

Digital Imaging and Communications in Medicine (DICOM)

Supplement 152

Ophthalmic Thickness Map Storage SOP Class

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Scope and Field of Application

5 This Supplement to the DICOM Standard introduces the Ophthalmic Thickness Map SOP Class for topographic representation of the thickness measurements of the posterior eye. This SOP Class will be used with several types of ophthalmic devices, alone and/or in conjunction with other DICOM IODs.

10 These ophthalmic devices produce thickness measurements of certain anatomical features of the posterior eye (e.g., optic nerve head topography, retinal thickness map) with analysis maps. A monochrome image is generated and the measurements are mapped topographically as Palette Color LUT, and used extensively for diagnostic purposes by clinicians.

There are different types of maps possible such as thickness and corneal maps. Thickness maps are very common in ophthalmology while corneal maps are much more complex and used less frequently; therefore, the scope of this IOD was limited to the thickness/height measurements of the posterior eye.

15

Changes to NEMA Standards Publication PS 3.2-2011
Digital Imaging and Communications in Medicine (DICOM)
Part 2: Conformance

Item: Add to table A.1-2 categorizing SOP Classes:

20 The SOP Classes are categorized as follows:

Table A.1-2
UID VALUES

UID Value	UID NAME	Category
...
<u>1.2.840.10008.5.1.4.1.1.81.1</u>	<u>Ophthalmic Thickness</u> <u>Map Storage</u>	<u>Transfer</u>
...

Changes to NEMA Standards Publication PS 3.3-2011
Digital Imaging and Communications in Medicine (DICOM)
Part 3: Information Object Definitions

Modify PS3.3 Table A.1-1 to add new IOD: Ophthalmic Thickness Map Object

IODs Modules	...	<u>OPM</u>	...
Patient		<u>M</u>	
Clinical Trial Subject		<u>U</u>	
General Study		<u>M</u>	
Patient Study		<u>U</u>	
Clinical Trial Study		<u>U</u>	
General Series		<u>M</u>	
Clinical Trial Series		<u>U</u>	
<u>Ophthalmic Thickness Map Series</u>		<u>M</u>	
General Equipment		<u>M</u>	
Enhanced General Equipment		<u>M</u>	
General Image		<u>M</u>	
Image Pixel		<u>M</u>	
Supplemental Palette Color Lookup Table		<u>C</u>	
Bitmap Display Shutter		<u>C</u>	
<u>Ophthalmic Thickness Map</u>		<u>M</u>	
<u>Ophthalmic Thickness Map Quality Rating</u>		<u>C</u>	
Ophthalmic Photography Acquisition Parameters		<u>M</u>	
Acquisition Context		<u>M</u>	
SOP Common		<u>M</u>	

Modify PS3.3 Annex A to Include OPM IOD

A.XX Ophthalmic Thickness Map Information Object Definition

35 A.XX.1 Ophthalmic Thickness Map IOD Description

The Ophthalmic Thickness Map IOD is generated by ophthalmic thickness mapping devices, such as retinal nerve fiber layer analyzers and optic nerve head analyzers, to generate measurements that are presented topographically using a monochromatic image and a pseudo-color map.

40 A.XX.2 Ophthalmic Thickness Map IOD Entity-Relationship Model

The E-R Model in Section A.1.2 of this Part depicts those components of the DICOM Information Model that are referenced by the Ophthalmic Thickness Map IOD. Below the Series IE, only the Image IE is used.

A.XX.3 Ophthalmic Thickness Map IOD Modules

45 Table A.XX.3-1 specifies the Modules of the Ophthalmic Thickness Map IOD.

**Table A.XX.3-1
OPHTHALMIC THICKNESS MAP IOD MODULES**

IE	Module	Reference	Usage
Patient	Patient	C.7.1.1	M
	Clinical Trial Subject	C.7.1.3	U
Study	General Study	C.7.2.1	M
	Patient Study	C.7.2.2	U
	Clinical Trial Study	C.7.2.3	U
Series	General Series	C.7.3.1	M
	Clinical Trial Series	C.7.3.2	U
	Ophthalmic Thickness Map Series	C.8.X.1	M
Equipment	General Equipment	C.7.5.1	M
	Enhanced General Equipment	C.7.5.2	M
Image	General Image	C.7.6.1	M
	Image Pixel	C.7.6.3	M
	Supplemental Palette Color Lookup Table	C.7.6.19	C – Required if Pixel Presentation (0008,9205) equals COLOR
	Bitmap Display Shutter	C.7.6.15	C - Required if a Shutter is to be applied to the image
	Ophthalmic Thickness Map	C.8.X.2	M
	Ophthalmic Thickness Map Quality Rating	C.8.X.3	C – Required if a quality rating value exists for the ophthalmic map
	Ophthalmic Photography Acquisition Parameters	C.8.17.4	M

Acquisition Context	C.7.6.14	M
SOP Common	C.12.1	M

A.XX.4 Ophthalmic Thickness Map IOD Content Constraints

50 The following constraints on Image attributes take precedence over the descriptions given in the Module Attribute Tables.

A.XX.4.1 Prohibited Modules

The Curve Module, Overlay Module and VOI LUT Module shall not be used in a Standard Extended SOP Class of the Ophthalmic Thickness Map.

55

Update PS3.3 C.7.6.19 for Supplemental Palette Color Lookup Table Module

C.7.6.19 Supplemental Palette Color Lookup Table Module

60 This module is used in conjunction with Single and Multi-frame IODs ~~that use RGB color in a number of frames. The value of the Pixel Presentation (0008,9205) for such frames equals COLOR.~~

Table C.7.6.19-1 specifies the Attributes that describe the Lookup table data.

65

Update PS3.3 Section 10 for generalized Macros

10.xx Numeric Value Macro

Table 10-xx describes the attributes used to relate and convey a numeric value to a coded concept.

70

**Table 10-xx
NUMERIC VALUE MACRO ATTRIBUTES**

Attribute Name	Tag	Type	Attribute Description
Concept Name Code Sequence	(0040,A043)	1	Coded concept name of this name-value Item. Only a single Item shall be permitted in this sequence.
<i>>Include 'Code Sequence Macro' Table 8.8-1. No Context ID is defined.</i>			
Numeric Value	(0040,A30A)	1	Numeric value for this name-value Item.
Measurement Units Code Sequence	(0040,08EA)	1	Units of Numeric Value (0040,A30A) in this name-value Item. Only a single Item shall be permitted in this sequence.
<i>>Include 'Code Sequence Macro' Table 8.8-1 Defined Context ID is 82</i>			

Update PS3.3 Annex C for Ophthalmic Thickness Map Modules

C.8.X Ophthalmic Thickness Map Modules

75

C.8.X.1 Ophthalmic Thickness Map Series Module

Table C.8.X.1-1 specifies the Attributes that identify and describe general information about the Ophthalmic Thickness Map Series.

**Table C.8.X.1-1
OPHTHALMIC THICKNESS MAP SERIES MODULE ATTRIBUTES**

Attribute Name	Tag	Type	Attribute Description
Modality	(0008,0060)	1	Type of equipment that created the maps in this Series. Enumerated Values: OPM See section C.7.3.1.1.1 for further explanation.

Referenced Performed Procedure Step Sequence	(0008,1111)	1C	Uniquely identifies the Performed Procedure Step SOP Instance to which the Series is related (e.g. a Modality or General-Purpose Performed Procedure Step SOP Instance). Only a single Item shall be permitted in this sequence. Required if the Modality Performed Procedure Step SOP Class, or General Purpose Performed Procedure Step SOP Class is supported.
>Include 'SOP Instance Reference Macro' Table 10-11			

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C.8.X.2 Ophthalmic Thickness Map Module

Table C.8.X.2-1 specifies the Attributes that describe an Image produced by ophthalmic thickness mapping devices.

Table C.8.X.2-1

OPHTHALMIC THICKNESS MAP MODULE ATTRIBUTES

85

Attribute Name	Tag	Type	Attribute Description
Ophthalmic Mapping Device Type	(0022,1415)	1	Describes the type of ophthalmic mapping acquisition device. See C.8.x.2.1.3 for further explanation. Defined Terms: OCT = Optical coherence tomography POLARIMETRY = Scanning laser polarimetry SLO_TOMO = Scanning Laser Ophthalmoscopy Tomography
Acquisition Method Code Sequence	(0022,1420)	1	The acquisition method used for obtaining ophthalmic thickness mapping. Only a single Item shall be permitted in this sequence.
>Include 'Code Sequence Macro' Table 8.8-1. Defined Context ID is 4261			
Acquisition Method Algorithm Sequence	(0022,1423)	1C	Software algorithm used to provide acquisition method. Required if Acquisition Method Code Sequence (0022,1420) contains an item with the value of (111923, DCM, "Corneal birefringence compensation") May be present otherwise. Only a single Item shall be permitted in this sequence.
>Include 'Algorithm Identification Macro' Table 10-19			
Instance Number	(0020,0013)	1	A number that identifies this instance.
Content Date	(0008,0023)	1	The date the data creation was started.
Content Time	(0008,0033)	1	The time the data creation was started.
Acquisition Date Time	(0008,002A)	1	The date and time that the acquisition of data that resulted in this image started. Note: The synchronization of this time with an external clock is specified in the Synchronization Module in Acquisition Time Synchronized (0018,1800).
Image Type	(0008,0008)	1	Image identification characteristics. See C.8.X.2.1.1 for specialization.

