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Dentistry — Digital impression devices —

Part 2:
Methods for assessing accuracy for implanted devices

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

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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,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 55, *Dentistry,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

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

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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.

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 are 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.[4] 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.

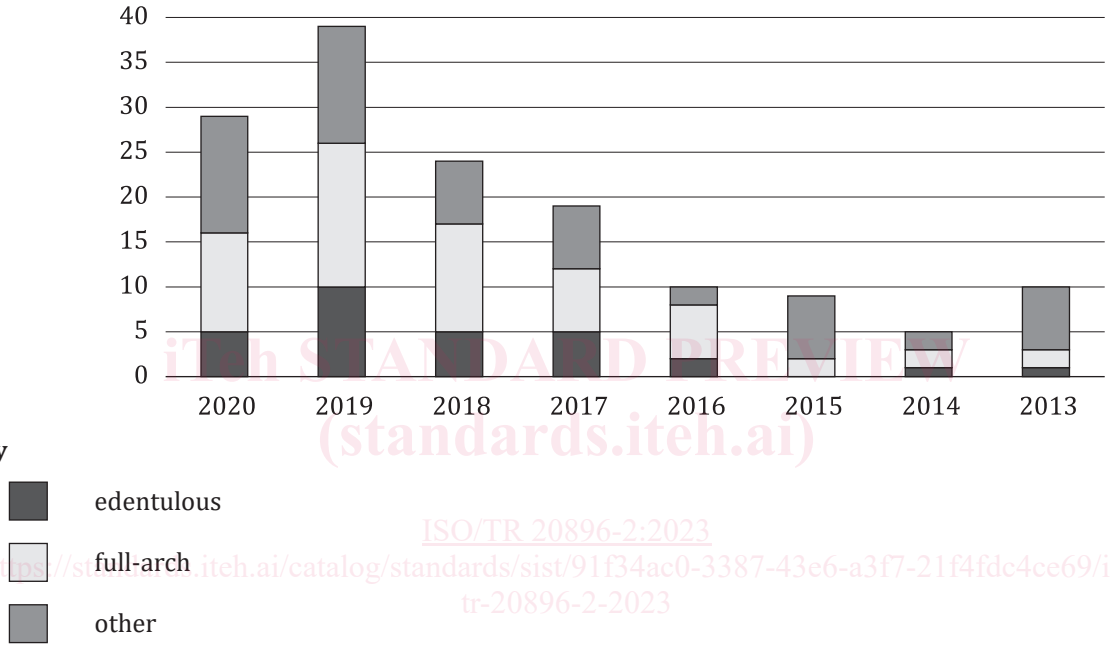

Figure 1 — Refereed articles with search keywords "intra-oral scanning" and "accuracy"

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[2] 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 σ. 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.

5.4 Reference measurement of test objects

5.4.1 Calibrated measures of interest

The dimensions of interest of the test object as designated in Annex B and Annex C are determined by an independent, calibrated measurement traceable to the internationally adopted standard of length. The values obtained are considered the true values for the dimensions of interest. The conditions of temperature and humidity under which the determination is made are measured and recorded.

Where precision is obtained from a Type B evaluation of standard uncertainty as defined by ISO/IEC Guide 98-3:2008, 4.3, an appropriate conversion to standard uncertainty is cited.

The standard uncertainty in the reference values of the measures of interest is not greater than one-fifth of (i.e. 0,2 times) the accuracy expected, required or claimed for the digitizing device.

5.4.2 Independent scanning device

Where trueness is assessed according to 5.2.2 b), or precision according to 5.2.3 b), the independent scanning device is capable of creating reference impression data to a precision with a standard uncertainty no greater than one-half the accuracy expected, required or claimed for the digitizing device being assessed.

5.5 Auxiliary devices

5.5.1 General

The purpose of an auxiliary measurement of the geometry of the dentition or mucosal surface is to allow closure of the linear series of scanning frames acquired by a digital impression device during a scanning procedure. The auxiliary measurement provides additional and more precise data on the relative positions within the scan pattern. The following clauses describe methods mentioned in published reports.

5.5.2 Calliper measurement

Caliper measurement can provide an independent estimate of the distance between an identifiable feature on each implant scan body on the scanning pattern. The distance between such features is in the range (40 ± 20) mm and the uncertainty in this dimension required for clinical acceptability is 100 µm (at 95 % confidence limit). This distance measurement imposes a significant constraint within the registration algorithm, if its uncertainty is less than or equal to 50 µm.

5.5.3 Extra-oral photogrammetry

For measuring implant positions and orientations, a device that acquires data in a single range image on distance and angular direction to specially designed scan bodies. In one implementation, the scan body has a flag-like superstructure, which is patterned to allow their orientation to be interpreted from a single optical image or a pair of stereographic images.

For this technique to improve to the accuracy of digital impression data, the resolution of the extra-oral data acquisition device must allow feature identification over approximately 40 mm at a distance of (100 ± 20) mm to provide a precision of 0,025 mm. To achieve this, features within an angular range of (25 ± 11)° are to be resolved to one part in two thousand. This requires up to 6 000 sensor elements in the lateral direction, where a minimum of three elements identify a feature.