TECHNICAL REPORT

ISO/TR 20896-2

First edition
2023-02

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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Published in Switzerland

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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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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 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 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.[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.

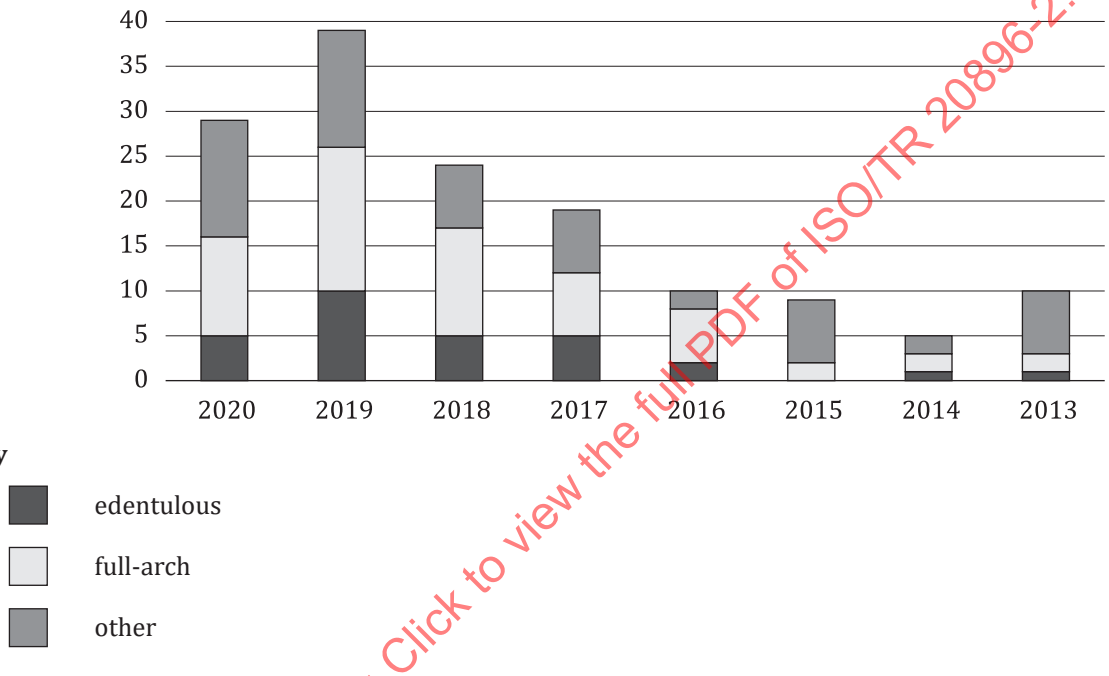


Figure 1 — Refereed articles with search keywords "intra-oral scanning" and "accuracy"

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.

6 Accuracy assessment methods

6.1 Measures of interest

6.1.1 General

The measures of interest are defined by positions and directions in an appropriate reference system. Recommended reference systems are described in Annex A and Annex B.

6.1.2 Position of interest

The recommended position of interest for an implant body is the point where the axis of implant body intersects the connecting interface. The geometrical description of the surface of a scan body takes this point as its origin.

NOTE 1 The term connecting interface is defined in ISO 16443:2014, 3.2.8

NOTE 2 Where an implant body is designed to receive an abutment screw, the position of interest can be defined as the intersection of the axis of the implant body with the surface of the implant body to which the abutment matches.

6.2 Assessment of trueness

6.2.1 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.

6.2.2 Multiple implants

The principles for the design and calibration of test objects designed to assess the accuracy of a digital impression device and auxiliary devices are outlined in Annex A and Annex B. Additional measures of interest are given in Annex C.

For assessment of trueness according to 4.1.1 a), the measures of interest are extracted from the digital impression data and compared directly with the corresponding reference values.

For assessment of trueness according to 4.1.1 b),

a) the digital impression data acquired by the digital impression device and the reference impression data are registered to minimize the goodness-of-fit statistic over the surface of one scan body (at one end of the scanning range where more than two scan bodies are scanned) and the mucosal surface. The goodness of fit is recorded;

b) the goodness of fit for the surface of the neighbouring scan body in the digital impression and in the reference impression is then evaluated and recorded.

