Digital Imaging and Communications in Medicine (DICOM)

Supplement 143

DICOM SR Template for Reporting of Macular Grid Thickness and Volume

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Scope and Field of Application

This Supplement to the DICOM Standard introduces a DICOM SR template for reporting of macular grid thickness and volume values derived from ophthalmic images, such as OPT images. This is part of an ongoing program by DICOM WG9 to create a comprehensive set of DICOM supplements for the full range of ophthalmic instruments.

Clinicians would employ such a report in routine care of patients with macular disease. This is also of interest for clinical trial workflow, to allow standardized reporting from different brands of OPT devices to reading centers. Defining a standard report will allow data to be compared more efficiently from eyes imaged by various OPT machine types. This is critically important in clinical research, where data from scans from multiple instrument makers will need to be pooled for analysis and for longitudinal study of eyes where baseline scans may come from one machine but later data comes from another.

Changes to NEMA Standards Publication PS 3.2-2008

Digital Imaging and Communications in Medicine (DICOM)

Part 2: Conformance

Conformance

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

The SOP Classes are categorized as follows:

Table A.1-2
UID VALUES

UID Value	UID NAME	Category
…	…	…
1.2.840.10008.5.1.4.1.1.79.1	**Macular Grid Thickness and Volume Report Storage SOP Class**	**Transfer**
…	…	…

Changes to NEMA Standards Publication PS 3.3-2008

Digital Imaging and Communications in Medicine (DICOM)

Part 3: Information Object Definitions

30 **Update PS3.3 Annex A to include Macular Grid Thickness and Volume Report**

A.1.4 Overview of the Composite IOD Module Content

Table A.1-2
COMPOSITE INFORMATION OBJECT MODULES OVERVIEW - NON-IMAGES

IODs Modules	Macular Grid Thickness and Volume Report
Patient	**M**
Clinical Trial Subject	**U**
General Study	**M**
Patient Study	**U**
Clinical Trial Study	**U**
General Equipment	**M**
Enhanced General Equipment	**M**
Clinical Trial Series	**U**
SR Document Series	**M**
SR Document General	**M**
SR Document Content	**M**
SOP Common	**M**

Add the following to Ophthalmic Measurements IODs PS 3.3 Annex A

A.35.x Macular Grid Thickness and Volume Report Information Object Definition

A.35.x.1 Macular Grid Thickness and Volume Report Information Object Description

The Macular Grid Thickness and Volume Report IOD is used to represent the macular grid thickness and volume values derived from ophthalmic images.

A.35.x.2 Macular Grid Thickness and Volume Report IOD Entity-Relationship Model

The E-R Model in Section A.1.2 of this Part applies to the Macular Grid Thickness and Volume Report IOD. Table A.35.x.3-1 specifies the Modules of the Thickness and Macular Volume Report IOD.

A.35.x.3 Macular Grid Thickness and Volume Report IOD Module Table

Table A.35.x.3-1 specifies the Modules of the Macular Grid Thickness and Volume Report IOD.

Table A.35.x.3-1
MACULAR GRID THIICKNESS AND VOLUME REPORT 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	SR Document Series	C.17.1	M
	Clinical Trial Series	C.7.3.2	U
Equipment	General Equipment	C.7.5.1	M
	Enhanced General Equipment	C.7.5.2	M
Document	SR Document General	C.17.2	M
	SR Document Content	C.17.3	M
	SOP Common	C.12.1	M

A.35.x.3.1 Macular Grid Thickness and Volume Report IOD Content Constraints

A.35.x.3.1.1 Value Type

Value Type (0040,A040) in the Content Sequence (0040,A730) of the SR Document Content Module is constrained to the following Enumerated Values (see Table C.17.3-1 for Value Type definitions):

TEXT
IMAGE
NUM
CONTAINER
CODE
PNAME

UIDREF
DATE

A.35.x.3.1.2 Relationship Constraints

Relationships between Content Items in the content of this IOD shall be conveyed in the by-value mode. See Table C.17.3-2 for Relationship Type definitions.

Note: Relationships by-reference are forbidden. Therefore, Referenced Content Item Identifier (0040,DB73) is not present in any of the Content Items within the SR Document Content Module.

Table A.35.x.3.1.2-1 specifies the relationship constraints of this IOD.

