
**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

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).

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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.

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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 mm², 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 (mm²)

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 (Phoropter) 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 (Phoropter) 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](#)).

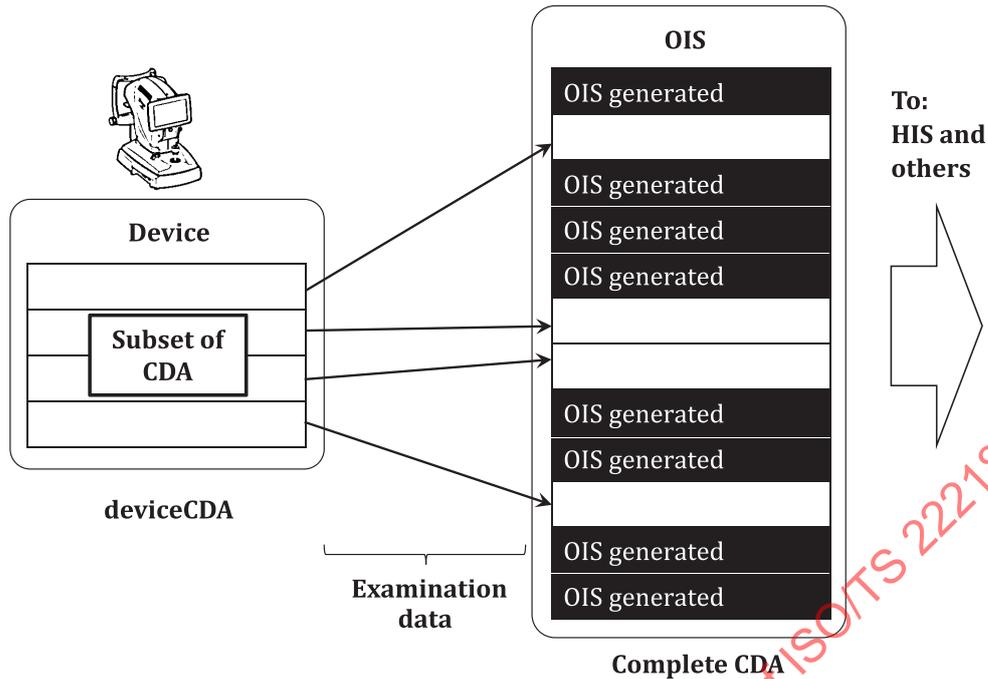


Figure 1 — Concept of a deviceCDA

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^[9].

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	P a t i e n t N o . (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 organ- ization 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 organiza- tion ID "NI": If id is none	C
name	Company name	C
custodian	custodian	C
assignedCustodian	Assigned custodian	C
representedCustodianOrganization	Represented custodian organization	C
<p>^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</p> <p>^b Multiple settings are allowed for Patient No. Also, nullFlavor="NI" is allowed.</p> <p>^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.</p> <p>^d Refer to "Annex B".</p>		

Table 3 (continued)

Tag name	Description	Necessity ^a
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 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 ".		

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:

```
<structuredBody>
```

```
<component>
```

```
<section>
```

```
---(Refer to 4.4.5.2 for detail content)
```

```
<section>
```

```
<component>
```

```
</structuredBody>
```

4.4.5.2 Ophthalmic examination data tags

[Table 4](#) shows basic composition of tags used for ophthalmic examination data:

Table 4 — Ophthalmic examination data tags

Tag name	Description	Necessity ^a
component	CDA-R2 component	D
structuredBody		D
Examination tag defined here		-
Component	CDA-R2 component	D
section	section	D
code	LOINC's Exam Details Code Ex) Set code of LOINC for SPECULAR: "100066-0"	D
title	examination title (HTML format)	D
text	detail of examination	D
entry		D
observation	Ex) classCode="OBS" moodCode="EVN" (OBS=observation, EVN=examination results)	D
code	Examination code Ex) Magnification= "100067-8"	D
effectiveTime	Date & time of the creation of the file (yyyymmddhhmmss)	D
entry		D
observation	Ex) classCode="OBS" moodCode="EVN" (OBS=observation, EVN=examination results)	D
entryRelationship	Detailed examination data	D
observation	Ex) classCode="OBS" moodCode="EVN" (OBS=observation, EVN=examination results)	D
code	Examination code Ex) Cell Density Right= "100070-2"	D
value	examination data & unit ^b	D
observationMedia	Ex) ID="IMAGE1" classCode="OBS" moodCode="EVN"	D
value	Ex) mediaType="image/png"	D
reference	Ex) value="01_20150702_123821_A_R_ENHANCE.png"	D
^a The items in the Necessity column have the following meanings: D - Tags and values are necessary for both Complete CDA and deviceCDA. - - No tags or values are necessary		
^b Refer to Annex C for detail of examination data measured by each ophthalmic examination device.		

