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BSI Standards Publication

## Dentistry - Mixing machines for dental amalgam

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## National foreword

This British Standard is the UK implementation of EN ISO 7488:2018. It is identical to ISO 7488:2018. It supersedes BS EN ISO 7488:1996, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/106/4, Dental Instruments and Equipment.

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

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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**Compliance with a British Standard cannot confer immunity from legal obligations.**

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English Version

## Dentistry - Mixing machines for dental amalgam (ISO 7488:2018)

Médecine bucco-dentaire - Mélangeurs pour  
amalgame dentaire (ISO 7488:2018)

Zahnheilkunde - Mischgeräte für  
zahnärztliches Amalgam (ISO 7488:2018)

This European Standard was approved by CEN on 15 March 2018.

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This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION  
COMITÉ EUROPÉEN DE NORMALISATION  
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

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## European foreword

This document (EN ISO 7488:2018) has been prepared by Technical Committee ISO/TC 106 "Dentistry" in collaboration with 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of an identical text or by endorsement, at the latest by November 2018, and conflicting national standards shall be withdrawn at the latest by November 2018.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 7488:1995.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

### Endorsement notice

The text of ISO 7488:2018 has been approved by CEN as EN ISO 7488:2018 without any modification.

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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](http://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](http://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](http://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;

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## 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.



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# 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.