Samples Per Pixel	(0028,0002)	1	Number of samples (planes) in this image. See C.7.6.3.1.1 for further explanation. Enumerated Values: 1
Photometric Interpretation	(0028,0004)	1	Specified the intended interpretation of the pixel data. See C.7.6.3.1.2 for further explanation. Enumerated Values: MONOCHROME2
Pixel Representation	(0028,0103)	1	Data representation of pixel samples. Enumerated Values: 0000H = unsigned integer
Pixel Spacing	(0028,0030)	1	Physical distance in the patient between the center of each pixel, specified by a numeric pair - adjacent row spacing (delimiter) adjacent column spacing in mm. Note: Since a patient's retina is curved, there can be a small error in using Pixel Spacing (0028,0030) for distance measurements in the periphery of the image. See 10.7.1.3 for further explanation.
Pixel Aspect Ratio	(0028,0034)	1	Ratio of the vertical size and horizontal size of the pixels in the image specified by a pair of integer values where the first value is the vertical pixel size, and the second value is the horizontal pixel size.
Bits Allocated	(0028,0100)	1	Number of bits allocated for each pixel sample. Each sample shall have the same number of bits allocated. See PS 3.5 for further explanation. Enumerated Values: 8 16
Bits Stored	(0028,0101)	1	Number of bits stored for each pixel sample. Enumerated Values: 8 16
High Bit	(0028,0102)	1	Most significant bit for pixel sample data. Each sample shall have the same high bit. See PS 3.5 for further explanation. Enumerated Values: 7 (if Bits Stored (0028,0101) = 8) 15 (if Bits Stored (0028,0101) = 16)
Pixel Presentation	(0008,9205)	1	The source of the color information for use during rendering. Enumerated Values: COLOR = Use Supplemental Palette Color LUT Module Attributes COLOR_REF = Use Referenced Color Palette Instance UID (0028,0304)

Referenced Color Palette Instance UID	(0028,0304)	1C	The identifier of the color palette (i.e. an instance of the Color Palette Storage SOP Class "1.2.840.10008.5.1.4.39.1") for use during rendering. Required if Pixel Presentation (0008,9205) is COLOR_REF.
Lossy Image Compression	(0028,2110)	1	Specifies whether an Image has undergone lossy compression. Enumerated Values: 00 = Image has NOT been subjected to lossy compression. 01 = Image has been subjected to lossy compression. See C.7.6.1.1.5 for further explanation.
Lossy Image Compression Ratio	(0028,2112)	1C	Describes the approximate lossy compression ratio(s) that have been applied to this image. See C.7.6.1.1.5 for further explanation. May be multivalued if successive lossy compression steps have been applied. Note: For example, a compression ratio of 30:1 would be described in this Attribute with a single value of 30. Required if Lossy Images Compression (0028,2110) is "01".
Lossy Image Compression Method	(0028,2114)	1C	A label for the lossy compression method(s) that have been applied to this image. See C.7.6.1.1.5 for further explanation. May be multivalued if successive lossy compression steps have been applied; the value order shall correspond to the values of Lossy Image Compression Ratio (0028,2112). Required if Lossy Images Compression (0028,2110) is "01".
Burned In Annotation	(0028,0301)	1	Indicates that the image does not contain burned in annotation to identify the patient and date the image was acquired. Enumerated Values: NO
Recognizable Visual Features	(0028,0302)	1	Indicates whether or not the image contains sufficiently recognizable visual features to allow the image or a reconstruction from a set of images to identify the patient. Enumerated Values: NO

Image Laterality	(0020,0062)	1	<p>Laterality of object imaged (as described in Anatomic Region Sequence (0008,2218)) examined.</p> <p>Enumerated Values: R = right eye L = left eye</p> <p>Note: This Attribute is mandatory, in order to ensure that images may be positioned correctly relative to one another for display.</p> <p>Shall be consistent with any laterality information contained in Primary Anatomic Structure Modifier Sequence (0008,2230), if present.</p> <p>Note: Laterality (0020,0060) is a Series level Attribute and must be the same for all Images in the Series, hence it must be absent.</p>
Ophthalmic Thickness Map Type Code Sequence	(0022,1436)	1	<p>The type of ophthalmic thickness map encoded in this SOP Instance. It specifies the meaning of the pixel values.</p> <p>Only a single Item shall be permitted in this sequence.</p>
<i>>Include 'Code Sequence Macro' Table 8.8-1. Defined Context ID is 4263</i>			
<i>Include 'Real World Value Mapping Macro' Table C.7.6.16-12 if Ophthalmic Thickness Map Type Code Sequence (0022,1436) contains an item with the value (111930, DCM, "Absolute ophthalmic thickness") or (111932, DCM, "Thickness deviation from normative data"). May be present otherwise.</i>		<i>Defined Context ID for Measurement Units Code Sequence is 4260</i>	
Pixel Value Mapping to Coded Concept Sequence	(0022,1450)	1C	<p>Provides a pixel value and the mapping of that pixel value to an associated Coded Concept.</p> <p>Required if Ophthalmic Thickness Map Type Code Sequence (0022,1436) contains an item with the value (111931, DCM, "Thickness deviation category from normative data").</p> <p>May be present otherwise.</p> <p>One or more Items shall be present.</p>
>Mapped Pixel Value	(0022,1452)	1	Pixel value to be mapped.
>Pixel Value Mapping Code Sequence	(0040,9098)	1	<p>The mapping from Mapped Pixel Value (0022,1452) to an associated Coded Concept.</p> <p>Only a single Item shall be permitted in this sequence.</p>
<i>>>Include 'Code Sequence Macro' Table 8.8-1 Defined CID 4265</i>			
>Pixel Value Mapping Explanation	(0022,1454)	3	Free form text explanation of the Coded Concept.
Ophthalmic Thickness Mapping Normals Sequence	(0022,1443)	1C	<p>Identifies the data set used for mapping values from a normative data base.</p> <p>Required if Ophthalmic Thickness Map Type Code Sequence (0022,1436) contains an item with the value or (111931, DCM, "Thickness deviation category from normative data") or (111932, DCM, "Thickness deviation from normative data").</p> <p>May be present otherwise.</p> <p>Only a single Item shall be permitted in this sequence.</p>

<i>>Include 'Data Set Identification Macro' Table 10-22</i>			
Relevant OPT Attributes Sequence	(0022,1472)	1C	Attributes from the OPT image that provide critical context for the interpretation of this ophthalmic map SOP Instance. Required if Ophthalmic Mapping Device Type (0022,1415) is OCT. Only a single Item shall be permitted in this sequence
>Depth Spatial Resolution	(0022,0035)	1	The inherent limiting resolution in microns for depth of the acquisition equipment for high contrast objects for the data gathering and reconstruction technique chosen. If variable, the value at the center of the scanning volume.
>Maximum Depth Distortion	(0022,0036)	1	Maximum distortion in depth direction in % of Depth Spatial Resolution.
Source Image Sequence	(0008,2112)	1C	The Image SOP Class/Instance pair of the Image that was used to generate this Image. Required if Ophthalmic Mapping Device Type (0022,1415) is OCT. May be present otherwise. Only a single Item shall be permitted in this sequence
<i>>Include 'Image SOP Instance Reference Macro' Table 10-3</i>			
>Purpose of Reference Code Sequence	(0040,A170)	1	Describes the purpose for which the reference is made, (i.e., the role the source image or frame(s) played in the generation of this image). Only a single Item shall be permitted in this sequence.
<i>>>Include 'Code Sequence Macro' Table 8.8-1 Defined CID 7202</i>			
Referenced Instance Sequence	(0008,114A)	1C	A sequence that provides reference to a set of SOP Class/Instance pairs identifying images or other composite SOP Instances to plan the acquisition or significant related information. Required if Ophthalmic Photography Reference Image available. May be present otherwise. See Section C.7.6.16.2.5.1 for further explanation. Zero or more Items may be included in this Sequence.
<i>>Include 'SOP Instance Reference Macro' Table 10-11</i>			
>Purpose of Reference Code Sequence	(0040,A170)	1	Code describing the purpose of the reference to the Instance(s). Only a single Item shall be permitted in this sequence.
<i>>>Include 'Code Sequence Macro' Table 8.8-1 Defined CID 4264</i>			
Registration to Localizer Sequence	(0022,1465)	3	Registration of current instance to a localizer SOP Instance referenced in Attribute Referenced Instance Sequence (0008,114A). See section C.8.x.2.1.2 for an example.
>Registered Localizer Units	(0022,1466)	1	Units of measure for the axes of the registered localizer image. Enumerated Values: PIXEL = See Bounding Box Annotation Units (0070,0003) for definition.
>Registered Localizer Top Left Hand Corner	(0022,1467)	1	Location of the Top Left Hand Corner (TLHC) of the registered localizer in Registered Localizer Units (0022,1466), given as column\row. Column is the horizontal offset and row is the vertical offset.