4.4.6 Handling of units of measurement

The unit of measurement for numerical data is described as attribute value "unit".

ex) <value xsi:type="PQ" value="2912,33" unit="cells/mm²" />

4.5 OEDD XML schema

To comply with CDA-R2, CDA.XSD is designated as XML Schema.

Ex) At the <Clinical document> tag, it is designated as an attribute as follows.

```
<ClinicalDocument xsi:schemaLocation="urn:hl7-org:v3 cda.xsd" xmlns:voc="urn:hl7-org:v3/voc"
xmlns:xsi="https://www.w3.org/2001/XMLSchema-instance" xmlns="urn:hl7-org:v3">
```

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Annex A (informative)

Use cases of specular microscope

A.1 Outline of specular microscope

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 salient and reliable non-invasive methods used to determine its condition. For observing corneal endothelial cells, specular microscopes have been introduced in almost all ophthalmic clinics. The analysis results of the specular microscope are indispensable for not only patients experiencing problems in the cornea but also anyone who holds contact lenses safety prescriptions. An image is occasionally attached to analysis results as a reference. This however is not for analysis purposes but for providing physicians with the idea that the detected boundary lines are acceptable.

A.2 Avoid surgically induced damage

Corneal endothelial cells do not regenerate, and they decrease with age, Fuchs' corneal dystrophy, and surgery. When the average density of corneal endothelial cells is $\leq 1\,000$ cells/mm², homeostasis cannot be maintained.

The analysis data of specular microscopes provide evidence for determining whether it is safe to perform cataract surgery, which causes additional loss of endothelial cells. In addition, it is used as a postoperative monitoring device for cataract surgery. Thus, the specular microscope is essential for surgical planning to avoid complications such as postoperative corneal opacification. The corneal endothelium damages due to dry eye, Fuchs' dystrophy, and epithelial basement membrane dystrophy before surgery can also decrease the potential for positive surgical outcomes.

Reportedly, Fuchs' corneal endothelial dystrophy has a potential prevalence of approximately 5 % in Europe and the United States. If it decreases further, it causes bullous keratopathy, which causes vision loss and eye pain. To estimate the prognosis of surgery, evaluation is indispensable before and after surgery, such as cataract surgery.

Another benefit of checking the corneal endothelium often is to decide a better suitable approach for cataract surgery. Occasionally, a less traumatic approach, such as a new femtosecond-phaco with reduced phaco energy, should be chosen rather than conventional cataract surgery.

A.3 Postoperative evaluation and follow-up

Bullous keratopathy, which develops owing to a decrease in corneal endothelial cells, is a major cause of corneal transplantation. In recent years, corneal endothelial transplantation and the injection of cultured corneal endothelial cells have also been performed.

To evaluate this therapeutic effect, it is necessary to compare data over a more extended period than ever before. Besides, there will be an international evaluation of new treatments. Further demands are for specular microscope data interoperability, persistence, and international standards.

A.4 Safe use of contact lenses

Periodic checking of the corneal endothelium provides optometrists useful information essential for high-level care of a patient who wears contact lenses. It is not just about fitting a patient with the right type of contact lens but also evaluating whether overnight wear might work successfully based on the condition of the corneal endothelium.

Today, hundreds of contact lenses are available in the market with different types and with different materials. A specular microscope helps optometrists to suitably choose contact lenses best fit to patients, determine the right wearing schedules and even more, provide necessary information for monitoring patients' use and care for the contact lenses properly.

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Annex B (informative)

Standard codes used for common data

Table B.1 — Standard codes for common data

Item	code	Standard system	Description
Patient's sex	F/M/UN	HL7 v3 Namespaces (Code Systems and Value Sets)	2.16.840.1.113883.5.1 (Refer to Reference [3])
Performer code	SNRS	HL7 v3 Namespaces (Code Systems and Value Sets)	2.16.840.1.113883.5.88 (Refer to Reference [4])

Annex C (informative)

Standard codes for ophthalmic examination data

C.1 SPECULAR (Specular Microscope)

