

1	Status	Letter Ballot
2	Date of Last Update	2019/02/23
3	Person Assigned	David Clunie
4		mailto:dclunie@dclunie.com
5	Submitter Name	David Clunie
6		mailto:dclunie@dclunie.com
7	Submission Date	2018/09/20

8	Correction Number CP-1856	
9	Log Summary: Unique device identification consistency and de-identification	
10	Name of Standard	
11	PS3.3, PS3.15, PS3.16 + CP 1860	
12	Rationale for Correction:	
13	CP 1418 added the regulatory UDI to PS3.3 but not to the PS3.16 device observer template.	
14	It failed to include the UDI in the PS3.15 de-identification profile.	
15	The PS3.16 device observer template includes a required device UID, and it would be useful to have this accessible in non-SR	
16	objects (e.g., the images accompanying an RDSR), so add the Device UID Attribute from the Identified Person or Device Macro to	
17	the General Equipment Module.	
18	The new content items should be added to the CP 1860 Clean Structured Content table.	
19	The LOINC code for UDI is used in PS3.16 (UMLS C3833472; there is also an NCIt code C112279).	
20	Correction Wording:	

Amend DICOM PS3.3 as follows (changes to existing text are bold and underlined for additions and ~~struckthrough~~ for removals):

10.29 UDI Macro

This Macro records details associated with a Unique Device Identifier (UDI).

Table 10.29-1. UDI Macro Attributes

Attribute Name	Tag	Type	Attribute Description
Unique Device Identifier	(0018,1009)	1	The entire Human Readable Form of the UDI as defined by the Issuing Agency. See Section 10.29.1.
Device Description	(0050,0020)	3	Further description in free form text describing the device. This can be used to distinguish between Items when multiple UDIs are recorded in a Sequence.

10.29.1 Unique Device Identifier

The UDI is a combination of the Device Identifier and the Production Identifier.

The format of the string is defined by a corresponding Issuing Agency, such as:

- GS1 - <http://www.gs1.org>
- HIBCC - <http://www.hibcc.org>
- ICCBBA - <http://www.iccbba.org>

Details for encoding a valid device identifier are managed by the Issuing Agency. For full documentation, refer to issuer materials.

The United States FDA requires the Issuing Agency to use only characters and numbers from the invariant character set of ISO/IEC 646 (ISO 7-bit coded character set also known as ISO IR 6). DICOM puts no constraints on the length of the string or the character sets beyond the UT Value Representation. Implementations should be prepared to handle very large strings and unusual characters.

C.7.5.1 General Equipment Module

Table C.7-8. General Equipment Module Attributes

Attribute Name	Tag	Type	Attribute Description
Manufacturer	(0008,0070)	2	Manufacturer of the equipment that produced the Composite Instances.
Institution Name	(0008,0080)	3	Institution where the equipment that produced the Composite Instances is located.
Institution Address	(0008,0081)	3	Mailing address of the institution where the equipment that produced the Composite Instances is located.
Station Name	(0008,1010)	3	User defined name identifying the machine that produced the Composite Instances.
Institutional Department Name	(0008,1040)	3	Department in the institution where the equipment that produced the Composite Instances is located.
Manufacturer's Model Name	(0008,1090)	3	Manufacturer's model name of the equipment that produced the Composite Instances.

