TECHNICAL SPECIFICATION

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Health informatics — Ophthalmic examination device data —

Part 1: General examination devices

Informatique de santé — Données relatives aux dispositifs d'examen ophtalmique —

Partie 1: Dispositifs pour les examens généraux

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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

Opthalmic devices are used in hospitals and clinics to conduct examinations for patients. The primary devices used in these opthalmic examinations provide 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. Most ophthalmic hospitals and clinics use devices in these examinations to provide the needed measurements. Since many different vendors supply the devices to perform these measurements, the interoperability of examination results is important. In addition, standard procedures for mutually communicating these measurements are required between the ophthalmic examination devices and the Ophthalmic Information System (OIS).

These examinations are indispensable not only for ophthalmic medical care but also for prescriptions for spectacles and contact lenses. Additionally, intraocular pressure measurement is important for other ophthalmic procedures such as glaucoma assessment.

However, due to the differing data formats provided by these ophthalmic examination devices and the lack of interoperability, integration of this information is difficult and potentially error prone. Integration of each device's information into an OIS or hospital information system (HIS) therefore requires significant individual effort for each manufacturer's device.

This document specifies the content and format for ophthalmic examination device measurements, identifying that information that may be included in examination reports, as well as how it should be formatted when communicated to an OIS, HIS or other similar system.

Health informatics — Ophthalmic examination device data —

Part 1: General examination devices

1 Scope

This document specifies the measurement data output formats for devices used in general ophthalmic examiniations, including the following modalities:

— Refractometer (REF) Refraction

— Keratometer (KM) Corneal curvature

— Tonometer (TM) Intraocular pressure

— Lensmeter (LM) Spectacle lens power

— Phoroptor (PHOR) Visual acuity

This document only addresses text-based device reporting of ophthalmic examination device data (OEDD). Images generated as needed during an ophthalmic examination are outside the scope of this document.

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
refractometer
device that measures the refractive state of the eye

Note 1 to entry: Measuring the refractive state of the eye is necessary to determine the refractive power of a correction lens to restore normal vision.

Note 2 to entry: Measuring devices can provide both analog or digital readouts.

3.2
intraocular pressure
IOP
measurement of the fluid pressure inside the eye

Note 1 to entry: This measurement is typically expressed in kPa; however, some devices also provide it in mmHg. 1 mmHg = 0,133 3 kPa

3.3
measured intraocular pressure
measured IOP
intraocular pressure that obtained without any compensation

Note 1 to entry: See *corrected intraocular pressure* (3.4).

3.4
corrected intraocular pressure
corrected IOP
intraocular pressure that results from compensation of the corneal thickness based on the measured intraocular pressure

3.5
refractive power
ability of a lens or optical surface to change the curvature of incident wavefront or its direction by refraction

3.6
interpupillary distance
PD
distance between the centres of the pupils when the eyes are fixating an object at an infinite distance in the straight-ahead position

3.7
corneal curvature
radius of curvature of the anterior cornea

Note 1 to entry: It is expressed in mm.

3.8
visual acuity
number characterizing the ability of the visual system to recognize optotypes

[SOURCE: ISO 8596:2017, 3.3]

3.9
sphere
spherical power
sph
S
value of the back vertex power of a spherical-power lens or the vertex power in one of the two principal meridians of an astigmatic-power lens, depending on the principal meridian chosen for reference

[SOURCE: ISO 13666:2019, 3.12.2]

3.10
cylindrical power
cylinder
cyl
plus or minus the astigmatic difference, depending on the principal meridian chosen for reference

Note 1 to entry: The commonly used symbol for cylindrical power is C.

[SOURCE: ISO 13666:2019, 3.13.7, modified — Note 1 to entry modified.]

3.11
Maddox
type of ophthalmic examation that uses a Maddox rod

Note 1 to entry: A point source through a small Maddox rod (filter with thin cylindrical red glasses lined up) forms a vertical red line when round glasses horizontally stand in a line, and forms a horizontal red line when round glasses stand vertically in a line. For this property, a Maddox tangent scale (scale with a cruciform scale and a point source at the center) is used to measure a heterophoria angle. By using a small Maddox rod horizontally (vertically) and viewing a tangent scale, a vertical (horizontal) red line can be seen with each eye. By seeing a point source at the center, a red line can be seen at the off-center position with the fellow eye. Measurement is performed by reading the horizontal (vertical) scale of the position.

3.12
accommodation
type of repeated measurement that is performed using the time required for focusing on a visual target

Note 1 to entry: This measurement reveals the nature of accommodation disorder by classifying the appearance of accommodation time into several types as contraction time, that is the time required for focusing on a near visual target, or relaxation time for the time required for focusing on a far visual target.

3.13
AC/A ratio
ratio of the accommodative convergence amount for +1,0D and the accommodation stimulation

Note 1 to entry: This is determined using a fusion test.

3.14
vergence
simultaneous movement of both eyes in different directions

Note 1 to entry: This occurs when the line of sight is moved to objects at different distances (depths) from a viewer. The movement of both eyes directed inward when one looks into the close distance is called “convergence”, and the movement of both eyes directed outward when one looks into the far distance is called “divergence”.

Note 2 to entry: Vergence is one of disconjugate eye movement of right and left eyeballs in the opposite directions, which is different from conjugate eye movement in which both eyes move in the same direction such as saccade and pursuit eye movement. In addition, the word “vergence” is commonly used for eye movement in a horizontal direction; however, besides this, vertical vergence and cyclovergence are included. The convergence divergence movement changes this convergence angle. The simultaneous movement of both eyes in opposite directions occurs when the line of sight is moved to objects at different depths; the convergence movement occurs when one looks into the close distance from the far distance; and on the contrary, the divergence movement occurs when one looks into the far distance from the close distance.