Table C.1 — Specular microscope tags

Tag name	Eye	Code (LOINC®)	Description	Necessity ^a
Specular		100066-0	Specular microscopy panel	M
<p>^a The items in the Necessity column have the following meanings:</p> <p>M - Tags and values are mandatory</p> <p>C - Tags and values are mandatory only if the corresponding eye (L and R) is analyzed</p> <p>O - Tags and values are optional</p> <p>Defining reference images:</p> <p>The reference images (optional) such as raw images and enhanced images are specified by using <observationMedia> with a file name containing the complete path. (See the example below)</p> <pre><entryRelationship typeCode="COMP"> <observationMedia classCode="OBS" moodCode="EVN"> <value mediaType="image/png"> <reference value="0000001_20150702_123821_ABCD_R_ENHANCE.png" /> </value> </observationMedia> </entryRelationship></pre> <p>The attached reference image file shall be JPEG, PNG, BMP, or PDF. The file name shall follow the file naming rule below:</p> <p style="text-align: center;">ID_YYMMDD_HHMMSS_MAKER_EYE_XXXXX.PNG (PNG example)</p> <p>where</p> <p>ID: Patient ID.</p> <p>YYMMDD: Date analyzed (YYYY = Year, MM = Month, DD = Day, with zero filling)</p> <p>HHMMSS: Time analyzed (HH = Hour, MM = Minute, SS = Second, with zero filling)</p> <p>MAKER: Manufacturer's identifier</p> <p>EYE: Analyzed eye (R = Right, L = Left, N = Unknown)</p> <p>XXXXX: Type of image, see the list below:</p> <p>"RAW" = Raw image data</p> <p>"ENHANCE" = Enhanced endothelial cell image</p> <p>"EDGE" = Endothelial cell image with detected cell boundaries</p> <p>"POLYMEGATHISM" = Endothelial cell image with a color-coded size distribution</p> <p>"PLEMORPHISM" = Endothelial cell image with a color-coded shape distribution</p> <p>"ANTERIOR" = Image of the anterior segment</p> <p>"TOTAL" = Integrated result images (Composite)</p> <p>"OTHER" = Other images</p>				

Table C.1 (continued)

Tag name	Eye	Code (LOINC®)	Description	Necessity ^a
Magnification		100067-8	Eye image magnification EX) value= "1,018828" unit="µm ² "	M
Point	R	100068-6	Right eye Fixation point [Angle] EX) value="-1,0" unit="degree" (center)	O
	L	100069-4	Left eye Fixation point [Angle]	O
Pachy	R	64744-6	Cornea thickness Right eye EX) value="474,8" unit="µm ² "	O
	L	66068-8	Cornea thickness Left eye	O
CD	R	100070-2	Right cornea Cell density EX) value="2912,33" unit="cells/mm ² "	C
	L	100071-0	Left cornea Cell density	C

^a The items in the Necessity column have the following meanings:

M - Tags and values are mandatory

C - Tags and values are mandatory only if the corresponding eye (L and R) is analyzed

O - Tags and values are optional

Defining reference images:

The reference images (optional) such as raw images and enhanced images are specified by using <observationMedia> with a file name containing the complete path. (See the example below)

```
<entryRelationship typeCode="COMP">
  <observationMedia classCode="OBS" moodCode="EVN">
    <value mediaType="image/png">
      <reference value="0000001_20150702_123821_ABCD_R_ENHANCE.png" />
    </value>
  </observationMedia>
</entryRelationship>
```

The attached reference image file shall be JPEG, PNG, BMP, or PDF. The file name shall follow the file naming rule below:

ID_YYMMDD_HHMMSS_MAKER_EYE_XXXXX.PNG (PNG example)

where

ID: Patient ID.

YYMMDD: Date analyzed (YYYY = Year, MM = Month, DD = Day, with zero filling)

HHMMSS: Time analyzed (HH = Hour, MM = Minute, SS = Second, with zero filling)

MAKER: Manufacturer's identifier

EYE: Analyzed eye (R = Right, L = Left, N = Unknown)

XXXXX: Type of image, see the list below:

"RAW" = Raw image data

"ENHANCE" = Enhanced endothelial cell image

"EDGE" = Endothelial cell image with detected cell boundaries

"POLYMEGATHISM" = Endothelial cell image with a color-coded size distribution

"PLEMORPHISM" = Endothelial cell image with a color-coded shape distribution

"ANTERIOR" = Image of the anterior segment

"TOTAL" = Integrated result images (Composite)

"OTHER" = Other images

Table C.1 (continued)

Tag name	Eye	Code (LOINC®)	Description	Necessity ^a
CV	R	100072-8	Right cornea Coefficient of variation EX) value="25,08" unit="%"	C
	L	100073-6	Left cornea Coefficient of variation	C
HEX	R	100074-4	Right cornea Hexagonality EX) value="61,12" unit="%"	C
	L	100075-1	Left cornea Hexagonality	C
N	R	100076-9	Right cornea Endothelial cells counted EX) value="204" unit="cells"	C
	L	100077-7	Left cornea Endothelial cells counted	C
MIN	R	100078-5	Right cornea Endothelial cell area.min EX) value="151,47" unit="µm ² "	C
	L	100079-3	Left cornea Endothelial cell area.min	C

