

Dental equipment — Mercury and alloy mixers and dispensers

The European Standard EN ISO 8282:1997 has the status of a
British Standard

ICS 11.060.20

National foreword

This British Standard is the English language version of EN ISO 8282:1997. It is identical with ISO 8282:1994.

The UK participation in its preparation was entrusted to Technical Committee CH/60, Dental equipment, which has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;
- monitor related international and European developments and promulgate them in the UK.

A list of organizations represented on this committee can be obtained on request to its secretary.

Cross-references

Attention is drawn to the fact that Annex ZA lists normative references to international publications with their corresponding European publications. The British Standards which implement these international or European publications may be found in the BSI Standards Catalogue under the section entitled “International Standards Correspondence Index”, or using the “Find” facility of the BSI Standards Electronic Catalogue.

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Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, the EN ISO title page, page 2, the ISO title page, pages ii to iv, pages 1 to 4 and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

This British Standard, having been prepared under the direction of the Health and Environment Sector Board, was published under the authority of the Standards Board and comes into effect on 15 June 1997

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Amendments issued since publication

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ICS 11.060.20

Descriptors: See ISO document

English version

Dental equipment — Mercury and alloy mixers and dispensers

(ISO 8282:1994)

Matériels dentaires — Mélangeurs et distributeurs de mercure et d'alliages
(ISO 8282:1994)

Zahnärztliche Ausrüstung — Mischgeräte und Dosierer für Quecksilber und Legierungen zur Herstellung von Amalgam
(ISO 8282:1994)

This European Standard was approved by CEN on 1997-02-28. CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

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CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

Central Secretariat: rue de Stassart 36, B-1050 Brussels

Foreword

The text of the International Standard from Technical Committee ISO/TC 106 “*Dentistry*” of the International Organization for Standardization (ISO) has been taken over as a European Standard by the Technical Committee CEN/TC 55 “*Dentistry*”, the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by September 1997, and conflicting national standards shall be withdrawn at the latest by September 1997.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of the International Standard ISO 8282:1994 has been approved by CEN as a European Standard without any modification.

NOTE Normative references to International Standards are listed in Annex ZA (normative).

INTERNATIONAL
STANDARD

ISO
8282

First edition
1994-10-01

**Dental equipment — Mercury and alloy
mixers and dispensers**

*Matériels dentaires — Mélangeurs et distributeurs de mercure et
d'alliages*



Reference number
ISO 8282:1994(E)

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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 8282 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 6, *Dental equipment*.

Descriptors: Dentistry, dental equipment, amalgams, mixers, dispensers, classification, specifications, tests, marking, packaging, instructions for use.

1 Scope

This International Standard specifies requirements and test methods for devices used for dispensing dental amalgam alloys and/or mercury. It includes the dispensing portion of devices which dispense the correct portions of alloy and mercury as well as mix the amalgam in a single, continuous operation.

It does not specify requirements and test methods for the efficacy of mixing.

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. ISO 1560:1985, *Dental mercury*.

3 Classification

Dispensers covered by this International Standard shall be classified as follows:

Type 1	Alloy dispensers
Category 1	Powder
Category 2	Tablet
Type 2	Mercury dispensers
Category 1	Fixed volume
Category 2	Adjustable volume
Type 3	Combination alloy/mercury dispensers
Category 1	Alloy powder
Category 2	Alloy tablet
Category 3	Adjustable volume alloy and/or mercury
Type 4	Dispensing and mixing devices

4 Requirements

4.1 Construction

Dispensers shall not exhibit any defects such as cracks or missing adhesive which could lead to failure of the dispenser during normal usage resulting in a sudden release of mercury or alloy.

Dispensers shall be made of materials that do not react with or contaminate the alloy or mercury. No deterioration of the surface of the reservoir shall be visible after the test and no visible change in the alloy or mercury is acceptable.

Testing shall be in accordance with **6.1** and **6.2**.

