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Dentistry — Metallic materials for fixed and removable restorations and appliances

Médecine bucco-dentaire — Matériaux métalliques pour les restaurations fixes et amovibles et les appareils

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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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, *Prosthodontic materials],* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 55, *Dentistry,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This third edition cancels and replaces the second edition (ISO 22674:2016), which has been technically revised.

The main changes are as follows:

— addition of products produced using additive and subtractive manufacturing;

— revision of definitions and addition of new definitions for modern manufacturing techniques;

— addition of an overview of symbols in Clause 4 as Table 1;

— harmonization of symbols in formulae and Figures;

— static determination of elastic modulus was added in 8.4.1.3 (as an additional option);

— a requirement for a test report was added as Clause 9;

— a requirement for labelling the alloy composition on the package was added in 10.4.

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

Specific qualitative and quantitative requirements for freedom from biological hazard are not included in this document, but it is recommended that, in assessing possible biological hazards, reference be made to ISO 10993-1 and ISO 7405.

Requirements for the performance of metals and alloys used for the metallic component of a metal-ceramic restoration contained in this document supersede such requirements formerly contained in ISO 9693. The requirements for the performance of ceramic material and the metal-ceramic bond in metal-ceramic restorative systems are specified in ISO 9693.

Requirements for the proof stress and minimum elongation after fracture for Type 0 metallic materials are not included in this document, but it is recommended to adopt the test procedure given in Annex A when measuring these properties.

Dentistry — Metallic materials for fixed and removable restorations and appliances

1 Scope

This document specifies requirements and test methods for metallic materials that are suitable for the fabrication of dental restorations and appliances. Included are metallic materials recommended for use either with or without a ceramic veneer, or recommended for both uses. Furthermore, this document specifies requirements for packaging and marking of the products and for the instructions for use of these materials, including products delivered for sale to a third party.

This document does not apply to alloys for dental amalgam (see ISO 24234), dental brazing materials (see ISO 9333), or metallic materials for orthodontic appliances (e.g. wires, brackets, bands and screws).

This document is not applicable to magnetic attachment, which are specified in ISO 13017.

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 3696, *Water for analytical laboratory use — Specification and test methods*

ISO 5832-2, *Implants for surgery — Metallic materials — Part 2: Unalloyed titanium*

ISO 5832-3, *Implants for surgery — Metallic materials — Part 3: Wrought titanium 6-aluminium 4-vanadium alloy*

ISO 6344-3, *Coated abrasives — Determination and designation of grain size distribution — Part 3: Microgrit sizes P240 to P5000*

ISO 6892-1, *Metallic materials — Tensile testing — Part 1: Method of test at room temperature*

ISO 7500-1, *Metallic materials — Calibration and verification of static uniaxial testing machines — Part 1: Tension/compression testing machines — Calibration and verification of the force-measuring system*

ISO 9513, *Metallic materials — Calibration of extensometer systems used in uniaxial testing*

ISO 9693, *Dentistry — Compatibility testing for metal-ceramic and ceramic-ceramic systems*

ISO 10271:2020, *Dentistry — Corrosion test methods for metallic materials*

ISO 15223-1:2021, *Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements*

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 terminology databases for use in standardization at the following addresses:

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

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

3.1
additive manufacturing
process of joining materials to make parts from 3D model data, usually layer upon layer, as opposed to *subtractive manufacturing* (3.19) and formative manufacturing methodologies

[SOURCE: ISO/ASTM 52900:2021, 3.1.2, modified — Notes 1 and 2 to entry have been deleted.]

3.2
appliance
prefabricated metallic device such as attachments and bars

3.3
as-cast state
metallurgical condition of the *metallic material* (3.15) in its solid state when removed from the casting machine

Note 1 to entry: This condition is dependent upon the manufacturer's recommended cooling procedure (e.g. bench cooling).

3.4
base metal
metallic element, with the exception of *noble metals* (3.16) and silver

3.5
base-metal alloy
alloy having a *base metal* (3.4) as the principal element

3.6
bench-cooling
process whereby a casting is retained in its investment with exposed metal uppermost and placed on a flat, insulating surface at ambient temperature in freely circulating air until its temperature falls to ambient

3.7
casting alloy
metallic material (3.15) designed for casting into an investment mould

3.8
ceramic veneer
thin ceramic surface layer present on a *metallic material* (3.15) restoration to provide an aesthetic effect

3.9
elastic modulus
Young's modulus
ratio of elastic stress to elastic strain

3.10
hardening
heat-treatment of a *metallic material* (3.15) producing a condition which provides a higher 0,2 % proof stress than the *as-cast state* (3.3)

Note 1 to entry: If recommended by the manufacturer, explicit instructions are required in the instructions for use.