Where more than two scan bodies are scanned,

c) the digital impression data are then registered to minimize the goodness-of-fit statistic over both the first and successive, neighbouring scan bodies, and the minimum goodness of fit evaluated and recorded;

d) steps 2 and 3 are repeated for the surfaces of further neighbouring scan bodies, each time including only previously assessed scan bodies in the registration.

Trueness is evaluated as the difference between the goodness of fit for the ultimate scan body as evaluated in 6.2.2 b) and the goodness of fit evaluated in 6.2.2 a).

6.3 Assessment of precision

6.3.1 Repeated scanning procedures

For assessment of precision, the recommended scanning procedure is performed at least five times according to the instructions provided for the given indication as described in 6.2. Precision is expressed as the largest standard uncertainty evaluated for the measures of interest or in the goodness of fit.

Data from all repetitions of the scanning procedure are included in the estimation of the standard uncertainty. Exclusion is allowed if the digitizing device itself identifies a scanning procedure as improperly or inadequately performed.

6.3.2 Design analysis

Since the major source of uncertainty in intra-oral scanning is registration of successive range images, the uncertainty in the relative orientation angles and displacements of overlapping frames can be evaluated from the numbers of data in two orthogonal directions in each overlap. The uncertainty estimation includes the number of data required to identify features in the overlap.

Where registration is based on overall shape of the scanned surface within an overlap and determined by minimizing a goodness-of-fit statistic, the residual misfit is propagated to estimate uncertainties in the change between overlapping range images in:

a) three angles describing camera rotation, and

b) three components of camera displacement.

The uncertainty estimates derived above are then propagated to derive the uncertainty in relative positions and orientations of scan bodies separated as described for the clinical indication for which assessment of precision is required.

6.4 Expression of accuracy

The accuracy in the measurement of a measure of interest is assessed as the combination of the trueness and the precision. The accuracy in the i^{th} measure of interest is evaluated as the greater of the standard uncertainty in the reference value and root-mean-square difference between the measured values and the reference value:

$$s_i = \sqrt{\frac{\sum_{j=1}^{n} \left(d_{j,i} - d_{R,i}\right)^2}{n}}$$

where

s_i is the root-mean-square difference between the measured values and reference value for the measure of interest;

$d_{j,i}$ is the j^{th} measured value of the i^{th} measure of interest;

$d_{R,i}$ is the reference value for the i^{th} measure of interest.

6.5 Assessment of reliability

The principles of estimating the reliability of a scanning procedure are described in Annex D. Reliability can be improved by increasing redundancy; that is by performing additional scanning on a different scanning pattern in order to reveal gross errors that can then be eliminated.

Reliability can also be improved by incorporating independent, auxiliary observations regarding the scan bodies or implant bodies into the numerical algorithm that minimizes the goodness of fit statistic. Such observations include:

a) dimensions of scan bodies;

b) dimensions of intra-oral calibration appliance;

c) independently measured intra-oral dimensions;

d) image data acquired by alternative means such as cone-beam computer tomography or extra-oral photography.

7 Test report

7.1 General

The test report documents the device that is being assessed for accuracy, the test object and its calibration, the method and conditions under which data sets were acquired and the results obtained for all relevant measures of interest. The test report identifies the statistical methods employed to test the significance of bias and, if appropriate, to estimate external reliability.

The units of measurement are clearly identified and used consistently. The use of different units, for example, millimetre and micrometre, is avoided.

7.2 Device

The test report identifies all components of the digital impression device including:

a) the hand-held scanning device;

b) scan bodies;

c) auxiliary devices;

d) the software version employed to produce the digital impression data;

e) if appropriate, the software employed to extract the dimensions of interest.

7.3 Test object

The following are reported:

a) the unique identifier of the test object;

b) the material from which it is constructed;

c) the surface roughness of markers and surfaces critical to measurement;

d) the nature of decoration, coating or incisions;

e) the method employed to determine reference values for each dimension of interest;

f) the identification of the equipment employed for the determination (including software version);

g) the reference or true value of each dimension of interest;

h) the precision of each reference value, expressed as a standard uncertainty.