Table A.35.x.3.1.2-1
RELATIONSHIP CONTENT CONSTRAINTS FOR MACULAR GRID THICKNESS AND VOLUME REPORT IOD

Source Value Type	Relationship Type (Enumerated Values)	Target Value Type
CONTAINER	HAS OBS CONTEXT	CODE, PNAME, TEXT, UIDREF, DATA, NUM
CONTAINER	CONTAINS	CONTAINER, NUM, TEXT, CODE
any type	HAS CONCEPT MOD	CODE
NUM	HAS OBS CONTEXT	TEXT
NUM	INFERRED FROM	IMAGE

A.35.x.3.1.3 Template Constraints

The document shall be constructed from TID 2100 Macular Grid Thickness and Volume Report invoked at the root node.

Changes to NEMA Standards Publication PS 3.4-2008

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Part 4: Service Class Specifications

Add Macular Grid Thickness and Volume Report SOP Classes to PS3.4 Annex B

B.3.1.4 Related General SOP Classes (A-ASSOCIATE-RQ)

SOP Class Name	Related General SOP Class Name
Macular Grid Thickness and Volume Report	**Enhanced SR**

B.5 Standard SOP Classes

Table B.5-1
STANDARD SOP CLASSES

SOP Class Name	SOP Class UID	IOD (See PS 3.3)
Macular Grid Thickness and Volume Report	**1.2.840.10008.5.1.4.1.1.79.1**	**Macular Grid Thickness and Volume Report**

B.5.1.5 Structured Reporting Storage SOP Classes

The requirements of Annex O apply to the following SOP Classes:

- Basic Text SR
- Enhanced SR, and SOP Classes for which it is the Related General SOP Class
- Comprehensive SR, and SOP Classes for which it is the Related General SOP Class
- Mammography CAD SR
- Chest CAD SR
- Procedure Log
- X-Ray Radiation Dose SR
- Spectacle Prescription Report
- **Macular Grid Thickness and Volume Report**

Add Macular Grid Thickness and Volume Report Storage SOP Class to PS3.4 Annex I

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)
Macular Grid Thickness and Volume Report	**1.2.840.10008.5.1.4.1.1.79.1**	**Macular Grid Thickness and Volume Report**

I.4.1.2 Structured Reporting Storage SOP Classes

The requirements of Annex O apply to the following SOP Classes:

- Basic Text SR
- Enhanced SR, and SOP Classes for which it is the Related General SOP Class
- Comprehensive SR, and SOP Classes for which it is the Related General SOP Class
- Mammography CAD SR
- Chest CAD SR
- Procedure Log
- X-Ray Radiation Dose SR
- Spectacle Prescription Report
- **Macular Grid Thickness and Volume Report**

Changes to NEMA Standards Publication PS 3.6-2008

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Part 6: Data Dictionary

Add the Macular Grid Thickness Report UIDs to PS3.6 Annex A:

Annex A (Normative): Registry of DICOM Unique Identifiers (UID)

UID Value	UID NAME	UID TYPE	Part
…			
1.2.840.10008.5.1.4.1.1.79.1	**Macular Grid Thickness and Volume Report Storage**	**SOP Class**	**3.4**

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

Table A-3
CONTEXT GROUP UID VALUES

Context UID	Context Identifier	Context Group Name
...		
1.2.840.10008.6.1.819	**4220**	**Visual Fixation Quality During Acquisition**
1.2.840.10008.6.1.820	**4221**	**Visual Fixation Quality Problem**
1.2.840.10008.6.1.821	**4222**	**Ophthalmic Macular Grid Problem**

Changes to NEMA Standards Publication PS 3.16-2008

Digital Imaging and Communications in Medicine (DICOM)

Part 16: Content Mapping Resource

Item: Add to PS3.16 Section 2 Normative References:

ETDRS ETDRS Report Number 10, Grading Diabetic Retinopathy from Stereoscopic Color Fundus Photographs- An Extension of the Modified Airlie House Classification. *Ophthalmology*, May 1991, vol98 (p786-805), Supplement

Item: Add Macular Template to PS3.16:

TID 2100 Macular Grid Thickness and Volume Report

The Macular Grid Thickness and Volume Report is a structured report encoding the macular grid thickness and volume values derived from ophthalmic images, such as ophthalmic OPT images. This may encode measurements of either or both eyes.

The macular grid conveyed by this report is based upon the grid employed by the Early Treatment of Diabetic Retinopathy Study (ETDRS) to measure area and proximity of macular edema to the anatomic center (fovea) of the macula. See *ETDRS Report Number 10*.

