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Zobozdravstvo - Medobratovalnost sistemov CAD/CAM (ISO/DIS 18618:2024)

Dentistry - Interoperability of CAD/CAM systems (ISO/DIS 18618:2024)

Médecine bucco-dentaire - Interopérabilité des systèmes de CFAO (ISO/DIS 18618:2024)

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Dentistry — Interoperability of CAD/CAM systems

Médecine bucco-dentaire — Interopérabilité des systèmes de **CFAO**

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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 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*, 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).

This third edition cancels and replaces the second edition (ISO 18618:2022), which has been technically revised.

The main change compared to the previous edition is as follows: Updated the XML schema for IDS (interface for dental CAD/CAM systems) examples of interoperability of digital dental products relating to inlay, onlay, crown, dental implant systems, removables, dental appliances, orthodontics, and dentures have been updated in Annex A due to the fast nature of the software system innovation and the need for ongoing testing.

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

Manufacturers of dental CAD/CAM systems differ in how they exchange manufacturing information and three dimensional data. This causes difficulty in data processing, design processes and manufacturing processes for users of those systems. In order to overcome these interoperability issues, this document has been prepared to facilitate open interoperability between CAD/CAM systems in dentistry.

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Dentistry — Interoperability of CAD/CAM systems

1 Scope

This document specifies an extensible markup language (XML) format to facilitate the transfer of dental case data and CAD/CAM data between software systems.

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 3166-1, Codes for the representation of names of countries and their subdivisions — Part 1: Country code

ISO 3950, Dentistry — Designation system for teeth and areas of the oral cavity

ISO 16443, Dentistry — Vocabulary for dental implants systems and related procedure

ISO 18739, Dentistry — Vocabulary of process chain for CAD/CAM systems

W3C — Extensible Markup Language (XML) 1.0 (Fifth Edition), November 2008

W3C XML Schema Definition Language (XSD) 1.1, April 2012

3 Terms and definitions Document Preview

For the purposes of this document, the terms and definitions given in ISO 1942, ISO 16443, ISO 18739, W3C XML 1.0, W3C XML XSD 1.1 and the following apply. \(\text{ISO} \) \(\text{186} \) \(\text{18} \) \(\text{2024} \)

ISO and IEC maintain terminological 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 General terms

3.1.1

broker

entity that acts as a middleman or intermediary

Note 1 to entry: Such organizations take multiple orders from multiple sources and consolidate them into a single order for a provider or they take single orders from an originator and split them among multiple providers or they just pass orders through between originators and providers.

3.1.2

interface for dental CAD/CAM systems

nodes immediately within the enveloping root element that provide traceability and source identification features as well as information on how to reply to a document transaction

Note 1 to entry: The IDS schema organizes the IDS document into structures for specific transactions. They represent a submission, a query, an update of a previous submission, a notification of an event or status change and a series of catalogs. A single IDS document can contain a combination of different transaction nodes or consist of only a single transactional node.

3.1.3

originator

entity (organization or person) that is responsible for creating the current document, order, submission

Note 1 to entry: As such, they are the "originator" of the data being exchanged.

Note 2 to entry: Most often an originator is a dental practice. In some cases, an originator is a dental laboratory that is outsourcing work to another lab.

3.1.4

provider

entity that is responsible for providing the services or products that are being requested in an order

Note 1 to entry: An entity can be a company, a lab.

Note 2 to entry: Most often, a provider is a dental laboratory or manufacturer.

3.2 Terms and definitions relating to XML content

3.2.1

brokerID

identifiers used by a *broker* (3.1.1) to identify itself, or by an *originator* (3.1.2) and a *provider* (3.1.3) to identify a broker

3.2.2

CADDataCatalog

collection of nodes describing CAD data associated with one or more of either the orders or restorations, or both

Note 1 to entry: It can include either a digital scan or design files, or both. 3ba-b05a3c80f223/osist-pren-iso-18618-2024

3.2.3

case

set of one or more orders for dental appliances, products or services, all of which are submitted for a single patient

EXAMPLE A case can contain one order for a crown and another order for a bridge.

3.2.4

catalog

data that are referenced in other elements or areas

Note 1 to entry: The catalogs are subdivided by the data they are grouping, making it easier to manage and reference.

3.2.5

character data

CDATA

certain portion of the document is general character data, rather than non-character data or character data with a more specific, limited structure

Note 1 to entry: CDATA is used for distinct, but related, purposes in the markup languages SGML and XML.

3.2.6

DataQuery

method to request data from another system or entity

Note 1 to entry: It provides elements to define the data elements to be searched or matched on as well as elements to define the data requested in response.

3.2.7

DeliveryRequest

information for the out-going, finished order, which is sent to the originator (or an originator's agent) as a separate delivery

Note 1 to entry: A delivery is either physical or electronic, or both.

3.2.8

dentist

node that defines the responsible clinician who requested the order

3.2.9

DentistCatalog

collection of *dentist* (3.2.8) nodes that provides attributes and elements to define the dentists being referenced in the IDS schema

Note 1 to entry: The definition can include billing information and license information.