7.4 Test method

The test report includes:

a) the International Standard used (including its year of publication);

b) the test method;

c) the date of each test;

d) the identity of the test object;

e) record of temperature and humidity under which the test is performed;

f) description of the external lighting of the test area;

g) the identity or description of the scanning pattern employed;

h) record of the number of individual scanning procedures performed;

i) description of deviations from the procedure;

j) unusual features observed during the procedure.

7.5 Test results

For each test object, the test report tabulates the following for each dimension of interest, labelled ($_i$):

a) the mean value, $< d_i >$,

b) the standard uncertainty $u(d_i)$,

c) the corresponding true value $d_{R,i}$,

d) the standard uncertainty in the true value $u(d_{R,i})$,

e) the bias Δd_i evaluated according to 5.4.2. If the bias is assessed as non-zero, the level of significance is cited, and

f) the accuracy s_i evaluated according to 6.4.

7.6 Test data

Where the external reliability of the individual values for the dimensions of interest has been estimated according to D.5 for each independent scanning procedure, the following are tabulated:

a) the individual value $d_{j,i}$,

b) the difference $d_{j,i} - d_{R,i}$, and

c) the external reliability $\nabla(d_{j,i})$ evaluated according to Clause D.6.

Annex A
(Informative)

Scan body for accuracy assessment

A.1 Generics of the design

A scan body that is suited to accuracy assessment is intended to allow for the estimation of the quality of the assessment itself. This is enabled by the design presented in Figure A.1 which has multiple instances of readily identifiable features on each body. By requiring the digitizing system to identify as many such features as are accessible to scanning, a statistical redundancy is created that can then be exploited using the techniques described in Annex D.

A.2 Geometry of the assessment scan body

The scan body has hexagonal symmetry except for a slanting cut that makes one of the six-fold directions unique. The design can be realized by machining a cylindrical body with a rotating milling tool as indicated in Figure A.1. The vertices of the upper part form rectangular corners if the centres of the milled diameters are located at a distance a which is $\sqrt{2}$ times the radius $b/2$; that is a equals b divided by $\sqrt{2}$.

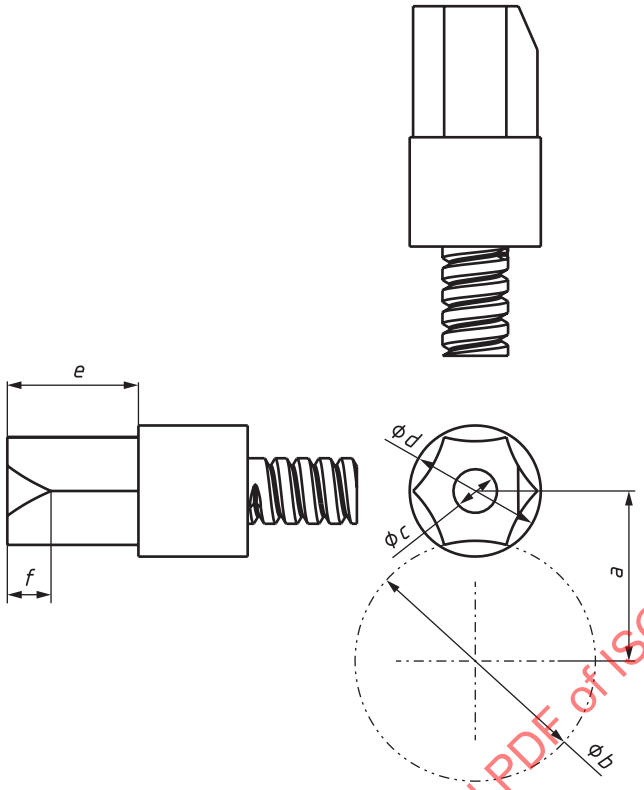
The diameter d of the cylindrical base of the scan body is detectably greater than the diameter between opposite vertices of the hexagonal part of the cylinder. This requires a milling diameter b less than 1,866 times the diameter d of the cylinder from which the body is milled.

