DICOM Correction Proposal Form

Tracking Information - Administration Use Only	
Correction Proposal Number	CP-1418
STATUS	Final Text
Date of Last Update	2016/09/08
Person Assigned	Kevin O'Donnell
Submitter Name	Kevin O'Donnell
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Correction Number CP-1418	
Log Summary: Add UDI (Universal Device ID) to objects	
Type of Modification: Addition	Name of Standard: PS3.3, PS3.6 2016c

Rationale for Correction:

FDA has released the final rule for the Universal Device Identifier (UDI) for medical devices. Other national regulators (especially those in IMDRF) are also moving towards requiring the use of UDIs.

UDI is a unique identifier for a specific device. The scope includes all implantable, life-saving or life-sustaining devices.

DICOM should facilitate recording the UDI of relevant devices associated with images, just as we facilitate recording make/model/serial.

UDI number is a combination of two numbers (UDI = DI + PI):

- A device id (DI) which is unique to the manufacturer, make & model
- A production id (PI) which is the serial #, or lot #, or manufacturing date, or expiration date depending on the type of device

Each DI is issued by an FDA accredited Issuing Agency. The Issuing Agency may choose a format for their DI's as long as the resulting UDI uses only characters and numbers from the invariant character set of ISO/IEC 646 (ISO 7-bit coded character set aka ISO IR 6) and complies with

- ISO/IEC 15459-2 – IT Unique identifiers – Part 2: Registration procedures;
- ISO/IEC 15459-4:2008 – IT Unique identifiers - Part 4: Individual items;
- ISO/IEC 15459-6:2007 – IT Unique identifiers - Part 6: Unique identifier for product groupings;

FDA guidance for medical software is a different major revision of a software package (e.g. V7.0 vs V6.0) should have a different DI; while a different minor revision (e.g. V7.0.1 vs V7.0.2) can have the same DI but should have a different PI. Software displays the UDI as text whenever the software is started, or through a menu command (e.g., an ''About . . .'' command).

The Global Unique Device Identification Database (GUDID) is a publicly searchable database administered by the FDA for cataloging UDIs of any type of device. The GUDID contains the DI (not PI) and the corresponding details like the Manufacturer, Make, Model, Trade Name, 510k Status, etc. The GUDID is not a recall/adverse event database, just an index. Other countries are moving towards similar databases.

FDA Final Rule: http://www.gpo.gov/fdsys/pkg/FR-2013-09-24/pdf/2013-23059.pdf

Correction Wording:

Add UDI Definition to PS3.3

2.6 Other References

[FDA UDI] U.S. Food and Drug Administration, 2016, Version 1.2, UDI formats by FDA-Accredited Issuing Agency,
http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/UDIIssuingAgencies/UCM489869.pdf

Add UDI Definition to new section in PS3.3

3.20 Device Identification Definitions

Unique Device Identifier (UDI):
an alphanumeric identifier issued by the unique device identification system established by the FDA to label and identify devices through distribution and use. See www.fda.gov/udi.

Add UDI acronym to PS3.3

4 Symbols and Abbreviations

…
TLHC Top Left Hand Corner
UDI Unique Device Identifier
UID Unique Identifier
UUID Universal Unique Identifier (ISO/IEC 11578)
…

Add 10.29 for UDI Macro to PS3.3

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 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.

Modify the General Equipment Module as shown:

C.7.5.1 General Equipment Module

Table C.7-8 specifies the Attributes that identify and describe the piece of equipment that produced a Series of Composite Instances.

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.
Device Serial Number	(0018,1000)	3	Manufacturer's serial number of the equipment that produced the composite instances. Note 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.
Software Versions	(0018,1020)	3	Manufacturer's designation of software version of the equipment that produced the composite instances. See Section C.7.5.1.1.3.

Attribute Name	Tag	Type	Attribute Description
Gantry ID	(0018,1008)	3	Identifier of the gantry or positioner.
UDI Sequence	**(0018,100A)**	**3**	**Unique Device Identifier (UDI) of the entire equipment. For example, the entire CT Scanner.** **Notes: 1) Multiple items may be present if the entire equipment has UDIs issued by different Issuing Authorities** **2) 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.** **3) 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.** **One or more Items are permitted in this Sequence.**
>Include Table 10.29-1 "UDI Macro"			
Spatial Resolution	(0018,1050)	3	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.
…			

In PS 3.6, Section 6, add the following new attributes:

(0018,1009)	**Unique Device Identifier**	**UniqueDeviceIdentifier**	**UT**	**1**
(0018,100A)	**UDI Sequence**	**UDISequence**	**SQ**	**1**