TECHNICAL SPECIFICATION

ISO/TS 11080

First edition
2009-06-01

Dentistry — Essential characteristics of test methods for the evaluation of treatment methods intended to improve or maintain the microbiological quality of dental unit procedural water

Art dentaire — Caractéristiques essentielles des méthodes d'essai pour l'évaluation des méthodes de traitement pour améliorer ou maintenir la qualité microbiologique de l'eau procédurale de l'unit dentaire

iTeh STANDARD PREVIEW
(standards.iteh.ai)
ISO/TS 11080:2009
https://standards.iteh.ai/catalog/standards/sist/abaf6c1a-f11f-4376-aaf1-154c84c43949/iso-ts-11080-2009

Reference number
ISO/TS 11080:2009(E)

© ISO 2009

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/TS 11080:2009
https://standards.iteh.ai/catalog/standards/sist/abaf6c1a-f11f-4376-aaf1-154c84c43949/iso-ts-11080-2009

COPYRIGHT PROTECTED DOCUMENT

© ISO 2009

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

 © ISO 2009 – All rights reserved

Contents

Page

iTeh STANDARD PREVIEW
(standards.iteh.ai)
ISO/TS 11080:2009
https://standards.iteh.ai/catalog/standards/sist/abaf6c1a-f11f-4376-aaf1-154c84c43949/iso-ts-11080-2009

© ISO 2009 – All rights reserved

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.

In other circumstances, particularly when there is an urgent market requirement for such documents, a technical committee may decide to publish other types of normative document:

— an ISO Publicly Available Specification (ISO/PAS) represents an agreement between technical experts in an ISO working group and is accepted for publication if it is approved by more than 50 % of the members of the parent committee casting a vote;

— an ISO Technical Specification (ISO/TS) represents an agreement between the members of a technical committee and is accepted for publication if it is approved by 2/3 of the members of the committee casting a vote.

iTeh STANDARD PREVIEW
(standards.iteh.ai)
ISO/TS 11080:2009
https://standards.iteh.ai/catalog/standards/sist/abaf6c1a-f11f-4376-aaf1-154c84c43949/iso-ts-11080-2009

An ISO/PAS or ISO/TS is reviewed after three years in order to decide whether it will be confirmed for a further three years, revised to become an International Standard, or withdrawn. If the ISO/PAS or ISO/TS is confirmed, it is reviewed again after a further three years, at which time it must either be transformed into an International Standard or be withdrawn.

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/TS 11080 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 6, *Dental equipment*.

© ISO 2009 – All rights reserved

Dentistry — Essential characteristics of test methods for the evaluation of treatment methods intended to improve or maintain the microbiological quality of dental unit procedural water

1 Scope

This Technical Specification provides guidelines for type test methods for evaluating the effectiveness of treatment methods intended to improve or maintain the microbiological quality of procedural water from dental units and other dental equipment under laboratory conditions.

It does not establish specific upper limits for microbial contamination or describe test methods to be used in clinical situations.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

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/TS 11080:2009
https://standards.iteh.ai/catalog/standards/sist/abaf6c1a-f11f-4376-aaf1-154c84c43949/iso-ts-11080-2009

ISO 1942, *Dentistry — Vocabulary*

ISO 7494-1, *Dentistry — Dental units — Part 1: General requirements and test methods*

ISO 7494-2, *Dentistry — Dental units — Part 2: Water and air supply*

ISO 19458, *Water quality — Sampling for microbiological analysis*

IEC 60601-1, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1, ISO 1942, ISO 7494-1 and ISO 7494-2 and the following apply. Two of the terms taken from other documents are reproduced below for convenience and the sake of clarity.

3.1
biofilm
structured community of microorganisms inhabiting a self-developed extracellular biopolymeric matrix attached to a surface

© ISO 2009 – All rights reserved

3.2
dental unit
combination of interconnected dental equipment and dental instruments constituting a functional assembly for use in the provision of dental treatment

[ISO 1942:—, definition 2.86]

3.3
procedural water
water supplied by the dental unit for use in the oral cavity

EXAMPLE Handpiece coolant water, syringe water, scaler coolant water or rinse cup water.

