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IHE Devices Technical Framework Supplement

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Service-oriented Device Point-of-care Interoperability (SDPi)

Revision 0.1.2 – Draft in Preparation for Public Comment (*or* Trial Implementation)

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[Editor's Note: Should this be DEV@ihe.net?]

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Foreword

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90 **CONTENTS**

	Introduction to this Supplement.....	21
	Open Issues and Questions	22
	Closed Issues	22
95	IHE Technical Frameworks General Introduction.....	23
9	Copyright Licenses.....	23
	9.1 Copyright of Base Standards	23
	9.1.1 DICOM (Digital Imaging and Communications in Medicine).....	23
	9.1.2 HL7 (Health Level Seven).....	23
100	9.1.3 LOINC (Logical Observation Identifiers Names and Codes)	24
	9.1.4 SNOMED CT (Systematized Nomenclature of Medicine -- Clinical Terms).....	24
	9.1.5 IEEE 11073 (Health Device Interoperability)	24
	10 Trademark	24
	IHE Technical Frameworks General Introduction Appendices.....	25
105	Appendix A – Actor Summary Definitions	25
	Appendix B – Transaction Summary Definitions.....	26
	Appendix D – Glossary	27
	Volume 1 – Profiles	29
	2 Devices Integration Profiles.....	29
110	2.2 Safety, Effectiveness & Security Considerations and Requirements.....	29
	2.3 Integration Profiles Overview	29
	10.2.1 <Option Name>.....	29
	2.X Service-oriented Device Point-of-care Interoperability (SDPi) – Overview & Framework	30
115	10 Service-oriented Device Point-of-care Interoperability – Plug-and-trust (SDPi-P) Profile	31
	10.1 SDPi-P Actors, Transactions, and Content Modules	32
	10.1.1 Actor Descriptions and Actor Profile Requirements.....	37
	10.1.1.1 SOMDS Participant.....	38
	10.1.1.2 SOMDS Provider.....	39
120	10.1.1.3 SOMDS Consumer	39
	10.1.1.4 SOMDS Connector.....	39
	10.1.1.5 SOMDS FHIR Gateway	41
	10.1.1.6 SOMDS V2 Gateway	42
	10.1.1.7 SOMDS Sensor Gateway	43
125	10.1.1.8 SOMDS Smart App Platform.....	43
	10.1.1.9 BICEPS Content Creator	44
	10.1.1.10 BICEPS Content Consumer	45
	10.2 SDPi-P Actor Options	45
	10.2.1 Streaming Option	47
130	10.2.2 Safe Data Transmission Option.....	47
	10.2.3 Compact Representation Option	48

	10.2.4 Patient Context Management Option	48
	10.2.5 Archive Service Option	48
	10.2.6 Localization Service Option	48
135	10.2.7 Ensemble Participation Option	49
	10.3 SDPi-P Required Actor Groupings	49
	10.4 SDPi-P Overview	52
	10.4.1 Concepts	52
	10.4.1.1 SOA & SOMDS Architecture Alignment	52
140	10.4.1.2 General Healthcare vs. Medical Interoperability Purposes	52
	10.4.1.3 Ensuring Time Synchronization	53
	10.4.1.3 Aggregators, Proxies, Sensors	53
	10.4.1.4 Protocol-specific Gateways	53
	10.4.1.5 Smart App Platforms	53
145	10.4.1.6 Workflow vs. Transport Actors and Interactions	54
	10.4.1.7 SDC / BICEPS MDIB Versioning Management	54
	10.4.2 Use Cases	54
	10.4.2.1 Use Case #1: Functional Endoscopic Sinus Surgery (FESS)	54
	10.4.2.1.1 FESS Use Case Description	55
150	10.4.2.1.2 FESS Process Flow	55
	10.4.2.2 Use Case #2: ICU Integration	57
	10.4.2.2.1 ICU Integration Use Case Description	57
	10.4.2.2.2 ICU Integration Process Flow	57
	10.5 SDPi-P Safety, Effectiveness, Security Considerations and Requirements	58
155	10.5.1 SES General Considerations	58
	10.5.2 Safety Requirements & Considerations	58
	10.5.3 Effectiveness Requirements & Considerations	58
	10.5.4 Security Requirements & Considerations	58
	10.6 SDPi-P Cross Profile Considerations	59
160	11 Service-oriented Device Point-of-care Interoperability - Reporting (SDPi-R) Profile	60
	11.1 SDPi-R Actors, Transactions, and Content Modules	60
	11.1.1 Actor Descriptions and Actor Profile Requirements	62
	11.1.1.1 SOMDS Medical Data Consumer	62
	11.1.1.2 SOMDS Medical Data Provider	63
165	11.1.1.3 SOMDS FHIR Medical Data Gateway	63
	11.1.1.4 SOMDS DEC Gateway	64
	11.2 SDPi-R Actor Options	65
	11.2.1 <Option Name>	65
	11.3 SDPi-R Required Actor Groupings	65
170	11.4 SDPi-R Overview	65
	11.4.1 Concepts	65
	11.4.2 Use Cases	65
	11.4.2.1 Use Case #1: <simple name>	65

	11.4.2.1.1 <simple name> Use Case Description.....	65
175	11.5 SDPi-R Safety, Effectiveness, Security Considerations and Requirements	65
	11.5.1 SES General Considerations	65
	11.5.2 Safety Requirements & Considerations	65
	11.5.3 Effectiveness Requirements & Considerations	65
	11.5.4 Security Requirements & Considerations	65
180	11.6 SDPi-R Cross Profile Considerations	66
	12 Service-oriented Device Point-of-care Interoperability - Alerting (SDPi-A) Profile	67
	12.1 SDPi-A Actors, Transactions, and Content Modules	67
	12.1.1 Actor Descriptions and Actor Profile Requirements.....	69
	12.1.1.1 SOMDS Medical Alert Consumer.....	69
185	12.1.1.2 SOMDS Medical Alert Provider	70
	12.1.1.3 SOMDS ACM Gateway	71
	12.2 SDPi-A Actor Options	72
	12.2.1 Alert Delegation	72
	12.2.1 Alert User Acknowledgement.....	72
190	12.3 SDPi-A Required Actor Groupings	72
	12.4 SDPi-A Overview	72
	12.4.1 Concepts	72
	12.4.1.1 Medical Alerting and SES MDI Risk Management	72
	12.4.1.1 Alert Delegation	72
195	12.4.1.2 Acknowledging Alert Conditions.....	72
	12.4.1.3 Integration with Alert Communication Management Profile (ACM)	73
	12.4.1.4 IEC 60601-1-8 DIS / DAS / CDAS Considerations.....	73
	12.4.2 Use Cases	73
	12.4.2.1 Use Case #1: <simple name>	73
200	12.4.2.1.1 <simple name> Use Case Description.....	73
	12.4.2.2 Use Case #2: Silent ICU	73
	12.4.2.2.1 Silent ICU Use Case Description	73
	12.4.2.2.2 Silent ICU Process Flow.....	73
	12.5 SDPi-A Safety, Effectiveness, Security Considerations and Requirements	74
205	12.5.1 SES General Considerations	74
	12.5.2 Safety Requirements & Considerations	74
	12.5.3 Effectiveness Requirements & Considerations	74
	12.5.4 Security Requirements & Considerations	74
	12.6 SDPi-A Cross Profile Considerations	74
210	13 Service-oriented Device Point-of-care Interoperability – external Control (SDPi-xC) Profile.....	75
	13.1 SDPi-xC Actors, Transactions, and Content Modules.....	75
	13.1.1 Actor Descriptions and Actor Profile Requirements.....	77
	13.1.1.1 SOMDS Medical Control Consumer.....	77
	13.1.1.2 SOMDS Medical Control Provider	77
215	13.2 SDPi-xC Actor Options	78

	13.2.1 <Option Name>.....	78
	13.3 SDPi-xC Required Actor Groupings.....	78
	13.4 SDPi-xC Overview	78
220	13.4.1 Concepts	78
	13.4.2 Use Cases	78
	13.4.2.1 Use Case #1: <simple name>	78
	13.4.2.1.1 <simple name> Use Case Description.....	78
	13.5 SDPi-xC Safety, Effectiveness, Security Considerations and Requirements	78
225	13.5.1 SES General Considerations	78
	13.5.2 Safety Requirements & Considerations	78
	13.5.3 Effectiveness Requirements & Considerations	78
	13.5.4 Security Requirements & Considerations	78
	13.6 SDPi-xC Cross Profile Considerations	79
	Appendices to Volume 1.....	80
230	Appendix A – Requirements Management for Plug-and-Trust Interoperability	81
	A.1 Requirements: From Narratives to Plug-and-Trust Interfaces	81
	A.1.1 Hanging Gardens “Layers” Model	81
	A.1.2 ISO/IEEE 11073 SDC Components.....	82
	A.1.3 Reference Frameworks – IHE and MDIRA / ICE.....	82
235	A.1.4 Assurance Case Integration as Basis of Trust	82
	A.1.5 <other subsections>.....	82
	A.2 Integrating Safety, Effectiveness & Security Requirements & Considerations.....	82
	A.2 Requirements Capture, Mapping & Traceability Layer-to-Layer.....	83
	A.3 Specifying SystemFunctionContribution (SFC) for Plug-and-Trust Interfaces.....	83
240	A.4 Requirements Management using Gherkin & ReqIF.....	83
	A.4.1 Use Case Formalization using Gherkin.....	83
	A.4.2 Requirements Specification using ReqIF	83
	A.4.3 Mapping ReqIF from Scenarios to Interfaces	83
	A.5 Approach for integrating ReqIF into the IHE DEV Technical Framework.....	83
245	Appendix B – ISO/IEEE 11073 SDC Requirements Coverage.....	85
	B.1 Implementation Conformance Statement (ICS) Table Overview	85
	B.2 ISO/IEC 11073-10207 BICEPS ICS Tables	85
	B.2.1 General.....	86
	B.2.2 Service Provider	87
250	B.2.3 Service Consumer.....	89
	B.2.4 Remote Control.....	89
	B.2.5 Context Processing	89
	B.3 ISO/IEC 11073-20701 SOMDA ICS Tables	91
	B.3.1 MDIB Version	91
255	B.3.2 Handle-based Filtering	91
	B.3.3 Cyber-Security.....	91
	B.3.4 Discovery	92

	B.3.5 Quality of Service (QoS)	92
	B.4 ISO/IEC 11073-20702 MDPWS ICS Tables	92
260	B.4.1 General	93
	B.4.2 Streaming	93
	B.4.3 Safe Data Transmission	94
	B.4.4 Compact Representation	94
	B.4.5 Secured Discovery	95
265	Appendix C – Device Point-of-care Interoperability (DPI) Use Cases	96
	C.1 Overview of DPI Narratives, Use Cases & Scenarios	96
	C.2 <specific groupings of use cases w/ Gherkin detail>	96
	Volume 2 – Transactions	97
	3.23 Announce Network Presence [DEV-23]	97
270	3.23.1 Scope	97
	3.23.2 Actor Roles	97
	3.23.3 Referenced Standards	97
	3.23.4 Messages	98
	3.23.4.1 BICEPS Announce Network Presence Message	98
275	3.23.4.1.1 Trigger Events	98
	3.23.4.1.2 Message Semantics	99
	3.23.4.1.3 Expected Actions	99
	3.23.5 Protocol Requirements	100
	3.23.6 Safety, Effectiveness, Security Requirements & Considerations	100
280	3.23.6.1 SES General Considerations	100
	3.23.6.2 Safety Requirements & Considerations	100
	3.23.6.3 Effectiveness Requirements & Considerations	100
	3.23.6.4 Security Requirements & Considerations	100
	3.23.6.4.1 Security Audit Considerations	100
285	3.23.6.4.1.(z) <Actor> Specific Security Considerations	101
	3.24 Discover Network Topology [DEV-24]	101
	3.24.1 Scope	101
	3.24.2 Actor Roles	101
	3.24.3 Referenced Standards	101
290	3.24.4 Messages	101
	3.24.4.1 BICEPS DiscoverNetworkProviders() Message	102
	3.24.4.1.1 Trigger Events	102
	3.24.4.1.2 Message Semantics	103
	3.24.4.1.3 Expected Actions	103
295	3.24.4.2 BICEPS DiscoverNetworkProvidersResponse() Message	103
	3.24.4.2.1 Trigger Events	103
	3.24.4.2.2 Message Semantics	103
	3.24.4.2.3 Expected Actions	104
	3.24.5 Protocol Requirements	104

