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Health informatics — Ophthalmic examination device data —

Part 2: Specular microscope

Informatique de santé — Données relatives aux dispositifs d'examen ophtalmique —
Partie 2: Microscope spéculaire

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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 215, *Health informatics*.

A list of all parts in the ISO 22218 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

Ophthalmic devices are used in hospitals and clinics to examine patients. The primary devices used in these ophthalmic examinations provide the measurement of refraction, corneal curvature, intraocular pressure, lens power, and visual acuity. Almost all patients who consult for a diagnosis in ophthalmology undergo these examinations.

Besides such general ophthalmic devices, specular microscopes are often used to capture and analyze an image of the corneal endothelium, which dehydrates the corneal stroma and maintains the cornea's clarity. Thus, measuring the cell density of the corneal endothelium is one of the most crucial and reliable methods to determine its condition. The analysis results of the specular microscope are indispensable for not only patients experiencing trouble in the cornea but also safe prescriptions for contact lenses.

Like other ophthalmic devices, various manufacturers supply specular microscopes. Thus, standardized procedures for mutually communicating analysis results are crucial between the specular microscope and ophthalmic information system (OIS).

However, the integration of this information is complex and potentially error-prone owing to variable data formats provided by specular microscopes from different manufacturers and the lack of interoperability. Thus, the integration of analysis results from various specular microscopes into an OIS or hospital information system (HIS) warrants significant individual effort for each manufacturer's specular microscope.

This document specifies the content and format for the analysis results of specular microscopes, identifying the information that could be included in the analysis results, as well as how it should be formatted when communicated to an OIS, HIS, or other similar systems.

Health informatics — Ophthalmic examination device data —

Part 2: Specular microscope

1 Scope

This document specifies the data output formats for the specular microscope. The data are usually sent from the specular microscope to either an ophthalmic information system (OIS) or a hospital information system (HIS).

This document addresses text-based analysis reporting of the specular microscope measured and analysed data such as the central corneal thickness, the density of endothelial cells per 1 mm^2, the coefficient variant, and the ratio of endothelial cells with a hexagonal shape.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions 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
corneal endothelium
monolayer of endothelial cells that constitutes the posterior corneal surface

Note 1 to entry: The corneal endothelium dehydrates the corneal stroma and maintains the cornea's clarity.

Note 2 to entry: Measuring the endothelial cell density provides valuable information about the cornea's condition.

3.2
endothelial cell density
CD
number indicating how many endothelial cells are present in one square millimeter (mm^2)

Note 1 to entry: This value is often referenced to determine the condition of the corneal endothelium. If the corneal endothelium is young and healthy, the value is high, and if the corneal endothelium is old and damaged, the value is low.

3.3
coefficient of variation
CV
ratio of the standard deviation to the mean in cell size, which is standardized measure of the dispersion of the size of each endothelial cell

Note 1 to entry: This value is often referenced to determine the condition of the corneal endothelium, owing to uniform cell size, healthy corneal endothelium has a small CV value.

3.4
hexagonality
HEX
morphology of endothelial cells, usually the percentage of hexagonal cells

Note 1 to entry: This value is often referenced to determine the condition of the corneal endothelium. Cells of healthy corneal endothelium have uniform size and are primarily hexagonal.

3.5
dry eye
disease in which the stability of the tear film is reduced

3.6
Fuchs' dystrophy
slowly progressing corneal dystrophy in which fluid builds up and the cornea gets swollen and puffy

3.7
bullous keratopathy
eye disorder due to oedema that involves a swelling of the cornea

3.8
ophthalmic information system
OIS
computer system that acquires, stores, retrieves and manages ophthalmic images and examination data

Note 1 to entry: The OIS gather and manage examination information from various ophthalmic devices and submit persistent examination reports in CDA RMIM format to HIS.

[SOURCE: ISO/TS 22218-1:2022, 3.19]

3.9
deviceCDA
subset of the CDA RMIM dataset that only includes the information contained in a device

Note 1 to entry: Most ophthalmic examination devices do not support all the mandatory information required by a complete CDA document, such as patient or operator identification, and additional information can be accessed after the report is sent to an OIS or HIS.

[SOURCE: ISO/TS 22218-1:2022, 3.20]

3.10
hospital information system
HIS
comprehensive, integrated information system designed to manage all the aspects of a hospital's operation

Note 1 to entry: In many implementations, a HIS covers hospital's operation such as medical, administrative, financial, and legal issues and the corresponding processing of services.

[SOURCE: IS4H-MM[6]]

4 Specifications

4.1 General

OEDD provides standards both for transferring clinical ophthalmic examination data from various types of examination devices to an OIS, as well as submitting persistent reports based on those examination data from an OIS to a HIS. The specular microscope is one such examination device.

Exemplary use cases are detailed in Annex A.