3.11
hazardous element
element that is known for its potential to produce an adverse biological effect

Note 1 to entry: The presence of such an element (as an alloying addition or as an impurity) in a dental alloy does not imply that the alloy, in itself, is hazardous.

3.12
heat treatment
thermal treatment of a *metallic material* (3.15) such as a material stress relieving process, including *softening* (3.18), *hardening* (3.10), ceramic firing

3.13
metal-ceramic restoration
dental restoration with a *ceramic veneer* (3.8) bonded to a *metallic material* (3.15) substructure by firing

Note 1 to entry: This can apply also to the metallic material used for such a restoration. In this context, metal-ceramic alloy is a synonym.

Note 2 to entry: If recommended, such a metallic material may be used without a ceramic veneer.

3.14
metallic base
metal with highest concentration by mass fraction in the alloy

3.15
metallic material
material with properties that are associated with an alloy, *noble metal* (3.16) or *base metal* (3.4)

Note 1 to entry: This may be a pure element, commercially pure metal or an alloy.

3.16
noble metal
metal containing gold, metal of the platinum group and/or rhenium

3.17
one-surface inlay
inlay restoration that is exposed to the oral environment on one and no more of the surfaces that are used to define the tooth for the purposes of charting

3.18
softening
heat-treatment of a *metallic material* (3.15) producing a condition which provides a lower 0,2 % proof stress than the *as-cast state* (3.3)

Note 1 to entry: If recommended by the manufacturer, explicit instructions are required in the instructions for use.

3.19
subtractive manufacturing
manufacturing process where a solid material such as milling blank is reduced by milling, grinding, eroding or similar techniques to the final shape

4 Symbols and classification

4.1 Symbols

Table 1 gives an overview about the symbols used in this document.

Table 1 — Symbols and their usage

Symbol	Description	Usage
$A_{15\,mm}$	percentage elongation after fracture	A.3.3, A.3.4
b	breadth	8.4.2.2, A.1.1, Clause B.2, B.2.1.1.1, B.4.1,C.3.2.1, C.3.2.2, Figures 3 and A.1, Formulae (3), (4), (5), (B.2), (B.5), (B.6) and (B.7), Tables 4 and 5
C_1	correction factor 1 for the elastic modulus	8.5.2, Formulae (2) and (3)
C_2	correction factor 2 for the shear modulus	8.5.3, Formulae (4) and (5)
D	minimum difference between two readings that the measuring instrument can discriminate	B.1, Formulae (B.1)
d	deflection	8.4.2.2, Formulae (3) and (6), Table 4
E	elastic modulus	B.2.1.2, B.3.1, B.4.2, Formulae (1), (3), (6), (B.1), (B.4), (B.5), (B.6), (B.7) and (C.1), Table 4
E_a	apparent elastic modulus	8.4.2.2, 8.4.2.3, C.3.2.2, C.3.2.3, Formula (C.1), Table 4
F	force	8.4.2.2, Table 4
F_5	force required to bring the lowest stressed part of the specimen to 5 % of material's $R_{P0,2}$	8.4.2.2
F_{60}	force required to bring the most highly stressed part of the specimen to 60 % of material's $R_{P0,2}$	8.4.2.2, Table 4
f_1	fundamental frequency measured in the flexural mode of vibration from acoustic measurement	8.5.2, B.4.2, B.4.3, Formulae (3), (B.7) and (B.8)
f_2	fundamental frequency measured for the torsional mode of vibration	8.5.3, B.4.2, B.4.3, Formulae (5), (B.7) and (B.8)
G	shear modulus	Formulae (5) and (6)
h	thickness (height)	8.4.2.2, 8.5.2, A.1.1, C.3.2.2, B.2.1.1.1, B.4.1, B.4.3, Figures 3 and A.1, Formulae (2), (3), (4), (5), (B.2), (B.5), (B.6), (B.7) and (B.8), Tables 4 and 5
h_1	greatest measured thickness	7.5.3, 7.5.4, Figure 4
h_2	least measured thickness	7.5.3, 7.5.4, Figure 4
l	length of specimen	8.5.2, B.4.1, B.4.2, B.4.3, A.1.1, Clause B.2, Figures 3, 6 and 7, Formulae (2), (3), (5), (B.7) and (B.8)
l_f	free length between grips	A.1.1, Figure A.1
l_g	initial gauge length	7.3, 8.4.1.2, A.3.4, Figures 1, 2 and A.1, Table 4
l_p	parallel length	7.3, Figures 1 and 2, Table 4
L_i	inner separation of load rollers	8.4.2.1.3, B.3.1, Figure 5, Formula (B.6), Table 4
L_o	outer separation of support load rollers	8.4.2.1.3, B.3.1, Figure 5, Formula (B.6), Table 4
m	mass	8.4.3.2, 8.5.2, B.4.1, Formulae (3), (5), (B.7)

