# Test Criteria: 170.315.a.14 – Implantable Device List

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| --- | --- |
| **Testing Result** |  |
| Participant and Product-with-version |  |
| Setting (Ambulatory or Inpatient) |  |
| Test Proctor |  |
| Test Date |  |
| Test Result | Pass:  Fail:  No Attempt: |
| Error Description (if applicable) |  |
| Modifications to Product Under Test |  |
| Additional Software Used |  |
| Additional Proctor Notes |  |

### Overview

In this document you will find:

* [Test Data and Test Tools](#_Test_Data_and)
* [Standards Support](#_Demonstrate_Standards_Support)
* [Drummond Test Report (Instructions, Expected Results, Points to Remember)](#_170.315(a)(14)_–_Implantable)
* [Test Procedures](#_1.1_Record_Unique)
* [Appendix A: Testing Guide](#_Appendix_A:_Testing)
* [Appendix B: ONC Criteria](#_Appendix_B:_ONC)

### Version of ONC Test Method

1.2

### Scope of Proctoring Sheet

The ONC test method associated with this criterion is the only approved test method for EHR Meaningful Use certification. This Proctoring Sheet is not a replacement test method but a test procedure document for performing the ONC test method and recording the results. Proctoring Sheet describe test data, test criteria and expected results. It is assumed the Health IT Developer or Participant under Test is familiar with the associated ONC test method.

# Robustness and Reliability Requirement

To satisfy the module criteria, it is expected that the Product-Under-Test is able to complete the testing requirements reliably, including repeat testing with the same result without error, and with a satisfactory level of robustness. This includes unexpected error messages produced through normal operation, multiple unintended restarts of the application or any other “buggy” facets of the product displayed while testing. These errors are record in the Additional Proctor Notes of the proctor sheet. Lack of reliability and robustness of design will result in failure of the module.

# Test Data and Tools

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| **Test Data Source:** | ONC-Supplied  DG-Supplied:  Developer-Supplied: |
| **Pre-Test Data Setup:**  Health IT developer should:   * Prepare at least one patient for recording implantable device data. * Prepare at least one inactive UDI to demonstrate for patient. * Obtain Unique Device Identifier (UDI) content from FDA’s [AccessGUDID](http://accessgudid.nlm.nih.gov/) database. | |
| **Test Data:**  Developer may elect to use the DG-supplied UDI numbers specified in test procedure below or may choose to supply their own UDI numbers. If developer-supplied, please notify the Test Proctor prior to test event. | |
| **Test Tools:**  Not applicable. | |

# Demonstrate Standards Support

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| **Test Result:** | PASS:  FAIL:  No Attempt: |
| **Instructions:** Implement standards to demonstrate recording of Implantable Device List. SNOMED CT is optional and based on implementation. For additional references, click [here](https://www.healthit.gov/policy-researchers-implementers/meaningful-use-stage-2-0/standards-hub) for the ONC Standards Hub. | |

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|  | **Standard** |  |
|  | Global Medical Device Nomenclature (GMDN) | International Health Terminology Standards Development Organization |
|  | §170.207(a)(3) | (IHTSDO) SNOMED CT® International Release July 2012 and US Extension to SNOMED CT® March 2012 Release |

# 170.315(a)(14) – Implantable Device List

|  |  |
| --- | --- |
| **Test Result:** | PASS:  FAIL:  No Attempt: |
| **Instructions:** Record, parse, and access unique device identifier (UDI) attributes obtained from AccessGUDID. Enable users to change the status of the UDI. | |
| **Expected Test Result:**  Health IT module must:   * Record unique device identifiers (UDI) in formats established by all three UDI issue agencies identified below. * Parse elements identifiers from the UDI * Record device identifier parsed from UDI * Obtain and associate the implantable device description with each UDI * Obtain and associate global unique device identification database attributes with each UDI * Display implantable device list to user containing specific identifiers and attributes * Enable user to access UDI for patient * Enable user to change UDI for patient | |
| **Points to Remember:**   * [AccessGUDID](http://accessgudid.nlm.nih.gov/) – Global Unique Device Identification Database (GUDID) contains key device information submitted to the FDA about medical devices that have Unique Device Identifiers (UDI). Data can be retrieved from GUDID using web interface, web services, or downloadable module. * UDI(s) are part of the Common Clinical Data Set definition for 2015 edition. * Drummond Group white paper explaining UDIs available for download in Zendesk. | |