The central hole in the top surface has a diameter c which is suited to the attachment of the scan body to the implant. It also facilitates the measurement by calliper of distances between scan bodies if the calliper has ball tips with diameters slightly greater than the central hole.

The lower section of the scan body is a circular cylinder shaped to suit the implant system. The height is chosen to suit the height of a tooth in the actual position. The internal and external surfaces of this section are shaped to suit the implant system.

The manufactured scan body conforms in each dimension a to f of its design to within ±0,02 mm.

The following dimensions: a = 7,778 mm, b = 11 mm, d = 6 mm and a height of 6 mm for the hexagonal section are recommended.



Key

a b/2 × √2 = b/√2
b [11 ± 2] mm; less than 1,866 × *d*
c [3 ± 2] mm
d [6 ± 2] mm
e [6 ± 0,1] mm
f [2 ± 0,5] mm

Figure A.1 — Scan body construction

A.3 Materials of test object

Polyether ether ketone (PEEK) is a suitable material from which to machine a scan body.

Annex B
(informative)

Test object — Single implant

B.1 Geometry of test object

The test object for a single implant is a model or cast from a lower or upper jaw with a dentition of 13 sound teeth. It is augmented as illustrated in Figure B.1 by an implant body to which a scan body described in Annex A is attached. The implant replaces one tooth in the lower or upper jaw.

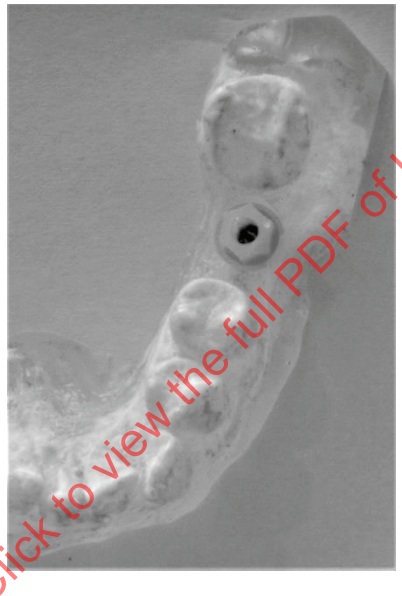
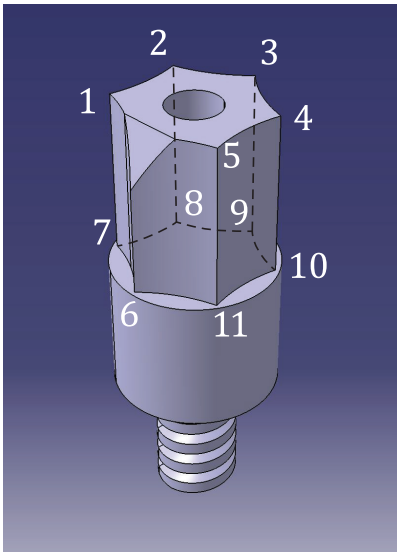


Figure B.1 — Single-implant test object showing the placement of a scan body at the position of tooth 36



Key

1, 2, 3, 4, 5	upper corners to be registered
6, 7, 8, 9, 10, 11	lower corners to be registered
1 - 7	edge defining the axis direction
2 - 8	edge defining the axis direction
3 - 9	edge defining the axis direction
4 - 10	edge defining the axis direction
5 - 11	edge defining the axis direction

Figure B.2 — Scan body with identified corner features

B.2 Materials of test object

The test object can be either:

a) cast or modelled in a dental gypsum product conforming to Type 4 according to ISO 6873:2013, or

b) manufactured as a denture made from denture base material conforming to ISO 20795-1:2013 and with artificial teeth conforming to ISO 22112:2017.

B.3 Measures of interest

For accuracy assessment, each set of corner coordinates is determined independently and without reference to the dimensions of the scan body. All measurements of position are referred to the reference system of the digital impression data obtained by the digitizing device.