4.2 Adjustment

Adjustable dispensers shall be provided with a means of ensuring that the adjustment will not change during normal use.

Testing shall be in accordance with **6.1**.

4.3 Mercury leakage

Mercury dispensers shall not exhibit a static leakage exceeding 1 mg.

NOTE 1 While 1 mg leakage is currently acceptable, the goal is to reach zero leakage in the near future.

Mercury leakage deposited during function after 100 dispensings shall not exceed 0,10 g.

For devices of type 4 no mercury should be visible after 100 dispensings in the interior of the, dispensing and mixing device except the mercury container, the connecting tube and the capsule.

Testing shall be in accordance with **6.3**.

4.4 Filling

The device shall be capable of being filled with mercury without spillage.

Testing shall be in accordance with **6.4**.

4.5 Accuracy and performance

4.5.1 Mercury and/or alloy powder dispensers

At each dispensing the mass of mercury or alloy powder shall fall within $\pm 3\%$ for powder and $\pm 1,5\%$ for mercury of the value claimed by the manufacturer.

Testing shall be in accordance with **6.5.1**.

4.5.2 Alloy tablet dispensers

In addition to the requirement in **4.5.1**, alloy tablet dispensers shall dispense tablets easily with no tendency for the dispenser to jam or bind, and no evidence of damage to the tablets. Samples of all brands of tablets recommended by the manufacturer shall be tested.

Testing shall be in accordance with **6.5.2**.

4.6 Stability

The dispenser shall not tip when submitted to the test in accordance with **6.6**.

4.7 Cleaning

Dispensers shall be cleanable following the manufacturer's instructions.

NOTE 2 Cleanability is necessary so that alloy and/or mercury may be changed to different brands and types while maintaining accurate operation.

Testing shall be in accordance with 6.7.

5 Sampling

One sample of the device shall be procured on the open market for testing for compliance with this International Standard.

6 Test methods

6.1 Visual inspection

Visually inspect the test piece at normal visual acuity without magnification to determine compliance with the stated requirements.

6.2 Construction

Fill the reservoirs for mercury and alloy to the maximum level and empty after 24 h. Conduct the tests of 6.3 to 6.6, and leave the device for a further 24 h. Then examine the alloy and mercury for visible changes and test the mercury for compliance with the requirements of ISO 1560. Empty the reservoirs and clean them according to the manufacturer's instructions.

Visually examine the surfaces and note any deteriorations.

6.3 Mercury leakage

6.3.1 Static

Select a tray that is large enough to contain the dispenser. Weigh the tray to the nearest 0,1 mg.

Place the filled dispenser in this tray. Cover the entire device with a cover to prevent contaminants from collecting in the tray from outside.

After 24 h, brush any adherent mercury into the tray, remove the dispenser and reweigh the tray.

6.3.2 Functional

If the dispenser is adjustable, adjust it to a mid-range setting and fill it with mercury.

Weigh a shallow tray to the nearest milligram. Place a small cup away from the weighed tray. Make alternate single and double dispensings into this cup which should be slightly larger than the dispensing port of the device, e.g. a mixing capsule, precisely following the manufacturer's instructions for operation. After each dispensing, set the device down on the previously weighed tray.

After 100 dispensings, visually inspect the outside surfaces of the dispenser for any evidence of mercury. Brush any droplets into the tray. Reweigh the tray to the nearest milligram and calculate the amount of the mercury leakage.

6.3.3 Type 4 devices

Fill the mercury container to the maximum recommended level. Set the timer to the maximum recommended mixing time. Run the mixing operation five times without dispensing.

Brush any mercury out of the connecting tube and the mixing capsule into a preweighed container. Reweigh the container to the nearest milligram and calculate the amount of mercury leakage.

Fill the mercury container to the maximum recommended level. Start the mixing device and dispense ten dispensings of mercury. Empty the capsule. Repeat this operation nine times.

