The Office of the National Coordinator for Health Information Technology

2015 Edition §170.315(a)(14) Implantable Device List

Testing Components: Health IT developer self-declaration to the testing outcomes

Test Procedure Version 1.3 – Last Updated 09/21/17

Please consult the Final Rule entitled: *2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications* for a detailed description of the certification criterion with which these testing steps are associated. We also encourage developers to consult the Certification Companion Guide in tandem with the test procedure as they provide clarifications that may be useful for product development and testing.

Note: The order in which the test steps are listed reflects the sequence of the certification criterion and does not necessarily prescribe the order in which the test should take place.

Required Tests

(a)(14) *Implantable device list.*

(i) Record Unique Device Identifiers associated with a patient's Implantable Devices.

Standard(s): None

Criteria ¶	System Under Test	Test Lab Verification
(i)	The user records the unique device identifiers for a patient's implantable device in all formats established by the 3 UDI Issuing Agencies.	The tester verifies the unique device identifiers are recorded for a patient's implantable device in all formats established by the 3 UDI Issuing Agencies.

(ii) Parse the following identifiers from a Unique Device Identifier (UDI):

(A) Device Identifier; and

(B) The following identifiers that compose the Production Identifier:

(1) The lot or batch within which a device was manufactured;

(2) The serial number of a specific device;

(3) The expiration date of a specific device;

(4) The date a specific device was manufactured; and

(5) For an HCT/P regulated as a device, the distinct identification code required by 21 CFR 1271.290(c).

Standard(s): None

Criteria ¶	System Under Test	Test Lab Verification
(ii)(A)	The Health IT Module parses the Device Identifier from each UDI in all formats established by the 3 UDI Issuing Agencies.	The tester verifies that the Health IT Module parses the Device Identifier from the UDI and records as easily readable plain-text in all formats established by the 3 UDI Issuing Agencies.
(ii)(B)	The Health IT Module parses the following identifiers from each UDI in all formats established by the 3 UDI Issuing Agencies: *(1)* The lot or batch within which a device was manufactured; *(2)* The serial number of a specific device; *(3)* The expiration date of a specific device; *(4)* The date a specific device was manufactured; and *(5)* For an HCT/P regulated as a device, the distinct identification code required by 21 CFR 1271.290(c).	The tester verifies that the Health IT Module parses the production identifiers from the UDI that includes the items listed in 1-5 and records as easily readable plain-text in all formats established by the 3 UDI Issuing Agencies.

(iii) Obtain and associate with each Unique Device Identifier:

(A) A description of the implantable device referenced by at least one of the following:
- *(1)* The "GMDN PT Name" attribute associated with the Device Identifier in the Global Unique Device Identification Database.
- *(2)* The "SNOMED CT Description" mapped to the attribute referenced in paragraph (a)(14)(iii)(A)(*1*) of this section.

(B) The following Global Unique Device Identification Database attributes:
- *(1)* "Brand Name";
- *(2)* "Version or Model";
- *(3)* "Company Name";
- *(4)* "What MRI safety information does the labeling contain?"; and
- *(5)* "Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437)."

Standard(s): Global Medical Device Nomenclature (GMDN) – www.gmdnagency.org
International Health Terminology Standards Development Organization (IHTSDO) SNOMED CT® International Release July 2012 and US Extension to SNOMED CT® March 2012 Release

Criteria ¶	System Under Test	Test Lab Verification
(iii)(A)	The Health IT Module obtains and associates with each UDI in all formats established by the 3 UDI Issuing Agencies the description of the implantable device as one of the following: *(1)* The "GMDN PT Name" attribute associated with the Device Identifier in the Global Unique Device Identification Database; or *(2)* The "SNOMED CT Description" mapped to the attribute in the "GMDN PT Name" section (a)(14)(iii)(A)(*1*).	The tester verifies the description is obtained and associated with each UDI in all formats established by the 3 UDI Issuing Agencies as either "GMDN PT Name" attribute or "SNOMED CT Description" mapped to the "GMDN PT Name." Optionally the testers can use the Implant API at https://accessgudid.nlm.nih.gov/resources/developers/implant_list_api "GMDN PT Name" attribute: The GUDID contains this attribute. See the Download section of https://accessgudid.nlm.nih.gov/download for the various methods of downloading this and other GUDID attributes. "SNOMED CT Description:" The GUDID does not contain this attribute. This attribute requires access to the Unified Medical Language Service (UMLS) and is only available using the Implant API at https://accessgudid.nlm.nih.gov/resources/developers/implant_list_api.
(iii)(B)	The Health IT Module is able to obtain and associate the following Global Unique Device Identification Database attributes: *(1)* "Brand Name"; *(2)* "Version or Model Number"; *(3)* "Company Name"; *(4)* "What MRI safety information does the labeling contain?"; and *(5)* "Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437)."	The tester verifies the Health IT Module obtains and associates the Global Unique Device Identification Database attributes 1-5.

(iv) Display to a user an implantable device list consisting of:

(A) The active Unique Device Identifiers recorded for a patient;

(B) For each active Unique Device Identifier recorded for a patient, the description of the implantable device specified by paragraph (a)(14)(iii)(A) of this section; and

(C) A method to access all Unique Device Identifiers recorded for a patient.

Standard(s): None

Criteria ¶	System Under Test	Test Lab Verification
(iv)	The user is provided an implantable device list that consists of the following: (A) The active UDIs recorded for a patient; (B) For each active UDI, the description of the implantable device specified by section (a)(14)(iii)(A); and (C) A method to access all Unique Device Identifiers recorded for a patient.	The tester verifies the user is provided an implantable device list consisting of the active UDI(s) recorded for a patient, the description of the implantable device specified by section (a)(14)(iii)(A) and method to access all Unique Device Identifiers recorded for a patient .

(v) For each Unique Device Identifier recorded for a patient, enable a user to access:

(A) The Unique Device Identifier;
(B) The description of the implantable device specified by paragraph (a)(14)(iii)(A) of this section;
(C) The identifiers associated with the Unique Device Identifier, as specified by paragraph (a)(14)(ii) of this section; and
(D) The attributes associated with the Unique Device Identifier, as specified by paragraph (a)(14)(iii)(B) of this section.

Standard(s): None

Criteria ¶	System Under Test	Test Lab Verification
(v)	For each UDI recorded for the patient, the user has access to: (A) The Unique Device Identifier; (B) The description of the implantable device specified by section (a)(14)(iii)(A); (C) The identifiers associated with the Unique Device Identifier specified by section (a)(14)(ii). (D) The attributes associated with the Unique Device Identifier specified in section (a)(14)(iii)(B).	The tester verifies the user has access to all the items listed in A-D for active and inactive UDI.

(vi) Enable a user to change the status of a Unique Device Identifier recorded for a patient.

Standard(s): None

Criteria ¶	System Under Test	Test Lab Verification
(vi)	The user is able to change the status of the Unique Device Identifier recorded for a patient.	The tester verifies the status of the Unique Device Identifier for a patient is changed.

Document History

Version Number	Description of Change	Date
1.0	Final Test Procedure	January 08, 2016
1.1	Removed active UDI from step (iv)	March 08, 2016
1.2	Updated (ii)A, (ii)B, and (iii)A to clarify in all formats established by the 3 UDI Issuing Agencies. Update (iv)(A) to UDIs, plural	April 08, 2016
1.3	As of September 21, 2017, Test Procedure has been moved to Attestation/Developer self-declaration only	September 21, 2017

Dependencies: For all related and required criteria, please refer to the Master Table of Related and Required Criteria.