Table 1 *(continued)*

Symbol	Description	Usage
n	number of individual readings	B.1, Formula (B.1)
q	mean of n individual readings	B.1, Formula (B.1)
q_i	value of the ith series of readings	B.1, Formula (B.1)
r	radius of specimen	B.2.1.1.2, Formula (B.3)
$R_{P0,2}$	proof stress of 0,2 % non-proportional extension	8.3.3.1, 8.4.2.2, A.3.1.3, A.3.3, A.3.4, Tables 3 and 4
S	cross-sectional area	7.5.2, 8.4.1.2, B.2.1.1.1, B.2.1.1.2, B.2.1.2, Formulae (1), (B.2), (B.3) and (B.4)
S_0	original cross-sectional area	A.3.3, A.3.4
$u(S)$	standard uncertainty in the measurement of cross-section	B.2.1.1.1, B.2.1.1.2, B.2.1.2, Formulae (B.2), (B.3) and (B.4)
$u(b)$	standard uncertainty in the measurement of breadth of specimen	B.2.1.1.1, B.3.1, Formulae (B.2), (B.5), (B.6) and (B.7)
$u(\mathrm{d})$	standard uncertainty in the measurement of Δd	B.3.1, Formulae (B.5) and (B.6)
$u(E)$	standard uncertainty in the measurement of elastic modulus	B.2.1.2, B.3.1, B.4.2, C.3.2.2, C.3.2.3, Formulae (B.4), (B.5), (B.6), (B.7), (B.8) and (C.1)
$u(F)$	standard uncertainty in the measurement of load force	B.2.1.2, B.3.1, Formulae (B.4), (B.5) and (B.6)
$u(f)$	standard uncertainty in frequency	B.4.1, B.4.2, B.4.3, Formulae (B.7) and (B.8)
$u(h)$	standard uncertainty in the measurement of thickness of specimen	B.2.1.1.1, B.3.1, Formulae (B.2), (B.5), (B.6), (B.7) and (B.8)
$u(l)$	standard uncertainty in the measurement of length of specimen	Formulae (B.7) and (B.8)
$u(L_o)$	standard uncertainty in the measurement of L_o	B.3.1, Formula (B.5)
$u(L_i)$	standard uncertainty in the measurement of L_i	B.3.1
$u(m)$	standard uncertainty in the measurement of mass	Formula (B.7)
$u(q)$	standard uncertainty in the measurement of q	B.1, Formula (B.1)
$u(r)$	standard uncertainty in the measurement of the radius of the specimen	B.2.1.1.2, Formula (B.3)
$u(v)$	combined standard uncertainty in Poisson's ratio	B.4.3, Formula (B.8)
$u(\Delta L)$	standard uncertainty in the measurements of ΔL	B.2.1.2, Formula (B.4)
v	Poisson's ratio	8.4.2.2, 8.5.1, B.4.3, C.3.2.3, Formulae (2), (6), (B.8), (C.1) and (C.2)
Δd	change in displacement of mid-point of specimen corresponding to the change ΔF in load force	B.3.1, Formulae (B.5) and (B.6)
ΔF	change in load force corresponding to the change in gauge length	8.4.1.2, B.2.1.2, B.3.1, Formulae (1), (B.4), (B.5) and (B.6)
Δh	separation of outer and inner reference planes	7.5.3, 7.5.4, Figure 4
ΔL	change in gauge length measured by the extensometer	8.4.1.2, B.2.1.2, Formulae (1) and (B.4)

4.2 Classification

For the purposes of this document, a metallic material is classified according to its mechanical properties by a Type number, of which there are six.