**Test Procedures**

### 1.1 Record Unique Device Identifier

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|  | User demonstrates health IT module records the following unique device identifiers (UDI) in formats established by all three UDI issue agencies using data obtained from [AccessGUDID](http://accessgudid.nlm.nih.gov/):   * **GS1 Issuing Agency**   (01)10884521062856(11)141231(17)150707(10)A213B1(21)1234   * **Health Industry Business Communications Council (HIBCC)**   +B066000325011NS1/$$420020216LOT123456789012345/SXYZ456789012345678/16D20130202C1   * **International Council for Commonality in Blood Banking Automation (ICCBBA)**   =/W4146EB0010T0475=,000025=A99971312345600=>014032=}013032&,1000000000000XYZ123 |

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### 1.2 Parse Identifiers from a Unique Device Identifier (UDI)

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|  | User demonstrates health IT module parses device identifiers (DI) from each UDI in all formats established by the 3 UDI issuing agencies and records in human readable form. |
|  | User demonstrates health IT module parses the following production identifiers from each UDI established by the 3 UDI issuing agencies and records in human readable form:   * Lot or batch within which a device was manufactured; * Serial number of a specific device; * Expiration date of a specific device; * Date a specific device was manufactured; and * Distinct identification code for a human cell, tissue, or cellular and tissue-based product (HCT/P) regulated as a device. |

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### 1.3 Obtain and Associate Implantable Device Description

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| --- | --- |
|  | User demonstrates health IT module obtains and associates with each UDI in all formats established by the 3 UDI Issuing Agencies the implantable device description using one of the following methods:   * GMDN PT Name * Attribute associated with the device identifier * Obtained from GUDID * SNOMED CT Description * Attribute mapped to “GMDN PT Name” * Obtained from Unified Medical Language System (UMLS) or the AccessGUDID API |
|  | User demonstrates health IT module obtains and associates the following five GUDID attributes for each UDI:   * Brand Name; * Version or Model Number; * Company Name; * “What MRI safety information does the labeling contain?”; and * Device required to be labeled as containing natural rubber latex or dry natural rubber |

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### 1.4 Display Implantable Device List

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|  | User verifies health IT module displays implantable device list including, at a minimum, the following information:   * All active UDIs recorded for a patient; * For each active UDI, the description of the implantable device (*as defined in section 1.3 above*) * Method to access inactive UDIs recorded for a patient that are not displayed on this list (*e.g., via link*) |

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### 1.5 Change Status for Unique Device Identifier

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|  | User changes the status of the Unique Device Identifier (UDI) for a patient to indicate that a UDI is inactive. |

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### 1.6 Access Implantable Device List

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|  | User accesses the following information for all active and inactive UDIs for a patient:   * Unique Device Identifier (UDI); * Description of implantable device *(as defined in section 1.3 above)*; * Identifiers associated with UDI *(as defined in section 1.2 above)*; and * Attributes associated with UDI *(as defined in section 1.3 above)* |

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# Appendix A: Testing Guide

*This appendix contains more details and background on the testing requirements, including explanation on underlying standards, notable issues and best practice suggestions.*

Rev 01-Apr-2016 Additions

* FDA has accredited three organizations as UDI issuing agencies: *GS1*, *Health Industry Business Communications Council (HIBCC)*, and *International Council for Commonality in Blood Banking Automation (ICCBBA)*. Each issuing agency has a unique unique device identifier (UDI) format that was reviewed and approved by FDA as part of its process for accrediting issuing agencies. Any changes to the format of the UDI by an issuing agency must be approved by FDA before implementation. UDI formats by Issuing Agency can be accessed here:

<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/GlobalUDIDatabaseGUDID/UCM396595.pdf>

* Consistent with the policy that UDIs should not be deleted from the implantable device list or from a patient's electronic health record, a UDI that has been designated inactive must still be accessible to the user so that users can access information about the device, even if it was explanted or recorded in error.
* Consistent with the policy that UDIs should not be deleted from the implantable device list or from a patient's electronic health record, a UDI that has been designated inactive must still be accessible to the user so that users can access information about the device, even if it was explanted or recorded in error.

