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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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## 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 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](http://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](http://www.iso.org/members.html).

## 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.

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

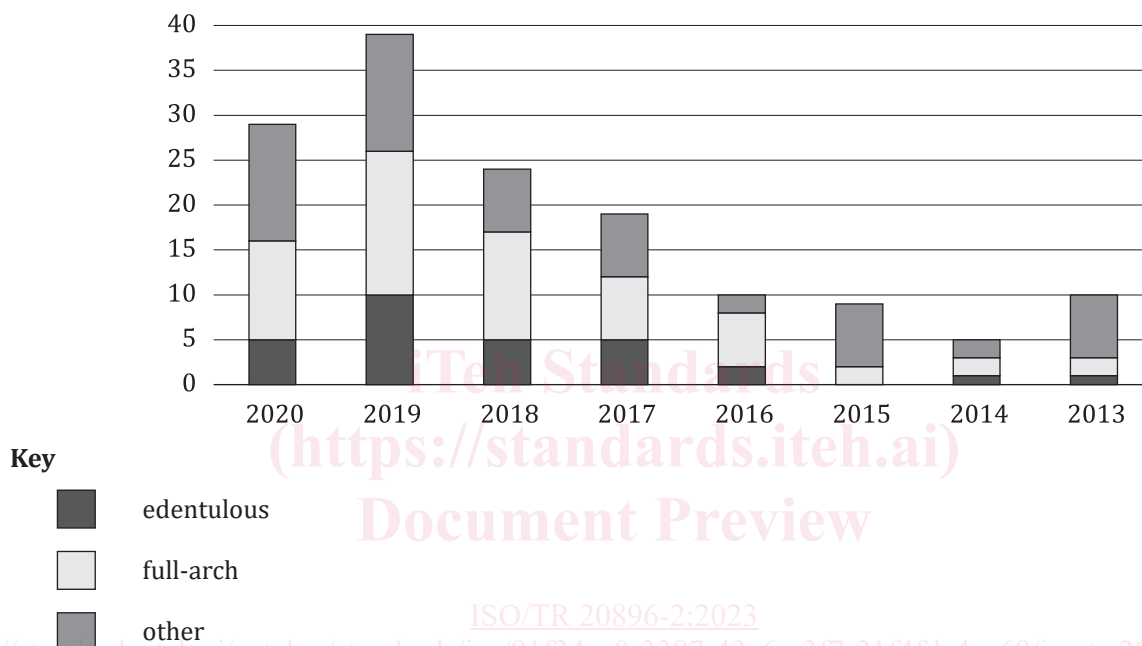
implant impression post with a numerically defined geometric shape from which the position and orientation of an implant body can be determined in a scanning procedure



## 4 Literature review

Intra-oral scanning builds on 170 years of development in photogrammetry. It belongs to the branch known as close-range photogrammetry and where it represents very close-range.<sup>[4]</sup> In the confines of the mouth, a scanning device requires miniature components with their attendant need for continual re-calibration in the face of considerable image distortion.

Articles relevant to assessing accuracy in scanning in the oral cavity to produce digital impression data for existing dentition or an edentulous jaw were searched by the keywords: “intra-oral scanning” and “accuracy”. Of an initial list totalling 158 articles from the period 2013 to June 2020, sub-lists for those concentrating on scanning an edentulous jaw (29 articles) and those scanning a full arch with full or partial dentition (59 articles) were chosen for review. [Figure 1](#) shows the number of articles by year of publication. Many studies compare digitizing devices from several manufacturers.



**Figure 1 — Refereed articles with search keywords “intra-oral scanning” and “accuracy”**

The diversity of methods and variety of statistics employed show that consensus on appropriate methods of benchmarking digital impression devices would benefit both device manufacturers, their customers and, in some jurisdictions, regulatory authorities.

## 5 Assessment of accuracy

### 5.1 General

#### 5.1.1 Clinical quality

Since digital impression data are the input to the process of designing and manufacturing, a dental prosthetic appliance, its accuracy, within clinically acceptable tolerances, is a quality factor to be controlled. When a prosthesis is placed on two or more prepared teeth, a clinical requirement on uncertainty in separation of critical features is that it be less than approximately 100 µm. When placing a prosthetic appliance on two or more implant abutments, the requirement on accuracy is more stringent.

