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Dentistry — Mixing machines for dental amalgam

Médecine bucco-dentaire — Mélangeurs pour amalgame dentaire

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Foreword

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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.

6.1.6.2 Digital a.c. voltmeter, with a resolution of 1 Vac and an accuracy of ±0,5 % of reading or better at the frequency of the power supply. True r.m.s. value shall be displayed.

6.1.6.3 Electronic counter-timer, with a resolution of 0,1 Hz and a time-base accuracy of 0,01 s or better.

Noise suppression equipment may be necessary to avoid spuriously high frequency readings.

6.1.7 Equipment setup

The power supply shall be adjusted to ±1 % of the rated voltage of the machine or if a supply voltage range is given, then control shall be to ±1 % of the midpoint of the stated range, or to ±1 % of the nominal test voltage as appropriate.

The frequency of the power supply shall be deemed to be controlled to within ±0,1 Hz of the nominal frequency.

The power supply frequency and voltage shall be monitored during frequency, timer and coherence time tests.

A deviation of supply frequency or voltage during the course of a test greater than permitted in this clause, which deviation is associated with a test result which would cause the machine under test to fail to meet the relevant requirements, shall permit that test result to be discarded and a repeat determination to be made.

6.2 Visual inspection

Visual inspection shall be used in determining conformity with 4.1.2, 4.2, and appropriate provisions of Clauses 7, 8, and 9.

6.3 Sound pressure

The mixing machine shall be tested in accordance with 6.1 using the maximum running duration, t_{max} (6.1.5).

6.3.1 Apparatus and setup

The machine shall be tested in a room or chamber such that the free-field radius about the centroid of the locus or mid-point of limits of motion of the mixing-capsule midpoint in three dimensions shall be not less than 0,50 m.

All test points shall be at (0,45 ± 0,01) m from the centroid of the locus of the mixing-capsule.

Appropriate acoustically absorbent materials may be employed to achieve the above free-field condition, attention being paid in particular to the glass surface (6.1.1) exposed around the machine under test which should be covered if of excessive area but by no more than a 5 mm thickness of sound absorbent material and to within no less than 200 mm of the machine at any point. The bench or other support of the glass surface should be non-resonant. The ambient sound pressure level shall be less than 45 dB (A).

Free-field' conditions shall be interpreted as follows: At the point of interest, the sound pressure level of reverberant sound shall be at least –10 dB (A) with respect to the sound pressure at that point due to direct sound. This is equivalent to a maximum error of +0,4 dB (A) in the observed reading of the direct sound pressure level.

A precision sound pressure level meter shall be used and be in accordance with IEC 61671-1:2013, Type 1, and provide a measurement of sound pressure level in dB(A) with the Impulse or I characteristic.

6.3.2 Procedure

The sound pressure level shall be monitored for a minimum of 10 s at a series of positions so as first to determine the direction of maximum sound intensity. The noise of the action of the timer switch or starting mechanism shall be ignored at both start and finish of operation.

A continuous chart recording of the sound pressure level may be found convenient, providing that the recorder response is faster than that of the sound pressure level meter.

Sufficient points shall be monitored to detect any directionality in sound emission.

A suitable initial scheme would consist of 6 observations at 60° intervals in the horizontal plane containing the mixing-capsule locus centroid and 4 observations at 90° intervals in the horizontal plane 870 mm above the centroid. Additional points should be monitored as required. Points below the level of the glass surface will not, in general, require monitoring, but points on, or near, the level of that surface may do so.

The direction of maximum intensity shall then be monitored for t_{max} (6.1.5) after a recovery period of not less than 15 min and not more than 30 min.

6.3.3 Variable-power machines

The initial testing shall be performed at the lowest power setting. The direction of maximum sound pressure level shall then be used to monitor the sound pressure level as the power is varied.