300	3.24.6 Safety, Effectiveness, Security Requirements & Considerations.....	104
	3.24.6.1 SES General Considerations.....	104
	3.24.6.2 Safety Requirements & Considerations.....	105
	3.24.6.3 Effectiveness Requirements & Considerations	105
	3.24.6.4 Security Requirements & Considerations	105
305	3.24.6.4.1 Security Audit Considerations.....	105
	3.24.6.4.1.(z) <Actor> Specific Security Considerations.....	105
	3.25 Discover BICEPS Services [DEV-25]	105
	3.25.1 Scope	105
	3.25.2 Actor Roles.....	105
310	3.25.3 Referenced Standards	105
	3.25.4 Messages	105
	3.25.4.1 “SDC Hello” Message.....	106
	3.25.4.1.1 Trigger Events	106
	3.25.4.1.2 Message Semantics.....	106
315	3.25.4.1.3 Expected Actions.....	106
	3.25.5 Protocol Requirements	106
	3.25.6 Safety, Effectiveness, Security Requirements & Considerations.....	107
	3.25.6.1 SES General Considerations.....	107
	3.25.6.2 Safety Requirements & Considerations.....	107
320	3.25.6.3 Effectiveness Requirements & Considerations	107
	3.25.6.4 Security Requirements & Considerations	107
	3.25.6.4.1 Security Audit Considerations.....	107
	3.25.6.4.1.(z) <Actor> Specific Security Considerations.....	107
	3.26 Discover System Context and Capabilities [DEV-26].....	107
325	3.26.1 Scope	107
	3.26.2 Actor Roles.....	108
	3.26.3 Referenced Standards	108
	3.26.4 Messages	108
	3.26.4.1 “SDC Hello” Message.....	108
330	3.26.4.1.1 Trigger Events	108
	3.26.4.1.2 Message Semantics.....	108
	3.26.4.1.3 Expected Actions.....	108
	3.26.5 Protocol Requirements	109
	3.26.6 Safety, Effectiveness, Security Requirements & Considerations.....	109
335	3.26.6.1 SES General Considerations.....	109
	3.26.6.2 Safety Requirements & Considerations.....	109
	3.26.6.3 Effectiveness Requirements & Considerations	109
	3.26.6.4 Security Requirements & Considerations	110
	3.26.6.4.1 Security Audit Considerations.....	110
340	3.26.6.4.1.(z) <Actor> Specific Security Considerations.....	110
	3.27 Manage BICEPS Subscription [DEV-27].....	110

	3.27.1 Scope	110
	3.27.2 Actor Roles	110
	3.27.3 Referenced Standards	110
345	3.27.4 Messages	110
	3.27.4.1 “SDC Hello” Message	110
	3.27.4.1.1 Trigger Events	111
	3.27.4.1.2 Message Semantics	111
	3.27.4.1.3 Expected Actions	111
350	3.27.5 Protocol Requirements	111
	3.27.6 Safety, Effectiveness, Security Requirements & Considerations.....	111
	3.27.6.1 SES General Considerations.....	111
	3.27.6.2 Safety Requirements & Considerations.....	112
	3.27.6.3 Effectiveness Requirements & Considerations	112
355	3.27.6.4 Security Requirements & Considerations	112
	3.27.6.4.1 Security Audit Considerations	112
	3.27.6.4.1.(z) <Actor> Specific Security Considerations.....	112
	3.28 Notify Change in System Context and Capabilities [DEV-28]	112
	3.28.1 Scope	112
360	3.28.2 Actor Roles	112
	3.28.3 Referenced Standards	112
	3.28.4 Messages	112
	3.28.4.1 “SDC Hello” Message	113
	3.28.4.1.1 Trigger Events	113
365	3.28.4.1.2 Message Semantics	113
	3.28.4.1.3 Expected Actions	113
	3.28.5 Protocol Requirements	113
	3.28.6 Safety, Effectiveness, Security Requirements & Considerations.....	114
	3.28.6.1 SES General Considerations.....	114
370	3.28.6.2 Safety Requirements & Considerations.....	114
	3.28.6.3 Effectiveness Requirements & Considerations	114
	3.28.6.4 Security Requirements & Considerations	114
	3.28.6.4.1 Security Audit Considerations	114
	3.28.6.4.1.(z) <Actor> Specific Security Considerations.....	114
375	3.29 Publish BICEPS Update Reports [DEV-29]	114
	3.29.1 Scope	114
	3.29.2 Actor Roles	115
	3.29.3 Referenced Standards	115
	3.29.4 Messages	115
380	3.29.4.1 “SDC Hello” Message	115
	3.29.4.1.1 Trigger Events	115
	3.29.4.1.2 Message Semantics	115
	3.29.4.1.3 Expected Actions	115

	3.29.5 Protocol Requirements	116
385	3.29.6 Safety, Effectiveness, Security Requirements & Considerations.....	116
	3.29.6.1 SES General Considerations.....	116
	3.29.6.2 Safety Requirements & Considerations.....	116
	3.29.6.3 Effectiveness Requirements & Considerations	116
	3.29.6.4 Security Requirements & Considerations	116
390	3.29.6.4.1 Security Audit Considerations	116
	3.29.6.4.1.(z) <Actor> Specific Security Considerations	117
	3.30 Retrieve BICEPS Content [DEV-30]	117
	3.30.1 Scope	117
	3.30.2 Actor Roles.....	117
395	3.30.3 Referenced Standards	117
	3.30.4 Messages	117
	3.30.4.1 “SDC Hello” Message	117
	3.30.4.1.1 Trigger Events	117
	3.30.4.1.2 Message Semantics	117
400	3.30.4.1.3 Expected Actions	118
	3.30.5 Protocol Requirements	118
	3.30.6 Safety, Effectiveness, Security Requirements & Considerations.....	118
	3.30.6.1 SES General Considerations.....	118
	3.30.6.2 Safety Requirements & Considerations.....	118
405	3.30.6.3 Effectiveness Requirements & Considerations	118
	3.30.6.4 Security Requirements & Considerations	119
	3.30.6.4.1 Security Audit Considerations	119
	3.30.6.4.1.(z) <Actor> Specific Security Considerations	119
	3.31 Set Provider State [DEV-31].....	119
410	3.31.1 Scope	119
	3.31.2 Actor Roles.....	119
	3.31.3 Referenced Standards	119
	3.31.4 Messages	119
	3.31.4.1 “SDC Hello” Message	119
415	3.31.4.1.1 Trigger Events	119
	3.31.4.1.2 Message Semantics	120
	3.31.4.1.3 Expected Actions	120
	3.31.5 Protocol Requirements	120
	3.31.6 Safety, Effectiveness, Security Requirements & Considerations.....	120
420	3.31.6.1 SES General Considerations.....	120
	3.31.6.2 Safety Requirements & Considerations.....	121
	3.31.6.3 Effectiveness Requirements & Considerations	121
	3.31.6.4 Security Requirements & Considerations	121
	3.31.6.4.1 Security Audit Considerations	121
425	3.31.6.4.1.(z) <Actor> Specific Security Considerations	121

	3.32 Retrieve Archive Data [DEV-32].....	121
	3.32.1 Scope	121
	3.32.2 Actor Roles.....	122
	3.32.3 Referenced Standards	122
430	3.32.4 Messages	122
	3.32.4.1 “SDC Hello” Message.....	122
	3.32.4.1.1 Trigger Events	122
	3.32.4.1.2 Message Semantics	122
	3.32.4.1.3 Expected Actions	123
435	3.32.5 Protocol Requirements	123
	3.32.6 Safety, Effectiveness, Security Requirements & Considerations.....	123
	3.32.6.1 SES General Considerations.....	123
	3.32.6.2 Safety Requirements & Considerations.....	123
	3.32.6.3 Effectiveness Requirements & Considerations	123
440	3.32.6.4 Security Requirements & Considerations	123
	3.32.6.4.1 Security Audit Considerations.....	124
	3.32.6.4.1.(z) <Actor> Specific Security Considerations.....	124
	3.33 Retrieve Localization Information [DEV-33].....	124
	3.33.1 Scope	124
445	3.33.2 Actor Roles.....	124
	3.33.3 Referenced Standards	124
	3.33.4 Messages	124
	3.33.4.1 “SDC Hello” Message.....	124
	3.33.4.1.1 Trigger Events	124
450	3.33.4.1.2 Message Semantics	124
	3.33.4.1.3 Expected Actions	125
	3.33.5 Protocol Requirements	125
	3.33.6 Safety, Effectiveness, Security Requirements & Considerations.....	125
	3.33.6.1 SES General Considerations.....	125
455	3.33.6.2 Safety Requirements & Considerations.....	125
	3.33.6.3 Effectiveness Requirements & Considerations	126
	3.33.6.4 Security Requirements & Considerations	126
	3.33.6.4.1 Security Audit Considerations.....	126
	3.33.6.4.1.(z) <Actor> Specific Security Considerations.....	126
460	3.34 Announce Network Departure [DEV-34]	126
	3.34.1 Scope	126
	3.34.2 Actor Roles.....	126
	3.34.3 Referenced Standards	126
	3.34.4 Messages	126
465	3.34.4.1 “SDC Hello” Message.....	126
	3.34.4.1.1 Trigger Events	127
	3.34.4.1.2 Message Semantics	127

	3.34.4.1.3 Expected Actions	127
	3.34.5 Protocol Requirements	127
470	3.34.6 Safety, Effectiveness, Security Requirements & Considerations.....	127
	3.34.6.1 SES General Considerations.....	127
	3.34.6.2 Safety Requirements & Considerations.....	128
	3.34.6.3 Effectiveness Requirements & Considerations	128
	3.34.6.4 Security Requirements & Considerations	128
475	3.34.6.4.1 Security Audit Considerations	128
	3.34.6.4.1.(z) <Actor> Specific Security Considerations.....	128
	3.35 Establish Medical Data Exchange [DEV-35]	128
	3.35.1 Scope	128
	3.35.2 Actor Roles.....	128
480	3.35.3 Referenced Standards.....	128
	3.35.4 Messages	129
	3.35.4.1 “SDC Hello” Message.....	129
	3.35.4.1.1 Trigger Events	129
	3.35.4.1.2 Message Semantics.....	129
485	3.35.4.1.3 Expected Actions	129
	3.35.5 Protocol Requirements	130
	3.35.6 Safety, Effectiveness, Security Requirements & Considerations.....	130
	3.35.6.1 SES General Considerations.....	130
	3.35.6.2 Safety Requirements & Considerations.....	130
490	3.35.6.3 Effectiveness Requirements & Considerations	130
	3.35.6.4 Security Requirements & Considerations	130
	3.35.6.4.1 Security Audit Considerations.....	130
	3.35.6.4.1.(z) <Actor> Specific Security Considerations.....	130
	3.36 Publish Medical Data [DEV-36].....	130
495	3.36.1 Scope	131
	3.36.2 Actor Roles.....	131
	3.36.3 Referenced Standards.....	131
	3.36.4 Messages	131
	3.36.4.1 “SDC Hello” Message.....	131
500	3.36.4.1.1 Trigger Events	131
	3.36.4.1.2 Message Semantics.....	131
	3.36.4.1.3 Expected Actions	132
	3.36.5 Protocol Requirements	132
	3.36.6 Safety, Effectiveness, Security Requirements & Considerations.....	132
505	3.36.6.1 SES General Considerations.....	132
	3.36.6.2 Safety Requirements & Considerations.....	132
	3.36.6.3 Effectiveness Requirements & Considerations	132
	3.36.6.4 Security Requirements & Considerations	132
	3.36.6.4.1 Security Audit Considerations.....	133

510	3.36.6.4.1.(z) <Actor> Specific Security Considerations	133
	3.37 Retrieve Medical Data [DEV-37]	133
	3.37.1 Scope	133
	3.37.2 Actor Roles	133
	3.37.3 Referenced Standards	133
515	3.37.4 Messages	133
	3.37.4.1 “SDC Hello” Message	133
	3.37.4.1.1 Trigger Events	133
	3.37.4.1.2 Message Semantics	134
	3.37.4.1.3 Expected Actions	134
520	3.37.5 Protocol Requirements	134
	3.37.6 Safety, Effectiveness, Security Requirements & Considerations	134
	3.37.6.1 SES General Considerations	134
	3.37.6.2 Safety Requirements & Considerations	135
	3.37.6.3 Effectiveness Requirements & Considerations	135
525	3.37.6.4 Security Requirements & Considerations	135
	3.37.6.4.1 Security Audit Considerations	135
	3.37.6.4.1.(z) <Actor> Specific Security Considerations	135
	3.38 Establish Medical Alert Exchange [DEV-38]	135
	3.38.1 Scope	135
530	3.38.2 Actor Roles	135
	3.38.3 Referenced Standards	135
	3.38.4 Messages	135
	3.38.4.1 “SDC Hello” Message	135
	3.38.4.1.1 Trigger Events	136
535	3.38.4.1.2 Message Semantics	136
	3.38.4.1.3 Expected Actions	136
	3.38.5 Protocol Requirements	136
	3.38.6 Safety, Effectiveness, Security Requirements & Considerations	137
	3.38.6.1 SES General Considerations	137
540	3.38.6.2 Safety Requirements & Considerations	137
	3.38.6.3 Effectiveness Requirements & Considerations	137
	3.38.6.4 Security Requirements & Considerations	137
	3.38.6.4.1 Security Audit Considerations	137
	3.38.6.4.1.(z) <Actor> Specific Security Considerations	137
545	3.39 Publish Medical Alert Update [DEV-39]	137
	3.39.1 Scope	137
	3.39.2 Actor Roles	138
	3.39.3 Referenced Standards	138
	3.39.4 Messages	138
550	3.39.4.1 “SDC Hello” Message	138
	3.39.4.1.1 Trigger Events	138

