

DICOM Correction Item

Correction Number CP-736	
Log Summary: TID 4023, CID 6048 updates	
Type of Modification	Name of Standard
Correction	PS 3.16-2006 + CP-624_ft
<p>Rationale for Correction:</p> <p>The Operating Points can be used to represent different Algorithm performance points without giving specific values for the X and Y coordinates of the operating points (e.g., Sensitivity and False Positive figures). Making the (X,Y) values mandatory takes away this flexibility.</p> <p>On the regulatory side, the FDA requires clinical trials to be done to support Sensitivity and False Positive figures. Other national regulatory bodies may or may not have similar regulations. If the Algorithm performance (X,Y) values are mandatory the manufacturers will be forced to do clinical trials if they want to include the Operating Point table.</p> <p>Propose to make rows 8 and 9 of TID 4023 User optional.</p> <p>Clarify definitions of specificity and false marker concepts.</p>	
<p>Sections of documents affected</p> <p>PS 3.16 TID 4023, CID 4068</p>	
<p>Correction Wording:</p> <p>See below.</p>	

Item 1: update TID 4023 as follows

TID 4023 CAD Operating Points

This template describes CAD operating points. The description is deliberately left flexible and optional to allow implementation at differing levels of complexity.

TID 4023
CAD OPERATING POINTS
Type: Non-Extensible

	NL	Rel with Parent	VT	Concept Name	VM	Req Type	Condition	Value Set Constraint
1		HAS PROPERTIES	NUM	(111072, DCM, "Maximum CAD Operating Point")	1	M		UNITS = DT ([arb'U], UCUM, "arbitrary unit") Value is restricted to being an integer
2		HAS PROPERTIES	NUM	(111092, DCM, "Recommended CAD Operating Point")	1	U		UNITS = DT ({0:n}, UCUM, "range: 0:n"), where n is the value specified in row 1 Value is restricted to being an integer
3		HAS PROPERTIES	CONTAINER	(111093, DCM, "CAD Operating Point Table")	1	U		
4	>	CONTAINS	CODE	(122698, DCM, "X-Concept")	1	M		DCID (6048) CAD Operating Point Axis Label
5	>	CONTAINS	CODE	(122699, DCM, "Y-Concept")	1	M		DCID (6048) CAD Operating Point Axis Label

	NL	Rel with Parent	VT	Concept Name	VM	Req Type	Condition	Value Set Constraint
6	>	CONTAINS	NUM	(111071, DCM, "CAD Operating Point")	1-n	M	Number of instances of this row shall equal value of row 1, plus 1.	UNITS = DT ((0:n), UCUM, "range: 0:n"), where n is the value of Row 1. Value is restricted to being an integer that is unique within the invocation of this template.
7	>>	HAS PROPERTIES	TEXT	(111081, DCM, "CAD Operating Point Description")	1	U		
8	>>	HAS PROPERTIES	NUM	The value of Row 4	1	<u>MU</u>		
9	>>	HAS PROPERTIES	NUM	The value of Row 5	1	<u>MU</u>		

Item 2: correct CID 6048 as follows

CID 6048 CAD Operating Point Axis Label

Context ID 6048

CAD Operating Point Axis Label

Type: Extensible

Version: 20060612

Coding Scheme Designator (0008,0102)	Code Value (0008,0100)	Code Meaning (0008,0104)
DCM	1110 23 <u>12</u>	Certainty of Finding
DCM	111047	Probability of cancer
DCM	111086	False Markers per Image
DCM	111087	False Markers per Case
DCM	111088	Case Sensitivity
DCM	111089	Lesion Sensitivity
DCM	111090	Case Specificity
DCM	111091	Image Specificity

Update PS 3.16, Annex D

Code Value	Code Meaning	Definition	Notes
111086	False Markers per Image	The number of false CAD markers per image. <u>Correlates to inverse of Image Specificity.</u>	
111087	False Markers per Case	The number of false markers per collection of images that are CAD processed as a group. <u>Correlates</u>	

		<u>to inverse of Case Specificity.</u>	
111090	Case Specificity	The percentage of cases (collections of images CAD processed as a group) without cancer that have no CAD findings whatsoever. <u>Correlates to inverse of False Markers per Case.</u>	
111091	Image Specificity	The percentage of images without cancer that have no CAD findings whatsoever. <u>Correlates to inverse of False Markers per Image.</u>	