INTERNATIONAL STANDARD

ISO 7488

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Dental amalgamators

Amalgamateurs dentaires

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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.

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.

International Standard ISO 7488 was prepared by Technical Committee ISO/TC 106, *Dentistry*.

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Introduction

Electrically powered amalgamators are machines used primarily for mixing (trituration) of amalgam alloys and mercury to produce dental amalgams but they may also be used for mixing other dental materials.

In many amalgamators a removable capsule is used to contain the alloy and mercury. Although the capsule must be considered as part of the amalgamator when in use or under test, the requirements for capsules are not dealt with in this International Standard; they may be the subject of a separate Standard.

Some amalgamators may incorporate a mechanism for dispensing the alloy or mercury or both. These devices may be subjected to the test in this International Standard except for the dispensing stage.

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Dental amalgamators

1 Scope

This International Standard specifies requirements, test methods to determine compliance with these requirements and details of marking of electrically powered mixing amalgamators suitable for mixing dental amalgam alloy and mercury for dental amalgams.

It provides methods of comparing uniformity of operation and performance of these amalgamators and is intended to ensure reproducibility of amalgamation.

2 Normative reference

The following standard contains provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the edition indicated was valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent edition of the standard indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

IEC 335-1:1976, *Safety of household and similar electrical appliances — Part 1: General requirements*.

3 Definitions

For the purposes of this International Standard, the following definitions apply.

3.1 coherence: State when all the alloy and the mercury are combined in a single unified mass.

NOTE 1 Small cracks or a dry looking surface do not detract from coherence.

3.2 working length of capsule: Maximum internal dimension lying parallel to the direction of the greatest motion or, where uniform circular motion applies, the greatest internal dimension parallel to a principal axis of the capsule in the plane of motion when the capsule is in its normal working or "activated" configuration.

3.3 amplitude of capsule motion: Range of movement, in millimetres, of the midpoint of the capsule while running, measured in the direction of the working length.

4 Classification

Amalgamators are classified as follows:

Type 1: Fixed frequency

Type 2: Variable frequency

5 Requirements

5.1 Electrical safety

Amalgamators shall comply as regards the electrical requirements and the testing with the relevant clauses of IEC 335-1.

NOTE 2 Compliance with IEC 335-1 is required pending development and publication of IEC requirements for laboratory and related equipment.

5.2 Mechanical safety

5.2.1 The amalgamator shall have an enclosure that will contain a capsule, its contents, or a machine part that may become dislodged or broken during use.

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

5.2.3 In addition, the following requirements shall apply.

a) During normal operation, insertion, or removal, the capsule shall not be damaged in such a way as to allow leakage of mercury.

b) The capsule shall be securely and firmly retained during operation of the amalgamator at the highest power recommended by the manufacturer [see clause 8 e)].

c) The position of the capsule shall be definite and reproducible.

Testing shall be carried out in accordance with 7.2.

5.3 Capsule oscillation frequency

5.3.1 General

The operating frequency of the amalgamator shall not vary by more than ± 2 Hz at any frequency setting during any run of not less than 15 s or the maximum duration recommended by the manufacturer for that setting when subjected individually to each of the following:

a) variation of the supply voltage by ± 5 % of the rated voltage, or if a supply voltage range is given, variation of the voltage throughout the stated range;

b) variation of the mass of the capsule and contained alloy and mercury within the range recommended by the manufacturer;

c) three immediately successive mixing operations for the maximum duration recommended by the manufacturer.

Testing shall be carried out in accordance with 7.3.

5.3.2 Variable frequency amalgamators

At any frequency or power setting, variable amalgamators shall operate within ± 1 mm while the machine is running for the maximum duration recommended by the manufacturer.

Testing shall be carried out in accordance with 7.3.

5.4 Amplitude of capsule motion

The amplitude shall remain stable to ± 1 mm while the machine is running for the maximum duration recommended by the manufacturer.

Testing shall be carried out in accordance with 7.4.

5.5 Timing control

5.5.1 Timing device

Machines shall be provided with a timing device to allow selection and control of the duration of mixing.

5.5.2 Timing settings

The timing device may provide continuously variable settings or settings in steps. The intervals produced shall be accurate to ± 5 % of the nominal value of the setting or ± 0,5 s whichever is the larger: the intervals shall also be reproducible within ± 2 % of the actual value of the setting or ± 0,2 s whichever is the larger. These provisions shall further apply when the machine is subjected individually to 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.

Testing shall be carried out in accordance with 7.5.

5.6 Coherence

The amalgamator shall operate in a manner that will cause the amalgam to display coherence in any and all capsules and alloys, recommended for use by the manufacturer, in less time than the manufacturer recommends for trituration.

Testing shall be carried out in accordance with 7.2.

5.7 Stability

While running for the maximum duration recommended by the manufacturer at any frequency setting, the machine shall not move more than 5 mm across the glass surface.

Testing shall be carried out in accordance with 7.2.

6 Sampling

The test office shall procure its test sample devices including amalgamator, capsule and alloys for testing independently. Product names, descriptions and batch numbers shall be recorded.

7 Test methods

7.1 Test conditions

7.1.1 General

Put the amalgamator on a tray to prevent spillage of mercury and test it at (23 ± 2) °C. The amalgamator shall have in position a capsule recommended by the manufacturer.