It is possible to handle multiple data types such as SPECULAR (Specular microscope), REF (Refractometer), KM (Keratometer), TM (Tonometer), LM (Lensmeter), and PHOR (Phoroptor) within one XML file. It is acceptable to compile SPECULAR, REF, KM, TM, LM, and PHOR in one file or separate them into different files. Within the file, <ClinicalDocument> is the top tag in accordance with the rules for CDA.

REF (Refractometer), KM (Keratometer), TM (Tonometer), LM (Lensmeter), and PHOR (Phoroptor) are also ophthalmic examination devices described in this document.

For details, see 4.3.

The standard codes used in this document are shown in Annex C, and a sample XML file is shown in Annex D.

4.2 deviceCDA and persistent examination reports

Most OEDD devices only output examination data and related information, and cannot provide additional data items such as Patient, Operator, Custodian, and Authentication.

For such devices, OEDD introduces deviceCDA, a strict subset of CDA, that allows devices to transfer examination data and related information as a deviceCDA dataset without the additional detailed patient identification information that is required in complete CDA documents.

OIS plays the role of receiving examination data and related information as a deviceCDA dataset from a device and then submitting a persistent examination report to a HIS with additional information required for the complete CDA dataset.

deviceCDA is not a complete CDA dataset but still conforms to the same syntax. OIS, therefore, prepares a complete OEDD that includes the CDA RMIM dataset with information such as Patient, Operator, Custodian, and Authentication, and inserts the deviceCDA dataset received from the device into the OEDD. (See Figure 1)

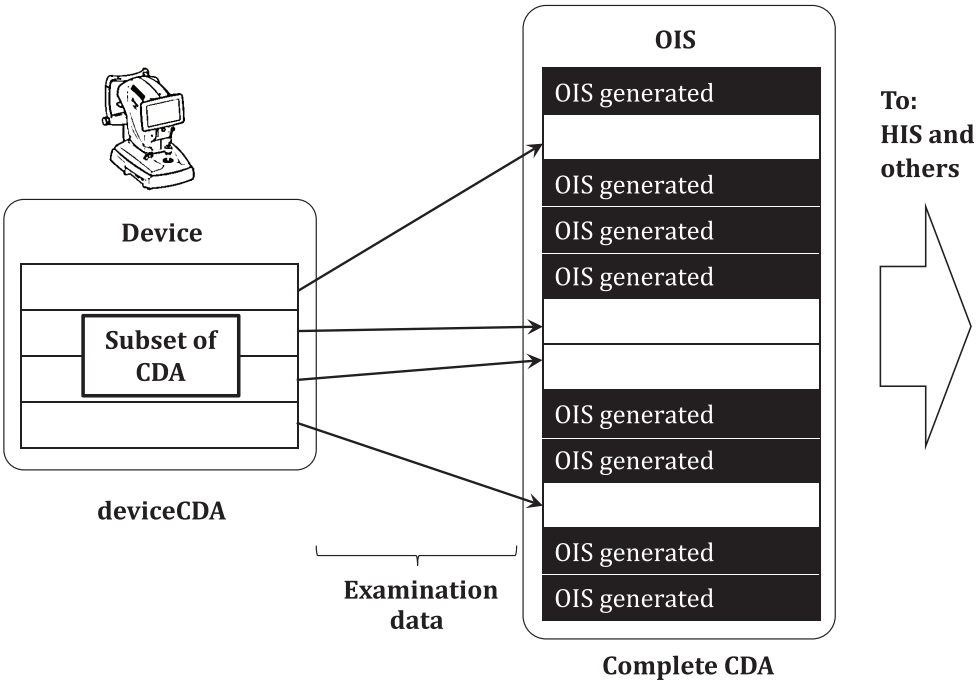

Figure 1 — Concept of a deviceCDA

4.3 Data classification constitution in the file

Both a deviceCDA and a complete CDA file has <ClinicalDocument> and <code code=" 100066-0"> as the top tag.

It is possible to collect information from all the OEDD classifications into one file, or they can be separated into different deviceCDA/Complete CDA files. In the case of a single composite OEDD deviceCDA/Complete CDA document, the data tags that are common across the devices shall be specified once, and the OEDD data tags integrated separately. Table 1 shows some examples of such deviceCDA File data block layouts. Data tags of REF, KM, RM, LM, and PHOR are stored in the file together with SPECULAR.

Implementations may encounter data classifications that are not included in the OEDD specification (e.g. private extensions), in which case, implementations shall ignore non-recognized data classifications and process the known data classifications accordingly.