After a total of 100 dispensings (10 operations) examine the device for the presence of mercury.

6.4 Filling

Fill the device with mercury following the manufacturer's instructions. Visually examine the device for any signs of spillage of mercury.

6.5 Accuracy and performance

6.5.1 Mercury and/or alloy powder dispensers

Fill the storage reservoir with the mercury of powder to the maximum recommended setting. Adjust the dispenser to the recommended setting. Following any preconditioning instructions of the manufacturer, weigh out the next 10 dispensings into a preweighed container.

6.5.2 Alloy tablet dispensers

Fill the alloy tablet reservoir to the maximum recommended level. Dispense all tablets into a suitable tray having a shock-absorbing surface and located 25 mm below the exit port.

Repeat the test on samples of all the brands of tablets recommended by the manufacturer, and observe the dispensing.

6.6 Stability

Place the empty device in its normal rest position on a non-skid surface inclined 10° from the horizontal.

Rotate the device on the surface through 360° in 45° increments and note whether the device tips at any of the orientations. Repeat the test with the device fully loaded with alloy and/or mercury.

6.7 Cleaning

Clean the dispenser and the reservoirs with the agents recommended by the manufacturer. Visually inspect the devices and note any signs of debris.

7 Manufacturer's instructions

Instructions for safe and proper use shall accompany each dispenser. These instructions shall include the following.

7.1 Loading

Instructions shall show how to fill the dispenser safely. This shall include the precautionary notes necessary to avoid spilling the mercury.

7.2 Operation

The proper method of holding and operating the dispenser shall be stated. This shall include an illustration of the proper adjustment procedure where appropriate.

7.3 Cleaning and maintenance

Procedures for cleaning and maintenance shall be stated along with the recommended frequency of applying these procedures.

7.4 Mercury delivered

The average mass, in milligrams, of mercury dispensed shall be stated by the manufacturer. For adjustable-volume dispensers, the average mass of the dispensings taken from at least three of the settings indicated on the dispenser and covering the entire recommended adjustment range for the specific alloys shall be stated.

7.5 Tablet dimensions

For tablet dispensers, the minimum and maximum tablet dimensions in terms of diameter and thickness which can be used effectively in the dispenser shall be stated by the manufacturer.

7.6 Identification

The manufacturer's name and address along with a model number or descriptive title which distinguishes the dispenser from all other dispensers currently or previously made by the manufacturer shall be listed in the instructions. The type and category, as defined by this International Standard shall also be included.

7.7 Caution statement

The following caution statement shall be, included in bold print:

Care should always be exercised to prevent mercury spills and leakage. Mercury and mercury dispensers should be kept at less than 25 °C.

8 Marking

8.1 Marking on label and package

The following markings shall be on the label and package, where appropriate:

- a) manufacturer's name;
- b) date of packaging;
- c) model number;
- d) power supply requirements, voltage, frequency and amperage, where appropriate;
- e) classification.

8.2 Marking of dispensers

8.2.1 Markings shall be clear, easily legible and permanent in nature.

To test the marking, vigorously clean the test sample 20 times with the agent recommended by the manufacturer. Visually examine the marking for changes or deterioration.

8.2.2 Dispensers of mercury and powdered alloy shall have level markings on the reservoirs indicating the minimum level below which compliance with the accuracy claims is not guaranteed by the manufacturer. This shall be done such that the user can visually determine when a refill is necessary. There shall be also an indication on the mercury reservoir of the maximum safe fill level.

8.2.3 The following statement shall be marked on the dispensers.

CAUTION: Operate with care to contain any mercury leakage.

9 Packaging

Dispensers shall be packaged in containers that, under normal conditions of shipment, preclude breakage.

Annex ZA (normative)**Normative references to international publications with their relevant European publications**

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN</u>	<u>Year</u>
ISO 1560	1985	<i>Dentistry — Dental mercury</i>	EN 21560	1991

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