
**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*

iTeh STANDARD PREVIEW
(standards.iteh.ai)

ISO 21530:2004

<https://standards.iteh.ai/catalog/standards/sist/08aa4085-93c6-43b9-a1df-c808c9a2dd47/iso-21530-2004>



PDF disclaimer

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

ISO 21530:2004

<https://standards.iteh.ai/catalog/standards/sist/08aa4085-93c6-43b9-a1df-c808c9a2dd47/iso-21530-2004>

© ISO 2004

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Contents

	Page
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Sampling	1
5 Test methods	2
5.1 General	2
5.2 Preconditioning of test specimens	2
5.3 Preparation of test agent	2
5.4 Immersion test	2
5.5 Spray test	5
5.6 Contact test	7
6 Inspection and evaluation criteria	9
6.1 General	9
6.2 Visual inspection	9
6.3 Tactile inspection	9
7 Test report	9
Annex A (informative) Overview of chemical disinfectant solutions	11
Bibliography	12

ITeh STANDARD PREVIEW
 (standards.iteh.ai)
 ISO 21530:2004
<https://standards.iteh.ai/catalog/standards/sist/08aa4085-93c6-43b9-a1df-c808c9a2dd47/iso-21530-2004>

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

iTeh STANDARD PREVIEW (standards.iteh.ai)

ISO 21530:2004

<https://standards.iteh.ai/catalog/standards/sist/08aa4085-93c6-43b9-a1df-c808c9a2dd47/iso-21530-2004>

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.

iTeh STANDARD PREVIEW (standards.iteh.ai)

[ISO 21530:2004](https://standards.iteh.ai/catalog/standards/sist/08aa4085-93c6-43b9-a1df-c808c9a2dd47/iso-21530-2004)

<https://standards.iteh.ai/catalog/standards/sist/08aa4085-93c6-43b9-a1df-c808c9a2dd47/iso-21530-2004>

iTeh STANDARD PREVIEW
(standards.iteh.ai)

ISO 21530:2004

<https://standards.iteh.ai/catalog/standards/sist/08aa4085-93c6-43b9-a1df-c808c9a2dd47/iso-21530-2004>

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.

iTeh STANDARD PREVIEW

2 Normative references (standards.iteh.ai)

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. standards.iteh.ai/catalog/standards/sist/08aa4085-93c6-43b9-a1df-c808c9a2dd47/iso-21530-2004

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 $\pm 0,01$ % 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.

iTeh STANDARD PREVIEW

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.

<https://standards.iteh.ai/catalog/standards/sist/08aa4085-93c6-43b9-a1df-iso-21530-2004>

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 $(23 \pm 2) ^\circ\text{C}$.

5.4.5.3 Time period

The time period for the immersion test is 14 days \pm 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.

STANDARD PREVIEW
(standards.iteh.ai)
ISO 21530:2004
<https://standards.iteh.ai/catalog/standards/sist/08aa4085-93c6-43b9-a1df-c808c9a2dd47/iso-21530-2004>

5.4.6.2 Interim inspection

Perform the interim inspection after 7 days \pm 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 \pm 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.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

5.5 Spray test

ISO 21530:2004

5.5.1 Principle <https://standards.iteh.ai/catalog/standards/sist/08aa4085-93c6-43b9-a1df-c808c9a2dd47/iso-21530-2004>

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.