

STN	Stomatológia Miešačky na dentálne amalgámy (ISO 7488:2018)	STN EN ISO 7488 85 6020
------------	---	---

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

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 10/18

Obsahuje: EN ISO 7488:2018, ISO 7488:2018

Oznámením tejto normy sa ruší
STN EN ISO 7488 (85 6020) z marca 2001

127250

EUROPEAN STANDARD

EN ISO 7488

NORME EUROPÉENNE

EUROPÄISCHE NORM

May 2018

ICS 11.060.20

Supersedes EN ISO 7488:1995

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.

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 CEN-CENELEC Management Centre or to any CEN member.

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.

CEN members are the national standards bodies of 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 United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG**CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels**

EN ISO 7488:2018 (E)

Contents	Page
European foreword.....	3

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.

INTERNATIONAL STANDARD

ISO 7488

Second edition
2018-04

Dentistry — Mixing machines for dental amalgam

Médecine bucco-dentaire — Mélangeurs pour amalgame dentaire



Reference number
ISO 7488:2018(E)

© ISO 2018

ISO 7488:2018(E)**COPYRIGHT PROTECTED DOCUMENT**

© ISO 2018

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

Foreword	v
Introduction	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Requirements	2
4.1 Safety.....	2
4.1.1 Electrical.....	2
4.1.2 Mechanical.....	2
4.2 Stability.....	2
4.3 Sound pressure.....	3
4.4 Frequency.....	3
4.4.1 General.....	3
4.4.2 Variable-power machines.....	3
4.5 Amplitude.....	3
4.6 Mixing time.....	3
4.6.1 Timing device.....	3
4.6.2 Timing settings.....	3
4.7 Coherence time.....	4
4.8 Long-term test.....	4
5 Sampling	4
5.1 Mixing machine.....	4
5.2 Mixing-capsules.....	4
5.2.1 General.....	4
5.2.2 Mixing-capsule selection.....	4
5.3 Test components.....	5
6 Measurement and test methods	5
6.1 Test conditions.....	5
6.1.1 General.....	5
6.1.2 Reference charge mass, m_{ref}	5
6.1.3 Minimum charge mass, m_{min}	5
6.1.4 Maximum charge mass, m_{max}	5
6.1.5 Maximum running duration, t_{max}	5
6.1.6 Power supply conditions and apparatus.....	5
6.1.7 Equipment setup.....	6
6.2 Visual inspection.....	6
6.3 Sound pressure.....	6
6.3.1 Apparatus and setup.....	6
6.3.2 Procedure.....	7
6.3.3 Variable-power machines.....	7
6.4 Frequency tests.....	7
6.4.1 Measurement of mixing-capsule oscillation frequency.....	7
6.5 Working length.....	8
6.5.1 Principle.....	8
6.5.2 Apparatus.....	8
6.5.3 Procedure.....	8
6.6 Amplitude.....	8
6.6.1 Apparatus.....	8
6.6.2 Procedure.....	8
6.7 Mixing time.....	9
6.7.1 Apparatus.....	9
6.7.2 Procedure.....	9

ISO 7488:2018(E)

6.8	Coherence time.....	9
6.8.1	Apparatus and materials.....	9
6.8.2	Procedure.....	9
6.9	Long-term test.....	10
7	Instructions for use	11
7.1	General.....	11
7.2	Identification	11
7.3	Safety.....	11
7.4	User maintenance.....	11
7.5	Other maintenance.....	11
7.6	Mixing-capsule requirements.....	11
7.7	Mixing-capsule amplitude.....	11
7.8	Operational limitations.....	12
7.8.1	Mixing machine limitations.....	12
7.8.2	Mass and frequency.....	12
8	Packaging.....	12
9	Marking.....	12
9.1	On the mixing-machine.....	12
9.2	On the packaging.....	12
	Bibliography.....	13

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;

ISO 7488:2018(E)**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*

koniec náhľadu – text ďalej pokračuje v platenej verzii STN