TID 2100
Macular Grid Thickness and Volume Report
Type: Extensible

	NL	Rel with Parent	VT	Concept Name	VM	Req Type	Condition	Value Set Constraint
1			CONTAINER	EV (111690, DCM, “Macular Grid Thickness and Volume Report”)	1	M		
2	>	HAS CONCEPT MOD	INCLUDE	DTID (1204) Language of Content Item and Descendants	1	M		
3	>	HAS OBS CONTEXT	INCLUDE	DTID (1001) Observation Context	1	M		
4	>	CONTAINS	INCLUDE	TID (2101) Macular Grid Thickness and Volume Measurement	1	MC	IF Row 5 is absent.	$Laterality = EV (G-A100,SRT, “Right”)
5	>	CONTAINS	INCLUDE	TID (2101) Macular Grid Thickness and Volume Measurement	1	MC	IF Row 4 is absent.	$Laterality = EV (G-A101,SRT, “Left”)

TID 2101 Macular Grid Thickness and Volume Measurement

This Template encodes the macular grid thickness and volume measurements for a single eye.

Parameter Name	Parameter Usage
$Laterality	Which eye

TID 2101
Macular Grid Thickness and Volume Measurement
Type: Extensible

	NL	Rel with Parent	VT	Concept Name	VM	Req Type	Condition	Value Set Constraint
1			CONTAINER	EV (121070,DCM, “Findings”)	1	M		
2	>	HAS CONCEPT MOD	CODE	EV (G-C0E3, SRT, “Finding Site”)	1	M		EV (T-AA000, SRT, “Eye”)
3	>>	HAS CONCEPT MOD	CODE	EV (G-C171, SRT, “Laterality”)	1	M		$Laterality
4	>	CONTAINS	NUM	EV (57108-3, LN, “Macular Grid.Center Point Thickness”)	1	M		UNITS=EV(um, UCUM, “micrometer”)
5	>	CONTAINS	NUM	EV (57109-1, LN, “Macular Grid.Center Subfield Thickness”)	1	M		UNITS=EV(um, UCUM, “micrometer”)
6	>	CONTAINS	NUM	EV (57110-9, LN, “Macular Grid.Inner Superior Subfield Thickness”)	1	M		UNITS=EV(um, UCUM, “micrometer”)
7	>	CONTAINS	NUM	EV (57111-7, LN, “Macular Grid.Inner Nasal Subfield Thickness”)	1	M		UNITS=EV(um, UCUM, “micrometer”)
8	>	CONTAINS	NUM	EV (57112-5, LN, “Macular Grid.Inner Inferior Subfield Thickness”)	1	M		UNITS=EV(um, UCUM, “micrometer”)
9	>	CONTAINS	NUM	EV (57113-3, LN, “Macular Grid.Inner Temporal Subfield Thickness”)	1	M		UNITS=EV(um, UCUM, “micrometer”)
10	>	CONTAINS	NUM	EV (57114-1, LN, “Macular Grid.Outer Superior Subfield Thickness”)	1	M		UNITS=EV(um, UCUM, “micrometer”)
11	>	CONTAINS	NUM	EV (57115-8, LN, “Macular Grid.Outer Nasal Subfield Thickness”)	1	M		UNITS=EV(um, UCUM, “micrometer”)
12	>	CONTAINS	NUM	EV (57116-6, LN, “Macular Grid.Outer Inferior Subfield Thickness”)	1	M		UNITS=EV(um, UCUM, “micrometer”)
13	>	CONTAINS	NUM	EV (57117-4, LN, “Macular Grid.Outer Temporal Subfield Thickness”)	1	M		UNITS=EV(um, UCUM, “micrometer”)
14	>	CONTAINS	NUM	EV (57118-2, LN, “Macular Grid.Total Volume”)	1	M		UNITS=EV(mm3, UCUM, “mm3”)
15	>	CONTAINS	NUM	EV (111691, DCM, “Number of Images Used for Macular Measurements”)	1	M		UNITS = EV ({images}, UCUM, “images”)

