UDI Pattern R2 Publication Request

Publication Request	Publication Request
1. Published Name of the Standard for which request is being made	
2. Standards Material/Document	Normative
3. Date of Request	Feb 27, 2020
4. Use Period	
5. Reason for extension, timeline, and actions	
6. Original Publication Date	
7. End date of the current STU period	
8. Length of the requested extension	
9. Review Process	
10. HL7 Work Group making this request and date	Orders & Observations
10a. Requesting WG Date	Feb 27, 2020
11. URL of approval minutes	https://confluence.hl7.org/display/OO/OO+Conf+Call+Minutes+-+Main+Call%3A+February+27%2C+2020
12. HL7 Product Management Group	FMG: 2020-03-04 CDA Management Group: 2020-03-11 v2 Mgmt Group: 2020-03-13
12a. Management Group Date of Approval	Mar 13, 2020
13. URL of approval minutes	https://confluence.hl7.org/display/V2MG/2020-03-13+v2MG+call
14. Is the artifact ready for final publication?	Yes
15. If not ready, please describe remaining steps.	
16. Tool name used to produce the machine processable artifacts in the IG	
17. The name of the “IG artifact” within the context of the above mentioned tool.	
18. Balloted Name of the standard for which request is being made	HL7 Cross Paradigm Implementation Guide: UDI Pattern, Release 2
19. Requested name for published standard	HL7 Cross Paradigm Implementation Guide: UDI Pattern, Release 2

20. If CMET, list IDs balloted	
21. Project Insight Number	1512
22. Document Realm	Universal
23. Ballot cycle in which the document was successfully balloted	2020-JAN
24. Results of that ballot (following reconciliation activities):	24. Results of that ballot (following reconciliation activities): (not needed for errata, STU extension, or unballoted STU update)
25. Affirmative	56
26. Negative	1
27. Abstentions	53
28. Not Returned	11
29. Total in ballot pool	121
30. Date on which final document/standards material was supplied to HQ	
31. URL of publication material/ SVN repository	http://www.hl7.org/documentcenter/public/wg/orders/UDI_Pattern_20191031%20-%20Final.docx
32. Publishing Facilitator	Hans Buitendijk
33. Special Publication Instructions	
34. URL of ballot reconciliation document	http://www.hl7.org/documentcenter/public/ballots/2019MAY/reconciliation/recon_hl7_ig_udi_r2_n1_2019may.xls
35. Has the Work Group posted its consideration of all comments received in its reconciliation document on the ballot desktop?	Yes
36. Substantive Changes Since Last Ballot?	No
37. Product Brief Reviewed By	Orders & Observations
38. Date Product Brief Reviewed	
39. Has the Product Brief changed?	
Product Brief	Product Brief
40. Family	Cross-Paradigm
41. Section	Clinical and Administrative Domains, Implementation Guides
42. Topic	Attachments

43. Please Describe the Topic	Device Identification
44. Product Type	
45. Parent standard	HL7 v2, HL7 CDA C-CDA, HL7 FHIR
46. Parent Standard Status	
47. Update/replace standard	HL7 Cross Paradigm Implementation Guide: UDI Pattern, Release 1
48. Common name/search keyword	UDI Pattern R2 "HL7 XParadigm IG: UDI Pattern, R1", Unique Device Identifier, UDI, Pattern, HL7 Version 3 Cross Paradigm Implementation Guide: Medical Devices and Unique Device Identification (UDI) Pattern, Release 1
49. Description	The Unique Device Identifier (UDI) Pattern provides the guidelines for exchanging UDI information associated with medical devices, initially implantable devices in patients. This document will not give implementation guidance for specific use cases and worfklows, but will set the overarching guidelines for all working groups that need to exchange the unique device identification on the fields and format intended for expressing UDI related data using V2, V3, and FHIR. The goal of the UDI Pattern is to enable semantic interoperability for recording UDI information on medical devices used on or implanted in patients regardless of the information exchange standard used to move the information across (e.g., HL7 Version 2.x, HL7 v3 messages or CDA, HL7 FHIR).
Targets	Targets These are categories of potential users, implementers, or other interested parties such as those that are indicated on the Project Scope Statement under “Stakeholders/Vendors/Providers”. Select those that are applicable, or suggest others:
50. Stakeholders	Clinical and Public Health Laboratories, Quality Reporting Agencies, Regulatory Agency, Standards Development Organizations (SDOs), Payors
51. Vendors	EHR, PHR, Equipment, Health Care IT, HIS
52. Providers	Emergency Services Local and State Departments of Health Medical Imaging Service Healthcare Institutions (hospitals, long term care, home care, mental health)
53. Benefits	- Creates clarity on where and how to document UDI related information in the base standards - Enables implementation guides that require access and/or exchange of UDI related information to consistently define how to communicate it
54. Implementations/Case Studies	EHRs Certified to ONC’s 2015 Certification Edition US FDA GUDID IHE Patient Care Device Technical Framework
55. Development Background	The UDI Pattern was initially defined as a harmonization document. As the definitions solidified in the respective standard, the guidance was put in normative, cross-paradigm specification to ensure a higher degree of conformance. With Release 2, updates resulting from HL7 v2.9 and HL7 FHIR R4 were included.