	3.39.4.1.2 Message Semantics	138
	3.39.4.1.3 Expected Actions	138
555	3.39.5 Protocol Requirements	139
	3.39.6 Safety, Effectiveness, Security Requirements & Considerations.....	139
	3.39.6.1 SES General Considerations.....	139
	3.39.6.2 Safety Requirements & Considerations.....	139
	3.39.6.3 Effectiveness Requirements & Considerations	139
	3.39.6.4 Security Requirements & Considerations	139
560	3.39.6.4.1 Security Audit Considerations	139
	3.39.6.4.1.(z) <Actor> Specific Security Considerations	140
	3.40 Retrieve Medical Alert Status [DEV-40]	140
	3.40.1 Scope	140
	3.40.2 Actor Roles	140
565	3.40.3 Referenced Standards	140
	3.40.4 Messages	140
	3.40.4.1 “SDC Hello” Message	140
	3.40.4.1.1 Trigger Events	140
	3.40.4.1.2 Message Semantics	140
570	3.40.4.1.3 Expected Actions	141
	3.40.5 Protocol Requirements	141
	3.40.6 Safety, Effectiveness, Security Requirements & Considerations.....	141
	3.40.6.1 SES General Considerations.....	141
	3.40.6.2 Safety Requirements & Considerations.....	141
575	3.40.6.3 Effectiveness Requirements & Considerations	142
	3.40.6.4 Security Requirements & Considerations	142
	3.40.6.4.1 Security Audit Considerations	142
	3.40.6.4.1.(z) <Actor> Specific Security Considerations	142
	3.41 Manage Medical Alert Delegation [DEV-41]	142
580	3.41.1 Scope	142
	3.41.2 Actor Roles	142
	3.41.3 Referenced Standards	142
	3.41.4 Messages	142
	3.41.4.1 “SDC Hello” Message	142
585	3.41.4.1.1 Trigger Events	143
	3.41.4.1.2 Message Semantics	143
	3.41.4.1.3 Expected Actions	143
	3.41.5 Protocol Requirements	143
	3.41.6 Safety, Effectiveness, Security Requirements & Considerations.....	143
590	3.41.6.1 SES General Considerations.....	143
	3.41.6.2 Safety Requirements & Considerations.....	144
	3.41.6.3 Effectiveness Requirements & Considerations	144
	3.41.6.4 Security Requirements & Considerations	144

	3.41.6.4.1 Security Audit Considerations	144
595	3.41.6.4.1.(z) <Actor> Specific Security Considerations	144
	3.42 Delegate Medical Alert [DEV-42]	144
	3.42.1 Scope	144
	3.42.2 Actor Roles	144
	3.42.3 Referenced Standards	144
600	3.42.4 Messages	145
	3.42.4.1 “SDC Hello” Message	145
	3.42.4.1.1 Trigger Events	145
	3.42.4.1.2 Message Semantics	145
	3.42.4.1.3 Expected Actions	145
605	3.42.5 Protocol Requirements	146
	3.42.6 Safety, Effectiveness, Security Requirements & Considerations	146
	3.42.6.1 SES General Considerations	146
	3.42.6.2 Safety Requirements & Considerations	146
	3.42.6.3 Effectiveness Requirements & Considerations	146
610	3.42.6.4 Security Requirements & Considerations	146
	3.42.6.4.1 Security Audit Considerations	146
	3.42.6.4.1.(z) <Actor> Specific Security Considerations	146
	3.43 Update Alert Acknowledgement Status [DEV-43]	146
	3.43.1 Scope	147
615	3.43.2 Actor Roles	147
	3.43.3 Referenced Standards	147
	3.43.4 Messages	147
	3.43.4.1 “SDC Hello” Message	147
	3.43.4.1.1 Trigger Events	147
620	3.43.4.1.2 Message Semantics	147
	3.43.4.1.3 Expected Actions	148
	3.43.5 Protocol Requirements	148
	3.43.6 Safety, Effectiveness, Security Requirements & Considerations	148
	3.43.6.1 SES General Considerations	148
625	3.43.6.2 Safety Requirements & Considerations	148
	3.43.6.3 Effectiveness Requirements & Considerations	148
	3.43.6.4 Security Requirements & Considerations	148
	3.43.6.4.1 Security Audit Considerations	149
	3.43.6.4.1.(z) <Actor> Specific Security Considerations	149
630	3.44 Manage Medical External Control [DEV-44]	149
	3.44.1 Scope	149
	3.44.2 Actor Roles	149
	3.44.3 Referenced Standards	149
	3.44.4 Messages	149
635	3.44.4.1 “SDC Hello” Message	149

	3.44.4.1.1 Trigger Events	149
	3.44.4.1.2 Message Semantics	150
	3.44.4.1.3 Expected Actions	150
	3.44.5 Protocol Requirements	150
640	3.44.6 Safety, Effectiveness, Security Requirements & Considerations.....	150
	3.44.6.1 SES General Considerations.....	150
	3.44.6.2 Safety Requirements & Considerations.....	151
	3.44.6.3 Effectiveness Requirements & Considerations	151
	3.44.6.4 Security Requirements & Considerations	151
645	3.44.6.4.1 Security Audit Considerations	151
	3.44.6.4.1.(z) <Actor> Specific Security Considerations	151
	3.45 Invoke Medical Control Services [DEV-45].....	151
	3.45.1 Scope	151
	3.45.2 Actor Roles.....	151
650	3.45.3 Referenced Standards	151
	3.45.4 Messages	151
	3.45.4.1 “SDC Hello” Message.....	151
	3.45.4.1.1 Trigger Events	152
	3.45.4.1.2 Message Semantics	152
655	3.45.4.1.3 Expected Actions	152
	3.45.5 Protocol Requirements	152
	3.45.6 Safety, Effectiveness, Security Requirements & Considerations.....	153
	3.45.6.1 SES General Considerations.....	153
	3.45.6.2 Safety Requirements & Considerations.....	153
660	3.45.6.3 Effectiveness Requirements & Considerations	153
	3.45.6.4 Security Requirements & Considerations	153
	3.45.6.4.1 Security Audit Considerations	153
	3.45.6.4.1.(z) <Actor> Specific Security Considerations	153
	Appendices to Volume 2.....	154
665	Appendix A – ISO/IEEE 11073 SDC / MDPWS Message Specifications (Normative).....	155
	A.1 SDC/BICEPS to SDC/MDPWS Message Specifications	156
	A.1.1 <Title>	156
	A.2 SDC Messages for BICEPS Discovery Model	157
	A.2.1 MDPWS: Hello().....	158
670	A.2.2 MDPWS: Probe ()	159
	A.2.3 MDPWS: ProbeMatches().....	159
	A.2.4 MDPWS: Bye()	160
	A.3 SDC Messages for Secure Connections	160
	A.4 SDC Messages for PROVIDER MDIB Discovery	160
675	A.5 SDC Messages for Update Publication / Subscription Services	161
	A.6 SDC Messages for <...>	161
	A.7 SDC Messages for PARTICIPANT Context Management	161

	Appendix B – <Appendix Title>	162
	B.1 <Title>	162
680	B.1.1 <Title>	162
	Namespace Additions for Volume 2.....	163
	Volume 3 – Content Modules	164
	5 IHE Namespaces, Concept Domains and Vocabularies	165
	5.1 IHE Devices Namespaces	165
685	5.2 IHE Devices Concept Domains	165
	5.3 IHE Devices Format Codes and Vocabularies	166
	5.3.1 IHE Format Codes.....	166
	5.3.2 IHEActCode Vocabulary	166
	5.3.3 IHERoleCode Vocabulary.....	167
690	6 DEV HL7 V3 CDA Content Modules	168
	7 DEV DICOM Content Definitions	169
	8 DEV Semantic Content Modules	170
	8.1 Overview of device semantic content	170
	8.2 General device content considerations.....	170
695	8.2.8 SDC/BICEPS semantic content	170
	8.2.8.1 SDC/BICEPS Content Module.....	170
	8.2.8.2 SDC/BICEPS Descriptive Model.....	170
	8.2.8.3 SDC/BICEPS Relationship to Classic DIM	170
	8.2.8.4 Safety, Effectiveness, Security Content Requirements & Considerations	170
700	8.2.8.5 SDC/BICEPS Conventions for device specialization content modules	170
	8.2.8.6 Device Aggregators & Proxies Modeling	171
	8.2.8.7 SDC/BICEPS Mapping of SOMDS Connector Content Modules	171
	8.2.8.8 SOMDA System Function Contribution Content Module	171
	8.3 Device specialization content modules	171
705	8.3.1 Device: Infusion Pump	172
	8.3.1.4 SDC/BICEPS content module	172
	8.3.2 Device: Ventilator.....	172
	8.3.2.4 SDC/BICEPS content module	172
	8.3.3 Device: Physiologic monitor	173
710	8.3.3.4 SDC/BICEPS content module	173
	8.3.4 Devices: Surgery.....	173
	8.3.5 Devices: Anesthesia.....	174
	8.3.6 Devices: Dialysis	174
	Appendices to Volume 3.....	175
715	Appendix A – <Appendix Title>	176
	A.1 <Title>.....	176
	A.1.1 <Title>	176
	Appendix B – <Appendix Title>	177
	B.1 <Title>	177

720	B.1.1 <Title>	177
	Volume 4 – National Extensions	178
3	National Extensions for <Country Name or IHE Organization>.....	179
	3.1 Comments	179
	3.2 IHE <Country Name> Scope of Changes	179
725	3.3 <Profile Name> <(Profile Acronym)>	180
	3.3.1 <Profile Acronym> Value Set Binding for <Country Name or IHE Organization> Realm Concept Domains	180
	3.3.2 <Profile Acronym> <Type of Change>.....	180
	4 National Extensions for <Country Name or IHE Organization>.....	181
730	Appendices to Volume 4.....	182
	Appendix A – <Appendix Title>	183
	A.1 <Title>.....	183
	A.1.1 <Title>	183
	Appendix B – <Appendix Title>	184
735	B.1 <Title>	184
	B.1.1 <Title>	184

[Editor's Note: Check list before submitting for pre-Public Comment Review –

- 740 1. Glossary Table & First Mentions – make sure they are sync'd and descriptions / definitions properly attributed.
2. Review all “?” marks and either resolve OR convert to Public Comment / Future Consideration designations.
- 745 3. Section & Figure & Table #’ing – especially references to Tables that are hard coded! (e.g., Table W.2-1)
4. ...

]

Introduction to this Supplement

<If this is a FHIR based profile, include the following boxed in text and complete the table within; otherwise, delete the text in its entirety.>

[Editor's Note: Note that it is TBD if the SDPi 1.0 version of the document will include FHIR-related specifications or if that will be deferred to a later revision.]

Whenever possible, IHE profiles are based on established and stable underlying standards. However, if an IHE domain determines that an emerging standard has high likelihood of industry adoption, and the standard offers significant benefits for the use cases it is attempting to address, the domain may develop IHE profiles based on such a standard. During Trial Implementation, the IHE domain will update and republish the IHE profile as the underlying standard evolves.

Product implementations and site deployments may need to be updated in order for them to remain interoperable and conformant with an updated IHE profile.

This <profile acronym> Profile (or This Technical Framework Supplement) is based on Release 4 of the emerging HL7^{®1} FHIR^{®2} specification. HL7 describes FHIR Change Management and Versioning at <https://www.hl7.org/fhir/versions.html>.

HL7 provides a rating of the maturity of FHIR content based on the FHIR Maturity Model (FMM): level 0 (draft) through N (Normative). See <http://hl7.org/fhir/versions.html#maturity>.

The FMM levels for FHIR content used in this profile are:

FHIR Content (Resources, ValueSets, etc.)	FMM Level
<e.g., Communication	2>

This IHE Devices Technical Framework supplement introduces a new *family of interoperability profiles*, Service-oriented Device Point-of-care Interoperability (SDPi), that comprise (4) separate profiles:

- SDPi-Plug-and-trust (**SDPi-P**) Profile

¹ HL7 is the registered trademark of Health Level Seven International.

² FHIR is the registered trademark of Health Level Seven International.

- SDPi-Reporting (**SDPi-R**) Profile
- SDPi-Alerting (**SDPi-A**) Profile
- SDPi-external Control (**SDPi-xC**) Profile

780 To that end, the supplement includes updates to all (3) IHE DEV TF volumes, including:

TF-1 Integration Profiles

- General overview of the SDPi architectural approach & integrated set of profiles
- Profile specific sections
- Related appendices, for example the integration of this family of SDPi profiles with other sources of requirements, or the application of Service Oriented Architecture (SOA) to these profiles

785

TF-2 Transactions

- Extensive new set of transactions based on ISO/IEEE 11073 Service-oriented Device Connectivity (SDC) medical device interoperability standards.
- Related appendices, for example the specialized use of

790

TF-3 Content Modules

- New content covering the application of ISO/IEEE 11073 SDC semantic standards to device content modules, with a primary focus on specifications related to the ISO/IEEE 11073-10207 BICEPS standard.

795

Open Issues and Questions

<List the open issues/questions that need to be addressed. These are particularly useful for highlighting problematic issues and/or specifically soliciting public comments.>

800 [Editor's Note: Need to determine how to use this when "issues" are being tracked using other systems (e.g., GitHub or Confluence or ... Jira ...); Intent is to migrate the confluence-based Topics to this list and link them to GitHub Issues with summaries only here.]

Closed Issues

805 *<List the closed issues/questions with their resolutions. These are particularly useful for recording the rationale for closed issues to forestall unnecessary rehashing in the future and/or to make it easier to identify when a closed issue should be re-opened due to new information.>*

IHE Technical Frameworks General Introduction

The [IHE Technical Framework General Introduction](#) is shared by all of the IHE domain technical frameworks. Each technical framework volume contains links to this document where appropriate.