Examples of the applications for which these Types are intended are as follows:

— Type 0: intended for low stress bearing single-tooth fixed prostheses, for example, small veneered one-surface inlays, veneered crowns;

NOTE 1 Metallic materials for metal-ceramic crowns produced by electroforming or sintering belong to Type 0.

— Type 1: for low stress bearing single-tooth fixed prostheses, for example, veneered or unveneered one-surface inlays, veneered crowns;

— Type 2: for single tooth fixed prostheses, for example, crowns or inlays without restriction on the number of surfaces;

— Type 3: for multiple unit fixed prostheses;

— Type 4: for appliances with thin sections that are subject to very high forces, for example, removable partial dentures, clasps, thin veneered single crowns, full arch fixed dental prostheses or those with small cross-sections, bars, attachments, implant retained superstructures;

— Type 5: for appliances in which parts require the combination of high stiffness and proof stress, for example, thin removable partial dentures, parts with thin cross-sections, clasps.

NOTE 2 The higher application type can include lower application types.

NOTE 3 Multiple-unit and full-arch, fixed dental prostheses are also referred to as bridges.

5 Requirements

5.1 Chemical composition

5.1.1 Reported composition

For all elements that are present in excess of mass fraction of 1,0 %, each constituent element shall be declared by the manufacturer and shall be reported [see 10.1, a)] to a precision of a mass fraction of 0,1 %.

Any element that is present in excess of mass fraction of 0,1 %, and with a lower or equal mass fraction of 1,0 %, shall be identified [see 10.1 a)] either by name or symbol.

If the metallic material contains less than or equal to a mass fraction of 0,1 % of a specified element (other than one named in 5.2), it may be named as “free of" this specified element [see 10.1 p) and 10.4 j)].

If applicable, the name of the metallic base shall precede the words “-based metallic material for dental restoration” or “-based casting alloy” or “-based metal-ceramic material”, as is appropriate.

5.1.2 Permitted deviation from the reported composition for elements

The permitted deviation of the reported composition for elements from the value stated on the package or label or insert [see 10.1 a)] is given in Table 2.

Table 2 — Permitted deviation from the reported composition for elements

Alloy	Elemental content	
	1,0 % < w ≤ 20 %	w > 20 %
Base-metal alloy	maximum 1,0 %	maximum 2,0 %
Silver-based and noble metal alloy	maximum 0,5 %	maximum 0,5 %
Key w : mass fraction		

5.2 Hazardous elements

5.2.1 Hazardous elements

For the purposes of this document, the elements nickel, cadmium, beryllium and lead are designated to be hazardous elements.

5.2.2 Limits for the hazardous elements

The metallic material shall not contain more than a mass fraction of 0,02 % of beryllium, cadmium or lead.

Beryllium, cadmium or lead are neither alloying elements nor elements inherent to the manufacturing process of titanium metallic materials. Apply the requirements of chemical composition of ISO 5832-2 and ISO 5832-3 to titanium metallic materials; beryllium, cadmium or lead do not need to be analysed.

5.2.3 Nickel

5.2.3.1 Manufacturer's reported nickel content and permitted deviation

If the metallic material contains more than a mass fraction of 0,1 % of nickel, this content shall be given to an accuracy of mass fraction of 0,1 % in the literature which accompanies the package [see 10.1 n)] and on the package, label or insert [see 10.4 h)].

The mass fraction shall not exceed the value stated in 10.1 n) and 10.4 h).

5.2.3.2 Nickel-free products

For the purposes of this document, alloys with a maximum of mass fraction of 0,1 % nickel can be labelled “nickel free” [see 10.1 o) and 10.4 j)].

If nickel is not declared, it shall be limited to a maximum of 0,1 %. This limit shall be adhered to when nickel is a natural impurity in a component of the alloy.

5.3 Biocompatibility

Refer to the introduction for guidance on biocompatibility.

5.4 Mechanical properties

5.4.1 General

The mechanical properties (see Table 3) shall be met by the metallic material after the recommended processing techniques (e.g. casting, bench-cooling, machining, thermal treatment) and after the ceramic firing schedule (if appropriate) have been applied. A metallic material recommended for use either with or without a ceramic veneer shall meet this requirement in both metallurgical conditions.