BRITISH STANDARD

BS EN ISO 21530:2004

Dentistry — Materials used for dental equipment surfaces — Determination of resistance to chemical disinfectants

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ICS 11.060.20

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National foreword

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The UK participation in its preparation was entrusted by Technical Committee CH/106, Dentistry, to Subcommittee CH/106/6, Dental equipment, which has the responsibility to:

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Summary of pages

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Dentistry - Materials used for dental equipment surfaces - Determination of resistance to chemical disinfectants (ISO 21530:2004)

Art dentaire - Matériaux utilisés pour les surfaces du matériel dentaire - Détermination de la résistance aux désinfectants chimiques (ISO 21530:2004)

Zahnheilkunde - Materialien für Oberflächen von zahnärztlichen Ausrüstungen - Bestimmung der Beständigkeit gegen chemische Desinfektionsmittel (ISO 21530:2004)

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Foreword

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This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by December 2004, and conflicting national standards shall be withdrawn at the latest by December 2004.

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INTERNATIONAL STANDARD

ISO 21530

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Dentistry — Materials used for dental equipment surfaces — Determination of resistance to chemical disinfectants

Art dentaire — Matériaux utilisés pour les surfaces du matériel dentaire — Détermination de la résistance aux désinfectants chimiques

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Foreword

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ISO 21530 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 6, *Dental equipment*.

Introduction

All materials used for external and touchable surfaces of dental equipment which can be contaminated by aerosols, splatters and droplets in normal use should be capable of undergoing disinfection without deterioration or discoloration when using the relevant disinfectant agent recommended by the manufacturer of the dental equipment.

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Dentistry — Materials used for dental equipment surfaces — Determination of resistance to chemical disinfectants

1 Scope

This International Standard specifies test methods for determining the resistance to chemical disinfectants of all materials used for external surfaces of dental equipment intended for such disinfection.

Three test methods are specified: an immersion test, a spray test and a contact test. The choice of test method to be used is left to the discretion of the party conducting the testing.

This International Standard does not address the bactericidal, virucidal and fungicidal effectivity of the disinfectants.

This International Standard does not provide for testing the possible detrimental effects of applied stress on the resistance of test materials to the test reagents.

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 554, *Standard atmospheres for conditioning and/or testing — Specifications*

ISO 1942, *Dentistry — Vocabulary*

ISO 2812-1, *Paints and varnishes — Determination of resistance to liquids — Part 1: General methods*

ISO 3585, *Borosilicate glass 3.3 — Properties*

ISO 3696:1987, *Water for analytical laboratory use — Specification and test methods*

3 Terms and definitions

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

4 Sampling

All tests described in this International Standard are type tests.

As far as possible, carry out all tests on a representative test specimen of the material from the dental equipment. Where possible, use flat slabs as test specimens. One of the following options shall be used.

a) Use new parts of dental equipment.

b) If this is not possible, use standard exemplars and test specimens made of semi-finished products (e.g. slabs, plates, or round material).

c) Test specimens can also be made by splitting the original parts or semi-finished products (e.g. by cutting or sawing), if the resulting new edges and surfaces of the test specimens are expected to have comparable properties to the original surfaces. The area of the resulting new edges and surfaces should be protected; new surface areas should be a small proportion of the test specimens.

All test specimens should be free from dirt and grease.

5 Test methods

5.1 General

One or more of the three test methods described in 5.4, 5.5 and 5.6 shall be used. The party conducting the testing shall determine which test method(s) shall be used.

5.2 Preconditioning of test specimens

After preparing the test specimens for the intended use, testing shall be carried out under the following conditions:

a) ambient temperature of (23 ± 2) °C, according to ISO 554;

b) atmospheric humidity of (50 ± 5) %, according to ISO 554;

c) air pressure between 860 hPa and 1 060 hPa (between 645 mmHg and 795 mmHg), according to ISO 554.

5.3 Preparation of test agent

Prepare the test agent according to the instructions for use provided by the manufacturer of the disinfectant agent. Annex A gives an overview of commercially used disinfectants.

Surface disinfectants to be used as test agents shall not have passed their expiry date.

Test agents made from concentrates and water shall be prepared in chemically inert containers. Water, in accordance with grade 3 of ISO 3696:1987, shall be used to prepare aqueous solutions of the disinfectants.

5.4 Immersion test

5.4.1 Principle

Testing shall be performed as described in ISO 2812-1.

During the immersion test, one test specimen shall be totally immersed into the test agent and one test specimen shall be partially immersed (approximately 50 % of surface area) into the test agent. At least three tests are required (parallel testing of all test specimens is possible). For the evaluation, one additional test specimen shall be used as a reference specimen. Record the changes in mass of the test specimens.