16	>	CONTAINS	NUM	EV (111692, DCM, “Number of Samples Used per Image”)	1	M		UNITS = EV ({samples},UCUM, “samples”)
17	>	CONTAINS	NUM	EV (111693, DCM, “Analysis Quality Rating”)	1	M		UNITS = EV({0:100}, UCUM, “range:0:100”) Value = 0 – 100
18	>>	HAS OBS CONTEXT	INCLUDE	DTID (2102) Quality Rating Identification	1	M		
19	>	CONTAINS	NUM	EV (111694, DCM, “Image Set Quality Rating”)	1	M		UNITS = EV({0:100}, UCUM, “range:0:100”) Value = 0 – 100
20	>>	HAS OBS CONTEXT	INCLUDE	DTID (2102) Quality Rating Identification	1	M		
21	>	CONTAINS	NUM	EV (111029, DCM, “Image Quality Rating”)	1-n	U		UNITS = EV({0:100}, UCUM, “range:0:100”) Value = 0 – 100
22	>>	INFERRED FROM	IMAGE	No purpose of reference	1	M		
23	>>	HAS OBS CONTEXT	INCLUDE	DTID (2102) Quality Rating Identification	1	M		
24	>	CONTAINS	CODE	EV (111696, DCM, “Visual Fixation Quality During Acquisition”)	1	U		DCID (4220) Visual Fixation Quality During Acquisition
25	>>	HAS CONCEPT MOD	CODE	EV (111697, DCM, “Visual Fixation Quality Problem”)	1-n	U		DCID (4221) Visual Fixation Quality Problem
26	>	CONTAINS	CODE	EV (111698, DCM, “Ophthalmic Macular Grid Problem”)	1-n	U		DCID (4222) Ophthalmic Macular Grid Problem
27	>	CONTAINS	TEXT	EV (121106, DCM, “Comments”)	1	U		

TID 2102 Quality Rating Identification

This template specifies the algorithm (and parameters) used to create a quality rating for an image or image set.

It is expected that the identified algorithm will create a consistent quality rating when analyzing a given image. If the algorithm allows change to its parameters which would alter the quality rating created, the specific parameters used should be specified.

TID 2102
QUALITY RATING IDENTIFICATION
Type: Non-Extensible

	NL	Rel with Parent	VT	Concept Name	VM	Req Type	Condition	Value Set Constraint
1			TEXT	EV (111001, DCM, “Algorithm Name”)	1	M		
2			TEXT	EV (111003, DCM, “Algorithm Version”)	1	M		
3			TEXT	EV (122405, DCM, “Algorithm Manufacturer”)	1	M		
4			TEXT	EV (111002, DCM, “Algorithm Parameters”)	1-n	U		

Add the following to PS3.16 Annex C:

CID 4220 Visual Fixation Quality During Acquisition

Context ID 4220
Visual Fixation Quality During Acquisition

Type: Extensible **Version: 20090917**

Coding Scheme Designator (0008,0102)	Code Value (0008,0100)	Code Meaning (0008,0104)
SRT	G-A555	Steady
SRT	G-A556	Not Steady
SRT	G-A385	Indeterminate

CID 4221 Visual Fixation Quality Problem

Context ID 4221
Visual Fixation Quality Problem

Type: Extensible **Version: 20090917**

Coding Scheme Designator (0008,0102)	Code Value (0008,0100)	Code Meaning (0008,0104)
DCM	110518	Patient Movement
SRT	F-02FA4	Eccentric Fixation
DCM	110519	Operator Error
DCM	110501	Equipment failure

CID 4222 Ophthalmic Macular Grid Problem

Context ID 4222
Ophthalmic Macular Grid Problem

Type: Extensible **Version: 20090917**

Coding Scheme Designator (0008,0102)	Code Value (0008,0100)	Code Meaning (0008,0104)
Include CID 4221 Visual Fixation Quality Problem		
SRT	F-0123A	Constricted Pupil
SRT	DA-73402	Lens Opacity
SRT	DA-75300	Corneal Opacity
SRT	DA-7931D	Vitreous Opacity
SRT	R-20839	Poor Visual Fixation
SRT	DA-76000	Eyelid Disease

DCM	111695	Interfering Tears or Drops
SRT	DA-74100	Refractive Error
DCM	111209	Patient Positioning Problem
SRT	F-F1722	Dry Eyes Problem

210 **Add to PS3.16 – Add To Annex D DICOM Controlled Terminology Definitions (Normative)**

