INTERNATIONAL STANDARD

ISO
10271

Second edition
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Dentistry — Corrosion test methods for metallic materials

Médecine bucco-dentaire — Méthodes d'essai de corrosion des matériaux métalliques

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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.

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 10271 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 2, *Prosthodontic materials*.

This second edition cancels and replaces the first edition (ISO 10271:2001), which has been technically revised, in particular by the inclusion of two additional test methods. It also incorporates Technical Corrigendum ISO 10271:2001/Cor.1:2005.

Introduction

This International Standard was developed from the original Technical Report (ISO/TR 10271) as a result of worldwide demand for standard test methods to determine acceptability of metallic materials for oral restorations in relation to corrosion.

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

The testing of the corrosion behavior of metallic materials in dentistry is complicated by the diversity of the materials themselves, their applications and the environment to which they are exposed. Variation occurs between devices and within the same device during the exposure time. The type of corrosion behavior or effect can also vary with exposure time. Accordingly, it is not possible to specify a single test capable of covering all situations, nor is it a practical proposition to define a test for each situation. This International Standard, therefore, gives detailed procedures for test methods that have been found to be of merit as evidenced by considerable use.

This second edition differs from the first edition by the addition of two new test methods. To supplement the existing static immersion test, a static immersion test with periodic analysis has been added. A major reason for the addition of this test is that the rate of corrosion of most dental metallic materials varies over time. Thus, the aim of this supplementary test is to provide information on this variation in the corrosion of a dental metallic material. A classification scheme to interpret the rate of corrosion of a tested material with time (i.e. steady, decreasing, increasing) was not included as part of the static immersion test with periodic analysis. It is intended to monitor the use of the test through appropriate working groups of ISO/TC 106 to ascertain whether a classification scheme is needed in a future revision of this International Standard.

To supplement the sulfide tarnish test (cyclic immersion), a sulfide tarnish test (static immersion) has also been added to this second edition of ISO 10271. This test has been used successfully for many years to evaluate the corrosion of silver alloys.

In addition, an informative annex (Annex A) is provided that sets out a procedure for each element of the test system such that a consistent approach can be taken for the development of further test methods. Equally, it is recognized that any element can represent only the current recommendation, but changes in the future are unlikely to change the framework.

It is not the purpose of this International Standard to propose corrosion test methods for specific applications or to set limits as precise as those in the standard relating to the type of product and its application.

Dentistry — Corrosion test methods for metallic materials

1 Scope

This International Standard provides test methods and procedures to determine the corrosion behavior of metallic materials used in the oral cavity. It is intended that the test methods and procedures in this International Standard be referred to in the individual International Standards specifying such metallic materials.

This International Standard is not applicable to instruments and dental amalgam and appliances for orthodontics.

2 Normative references

The following referenced documents are indispensable for the application 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 1042, *Laboratory glassware — One-mark volumetric flasks*

ISO 1942, *Dentistry — Vocabulary*

ISO 3585, *Borosilicate glass 3.3 — Properties*

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

ISO 6344-1, *Coated abrasives — Grain size analysis — Part 1: Grain size distribution test*

ISO 7183, *Compressed-air dryers — Specifications and testing*

3 Terms and definitions

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

3.1
breakdown potential
E_p
least noble potential at which pitting or crevice corrosion, or both, initiates and propagates

3.2
corrosion
physicochemical interaction between a metallic material and its environment that results in a partial or total destruction of the material or in a change of its properties

3.3
corrosion potential
E_{corr}
open-circuit potential measured under either service conditions, or laboratory conditions that closely approximate service conditions

3.4
corrosion product
substance formed as a result of corrosion

3.5
crevice corrosion
corrosion associated with and taking place in or near a narrow aperture or crevice

3.6
current density
value of electric current per unit surface area flowing through a conductor

3.7
dynamic immersion test
test in which the sample is exposed to a corrosive solution under conditions of relative motion between sample and solution

3.8
electrode potential
potential difference between the sample and a reference electrode

3.9
electrolyte
solution or liquid that conducts an electrical current by means of ions

3.10
open-circuit potential
E_{ocp}
potential of an electrode measured with respect to a reference electrode or another electrode when no current flows

3.11
pitting corrosion
localized corrosion which results in pits

3.12
potentiodynamic test
test in which the electrode potential is varied at a preprogrammed rate and the relationship between current density and electrode potential is recorded

3.13
potentiostatic test
test in which the electrode potential is maintained constant

3.14
sample
totality of material for one type being tested, the group of all such specimens

