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Dentistry — Mixing machines for dental amalgam

Médecine bucco-dentaire — Mélangeurs pour amalgame dentaire

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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 on 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 the following URL: www.iso.org/iso/foreword.html.

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

This second edition cancels and replaces the first edition (ISO 7488:1991), which has been technically revised.

The main changes compared to the previous edition are as follows:

— clarification of the scope;

— deletion of the classification (according to frequency);

— addition of the requirements for the maximum sound pressure level in 4.3;

— addition of measurement and test methods;

Introduction

The mixing performance requirement in this document is based on the concept of coherence time. This arises because it is not possible to define precisely just what constitutes a “clinically usable” mix, this being a subjective and vague value judgment. It is to be noted that the readily identifiable stage in the mixing process designated coherence is an intermediate stage and is an indication that satisfactory mixing is occurring. A “clinically usable” amalgam mix or other material mix cannot be obtained unless coherence is first achieved. A “clinically usable” mix generally requires mixing further to that required for coherence.

The scope is intended in due course to include machines for mixing material other than dental amalgam, such as cements. However, the relevant information is not yet to be available, and all mixing related references in this document are in respect of dental amalgam. The scope will be extended to include capsulated cements as soon as suitable data become available and consequential additions will be included in the requirements and test methods.

Dentistry — Mixing machines for dental amalgam

1 Scope

This document specifies requirements for electrically-powered mixing machines for mixing dental amalgam alloy, and dental mercury in capsules to produce dental amalgam.

This document specifies the test methods used to determine conformity with these requirements.

This document refers to those machines that mix by an oscillating action and which are sold by the manufacturer for the purpose of mixing dental amalgam whether or not they are intended for mixing any other type of product.

This document does not specify requirements for removable mixing-capsules, as are used in many machines to contain the material to be mixed, although considered as part of the machine when in use or under test.

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*

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

IEC 61671-1:2013, *Electroacoustics — Sound level meters — Part 1: Specifications*

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 terminological databases for use in standardization at the following addresses:

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

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

3.1
coherence
<dental amalgam> condition of the powder and liquid having been combined into a single mass

Note 1 to entry: Small cracks or a dry-looking surface do not detract from coherence.

3.2
coherence time
<dental amalgam> time taken for mixing all powder and liquid to achieve coherence

Note 1 to entry: The mix produced for the purposes of this definition is not necessarily mixed to the degree necessary for clinical use.

3.3
length to amplitude ratio
ratio of *mixing-capsule working length* (3.5) to *mixing-capsule amplitude* (3.4) of its motion

Note 1 to entry: Length to amplitude ratio is the principal (non-monotonic) determinant of the efficiency of the mixing process.

3.4
mixing-capsule amplitude
range of movement of the midpoint of the mixing capsule while running measured in the direction of the *mixing-capsule working length* (3.5)

3.5
mixing-capsule working length
maximum internal dimension of the mixing capsule lying parallel to the direction of the oscillatory motion

3.6
mixing machine for dental amalgam
electrically-powered devices for mixing by an oscillating action dental amalgam alloy and dental mercury in capsules to produce dental amalgam

3.7
power rating
cube of oscillation frequency, expressed in hertz, multiplied by the square of the *mixing-capsule amplitude* (3.4), expressed in metres

Note 1 to entry: Power rating is proportional to the maximum power available for the mixing process, but is not in itself a measure or determinant of efficiency or efficacy.

Note 2 to entry: See Formula (1). Power rating is expressed in mW/g.

4 Requirements

4.1 Safety

4.1.1 Electrical

The mixing machine for dental amalgam shall be in accordance with the relevant clauses of IEC 60601-1.

4.1.2 Mechanical

The mixing machine for dental amalgam shall have an enclosure that will contain a mixing-capsule, its contents or a machine part that may become dislodged or broken during use.

Movable components with which the user may normally be expected to come into contact shall be free from rough or sharp edges and corners.

Test in accordance with 6.2.

4.2 Stability

The mixing machine for dental amalgam shall not visibly move across the glass surface while running for the maximum running duration, t_{max} (6.1.5), using the maximum charge mass, m_{max} (6.1.4) at any frequency setting.

Test in accordance with 6.1 and 6.2.

4.3 Sound pressure

The acoustic power output of the mixing machine for dental amalgam shall not exceed 70 dB(A).

Test in accordance with 6.3.

4.4 Frequency

4.4.1 General

The frequency of operation of the mixing machine shall not vary by more than 0,5 Hz at any frequency setting during any run of duration t_{max} (6.1.5) for that setting when subjected individually to each of the following:

a) supply voltage variation of ±5 % of the rated voltage, or if a supply voltage range is given, variation of the voltage over the stated range, using the reference charge mass, m_{ref} (6.1.2);

b) variation of the charge mass, using the minimum and maximum charge, m_{min} (6.1.3) and m_{max} (6.1.4);

c) three immediately successive mixing operations, using the reference charge mass, m_{ref} (6.1.2);

d) variation of the ambient temperature over the range 18 °C to 28 °C, using the reference charge mass, m_{ref} (6.1.2).

Test in accordance with 6.4.1.

4.4.2 Variable-power machines

At any frequency or power setting, variable-power machines shall operate within 5 % of the indicated frequency, if given, with a reproducibility of ±0,5 Hz, and shall also conform to the requirements of 4.4.1 at each setting.

