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# 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*

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# Contents

Page

**Foreword** ... **v**
**Introduction** ... **vi**
**1 Scope** ... **1**
**2 Normative references** ... **1**
**3 Terms and definitions** ... **1**
**4 Literature review** ... **3**
**5 Assessment of accuracy** ... **3**
5.1 General ... 3
5.1.1 Clinical quality ... 3
5.1.2 Sources of uncertainty ... 4
5.1.3 Auxiliary methods ... 4
5.2 Accuracy ... 4
5.2.1 General ... 4
5.2.2 Trueness ... 4
5.2.3 Precision ... 5
5.2.4 External reliability ... 5
5.3 Test objects ... 5
5.3.1 General ... 5
5.3.2 Single implant ... 5
5.3.3 Multiple implants ... 5
5.4 Reference measurement of test objects ... 6
5.4.1 Calibrated measures of interest ... 6
5.4.2 Independent scanning device ... 6
5.5 Auxiliary devices ... 6
5.5.1 General ... 6
5.5.2 Calliper measurement ... 6
5.5.3 Extra-oral photogrammetry ... 6
**6 Accuracy assessment methods** ... **7**
6.1 Measures of interest ... 7
6.1.1 General ... 7
6.1.2 Position of interest ... 7
6.2 Assessment of trueness ... 7
6.2.1 Single implant ... 7
6.2.2 Multiple implants ... 7
6.3 Assessment of precision ... 8
6.3.1 Repeated scanning procedures ... 8
6.3.2 Design analysis ... 8
6.4 Expression of accuracy ... 8
6.5 Assessment of reliability ... 8
**7 Test report** ... **9**
7.1 General ... 9
7.2 Device ... 9
7.3 Test object ... 9
7.4 Test method ... 10
7.5 Test results ... 10
7.6 Test data ... 10
**Annex A** (Informative) **Scan body for accuracy assessment** ... **11**
**Annex B** (informative) **Test object — Single implant** ... **13**
**Annex C** (informative) **Test object — Multiple implants** ... **16**
**Annex D** (informative) **Guidance on evaluating precision and external reliability** ... **18**

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**Bibliography** ..... **22**


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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).

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).

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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.

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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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Note 2 to entry: A set of digital impression data is distinct from a virtual model as defined in ISO 18739. A virtual model is produced by design or similar software.

**3.2**
**external reliability**
confidence interval for an estimated dimension after eliminating *gross errors* (3.3) in the data as detected by the digitizing system's software

Note 1 to entry: External reliability is evaluated by propagation of uncertainties as estimated from the *redundancy* (3.7) in an accepted data set, as described in Annex D.

**3.3**
**gross error**
error in an observation arising from partial failure or incorrect calibration of a measurement device, incorrect pattern recognition or data interpretation and leading to unacceptable error of measurement in the digital impression

Note 1 to entry: Detection and elimination of gross errors is an essential function of the registration software for a digital impression device.

**3.4**
**intra-oral calibration appliance**
extended *scan body* (3.9) that is scanned together with the mucosa, residual dentition and other scan bodies and provides internal calibration of *digital impression data* (3.1)

**3.5**
**position of interest**
coordinates of a feature on an implant body that define the placement of the implant body

Note 1 to entry: The feature can be defined by the symmetry of the implant body, for example, its axis. It lies on a surface of the body that is accessible when placed in a jaw.

**3.6**
**range image**
two-dimensional array of data on the distances from the scanning device to the surfaces being scanned

Note 1 to entry: The array indices define direction with respect to the axis of the scanning device for which the distance applies.

**3.7**
**redundancy**
difference between the number of observations judged to be validly measured and the number of parameters that need to be estimated to calibrate and describe movement of the scanning device and to produce *digital impression data* (3.1)

Note 1 to entry: The software of a digitizing device may exploit redundancy to perform an assessment of raw data in order to detect *gross errors* (3.3) by statistical testing (see Annex D).

**3.8**
**reference impression data**
set of three-dimensional coordinates acquired by a digital impression device or a combination of scanning device and digitizing device that represent the surfaces to a better precision than that of the device being assessed

**3.9**
**scan body**
implant impression post with a numerically defined geometric shape from which the position and orientation of an implant body can be determined in a scanning procedure


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