The measures of interest are:

a) the coordinates x_i, y_i, z_i in millimetres of the five rectangular corners around the top surface of the scan body. These vertices are numbered i = 1 to 5 clockwise from the slanting cut. See Figure B.2;

b) the coordinates x_j, y_j, z_j in millimetres of each right-angled edge where it meets the base of the hexagonal part of the scan body. These positions are numbered j = 6 to 11 clockwise from the unique (cut) edge. See Figure B.2.

NOTE Where the corners of the scan body are rounded or bevelled, the coordinates of the corner feature are those of a rectangular template that is adjusted to the three edges leading into the corner.

From these measurements, the position and direction of the implanted body is determined as follows:

c) the position of the scan body is estimated as the average $(x_{pos}, y_{pos}, z_{pos})$ of positions of opposing vertices; for example $x_{pos,1} = (x_1 + x_4)/2$ or $z_{pos,2} = (z_2 + z_5)/2$. The norm of the difference between these estimates of position is the measure of its uncertainty $u(x_{pos}, y_{pos}, z_{pos})$;

d) coordinates for a vertex at the base of the hexagonal part are paired with those for the corresponding vertex around the top of the scan body. The direction of each edge is determined by subtraction; for example, $x_{edge,1} = x_1 - x_7$, $x_{edge,2} = x_2 - x_8$, $y_{edge,4} = y_4 - y_{10}$. The vectors $(x_{edge,1}, y_{edge,1}, z_{edge,1})$ and $(x_{edge,2}, y_{edge,2}, z_{edge,2})$ are independent measures of the direction of the implant axis. Their average is the axis vector $(x_{axis}, y_{axis}, z_{axis})$. The angle between the vectors estimates the uncertainty in the axis direction. Where more than three or more such angles can be estimated, the largest is taken as the uncertainty;

e) the position of the implant body is estimated by extending the axis vector as determined in iv) by the ratio of the full length, *l*, of the scan body to the length, *f*, of its hexagonal part. This is then subtracted from the position of the scan body as determined in c). The uncertainty in the position of the implant is given by:

$$u(x_{implant}, y_{implant}, z_{implant}) = \sqrt{[u^2(x_{pos}, y_{pos}, z_{pos}) + (l/f)^2 \times u^2(x_{axis}, y_{axis}, z_{axis})]}$$

Annex C
(informative)

Test object — Multiple implants

C.1 General

For a test object for assessment of the accuracy of a digital impression device for application to a jaw with two or more implant bodies that are intended to support a prosthetic superstructure across edentulous mucosa, the principles given in this annex apply.

C.2 Geometry of a test object

A test object for multiple implants is a model of a jaw which has implant bodies fixed in a suitable denture base material in positions expected for the clinical indication being trialled.

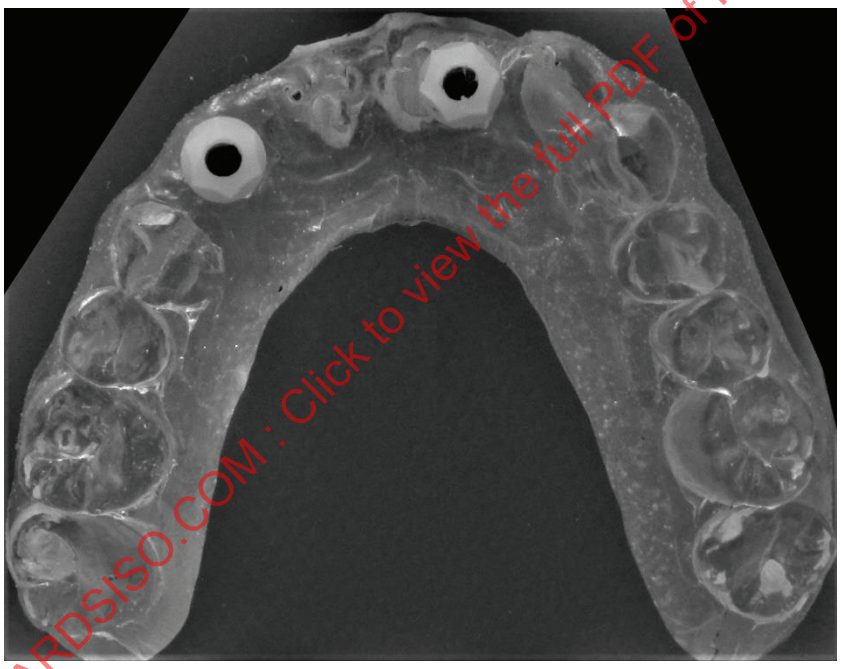


Figure C.1 — Test object with two scan bodies placed near tooth positions 13 and 21