Test in accordance with 6.4.1.3.

4.5 Amplitude

The mixing-capsule amplitude shall remain stable to ±1 mm while the machine is running for the maximum duration, t_{max} (6.1.5) and using the reference charge mass, m_{ref} (6.1.2).

Test in accordance with 6.1 and 6.6.

4.6 Mixing time

4.6.1 Timing device

Machines shall include a timing device to allow selection and control of the duration of mixing.

4.6.2 Timing settings

The timing device may be continuously variable or provide settings in steps not greater than 5 % of the indicated maximum but which shall not in any case exceed 1 s.

The intervals produced shall be accurate to ±5 % of the nominal value of the setting or ±0,5 s, whichever is the larger and be reproducible within ±2 % of the actual value of the setting or ±0,2 s, whichever is the larger.

These requirements shall also apply when subjected individually to both:

a) temperature variation in the range 18 °C to 28 °C.

b) supply voltage variation of ±5 % at the rated voltage, or if a supply voltage range is given, variation of the voltage over the stated range.

Test in accordance with 6.7.

4.7 Coherence time

When using any of the manufacturer's recommended mixing-capsules and using materials in accordance with 6.8.1.3, the coherence time shall not be more than the manufacturer recommends for mixing.

Test in accordance with 6.8.

4.8 Long-term test

Mixing machines shall comply with the requirements of 4.1 to 4.6 after 5 000 cycles of operation under the conditions given in 6.1 and 6.9. The mixing-capsule amplitude shall not differ from the reference value (6.6) by more than ±1,0 mm.

Test in accordance with 6.9.

5 Sampling

5.1 Mixing machine

At least one mixing machine shall be evaluated for its conformity with this document.

5.2 Mixing-capsules

5.2.1 General

The mixing-capsules to be used as part of the mixing machine shall be produced for retail and be in accordance with the manufacturer's recommendations, if any, or at the discretion of the testing authority in accordance with 5.2.2.

5.2.2 Mixing-capsule selection

5.2.2.1 Principle

To select mixing-capsules for testing coherence time when two or more capsules are recommended by the manufacturer.

NOTE The efficiency of the mixing process is strongly dependent on the length to amplitude ratio; values of that ratio less than 0,4 and greater than 1,6 have a greater likelihood of performing unsatisfactorily.

5.2.2.2 Procedure

For each mixing-capsule recommended by the manufacturer determine the working length of the capsule. A cylinder of wax, such as dental base plate wax, may be used to form an impression of the internal end faces of the capsule. Any suitable gauging or measuring apparatus may be employed for the determination of the working length to ±0,1 mm.

Determine the mixing-capsule amplitude. Calculate the length to amplitude ratio.

5.2.2.3 Selection criteria

Those mixing-capsules having respectively the highest and the lowest values of the length: amplitude ratio shall be selected for testing coherence time. In the event of a tie or ties at either or both limits,

the lightest mixing-capsule shall be selected at the highest length: amplitude ratio, and the heaviest mixing-capsule at the lowest length: amplitude ratio.

5.3 Test components

Materials to be tested shall satisfy the requirements of the appropriate ISO standard. Product names, descriptions and batch numbers shall be recorded.

6 Measurement and test methods

6.1 Test conditions

6.1.1 General

Unless otherwise specified the following conditions shall apply.

The mixing-machine shall be tested at an ambient temperature of (23 ± 5) °C and shall have in position any mixing-capsule recommended by the manufacturer containing only a charge of any fine grain dental amalgam alloy powder. A pestle shall be included when recommended by the manufacturer of the dental amalgam alloy or a normal component of the capsule (5.2.2). The mixing-machine shall be placed upon a rigidly supported, smooth, flat, horizontal glass surface, using any of the bases or supports recommended by the manufacturer, if any.

Operational limitations as specified by the manufacturer shall be recognized.

The individual test conditions are specified, to be used as required.

6.1.2 Reference charge mass, m_{ref}

The mixing-capsule shall contain (600,0 ± 2,5) mg of dental amalgam alloy powder.

NOTE This mass corresponds to what is generally termed “double spill”.

6.1.3 Minimum charge mass, m_{min}

The mixing-capsule shall contain a mass of dental amalgam alloy powder equal to the mass of the minimum charge stated by the manufacturer, if any, within ±2,5 mg, or else (400,0 ± 2,5) mg.

NOTE This mass corresponds to what is generally termed “single spill”.

6.1.4 Maximum charge mass, m_{max}

The mixing-capsule shall contain a mass of dental amalgam alloy powder equal to the mass of the maximum charge stated by the manufacturer, if any, within ±2,5 mg, or else (800,0 ± 2,5) mg.

NOTE This mass corresponds to what is generally termed “triple spill”.

6.1.5 Maximum running duration, t_{max}

The mixing machine shall be run for the maximum duration permitted by timer setting, or the maximum duration recommended by the manufacturer, at any frequency setting, if stated.

6.1.6 Power supply conditions and apparatus

6.1.6.1 Autotransformer, or any other suitable means of providing a variable voltage power supply with a setting resolution of ±1 % of the voltage to be supplied or better.

Attention shall be paid to maintain an adequate earth connection to the machine under test.