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9.1.2 HL7 (Health Level Seven)

<Please refer to the Fast Healthcare Interoperability Resources as the "HL7[®] FHIR[®] standard".>

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9.1.4 SNOMED CT (Systematized Nomenclature of Medicine -- Clinical Terms)

Some IHE Profiles incorporate SNOMED® CT, which is used by permission of the International Health Terminology Standards Development Organisation. SNOMED CT® was originally created by the College of American Pathologists. SNOMED CT is a registered trademark of the International Health Terminology Standards Development Organisation, all rights reserved.

<i>Amend section 9.1.x by adding the following:</i>

9.1.5 IEEE 11073 (Health Device Interoperability)

[Editor's Note: Include IEEE blanket IP language for what is specifically leveraged in the 11073 family of standards. This includes terminology, information modeling, exchange protocols, etc.]

2020.09.18 Discussion w/ IEEE Staff ...

1. Add language to TF-1 Appendix B regarding utilization of the SDC ICS tables (language to be supplied by IEEE)

2. This section could at a minimum declare IEEE & IEEE 11073 as registered trademarks. Etc.

At this point, it was not clear if / whether there was any general agreement or need for language similar to what HL7 has above. TBD.

]

10 Trademark

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IHE Technical Frameworks General Introduction Appendices

The [IHE Technical Framework General Introduction Appendices](#) are components shared by all of the IHE domain technical frameworks. Each technical framework volume contains links to these documents where appropriate.

870

*Update the following appendices to the General Introduction as indicated below. Note that these are **not** appendices to this domain's Technical Framework (TF-1, TF-2, TF-3 or TF-4) but rather, they are appendices the IHE Technical Frameworks General Introduction located [here](#).*

875

NEW: REQUIRED APPROVAL OF ACTORS, TRANSACTIONS and TERMS - To avoid duplication and insure consistency across domains, all **new or modified** actors, transactions and glossary terms need approval by IHE's Domain Coordination Committee (DCC) before they are published in a trial implementation supplement. Please see [this Wiki page](#) for additional guidance and links to the forms for approval submission.

880

Appendix A – Actor Summary Definitions

Add the following **new or modified** actors to the IHE Technical Frameworks General Introduction Appendix A:

885

<Add any actor definitions for **new or modified actors** defined specifically for this profile in the table below. These will be added to the IHE TF General Introduction Appendix A after publication for trial implementation. Verify that any actors added here are not already contained in the [IHE General Introduction Appendix A](#).>

New (or modified) Actor Name	Definition
<Verb-Noun format (e.g., Store Image, Register Document Set)>	If this is a modified actor description, add the original description and use <u>underline</u> to indicate where the amendment adds text and bold strikethrough, where the amendment removes text
BICEPS Content Consumer	[Editor's Note: Move Definitions here from Actor Description sections below]
BICEPS Content Creator	[Editor's Note: Move Definitions here from Actor Description sections below]
SOMDS Connector	[Editor's Note: Move Definitions here from Actor Description sections below]
SOMDS Consumer	[Editor's Note: Move Definitions here from Actor Description sections below]
SOMDS FHIR Gateway	[Editor's Note: Move Definitions here from Actor Description sections below]
SOMDS Participant	[Editor's Note: Move Definitions here from Actor Description sections below]
SOMDS Provider	[Editor's Note: This is defined in the Actor list BUT is defined as "Service Provider" (100% self referential!!!). This probably has two definitions: one as a clinical service provider and the other here as a SOA actor.]

New (or modified) Actor Name	Definition
SOMDS Sensor Gateway	[Editor's Note: Move Definitions here from Actor Description sections below]
SOMDS Smart App Platform	[Editor's Note: Move Definitions here from Actor Description sections below]
SOMDS V2 Gateway	[Editor's Note: Move Definitions here from Actor Description sections below]

890 <For the benefit of the reader, you may decide to list all actors associated with this profile. If so, add them in the table below. If you choose not to add them here, the text and table below should be deleted.>

The table below lists *existing* actors that are utilized in this profile.

Complete List of Existing Actors Utilized in this Profile

Existing Actor Name	Definition
[Editor's Note: CT and ATNA actors?]	

Appendix B – Transaction Summary Definitions

895 Add the following **new or modified** transactions to the IHE Technical Frameworks General Introduction Appendix B:

900 <Add any transaction definitions for **new (or modified) transactions** defined specifically for this profile. These will be added to the IHE TF General Introduction Appendix B after publication for trial implementation. Verify that any transactions added here are not already contained in the [IHE General Introduction Appendix B](#).>

<After determining that a suitable transaction does not already exist, please note that the “verb-noun” construction for transaction names is preferred where possible. For additional guidance, see the IHE wiki at http://wiki.ihe.net/indeW.php/IHE_Profile_Design_Principles_and_Conventions#Transactions.

905

New (or modified) Transaction Name and Number	Definition
<Verb-Noun formation (e.g., Send Data [DOM-xx])>	If this is a modified transaction description, add the original description and use <u>bold underline</u> to indicate where the amendment adds text and bold strikethrough where the amendment removes text
[Editor's Note: Move from transaction definitions below]	

Appendix D – Glossary

Add the following **new or updated glossary** terms to the IHE Technical Frameworks General Introduction Appendix D.

910

[Editor's Note: The columns of the table below were modified to match those in the currently published Glossary appendix.]

New (or modified) Glossary Term	Definition	Synonyms	Acronyms / Abbreviation
Basic ICE Protocol Specification	General reference to the abstract, implementation technology independent SDC components defined in the ISO/IEEE 11073-10207 standard. (See ISO/IEEE 11073-10207)		BICEPS
Integrated Clinical Environment	Environment that combines interoperable heterogeneous POINT-OF-CARE (PoC) MEDICAL DEVICES and other equipment integrated to create a medical device system for the care of a single high acuity patient. (See ISO/IEEE 11073-20701 and AAMI 2700-1).		ICE
Medical Data Information Base	Structured collection of any data objects that are provided by a SOMDS Provider or BICEPS Content Creator, including both descriptive and state information. (See ISO/IEEE 11073-10207)		MDIB
Medical Device Interoperability	The application of informatics technology standards to achieve seamless and dynamic connection of <i>Point of Care Devices</i> .		MDI
Plug-and-Trust	The integration of an SES framework and MDI plug-and-play technology to enable the dynamic establishment of trust between participant systems at the point of connection to a SOMDS network.	SES MDI	PnT
Point of Care Device	A healthcare device that is used at a <i>point of care</i> , typically at a patient's clinical bedside. May include patient-connected mobile devices, such as telemetry monitors.		PoCD
Safe, Effective & Secure	General name given to the requirements, general and specific, derived by the application of medical device and health software quality standards, including ISO 81001-1 and IEC 80001-1.		SES
Service-oriented Device Connectivity	Application of service-oriented architecture to support healthcare device interoperability. (See ISO/IEEE 11073-20701)		SDC

New (or modified) Glossary Term	Definition	Synonyms	Acronyms / Abbreviation
Service-Oriented Medical Device System	A point-of-care system of products that implements a service-oriented SDC architecture composed of service providers and service consumers. (See ISO/IEEE 11073-10207)		SOMDS
System Function Contribution	A detailed specification of the capabilities of a SOMDS network participant		SFC

Volume 1 – Profiles

915 2 Devices Integration Profiles

[Editor's Note:

This section is assuming that the DEV TF-1 10.0 will be updated per the latest greatest template.

That template includes considerable information before 2.1 Required Actor Groupings & Bindings.

920 Consider adding here:

1. General IHE Devices Architecture / Use Context section + (4) KIPs

2. General SDPi Family of Profiles Overview section.

]

2.2 Safety, Effectiveness & Security Considerations and Requirements

925 [Editor's Note: This section is modified from the original template to show SES ...
"Implications" was changed to "Considerations and Requirements" for. Note additional section in Appendix 1]

2.3 Integration Profiles Overview

930 [Editor's Note: The template only has a reference to the http://www.ihe.net/Profiles_page.

Do we add content in this document first or does it get generated from content below?

<Mary?>

]

<NUMBERING??? 10.2.1??>

935 10.2.1 <Option Name>

<First, include a sentence with a high-level description of the option. What capability does this option enable in the profile? Then, enumerate the specific requirements for the actor(s) that support this option.>

940 An <actor name> that supports this option shall *<Describe the requirements associated with this option.>*

<Sometimes an option requires that an optional transaction becomes mandatory. In that case, list the transaction as Optional in Table 10.1-1, but indicate in this section that it is required, e.g., Transaction [DOM-Y4 is required for Actor-B that supports this option.">

<Sometimes an option requires that the actor be grouped with an actor in another profile. In that case, describe that here and also refer to the Required Grouping table in the next section. E.g., “An Actor-A that supports the Really Secure Option shall be grouped with an Secure Node or Secure Application in the ATNA Profile. See Table 10.3-1.”>

<Repeat this section (and increment numbering) as needed for additional options.>

2.X Service-oriented Device Point-of-care Interoperability (SDPi) – Overview & Framework

[Editor’s Note: This is the general section on SDPi. An overview of SOA, SOMDS, etc.]

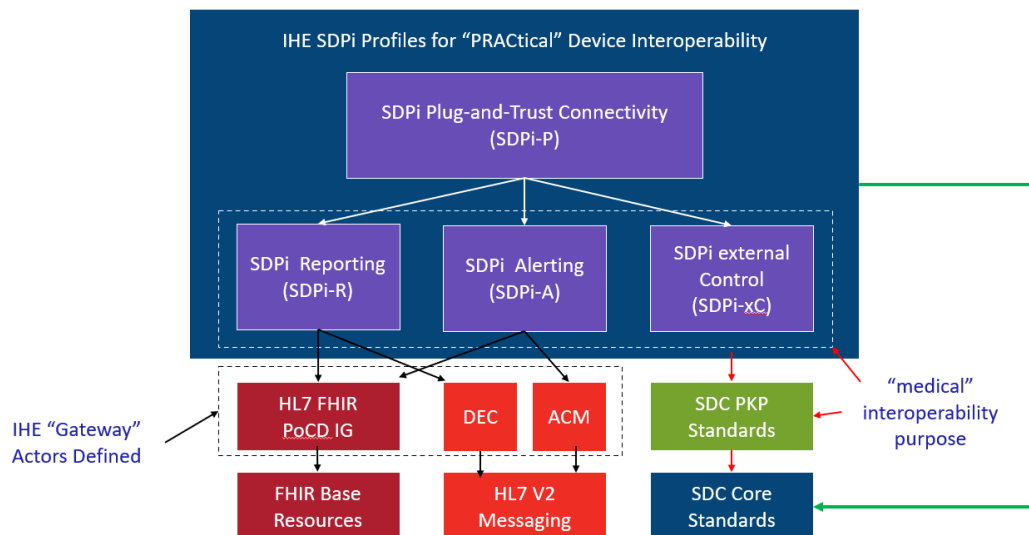


Figure 2.X-1: SDPi Profiles & Foundational Standards

<add caption + explain model>

<give reference to appendix 1>

Add new Section #

<Reserve a subsequent section number in the current domain Technical Framework Volume 1 (DOM TF-1). Replace the letter “X” with that section heading number. This number should not change when this supplement is added to the Final Text Technical Framework. In this manner, references should be able to be maintained going forward.>

10 Service-oriented Device Point-of-care Interoperability – Plug-and-trust (SDPi-P) Profile

The SDPi-Plug-and-trust (SDPi-P) profile supports foundational seamless connectivity, information exchange and service invocation as defined in the SDPi architecture detailed in section 2.X *Service-oriented Device Point-of-care Interoperability (SDPi) – Overview & Framework* above. Whereas the related SPDI profiles for reporting, alerting and external control are explicitly intended to support medical care capabilities, the SDPi-P profile focuses on healthcare interoperability. All the capabilities defined in SDPi-P are leveraged by and extended in the medically focused profiles. This foundational profile not only supports medical device interoperability (“MDI”), providing for “plug-and-play” capabilities, but also with a tightly integrated “trust” framework (see *Appendix A – Requirements Management for Plug-and-Trust Interoperability*). The establishment of a trusted ecosystem of medical and non-medical devices and applications³ begins at the start of discovery and a secure connection. Therefore, the profile name: Plug-and-Trust.

This is primarily an IHE *transport profile*⁴, although it does define several content modules detailed in IHE Devices TF-3. It supports the transactions and information exchanged in accordance to a Service-Oriented Architecture (SOA) specialized for high-acuity points of care (e.g., operating table or ICU bed), defined as a Service-Oriented Medical Device System (SOMDS). All the SDPi-P actors are therefore scoped with “SOMDS” to clearly identify their application context and scope.

Although all information exchanged between SDPi-P SOMDS participating systems and applications must conform to the basic SDC/BICEPS content module⁵ requirements, content modules have been defined for common high-acuity medical devices such as infusion pumps, ventilators and physiologic monitors.

Note that future IHE *workflow profiles* may be defined that build upon the transport & content module foundation established by the SDPi-P profile. For example, Operating Room / Surgery

³ Note that SDPi-P supports application interoperability including “Software as a Medical Device” (SaMD).

⁴ See the IHE Technical Frameworks General Introduction for a more detailed description of IHE profile types, published at http://ihe.net/Technical_Frameworks/#GenIntro .