Code Value	Code Meaning	Definition	Notes
…			
110518	Patient Movement	A movement of the patient affecting test quality	
110519	Operator Error	An error of the operator affecting test quality	
…			
111690	Macular Grid Thickness and Volume Report	A macular grid thickness and volume report for a patient. The macular grid is an analytic tool described in PS3.17 Annex X.	
111691	Number of Images Used for Macular Measurements	Number of images used for the macular grid measurement.	
111692	Number of Samples Used per Image	Number of samples used per Image for analysis	
111693	Analysis Quality Rating	A numeric rating of the quality of the entire analysis with respect to grading and diagnostic purposes. Higher numbers indicate greater quality.	
111694	Image Set Quality Rating	A numeric rating of the quality of an entire image set with respect to grading and diagnostic purposes. Higher numbers indicate greater quality.	
111695	Interfering Tears or Drops	Tear film or drops affecting test quality	
111696	Visual Fixation Quality During Acquisition	The assessment of the centricity and persistence of the visual fixation (direction of gaze) during the acquisition	
111697	Visual Fixation Quality Problem	The reason why the patient's visual fixation was not steady or was indeterminate	
111698	Ophthalmic Macular Grid Problem	The reason why the macular grid measurements may be questionable	

Changes to NEMA Standards Publication PS 3.17-2008

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Part 17: Explanatory Information

Add to PS3.17 – Add Use Cases for Macular Grid Thickness and Volume Reports

Annex X Macular Grid Thickness and Volume Report Use Cases (Informative)

X.1 Introduction

Ophthalmologists use OPT data to diagnose and characterize tissues and abnormalities in transverse and axial locations within the eye. For example, an ophthalmologist might request an OPT of the macula, the optic nerve or the cornea in either or both eyes for a given patient. Serial reports can be compared to monitor disease progression and response to treatment. OPT devices produce two categories of clinical data: B-scan images and tissue measurements.

X.2 Use of B-scan Images

Prior to interpreting an OPT B-scan (or set of B-scans), users must first determine if the study is of adequate quality to answer the diagnostic question. Examples of inadequate studies include:

1. The pathology that needs to be visualized does not appear within the field of the scan
2. The image quality is not sufficient to see the tissue layers of interest (i.e. media opacity, blink, etc)
3. The scans are not in the expected anatomic order (i.e. due to eye movements)

In some cases, inadequate images can be corrected by capturing another scan in the same area. However, in other cases, the patient's eye disease interferes with visualization of the tissues of interest making adequate image quality impossible. Ideally, when choosing between multiple scans of the same tissue area, physicians would have access to information about the above questions so they can select only the best scan(s).

The physician may then choose to view and assess each B-scan in the dataset individually. When assessing OPT B-scans, ophthalmologists often identify normal or expected tissue boundaries first, then proceed to identify abnormal interfaces or structures next. The identification of pathology is both qualitative (i.e. does a structure exist) and quantitative (i.e. how thick is it). If previous scans are present for this patient, the physician may choose to compare the most recent scan data with prior visits. Due to workflow constraints, it may be difficult for B-scan interpretations to happen on the same machine that captures the images. Therefore, remote image assessment, such as image viewing in the examining room with the patient, is optimal.

X.3 Use of Tissue Measurements

In addition to viewing B-scan image data, clinicians also use quantitative measurements of tissue thicknesses or volumes extracted automatically from the OPT images. As with image quality, the accuracy of automated segmentation must be assessed prior to use of the numerical

measurements based on these boundaries. This is typically accomplished by visual inspection of boundary lines placed on the OPT images but also can be inferred from analysis confidence measurements provided by the device software. In addition to segmentation accuracy, it is also important to determine if the region of interest has been aligned appropriately with the intended sampling area of the OPT.

The analysis software application segments OPT images using the raw data of the instrument to quantify tissue optical reflectivity and location in longitudinal scan or B-scan images. Many boundaries can be identified automatically with software algorithms, see Figure x.3-1.