>Registered Localizer Bottom Right Hand Corner	(0022,1468)	1	Location of the Bottom Right Hand Corner (BRHC) of the registered localizer in which Registered Localizer Units (0022,1466), given as column\row. Column is the horizontal offset and row is the vertical offset.
<i>Include 'General Anatomy Mandatory Macro' Table 10-5</i>			<p><i>The concept code for Anatomic Region Sequence (0008,2218) shall be (T-AA000, SRT, "Eye"), and Defined Context ID 244 shall be used for Anatomic Region Modifier Sequence (0008,2220).</i></p> <p><i>Defined Context ID 4266 shall be used for Primary Anatomic Structure Sequence (0008,2228). Only a single Item shall be permitted in this sequence.</i></p> <p>Note: Although Primary Anatomic Structure Sequence (0008,2228) is Type 3, it is important to convey this information if able to be determined.</p>
Relative Image Position Code Sequence	(0022,001D)	3	The position of this image on the retina (as defined by a specified nomenclature; the nomenclature is implicit in the code used). Only a single Item shall be permitted in this sequence.
<i>>Include 'Code Sequence Macro' Table 8.8.1 Baseline Context ID 4207</i>			
Anatomic Structure Reference Point	(0022,1463)	1C	<p>Location of a point in the image identified by an anatomic structure. This is used in ophthalmology for a landmark within a patient's eye. Given as column\row. Column is the horizontal offset and row is the vertical offset.</p> <p>Image relative position specified with sub-pixel resolution such that the origin at the Top Left Hand Corner (TLHC) of the TLHC pixel is 0.0\0.0, the Bottom Right Hand Corner (BRHC) of the TLHC pixel is 1.0\1.0, and the BRHC of the BRHC pixel is Columns\Rows (see figure C.10.5-1). The values must be within the range 0\0 to Columns\Rows.</p> <p>Required if Primary Anatomic Structure Sequence (0008,2228) contains an item with the value (T-AA621, SRT "Fovea centralis") or (T-AA630, SRT, "Optic nerve head") or (M-01000, SRT, "Lesion") or (111934, DCM, "Disc-Fovea").</p> <p>May be present otherwise.</p>
Retinal Thickness Definition Code Sequence	(0022,1445)	1C	<p>The definition of the retinal thickness for this image.</p> <p>Required if Attribute Image Type (0008,0008) value 3 is RETINAL_THICK.</p> <p>Only a single Item shall be permitted in this sequence.</p>
<i>>Include 'Code Sequence Macro' Table 8.8-1. Defined Context ID is 4262</i>			

C.8.X.2.1 Ophthalmic Thickness Map Module Attribute Descriptions

C.8.X.2.1.1 Image Type

For Ophthalmic Thickness Maps, Image Type (0008,0008) is specified to be Type 1 and uses one of the following Defined Terms for Value 3:

90

ONH

identifies a topographic map of an optic nerve head

RETINAL_THICK identifies a Thickness Map for retinal layers or combination of several sub-layers

95 Note1: The images created based upon the source data of the patient examination would be ORIGINAL/PRIMARY.

Note2: If the value is specified as "RETINAL_THICK", the definition of the retinal thickness is in Retinal Thickness Definition Code Sequence (0022,1445).

100 C.8.X.2.1.2 Referenced Instance Sequence

Equipment generating an ophthalmic map (OPM) image, may also obtain an accompanying "reference/localizer" image. This "reference/localizer" image serves the purpose of orienting and registering the OPM image to the actual retinal location. For example, a fundus photo may be obtained with ophthalmic tomography (OPT). When the retinal thickness map is generated based on OPT data, the OPM is registered with pixel precision to the fundus photo. This "reference/localizer" image is referenced in the OPM SOP Instance using the attribute Referenced Instance Sequence (0008,114A).

110 An example of a "reference/localizer" image and its relationship to an OPM image is shown in Figure C.8.x.2.1.2-1. Legend: (A) a fundus photo is taken as the "reference/localizer" image. The green box indicates the area the OPT scans are obtained. (B) The retinal thickness map (OPM object) is overlaid on the "reference/localizer" fundus photo to show the correspondence. These examples could be referenced from different types of SOP Classes, such as Color Softcopy Presentation State Storage (referencing the OP SOP Instance of a fundus photo), True Color Secondary Capture Image Storage, Encapsulated PDF, etc. The Purpose of Reference Code Sequence (0040,A170) code is set to (DCM, 121311, Localizer) for example A. Registration to Localizer Sequence (0022,1465) would be used for example B.

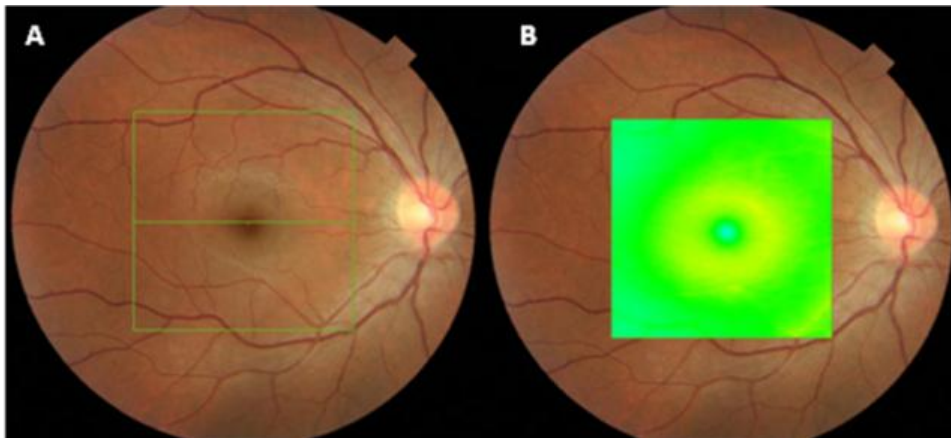
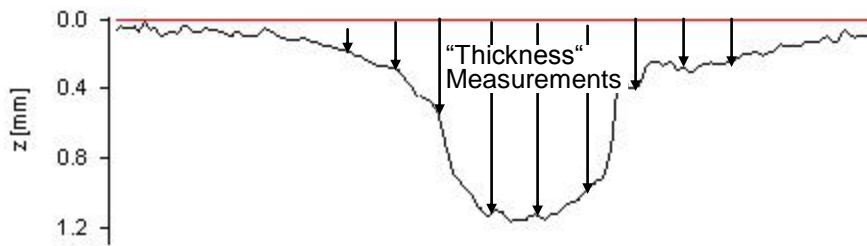
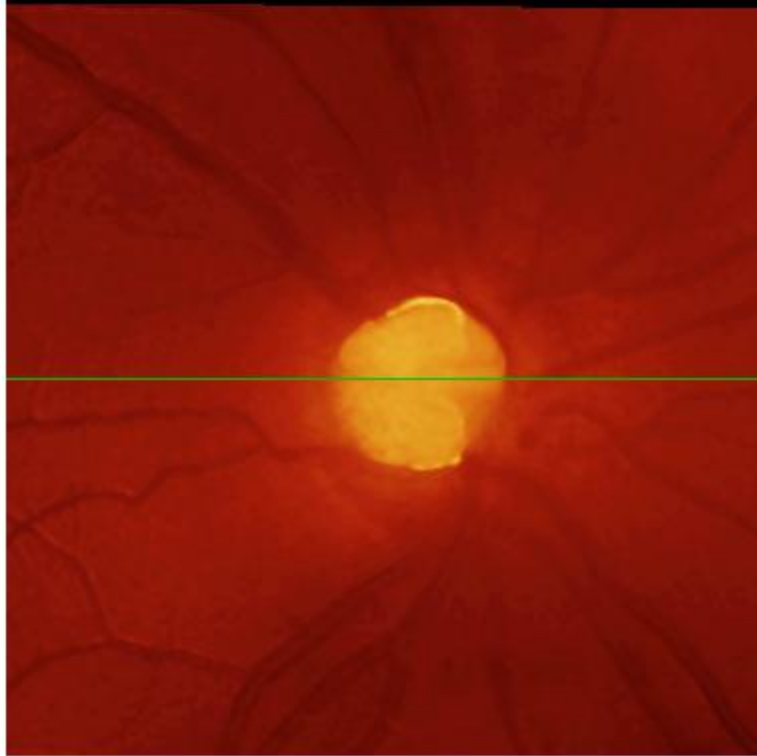


Figure C.8.X.2.1-1 Reference/Localizer Image Related to OPM Image

120 C.8.X.2.1.3 Ophthalmic Mapping Device Type

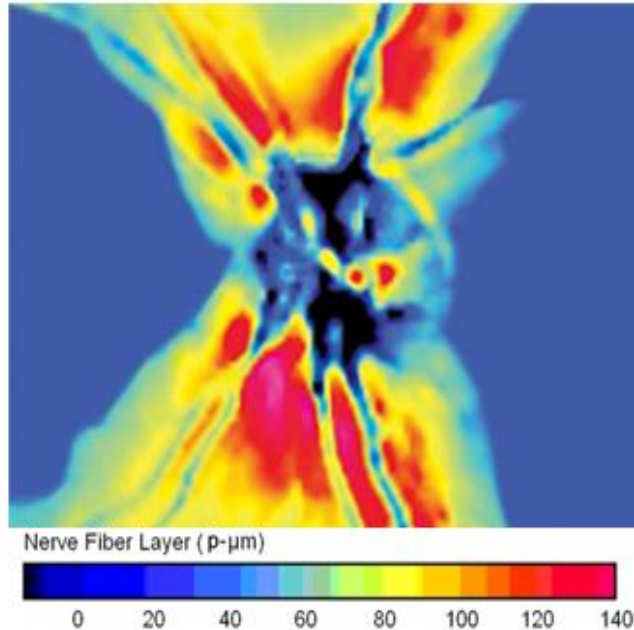
125 For Ophthalmic Mapping Device Type (0022,1415), Scanning Laser Ophthalmoscopy Tomography (SLO_TOMO) produces a topographical representation of the optic nerve head (ONH) rather than a thickness depiction. However, the topographical depiction can be considered as "thickness" measurements of multiple points of the ONH surface relative to an assigned datum plane. For this reason, the topographical image is included in the ophthalmic thickness map module.