Table 1 — Example deviceCDA file data block layouts

Common Data <ClinicalDocument> <code code=”78513-9”>	Common Data <ClinicalDocument> <code code=”78513-9”>	Common Data <ClinicalDocument> <code code=”78513-9”>	Common Data <ClinicalDocument> <code code=”78513-9”>
SPECULAR Data <component> <structuredBody> <component> <section> <code code="100066-0">	SPECULAR Data <component> <structuredBody> <component> <section> <code code="100066-0">	SPECULAR Data <component> <structuredBody> <component> <section> <code code="100066-0">	TM Data <component> <structuredBody> <component> <section> <code code="79896-7">

Table 1 *(continued)*

	TM Data <component> <structuredBody> <component> <section> <code code="79896-7">	REF Data <component> <structuredBody> <component> <section> <code code="79898-3">	KR Data <component> <structuredBody> <component> <section> <code code="95298-6">
		TM Data <component> <structuredBody> <component> <section> <code code="79896-7">	SPECULAR Data <component> <structuredBody> <component> <section> <code code="100066-0">
		LM Data <component> <structuredBody> <component> <section> <code code="95318-2">	PHOR Data <component> <structuredBody> <component> <section> <code code="79895-9">
File 1	File 2	File 3	File 4

4.4 OEDD structure

4.4.1 General

This specification is compliant with CDA-R2. For this reason, the complete detailed file structure can be reviewed in HL7 CDA® Release 2[6].

In this document, only descriptions particular to ophthalmology are included.

4.4.2 Data classifications

The data classifications of refractometer, keratometer, tonometer, and such are maintained as attribute value (type) of <code> tags.

4.4.3 Attribute value and classification

Table 2 shows ophthalmic examination device data classification values.

Table 2 — OEDD device classification values

Attribute value (code)	Data classification
100066-0	Specular microscope data

Figure 2 shows the example of specular microscope data (SPECULAR) that uses a LOINC®[1)] code.

1) LOINC is the registered trademark of Regenstrief Institute. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of the product named.

```
<---Specular microscope data--->
<code code="100066-0" displayName="SPECULAR" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
```

Figure 2 — OEDD section tags

4.4.4 Handling of common data

4.4.4.1 General

Common data such as ophthalmic examination title are described in the CDA Header part between the <ClinicalDocument> tag and < structuredBody>. This common data will be present only once in a file.

4.4.4.2 Common data tags

Table 3 shows available Common data tags.

Table 3 — Common data tags

Tag name	Description	Necessity [a]
ClinicalDocument	CDA-R2	D
typeId	Type ID. The compliant CDA R2 specifications are identified.	D
id	ID for unique identification specified at hospitals, etc. or groups	D
code	A code that represents the reporting category	D
title	Ex) Ophthalmic examinations	D
effectiveTime	Date & time of the creation of the file (yyyymmddhhmmss)	C
confidentialityCode	Confidentiality level code. The confidentiality value in the HL7 vocabulary domain is used Ex) code="N"	D
languageCode	languageCode Ex) code="jpn"	D
versionNumber	Document version number	D
recordTarget	Patient	D
patientRole	Patient information	D

[a] The items in the Necessity column have the following meanings:

D - Tags and values are necessary for both Complete CDA and deviceCDA

C - Tags and values are necessary for Complete CDA

O - No tags or values are necessary

[b] Multiple settings are allowed for Patient No. Also, nullFlavor="NI" is allowed.

[c] Multiple settings are allowed for the Patient names. If First name and Last name cannot be separated, the Last name should be entered in the First name section. Also, nullFlavor="NI" is allowed.

[d] Refer to "Annex B".

Table 3 *(continued)*

Tag name	Description	Necessity [a]
id	Patient No. (number of the order of examination) [b] Ex) extension="123456"	D
patient	Patient name [c]	C
name	Alphabetic expression [c]	C
family	family name [c]	C
given	Given name [c]	C
name	Regional ideographic or phonetic name [c]	O
family	family name [c]	O
given	Given name [c]	O
administrativeGenderCode	Patient's sex EX) F/M/UN [d]	C
birthTime	Patient's date of birth (yyyymmdd)	C
author	Author	D
time	Date & time of the creation (yyyymmddhhmmss)	D
assignedAuthor	Information of the organization that prepares the document.	D
id	Assigned author ID "NI": If id is none	D
assignedAuthoringDevice	Assigned authoring device	D
manufacturerModelName	Model name and No. for distinction among the devices of the same model	D
softwareName	Software and ROM version	D
representedOrganization	Represented organization	C
id	Represented organization ID "NI": If id is none	C
name	Company name	C
custodian	custodian	C
assignedCustodian	Assigned custodian	C
representedCustodianOrganization	Represented custodian organization	C

[a] The items in the Necessity column have the following meanings:

D - Tags and values are necessary for both Complete CDA and deviceCDA

C - Tags and values are necessary for Complete CDA

O - No tags or values are necessary

[b] Multiple settings are allowed for Patient No. Also, nullFlavor="NI" is allowed.

[c] Multiple settings are allowed for the Patient names. If First name and Last name cannot be separated, the Last name should be entered in the First name section. Also, nullFlavor="NI" is allowed.

[d] Refer to "Annex B".