3.2.10

ExtraInfo

child node that can be used to extend the schema with undefined XML

Note 1 to entry: Many of the elements contain child nodes with the suffix "ExtraInfo" (i.e. <DentistExtraInfo>, <OrderExtraInfo>, etc). These are intended to be areas that can be used to extend the defined schema with proprietary or undefined XML. For example, an implementation can use one (or more) of these to embed XML that is only of use to the implementer for an internal workflow. Another use can be two business partners using these to experiment with XML they intend to propose for future versions or to pass proprietary XML they have previously defined between themselves. The IDS schema and XSD ignore the contents of these so they are not validated as part of the IDS schema. It is highly recommended that if these are used, that any XML be enclosed within some proprietary element tag so that if the XML document passes through multiple handlers, there are no conflicts:

<DentistExtraInfo>

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<MvCompanyData>

data specific and of use only to "MyCompany"...

</MyCompanyData>

</DentistExtraInfo>

3.2.11

FileCatalog

collection of <IDSFile> nodes that describe files associated with the <Case>, <Order> or CAD data (scans, design files, etc.)

3.2.12

host service

system that receives the IDS document and processes the contents

3.2.13

IDMapCatalog

collection of <IDMapItem> nodes which provide a means of defining alternate identifiers for key elements within the IDS

3.2.14

notification

means for publishing or returning a defined status, event or message related to an order

Note 1 to entry: Within the notification node is an untyped element that can be defined in accordance with the needs of the parties exchanging information.

3.2.15

order

request for a self-contained dental appliance, service or product that is being requested by an originator

Note 1 to entry: Each order in a case can be created or manufactured by a different provider. Each order contains its own delivery (or reply) instruction nodes.

3.2.16

OrderCatalog

collection of <Order> nodes that provide attributes and elements necessary to define or describe an order

Note 1 to entry: An <Order> will often contain one or more <Restoration> nodes but can omit those nodes when not needed.

3.2.17

parcel

physical package that is mailed

3.2.18

patient

node that defines the person for whom a case is being manufactured

Note 1 to entry: Patient infomation is not a mandatory part of the IDS schema.

3.2.19

PatientCatalog

collection of <Patient> nodes that provide attributes and elements to define patients that are referenced in the <Order> or <Case> elements

Note 1 to entry: Because patients are referenced in either multiple <Order> nodes or multiple <Case> nodes, or both, the patient information is grouped into a catalog.

3.2.20

prescription

written directive from the dentist or responsible clinician to the supplier specifying the product that should be manufactured for the patient

3.2.21

ProductCatalog

means for a provider or *broker* (3.1.1) to publish the products that will be available for ordering

Note 1 to entry: The node provides attribute and elements to define a product, include multiple descriptions in different languages and specify ordering options and variations.

3.2.22

productSKU

product stocking unit used by manufacturers to identify their products to their internal systems

3.2.23

providerID

identifiers used by a *broker* (3.1.1) and a *originator* (3.1.2) to identify a *provider* (3.1.3), or by a provider to identify itself

3.2.24

submission

batch or group of one or more <Cases> described in the IDS document

Note 1 to entry: In traditional (non digital) dentistry, a submission is equivalent to receiving a physical package [parcel (3.2.17)] containing one or more cases. In the digital IDS realm, the submission represents any combination of one or more either physical or digital, or both, cases that are being "submitted" to a provider for production.

3.2.25

UUID

universally unique identifier

label used for identifying key elements

Note 2 to entry: An <IDMap> within the <Catalogs> of the document provides a means of equating the UUID with alternate identifiers that carry external meaning, such as a lab management system ids for a dentist, case or patient.

Note 3 to entry: UUID values can have multiple alternate ids in the <IDMap> but each UUID is defined only once and used on a single key element.

EXAMPLE If the UUID "107face6-fc51-4366-805d-2ee23014d835" is assigned to the dentist "smith", that UUID value can possibly not be used on any other element as a key identifier and can only be used as a reference in other elements needing to associate with that specific dentist.

3.2.26

update

means to send an abbreviated set of data elements to update or modify a previously submitted <Order>

Note 1 to entry: It contains elements that allow the update to match expected values in addition to providing the new values.

4 Data security and storage methods

The Internet has proven to be an effective means of communication, yet its vulnerability to interception raises issues of privacy, authentication and integrity of the communicated message. Therefore, data security is of utmost importance to users of dental information systems.

Because of the personal and private nature of health records, the dental practitioner needs to understand 2024 the security issues associated with "data at rest" and "data in transit." This document is not intended to explain security concepts and the risks associated with the maintenance of data in storage and transit, and over an internet connection. The ADA Standards Committee on Dental Informatics has published a series of technical reports that provide dental practitioners with guidelines in addressing issues of security of data in storage and transmission over the internet.

A ZIP file format is recommended for transport of the IDS XML file and related files, however, implementation of a file container is left up to the implementer.

5 Naming

The file name shall end with an ids extension. The file name can be prepended with any naming convention that the user desires.

6 Tooth numbering system

Throughout the entire document, the tooth number system shall be based on ISO 3950 for tooth numbering.

7 Measurement units

All units are in millimetres unless otherwise specified.

8 Additional restrictions on IDS XML documents

In addition to the schema provided above, a valid IDS document shall also meet the following requirements.

- a) The total length of the document shall not exceed 2 MB.
- b) The document shall contain a unique identifier for ProviderIDs.
- c) The document shall contain a unique identifier for BrokerIDs.

9 XSD Description

The definition of the elements of the XSD schema provided in <u>Annex A</u> shall be used. A sample XML schema of IDS is shown in <u>Annex B</u>. The XSD definition document can be obtained by e-mailing standards@ada.org.

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