3.15
set
subgroup of the specimens of a sample

3.16
specimen
individual single example of an object for testing

3.17
static immersion test
test in which the sample is exposed to a corrosive solution under conditions of effectively no relative motion between sample and solution

3.18
stress corrosion
corrosion resulting from the combined action of static tensile stress and an electrolyte

3.19
synthetic saliva
test medium that simulates the chemistry of natural saliva

3.20
tarnish
surface discoloration due to the chemical reaction between a metallic material and its environment

3.21
zero-current potential
potential at which cathodic and anodic currents are equal

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4   Test methods

4.1   Static immersion test

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4.1.1   Information required
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Composition, including hazardous elements, in accordance with the appropriate ISO standard is required.

4.1.2   Application

This is an accelerated test that is intended to provide quantitative data on the metallic ion released from metallic materials under in vitro conditions relevant to those expected in the oral cavity.

4.1.3   Reagents

4.1.3.1   **Lactic acid** ($C_3H_6O_3$), 90 %, analytical grade.

4.1.3.2   **Sodium chloride** (NaCl), analytical grade.

4.1.3.3   **Water**, complying with grade 2 of ISO 3696.

4.1.3.4   **Ethanol** or **methanol** (C_2H_5OH or CH_3OH), analytical grade.

4.1.3.5   **Compressed air**, oil- and water-free, complying with ISO 7183.

4.1.4   Apparatus

4.1.4.1   **Containers**, of borosilicate glass, complying with ISO 3585 and with dimensions of approximately 16 mm inner diameter by 160 mm in height.

4.1.4.2   **pH meter**, with a sensitivity of at least ±0,05 pH units.

4.1.4.3   **Chemical analysis instrumentation**, capable of measuring ion concentration in µg/ml (e.g. ICP and AAS).

4.1.4.4   **Micrometer gauge**, accurate to 0,01 mm.

4.1.4.5   **Silicon carbide paper**, complying with ISO 6344-1.

4.1.4.6   **Volumetric flasks**, of borosilicate glass, 1 000 ml, class A, complying with ISO 1042.

4.1.5   Solution preparation

Prepare an aqueous solution comprising 0,1 mol/l lactic acid and 0,1 mol/l sodium chloride immediately before use. For example, dissolve $(10,0 \pm 0,1)$ g 90 % $C_3H_6O_3$ (4.1.3.1) and $(5,85 \pm 0,005)$ g NaCl (4.1.3.2) in approximately 300 ml of water (4.1.3.3). Transfer into a 1 000 ml volumetric flask (4.1.4.6) and fill to mark. The pH shall be $2,3 \pm 0,1$. If not, the solution shall be discarded and reagents checked.

4.1.6   Samples

4.1.6.1   Fabrication

4.1.6.1.1   Cast

Specimens shall be cast in accordance with the manufacturer's recommendations.

4.1.6.1.2   Prefabricated

Prefabricated parts/devices shall be used in the as-received condition.

4.1.6.1.3   Other

Specimens prepared by other methods, e.g. machined, sintered, eroded, etc., shall be tested in the as-manufactured condition after suitable cleaning.

4.1.6.2   Sampling

The number of specimens shall be sufficient to provide at least two parallel sets. (The number of specimens in a set may vary.)

4.1.6.3   Sample surface area

The total surface area of the sample shall be at least 10 cm^2 after preparation.

4.1.6.4   Preparation

4.1.6.4.1   Cast samples

Remove any sprues, runners or other projections from surface. Blast surfaces with 125 µm pure alumina to remove investment.

If recommended, heat-treat according to the manufacturer's instructions.

In the case of metal-ceramic materials, heat-treat for 10 min at the highest firing temperature recommended by the metallic material manufacturer and bench cool.

Remove at least 0,1 mm, measured using a measuring instrument [e.g. micrometer gauge (4.1.4.4)], from each surface using standard metallographic procedures unless specimens are being tested in the as-received

condition. Use fresh abrasive paper for each metallic material. Finish with P1200 wet silicon carbide paper (4.1.4.5). If the described procedure is not applicable, treat the surfaces according to the manufacturer's instructions for clinical use.

Determine each sample surface area to the nearest 1 %.

Clean surfaces ultrasonically for 2 min in ethanol or methanol (4.1.3.4). Rinse with water (4.1.3.3). Dry with oil- and water-free compressed air (4.1.3.5).

If a specimen contains any porosity visible on the surfaces being exposed to the solution, the specimen shall be rejected and replaced with a new one.