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Figure C.8.X.2.1-2 Optic Nerve Head Thickness Example

For Ophthalmic Mapping Device Type (0022,1415), Polarimetric Tomography (POLARIMETRY) produces a thickness depiction based on birefringent phase shifts. This is a thickness measure but does not use typical international system of units such as micrometer, etc. Due to this, the unit of measurement is the defined by the implementation, such as 'p-um'.



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Figure C.8.X.2.1-3 Polarimetry Optic Nerve Head Thickness Example

C.8.X.3 Ophthalmic Thickness Map Quality Rating Module

Table C.8.X.3-1 specifies the Attributes that describe the quality rating for the ophthalmic mapping.

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**Table C.8.X.3-1
OPHTHALMIC THICKNESS MAP QUALITY RATING MODULE ATTRIBUTES**

Attribute Name	Tag	Type	Attribute Description
Ophthalmic Thickness Map Quality Rating Sequence	(0022,1470)	1	Type of metric and metric value used to evaluate the quality of the ophthalmic mapping for grading and diagnostic purposes for this SOP Instance. Only a single Item shall be permitted in this sequence.
>Include 'Numeric Value Macro' Table 10-xx.			Defined Context ID 4243 shall be used for Concept Name Code Sequence (0040,A043)
>Ophthalmic Thickness Map Quality Threshold Sequence	(0022,1458)	1	Quality threshold value and software algorithm used to provide the ophthalmic thickness map quality rating for this SOP Instance. Only a single Item shall be permitted in this sequence.
>>Ophthalmic Thickness Map Threshold Quality Rating	(0022,1460)	1	Quality rating threshold value for acceptable ophthalmic map. Note: The units of this Attribute is the same as defined in Measurement Unit Code Sequence (0040,08EA) of the Ophthalmic Thickness Map Quality Rating Sequence (0022,1470). The threshold value is not the same as the attribute Numeric Value (0049,A30A) of the Ophthalmic Thickness Map Quality Rating Sequence (0022,1470). Therefore, it conveys

			the least stringent value that is acceptable, not the actual rating for this SOP Instance.
>>Include 'Algorithm Identification Macro' Table 10-19			

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Changes to NEMA Standards Publication PS 3.4-2011
Digital Imaging and Communications in Medicine (DICOM)
Part 4: Service Class Specifications

Add to PS3.4 Annex B.5.

B.5 Standard SOP Classes

150

Table B.5-1
STANDARD SOP CLASSES

SOP Class Name	SOP Class UID	IOD (See PS 3.3)
...		
<u>Ophthalmic Thickness Map Storage</u>	<u>1.2.840.10008.5.1.4.1.1.81.1</u>	<u>Ophthalmic Thickness Map</u>

Add to Annex B.5.1 for Ophthalmic Thickness Map Storage SOP Class

B.5.1.x Ophthalmic Thickness Map Storage SOP Class

155

The Ophthalmic Thickness Map SOP Class encodes a topographic representation of the thickness/height measurements of the posterior eye.

For a device that is both a SCU and a SCP of the Ophthalmic Thickness Map Storage SOP Class, in addition to the behavior for the Storage Service Class specified in B.2.2, the following additional requirements are specified for Ophthalmic Thickness Map Storage SOP Classes:

160

- A SCP of this SOP Class shall support Level 2 Conformance as defined in Section B.4.1.

Note: This requirement means that all Type 1, Type 2, and Type 3 Attributes defined in the Information Object Definition and Private Attributes associated with the SOP Class will be stored and may be accessed.

165

Add to PS3.4 Annex I.4.

I.4 Media Standard Storage SOP Classes

Table I.4-1
Media Storage Standard SOP Classes

SOP Class Name	SOP Class UID	IOD (See PS 3.3)
...		
<u>Ophthalmic Thickness Map Storage</u>	<u>1.2.840.10008.5.1.4.1.1.81.1</u>	<u>Ophthalmic Thickness Map</u>

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Changes to NEMA Standards Publication PS 3.6-2011
Digital Imaging and Communications in Medicine (DICOM)
Part 6: Data Dictionary

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Add to PS3.6 Annex A

UID Value	UID NAME	UID TYPE	Part
...			
<u>1.2.840.10008.5.1.4.1.1.81.1</u>	<u>Ophthalmic Thickness Map Storage</u>	<u>SOP Class</u>	<u>PS 3.4</u>

Add the following data elements to PS 3.6:

Tag	Name	Keyword	VR	VM
<u>(0022,1415)</u>	<u>Ophthalmic Mapping Device Type</u>	<u>OphthalmicMappingDeviceType</u>	<u>CS</u>	<u>1</u>
<u>(0022,1420)</u>	<u>Acquisition Method Code Sequence</u>	<u>AcquisitionTypeMethodSequence</u>	<u>SQ</u>	<u>1</u>
<u>(0022,1423)</u>	<u>Acquisition Method Algorithm Sequence</u>	<u>AcquisitonMethodAlgorithmSequence</u>	<u>SQ</u>	<u>1</u>
<u>(0022,1436)</u>	<u>Ophthalmic Thickness Map Type Code Sequence</u>	<u>OphthalmicThicknessMapTypeCodeSequence</u>	<u>SQ</u>	<u>1</u>
<u>(0022,1443)</u>	<u>Ophthalmic Thickness Mapping Normals Sequence</u>	<u>OphthalmicThicknessMappingNormalsSequence</u>	<u>SQ</u>	<u>1</u>
<u>(0022,1445)</u>	<u>Retinal Thickness Definition Code Sequence</u>	<u>RetinalThicknessDefinitionCodeSequence</u>	<u>SQ</u>	<u>1</u>
<u>(0022,1450)</u>	<u>Pixel Value Mapping to Coded Concept Sequence</u>	<u>PixelValueMappingtoCodedConceptSequence</u>	<u>SQ</u>	<u>1</u>
<u>(0022,1452)</u>	<u>Mapped Pixel Value</u>	<u>MappedPixelValue</u>	<u>US or SS</u>	<u>1</u>
<u>(0022,1454)</u>	<u>Pixel Value Mapping Explanation</u>	<u>PixelValueMappingExplanation</u>	<u>LO</u>	<u>1</u>
<u>(0022,1458)</u>	<u>Ophthalmic Thickness Map Quality Threshold Sequence</u>	<u>OphthalmicThicknessMapQualityThresholdSequence</u>	<u>SQ</u>	<u>1</u>
<u>(0022,1460)</u>	<u>Ophthalmic Thickness Map Threshold Quality Rating</u>	<u>OphthalmicThicknessMapThresholdQualityRating</u>	<u>FL</u>	<u>1</u>
<u>(0022,1463)</u>	<u>Anatomic Structure Reference Point</u>	<u>AnatomicStructureReferencePoint</u>	<u>FL</u>	<u>2</u>
<u>(0022,1465)</u>	<u>Registration to Localizer Sequence</u>	<u>RegistrationtoLocalizerSequence</u>	<u>SQ</u>	<u>1</u>
<u>(0022,1466)</u>	<u>Registered Localizer Units</u>	<u>RegisteredLocalizerUnits</u>	<u>CS</u>	<u>1</u>

(0022,1467)	<u>Registered Localizer Top Left Hand Corner</u>	<u>RegisteredTopLeftHandCorner</u>	<u>FL</u>	<u>2</u>
(0022,1468)	<u>Registered Localizer Bottom Right Hand Corner</u>	<u>RegisteredBottomRightHandCorner</u>	<u>FL</u>	<u>2</u>
(0022,1470)	<u>Ophthalmic Thickness Map Quality Rating Sequence</u>	<u>OphthalmicThicknessMapQualityRatingSequence</u>	<u>SQ</u>	<u>1</u>
(0022,1472)	<u>Relevant OPT Attributes Sequence</u>	<u>RelevantOPTAttributesSequence</u>	<u>SQ</u>	<u>1</u>

Add new rows to PS 3.6 Annex A Table A-3

180

**Table A-3
CONTEXT GROUP UID VALUES**

Context UID	Context Identifier	Context Group Name
...
1.2.840.10008.6.1.936	4260	Ophthalmic Mapping Units for Real World Value Mapping
1.2.840.10008.6.1.937	4261	Ophthalmic Mapping Acquisition Method
1.2.840.10008.6.1.938	4262	Retinal Thickness Definition
1.2.840.10008.6.1.939	4263	Ophthalmic Thickness Map Value Type
1.2.840.10008.6.1.940	4264	Ophthalmic Thickness Map Purposes of Reference
1.2.840.10008.6.1.941	4265	Ophthalmic Thickness Deviation Categories
1.2.840.10008.6.1.942	4266	Ophthalmic Anatomic Structure Reference Point

Coding Scheme Designator (0008,0102)	Code Value (0008,0100)	Code Meaning (0008,0104)
....
<u>SRT</u>	<u>A-00E8C</u>	<u>Scanning Laser Polarimeter</u>
...