All data (initial data, interim data and final data) shall be recorded.

5.4.2 Reagents

Use the following reagents for conducting the test.

5.4.2.1 Test agent, prepared in accordance with 5.3.

5.4.2.2 Water, complying with grade 3 of ISO 3696:1987.

5.4.3 Apparatus

Use the following apparatus for conducting the test.

5.4.3.1 Containers.

5.4.3.2 Absorbent pad.

5.4.3.3 Laboratory balance, with a reading accuracy of ± 0,01 % of the mass of the specimens.

5.4.4 Preparation and conditioning of test samples

5.4.4.1 Test specimen

All test specimens shall be single parts. At least seven test specimens are necessary.

Two test specimens are used in each test (one specimen is totally immersed and one specimen is partially immersed). Because at least three tests are required, six test specimens are necessary. For the evaluation, one additional test specimen is required as a reference specimen.

Prepare the test specimens in accordance with Clause 4. Precondition the test specimens in accordance with 5.2.

Using the balance (5.4.3.3), weigh each test specimen to be used for total immersion, and record the initial mass before the test. When test specimens are small, multiple test specimens may be weighed to achieve the specified accuracy. If multiple specimens are weighed together, the replicate testing shall be conducted using the multiple specimens for each test in accordance with 5.4.5.

Measure or calculate the area of the test surfaces.

Inspect all specimens for surface defects before testing, and discard defective specimen(s).

5.4.4.2 Reference specimen

Prepare the reference specimen in the same way as the test specimens.

5.4.4.3 Container

Use two containers for each test. One container is used for storing the totally immersed test specimen, the other container is used for storing the partially immersed test specimen.

If parallel testing is carried out, six containers are required.

Depending on the test agent, chemically inert containers, such as borosilicate glass containers complying with ISO 3585, shall be used.

5.4.5 Procedure

5.4.5.1 Total immersion

Place each test specimen in a container. Then add the test agent until all test specimens are completely covered with the test agent. Close the containers tightly and maintain at (23 ± 2) °C.

5.4.5.2 Partial immersion

Place each test specimen in a container. Then add the test agent until approximately 50 % of the surfaces of all test specimens are covered with the test agent. Close the containers tightly and maintain at (23 ± 2) °C.

5.4.5.3 Time period

The time period for the immersion test is 14 days ± 2 h.

5.4.5.4 Replacement of test agent

Replace the test agent with a freshly prepared test agent every day except weekends. Document and report in the test report any deviation from this schedule.

5.4.6 Inspection

5.4.6.1 General schedule

Assess the condition of the test specimens at one interim inspection and one final inspection.

Assess the condition of the totally immersed test specimens by visual, tactile and gravimetric testing.

Assess the condition of the partially immersed test specimens by visual and tactile inspection of the following three areas of the test specimens:

a) immersed area;

b) non-immersed area;

c) border area between immersed and non-immersed areas.

5.4.6.2 Interim inspection

Perform the interim inspection after 7 days ± 2 h as follows.

Remove the test specimens from the test agent. Immediately after removal, rinse the test specimens with freshly prepared test agent and rinse finally with water (5.4.2.2).

Place the test specimens on an absorbent pad and dry the test specimens with unheated air. After 15 min, carry out visual inspection of the test specimens according to 6.2 and tactile inspection according to 6.3, and compare them with the reference specimens for any changes (e.g. discoloration, bubbles, changes in dimension).

For totally immersed test specimens, determine and record the mass of each specimen.

For partially immersed test specimens, inspect the three surfaces specified in 5.4.6.1 separately, according to 6.3.

Continue the immersion test after the interim inspection, using freshly prepared test agent.

5.4.6.3 Final inspection

Perform the final inspection after 14 days ± 2 h.

Remove the test specimens from the test agent. Immediately after removal, rinse the test specimens with freshly prepared test agent and rinse finally with water (5.4.2.2).

Place the test specimens on an absorbent pad and dry the test specimens with unheated air. After 15 min, carry out visual inspection of the test specimens according to 6.2 and tactile inspection according to 6.3, and compare them with the reference specimen for any changes (e.g. discoloration, bubbles, changes in dimension).

For totally immersed test specimens, determine and record the mass of each specimen.

Perform final inspection of the test specimens in accordance with Clause 6.

In particular, record any difference observed between the immersed and non-immersed parts of the test specimens.

Store the test specimens for (24 ± 2) h at (23 ± 2) °C. Then repeat the visual inspection and the gravimetric evaluation. Finally perform a tactile test to check if the test specimens are sticky.