C.3 Materials of test object

The material of the jaw is mechanically rigid and stable for the duration of testing including calibration. Relative positions of the implant bodies do not change by an amount greater than half that expected, required or claimed for the digitizing device being assessed. If necessary, the model can be mounted on a rigid base. The material of the model exhibits limited translucency – that is a gradation of refractive index, in the surface layers. The denture-base can be moistened to reproduce the clinical situation more closely.

NOTE Polymethyl metacrylate (PMMA) is one material used for models [3].

C.4 Dimensions of interest

The dimensions of interest are derived from the positions in the digital impression of the implant bodies determined according to Clause B.3 e), and the scan bodies determined according to Clause B.3 c) for each implant and scan body.

For each pair of implant bodies, the dimensions of interest are the distances between the implant bodies, between the scan bodies, and between one implant body and the other scan body; that is from the top of the scan body to the implant body of the other implant. These four distances and the height of the scan bodies fully define the relative orientation of two implants. They can be compared with the same distances measured by means of callipers with ball tips matched to the diameter denoted c in Figure A.1.

The internal reliability of the implant and scan body positions, and the distances between them are obtained using the analysis outlined in Annex D.

Annex D
(informative)

Guidance on evaluating precision and external reliability

D.1 General

This annex outlines data analyses by which to assess the reliability in the estimates of dimensions of interest from data acquired with a digital impression device. External reliability and precision are two statistics that can indicate the magnitude of differences between digital impression data and the object that was scanned. They can be determined when there are redundant measurements, i.e. observations in excess of the minimum number required to derive all the parameters of the digital impression and of the scanning process.

NOTE This presentation is simplified to the extent that assignment of different uncertainties to observations has been ignored. Standard numerical software for matrix computation can take uncertainty into account[6].

D.2 Processing of data from scanning to digital impression or virtual model

The data acquired by means of a hand-held scanning device is initially converted to a set or array of coordinates, referred to the scanning device, of points in a region on the surface of the test object. Successively acquired sets of coordinates or range images cover regions that overlap partially.

Registration software determines the areas of overlap by predictive techniques and recognizes common features on the surface. It estimates the change in position and orientation of the scanning device between the acquisition of one range image and a subsequent range image by requiring the coordinates of features in the overlapping area to match a common surface. The parameters that describe the full set of common surfaces in an arbitrary Cartesian frame of reference become a first approximation to the digital impression of the test object.

There is an intrinsic source of uncertainty in registration that arises from the number N of data recorded within each area of overlap. About the direction in which the scanning device is pointed, angular uncertainty is approximately $1/\sqrt{N}$ radians. About axes normal to the pointing direction, the uncertainty in angle equals the ratio of the resolution of range as measured by the scanning device to the linear dimension of the area of overlap on the test object. When scanning over many frames, the uncertainties in these angles propagate to become larger uncertainties in translation and rotation between the first and last frames.

D.3 Elimination of gross errors of measurement

The total number of data in the overlap of range images exceeds the total number of parameters required to perform registration and to describe the movements of the scanning device. This redundancy permits statistical techniques to be employed to detect, identify and remove individual observations that can be shown to be gross errors of measurement. Gross errors arise from many sources including incomplete correction of optical distortion in the scanning device, ambient light or translucency confounding the scanning device and incorrect identification of common features during registration.

For any given statistical criterion of significance for eliminating gross errors, there will remain individual observations that border on being rejected. Their presence in the accepted set of observations from which the digital impression is constructed, make a major contribution to uncertainty in the digital impression data. The magnitudes of the largest such errors are estimated from the redundancy according to Clause D.6.