200 **CID 4260 Ophthalmic Mapping Units for Real World Value Mapping**

Context ID 4260

Ophthalmic Mapping Units for Real World Value Mapping

Type: Extensible Version: 20110825

Coding Scheme Designator (0008,0102)	Code Value (0008,0100)	Code Meaning (0008,0104)
UCUM	um	micrometer

205 **CID 4261 Ophthalmic Mapping Acquisition Method**

Context ID 4261

Ophthalmic Mapping Acquisition Method

Type: Extensible Version: 20110825

Coding Scheme Designator (0008,0102)	Code Value (0008,0100)	Code Meaning (0008,0104)
DCM	111920	Time domain
DCM	111921	Spectral domain
DCM	111922	No corneal compensation
DCM	111923	Corneal birefringence compensation
DCM	111924	Retinal topography

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CID 4262 Retinal Thickness Definition

Context ID 4262

Retinal Thickness Definition

Type: Extensible Version: 20110825

Coding Scheme Designator	Code Value	Code Meaning
DCM	111925	Retinal nerve fiber layer thickness
DCM	111926	Ganglion cell complex thickness
DCM	111927	Total retinal thickness (ILM to IS-OS)
DCM	111928	Total retinal thickness (ILM to RPE)

215

DCM	111929	Total retinal thickness (ILM to BM)
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CID 4263 Ophthalmic Thickness Map Value Type

**Context ID 4263
 Ophthalmic Thickness Map Value Type**

Type: Extensible Version: 20110825

220

Coding Scheme Designator	Code Value	Code Meaning
DCM	111930	Absolute ophthalmic thickness
DCM	111931	Thickness deviation category from normative data
DCM	111932	Thickness deviation from normative data

CID 4264 Ophthalmic Thickness Map Purposes of Reference

**Context ID 4264
 Ophthalmic Thickness Map Purposes of Reference**

Type: Extensible Version: 20110825

225

Coding Scheme Designator (0008,0102)	Code Value (0008,0100)	Code Meaning (0008,0104)
DCM	121311	Localizer
DCM	121322	Source image for image processing operation
DCM	111933	Related ophthalmic thickness map

CID 4265 Ophthalmic Thickness Deviation Categories

**Context ID 4265
 Ophthalmic Thickness Deviation Categories**

Type: Extensible Version: 20110825

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Coding Scheme Designator (0008,0102)	Code Value (0008,0100)	Code Meaning (0008,0104)
DCM	111935	p>5%
DCM	111936	p<5%
DCM	111937	p<2%
DCM	111938	p<1%
DCM	111939	p<0.5%

CID 4266 Ophthalmic Anatomic Structure Reference Point

Context ID 4266

Ophthalmic Anatomic Structure Reference Point

Type: Extensible Version: 20110825

Coding Scheme Designator (0008,0102)	Code Value (0008,0100)	Code Meaning (0008,0104)
SRT	M-01000	Lesion
SRT	T-AA621	Fovea centralis
SRT	T-AA630	Optic nerve head
DCM	111934	Disc-Fovea

235

Add the following definitions to Part 16 Annex D DICOM Controlled Terminology Definitions (Normative)

Annex D DICOM Controlled Terminology Definitions (Normative)

Code Value	Code Meaning	Definition	Notes
...	
<u>111900</u>	<u>Macula centered</u>	<u>An image of at least 15° angular subtend that is centered on the macula. See PS3.17 Relative Image Position Definitions.</u>	
<u>111901</u>	<u>Disc centered</u>	<u>An image of at least 15° angular subtend that is centered on the optic disc. See PS3.17 Relative Image Position Definitions.</u>	
<u>111902</u>	<u>Lesion centered</u>	<u>An image of any angular subtend that is centered on a lesion located in any region of the fundus. See PS3.17 Relative Image Position Definitions.</u>	
<u>111903</u>	<u>Disc-macula centered</u>	<u>An image of at least 15° angular subtend centered midway between the disc and macula and containing at least a portion of the disc and both the disc and the macula. See PS3.17 Relative Image Position Definitions.</u>	
<u>111904</u>	<u>Mid-peripheral-superior</u>	<u>An image of at least 15° angular subtend positioned between the central zone and the equator, and spanning both the superior-temporal and superior-nasal quadrants of the fundus. See PS3.17 Relative Image Position Definitions.</u>	
<u>111905</u>	<u>Mid-peripheral-superior temporal</u>	<u>An image of at least 15° angular subtend positioned between the central zone and the equator in the superior-temporal</u>	

		<u>quadrant of the fundus. See PS3.17 Relative Image Position Definitions.</u>	
<u>111906</u>	<u>Mid-peripheral-temporal</u>	<u>An image of at least 15° angular subtend positioned between the central zone and the equator, and spanning both the superior-temporal and inferior-temporal quadrants of the fundus. See PS3.17 Relative Image Position Definitions.</u>	
<u>111907</u>	<u>Mid-peripheral-inferior temporal</u>	<u>An image of at least 15° angular subtend positioned between the central zone and the equator in the inferior-temporal quadrant of the fundus. See PS3.17 Relative Image Position Definitions.</u>	
<u>111908</u>	<u>Mid-peripheral-inferior</u>	<u>An image of at least 15° angular subtend positioned between the central zone and the equator, and spanning both the inferior-temporal and inferior-nasal quadrants of the fundus. See PS3.17 Relative Image Position Definitions.</u>	
<u>111909</u>	<u>Mid-peripheral-inferior nasal</u>	<u>An image of at least 15° angular subtend positioned between the central zone and the equator in the inferior-nasal quadrant of the fundus. See PS3.17 Relative Image Position Definitions.</u>	
<u>111910</u>	<u>Mid-peripheral-nasal</u>	<u>An image of at least 15° angular subtend positioned between the central zone and the equator, and spanning both the superior-nasal and inferior-nasal quadrants of the fundus. See PS3.17 Relative Image Position Definitions.</u>	
<u>111911</u>	<u>Mid-peripheral-superior nasal</u>	<u>An image of at least 15° angular subtend positioned between the central zone and the equator in the superior-nasal quadrant of the fundus. See PS3.17 Relative Image Position Definitions.</u>	
<u>111912</u>	<u>Peripheral-superior</u>	<u>An image of at least 15° angular subtend positioned between the equator and the ora serrata, and spanning both the superior temporal and superior nasal quadrants of the fundus. See PS3.17 Relative Image Position Definitions.</u>	
<u>111913</u>	<u>Peripheral-superior temporal</u>	<u>An image of at least 15° angular subtend positioned between the equator and ora serrata in the superior-temporal quadrant of the fundus. See PS3.17 Relative Image Position Definitions.</u>	
<u>111914</u>	<u>Peripheral-temporal</u>	<u>An image of at least 15° angular subtend positioned between the equator and ora serrata, and spanning both the superior-temporal and inferior-temporal quadrants of the fundus. See PS3.17 Relative Image</u>	

