SLOVENSKI STANDARD
oSIST prEN ISO 20896:2018

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Zobozdravstvo - Digitalni pripomočki za sisteme CAD/CAM - Metode za ugotavljanje točnosti (ISO/DIS 20896:2018)

Dentistry - Digital impression devices - Methods for assessing accuracy (ISO/DIS 20896:2018)

Zahnheilkunde - Genauigkeit von handgehaltenen Scanner für CAD/CAM-Systeme am Behandlungsstuhl (ISO/DIS 20896:2018)

Médecine bucco-dentaire - Précision du balayage des dispositifs portatifs pour systèmes CAO/FAO de fauteuils dentaires (ISO/DIS 20896:2018)

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Dentistry — Digital impression devices — Methods for assessing accuracy

Médecine bucco-dentaire — Précision du balayage des dispositifs portatifs pour systèmes CAO/FAO de fauteuils dentaires

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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).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on 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 the following URL: www.iso.org/iso/foreword.html.

The committee responsible for this document is Technical Committee ISO/TC 106, Dentistry, Subcommittee SC 9, *Dental CAD/CAM Systems*.

Introduction

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

This document describes test methods for evaluating the accuracy of digitizing devices that acquire data by direct scanning of a patient's dentition with a manually guided; that is hand-held, device in order to obtain a digital impression. A companion document, ISO 12836, provides test methods for assessing the accuracy of fixed devices for digitizing physical impressions or models cast from such impressions. Separate standards were deemed necessary after it became apparent that two of the test objects described in ISO 12836 are unsuited for successful interpretation of data acquired from these objects with a hand-held scanning device.

It is to be noted that testing conducted outside the oral cavity on objects that are ideal – in having both surface characteristics suitable for a given scanning technology and sufficient recognizable features for registration algorithms to function well – will give a better result than can be achieved under less ideal, clinical conditions. As a first stage in developing standard methods for estimating and representing the degradation in precision that arises in the clinical use of digitizing devices, this document includes an informative annex on the evaluation of external reliability.

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Dentistry — Digital impression devices — Methods for assessing accuracy

1 Scope

This document specifies test methods and procedures for assessing the accuracy and external reliability of a three-dimensional numerical description of intra-oral surfaces acquired directly from a patient with a hand-held scanning device. The test methods are not applicable to ultrasonic, radiographic or magnetic resonance imaging methods.

Note: ISO 12836:2015 specifies the test methods for the assessment of accuracy of digitizing devices that use a fixed or a mechanically guided scanning device.

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 6873:2013, Dentistry — Gypsum Products

ISO 12836 Dentistry — Digitizing devices for CAD/CAM systems for indirect dental restorations — Test methods for assessing accuracy

ISO 18739 Dentistry — Vocabulary of process chain for CAD/CAM systems ISO 20795-1, Dentistry — Base polymers — Part 1: Denture base polymers

ISO 22112 Dentistry — Artificial teeth for dental prostheses

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

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

3 Terms and definitions

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

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

IEC Electropedia: available at http://www.electropedia.org/

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

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3.1
accuracy
closeness of agreement between a test result and an accepted reference value.

[SOURCE: ISO 18739:2016]

Note 1 to entry: Accuracy is a qualitative concept. For the purpose of this document accuracy is to be expressed as specified in 5.4.3.

3.2
bias
difference between the expectation of the test results and an accepted reference value.

[SOURCE: ISO 3534-1]

Note 1 to entry: For the purpose of this document bias is to be expressed as given in 5.4.2

3.3
digital impression
acquisition of a data set with the numerical 3-dimensional representation of the surfaces from the patient directly, or the outcome of such an acquisition.

[SOURCE: ISO 18739:2016, Clause 3.1.20, modified]

Note 1 to entry: This definition extends ISO 18739:2016, Clause 3.1.20 to include the outcome of data acquisition.

Note 2 to entry: A digital impression may be supplemented by data on surface colour.

Note 3 to entry: A digital impression is distinct from a virtual model as defined in ISO 18739:2016, Clause 3.1.40. A virtual model is the graphical output from design or similar software; a digital impression is the input to this software.

3.4
digital-impression device
combination of a hand-held scanning device suited for use in the oral cavity, and computer hardware and software that outputs a numerical, three-dimensional description of scanned surfaces.

3.5
dimension of interest
distance between features of a test object that are required to be both measured independently as a reference or true value and estimated by the digital impression device using a prescribed scanning procedure.

3.6
external reliability
confidence interval for an estimated dimension after eliminating gross errors in the data as detected by the digitizing system's software.

Note 1 to entry: Note to entry: External reliability is evaluated by propagation of uncertainties as estimated from the redundancy in an accepted dataset, as described in Annex D.

3.7
gross error
observation that can be demonstrated to be inconsistent with other data.

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

Note 2 to entry: A gross error can arise from partial failure of a measurement device, or from incorrect calibration, pattern recognition or data interpretation.

3.8
hand-held scanning device
camera or similar sensor which may be moved freely as it captures light reflected or diffusely scattered from a surface and converts it into a sequence of data from which distances and corresponding directions to the surface can be determined.

Note 1 to entry: The instrument may have its own source of illumination.

Note 2 to entry: The scanning device may operate by any technology that provides data on range and direction from the device to the surface.

Note 3 to entry: The values of distances and corresponding directions constitute the raw data for creating the digital impression.

3.9
observation
single item of data or of information relating items of data.

Note 1 to entry: Examples of observations in intra-oral scanning are: i) a range or a component of direction in an array of digitized data, ii) the identification of a single feature in two arrays of digitized data.

3.10
precision
the closeness of agreement between independent results of measurement obtained under stipulated conditions.

Note 1 to entry: Precision is a qualitative concept. The operational definition that applies in this document is the standard deviation.

[SOURCE: ISO 18739:2016, 3.2.7]

3.11
range
measured distance from the hand-held scanning device to a scanned surface.

3.12
redundancy
3.12.1 total redundancydifference between the number of observations and the number of parameters in the digital impression and required to describe the movement of the hand-held scanning device.3.12.2 redundancy numberrelative part of an observation which does not contribute significantly to the estimation of parameters.

Note 1 to entry: Total redundancy is also known as the number of degrees of freedom.

Note 2 to entry: Redundancy numbers range from 0 to 1. A redundancy number near 1 allows an observation to be controlled for gross error. A redundancy number near zero means that an observation cannot be controlled for gross error and yet the observation has a direct influence on the parameters.

Note 3 to entry: The sum of redundancy numbers for all observations is equal the total redundancy.

3.13
registration
sub-process in analysis of scanning data in which segments of surface topography derived from data acquired by a scanning device in successive positions and orientations are matched in order to estimate the relative translation and rotation of the scanning device.

3.14
scanning pattern
sequence of translations and rotations of a hand-held scanning device relative to the object being scanned as it acquires data from which to render the surface of the object as a digital impression.