⁵ See DEV TF-3 8.2.8.1 *SDC/BICEPS Content Module*.

Point-of-Care Integration, ICU Point-of-Care Integration, or more service-focused profiles such as Silent ICU or Quiet Hospital where the acute point-of-care is integrated with enterprise systems around device alerting and alert distribution to provide an improved environment of care (reduced noise level and improved safety) and clinician interaction.

10.1 SDPi-P Actors, Transactions, and Content Modules

This section defines the actors, transactions, and/or content modules in this profile. General definitions of actors are given in the Technical Frameworks General Introduction Appendix A. IHE Transactions can be found in the Technical Frameworks General Introduction Appendix B. Both appendices are located at http://ihe.net/Technical_Frameworks/#GenIntro

Figure 10.1-1 shows the actors directly involved in the SDPi-P Profile. The relevant transactions between them are detailed in the subsequent Table 10.1-1. Abstract Actors (i.e., those that provide common specifications that are utilized in other “concrete” or implementation actors) are indicated by names in *italics*, and with the actors that inherit their capabilities grouped in boxes with dotted lines and non-italics names. Actor groupings, including abstract with concrete are detailed in Section 10.3.

[Editor’s Notes:

1. “Discovery Proxy” – if this is postulated, would it be a new “actor”, an option for Discovery, buried / leveraged by the proposed MDIRA Profile?

]

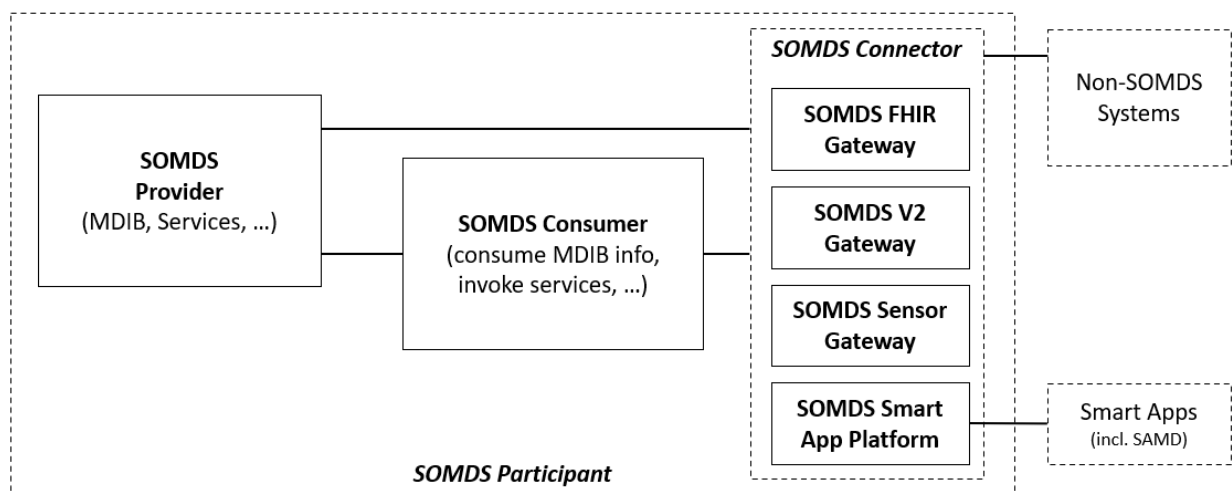


Figure 10.1-1: SDPi-P Actor Diagram

[Editor’s Notes: Considerations / discussion for the actor diagram above

1. See notes around line #545 ...
2. Descriptions of these actors are in the sections below

3. SOMDS is the overarching concept ... obviously! But keeps away from SDC (confusion & implementation specific)

4. Three core actors: Participant, Provider, Consumer

1020

a. Analogous to the ACM profile, these actors could include contained boxes / graphics for the components that are currently listed in text ...

b. OR we can just list them in text!

1025

5. The approach with a Participant being in a dashed box around the others is leveraged from XDS.b for the “Integrated Document Source/Repository Actor” – note that if IHE had the concept of actor specialization / generalization ... that would be a good thing

6. SOMDS Connector/Proxy :

a. Note: XCA has “gateway” actors

b. Clearly this actor CAN integrate a provider and / or consumer actor

1030

c. Technically this could be a grouped actor but it would probably be grouped with a Participant ... which can be Provider / Consumer / both ... In UML this would be easy to capture ... and grouping with a Participant when that is the dotted line box is clear-as-mud IMHO

7. Protocol-specific Gateway Actors

1035

a. SDPi-P will define three gateways: FHIR, V2, IHE DEV PCD (e.g., DEC & ACM); FHIR is called out here since it is a specific instance and currently the top priority

b. Gateways are indicated as specialized versions of the

c. A “generic” gateway will also support proprietary or other protocols / adaptors / connectors not otherwise specified here

1040

8. ...

I

Table 10.1-1 lists the transactions for each actor directly involved in the SDPi-P Profile. To claim compliance with this profile, an actor shall support all required transactions (labeled “R”) and may support the optional transactions (labeled “O”). Note that “Consumer” is indicated for actors that receive but do not directly respond to a specific transaction.

1045

[Editor’s Notes: The table below does not account for additional capabilities such as

1. waveform service negotiation and streaming.

2. Set for SystemContext type stuff for example (localization / patient info)

1050 3. Time Synchronization ... and leveraging CT or profiling CT for use with SDC-enabled systems?

4. ...

]

1055 Table 10.1-1: SDPi-P Profile - Actors and Transactions

Actors	Transactions	Initiator or Responder	Optionality	Reference
<i>SOMDS Participant</i>	[Editor's Note: TBD specific transactions / abstract actor!]			DEV TF-2:3.xyz
SOMDS Provider	Announce Network Presence	Initiator	R	DEV TF-2:3.23
	Discover Network Topology	Responder	R	DEV TF-2:3.24
	Discover BICEPS Services	Responder	R	DEV TF-2:3.25
	Discover System Context and Capabilities	Responder	R	DEV TF-2:3.26
	Manage BICEPS Subscription	Responder	R	DEV TF-2:3.27
	Notify Change in System Context and Capabilities	Initiator	O (See Note 1)	DEV TF-2:3.28
	Publish BICEPS Update Reports	Initiator	R	DEV TF-2:3.29
	Retrieve BICEPS Content	Responder	O	DEV TF-2:3.30
	Set Provider State	Responder	O	DEV TF-2:3.31
	Retrieve Archive Data	Responder	O	DEV TF-2:3.32
	Retrieve Localization Information	Responder	O	DEV TF-2:3.33
	Announce Network Departure	Initiator	R	DEV TF-2:3.34
SOMDS Consumer	Announce Network Presence	Consumer	O	DEV TF-2:3.23
	Discover Network Topology	Initiator	R	DEV TF-2:3.24
	Discover BICEPS Services	Initiator	R	DEV TF-2:3.25

Actors	Transactions	Initiator or Responder	Optionality	Reference
	Discover System Context and Capabilities	Initiator	R	DEV TF-2:3.26
	Manage BICEPS Subscription	Initiator	R	DEV TF-2:3.27
	Notify Change in System Context and Capabilities	Responder	O	DEV TF-2:3.28
	Publish BICEPS Update Reports	Responder	R	DEV TF-2:3.29
	Retrieve BICEPS Content	Initiator	O	DEV TF-2:3.30
	Set Provider State	Initiator	O	DEV TF-2:3.31
	Retrieve Archive Data	Initiator	O	DEV TF-2:3.32
	Retrieve Localization Information	Initiator	O	DEV TF-2:3.33
	Announce Network Departure	Consumer		DEV TF-2:3.34
SOMDS Connector	<TBD specific transactions / abstract actor! See actor description below>			DEV TF-2:3.xyz
SOMDS FHIR Gateway	<TBD specific transactions; see actor description below>			DEV TF-2:3.xyz
SOMDS V2 Gateway	<TBD specific transactions; see actor description below>			DEV TF-2:3.xyz
SOMDS Sensor Gateway	<TBD specific transactions; see actor description below>			DEV TF-2:3.xyz
SOMDS Smart App Platform	<TBD specific transactions; see actor description below>			DEV TF-2:3.xyz

Note 1: The “Notify Change in System Context and Capabilities” is required if there are dynamic changes that may need to be sent to subscribing systems.

[Editor’s Note:]

1060

1. Should we include a description of SOMDS Participant MDIB & device specializations etc. here?
2. We have loosely talked about Content Modules in the past; however, not explicitly integrated them in any serious way

3. IF we did update the diagram ...

a. SDPi MDIB Creator / Reporter?

b. SDPi MDIB Content / Consumer?

c. “Share Content” => ??? [note that this could apply both across a SOMDS and gateway to enterprise ... the content would remain the same!]

]

Figure 10.1-2 shows the content-related actors defined in the SDPi-P Profile and the direction that the content is exchanged. In general, a SOMDS Provider actor will create content for consumption by a SOMDS Consumer actor; however, in the case of external control where a SOMDS Provider actor is creating and sending content (e.g., patient demographics information) to a SOMDS Provider actor, the content module creator / consumer roles will be reversed.

A product implementation using this profile may group actors from this profile with actors from a workflow or transport profile to be functional. The grouping of the content module described in this profile to specific actors is described in more detail in *10.3 SDPi-P Required Actor Groupings* or in *10.6 SDPi-P Cross Profile Considerations*.

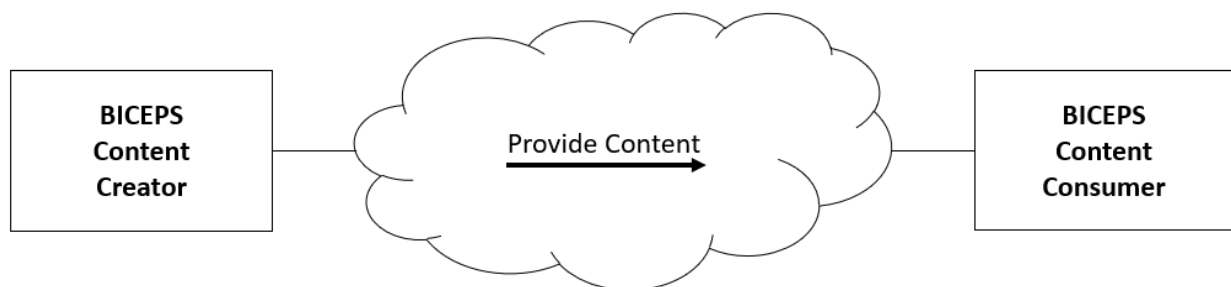


Figure 10.1-2: SDPi-P BICEPS Content Actor Diagram

Table 10.1-2 lists the content module(s) defined in the SDPi-P Profile. To claim support with this profile, an actor shall support all required content modules (labeled “R”) and may support optional content modules (labeled “O”).

[Editor’s Note: Consider SFC and Gateway Content Modules etc. etc. etc. In the table below or wrapped into the core BICEPS Content Module?]

Table 10.1-2 SDPi-P – Actors and Content Modules

Actors	Content Modules	Optionality	Reference
BICEPS Content Creator	SDC/BICEPS Content Module	R See Note 1	DEV TF-3: 8.2.8.1

Actors	Content Modules	Optionality	Reference
	Infusion Pump SDC/BICEPS Content Module	O	DEV TF-3: 8.3.1.4
	Ventilator SDC/BICEPS Content Module	O	DEV TF-3: 8.3.2.4
	Physiologic Monitor SDC/BICEPS Content Module	O	DEV TF-3: 8.3.3.4
	Surgery Devices SDC/BICEPS Content Module	O	DEV TF-3:8.3.4
	Anesthesia Devices SDC/BICEPS Content Module	O	DEV TF-3:8.3.5
	Dialysis Devices SDC/BICEPS Content Module	O	DEV TF-3:8.3.6
BICEPS Content Consumer	SDC/BICEPS Content Module	R See Note 1	DEV TF-3: 8.2.8.1
	Infusion Pump SDC/BICEPS Content Module	O	DEV TF-3: 8.3.1.4
	Ventilator SDC/BICEPS Content Module	O	DEV TF-3: 8.3.2.4
	Physiologic Monitor SDC/BICEPS Content Module	O	DEV TF-3: 8.3.3.4
	Surgery Devices SDC/BICEPS Content Module	O	DEV TF-3:8.3.4
	Anesthesia Devices SDC/BICEPS Content Module	O	DEV TF-3:8.3.5
	Dialysis Devices SDC/BICEPS Content Module	O	DEV TF-3:8.3.6

Note 1: All content exchanged on a SOMDS shall conform to the general SDPi “BICEPS Content Module” (see 8.2.8 SDC/BICEPS semantic content). SOMDS Provider-specific content modules (e.g., infusion pumps) may be optionally supported as indicated.

10.1.1 Actor Descriptions and Actor Profile Requirements

SDPi-P actor roles and responsibilities are described in the subsections below.

Unless otherwise specified in these sections, specific transaction requirements are specified in in the DEV TF-2 Transactions volume, and requirements related to content modules are detailed in

DEV TF-3 *DEV Semantic Content Modules*. This section documents any additional requirements on profile’s content actors.