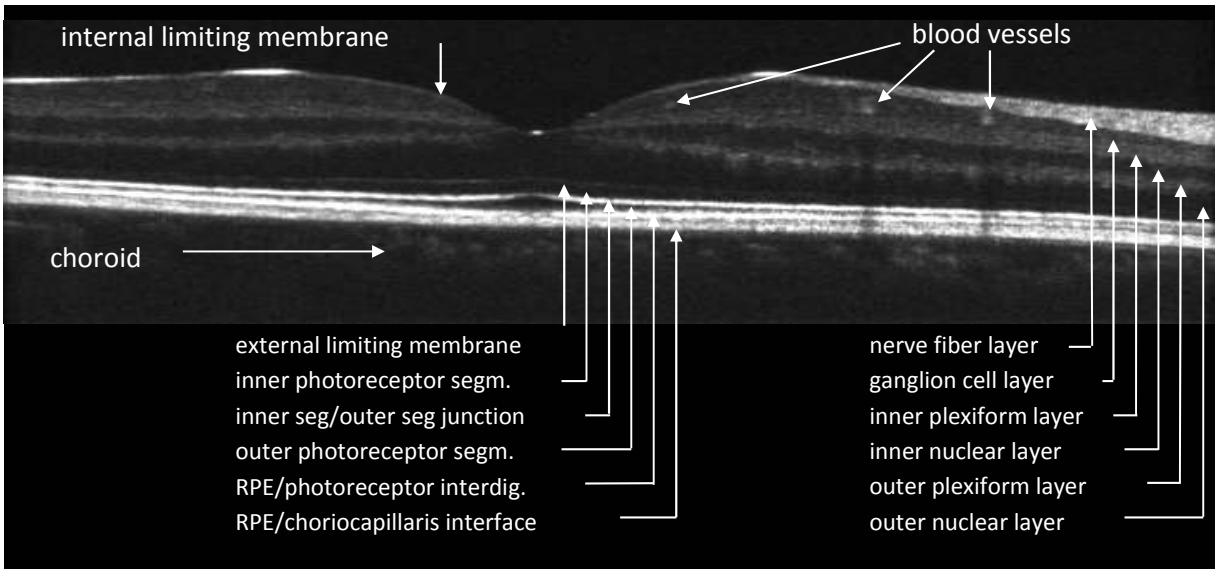

Figure X.3-1 OPT B-scan with Layers and Boundaries Identified

X.4 Axial Measurements

The innermost (anterior) layer of the retina, the internal limiting membrane (ILM) is often intensely hyperreflective and defines the innermost border of the nerve fiber layer. The nerve fiber layer (NFL) is bounded posteriorly by the ganglion cell layer and is not visible within the central foveal area. In high quality OPT scans, the sublamina of the inner plexiform layer may be identifiable. The external limiting membrane is the subtle interface between the outer nuclear layer and the photoreceptors. The junction between the photoreceptor inner segments and outer segments (IS/OS junction) is often intensely hyperreflective and in time domain OPT systems, was thought to represent the outermost boundary of the retina. Current thought, however, suggests that the photoreceptors extend up to the next bright interface, often referred to as the retinal pigment epithelium (RPE) interdigitation. This interface may be more than 35 micrometers beyond the IS/OS junction. When three high intensity lines are not present under the retina, however, this interdigitation area may not be visible. The next bright region typically represents the RPE cell bodies which consist of a single layer of cuboidal cells with reflective melanosomes oriented at the innermost portion of the cells. Below the RPE cells is a structure called Bruch's membrane which is contiguous with the outer RPE cell membrane.

The axial thickness and volume of tissue layers can be measured using the boundaries defined above. For example, the nerve fiber layer is typically measured from the innermost ILM interface to the interface of the NFL with the retina. Time domain OPT systems measure retinal thickness as the axial distance between the innermost ILM interface and the IS/OS junction. However, high resolution OPT systems now offer the potential to measure true retinal thickness (ILM to

outermost photoreceptor interface) in addition to variants that include tissue and fluid that may intervene between the retina and the RPE. The RPE layer is measured from the innermost portion of the RPE cells, which is the hyper reflective melanin-containing layer to the outermost highly reflective interface. Pathologic structures that may intervene between normal tissue layers may obscure their appearance but often can be measured using the same methods as normal anatomic layers.

X.5 En Face Measurements

The macular grid is based upon the grid employed by the Early Treatment of Diabetic Retinopathy Study (ETDRS) to measure area and proximity of macular edema to the anatomic center of the macula, also called the fovea. This grid was developed as an overlay for use with 32mm film color transparencies and fluorescein angiograms in the seminal trials of laser photocoagulation for the treatment of diabetic retinopathy. Subsequently, this grid has been in common use at reading centers since the 1970s, has been incorporated into ophthalmic camera digital software, and has been employed in grading other macular disease in addition to diabetic retinopathy. This grid was slightly modified for use in Time Domain OPT models developed in the 1990s and early 2000s in that the dimensions of the grid were sized to accommodate a 6 mm diameter sampling area of the macula.

