

## DICOM Correction Proposal

STATUS	Final Text
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Correction Number	CP-1811
Log Summary: Key measurements in Encapsulated PDF	
Name of Standard	PS 3.3 2018e
<p>Rationale for Correction:</p> <p>Eye care device modalities generate pdf reports that clinicians store in a patient’s medical record, such as within an EMR and/or PACS. These pdf reports are commonly used in current eye care implementations (OCT optic disc, OCT RNFL, visual field reports, and more.). The encapsulated pdf report is used because EMR systems are not considered “medical 510K devices” and are not required to support FDA 510K guidelines. PDF is a common method displaying reports for information systems.</p> <p>Each modality also outputs important “key” numeric measurements that are critical for the long-term care of patients related to these pdf reports. These measurements are “displayed” in the pdf report but cannot be incorporated into an EMR database.</p> <p>Vendors have created ways to pass this information between eye care devices and EMRs using proprietary communications. WG9 wishes to use DICOM to accomplish this task as some clinics are turning off DICOM capabilities in favor of using the proprietary communications. As of result these clinics are losing features from DICOM MWL, etc. which introduces risk and patient safety.</p> <p>Another use case for key measurements is to communicate this information to eye care clinical registries, such as the AAO IRIS Registry. Which uses this data to assess population health data and regulatory compliance, etc.</p> <p>WG9 believes this need is not specific to eye care, therefore, proposes to include a generic mechanism to encode key measurements in the Encapsulate PDF SOP Class. The Content Sequence is chosen as it provides a flexible and extensible mechanism for including such measurements.</p>	
Correction Wording:	

### C.24.2 Encapsulated Document Module

Table C.24-2 defines the Encapsulated Document Attributes.

**Table C.24-2. Encapsulated Document Module Attributes**

Attribute Name	Tag	Type	Attribute Description
.....	....	....	.....
Document Title	(0042,0010)	2	The title of the document.

Attribute Name	Tag	Type	Attribute Description
			<p>Note</p> <p>In the case of a PDF encapsulated document, this may be the value of the "Title" entry in the "Document Information Directory" as encoded in the PDF data.</p>
Concept Name Code Sequence	(0040,A043)	2	<p>A coded representation of the document title.</p> <p>Zero or one Item shall be included in this Sequence.</p>
<i>&gt;Include Table 8.8-1 "Code Sequence Macro Attributes"</i>			<i>Baseline CID 7020 "Document Titles".</i>
Document Class Code Sequence	(0040,E008)	3	<p>Additional classifications of the document, beyond the title represented in Concept Name Code Sequence. Equivalent to HL7 v2.x TXA-2.</p> <p>One or more Items are permitted in this Sequence.</p>
<i>&gt;Include Table 8.8-1 "Code Sequence Macro Attributes"</i>			<i>No Baseline CID is defined.</i>
.....	.....	.....	.....
<b><u>Value Type</u></b>	<b><u>(0040,A040)</u></b>	<b><u>1C</u></b>	<p><b><u>The type of the value encoded in this Content Item.</u></b></p> <p><b><u>Enumerated Value:</u></b></p> <p><b><u>CONTAINER</u></b></p> <p><b><u>Required if Content Sequence (0040,A730) is present.</u></b></p>
<b><u>Content Sequence</u></b>	<b><u>(0040,A730)</u></b>	<b><u>3</u></b>	<p><b><u>A potentially recursively nested Sequence of Items that conveys structured content.</u></b></p> <p><b><u>One or more Items are permitted in this Sequence.</u></b></p> <p><b><u>See Section C.17.3.2.4 and C.24.2.2 for further explanation.</u></b></p>
<b><u>&gt;Relationship Type</u></b>	<b><u>(0040,A010)</u></b>	<b><u>1</u></b>	<p><b><u>The type of relationship between the (enclosing) Source Content Item and the Target Content Item.</u></b></p> <p><b><u>IODs specify additional constraints on Relationships (including lists of Enumerated Values).</u></b></p> <p><b><u>Enumerated Values:</u></b></p> <p><b><u>CONTAINS</u></b></p> <p><b><u>HAS OBS CONTEXT</u></b></p> <p><b><u>HAS ACQ CONTEXT</u></b></p> <p><b><u>HAS CONCEPT MOD</u></b></p> <p><b><u>See Section C.17.3.2.4 for further explanation.</u></b></p>
<b><u>&gt;Include Table C.17-6 "Document Relationship Macro Attributes"</u></b>			
<b><u>&gt;Include Table C.17-5 "Document Content Macro Attributes"</u></b>			
<b><u>Continuity of Content</u></b>	<b><u>(0040,A050)</u></b>	<b><u>1C</u></b>	<b><u>This flag specifies for a CONTAINER whether or not its</u></b>