The following sequence diagram illustrates a typical (not comprehensive) exchange scenarios between SDPi-P actors:

1100

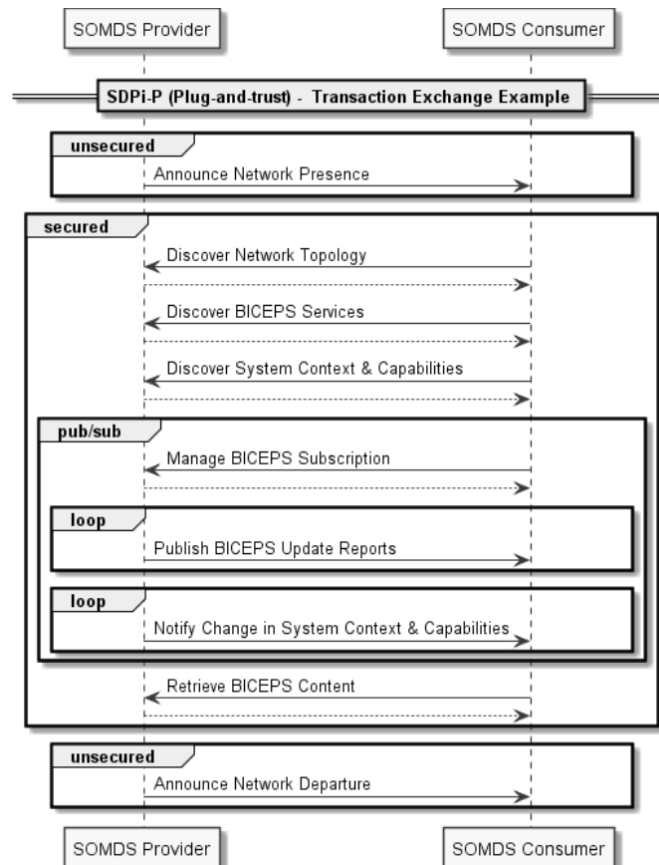


Figure W.1.1-1: SDPi-P Example Sequence Diagram

1105 [Editor’s Note: Each of the sections below will include an Actor Summary Definition section that can be moved to Appendix A in the General Introduction when appropriate.]

10.1.1.1 SOMDS Participant

Actor Summary Definition: [to be copied to Appendix A – Actor Summary Definitions above]

1110 A foundational abstract actor that provides the SOA architectural constructs for interoperating in a Service-Oriented Medical Device System (SOMDS) network instance,

including information, messaging and dynamic behavior models. (See ISO/IEEE 11073-10201 “PARTICIPANT” definition)

All systems participating in a SOMDS network instance must implement this abstract actor.

- 1115 All SDPi profiles actors are grouped (inherit from) this actor, including both transport / transaction actors and content module actors. This required grouping ensures that all systems connecting to a SOMDS network support the SES MDI⁶ requirements necessary for establishing a plug-and-trust ecosystem, including the secure and dynamic provision of an implementation’s system function contribution (SFC). See A.3 *Specifying SystemFunctionContribution (SFC) for Plug-and-Trust Interfaces* for more information.

1120 10.1.1.2 SOMDS Provider

Actor Summary Definition: [to be copied to Appendix A – Actor Summary Definitions above]

A *SOMDS Participant* that provides at least one service to the other participant systems. (See ISO/IEEE 11073-10201 “SERVICE PROVIDER” definition)

Every SOMDS Provider is paired with (inherits from) the abstract *SOMDS Provider* actor.

- 1125 A system that participates in a SOMDS network instance can include both SOMDS Consumer and SOMDS Provider actors.

10.1.1.3 SOMDS Consumer

Actor Summary Definition: [to be copied to Appendix A – Actor Summary Definitions above]

- 1130 A *SOMDS Participant* that discovers and utilizes at least one service, functional capability, exposed to a network communications backbone by a SOMDS Provider. (See ISO/IEEE 11073-10207 “SERVICE CONSUMER” and “SERVICE” definitions.)

Every SOMDS Consumer is paired with (inherits from) the abstract *SOMDS Provider* actor.

A system that participates in a SOMDS network instance can include both SOMDS Consumer and SOMDS Provider actors.

1135 10.1.1.4 SOMDS Connector

Actor Summary Definition: [to be copied to Appendix A – Actor Summary Definitions above]

- 1140 A *SOMDS Participant* that enables seamless interaction with systems and software applications that are outside the scope of the SOMDS network instance. This abstract actor provides a consistent method for interacting, as a SOMDS Consumer and / or SOMDS Provider, with a specific SOMDS instance, as the foundation for protocol-specific gateway and platform actors.

⁶ See Safety, Effectiveness & Security (SES) and Medical Device Interoperability (MDI) sections in the DEV technical framework and detailed in *Appendix A – Requirements Management for Plug-and-Trust Interoperability*.

Every abstract *SOMDS Connector* actor is grouped with (inherits from) the abstract *SOMDS Provider* actor.

A *SOMDS Connector* can implement both SOMDS Consumer and SOMDS Provider actors.

- 1145 In the case of a connector implementing a SOMDS Consumer actor, it is able to interact with other SOMDS Provider actors to either obtain information that is then made available to Non-SOMDS Systems or invoke services that are requested from the external Non-SOMDS Systems. For example, forwarding patient respiratory rate readings to an external “flow sheet” application or invoking a device’s “pause alert audio” service when a clinician indicates they are responding to a physiological alert condition (e.g., high respiratory rate).

In the case of a connector implementing a SOMDS Provider actor, service capabilities for interacting with Non-SOMDS Systems are provided to the other networked SOMDS Consumer actors. For example, an application that wants to retrieve patient information from an EHR or check the latest patient laboratory results.

- 1155 Note that the term “connector” is used to allow for SOMDS interaction with other systems that do not require protocol “gateway” adaptation, but do require a consistent interface to the other participants within a SOMDS environment. See 10.1.1.7 *SOMDS Sensor Gateway* and 10.1.1.8 *SOMDS Smart App Platform* for examples.

- 1160 Each SOMDS Connector gateway implementation will include the *protocol*-specific rules for connecting to and interacting with external Non-SOMDS Systems, including semantic mappings, message formats, and interaction sequences. See related discussion at DEV TF-3 8.2.8.7 *SDC/BICEPS Mapping of SOMDS Connector Content Modules*.

- 1165 [Editor’s Note: One question is whether SDC should be explicitly named here or not? THE protocol for SOMDS is SDC but it also creates confusion on the non-SDPi front with “structured data capture” for example. These actors could be an SDC Gateway and an SDC-FHIR Gateway etc. The approach chosen here keeps the focus on SOMDS and non-SOMDS, relegating SDC specific content to TF-2.]

- 1170 Although the SDPi-P profile SOMDS Connector actor provides for non-SOMDS *protocol-specific* adaptors, they establish the foundation for specifying system and application-specific interfaces such as for EHR or decision support systems (e.g., sepsis determination). See 10.4.1.3 *Ensuring Time Synchronization*

- 1175 [Editor’s Note: This is a key topic for all health information exchange, and especially that of medical data. A consuming system has to know, for example, that the time stamps provided in the BICEPS content or in the messages is accurate (and to what degree). Requirements will be included HERE for SOMDS Participant & all other actors including BICEPS Content <xyz>. Additional requirements may be added to the TF-3 BICEPS Content Module section as well.

Integration of CT and ATNA (TBD) below in required groupings is assumed.

]

1180 10.4.1.3 Aggregators, Proxies, Sensors for additional perspectives and concepts on how SOMDS Connectors may be implemented.

SOMDS Connector system implementations may support multiple protocols where there is one SOMDS-facing participant model or API but with multiple protocols for non-SOMDS system integration. For example, a SOMDS “Alert” Gateway would interact with other SOMDS Participants in a single consistent way but may support both HL7 FHIR and HL7 Version 2 (V2) protocols for interacting with healthcare enterprise systems.

1185 *SOMDS Connector* actors are also utilized in other SDPi profiles for medical device information reporting (SDPi-R), alerting (SDPi-A) and external control (SDPi-xC). See those profile specifications for detailed usage. In some cases, IHE profiles have been defined for supporting integration with Non-SOMDS Systems, such as the V2-based IHE Devices Device to Enterprise Communication (DEC) profile, or the IHE ITI XDS-I for locating and retrieving images for a specific patient using the XDS.b profile. In these cases, *profile*-specific SOMDS Connector adaptors may be specified as well.

[Editor’s Note: Specialized versions of SOMDS Connector ...]

1. Are there unique transactions at the -P level or only when grouped with -R/-A?
- 1195 2. Does the abstract SOMDS Connector / SOMDS Provider define core services as well? For example, discovery of the protocols and protocol-specific capabilities and content?
3. Are there unique transactions on the non-SOMDS exchange?
4. For example: Service to “Send V2 Message (ORU, R01, <header info>, etc.) OR is most of that pre-configured in the gateway actor separately? And only the end point and BICEPS content provided?
- 1200 5. Or does the gateway have an SDC Consumer sucking in the world and then internally push out PCD-1 based on pre-configuration?
6. NOTE: That the SOMDS V2 Gateway, for example, could define a generic V2 message service (for stuff that isn’t part of an IHE DEV PCD profile), and that transaction would be included here at the -P level!
- 1205 a. Perhaps it would be good to define that just to push the point and get feedback one way or the other.

]

1210 10.1.1.5 SOMDS FHIR Gateway

Actor Summary Definition: [to be copied to Appendix A – Actor Summary Definitions above]

A *SOMDS Connector* that supports use of HL7 FHIR for interoperating with Non-SOMDS Systems.

1215 SOMDS FHIR Gateway actors shall be grouped with (inherit from) the abstract *SOMDS Connector* actor. They shall implement either a SOMDS Provider and / or SOMDS Consumer actor.

1220 The SOMDS FHIR Gateway actor identifies and specifies the logic necessary for connecting a SOMDS network environment with Non-SOMDS Systems that utilize HL7 FHIR for their interoperability protocol. Generally, this logic is defined in the HL7 Devices on FHIR (DoF) implementation guide for Point-of-Care Devices⁷.

[Editor's Note:

1. Include reference / example to **QEDm profile** ... and those FHIR transactions being supported by SOMDS Provider service definitions.
- 1225 2. Include SOMEWHERE utilization of Inferno & Asbestos ... in the supplement document as examples in a testing section?
3. Other IHE FHIR-based profiles to also integrate? MHD (for SOMDS Consumer systems that want to retrieve (or supply!) documents. PDQm / PIXm for demographic info. Etc.

]

1230 Gateways implementing this actor can support any of the FHIR architectural approaches: RESTful, messaging, documents, and SOA. For example, a SOMDS FHIR Gateway can utilize a SOMDS Consumer to retrieve information from other SOMDS Participant systems, map it into FHIR Bundle resources and forward it on to non-SOMDS systems in a FHIR message.

1235 Alternatively, the SOMDS FHIR Gateway could implement a FHIR server and provide support for systems to discover and retrieve information asynchronously, including the use of FHIR publication / subscription (“pub/sub”) services.

The SOMDS FHIR Gateway can also support SOMDS services invoked by FHIR-based systems, such as requesting a snapshot of the latest vital signs measurements for a specific patient and triggering a blood-pressure cuff reading.

10.1.1.6 SOMDS V2 Gateway

1240 Actor Summary Definition: [to be copied to Appendix A – Actor Summary Definitions above]

A *SOMDS Connector* that supports use of HL7 Version 2 (V2) for interoperating with Non-SOMDS Systems.

SOMDS V2 Gateway actors shall be grouped with (inherit from) the abstract *SOMDS Connector* actor. They shall implement either a SOMDS Provider and / or SOMDS Consumer actor.

1245 The SOMDS V2 Gateway actor identifies and specifies the logic necessary for connecting a SOMDS network environment with Non-SOMDS Systems that utilize HL7 v2 for their

⁷ See the HL7 Devices on FHIR implementation guide information at <https://confluence.hl7.org/x/k4FE>.

interoperability protocol. Since V2 is a message-based protocol, the primary implementation guide logic is defined in the IHE DEV TF-2 appendices for V2 messaging, such as *Appendix B Common Segment Descriptions* and *Appendix C Common Data Types*. The logic for semantic content modules is detailed in IHE DEV TF-3, including 8.2.8.3 *SDC/BICEPS Relationship to Classic DIM*.

Generally, the SOMDS V2 Gateway actor supports messaging *from* a SOMDS environment to V2-enabled systems, utilizing a SOMDS Consumer actor to collect information from SOMDS Provider systems and translate them to V2 messages sent to other Non-SOMDS Systems. There are cases, though, where information may be sent to a SOMDS-based system such as an alert conformation utilizing a DEV-05 (i.e., PCD-05) transaction (see the *Service-oriented Device Point-of-care Interoperability - Alerting (SDPi-A) Profile* below).

10.1.1.7 SOMDS Sensor Gateway

Actor Summary Definition: [to be copied to Appendix A – Actor Summary Definitions above]

A *SOMDS Connector* that supports integration of sensors external to a SOMDS network. SOMDS Sensor Gateway actors shall be grouped with (inherit from) the abstract *SOMDS Connector* actor. They shall implement either a SOMDS Provider and / or SOMDS Consumer actor.

The SOMDS V2 Gateway actor identifies and specifies the logic necessary for integration of signals and controls from small sensor and actuator devices that do not have the resources to support direct integration into a SOMDS network. This includes integration of both wired and wireless sensor networks (“WSN”). This also includes SOMDS integration of IoT (“Internet of Things”) architectures / networks.