^a The items in the Necessity column have the following meanings:

M - Tags and values are mandatory

C - Tags and values are mandatory only if the corresponding eye (L and R) is analyzed

O - Tags and values are optional

Defining reference images:

The reference images (optional) such as raw images and enhanced images are specified by using <observationMedia> with a file name containing the complete path. (See the example below)

```
<entryRelationship typeCode="COMP">
  <observationMedia classCode="OBS" moodCode="EVN">
    <value mediaType="image/png">
      <reference value="0000001_20150702_123821_ABCD_R_ENHANCE.png" />
    </value>
  </observationMedia>
</entryRelationship>
```

The attached reference image file shall be JPEG, PNG, BMP, or PDF. The file name shall follow the file naming rule below:

ID_YYYYMMDD_HHMMSS_MAKER_EYE_XXXXX.PNG (PNG example)

where

ID: Patient ID.

YYYYMMDD: Date analyzed (YYYY = Year, MM = Month, DD = Day, with zero filling)

HHMMSS: Time analyzed (HH = Hour, MM = Minute, SS = Second, with zero filling)

MAKER: Manufacturer's identifier

EYE: Analyzed eye (R = Right, L = Left, N = Unknown)

XXXXX: Type of image, see the list below:

"RAW" = Raw image data

"ENHANCE" = Enhanced endothelial cell image

"EDGE" = Endothelial cell image with detected cell boundaries

"POLYMEGATHISM" = Endothelial cell image with a color-coded size distribution

"PLEMORPHISM" = Endothelial cell image with a color-coded shape distribution

"ANTERIOR" = Image of the anterior segment

"TOTAL" = Integrated result images (Composite)

"OTHER" = Other images

Table C.1 (continued)

Tag name	Eye	Code (LOINC®)	Description	Necessity ^a
MAX	R	100080-1	Right cornea Endothelial cell area.max EX) value="636,47" unit="µm ² "	C
	L	100081-9	Left cornea Endothelial cell area.max	C
AVG	R	100082-7	Right cornea Endothelial cell area.mean EX) value="343,19" unit="µm ² "	C
	L	100083-5	Left cornea Endothelial cell area.mean	C
SD	R	100084-3	Right cornea Cell area.standard deviation EX) value="85,65" unit="µm ² "	C
	L	100085-0	Left cornea Cell area.standard deviation	C

^a The items in the Necessity column have the following meanings:

M - Tags and values are mandatory

C - Tags and values are mandatory only if the corresponding eye (L and R) is analyzed

O - Tags and values are optional

Defining reference images:

The reference images (optional) such as raw images and enhanced images are specified by using <observationMedia> with a file name containing the complete path. (See the example below)

```
<entryRelationship typeCode="COMP">
  <observationMedia classCode="OBS" moodCode="EVN">
    <value mediaType="image/png">
      <reference value="0000001_20150702_123821_ABCD_R_ENHANCE.png" />
    </value>
  </observationMedia>
</entryRelationship>
```

The attached reference image file shall be JPEG, PNG, BMP, or PDF. The file name shall follow the file naming rule below:

ID_YYMMDD_HHMMSS_MAKER_EYE_XXXXX.PNG (PNG example)

where

ID: Patient ID.

YYMMDD: Date analyzed (YYYY = Year, MM = Month, DD = Day, with zero filling)

HHMMSS: Time analyzed (HH = Hour, MM = Minute, SS = Second, with zero filling)

MAKER: Manufacturer's identifier

EYE: Analyzed eye (R = Right, L = Left, N = Unknown)

XXXXX: Type of image, see the list below:

"RAW" = Raw image data

"ENHANCE" = Enhanced endothelial cell image

"EDGE" = Endothelial cell image with detected cell boundaries

"POLYMEGATHISM" = Endothelial cell image with a color-coded size distribution

"PLEMORPHISM" = Endothelial cell image with a color-coded shape distribution

"ANTERIOR" = Image of the anterior segment

"TOTAL" = Integrated result images (Composite)

"OTHER" = Other images

Table C.1 (continued)

Tag name	Eye	Code (LOINC®)	Description	Necessity ^a
AnalysisMethod	R	100086-8	LA33379-1: "Auto"	C
	L	100155-1	LA19016-7: "Manual"	C
			LA14198-8: "Center"	
			LA33380-9: "Flex center"	
			LA46-8: "Other"	

^a The items in the Necessity column have the following meanings:
 M - Tags and values are mandatory
 C - Tags and values are mandatory only if the corresponding eye (L and R) is analyzed
 O - Tags and values are optional