Attribute Name	Tag	Type	Attribute Description
			<p><u>contained Content Items are logically linked in a continuous textual flow, or are separate Items.</u></p> <p><u>Enumerated Values:</u></p> <p><u>SEPARATE</u></p> <p><u>CONTINUOUS</u></p> <p><u>See Section C.18.8.1.1 for further explanation.</u></p> <p><u>Required if Content Sequence (0040,A730) is present.</u></p>
<u>Content Template Sequence</u>	<u>(0040,A504)</u>	<u>1C</u>	<p><u>Template that describes the content of this Content Item and its subsidiary Content Items.</u></p> <p><u>Only a single Item shall be included in this Sequence.</u></p> <p><u>Required if Content Sequence (0040,A730) is present and if a template defined and known to the implementation at the time of encoding was used to define the content of this Item, and the template consists of a single CONTAINER with nested content, and it is the outermost invocation of a set of nested templates that start with the same CONTAINER (see Section C.18.8.1.2).</u></p>
<u>&gt;Mapping Resource</u>	<u>(0008,0105)</u>	<u>1</u>	<p><u>Mapping Resource that defines the template. See Section 8.4.</u></p> <p><u>Defined Terms:</u></p> <p><u>DCMR DICOM Content Mapping Resource</u></p>
<u>&gt;Mapping Resource UID</u>	<u>(0008,0118)</u>	<u>3</u>	<p><u>Uniquely identifies the Mapping Resource that defines the template.</u></p> <p><u>Note; The unique identifier for the DICOM Content Mapping Resource "DCMR" is defined in PS3.6.</u></p>
<u>&gt;Template Identifier</u>	<u>(0040,DB00)</u>	<u>1</u>	<p><u>Template identifier.</u></p>

**C.24.2.2 Content Sequence**

Content Sequence (0040,A730) encodes structured content relevant to the Encapsulated Document (0042,0011). This allows structured data in DICOM encoded form to accompany or describe some or all of the contents of the otherwise opaque encapsulated document, and enables receiving implementations to extract that data, e.g., to tabulate numeric measurements, provide them as merge fields for dictation, or store them in a database.

Note: Some encapsulated document formats may themselves have some structured content, e.g., the non-narrative part of an HL7 CDA object, or the XMP metadata of a PDF object. This mechanism allows a DICOM-aware system to extract data without needing to parse or understand what is encapsulated.

There is no expectation that all of the narrative or visually rendered content in the encapsulated document be replicated in a structured form in the Content Sequence (0040,A730), nor is it expected that all of the information in the Content Sequence (0040,A730) be present in the encapsulated document. E.g., the structured content might contain codes describing the encapsulated document, or the encapsulated document may contain observations that are not replicated in the structured content.

The use of the Content Sequence (0040,A730) follows the pattern established for Structured Reports, and each Item of the Sequence in the top level data set is a Content Item (see Section C.17.3.2 Content Item Attributes).

Each Item of the Sequence in the top level data set may, for instance, be a numeric measurement content item (see Section C.18.1 Numeric Measurement Macro). E.g.:

- NUM (8821-1, LN, "Left Ventricular ED Volume") = 98 (mm3, UCUM, "mm3")
- NUM (8808-8, LN, "Left Ventricular Ejection Fraction by Angiography") = 65 (% , UCUM, "Percent")

Alternatively, nested content items may be used in the manner of a typical Structured Report, and an appropriate template from PS3.16 invoked (e.g., the TID 1500 Measurement Report template), in which case the Concept Name Code Sequence (0040,A043) serves as Document Title and the name of the top level CONTAINER content item of the Structured Report, and such Content Items as measurements are nested within containers, may be related to regions of interest, given tracking identifiers, etc.