10.1.1.8 SOMDS Smart App Platform

Actor Summary Definition: [to be copied to Appendix A – Actor Summary Definitions above]

A *SOMDS Connector* that supports connection to a SOMDS network that is optimized for applications, including Software as a Medical Device (SAMD)

SOMDS Smart App Platform actors shall be grouped with (inherit from) the abstract *SOMDS Connector* actor. They shall implement either a SOMDS Provider and / or SOMDS Consumer actor.

[Editor’s Note:

1. Need to define “smart app” ... where?

2. Need to reference SAMD ... which of the volumes of documents?!

3. Differentiate here (or in Concept below) the difference between a SOMD “local” app platform (e.g., within a dashboard application) and a “remote” (like within a SMART on FHIR EHR app that consumes real-time device-sourced data)

4. Discuss “intelligence” and levels of interaction + how app requirements (SES MDI) are aggregated by a platform actor

5.

1285]

This actor leverages the consistent integration of a *SOMDS Connector* to a SOMDS network environment but provides a simplified platform specification to support “smart apps” including Software as a Medical Device (SAMD). For example, an application may only need to identify and consume a few parameters from one or more SOMDS Participant systems and not be required to implement a complete SOMDS interface including security, discovery, subscription management, filtering of unneeded MDIB information, etc.

1290

SOMDS Smart App Platform actors provide an abstraction layer between application software and the requirements for interoperating in a SOMDS network backbone. Since a single platform actor can support multiple Smart Apps, network traffic may be significantly reduced, as well as processing overhead for SOMDS Provider systems that have multiple SOMDS Consumers simultaneously invoking their services.

1295

The platform must not only support non-smart app critical functions (such as network topology discovery and maintenance) but also aggregate app requirements (e.g., quality of service necessary to support an application’s algorithms).

1300

See *10.4.1.5 Smart App Platforms* for additional discussion.

10.1.1.9 BICEPS Content Creator

Actor Summary Definition: [to be moved to Appendix A – Actor Summary Definitions above]

Provides MDIB content conformant to ISO/IEEE 11073-10207 BICEPS specification and for consumption by other BICEPS Content Consumer systems.

1305

All content created and provided by a BICEPS Content Creator shall be conformant to the BICEPS content module specifications in DEV TF-3 8.2.8.1 *SDC/BICEPS Content Module* and related sections.

1310

Note that although this SDPi-P content actor primarily supports information exchange between systems participating in a SOMDS network environment, they may be referenced by other non-SDPi profiles that utilize non-SOMDS exchange architectures, transactions and technologies.

1315

Content is provided by one SOMDS Participant to another. Typically, this will be a SOMDS Provider system to a SOMDS Consumer system; however, as noted previously, in some cases such as changing configuration settings within a SOMDS Provider (e.g., Patient Context), content creation and provision is from a SOMDS Consumer (initiating the configuration change request) to a SOMDS Provider system.

10.1.1.10 BICEPS Content Consumer

Actor Summary Definition: [to be copied to Appendix A – Actor Summary Definitions above]

Processes MDIB information conformant to ISO/IEEE 11073-10207 BICEPS specifications provided by BICEPS Content Creator systems.

1320 A BICEPS Content Consumer actor shall be capable of processing information provided by a BICEPS Content Creator, in accordance to the BICEPS content module specifications in DEV TF-3 8.2.8.1 *SDC/BICEPS Content Module* and related sections. The supported BICEPS content processing shall include one or more of the options identified for this actor in *Table 10.2-1: SDPi-P – Actors and Options* below.

1325 For robustness, a BICEPS Content Consumer need only process the content that is necessary to support its capabilities, but shall also be able to accept and ignore any additional content that may be provided but is out-of-scope for its internal requirements.⁸

Note that although this SDPi-P content actor primarily supports information exchange between systems participating in a SOMDS network environment, they may be referenced by other non-SDPi profiles that utilize other non-SOMDS exchange architectures, transactions and technologies.

1330

10.2 SDPi-P Actor Options

Options that may be selected for each actor in this profile, if any, are listed in the Table 10.2-1. Dependencies between options, when applicable, are specified in notes.

1335 [Editor's Note:

1. Sync with the SDC ICS Options in DEV TF-1 *Appendix B – ISO/IEEE 11073 SDC Requirements Coverage*

2. Note that not all SDC options will be carried over as SDPi options ... specialization by constraint! (e.g., new Secured Discovery included here)

1340 3. No SOMDA options are included in the table below ... OK? For example, what about handle-based filtering?

4. Trick is identifying what should be specified as a formal *OPTION* (and thus tested as a bundle and called out on SDOC / IHE Conformance Statements) and what should be simply left for runtime discovery per “Note 1” after the table below.

1345 5. Consider also:

a. *Archive Service Support*

b. *Locationalization Service Support*

⁸ Apply Postel's Law: Send conservatively, Accept liberally.

c. *SystemContext (and related contexts) Configuration Support*

d. *Ensemble Support*

1350

6. *Note also that some OPTIONS that are allowed here may be mandatory in the medical profiles.*

a. *SDPi-A Alert Delegation Option*

b. *SDPi-A Alert Confirmation Option*

c. *SDPi-xC “You Could Kill Someone” Option*

1355

d. *SDPi-xC Closed-Loop Control Ensemble Option*

e. ...

]

Table 10.2-1: SDPi-P – Actors and Options

Actor	Option Name	Reference
SOMDS Participant	No options defined	
SOMDS Provider (See Note 1)	Streaming Option [Editor’s Note: Which can be waveform or other content; but is that in SDPi-R vs. here? And should we have a waveform option? What about SCO or polling mode type support options?]	DEV TF-1 10.2.1 <i>Streaming Option</i>
	Safe Data Transmission Option	DEV TF-1 10.2.2 <i>Safe Data Transmission Option</i>
	Compact Representation Option	DEV TF-1 10.2.3 <i>Compact Representation Option</i>
	Patient Context Management Option	DEV TF-1 10.2.4 <i>Patient Context Management Option</i>
	Archive Service Option	DEV TF-1 10.2.5 <i>Archive Service Option</i>
	Localization Service Option	DEV TF-1 10.2.6 <i>Localization Service Option</i>
	Ensemble Participation Option	DEV TF-1 10.2.7 <i>Ensemble Participation Option</i>
SOMDS Consumer (See Note 1)	Streaming Option	DEV TF-1 10.2.1 <i>Streaming Option</i>
	Safe Data Transmission Option	DEV TF-1 10.2.2 <i>Safe Data Transmission Option</i>
	Compact Representation Option	DEV TF-1 10.2.3 <i>Compact Representation Option</i>
	Patient Context Management Option	DEV TF-1 10.2.4 <i>Patient Context Management Option</i>

Actor	Option Name	Reference
	Archive Service Option	DEV TF-1 10.2.5 Archive Service Option
	Localization Service Option	DEV TF-1 10.2.6 Localization Service Option
	Ensemble Participation Option	DEV TF-1 10.2.7 Ensemble Participation Option
SOMDS Connector	No options defined [Editor's Note: we could define SOMDS Provider as an option indicating bi-directional gateway capability.]	
SOMDS FHIR Gateway	No options defined	
SOMDS V2 Gateway	No options defined	
SOMDS Sensor Gateway	No options defined	
SOMDS Smart App Platform	No options defined	
BICEPS Content Creator	No options defined	
BICEPS Content Consumer	[Editor's Note: Normal PCC TF-2 3.1. Options are document focused; What options would be appropriate here? For example: aggregation, comprehensive, <app only>, translation, trending, ...???	

Note 1: These options may be dynamically discovered by SOMDS Consumers when querying the capabilities of a specific SOMDS Provider.

10.2.1 Streaming Option

[Editor's Note:

1. MDPWS Capability, e.g., for streaming waveforms

2. NOTE: There is discussion / change tickets about secure streaming vs. current UDP-based unsecured streaming

3. See ICS Appendix B below

]

10.2.2 Safe Data Transmission Option

[Editor's Note:

1. MDPWS Capability, e.g., for high-reliability safety-critical data exchange

2. Involves implementation of the dual-path design construct

3. Will this be mandatory or an option for the medical profiles?

]

1375

10.2.3 Compact Representation Option

[Editor's Note:

1. Compression enablement
2. NOTE: This applies to a compressed XML representation ... right?
3. And/or does it apply to compression of streams / waveforms, specific bulky data?

1380

]

10.2.4 Patient Context Management Option

[Editor's Note:

1. Indicates that a SOMDS Provider not only supplies BICEPS PatientContext information but that it also allows a SOMDS Consumer to update / “manage” that patient context.
2. NOTE: This directly supports patient-device association management or the IHE DEV PCIM profile constructs.
3. And/or does it apply to compression of streams / waveforms, specific bulky data?

1385

1390

]

10.2.5 Archive Service Option

[Editor's Note:

1. Indicates support for a SOMDS Provider to archived information to a SOMDS Consumer systems
2. NOTE: This includes support for the BICEPS Archive Service
3. This will be detailed in a post 1.0 version of the SDPi Supplement

1395

]

10.2.6 Localization Service Option

[Editor's Note:

1400

1. Indicates support for a SOMDS Provider to supply natural language specific strings to SOMDS Consumer systems
2. NOTE: This includes support for the BICEPS Localization Service
3. This will be detailed in a post 1.0 version of the SDPi Supplement

]

10.2.7 Ensemble Participation Option

[Editor's Note:

1. Bundle of capabilities related to the establishment & operation of an Ensemble Context
2. NOTE: This includes support for CLC systems
3. This will be detailed in a post 1.0 version of the SDPi Supplement

]

10.3 SDPi-P Required Actor Groupings

<Describe any requirements for actors in this profile to be grouped with other actors.>

[Editor's Note: Actors from OTHER profiles. These would include -R -A -xC ... "... may be grouped with..." forward looking? What about CT? This would be grouped with SOMDS Participant actors.]

<This section specifies all REQUIRED Actor Groupings (although "required" sometimes allows for a selection of one of several). To SUGGEST other profile groupings or helpful references for other profiles to consider, use Section 10.6 Cross Profile Considerations. Use Section 10.5 for security profile recommendations.>

An actor from this profile (Column 1) shall implement all of the required transactions and/or content modules in this profile ***in addition to all*** of the requirements for the grouped actor (Column 2) (Column 3 in alternative 2).

If this is a content profile, and actors from this profile are grouped with actors from a workflow or transport profile, the Reference column references any specifications for mapping data from the content module into data elements from the workflow or transport transactions.

In some cases, required groupings are defined as at least one of an enumerated set of possible actors; this is designated by merging column one into a single cell spanning multiple potential grouped actors. Notes are used to highlight this situation.

Section 10.5 describes some optional groupings that may be of interest for security considerations and Section 10.6 describes some optional groupings in other related profiles.

1435 <Two alternatives for Table 10.3-1 are presented below.

- If there are no required groupings for any actor in this profile, use alternative 1 as a template.
- If an actor in this profile (with no option), has a required grouping, use alternative 1.
- If any required grouping is associated with an actor/option combination in this profile, use alternative 2.>

1440

[Editor's Note: Selected "alternative 1" below because it provides for tighter integration with content modules + completeness in integrating ALL actors whether or not they have a grouping or content module requirement.]

1445 <alternative 1> Table 10.3-1: SDPi-P - Required Actor Groupings

<All actors from this profile should be listed in Column 1, even if none of the actors has a required groupings. If no required grouping exists, "None" should be indicated in Column 2. If an actor in a content profile is required to be grouped with an actor in a transport or workflow profile, it will be listed **with at least one** required grouping. Do not use "XD*" as an actor name.>

1450

<In some cases, required groupings are defined as at least one of an enumerated set of possible actors; to designate this, create a row for each potential actor grouping and merge column one to form a single cell containing the profile actor which should be grouped with at least one of the actors in the spanned rows. In addition, a note should be included to explain the enumerated set.