### 5.1.2 Sources of uncertainty

Digital impression devices that rely solely on numerical registration methods to combine a large number of small range images of three-dimensional surfaces into a large model are subject to uncertainties. These arise from the registration of overlapping range images where the uncertainty depends on the number of data elements in the overlap. The uncertainty increases as it is propagated across a scanned region, leading to large uncertainties in relative positions and orientations derived for features at the extreme ends of a scanning pattern. For full-arch scanning, the accuracy has been shown to be unacceptably poor, but techniques are evolving to improve accuracy. It is therefore desirable that standard methods for comparing techniques and instrumentation be available by providing measures of interest by which accuracy can be assessed.

### 5.1.3 Auxiliary methods

Some solutions for reducing uncertainties employ auxiliary methods of measurement or calibration. These can be both intra- and extra-oral. The auxiliary data are utilized either directly in the registration of range images or employed in a separate numerical algorithm to correct for distortion in the digital impression data. In order to be utilized directly, the results or data from auxiliary measurements are available prior to taking the digital impression data.

## 5.2 Accuracy

### 5.2.1 General

Accuracy is a general concept that includes both trueness and precision or reliability. Operational procedures for estimating trueness, precision and reliability are presented as means for assessing accuracy.

### 5.2.2 Trueness

For digital impression data, the operations by which trueness is assessed can be of two types:

- a) Direct comparison with independent, calibrated measurements of particular measures of interest: these measures are distances or angles relative to a reference plane which itself is defined by the dentition, as in [Annex A](#) or by one or more auxiliary devices.
- b) Estimation of a goodness-of-fit statistic derived from overall comparison with reference impression data: this method of assessment frequently disguises serious discrepancies that are of limited spatial extent. Assessments employing this methodology can require the digital impression data to fit reference impression data at a clinically relevant, limited, contiguous subset of points at or near one extreme of the scanning pattern, for example, a scan body, and then determine the quality of fit of a similar feature (e.g. a second scan body) near the opposite extreme.

Goodness-of-fit statistics expressed in the units of the measures of interest give the user a clearer basis for comparison than those expressed as in relative terms; i.e. as percentages.

Clinically, trueness is ultimately determined when a prosthetic appliance, which has been designed and manufactured from the digital impression data, is placed in the patient's mouth. Quality management procedures and systems<sup>[2]</sup> can build up data records that, on review, allow assessment of trueness of the digital impressions upon which prosthesis design and manufacturing are based.

### 5.2.3 Precision

By precision is meant that repeated measurements with the digital impression device agree to within a nominated tolerance regardless of operator, provided the scanning is performed within the guidelines supplied with the device. Assessments of precision are of two types:

- a) Repeated measurements of measures of interest and evaluation of statistics that describe variability, as described in Part 1, This is a Type A evaluation of uncertainty.

The precision of this determination is expressed as standard uncertainty  $\sigma$ . When the precision in a value is derived from the standard deviation  $S$  of  $n$  repeated measurements, the standard uncertainty is:

$$\sigma = S/\sqrt{n}$$

- b) Deduction from knowledge of the design and mode of operation of the scanning device and the algorithms employed to extract a digital impression from raw data. This is a Type B evaluation of uncertainty.

### 5.2.4 External reliability

Determination of reliability (see [Annex D](#)) assesses the precision of given digital impression data derived from a single scanning procedure. It provides a measure of the contribution of errors in observations to uncertainties in the digital impression data. The determination of reliability exploits the excess over the minimum necessary number of measurements, or redundancy, in the data acquired in the course of a single scanning procedure, and employs it either

- a) within the scanning and registration algorithm to indicate when adequate data have been acquired to achieve a given precision, or
- b) in post-analysis to detect and eliminate gross errors arising from unpredictable sources and then to estimate the residual uncertainties.

## 5.3 Test objects

### 5.3.1 General

Test objects are material models of dentition or edentulous tissue on one jaw employed for assessing the accuracy of a digital impression device. When scanned in order to assess the accuracy of a digital impression device, the scanning pattern conforms to that used in a clinical situation.

The principles outlined in this document for assessing precision and accuracy, are not compatible with the exploitation of the dimensions for the proposed scan body. The scan body design in [Annex A](#) includes features intended to be measured independently as noted in [Clause B.3](#), in order to build up a redundant set of observations that can be assessed for external reliability by the method in [Annex D](#).

### 5.3.2 Single implant

[Annex A](#) describes a test object and measures of interest for assessing accuracy when scanning a single implant body with an attached scan body.

### 5.3.3 Multiple implants

[Annex B](#) describes a test object with more than one implant where design of a clinically acceptable prosthetic device requires accuracy in relative position and orientation.