4.1.6.4.2   Machined, sintered, eroded or electroformed samples

Heat-treat the specimens if recommended.

Remove at least 0,1 mm, measured using a measuring instrument [e.g. micrometer gauge (4.1.4.4)], from each surface using standard metallographic procedures unless specimens are being tested in the as-received condition. Use fresh abrasive paper for each metallic material. Finish with P1200 wet silicon carbide paper (4.1.4.5).

Determine each sample surface area to within ±0,1 cm^2.

Clean surfaces ultrasonically for 2 min in ethanol or methanol (4.1.3.4).

Rinse with water (4.1.3.3). Dry with oil- and water-free compressed air (4.1.3.5).

4.1.6.4.3   Prefabricated parts/devices

Treat the surfaces according to the manufacturer's instructions for clinical use.

Determine each sample surface area to within ±0,1 cm^2.

Clean the surfaces ultrasonically for 2 min in ethanol or methanol (4.1.3.4).

Rinse with water (4.1.3.3). Dry with oil- and water-free compressed air (4.1.3.5).

4.1.7   Test procedure

Parallel specimen sets shall be treated in identical fashion. If a set consists of one specimen, it shall be placed in a container (4.1.4.1) such that it does not touch the container surface except in a minimum support line or point. If a set consists of two or more specimens, they may be placed in the same or a number of separate containers, but if more than one is placed in a container they shall not touch.

Record the pH of the solution. Add the solution to each container sufficient to produce a ratio of 1 ml of solution per 1 cm^2 of sample surface area. The specimens shall be covered completely by the solution. Record the volume of solution to an accuracy of 0,1 ml. Close the container to prevent evaporation of the solution. Maintain at (37 ± 1) °C for 7 d $\pm$ 1 h. Remove the specimens and record the pH of the residual solution.

Use an additional container (4.1.4.1) to hold a reference solution to be maintained in parallel with the solutions containing the specimens. The reference solution shall be used to establish the impurity level for each element of interest in the solution. Add approximately the same volume of solution as used for the solutions containing the specimens and record the volume to an accuracy of 0,1 ml. Close the container to prevent evaporation of the solution and maintain at (37 ± 1) °C for the same time period as the solutions containing the specimens.

4.1.8 Elemental analysis

Use chemical analysis instrumentation (4.1.4.3) of adequate sensitivity. Analyze the solution qualitatively and quantitatively. Emphasis shall be on those elements indicated in 4.1.1, but if impurities are found in a concentration greater than 0,1 %, they shall also be reported. For each element of interest, subtract the value obtained for the element in the reference solution from the value obtained in the test solution. The elements boron, carbon, and nitrogen shall be disregarded.

4.1.9 Test report

The test report shall contain the following information.

a) Report the method of analysis and detection limits of all the analyzed elements.

b) Report and justify any deviations from preparation of specimens (see 4.1.6.4) or test procedure (see 4.1.7).

c) Report the number of specimens making up a set and the number of sets tested (see 4.1.6.2).

d) From the elemental analysis of the corrosion solution (see 4.1.8), calculate and report the ion release for each element of each set (see 4.1.6.2) separately in $\mu g/cm^2/7$ d. The elements indicated in 4.1.1 shall be reported as well as any others found. From this information, sum the ion release values for all the elements of each set to obtain the total metal ion release for the dental material. Average the results by dividing by the number of sets tested and report as the average total ion release for the dental material in $\mu g/cm^2/7$ d.

e) Report undissolved corrosion product like precipitates and discoloration of the specimen surface.

4.2 Electrochemical test

4.2.1 Information required

Composition, including hazardous elements, in accordance with the appropriate material standard is required.

4.2.2 Application

This test is intended to assess the corrosion susceptibility of metallic materials used in the oral cavity using potentiodynamic polarization.

4.2.3 Reagents

4.2.3.1 **Lactic acid** ($C_3H_6O_3$), 90 %, chemically pure.

4.2.3.2 **Sodium chloride** (NaCl), analytical grade.

4.2.3.3 **Sodium hydroxide** (NaOH), analytical grade.

4.2.3.4 **Water**, complying with grade 2 of ISO 3696.

4.2.3.5 **Argon** or **nitrogen gas**, with a minimum purity of 99,99 %.

4.2.3.6 **Ethanol** or **methanol** (C_2H_5OH or CH_3OH), analytical grade.

4.2.3.7 **Acetone** (C_3H_6O), analytical grade.