		<u>Position Definitions.</u>	
<u>111915</u>	<u>Peripheral-inferior temporal</u>	<u>An image of at least 15° angular subtend positioned between the equator and ora serrata in the inferior-temporal quadrant of the fundus. See PS3.17 Relative Image Position Definitions.</u>	
<u>111916</u>	<u>Peripheral-inferior</u>	<u>An image of at least 15° angular subtend positioned between the equator and ora serrata, and spanning both the inferior-temporal and inferior-nasal quadrants of the fundus. See PS3.17 Relative Image Position Definitions.</u>	
<u>111917</u>	<u>Peripheral-inferior nasal</u>	<u>An image of at least 15° angular subtend positioned between the equator and ora serrata in the inferior-nasal quadrant of the fundus. See PS3.17 Relative Image Position Definitions.</u>	
<u>111918</u>	<u>Peripheral-nasal</u>	<u>An image of at least 15° angular subtend positioned between the equator and ora serrata, and spanning both the superior-nasal and inferior-nasal quadrants of the fundus. See PS3.17 Relative Image Position Definitions.</u>	
<u>111919</u>	<u>Peripheral-superior nasal</u>	<u>An image of at least 15° angular subtend positioned between the equator and ora serrata in the superior-nasal quadrant of the fundus. See PS3.17 Relative Image Position Definitions.</u>	
<u>111920</u>	<u>Time domain</u>	<u>Identifies the use of physical signals with respect to time to capture information.</u>	
<u>111921</u>	<u>Spectral domain</u>	<u>Identifies the use of physical signals with respect to multiple frequencies to capture information.</u>	
<u>111922</u>	<u>No corneal compensation</u>	<u>No compensation algorithm for corneal birefringence.</u>	
<u>111923</u>	<u>Corneal birefringence compensation</u>	<u>Algorithm to compensate for variability in corneal birefringence .</u>	
<u>111924</u>	<u>Retinal topography</u>	<u>Measurement of the retinal surface contour relative to an assigned datum plane.</u>	
<u>111925</u>	<u>Retinal nerve fiber layer thickness</u>	<u>Measurement approximating the distance related to the structure between the internal limiting membrane (ILM) and the outer boarder of the retinal nerve fiber layer (RNFL). See PS3.17 Retinal Thickness Definition.</u>	
<u>111926</u>	<u>Ganglion cell complex thickness</u>	<u>Measurement approximating the distance related to the structure between the ILM and the outer border of the inner</u>	

		<u>plexiform layer (IPL), called the ganglion cell complex (GCC). See PS3.17 Retinal Thickness Definition.</u>	
<u>111927</u>	<u>Total retinal thickness (ILM to IS-OS)</u>	<u>Measurement approximating the distance related to the structure between the ILM and the inner-outer segment junction (IS-OS). See PS3.17 Retinal Thickness Definition.</u>	
<u>111928</u>	<u>Total retinal thickness (ILM to RPE)</u>	<u>Measurement approximating the distance related to the structure between the ILM and the retinal pigment epithelium (RPE). See PS3.17 Retinal Thickness Definition.</u>	
<u>111929</u>	<u>Total retinal thickness (ILM to BM)</u>	<u>Measurement approximating the distance related to the structure between the ILM and the Bruch's membrane (BM). See PS3.17 Retinal Thickness Definition.</u>	
<u>111930</u>	<u>Absolute ophthalmic thickness</u>	<u>Thickness of a component of the posterior segment of the eye. For example, thickness of retina, choroid, etc.</u>	
<u>111931</u>	<u>Thickness deviation category from normative data</u>	<u>Ophthalmic Thickness map based upon statistical significance category (such as percentile) from a normative data set.</u>	
<u>111932</u>	<u>Thickness deviation from normative data</u>	<u>Ophthalmic Thickness map based upon deviation (such as microns) from a normative data set.</u>	
<u>111933</u>	<u>Related ophthalmic thickness map</u>	<u>Ophthalmic Thickness Map related to another Ophthalmic Thickness Map or another SOP Instance.</u>	
<u>111934</u>	<u>Disc-Fovea</u>	<u>An anatomic point centered midway between the disc and fovea centralis.</u>	
<u>111935</u>	<u>p>5%</u>	<u>Assuming the null hypothesis is true, the conditional percent probability of observing this result is not statistically significant.</u>	
<u>111936</u>	<u>p<5%</u>	<u>Assuming the null hypothesis is true, the conditional percent probability of observing this result is statistically significant, 95% unlikely to happen by chance.</u>	
<u>111937</u>	<u>p<2%</u>	<u>Assuming the null hypothesis is true, the conditional percent probability of observing this result is statistically significant, 98% unlikely to happen by chance.</u>	
<u>111938</u>	<u>p<1%</u>	<u>Assuming the null hypothesis is true, the conditional percent probability of observing this result is statistically significant, 99% unlikely to happen by chance.</u>	

<u>111939</u>	<u>p<0.5%</u>	<u>Assuming the null hypothesis is true, the conditional percent probability of observing this result is statistically significant, 99.5% unlikely to happen by chance.</u>	
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Changes to NEMA Standards Publication PS 3.17-2011
Digital Imaging and Communications in Medicine (DICOM)
Part 17: Explanatory Information

245

Add to PS3.17 Annex Y

Annex Y Ophthalmic Thickness Map Use Cases (Informative)

Y.1 Introduction

250 Several ophthalmic devices produce thickness and/or height measurements of certain anatomical features of the posterior eye (e.g., optic nerve head topography, retinal thickness map, etc.). The measurements are mapped topographically as monochromatic images with pseudo color maps, and used extensively for diagnostic purposes by clinicians.

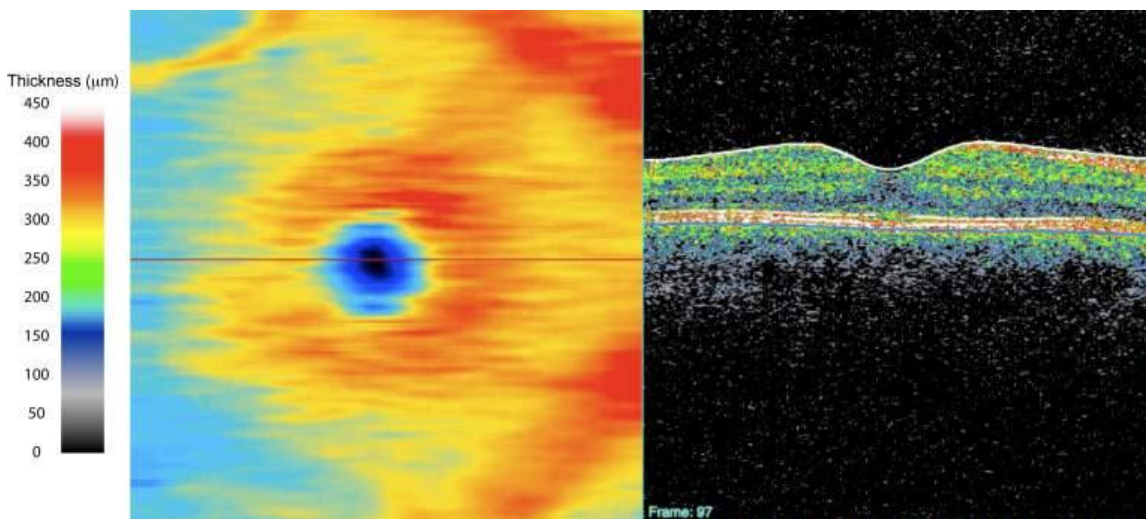
Y.2 Macular Retinal Thickness Example

255 Quantitative ophthalmic OCT image analysis provides essential thickness measurement data of the retina. In the clinical practice two thickness parameters are commonly used: total retinal thickness (TR) in macular region and retinal nerve fiber layer thickness (RNFL) in optic nerve head (ONH) region. TR is widely applied to assess various retinal pathologies involving macula (e.g. cystoid macular edema, age-related macular degeneration, macular hole, etc.). The RNFL thickness measurement is most commonly used for glaucoma assessment.

260

Figure Y.2-1 is an example of 2D TR map computed on a 3D OCT cube data from a healthy eye. The color bar on the left provides a color-to-thickness representation to allow interpretation of the false color coded 2D thickness map in the middle. The image on the right shows one OCT frame representing a retinal cross section along the red line (across the middle of the thickness map).

265 TR is defined as the thickness between internal limiting membrane (white line on the OCT frame on the right) and RPE/Choroid interface (blue line on the OCT frame). These two borders are automatically detected using a segmentation algorithm applied to the entire 3D volume.



270

Figure Y.2-1 Macular Example Mapping

Y.3 RNFL Example

275 Figure Y.3-1 is an example of a 2D RNFL map computed on a 3D OCT cube data from a healthy eye. The figure layout is the same as the previous example. The RNFL thickness is limited to the thickness of this single layer of the retina that is comprised of the ganglion cell axons that course to the optic nerve head and exit the eye as the optic nerve. Note that this image depicts a BMP mask in the center of the map where the optic nerve head (ONH) exists and no RNFL measurements can be obtained. In this example, the mask is displayed as a black area, which does not contain any thickness information (not zero micron thickness). Since the color bar representation is not relevant at the ONH, common practice is to mask it to avoid confusion or misinterpretation due to meaningless thickness data in this area.