Defining reference images:

The reference images (optional) such as raw images and enhanced images are specified by using <observationMedia> with a file name containing the complete path. (See the example below)

```
<entryRelationship typeCode="COMP">
  <observationMedia classCode="OBS" moodCode="EVN">
    <value mediaType="image/png">
      <reference value="0000001_20150702_123821_ABCD_R_ENHANCE.png"/>
    </value>
  </observationMedia>
</entryRelationship>
```

The attached reference image file shall be JPEG, PNG, BMP, or PDF. The file name shall follow the file naming rule below:

ID_YYMMDD_HHMMSS_MAKER_EYE_XXXXX.PNG (PNG example)

where

- ID: Patient ID.
- YYMMDD: Date analyzed (YYYY = Year, MM = Month, DD = Day, with zero filling)
- HHMMSS: Time analyzed (HH = Hour, MM = Minute, SS = Second, with zero filling)
- MAKER: Manufacturer’s identifier
- EYE: Analyzed eye (R = Right, L = Left, N = Unknown)
- XXXXX: Type of image, see the list below:
 - “RAW” = Raw image data
 - “ENHANCE” = Enhanced endothelial cell image
 - “EDGE” = Endothelial cell image with detected cell boundaries
 - “POLYMEGATHISM” = Endothelial cell image with a color-coded size distribution
 - “PLEMORPHISM” = Endothelial cell image with a color-coded shape distribution
 - “ANTERIOR” = Image of the anterior segment
 - “TOTAL” = Integrated result images (Composite)
 - “OTHER” = Other images

Annex D (informative)

Sample files

D.1 Common data (Complete CDA)

```

=====
<?xml version="1.0" encoding="utf-8"?>
<ClinicalDocument xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd" xmlns:voc="urn:hl7-org:v3/voc"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">
  <typeId root="2.16.840.1.113883.1.3" extension="POCD_HD000040"/>
  <id extension="xxxx" root="2.16.392.9.999999.9.9"/>
  <code code="78513-9" displayName="Ophthalmology" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC"/>
  <title>Ophthalmology</title>
  <effectiveTime value="20150702123821"/>
  <confidentialityCode code="N" codeSystem="2.16.840.1.113883.5.25"/>
  <languageCode code="jpn"/>
  <versionNumber value="1"/>
  <recordTarget>
    <patientRole>
      <id root="1.2.16.392.9.888888.9.9.12345678901" extension="123456"/>
      <id root="1.2.16.392.9.777777.9.9.98765432101" extension="ABCDEFGF"/>
      <patient>
        <name use="ABC">
          <family>TAROU</family>
          <given>TANAKA</given>
        </name>
        <administrativeGenderCode codeSystem="2.16.840.1.113883.5.1" code="M" displayName="male"/>
        <birthTime value="19750816"/>
      </patient>
    </patientRole>
  </recordTarget>
  <author>
    <time value="20080901193628"/>
    <assignedAuthor>
      <id nullFlavor="NI"/>
      <assignedAuthoringDevice>
        <manufacturerModelName codeSystemVersion="1234">ABC-123</manufacturerModelName>
        <softwareName codeSystemVersion="1.0">1.4</softwareName>
      </assignedAuthoringDevice>
      <representedOrganization>
        <id nullFlavor="NI"/>
        <name>ABCD</name>
      </representedOrganization>
    </assignedAuthor>
  </author>
  <custodian>
    <assignedCustodian>
      <representedCustodianOrganization>
        <id nullFlavor="NI"/>

```

```
</representedCustodianOrganization>  
</assignedCustodian>  
</custodian>  
<documentationOf>  
  <serviceEvent classCode="ACSN">  
    <code code="78513-9" displayName="Ophthalmology" codeSystem="2.16.840.1.113883.6.1"  
codeSystemName="LOINC"/>  
    <performer typeCode="PRF">  
      <functionCode code="SNRS" displayName="operator" codeSystemName="HL7 v3"  
codeSystem="2.16.840.1.113883.5.88"/>  
      <assignedEntity>  
        <id root="1.2.16.392.9.777777.9.9.12345678901" extension="123456"/>  
        <id root="1.2.16.392.9.777777.9.9.98765432101" extension="ABCDEFGH"/>  
      </assignedEntity>  
    </performer>  
  </serviceEvent>  
</documentationOf>  
<component>  
  <structuredBody>  
    <component>
```

Examination data (D.3 SPECULAR)

```
</component>  
</structuredBody>  
</component>  
</ClinicalDocument>
```

=====

D.2 Common data (deviceCDA)