Attribute Name	Tag	Type	Attribute Description
Device Serial Number	(0018,1000)	3	<p>Manufacturer's serial number of the equipment that produced the Composite Instances.</p> <p>Note</p> <p>This identifier corresponds to the device that actually created the images, such as a CR plate reader or a CT console, and may not be sufficient to identify all of the equipment in the imaging chain, such as the generator or gantry or plate.</p>
Software Versions	(0018,1020)	3	<p>Manufacturer's designation of software version of the equipment that produced the Composite Instances. See ???.</p>
Gantry ID	(0018,1008)	3	<p>Identifier of the gantry or positioner.</p>
UDI Sequence	(0018,100A)	3	<p>Unique Device Identifiers (UDIs) of the entire equipment. For example, the entire CT Scanner.</p> <p>Note</p> <ol style="list-style-type: none"> Multiple Items may be present if the entire equipment has UDIs issued by different Issuing Authorities. Multiple Items may be present if multiple pieces of equipment were involved in the creation of this instance, e.g., the DR plate and the DR reader. This is not intended to contain the UDIs of the components of the equipment, such as the X-Ray tube of the CT scanner. Such information is stored elsewhere and accessible using the UDI of the entire equipment and a date. <p>One or more Items are permitted in this Sequence.</p>
<i>>Include Table 10.29-1 "UDI Macro Attributes"</i>			
<u>Device UID</u>	<u>(0018,1002)</u>	<u>3</u>	<p><u>Unique identifier of the device identified.</u></p> <p>Note</p> <p><u>If present in an SR object, the value is expected to be the same as the (121012, DCM, "Device Observer UID") in TID 1004 Device Observer Identifying Attributes.</u></p>
Spatial Resolution	(0018,1050)	3	<p>The inherent limiting resolution in mm of the acquisition equipment for high contrast objects for the data gathering and reconstruction technique chosen. If variable across the images of the Series, the value at the image center.</p>
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Amend DICOM PS3.15 as follows (changes to existing text are bold and underlined for additions and ~~struckthrough~~ for removals):

E.1.1 De-identifier

Table E.1-1. Application Level Confidentiality Profile Attributes

Attribute Name	Tag	Retd. (from ????)	In Std. Comp. IOD (from ????)	Basic Prof.	Rtn. Safe Priv. Opt.	Rtn. UIDs Opt.	Rtn. Dev. Id. Opt.	Rtn. Inst. Id. Opt.	Rtn. Pat. Chars. Opt.	Rtn. Long. Full Dates Opt.	Rtn. Long. Modif. Dates Opt.	Clean Desc. Opt.	Clean Struct. Cont. Opt.	Clean Graph. Opt.
Device Description	(0050.0020)	N	Y	X			K							
Device Serial Number	(0018,1000)	N	Y	X/Z/D			K							
Device UID	(0018,1002)	N	Y	U		K	K							
UDI Sequence	(0018.100A)	N	Y	X			K							
Unique Device Identifier	(0018.1009)	N	Y	X			K							

Table E.3.4-1. Application Level Confidentiality Profile Clean Structured Content Option Content Item Concept Name Codes

Code Meaning	Code Value	Coding Scheme Designator	Value Type	Retd. (from ????)	In Std. Tpl. (from ????)	Basic Prof.	Rtn. UIDs Opt.	Rtn. Dev. Id. Opt.	Rtn. Inst. Id. Opt.	Rtn. Pat. Chars. Opt.	Rtn. Long. Full Dates Opt.	Rtn. Long. Modif. Dates Opt.	Clean Desc. Opt.
Device Description	ddd003	DCM	TEXT	N	Y	X		K					
Device Name	113877	DCM	TEXT	N	Y	X		K					
Device Observer Name	121013	DCM	TEXT	N	Y	X		K					
Device Observer Physical Location During Observation	121017	DCM	TEXT	N	Y	X			K				
Device Observer Serial Number	121016	DCM	TEXT	N	Y	X		K					
Device Observer UID	121012	DCM	UIDREF	N	Y	X/D	K	K					
Device Serial Number	113880	DCM	TEXT	N	Y	X/D		K					
Device Subject Name	121193	DCM	TEXT	N	Y	D		K					
Device Subject Physical Location during observation	121197	DCM	TEXT	N	Y	X			K				
Device Subject Serial Number	121196	DCM	TEXT	N	Y	X		K					
Device Subject UID	121198	DCM	UIDREF	N	Y	X	K	K					
Station AE Title	110119	DCM	TEXT	N	Y	X		K					

