

Dentistry - Digital impression devices - Part 1: Methods
for assessing accuracy (ISO 20896-1:2019)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 20896-1:2019 sisaldab Euroopa standardi EN ISO 20896-1:2019 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 20896-1:2019 consists of the English text of the European standard EN ISO 20896-1:2019.
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English Version

**Dentistry - Digital impression devices - Part 1: Methods for
assessing accuracy (ISO 20896-1:2019)**

Médecine bucco-dentaire - Dispositifs d'empreinte
numérique - Partie 1: Méthodes d'évaluation de
l'exactitude (ISO 20896-1:2019)

Zahnheilkunde - Genauigkeit von handgehaltenen
Scanner für CAD/CAM-Systeme am Behandlungsstuhl
(ISO 20896-1:2019)

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European foreword

This document (EN ISO 20896-1:2019) 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of an identical text or by endorsement, at the latest by April 2020, and conflicting national standards shall be withdrawn at the latest by April 2020.

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.

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Endorsement notice

The text of ISO 20896-1:2019 has been approved by CEN as EN ISO 20896-1:2019 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).

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For an explanation of 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 www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 9, *Dental CAD/CAM Systems*.

A list of all parts in the ISO 20896 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Dental CAD/CAM systems that produce indirect dental restorations require a three dimensional digitized description, often called a digital impression, of a patient's dentition as a starting point for the design and fabrication of inlays, crowns, bridges and larger fixed or removable appliances. The device that digitizes the three dimensional surface shall be sufficiently accurate to enable the design and manufacture of a clinically acceptable restoration.

This document describes test methods for evaluating the accuracy of digitizing devices that acquire data by direct scanning of a patient's dentition with a manually guided; that is hand-held, device in order to obtain a digital impression. A companion document, ISO 12836, provides test methods for assessing the accuracy of fixed devices for digitizing physical impressions or models cast from such impressions. Separate standards were deemed necessary after it became apparent that two of the test objects described in ISO 12836 are unsuited for successful interpretation of data acquired from these objects with a hand-held scanning device.

NOTE Testing conducted outside the oral cavity on objects that are ideal – in having both surface characteristics suitable for a given scanning technology and sufficient recognizable features for registration algorithms to function well – will give a better result than can be achieved under less ideal, clinical conditions.

Dentistry — Digital impression devices —

Part 1: Methods for assessing accuracy

1 Scope

This document specifies test methods and procedures for assessing the accuracy of a three dimensional numerical description of intra-oral surfaces acquired directly from a patient with a hand-held scanning device. The test methods are not applicable to ultrasonic, radiographic or magnetic resonance imaging methods.

NOTE ISO 12836 specifies the test methods for the assessment of accuracy of digitizing devices that use a fixed or a mechanically guided scanning device.

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*

ISO 3534-1, *Statistics — Vocabulary and symbols — Part 1: General statistical terms and terms used in probability*

ISO 5725-1, *Accuracy (trueness and precision) of measurement methods and results — Part 1: General principles and definitions*

ISO 6873:2013, *Dentistry — Gypsum products*

ISO 18739:2016, *Dentistry — Vocabulary of process chain for CAD/CAM systems*

ISO 20795-1, *Dentistry — Base polymers — Part 1: Denture base polymers*

ISO 22112, *Dentistry — Artificial teeth for dental prostheses*

ISO/IEC Guide 99, *International vocabulary of metrology — Basic and general concepts and associated terms (VIM)*

ISO/IEC Guide 98-3:2008, *Uncertainty of measurement — Part 3: Guide to the expression of uncertainty in measurement (GUM:1995)*

3 Terms and definitions

For the purposes of this document, the terms and definitions from ISO 1942, ISO 3534-1, ISO 5725-1, ISO 18739, ISO/IEC Guide 99, ISO/IEC Guide 98-3, and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>