=====

```
<?xml version="1.0" encoding="UTF-8"?>  
  
<ClinicalDocument xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd" xmlns:voc="urn:hl7-org:v3/voc"  
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">  
  <typeId root="2.16.840.1.113883.1.3" extension="POCD_HD000040UV00"/>  
  <id extension="xxxx" root="2.16.392.9.999999.9.9"/>  
  <code code="78513-9" displayName="Ophthalmology" codeSystem="2.16.840.1.113883.6.1"  
codeSystemName="LOINC"/>  
  <title>Ophthalmology</title>  
  <confidentialityCode code="N" codeSystem="2.16.840.1.113883.5.25"/>  
  <languageCode code="jpn"/>  
  <versionNumber value="1"/>  
  <recordTarget>  
    <patientRole>  
      <id root="1.2.16.392.9.888888.9.9.12345678901" extension="123456"/>  
    </patientRole>  
  </recordTarget>  
  <author>  
    <time value="20121011112928"/>  
    <assignedAuthor>  
      <id nullFlavor="NI"/>  
      <assignedAuthoringDevice>  
        <manufacturerModelName codeSystemVersion="1234">ABC-123</manufacturerModelName>  
        <softwareName codeSystemVersion="1.00">1.4</softwareName>
```

```

</assignedAuthoringDevice>
<representedOrganization>
<id nullFlavor="NI"/>
<name>ABCD</name>
</representedOrganization>
</assignedAuthor>
</author>
<component>
<structuredBody>
<component>

```

Examination data (D.3 SPECULAR)

```

</component>
</structuredBody>
</component>
</ClinicalDocument>

```

=====

D.3 SPECULAR (Specular microscope)

=====

```
<section>
```

```

<templateId root="2.16.840.1.113883.2.2.1.5.43"/>
<code code="100066-0" displayName="SPECULAR" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" />
<title>Specular Microscope Data</title>
<!--
Header information
-->
<text>
<html>
<body>
<strong>System Setting</strong>
<br></br>
<table border="1" Cellspacing="0">
<TR align="center">
<td bgcolor="#00CED1" width="250"><font color="#ffffff">Examination Name</font></td><td
width="250">Ophthalmology</td>
</TR>
<TR align="center">
<td bgcolor="#00CED1" width="250"><font color="#ffffff">Title</font></td><td
width="250">Ophthalmology</td>
</TR>
</table>
<br></br>
<strong>Patient Data</strong>
<br></br>
<table border="1" Cellspacing="0">
<TR align="center">
<td bgcolor="#00CED1" width="250"><font color="#ffffff">PatientID</font></td><td
width="250">
<br></br>
123456
<br></br>

```

ISO/TS 22218-2:2023(E)

```

    ABCDEFG
  </td>
</TR>
<TR align="center">
  <td bgcolor="#00CED1" width="250"><font color="#ffffff">Patient Name</font></td><td
width="250">TAROU:TANAKA</td>
</TR>
<TR align="center">
  <td bgcolor="#00CED1" width="250"><font color="#ffffff">Sex</font></td><td
width="250">male</td>
</TR>
<TR align="center">
  <td bgcolor="#00CED1" width="250"><font color="#ffffff">BirthDay</font></td><td
width="250">1975/08/16 (37)</td>
</TR>
</table>
<br></br>
<strong>Device information</strong>
<br></br>
<table border="1" Cellspacing="0">
  <TR align="center">
    <td bgcolor="#00CED1" width="250"><font color="#ffffff">EffectiveTime</font></td><td
width="250">2015/07/02</td>
  </TR>
  <TR align="center">
    <td bgcolor="#00CED1" width="250"><font color="#ffffff">Company</font></td><td
width="250">ABCD</td>
  </TR>
  <TR align="center">
    <td bgcolor="#00CED1" width="250"><font color="#ffffff">CodeSystemVersion</font></td><td
width="250">1234</td>
  </TR>
  <TR align="center">
    <td bgcolor="#00CED1" width="250"><font color="#ffffff">ManufacturerModelName</font></
td><td width="250">ABC-123</td>
  </TR>
  <TR align="center">
    <td bgcolor="#00CED1" width="250"><font color="#ffffff">SoftwarecodeSystemVersion</font></
td><td width="250">1.0</td>
  </TR>
  <TR align="center">
    <td bgcolor="#00CED1" width="200"><font color="#ffffff">SoftwareName</font></td><td
width="250">1.2</td>
  </TR>
</table>
<br></br>
<strong>Operator</strong>
<br></br>
Operator code is
  <TR align="center">
    <td>123456</td>
  </TR>
  <TR align="center">
    <td>ABCDEFG</td>
  </TR>
<!--
SPCCULAT Data begins
-->
```

```

<br></br>
<strong>Examination data title is SPECULAR</strong>
<br></br>
<table border="1" Cellspacing="0">
  <TR>
    <TD width="200">Magnification </TD><TD width="150">1,018828</TD>
  </TR>
</table>
<!--
Specular Examination (1) - R
-->
<br></br>
<table border="1" Cellspacing="0">
  <TR align="left">
    <td bgcolor="#FFCC99" width="600"><b>Specular Examination (1) - R</b></td>
  </TR>
</table>
<br></br>
<table border="1" Cellspacing="0">
  <TR>
    <TD width="200">PointR</TD><TD width="150">-1,0</TD>
  </TR>
</table>
<table border="1" Cellspacing="0">
  <TR>
    <TD width="200"> PACHYR </TD><TD width="150">474,8</TD>
  </TR>
</table>
<table border="1" Cellspacing="0">
  <TR>
    <TD width="200">CDR</TD><TD width="150">2912,57</TD>
  </TR>
</table>
<table border="1" Cellspacing="0">
  <TR>
    <TD width="200">CVR </TD><TD width="150">25,08</TD>
  </TR>
</table>
<table border="1" Cellspacing="0">
  <TR>
    <TD width="200">HEXR</TD><TD width="150">61,12</TD>
  </TR>
</table>
<table border="1" Cellspacing="0">
  <TR>
    <TD width="200">NR</TD><TD width="150">204</TD>
  </TR>
</table>
<table border="1" Cellspacing="0">
  <TR>
    <TD width="200">MINR</TD><TD width="150">151,47</TD>
  </TR>
</table>
<table border="1" Cellspacing="0">
  <TR>
    <TD width="200">MAXR</TD><TD width="150">636,47</TD>
  </TR>
</table>

