PD ISO/TR 20896-2:2023



BSI Standards Publication

Dentistry — Digital impression devices

Part 2: Methods for assessing accuracy for implanted devices

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National foreword

This Published Document is the UK implementation of ISO/TR 20896-2:2023.

The UK participation in its preparation was entrusted to Technical Committee CH/106/-/1, Dental CAD/CAM systems.

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

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Published by BSI Standards Limited 2023

ISBN 978 0 539 02592 7

ICS 11.060.01

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This Published Document was published under the authority of the Standards Policy and Strategy Committee on 30 April 2023.

Amendments/corrigenda issued since publication

Date	Text affected

PD ISO/TR 20896-2:2023

TECHNICAL REPORT

ISO/TR 20896-2

First edition
2023-02-16

Dentistry — Digital impression devices —

Part 2: Methods for assessing accuracy for implanted devices

Médecine bucco-dentaire — Dispositifs d'empreinte numérique —

Partie 2: Méthodes d'évaluation de l'exactitude de dispositifs implantés

Reference number
ISO/TR 20896-2:2023(E)

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Foreword

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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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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.

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Introduction

Dental CAD/CAM systems that produce indirect dental restorations require a 3-dimensional digitized description, often called a digital impression, of the patient's dentition as a starting point for the design and fabrication of inlays, crowns, bridges and larger prosthetic or orthodontic appliances. The device that acquires and digitizes the 3-dimensional metrology data must be sufficiently accurate to enable the manufacture of a clinically acceptable restoration.

This document describes possible test methods for evaluating the accuracy of digital impression devices designed for direct oral scanning of implant bodies, intended as support for prosthetic appliances to replace a patient's dentition, in order to obtain a digital impression. It is a complement to ISO 20896-1, which assesses the accuracy of digital impression devices from which a digital impression of a patient’s dentition can be created. A companion standard, ISO 12836, provides test methods for assessing the accuracy of fixed devices for digitizing physical impressions or models/casts made from such impressions. Separate standards were deemed necessary after it became apparent that two of the test objects described in ISO 12836 were unsuited for successful interpretation of data acquired with a digital impression device.

Assessment of the accuracy of digital impression devices for a full-arch test object as described in Part 1 or similar tests has revealed that intra-oral, digital impression devices are intrinsically limited in accuracy to taking impressions of just a few teeth. Furthermore, experience and experiments with these devices to create a digital impression after the placement of single implants, indicate that a scan body fitted to the implant body allows an accuracy in position and orientation at least as good as for a tooth preparation. Implants are however also an indicated treatment for fully or partially edentulous patients. For such indications, several implant bodies are placed in the upper or lower jaw. Scanning technology is developing rapidly, to overcome inaccuracies that occur when scanning an edentulous patient. One hindrance to the development of a relevant method of assessing accuracy for this clinical case is the lack of a mechanically stable material that can adequately represent mucosal tissue in a test object.

This document reviews the theory and techniques employed to exploit scan bodies to overcome the challenges of scanning edentulous mucosal tissue by optical methods.

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Dentistry — Digital impression devices —

Part 2: Methods for assessing accuracy for implanted devices

1 Scope

This document describes methods of acquiring and analysing data from which the accuracy of a numerical model of the geometry of the mucosa and implant bodies in the jaw of a patient can be assessed.

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 16443:2014, *Dentistry — Vocabulary for dental implants systems and related procedure*

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

ISO 20896-1, *Dentistry — Digital impression devices — Part 1: Methods for assessing accuracy*

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

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

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942, ISO 3534-1, ISO 5725-1, ISO 16443, ISO 18739, ISO 20896-1, ISO/IEC Guide 98-3, ISO/IEC Guide 99 and the following apply.

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

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
digital impression data
set of numerical coordinates providing a three-dimensional representation of the surfaces of teeth and surrounding tissue acquired directly from the patient by a *digital impression device* and presented in a format suited to a computer-aided dental design and manufacturing (CAD/CAM) process

Note 1 to entry: A digital impression data set can be supplemented by data on surface colour.

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