For machines having discrete settings, each setting shall be monitored in accordance with 6.3.1 and 6.3.2. For machines having continuously variable settings, the control shall be operated manually, so as to provide a continuous sweep at a near constant rate of rotation or travel of the control, and so as to cover the range of power provided in not less than 30 s. Multiple operations with overlapping sweep ranges shall be permitted.

6.4 Frequency tests

Prior to the start of frequency tests in accordance with 4.4, and for each variation of ambient temperature for testing purposes, the mixing-machine shall not be operated for a minimum of two hours (to allow equilibration with the changed ambient temperature).

6.4.1 Measurement of mixing-capsule oscillation frequency

6.4.1.1 Apparatus

Any suitable "non-contact" means of determining oscillation frequency may be employed.

Calibrated stroboscopic illumination is most convenient in this respect, but care needs to be taken to avoid false determinations at sub-multiple frequencies.

6.4.1.2 Procedure for fixed frequency mixing-machines

The frequency first determined under conditions stated in 6.1 using m_{ref} (6.1.2) shall be taken as the reference value for all other frequency tests. The first second of running shall be excluded for measurement purposes in all tests. Testing shall use mixing-capsules with the minimum and maximum charge, m_{min} (6.1.3) and m_{max} (6.1.4), for each type of mixing-capsule tested.

The test shall be carried out three times. The average of three determinations shall establish the frequency.

6.4.1.3 Procedure for variable-power mixing-machines

Normally, only three points in the range shall be tested, the two extremes and one setting close to the mid-point of the frequency range.

A total of five determinations at each point shall be made in alternatively ascending and descending sequence, *i.e.* in the order 1, 2, 3, 3, 2, 1, and such as to approach the set point from alternating directions where the device permits, repeated to the total required number of determinations.

In the case of continuously variable controls, the extremes of the range shall be interpreted as the extreme points which are calibrated or bear index marks. The limits of travel of the control shall not be employed unless they are so calibrated.

The mean of the five determinations rounded to the nearest 0,1 Hz shall be taken as indicating the actual value at each setting. The accuracy is determined by the difference between the actual and nominal values of the setting.

Conformity with the reproducibility requirement is determined by comparison of each recorded value, rounded to the nearest 0,1 Hz, with the limits stated (4.4.2) referred to the indicated value of the setting.

6.5 Working length

6.5.1 Principle

The range of movement of the mixture inside the mixing-capsule controls mixing efficacy and can be determined by taking a suitable moulding.

6.5.2 Apparatus

6.5.2.1 Material for forming an impression of the end walls of the mixing-capsule, such as dental baseplate wax.

6.5.2.2 Measuring device to determine the length of the impression of the inside of the mixing-capsule, e.g. vernier caliper gauge.

6.5.3 Procedure

A suitably-sized length of the impression material (e.g. a cylindrical roll of wax) is inserted into the opened, empty mixing-capsule, which is then reassembled into its normal working condition such that the impression material is compressed between the ends, allowing a short time for relaxation.

On retrieving the moulded material, the greatest dimension parallel to the mixing-capsule's axis is determined using the measuring device to ±0,1 mm.

6.6 Amplitude

6.6.1 Apparatus

6.6.1.1 Lamp providing strong continuous illumination, e.g. tungsten filament lamp.

6.6.1.2 Measuring device to determine the distance between the end points of the mixing-capsule motion, e.g. vernier caliper gauge, cathetometer, or calibrated photographic system.

6.6.2 Procedure

Mark the approximate mid-point of the mixing-capsule in its normal working configuration, viewed in a direction perpendicular to the measured working length and the plane of oscillation. The mark

should be visible clearly when the machine is running under strong illumination (6.6.1.1). White paint is generally useful.

Mount the mixing-capsule containing the specified charge mass so that the mark is at the mean radius of movement or otherwise such as to obtain a measurement of amplitude as given in 4.5.

Start the mixing-machine and under strong illumination (6.6.1.1), determine the distance between the extremes of the motion of the centre of the mark, which distance shall be taken as the reference value for the amplitude test of 4.5.

The first second of running shall be excluded for measurement purposes in all tests.