```

```

<table border="1" Cellspacing="0">
  <TR>
    <TD width="200">AVGR</TD><TD width="150">343,19</TD>
  </TR>
</table>
<table border="1" Cellspacing="0">
  <TR>
    <TD width="200">SDR</TD><TD width="150">80,94</TD>
  </TR>
</table>
<table border="1" Cellspacing="0">
  <TR>
    <TD width="200"> AnalysisMethodR</TD><TD width="150">Auto</TD>
  </TR>
</table>
<table border="1" Cellspacing="0">
  <TR>
    <TD width="200"> ReferenceFileR</TD><TD width="450">0000001_20150702_123821_ABCD_R_
ENHANCE.png</TD>
  </TR>
</table>
<table border="1" Cellspacing="0">
  <TR>
    <TD width="200"> ReferenceFileR</TD><TD width="450">0000001_20150702_123821_ABCD_R_
EDGE.png</TD>
  </TR>
</table>
<table border="1" Cellspacing="0">
  <TR>
    <TD width="200"> ReferenceFileR</TD><TD width="450">0000001_20150702_123821_ABCD_R_
POLYMEGATHISM.png</TD>
  </TR>
</table>
<table border="1" Cellspacing="0">
  <TR>
    <TD width="200"> ReferenceFileR</TD><TD width="450">0000001_20150702_123821_ABCD_R_
PLEOMOPHISM.png </TD>
  </TR>
</table>
<!--
Specular Examination (1) - L
-->
<br></br>
<table border="1" Cellspacing="0">
  <TR align="left">
    <td bgcolor="#FFCC99" width="600"><b>Specular Examination (1) - L</b></td>
  </TR>
</table>
<br></br>
<table border="1" Cellspacing="0">
  <TR>
    <TD width="200">PointL</TD><TD width="150">-1,0</TD>
  </TR>
</table>
<table border="1" Cellspacing="0">
  <TR>
    <TD width="200"> PACHYL </TD><TD width="150">485,8</TD>
  </TR>

```

```

</table>
<table border="1" Cellspacing="0">
  <TR>
    <TD width="200">CDL</TD><TD width="150">2857,33</TD>
  </TR>
</table>
<table border="1" Cellspacing="0">
  <TR>
    <TD width="200">CVL</TD><TD width="150">24,68</TD>
  </TR>
</table>
<table border="1" Cellspacing="0">
  <TR>
    <TD width="200">HEXL</TD><TD width="150">64,12</TD>
  </TR>
</table>
<table border="1" Cellspacing="0">
  <TR>
    <TD width="200">NL</TD><TD width="150">252</TD>
  </TR>
</table>
<table border="1" Cellspacing="0">
  <TR>
    <TD width="200">MINL</TD><TD width="150">168,55</TD>
  </TR>
</table>
<table border="1" Cellspacing="0">
  <TR>
    <TD width="200">MAXL</TD><TD width="150">631,37</TD>
  </TR>
</table>
<table border="1" Cellspacing="0">
  <TR>
    <TD width="200">AVGL</TD><TD width="150">350,47</TD>
  </TR>
</table>
<table border="1" Cellspacing="0">
  <TR>
    <TD width="200">SDL</TD><TD width="150">86,65</TD>
  </TR>
</table>
<table border="1" Cellspacing="0">
  <TR>
    <TD width="200"> AnalysisMethodL</TD><TD width="150">Auto</TD>
  </TR>
</table>
<table border="1" Cellspacing="0">
  <TR>
    <TD width="200"> ReferenceFileL</TD><TD width="450">0000001_20150702_124557_ABCD_R_
ENHANCE.png</TD>
  </TR>
</table>
<table border="1" Cellspacing="0">
  <TR>
    <TD width="200"> ReferenceFileL</TD><TD width="450">0000001_20150702_124557_ABCD_R_
EDGE.png</TD>
  </TR>
</table>