[ISO 7494-2:2003, definition 3.1]

4 Dental unit water treatment methods

Technical approaches for improving or maintaining the microbiological quality of dental unit procedural water, which are currently available, include, but need not be limited to:

— dental units with automatic or passive water treatment devices and/or antimicrobial materials;

— independent water bottles with intermittent or continuous chemical treatment.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

The test method used to evaluate a treatment method shall be specified with consideration for the technical approach of the method. Depending upon the specific technical approach of a treatment method and its intended benefits, the test method shall evaluate one or both of the following aspects:

ISO/TS 11080:2009
https://standards.iteh.ai/catalog/standards/sist/abaf6c1a-f11f-4376-aaf1-154e84e435d5/iso-ts-11080-2009

— removal of biofilm from surfaces within the dental unit water delivery system;

— prevention or inhibition of biofilm formation on surfaces within the dental unit water delivery system.

Separate test method characteristics are specified in Clause 5 for each of the above performance metrics.

5 Test methods

5.1 General

Test methods shall replicate the conditions of use and the technical approach specified by the manufacturer of the dental unit or waterline treatment product.

The test apparatus should preferably consist of dental units. As an alternative, surrogate systems, which closely replicate the dental unit water system, may be used as the test apparatus. Test apparatus design and operation characteristics are specified in Clause 6.

Initial validation testing shall be performed under controlled laboratory conditions and not in clinical settings.

Test methods shall include untreated controls.

Since there is inherent variation in biofilm formation, testing should be replicated on separate dental units or surrogate waterline systems. Test methods shall specify the number of test replicates to be included in the test group and control group. At least two units shall be included in the test group and at least one unit shall be included in the control group.

© ISO 2009 – All rights reserved

5.2 Test methods for evaluating biofilm removal

5.2.1 General

Test methods for evaluating treatment methods that are intended to remove dental waterline biofilms shall include the following steps.

5.2.2 Biofilm formation and characterization

A biofilm shall be established in the test apparatus in a manner consistent with biofilms occurring in typical clinical situations. The method for establishing a biofilm in the test apparatus shall be able to be replicated by independent evaluators.

The preferred method for generating a biofilm in the test apparatus consists of conditioning the test apparatus by flowing a microbiological challenge suspension through the test apparatus for a period sufficient to establish a reproducible biofilm.

Test apparatus design and operation characteristics are specified in Clause 6.

Microbiological challenge characteristics are specified in 7.1 and 7.2.2.

Chemical characteristics of the water used in the biofilm formation shall be consistent with the specifications in Clause 8.

The presence of an established biofilm shall be verified using the methods specified in Clause 9. Colony counts in the effluent water from the test apparatus should be consistent with those found in typical clinical situations: 10^4 CFU/ml to 10^6 CFU/ml.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

5.2.3 Application of the treatment method

ISO/TS 11080:2009
https://standards.iteh.ai/catalog/standards/sist/abaf6c1a-f11f-4376-aaf1-154c84e43949/iso-ts-11080-2009

The treatment method for removal of the established biofilm shall be administered in accordance with the instructions of the manufacturer of the dental unit or waterline treatment product (except for the untreated control group).

Chemical characteristics of the water used in the application of the treatment method shall be consistent with the specifications in Clause 8.

5.2.4 Microbiological sampling and testing

To determine the effectiveness of the treatment method, microbiological sampling and testing of both the treated and untreated controls shall be performed in accordance with Clause 9.

Consideration shall be given to specify the most appropriate time to sample after administering the treatment. If flushing with procedural water or another solution is specified by the manufacturer, this shall be performed before sampling and testing.

5.2.5 Analysis of results

The effectiveness of the treatment method to remove biofilm shall be evaluated against criteria defined prior to testing. The criteria should include at least specifications for a maximum allowable level of bacteria counts in the effluent water from the treated test group and a minimum level of bacteria counts in the effluent water of the control group. Preferably, criteria which more directly indicate whether biofilm has been removed should also be specified.

© ISO 2009 – All rights reserved

5.3 Test methods for evaluating biofilm prevention or inhibition

5.3.1 General

Test methods for evaluating treatment methods that are intended to inhibit or prevent biofilm formation shall include the following steps.

Test apparatus design and operation characteristics are specified in Clause 6.

5.3.2 Pretreatment of the test apparatus

The test apparatus shall be pretreated according to the instructions of the manufacturer of the dental unit or waterline treatment product prior to testing.

5.3.3 Concurrent exposure to microbiological challenge and the treatment method

A microbiological challenge suspension with a bacterial colony count level that is consistent with the type of procedural water source recommended by the manufacturer shall be administered to the test apparatus concurrently with the treatment method.