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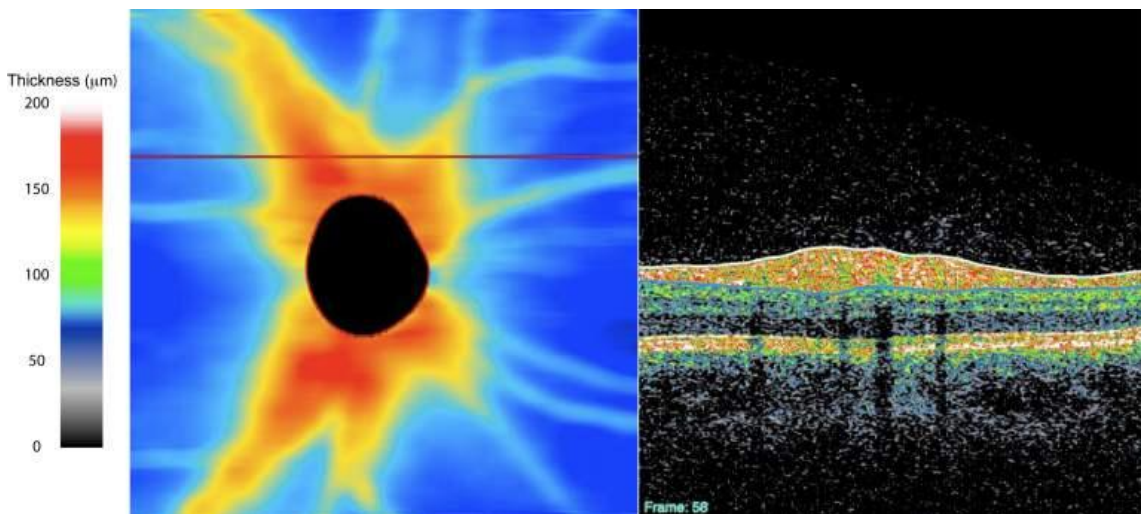


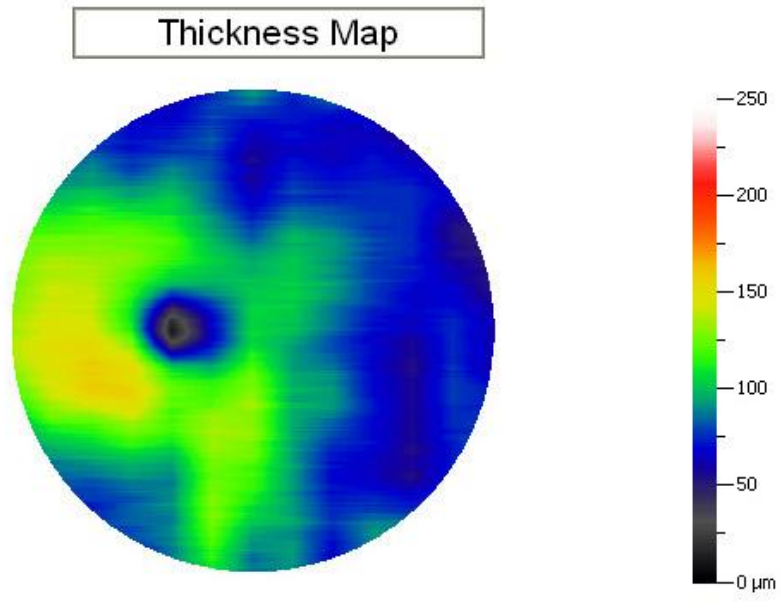
Figure Y.3-1 RNFL Example Mapping

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Y.4 Diabetic Macular Edema Example

A 48 year old Navajo male with diabetes, decreased visual acuity and fundoscopic stigmata of diabetic retinopathy receives several tests to assess his likelihood of macular edema. Optical coherence tomography (OCT) is performed to assess the thickness of the retina in the macular area. This is performed with retinal thickness depicted by ophthalmic mapping. The results is an Ophthalmic Thickness Map SOP instance with the Ophthalmic Thickness Mapping Type Code Sequence (0022,1436) set to "Absolute Ophthalmic Thickness" and the Measurements Units Code Sequence (0040,08EA) in the Real World Value Mapping Macro, set to "micrometer". The OCT image is also referenced in attribute Referenced Instance Sequence (0008,114A).

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Figure Y.4-1 Macula Edema Thickness Map Example

Since the thickness of the macula varies normally based upon a number of dependencies such as age, gender, race, etc. Interpretation of the retinal thickness in any given patient may be done in the context of normative data that accounts for these variables. The thickness data used to generate the thickness map is analyzed using a manufacturer specific algorithm for comparison to normative data relevant to this specific patient. The results of this analysis is depicted on a second thickness “map” (second SOP Instance) showing each pixel’s variation from normal in terms of confidence that the variation is real and not due to chance. Specific confidence levels are then depicted by arbitrary color mapping registered to the fundus photograph. This is typically noted as the percent probability that the variation is abnormal e.g. $p > 5\%$, $p < 5\%$, $p < 1\%$ etc. The results is an Ophthalmic Thickness Map SOP instance with the Ophthalmic Thickness Mapping Type Code Sequence (0022,1436) set to “Thickness deviation category from normative data”. Mapping the “categories” to a code concept is accomplished via Attribute Pixel Value Mapping to Coded Concept Sequence (0022,1450).

300

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310

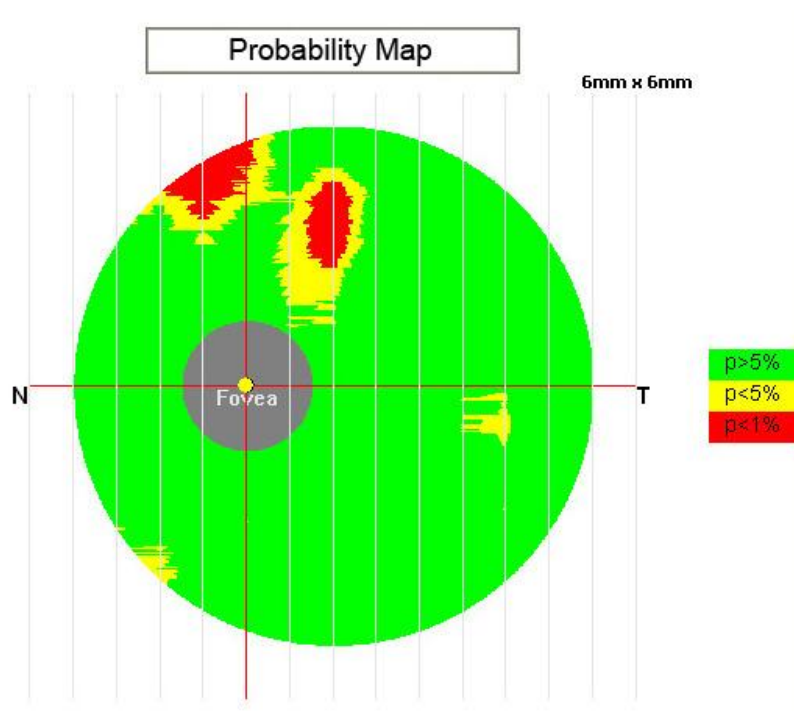


Figure Y.4-2 Macula Edema Probability Map Example

Y.5 Glaucoma Example

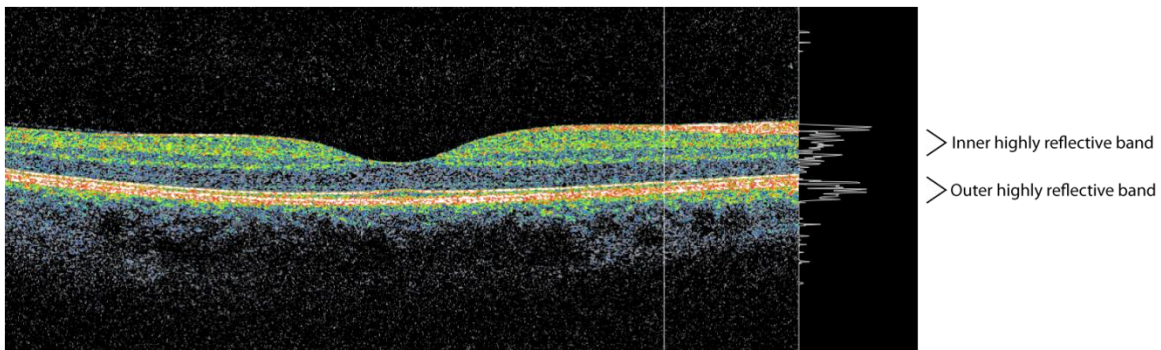
315 A patient was presented with normal visual acuity OU (both eyes), intraocular pressures (IOP) of
18 mm Hg OU (both eyes), and 0.7 C/D OD (right eye) and 0.6 C/D ratio OS (left eye). Corneal
pachymetry showed slight thinning in both eyes at 523 μ OD (right eye) and 530 μ OS (left eye).
Static threshold perimetry testing showed nonspecific defects OU (both eyes) and was unreliable
due to multiple fixation losses. Confocal scanning laser ophthalmoscopy produced OPM
320 topographic representations of both optic nerves suggestive of glaucoma. The contouring of the
optic nerve head (ONH) in the left eye showed a slightly enlarged cup with diffuse thinning of the
superior neural rim. In the right eye, there was greater enlargement of the cup and sloping of the
cup superior-temporally with a clear notch of the neural rim at the 12:30 position. Corneal
compensated scanning laser polarimetry was performed bilaterally. Analysis of the OPM
325 representation of the retinal nerve fiber layer (RNFL) thickness map showed moderate retinal
nerve fiber loss with accentuation at the superior pole bilaterally. The patient was diagnosed with
normal tension glaucoma and started on a glaucoma medication. Follow-up examinations showed
stable reduction in his IOP to 11 mm Hg OU (both eyes) and no further progression of his ONH or
RNFL defects.