The grid for macular OPT is bounded by circular area with a diameter of 6 mm. The center point of the grid is the center of the circle. The grid is divided into 9 standard subfields. The center subfield is a circle with a diameter of 1 mm. The grid is divided into 4 inner and 4 outer subfields by a circle concentric to the center with a diameter of 3 mm. The inner and outer subfields are each divided by 4 radial lines extending from the center circle to the outermost circle, at 45, 135, 225, and 315 degrees, transecting the 3 mm circle in four places. Each of the 4 inner and 4 outer subfields is labeled by its orientation with regard to position relative to the center of the macula – superior, nasal, inferior, and temporal. For instance, the superior inner subfield is the region bounded by the center circle and the 3 mm circle the 315 degree radial line, and the 45 degree radial line. The nasal subfields are those oriented toward the midline of the patient's face, nearest to the optic nerve head. The grids for the left and right eyes are reversed with respect to the positions of the nasal and temporal subfields – in viewing the grid for the left eye along the antero-posterior (Z) axis, the nasal subfields are on the left side and in the right eye the nasal subfields are on the right side (nasal as determined by the location of the subfield closest to the nose).

The OPT macula thickness report consists of the thickness at the center point of the grid, and the mean retinal thickness calculated for each of the 9 subfields of the grid. In the context of the macular disease considered for the diagnosis, and qualitative interpretation of morphology from examination and OPT and/or other modalities, the clinician uses the macula thickness report to determine if the center and the grid subfield averages fall outside the normative range. Monitoring of macular disease by serial grid measurements allows assessment of disease progression and response to intervention. Serial measurements are assessed by comparing OPT thickness or volume reports, provided that the grids are appropriately centered upon the same location in the macula for each visit.