Rev 01-Mar-2016 Additions

* A UDI is a unique numeric or alphanumeric code that consists of two parts:

(1) a device identifier (DI), a mandatory, fixed portion of a UDI that identifies the labeler and the specific version or model of a device, and

(2) a production identifier (PI), a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of a device: the lot or batch number within which a device was manufactured; the serial number of a specific device; the expiration date of a specific device; the date a specific device was manufactured; the distinct identification code required by 21 CFR 1271.290(c) for a human cell, tissue, or cellular and tissue-based product (HCT/P) regulated as a device.

* Global Unique Device Identification Database (GUDID) Guidance for Industry and Food and Drug Administration Staff: <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM458634.pdf>
* GUDID Data Elements and attributes can be found here: [GUDID Data Elements Reference Table - May 1, 2015 (XLS - 104KB)](http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/GlobalUDIDatabaseGUDID/UCM396592.xls)
* The attributes described above can be retrieved from the GUDID using the GUDID's web interface, web services, downloadable module, or any other method of retrieval permitted under FDA's GUDID guidance. Thus GUDID attributes could be retrieved from a local system, provided the information in that system is up to date and is based upon the data downloaded from the GUDID. That said, we encourage the use of the AccessGUDID web services, which are being designed specifically to support health IT developers to meet this implantable device list certification criterion.
* When displaying the implantable device list to users:
  + The display may but need not contain inactive UDIs recorded for the patient. If inactive UDIs are recorded for a patient and not displayed, the list must display to the user a method (such as a jump link) for accessing such UDIs. For example, the implantable device list could display only active UDIs so long as it also contained a link or other obvious way for a user to access all other UDIs recorded for the patient.
  + Displaying each of the discrete components (Device Identifier + Production Identifier(s)) is considered the equivalent of displaying the full UDI in an easily readable plain-text form, or human readable form.
* In reference to concerns user labeling for devices that contain natural rubber:
  + The term “natural rubber latex” means rubber that is produced by the natural rubber latex process that involves the use of natural latex in a concentrated colloidal suspension. Products are formed from natural rubber latex by dipping, extruding, or coating.
  + The term “dry natural rubber” means rubber that is produced by the dry natural rubber process that involves the use of coagulated natural latex in the form of dried or milled sheets. Products are formed from dry natural rubber by compression molding, extrusion, or by converting the sheets into a solution for dipping.

# Appendix B: ONC Criteria and Standards

*This appendix contains copy of the relevant ONC criteria and standards for this proctor sheet as a reference. In the event of a discrepancy with the ONC Final Rule, the ONC Final Rule takes precedence.*

**§170.315(a)(14) Implantable Device List.**

(i) Enable a user to record, change, and access, a list of Unique

Device Identifiers associated with a patient’s Implantable Device(s).

(ii) Parse the following data elements from a Unique Device Identifier:

(A) Device Identifier;

(B) Batch/lot number;

(C) Expiration date;

(D) Production date; and

(E) Serial number

(iii) Retrieve the “Device Description” attribute associated with a Unique Device Identifier in the Global Unique Device Identification Database.

(iv) For each Unique Device Identifier in a patient’s list of implantable devices, enable a user to access the following:

(A) The parsed data elements specified under paragraph (a)(20)(ii) of this section that are associated with the UDI; and

(B) The retrieved data element specified under paragraph (a)(20)(iii) of this section.

# Change Log

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| --- | --- |
| Revision | Change Description |
| 01-Dec-2016 | Re-ordered section 1.5 (“change status”) and section 1.6 (“access”). Added reference to DG white paper. |
| 01-Oct-2016 | Added test data sets. |
| 01-Aug-2016 | Corrected SNOMED CT standard listing under “Standards Support”. |
| 01-May-2016 | Clarified test procedures must include formats established by all 3 UDI issuing agencies. |
| 01-Apr-2016 | Added information on “UDI formats by Issuing Agency under Appendix A. |
| 01-Mar-2016 | Initial Release. |
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**About Drummond Group LLC**

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