Prepare a written test report in accordance with Clause 7.

5.4.7 Expression of results

Determine and record the mass of the test specimens. Determine the mass change, in milligrams per square millimetre, before, during and after the immersion period, and record the mass change as a percent of the initial test mass.

5.5 Spray test

5.5.1 Principle

The spray test is performed by repeated spraying of the test specimens with the test agent. At least three tests are required (parallel testing of all test specimens is possible). For the evaluation, one additional test specimen shall be used as a reference specimen.

All data (initial data, interim data and final data) shall be recorded.

5.5.2 Reagents

Use the following reagents for conducting the test.

5.5.2.1 Test agent, prepared in accordance with 5.3.

5.5.2.2 Water, complying with grade 3 of ISO 3696:1987.

5.5.3 Apparatus

Use the following apparatus for conducting the test. All parts of the test apparatus in contact with the test agent shall be made from inert materials.

5.5.3.1 Closed cupboard, of suitable size, fitted with ventilation equipment.

5.5.3.2 Spraying device.

5.5.4 Preparation and conditioning of test samples

5.5.4.1 Test specimens

All test specimens shall be single parts or a combination of single parts. At least four test specimens are necessary.

One test specimen is used in each test. Because at least three tests are required, three test specimens are necessary. For the evaluation, one additional test specimen is required as a reference specimen.

Prepare the test specimens in accordance with Clause 4. Precondition the test specimens in accordance with 5.2.

5.5.4.2 Reference specimen

Prepare the reference specimen in the same way as the test specimens.

5.5.5 Procedure

5.5.5.1 General

For conducting the test, use a closed cupboard system with ventilation equipment, following laboratory procedures to protect the laboratory personnel. Spray the test specimens by automated (mechanical) spraying or by manual spraying.

Place the test specimens in the test arrangement in such a way that the test agent can drain away.

Provisions should be made to prevent excess spray from contacting other test specimens.

5.5.5.2 Spray procedure

Carry out one test cycle of the spray procedure as follows.

Spray the test specimens with the test agent until it is completely moistened. Check the time required for complete moistening (e.g. by visual inspection). Then wait the following time period:

a) for alcoholic test agents, at least 15 min;

b) for aqueous test agents, at least 30 min.

Begin the next test cycle. Perform a total of 250 test cycles.

Between test cycles it is not permitted to rinse or wipe (e.g. with tissues) the test specimens.

Document and report any deviation from this schedule.

5.5.6 Inspection

5.5.6.1 General procedure

The condition of the test specimens is assessed at one interim inspection and one final inspection.

Both visual and tactile inspections shall be carried out.

5.5.6.2 Interim inspection

Perform the interim inspection after 150 test cycles.

Rinse the test specimens with water (5.5.2.2), maintaining the test specimens at (23 ± 2) °C. Let the specimens dry at this temperature. After (24 ± 2) h, inspect the dry test specimens visually and compare them with the reference specimen for changes (e.g. discoloration, distortion) in accordance with Clause 6.

If the test specimens show no effect of the test agent, continue the spray test immediately after the interim inspection.

5.5.6.3 Final inspection

Perform the final inspection after 250 test cycles.

Rinse the test specimens with water (5.5.2.2), maintaining the test specimens at (23 ± 2) °C. Let the specimens dry at this temperature. After (24 ± 2) h, inspect the dry test specimens visually and compare them with the reference specimen for changes (e.g. discoloration, distortion).

Perform a final inspection of the test specimens in accordance with Clause 6.

Perform visual inspection and a tactile test for stickiness of the test surfaces.

Prepare a written test report in accordance with Clause 7.

5.6 Contact test

5.6.1 Principle

The contact test shall be performed by placing an absorbent pad, which is completely soaked with the test agent, on the test specimens. At least three tests are required (parallel testing of all test specimens is possible). For the evaluation, one additional test specimen shall be used as a reference specimen.

All data (initial data, interim data and final data) shall be recorded.

5.6.2 Reagents

Use the following reagents for conducting the test.

5.6.2.1 Test agent, prepared in accordance with 5.3.

5.6.2.2 Water, complying with grade 3 of ISO 3696:1987.

5.6.3 Apparatus

Use the following apparatus for performing the test.

5.6.3.1 Absorbent pad (e.g. parts from cellulose strips, cotton pads, or similar material).

5.6.3.2 Sealing material (e.g. polyethylene foil or glass covers).

5.6.4 Preparation and conditioning of test samples

5.6.4.1 Test specimens

Test specimens shall be single parts or a combination of single parts. At least four test specimens are necessary.