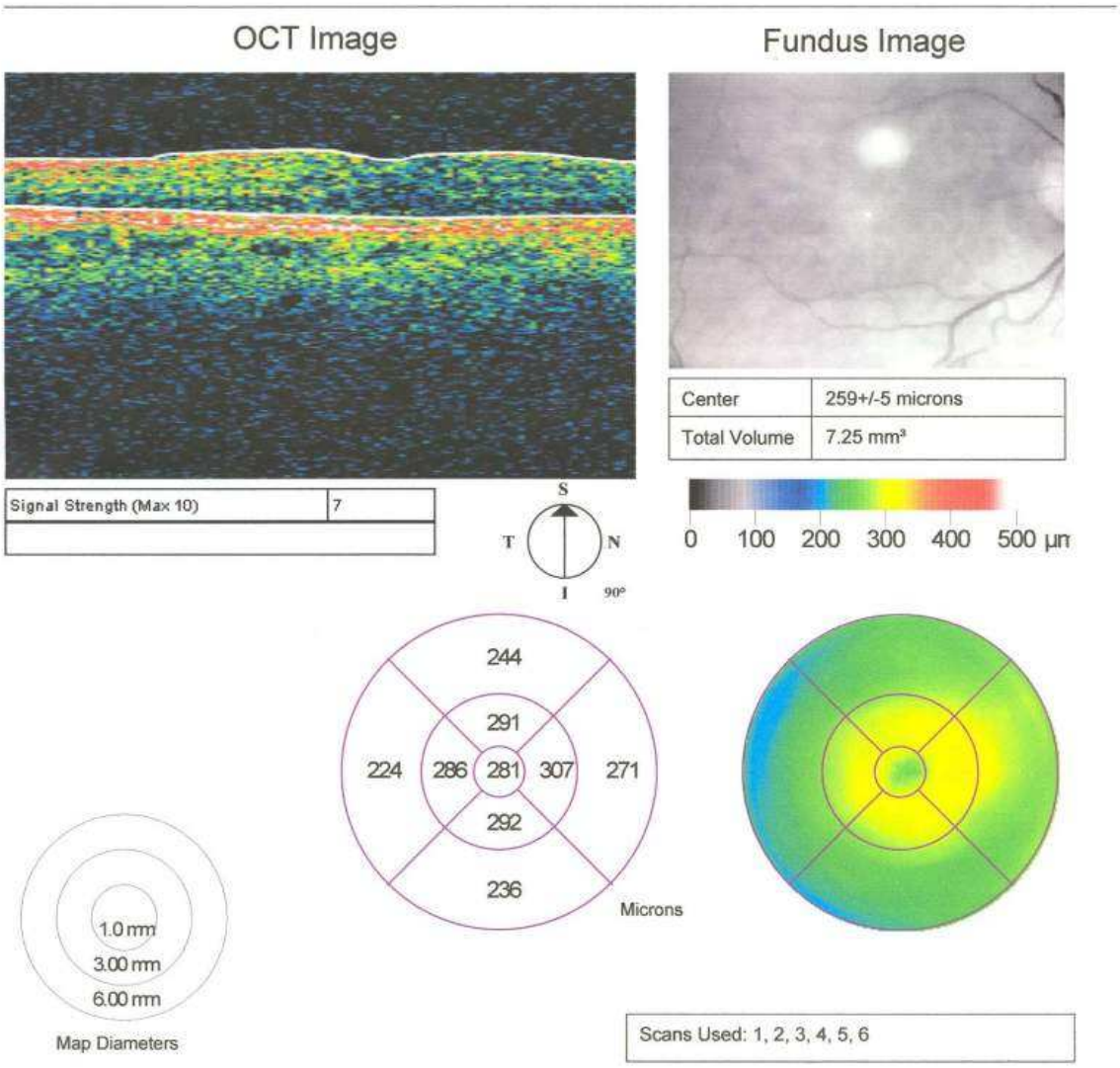

Figure X.5-1 Macular Grid Thickness Report Display Example

The center point of the grid should be aligned with the anatomic center of the macula, the fovea. This can be approximated by having the patient fixate upon a target coincident with the center of the grid. However, erroneous retinal thickness measurements are obtained when the center of the grid is not aligned with the center of the macula. This may occur in patients with low vision that cannot fixate upon the target, or in patients that blink or move fixation during the study. To determine the expected accuracy of intervisit comparisons, clinicians would benefit from knowing the alignment accuracy of the OPT data from the two visits. Ophthalmologists may also want to customize locations on the fundus to be monitored at each visit.

The following figure illustrates how the content items of the Macular Grid Thickness and Volume Report are related to the ETDRS Grid. Figure shown is not drawn to scale.

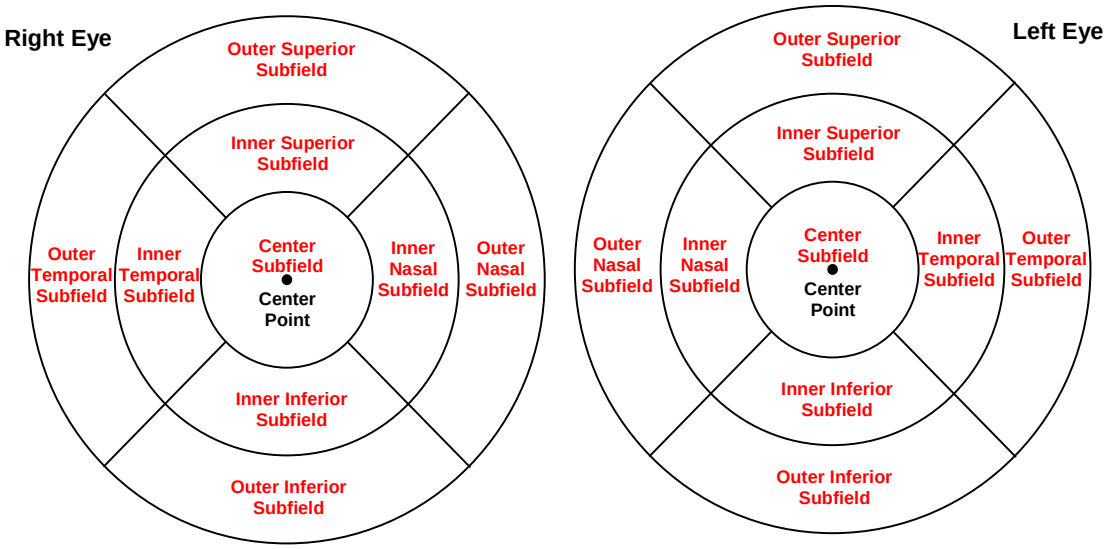

Figure X.5.2 – ETDRS GRID Layout

X.6 Interpretation of OPT

The process of evaluation of diabetic macular edema will help illustrate the role of the OPT macula thickness report. In diabetic macular edema there is a breakdown in the blood retina barrier which can lead to focal and/or diffuse edema (or thickening) of the macula. The report of the thickness of each subfield area of the macula grid will help direct treatment. For instance, laser treatment to a specific thickened quadrant would be expected to reduce the thickness of retina in the treated zone. Serial comparisons of OPT thicknesses should demonstrate a reduction in thickness in the successfully treated zone. A zone that subsequently became thicker on follow-up scans may warrant further treatment. In addition to an expected local response to specific zonal treatment such as laser, there are treatments with drugs and biologics which are less localized. For instance, the injection of intravitreal drugs in a successfully treated eye would be expected to have a global reduction of thickness in all zones with DME. Patients with severe retinal disease may lose the ability to fixate making the acquisition of OPT images to represent a specific zone less reliable.