```

```

<table border="1" Cellspacing="0">
  <TR>
    <TD width="200"> ReferenceFileL</TD><TD width="450">0000001_20150702_124557_ABCD_R_
POLYMEGATHISM.png </TD>
  </TR>
</table>
<table border="1" Cellspacing="0">
  <TR>
    <TD width="200"> ReferenceFileL</TD><TD width="450">0000001_20150702_124557_ABCD_R_
PLEOMOPHISM.png </TD>
  </TR>
</table>
<!--
Specular Examination (2) - R
-->
<br></br>
<table border="1" Cellspacing="0">
  <TR align="left">
    <td bgcolor="#FFCC99" width="600"><b>Specular Examination (2) - R</b></td>
  </TR>
</table>
<br></br>
<table border="1" Cellspacing="0">
  <TR>
    <TD width="200">PointR</TD><TD width="150">-1,0</TD>
  </TR>
</table>
<table border="1" Cellspacing="0">
  <TR>
    <TD width="200"> PACHYR </TD><TD width="150">475,2</TD>
  </TR>
</table>
<table border="1" Cellspacing="0">
  <TR>
    <TD width="200">CDR</TD><TD width="150">2945,81</TD>
  </TR>
</table>
<table border="1" Cellspacing="0">
  <TR>
    <TD width="200">CVR </TD><TD width="150">26,73</TD>
  </TR>
</table>
<table border="1" Cellspacing="0">
  <TR>
    <TD width="200">HEXR</TD><TD width="150">59,28</TD>
  </TR>
</table>
<table border="1" Cellspacing="0">
  <TR>
    <TD width="200">NR</TD><TD width="150">193</TD>
  </TR>
</table>
<table border="1" Cellspacing="0">
  <TR>
    <TD width="200">MINR</TD><TD width="150">142,84</TD>
  </TR>
</table>
<table border="1" Cellspacing="0">

```

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```

<TR>
  <TD width="200">MAXR</TD><TD width="150">650,06</TD>
</TR>
</table>
<table border="1" Cellspacing="0">
  <TR>
    <TD width="200">AVGR</TD><TD width="150">350,23</TD>
  </TR>
</table>
<table border="1" Cellspacing="0">
  <TR>
    <TD width="200">SDR</TD><TD width="150">78,17</TD>
  </TR>
</table>
<table border="1" Cellspacing="0">
  <TR>
    <TD width="200"> AnalysisMethodR</TD><TD width="150">Manual</TD>
  </TR>
</table>
<table border="1" Cellspacing="0">
  <TR>
    <TD width="200"> ReferenceFileR</TD><TD width="450">0000001_20150702_130232_ABCD_R_
ENHANCE.png</TD>
  </TR>
</table>
<table border="1" Cellspacing="0">
  <TR>
    <TD width="200"> ReferenceFileR</TD><TD width="450">0000001_20150702_130232_ABCD_R_
EDGE.png</TD>
  </TR>
</table>
<table border="1" Cellspacing="0">
  <TR>
    <TD width="200"> ReferenceFileR</TD><TD width="450">0000001_20150702_130232_ABCD_R_
POLYMEGATHISM.png</TD>
  </TR>
</table>
<table border="1" Cellspacing="0">
  <TR>
    <TD width="200"> ReferenceFileR</TD><TD width="450">0000001_20150702_130232_ABCD_R_
PLEOMOPHISM.png</TD>
  </TR>
</table>
</body>
</html>
</text>

```

```

<!--
Specular Examination Data begins
-->
<entry typeCode="COMP">
  <observation classCode="OBS" moodCode="EVN">
    <code code="100067-8" displayName="Magnification" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" />
    <effectiveTime value="20150702123821" />
    <value xsi:type="PQ" value="1,018828" unit="µm" />
  </observation>

```