The capsule shall contain (600 ± 2,5) mg of any fine grain amalgam alloy powder. No pestle shall be used. The amalgamator shall be placed on a rigidly supported, smooth, flat, horizontal glass surface, using any of the bases or supports recommended by the manufacturer.

7.1.2 Power supply

The power supply shall be stabilized to ±1 % of the rated voltage of the machine. If a supply voltage range is given, then control shall be ±1 % of the midpoint of the stated range, or ±1 % of nominal test voltage as appropriate. A record of supply frequency and voltage shall be maintained. If a supply frequency variation more than ±0,1 Hz or a voltage more than the limit cause the machine under test to fail, the results shall be discarded and the test rerun.

7.2 Visual inspection

Visually inspect to determine compliance with the specifications of this International Standard.

7.3 Capsule oscillation frequency

7.3.1 Apparatus

A suitable "non-contact" means of determining oscillation frequency is needed.

7.3.2 Procedure

Do not operate the machine for at least 2 h before the oscillation frequency tests are conducted according to 5.3.

7.3.2.1 Fixed frequency amalgamators

Determine the operating frequency of the triturator of the amalgamator under the conditions outlined in 7.1. Exclude the first 1 s of running for measurement purposes in all tests.

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

7.3.2.2 Variable frequency machines

Determine the trituration frequency of the amalgamator under the conditions outlined in 7.1.

Test only three points in the range, the two extremes and one setting close to the midpoint of the trituration frequency range. Make a total of five determinations at each point in alternately ascending and descending sequences, *viz*.: 1,2,3,3,2, ... and such as to approach the set point from alternating directions where the device permits. In the case of continuously variable controls, interpret the extremes of the range as the extreme points which are calibrated or bear index marks. Do not employ the limits of travel of the control unless they are so calibrated.

Take the mean of the five determinations rounded to the nearest 0,1 Hz as indicating the actual value at each setting. Determine the accuracy by the difference between the actual and nominal values of the setting. Determine compliance with the reproducibility requirement by comparison of each recorded value with the limits stated (5.3.2) referred to the actual value of the setting rounded to the nearest 0,1 Hz.

7.4 Amplitude of capsule motion

7.4.1 Apparatus

The following apparatus is needed:

a) lamp providing strong continuous illumination, e.g. tungsten filament lamp;

b) measuring device to determine the distance between the end points of the capsule motion, e.g. vernier caliper gauge, cathetometer, or calibrated photographic system.

7.4.2 Procedure

Mark the approximate midpoint of the capsule in its normal working configuration, viewed in a direction perpendicular to the measured working length. Mount the capsule containing (600 ± 2,5) mg of alloy powder so that the mark is at the mean radius of movement or otherwise such as to obtain a measurement of amplitude as given in 3.3. Start the machine and, under strong illumination [7.4.1 b)], determine the distance between the end points of the mark to the nearest 1 mm. Take the amplitude determined under the conditions in 7.1.1 and 7.1.2 as the reference value for the amplitude test of 3.3 and 5.4.

Exclude the first 1 s of running for measurement purposes in all tests.

7.5 Timing control

7.5.1 Apparatus

A timing device accurate to 0,02 s is needed.

7.5.2 Procedure

Evaluate the accuracy and reproducibility of the timer at four points, these being 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.

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 differ-

ence between the actual and nominal values of the setting. Determine compliance with the reproducibility requirement by comparison of each recorded value with the limits stated (5.5.2) referred to the actual value of the setting rounded to the nearest 0,1 s.

8 Instructions for use

Instructions for use shall accompany each package. These instructions shall be, where practicable, in the language of the country of intended use and include at least the following information:

a) Identification

The amalgamator model type, model number or other designation such as to distinguish the amalgamator unambiguously from all other models currently or formerly made by the manufacturer, the classification type of the amalgamator according to this International Standard and the manufacturer's name and address.

b) User maintenance

The recommended filling and — if applicable — cleaning procedure, including the procedure for recovery of spilled mercury, any relevant user maintenance schedule including any relevant parts identification literature or diagrams, e.g. exploded view.

c) Other maintenance

A list of service agencies or information on how service may be obtained. The recommended service interval, if any.

d) Capsule requirements

Recommended time and speed requirements for alloys and capsules identified and recommended by the manufacturer.

e) Operational limitations

Limitations in respect of normal usage, such as power supply voltage, duty cycle or duration of continuous operation, if any.

Compliance with these instructions shall be checked by visual inspection.

9 Packaging

Amalgamators shall be suitably packaged to prevent damage during normal transport and storage.

10 Marking

10.1 Compliance with marking

Compliance with the required marking in 10.2 and 10.3 shall be checked by visual inspection.

10.2 Amalgamator

The following information shall be legibly and durably marked on amalgamators:

a) name or registered trade-name or -mark and address of the manufacturer;

b) brand-name, if any;

c) model and serial number;

d) type of the amalgamator according to this International Standard;

e) electrical power requirements.

10.3 Packaging

The packaging shall be clearly marked as follows and should be in the language of the country where it is intended for sale:

a) name or registered trade-name or -mark and address of the manufacturer and supplier;

b) brand-name, if any, and product description;

c) model and serial number;

d) type of the amalgamator according to this International Standard (see clause 4);

e) electrical power requirements (voltage, frequency, etc.).

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