Characteristics of the microbiological challenge shall be consistent with the specifications in 7.1 and 7.2.3.

Chemical characteristics of the water used shall be consistent with the specifications in Clause 8.

Controls, which are exposed to the microbiological challenge but not the treatment method, shall be included.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

The duration of the period of concurrent exposure to microbiological challenge and the treatment method shall be specified. The duration may be specified as a fixed period of time. Alternatively, the duration may be specified based on the observed time required for the control group to achieve a specified condition. The duration of the exposure period should be at least sufficient to establish biofilm in the control group consistent with biofilms occurring in typical clinical situations: 10^4 CFU/ml to 10^6 CFU/ml in the effluent procedural water.

ISO/TS 11080:2009
https://standards.iteh.ai/catalog/standards/sist/aaafbc1a-f11f-4376-aaf1-154c84c43949/iso-ts-11080-2009

5.3.4 Microbiological sampling and testing

To determine the effectiveness of the treatment method, microbiological sampling and testing of both the treated test group and untreated controls shall be performed in accordance with Clause 9.

Microbiological sampling and testing shall be conducted at multiple time intervals to demonstrate that the test group prevents or inhibits biofilm formation for a period after the control group develops biofilm.

A method shall be specified to verify that a biofilm becomes established in the control group. Colony counts in the effluent water from the test apparatus may be used as an indicator that a biofilm is established in the control group, provided that the bacterial concentration in the effluent water is at least 100 × greater than that of the challenge suspension. Alternatively, sterile water or solution may be temporarily introduced to the test apparatus instead of the microbial challenge suspension. The colony counts in the control group effluent water should be at least two logarithmic orders greater than the water or solution supplied to the test apparatus and consistent with colony counts found in typical clinical situations: 10^4 CFU/ml to 10^6 CFU/ml.

5.3.5 Analysis of results

The effectiveness of the treatment method to prevent or inhibit biofilm shall be evaluated against criteria defined prior to testing. Examples of test criteria may include, but are not limited to, the following:

— a specified log reduction of bacteria counts in the effluent water of the test group versus the control group;

— a maximum allowable level of bacteria counts in the effluent water from the treated test group after a specified period and a specified minimum level of bacteria counts in the effluent water of the control group after the same period to verify that biofilm has formed in the control group.

© ISO 2009 – All rights reserved

6 Test apparatus design and operation

6.1 Test apparatus design

The characteristics of the test apparatus design shall be specified and include (if applicable):

- test apparatus configuration, including a schematic diagram (preferably, actual dental unit water system of dental unit with all relevant water bearing components);
- tubing diameter;
- tubing length;
- tubing composition;
- description of other components (control blocks, valves, dead legs etc.);
- location of water treatment devices (filters, automatic or passive treatment systems);
- apparatus used to prepare and/or administer microbiological challenge suspension, treatment solutions, water or other fluids to the test apparatus.

6.2 Test apparatus operation

The following operational parameters shall be specified:

iTeh STANDARD PREVIEW
(standards.iteh.ai)
ISO/TS 11080:2009
https://standards.iteh.ai/catalog/standards/sist/abaf6c1a-f11f-4376-aafl-154c84c43949/iso-ts-11080-2009

- flow rates;
- flow patterns (on-off cycles);
- schedule for administration of test chemicals or operation of treatment device;
- schedule for collection of samples;
- test environment temperature and preconditioning period.

Operational parameters shall be monitored and recorded periodically according to a specified schedule.

7 Microbiological challenge

7.1 Microbiological consortium

A reproducible microbiological challenge suspension shall be specified. A prepared microbiological challenge suspension containing a reproducible consortium of selected microorganisms of known origin and concentration may be used, provided that the selected species are among those commonly isolated from dental unit procedural water.

7.2 Microbiological characteristics

7.2.1 General information

Different microbiological challenges may be specified for biofilm removal test methods versus biofilm prevention or inhibition methods. A higher level of bacteria, organic matter and/or growth media will be generally preferable for biofilm removal test methods to more quickly condition the test apparatus. A lower bacteria level and little or no organic matter or growth media may be appropriate for test methods evaluating biofilm prevention or inhibition to more closely represent use conditions and manufacturer's instructions.

© ISO 2009 – All rights reserved