3.15
stereopsis
ability to use sensory information from both eyes to recognize three dimensional shaps sterioscopically

Note 1 to entry: This occurs when a planar image projected on the retina is subjected to integrative action in the visual areas of the cerebral cortex, and is recognized as a three-dimensional shape in three dimensional space.

3.16
depth perception
ability to recognize the difference in distance to multiple targets

3.17
phoria
state where the ocular position during the binocular vision test is normal; however, ocular displacement, infravergance or supravergence, appears as fusion disturbance

3.18
aniseikonia
condition in which one eye perceives an image to be larger compared to the other eye and can occur in a horizontal or vertical direction

3.19
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.

3.20
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. Additional information can be associated after the report is sent to an OIS or HIS. For additional details, see Clause 4.

3.21
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[11]]

3.22
optotype
variable-sized type used in testing visual acuity

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 an HIS.

Exemplary use cases are detailed in Annex A

It is possible to handle multiple data types such as REF, kerato, IOP, and lens meter within one XML file. It is acceptable to compile REF, kerato, IOP, and lens meter in one file or separate them into different files. Within the file, <ClinicalDocument> is the top tag in accordance with the rules for CDA.

For details, refer to 4.3.

The standard codes used in this document are shown in Annex C, and sample XML files are 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 an 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.

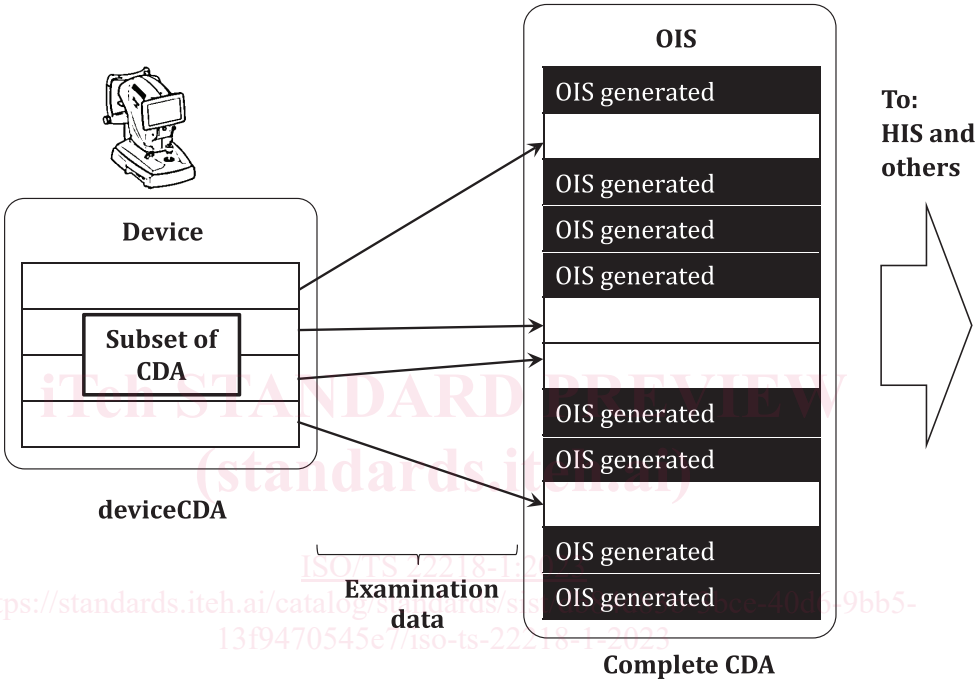

Figure 1 — Concept of a deviceCDA

4.3 Data classification constitution in the file

Both a deviceCDA and a complete CDA file has <ClinicalDocument> and <code code="**78513-9**"> 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. See Table 1.

When encountering a data classification 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

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

4.4 OEDD structure

4.4.1 General

This document is compliant with CDA-R2. For this reason, the complete detailed file structure can be reviewed in HL7 CDA®[1)] Release 2.

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

1) HL7 CDA is the registered trademark of Health Level Seven International. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of the product named.

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
79898-3	Refractometer data
95298-6	Keratometer data
79896-7	Tonometer data
95318-2	Lensmeter data
79895-9	Auto Phoroptor data

Figure 2 shows the examples with refractometer (REF), keratometer (KM), tonometer (TM), lensmeter (LM) and phoropter (PHOR) data These examications are designated using LOINC®[2] codes.

```
<---Refractometer data--->
 <code code="79898-3" displayName="REF" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
<---Keratometer data--->
 <code code="95298-6" displayName="KM" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
<---Tonometer data--->
 <code code="79896-7" displayName="TM" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
<---Lensmeter data--->
 <code code="95318-2" displayName="LM" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
<---Auto Phoroptor data--->
 <code code="79895-9" displayName="PHOR" 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

The items to be described in the necessity column have the following meanings. See details in Table 3.

2) 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.

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 which represents the reporting category.	D
title	Ex) Ophthalmic examinations	D
effectiveTime	Date & time of 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
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

[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 Patient name. 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]
time	Date & time of 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
id	Represented Custodian Organization ID "NI": If id is none	C
documentationOf	Operator	C
serviceEvent	serviceEvent code EX) classCode="ACSN"	C
code	serviceEvent code	C
performer	performer type code EX) typeCode="PRF"	C
functionCode	Function Code EX) code="SNRS" [d]	C
assignedEntity	assignedEntity	C
id	Operator ID	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 Patient name. 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.

4.4.5 Handling of ophthalmic examination data

4.4.5.1 General

Examination data are described in the <structuredBody> section of the deviceCDA as follows: