

DICOM Correction Proposal

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Correction Number	CP-1811
Log Summary: Key measurements in Encapsulated PDF	
Name of Standard	PS 3.3
<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
			Note 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.
Concept Name Code Sequence	(0040,A043)	2	A coded representation of the document title. Zero or one Item shall be included in this Sequence.
>Include Table 8.8-1 "Code Sequence Macro Attributes"			Baseline CID 7020 "Document Titles".
Document Class Code Sequence	(0040,E008)	3	Additional classifications of the document, beyond the title represented in Concept Name Code Sequence. Equivalent to HL7 v2.x TXA-2. One or more Items are permitted in this Sequence.
>Include Table 8.8-1 "Code Sequence Macro Attributes"			No Baseline CID is defined.
.....
<u>Content Sequence</u>	<u>(0040,A730)</u>	<u>3</u>	<u>A potentially recursively nested Sequence of Items that conveys content that is the Target of Relationships with the enclosing Source Content Item.</u> <u>One or more Items are permitted in this Sequence.</u> <u>See Section C.17.3.2.4 and C.24.2.2 for further explanation.</u>

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.