Code Meaning	Code Value	Coding Scheme Designator	Value Type	Retd. (from ????)	In Std. Tpl. (from ????)	Basic Prof.	Rtn. UIDs Opt.	Rtn. Dev. Id. Opt.	Rtn. Inst. Id. Opt.	Rtn. Pat. Chars. Opt.	Rtn. Long. Full Dates Opt.	Rtn. Long. Modif. Dates Opt.	Clean Desc. Opt.
<u>Unique Device Identifier</u>	<u>74711-3</u>	<u>LN</u>	<u>TEXT</u>	<u>N</u>	<u>Y</u>	<u>X</u>		<u>K</u>					
<u>Unique Device Identifiers</u>	<u>ddd001</u>	<u>DCM</u>	<u>CONTAINER</u>	<u>N</u>	<u>Y</u>	<u>X</u>		<u>K</u>					

Amend DICOM PS3.16 as follows (changes to existing text are bold and underlined for additions and ~~struckthrough~~ for removals):

TID 1004 Device Observer Identifying Attributes

This Template (derived from the DICOM General Equipment Module of ????) contains identifying (and optionally descriptive) attributes of devices that are observers.

Type: Extensible
 Order: Significant
 Root: No

Table TID 1004. Device Observer Identifying Attributes

	NL	Rel with Parent	VT	Concept Name	VM	Req Type	Condition	Value Set Constraint
1			UIDREF	EV (121012, DCM, "Device Observer UID")	1	M		<u>Defaults to value of Device UID (0008,1002) in General Equipment Module</u>
2			TEXT	EV (121013, DCM, "Device Observer Name")	1	U		Defaults to value of Station Name (0008,1010) in General Equipment Module
3			TEXT	EV (121014, DCM, "Device Observer Manufacturer")	1	U		Defaults to value of Manufacturer (0008,0070) in General Equipment Module
4			TEXT	EV (121015, DCM, "Device Observer Model Name")	1	U		Defaults to value of Manufacturer's Model Name (0008,1090) in General Equipment Module
5			TEXT	EV (121016, DCM, "Device Observer Serial Number")	1	U		Defaults to value of Device Serial Number (0018,1000) in General Equipment Module
6			TEXT	EV (121017, DCM, "Device Observer Physical Location During Observation")	1	U		
7			CODE	EV (113876, DCM, "Device Role in Procedure")	1-n	U		BCID 7445
8			TEXT	EV (110119, DCM, "Station AE Title")	1	U		
<u>9</u>			<u>CONTAINER</u>	<u>EV (ddd001, DCM, "Unique Device Identifiers")</u>	<u>1-n</u>	<u>U</u>		<u>Defaults to value of UDI Sequence (0018,100A) in General Equipment Module</u>
<u>10</u>	<u>≥</u>	<u>CONTAINS</u>	<u>TEXT</u>	<u>EV (74711-3, LN, "Unique Device Identifier")</u>	<u>1</u>	<u>M</u>		

	NL	Rel with Parent	VT	Concept Name	VM	Req Type	Condition	Value Set Constraint
11	≥	CONTAINS	TEXT	EV (ddd003.DCM, "Device Description")	1	U		

Content Item Descriptions

Row 7	If the device performing the observations has other roles, e.g., as the irradiating device in a dose report, this may be recorded here, if not implicit.
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D DICOM Controlled Terminology Definitions (Normative)

Table D-1. DICOM Controlled Terminology Definitions (Coding Scheme Designator "DCM" Coding Scheme Version "01")

Code Value	Code Meaning	Definition	Notes
<u>ddd001</u>	<u>Unique Device Identifiers</u>	<u>Unique Device Identifiers (UDIs) of the entire equipment.</u>	
<u>ddd003</u>	<u>Device Description</u>	<u>Description in free form text describing the device. This can be used to distinguish between multiple UDIs.</u>	