One test specimen is used in each test. Because at least three tests are required, three test specimens are necessary. For the evaluation, one additional specimen is required as a reference specimen.

Prepare the test specimens in accordance with Clause 4. Precondition the test specimens in accordance with 5.2.

5.6.4.2 Reference specimen

Prepare the reference specimen in the same way as the test specimens.

5.6.5 Procedure

Place an absorbent pad soaked with the test agent onto the test specimen so that approximately 50 % of its surface is covered. Cover the test area with a sealing material to prevent premature evaporation.

The time period for the contact test is 14 days $\pm$ 2 h.

Replace the absorbent pad with a new, freshly prepared absorbent pad every day except weekends. Document and report in the test report any deviation from this schedule.

5.6.6 Inspection

5.6.6.1 General schedule

The condition of the test specimens is assessed at one interim inspection and one final inspection.

The condition of the test specimens shall be assessed by visual and tactile testing.

5.6.6.2 Interim inspection

Perform an interim inspection after 7 days $\pm$ 2 h.

Remove the absorbent pad from the test specimens. Immediately after removal, rinse the test specimens with freshly prepared test agent and rinse finally with water (5.6.2.2).

Place the test specimens on an absorbent pad and dry the test specimens with unheated air. After (24 ± 2) h, carry out visual inspection of the test specimens according to 6.2 and tactile inspection according to 6.3, and compare them with the reference specimen for changes (e.g. discoloration, bubbles, changes in dimension).

Continue the contact test after the interim inspection with freshly prepared test agent.

5.6.6.3 Final inspection

Perform the final inspection (24 ± 2) h after the end of the test (14 days $\pm$ 2 h).

After the test, rinse the test specimen with water (5.6.2.2). Keep the test specimens at (23 ± 2) °C. After (24 ± 2) h, inspect the dry test specimens visually and compare them with the reference specimen for changes (e.g. discoloration, distortion).

Perform final inspection of the test specimens in accordance with Clause 6.

Prepare a written test report in accordance with Clause 7.

6 Inspection and evaluation criteria

6.1 General

All test specimens shall be inspected by one examiner and a test report shall be completed. Evaluation of the resistance of the surface is based on the sum of all observed criteria.

6.2 Visual inspection

6.2.1 General

Visual inspection shall be carried out at normal visual acuity without magnification. The light conditions shall be bright, diffuse daylight without direct sunlight on the test specimens.

6.2.2 Evaluation criteria for visual inspection

Evaluation criteria for visual inspection are observation of visible changes in

a) surface structure,

b) surface colour,

c) surface shine.

6.3 Tactile inspection

6.3.1 General

Tactile inspection shall be carried out using a finger or suitable probe.

6.3.2 Evaluation criteria for tactile inspection

Evaluation criteria for tactile inspection are perceptible changes in the characteristics of

a) surface texture,

b) surface tackiness,

c) surface hardness.

7 Test report

The test report shall include at least the following information:

a) all details necessary to identify the test specimens;

b) all details necessary to identify the test agents;

c) reference to this International Standard, i.e. ISO 21530;

d) reference to the test method(s) used;

e) any circumstances or conditions thought likely to affect the results or their validity;

f) any deviation from the test method specified;

g) name of the responsible person and the testing laboratory;

h) all details necessary to identify the person who carried out the test and the examiner;

i) dates of the test period;

j) observations of the examiner;

k) date of test report and signature of responsible person.

Annex A
(informative)

Overview of chemical disinfectant solutions

A.1 General

The following solutions are examples of chemical disinfectants commonly used in the dental office.

NOTE Regulatory requirements in some countries do not allow use of all of the listed chemical disinfection solutions.

A.2 Ready-for-use alcoholic preparations

a) **Mass fraction of alcohol** $>$ 50 % **and** $<$ 90 %

b) **Mass fraction of alcohol** $<$ 90 % **and with additional active substances**

Additional active substances may be as follows:

1) aldehydes;

2) higher alcohols;

3) quaternery ammonium compounds;

4) phenol derivates;

5) biguanides (e.g. chlorhexidine, parahexamethylene biguanide);

6) acids;

7) alkalis;

8) others.

A.3 Aqueous concentrates

Aqueous concentrates may contain the following substances:

a) aldehydes;

b) oxidizing substances;

c) phenols;

d) halogenides;

e) quaternery ammonium compounds;

f) acids;

g) alkalis;

h) others.

Bibliography

[1] ISO 6875, *Dental patient chair*

[2] ISO 7493, *Dental operator's stool*

[3] ISO 7494, *Dental units*

[4] ISO 9680, *Dental operating light*

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