6.7 Mixing time

6.7.1 Apparatus

6.7.1.1 Timer, accurate to 0,02 s.

6.7.2 Procedure

Evaluate the accuracy and reproducibility of the timer at four points, these being at 10 %, 40 %, 70 % and 100 % of the timer's range. If these exact points are not present on the device use those numbers closest to these percentages.

If the timing system has no clear or relevant upper limit, then that maximum time shall be taken as 60 s.

Make a total of five determinations at each of the four settings in alternately ascending and descending sequences approaching the set point from different directions where possible.

Take the mean of the five determinations rounded to the nearest 0,1 s as indicating the actual value at each setting. Determine the accuracy by the difference between the actual and nominal values of the setting recorded value with the limits stated (4.6.2) referred to the actual value of the setting rounded to the nearest 0,1 s.

6.8 Coherence time

6.8.1 Apparatus and materials

6.8.1.1 Analytical balance, with a resolution of, and accurate to, 0,1 mg.

6.8.1.2 Electrical time switch, with a range of 60 s or at least as long as the longest adjustable mixing time of the mixing machine, whichever is the greater, with a setting resolution of 1 s or better and an accuracy of 0,02 s where this is not supplied as part of the mixing-machine.

6.8.1.3 Dental amalgam alloy and dental mercury, conforming to the requirements of the appropriate ISO standard.

6.8.2 Procedure

6.8.2.1 Setting-up

If the mixing-machine timer meets the requirement of 4.6.2, further control is not necessary. If the mixing-machine's timer does not meet that requirement, it shall be activated prior to the commencement of the operation of the electrical time switch (6.8.1.2) having first set a time on the mixing-machine's timer conveniently greater than the mixing duration of the test then being conducted. The time stated by the manufacturer of the dental amalgam alloy shall be used for the test.

The electrical time switch (6.8.1.2), if used, shall be installed to control the supply of power to the machine. This timer would initiate the mixing process on the mixing-machine the timer of which is over-ridden (e.g. by the use of adhesive tape).

6.8.2.2 Determination of coherence time

Use the following procedure:

Step 1: Prepare the mixing-capsule charge based on the manufacturer's instructions.

Step 2: Mount the mixing-capsule on the mixing-machine and set the machine in operation for a predetermined period.

Step 3: Repeat step 1 and step 2 using successively longer or shorter mixing times so as to determine the minimum time required to produce a cohering pellet of the material.

The coherence time shall be determined to the nearest second or 5 % of the estimated coherence time, whichever is the larger.

A pestle shall be included if recommended, and as specified by, the manufacturer of the dental amalgam alloy or a normal component of the capsule (5.2.2).

6.9 Long-term test

Calculate the power rating, P, as shown in Formula (1):

$$P = f^3 A^2 \tag{1}$$

where

P is the power rating, expressed in mW/g;

f is the oscillation frequency, expressed in hertz (Hz = s^{-1});

A is the mixing-capsule amplitude, expressed in metres.

NOTE 1 The units stated are due to the dimensional equivalence:

W/kg = (J·s^{-1})/kg = (N·m)/(kg·s) = (kg·m·s^{-2}·m)/(kg·s) = m^2·s^{-3}

and Hz = s^{-1}.

NOTE 2 The units stated are also due to the scaling appropriate to the nature of the system in dentistry.

The mixing machine shall be tested with a duty cycle selected in accordance with power rating range from the following, for a total of 5 000 cycles:

10 mW/g to 30 mW/g: on for 20 s; off for 60 s minimum;

greater than 30 mW/g and up to 100 mW/g: on for 10 s; off for 60 s minimum;

greater than 100 mW/g : on for 5 s; off for 60 s minimum.

The off-period shall not in any case exceed 3 min, except as required for inspection or maintenance.

Where more than one power rating range of operation is claimed the 5 000 cycles shall be divided equally (or nearly so) between the categories.

The mixing-capsule shall contain the reference mass, m_{ref} (6.1.2).

