  and  $\Delta E^*_{ab} = 2,7$ , it represents an acceptable compatibility; if it is greater than  $\Delta E^*_{ab} = 2,7$ , it represents an unacceptable colour compatibility.

#### 7.1.3 Coverage error of dental shade guides

If the coverage error of a dental shade guide is at or below  $E^*_{ab}=2,7$ , it represents an excellent product; if the coverage error is between  $E^*_{ab}=2,7$  and 4,7[9][10][11], it represents an acceptable product; if the coverage error is higher than  $E^*_{ab}=4,7$ , it represents an unacceptable product.

#### 7.2 Colour stability

#### 7.2.1 Colour stability during fabrication/at placement

If the colour difference during fabrication (firing, glazing, polymerization, or other types of preparation) or at placement is at or below  $\Delta E^*_{ab} = 1,2$ , it represents an excellent colour stability; if this difference is between the  $\Delta E^*_{ab} = 1,2$  and  $\Delta E^*_{ab} = 2,7$ , it represents an acceptable colour stability; if this difference is above  $\Delta E^*_{ab} = 2,7$ , it represents an unacceptable colour stability.

#### 7.2.2 Colour stability after aging and staining[12]

If the colour difference measured before and after aging or staining is at or below  $\Delta E^*_{ab} = 1,2$ , it represents an excellent match; if this difference is between  $\Delta E^*_{ab} = 1,2$  and  $\Delta E^*_{ab} = 2,7$ , it represents an acceptable match; if this difference is above  $\Delta E^*_{ab} = 2,7$ , it represents an unacceptable match.

#### 7.3 Colour interactions

#### 7.3.1 Colour shifting of aesthetic restorative materials [13][14]

Colour shifting of aesthetic restorative materials is the change in perceived colour that is a sum of the blending effect (not-measurable by any instrument, optical illusion) and the effect of physical translucency. For the purpose of this document and corresponding comparisons, the colour difference between two objects, one surrounded with another or in edge-contact, should be between  $\Delta E^*_{ab} = 2.0$  and  $\Delta E^*_{ab} = 5.0$ .

Visual assessment: Comparison of the grade of perceived colour difference between tested material surrounded by another material (dual shade specimens) ["S"], and visual grade when the same two materials are viewed in isolation (single shade specimens) ["I"]. The following 0-to-4 scale should be used for visual comparisons associated with colour shifting:

- 0 exact match/no difference in colour;
- 1 very good match/small difference;
- 2 good match/acceptable;
- 3 poor match/hardly acceptable;

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4 - mismatch/totally unacceptable.

If the decrease in grade "S" compared to grade "I" is up to 15 %, the material exhibits low colour shifting potential; if this decrease is 15 % to 25 %, the material exhibits moderate colour shifting potential; if the decrease is above 25 %, the material exhibits pronounced colour shifting potential.

Instrumental measurements: Comparison of the measured colour difference between tested material surrounded by another material (dual shade specimens) ["S"], and visual grade when these two materials are viewed in isolation (single shade specimens) ["I"]. If the decrease of colour difference "S" compared to colour difference "I" is up to 15 %, the material exhibits low colour shifting potential; if this decrease is 15 % to 25 %, the material exhibits moderate colour shifting potential; if the decrease is above 25 %, the material exhibits pronounced colour shifting potential.

#### 7.3.2 Masking potential of opaque materials

If the translucency parameter (colour difference between the same specimen measured against white and black background) of 1 mm-thick opaque composite resin[15] and 0,3 mm-thick opaque porcelain[16] [17] is at or below  $\Delta E^*_{ab} = 1,2$ , it represents an excellent masking potential; if this difference is between  $\Delta E^*_{ab} = 1,2$  and  $\Delta E^*_{ab} = 2,7$ , it represents an acceptable masking potential; if this difference is above  $\Delta E^*_{ab} = 2,7$ , it represents an unacceptable masking potential.

#### 8 Reporting of colour and colour difference assessment

When applicable, a report of a colour assessment should contain or refer to the following details.

#### 8.1 Illuminant

- a) type;
- b) manufacturer;
- c) spectral power distribution;
- d) correlated colour temperature;
- e) colour rendering index;
- f) illuminant geometry;
- g) illuminance.

#### 8.2 Object

- a) type of object (tooth, soft tissue, dental material);
- b) type of colouration (monochromatic or with colour transition);
- c) size;
- d) placement of standard and trial when comparing colour (side by side or other placement);
- e) standard distribution, usage, storage, maintenance, and replacement (shade guides and other standards).

#### 8.3 Observer/instrument

#### 8.3.1 Observer

a) number of observers:

- b) colour competency;
- c) viewing geometry;
- d) distance from object to detector or observer;
- e) visual angle of subtense of the object;
- f) colour of background and surround.

#### 8.3.2 Instrument

- a) type (spectrophotometer, spectroradiometer, colourimeter, imaging system);
- b) manufacturer;
- c) model number;
- d) instrument number;
- e) instrument accuracy and precision;
- f) measurement mode: reflectance or transmittance;
- g) specular and UV component included/excluded, and other measurement details;
- h) aperture size;
- i) lens position;
- j) optical geometry;
- k) illuminant(s) and standard observer;
- l) wavelength sampling (e.g. 5 nm, 10 nm) and wavelength range (e.g. 360 nm to 750 nm);
- m) calibration method and certification;
- n) colour-notation system and formula.

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