330 Y.6 Retinal Thickness Definition

Using OCT technology, there are typically 2 major highly reflective bands generally visible; inner
and outer highly reflective bands (IHRB and OHRB).

335 The inner band corresponds to the inner portion of the retina, which consists of ILM (internal
limiting membrane), RNFL (retinal nerve fiber layer), GCL (ganglion cell layer), IPL (inner
plexiform layer), INL (inner nuclear layer), and OPL (outer plexiform layer). In terms of the
reflectivity, they present a high-low-high-low-high pattern, in general. Presumably RNFL, IPL, and
OPL are the highly reflective layers and GCL and INL are of low reflectivity. ILM itself may or may
not be visible in OCT images (depending on the scanning beam incidence angle), but for
convenience it is used to label the vitreo-retinal interface.

- 340 The outer band is considered as the RPE (retinal pigment epithelium)/Choroid complex that consist of portion of photoreceptor, RPE, Bruch's membrane, and portion of choroid. Within the RPE/Choroid complex, there are 3 highly reflective interfaces identifiable, presumably corresponding to IS/OS (photoreceptor inner/out segment junction), RPE, and Bruch's membrane.
- 345 Clinically 3 retinal thickness measurements are generally acknowledged and utilized; RNFL thickness, GCC (ganglion cell complex) thickness, and total retinal thickness.
- RNFL thickness is defined as the distance between ILM and outer interface of the inner most highly reflective layer presumably RNFL.
- 350 GCC thickness is defined as the distance between ILM and the outer interface of the second inner highly reflective layer presumably the outer border of inner plexiform layer (IPL).
- Total retinal thickness definition varies among OCT manufacturers. The classic definition is the distance between ILM and the first highly reflective interface (presumably IS-OS) in the OHRB (Total retinal thickness (ILM to IS-OS)). A second definition is the distance between ILM and the second highly reflective interface (presumably RPE) in the OHRB (Total retinal thickness (ILM to RPE)). A third definition is the distance between ILM and the third highly reflective interface (presumably Bruch's membrane) in the OHRB (Total retinal thickness (ILM to BM)).
- 355



360 **Figure Y.6-1 Observable Layer Structures**

Y.7 Thickness Calculations Between Various Devices

- When interpreting quantitative data obtained from imaging devices, comparing may be an issue. Using different devices manufactured by different companies usually ends up with non-comparable measurements because they use different optics and different algorithms to make measurements.
- 365

- Currently there are multiple SD-OCT devices independently manufactured, and data comparability has become problematic. When patients change doctors or otherwise receive care from more than one provider, previously acquired data may occur on different devices and become almost useless simply because the present doctor has no access to the same device.
- 370 Another problem occurs with longitudinal assessments on the same device after it has undergone upgrade to a newer generation. In this case new baseline measurements must be obtained due to incomparability of the data (this happens even for the same make different generation devices). Attempts to normalize the measurements have been unsuccessful.

- 375 The manufacturer, model, serial number, and software version information are available in the Equipment Module, and is very important for considering the significant importance of the information to the quantitative data between various SOP Instances.

Add to PS3.17 Annex U section U.1.8 Ophthalmology Photography Use Cases

U.1.8 Relative Image Position Definitions

380 Ophthalmic mapping usually occurs in the posterior region of the fundus, typically in the macula
or the optic disc. However, this or other imaging may occur anywhere in the fundus. The mapping
data has clinical relevance only in the context of its location in the fundus, so this must be
appropriately defined. PS3.16 Ophthalmic Image Position codes (CID 4207) and the ocular
fundus locations they represent are defined by anatomical landmarks and are described using
385 conventional anatomic references, e.g. superior, inferior, temporal, and nasal. Figure U.1.8-1 is a
schematic representation of the fundus of the left eye, and provides additional clarification of the
anatomic references used in the image location definitions. A schematic of the right eye is omitted
since it is identical to the left eye, except horizontally reversed (Temporal→Nasal,
Nasal→Temporal).

390 The spatial precision of the following location definitions vary depending upon their specific
reference. Any location that is described as “centered” is assumed to be positioned in the center
of the referenced anatomy. However, the center of the macula can be defined visually with more
precision than that of the disc or a lesion. The locations without a “center” reference are
approximations of the general quadrant in which the image resides.

395 Note: An image < 15° angular subtend in the same position should be considered Lesion Centered.
Following are general definitions used to understand the terminology used in the code definitions.

- Central zone- a circular region centered vertically on the macula and extending one disc diameter nasal to the nasal margin of the disc and four disc diameters temporal to the temporal margin of the disc.
- 400 • Equator- the border between the mid-periphery and periphery of the retinal and corresponding to a circle approximately coincident with the ampulae of the vortex veins
- Superior- any region that is located superiorly to a horizontal line bisecting the macula
- Inferior- any region that is located inferiorly to a horizontal line bisecting the macula
- Temporal- any region that is located temporally to a vertical line bisecting the macula
- 405 • Nasal- any region that is located nasally to a vertical line bisecting the macula
- Mid-periphery- A circular zone of the retina extending from the central zone to the equator
- Periphery- A zone of the retinal extending from the equator to the ora serrata.
- Ora Serrata- the most anterior extent and termination of the retina
- 410 • Lesion- any pathologic object of regard

Figure U.1.8-1 illustrates anatomical representation of defined regions of the fundus of the left eye according to anatomical markers. The right eye has the same representations but reversed horizontally so that temporal and nasal are reversed with the macula remaining temporal to the disc.

415 Modified after Welch Allyn: <http://www.welchallyn.com/wafor/students/Optomety-Students/BIO-Tutorial/BIO-Observation.htm>.

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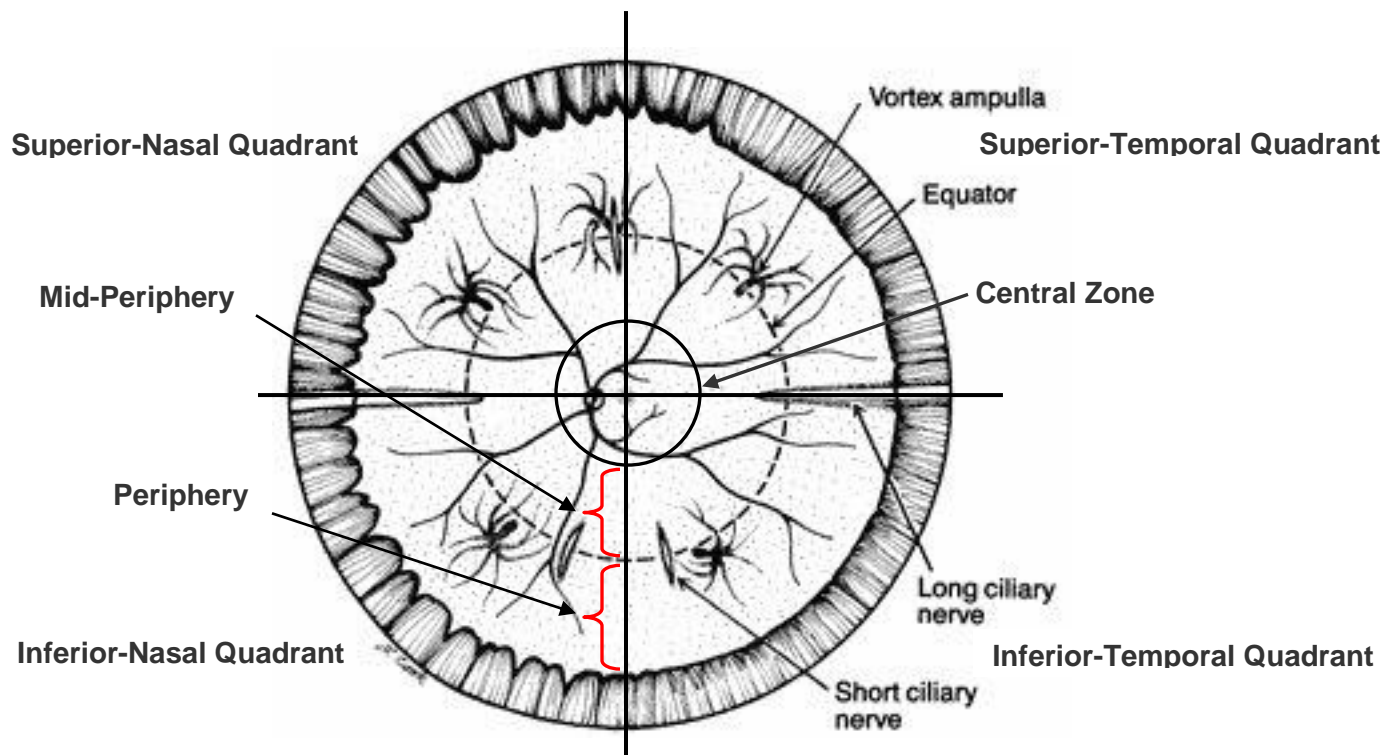


Figure U.1.8-1 Anatomical Landmarks and References of the Left Ocular Fundus