1455 See example below showing Document Consumer needing to be grouped with at least one of XDS.b Document Consumer, XDR Document Recipient or XDM Portable Media Importer>

<The author should pay special consideration to security profiles in this grouping section. Consideration should be given to **Consistent Time (CT) Client, ATNA Secure Node or Secure Application**, as well as other profiles. For the sake of clarity and completeness, even if this table begins to become long, a line should be added for each actor for each of the required grouping for security. Also see the ITI document titled 'Cookbook: Preparing the IHE Profile Security Section' at http://ihe.net/Technical_Frameworks/#IT for a list of suggested IT and security groupings.>

1460

SDPi-P Actor	Actor(s) to be grouped with	Reference	Content Bindings Reference
SOMDS Participant	[Editor's Note: CT grouping here? What about ATNA groupings? (Since security is at the Participant level); see also Note 2 at the bottom of this table]		[RAN OUT OF STEAM HERE]

IHE Devices Technical Framework Supplement – Service-oriented Device Point-of-care Interoperability (SDPi)

SDPi-P Actor	Actor(s) to be grouped with	Reference	Content Bindings Reference
SOMDS Provider	<i>SDPi-P/SOMDS Participant</i>		
SOMDS Consumer	<i>SDPi-P/SOMDS Participant</i>		
<i>SOMDS Connector</i> (See Note 1)	<i>SDPi-P/SOMDS Provider</i>		
	<i>SDPi-P/SOMDS Consumer</i>		
SOMDS FHIR Gateway	<i>SDPi-P/SOMDS Connector</i>		
SOMDS V2 Gateway	<i>SDPi-P/SOMDS Connector</i>		
SOMDS Sensor Gateway	<i>SDPi-P/SOMDS Connector</i>		
SOMDS Smart App Platform	<i>SDPi-P/SOMDS Connector</i>		
BICEPS Content Creator	See Note 2		<i>DEV TF-3 8.2.8.1 SDC/BICEPS Content Module</i>
BICEPS Content Consumer	See Note 2		<i>DEV TF-3 8.2.8.1 SDC/BICEPS Content Module</i>
Actor A	<external Domain Acronym or blank> <i>SDPi-P/<Actor></i> <e.g., ITI CT / Time Client>	<TF Reference; typically from Vol 1> <e.g., ITI-TF-1: 7.1>	--
Actor B	None	--	--
Actor C <In this example, Actor C shall be grouped with all three actors listed in column 2>	<external Domain Acronym or blank> <i>SDPi-P/<Actor></i>	--	See Note 1
	<external Domain Acronym or blank> <i>SDPi-P/<Actor></i>	--	See Note 1
	<external Domain Acronym or blank> <i>SDPi-P/<Actor></i>	--	See Note 1
Actor D (See note 1) <In this example, the note is used to indicate that the Actor D shall be grouped with one or more of the two actors of the two actors in column 2.>	<external Domain Acronym or blank> <i>SDPi-P/<Actor></i>	--	See Note 1
	<external Domain Acronym or blank> <i>SDPi-P/<Actor></i>	--	See Note 1

SDPi-P Actor	Actor(s) to be grouped with	Reference	Content Bindings Reference
Actor E <In rare cases, the actor to be grouped with must implement an option. An example is in column 2.)	<external Domain Acronym or blank> SDPi-P <Actor> <e.g., ITI RFD Form Filler with the Archive Form Option>	<TF Reference to the Option definition; typically from Vol 1> <(e.g., ITI TF-1: 17.3.11)>	
<e.g., Content Consumer (See Note 1)>	ITI XDS.b / Document Consumer	ITI TF-1: 10.1	PCC TF-2:4.1 (See Note 2)>
	ITI XDR / Document Recipient	ITI TF-1: 15.1	PCC TF-2:4.1 (See Note 2)>
	ITI XDM / Portable Media Importer	ITI TF-1: 16.1	PCC TF-2:4.1 (See Note 2)>
<e.g., Content Consumer	ITI CT / Time Client	ITI TF-1: 7.1>	--

1465 Note 1: This actor must be grouped with at least one of the actors in column 2. Multiple groupings are allowed.

Note 2: This actor shall be grouped with at least one other transport or workflow profile actor. By default, this actor is grouped with a DEV SDPi-p/SOMDA Participant actor; however, it may be included in non-SDPi profiles and profile actors, in which case it may be grouped with other actors. See actor description for additional discussion.

10.4 SDPi-P Overview

1470 <Volume 2 documents each transaction/content module in isolation. This section shows how the transactions/content modules of the profile are combined to address the use cases.>

<Use cases are informative, not normative, and “SHALL” language is not allowed in use cases.>

10.4.1 Concepts

1475 <If needed, this section provides an overview of the concepts that provide necessary background for understanding the profile. If not needed, state “Not applicable.” For an example of why/how this section may be needed, please see ITI Cross Enterprise Workflow (XDW).>

<It may be useful in this section but is not necessary, to provide a short list of the use cases described below and explain why they are different.>

10.4.1.1 SOA & SOMDS Architecture Alignment

[Editor’s Note: Link back to SDPi general overview at the top and how leveraged for SDPi-P Actors Model; SOMDS Participant ABSTRACT actor role]

10.4.1.2 General Healthcare vs. Medical Interoperability Purposes

1485 [Editor’s Note: All the transactions here are focused on healthcare information exchange with out any intended medical purpose; relationship to the other SDPi Profiles]

10.4.1.3 Ensuring Time Synchronization

1490 [Editor's Note: This is a key topic for all health information exchange, and especially that of medical data. A consuming system has to know, for example, that the time stamps provided in the BICEPS content or in the messages is accurate (and to what degree). Requirements will be included HERE for SOMDS Participant & all other actors including BICEPS Content <xyz>. Additional requirements may be added to the TF-3 BICEPS Content Module section as well.

Integration of CT and ATNA (TBD) below in required groupings is assumed.

]

10.4.1.3 Aggregators, Proxies, Sensors

1495 [Editor's Note: Include single / multiple patient variations. See [Topic on confluence](#); ultimately probably in TF-1 & -2 & -3. NOTE added a section in TF-3 as well.

Mention SENSORS and WSN referencing SOMDS Sensor Gateways w/ rationale.

Include CLINICAL WORKPLACE SOMDS PROXY SERVICE ...

See Gateways in the actors discussion above ... and below?]

1500 10.4.1.4 Protocol-specific Gateways

[Editor's Note: External interfaces "gateways" defined in the abstract and in the protocol-specific. These actors are leveraged in other profiles such as SDPi-Reporting for a DEC Gateway or in SDPi-Alerting for an ACM gateway. Include proprietary protocols as well.

1505 Given the discussion in Actors above, is this necessary here? Or should some of that content be moved here? YES ... show examples for how the Actors might be grouped into a real-world gateway to ... for example ... an EHR etc.]

10.4.1.5 Smart App Platforms

[Editor's Note:

- 1510 1. This section enhances the short actor description above to describe in more detail the various aspects of an application "platform"
2. Include forward looking applications such as for a MDIRA / ICE, incl. Supervisor actors, Central Station, Bedside Cockpit, etc.
3. Include "simple" reporting apps to DSS (running a specific algorithm) to CLC App.
- 1515 4. Note analogous to SMART on FHIR (or whatever the new name is) for launching apps from within a FHIR-enabled EHR +
5. SoF apps that want to consume medical device & include diagram of a possible DSS app that utilizes the Platform actor to integrate with and access information from a SOMDS

Workplace network. Note that this may include multiple grouped actors, including the SOMDS FHIR Gateway.

- 1520 6. WHAT IS IN / OUT OF SCOPE: For example, do we want to propose at least a default SOMDS App API? Or would that be something that gets defined in a subsequent SOMDS App API profile ... similar to SoF specification? Is there default behaviour that should be baked into the API (e.g., SOMDS System Context), provider / service / parameter discovery, service invocation, etc.)?

1525]

10.4.1.6 Workflow vs. Transport Actors and Interactions

[Editor's Note: discuss the challenges of drawing a line between transport profile actors in SDPi and applications of those actors in more care context / workflow applications, such as Smart Alarming or MDIRA/ICE or ICU Integration etc.]

1530 10.4.1.7 SDC / BICEPS MDIB Versioning Management

[Editor's Note: Where do we address profiling of MDIB versioning? TF-1, TF-2 (e.g., in Appendix), TF-3 in MDIB content module? Mix of all three?]

]

10.4.2 Use Cases

- 1535 [Editor's Note: These use cases are initially referenced here, although they apply to the other 3 SDPi profiles as well. TBD whether we have a section on multi-use context use cases in the preceding section.

- 1540 **BIGGER ISSUE:** New for SDPi is the new level of rigor for capturing requirements from MANY "use cases" and associating them with given profile constructs / capabilities etc. The format of this section does not support such rigorous detail – HOW TO LINK that from collateral documents ... ???

- 1545 **CONSIDER:** Linking high-level use cases (in the Top Hanging Garden) to this ... bringing in traceability UP from this TF-1

]

10.4.2.1 Use Case #1: Functional Endoscopic Sinus Surgery (FESS)

<One or two sentence simple description of this particular use case.>

- 1550 *<Note that Section 10.4.2.1 repeats in its entirety for additional use cases (replicate as Section 10.4.2.2, 10.4.2.3, etc.).>*

10.4.2.1.1 FESS Use Case Description

<Describe the key use cases addressed by the profile. Limit to a maximum of one page of text or consider an appendix.>

10.4.2.1.2 FESS Process Flow

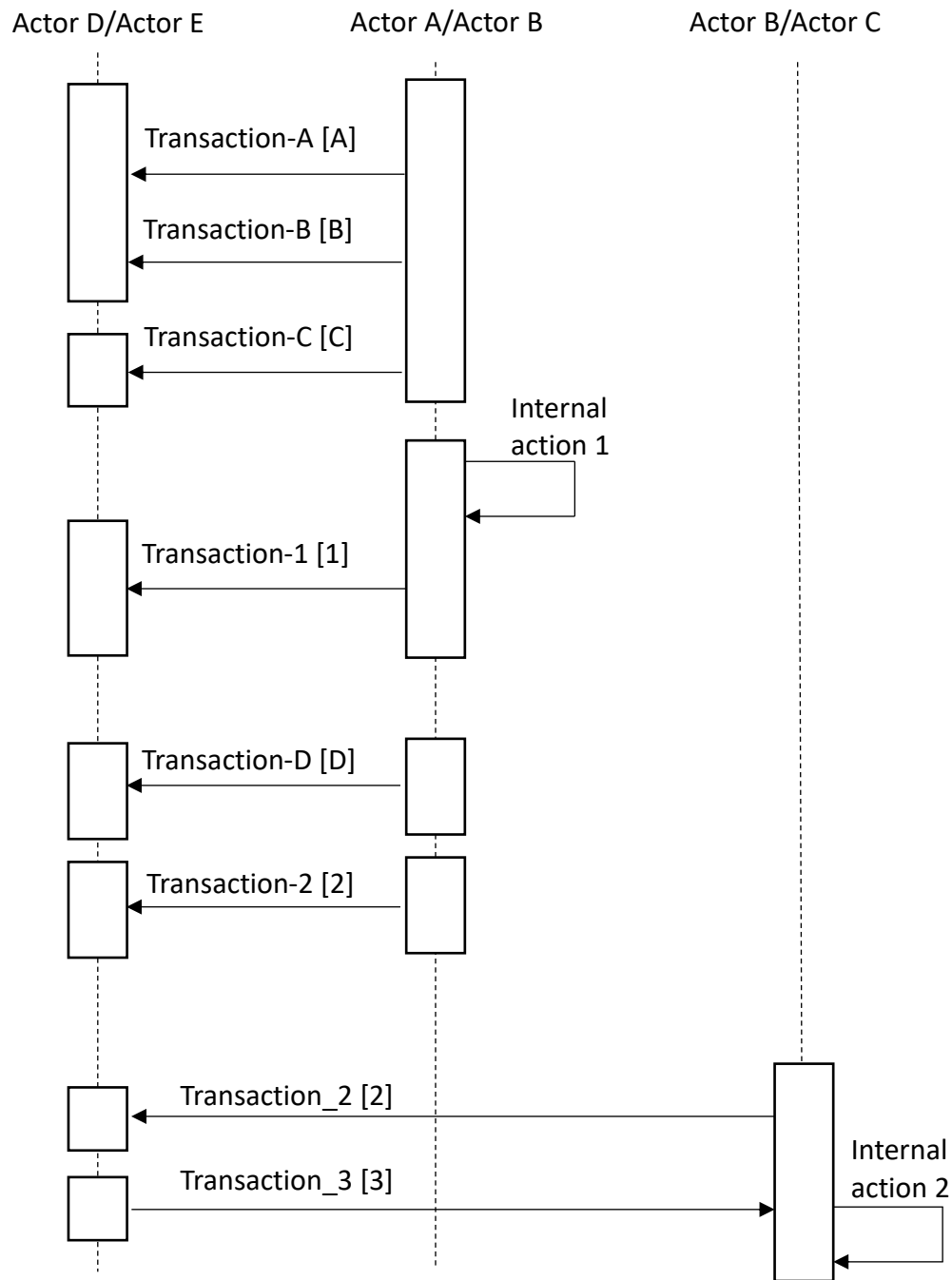
1555 *<Diagram and describe the process flow(s) covered by this profile in order to satisfy the use cases. Demonstrate how the profile transactions are combined/sequenced. To provide context and demonstrate how the profile interacts with other profiles, feel free to include transactions and events that are “external” to this profile (using appropriate notation.)*

1560 *The set of process flows will typically be exemplary, not exhaustive (i.e., it will address all the use cases, but will not show all possible combinations of actors, or all possible sequencing of transactions).*

If there are detailed behavioral rules that apply to a specific process flow or multiple process flows, an appendix may be added as needed.>

1565 *<The roles at the top of the swimlane diagram should correspond to actor names, include the profile acronym:actor name if referencing an actor from a different profile.>*

<Modify the following “Swimlane Diagram”.>



<If process flow “swimlane” diagrams require additional explanation to clarify conditional flows, or flow variations need to be described where alternate systems may be playing different actor roles, document those conditional flows here.>

1575 *<Delete the material below if this is a workflow or transport profile. Delete the material above if this profile is a content module only profile.>*

Pre-conditions:

<Very briefly (typically one sentence) describe the conditions or timing when this content module would be used.>

1580

Main Flow:

<Typically in an enumerated list, describe the clinical workflow when, where, and how this content module would be used.>

1585 **Post-conditions:**

<Very briefly (typically one sentence) describe the state of the clinical scenario after this content module has been created including examples of potential next steps.>

10.4.2.2 Use Case #2: ICU Integration

<One or two sentence simple description of this particular use case.>

1590 **[Editor’s Notes:**

1. Detailed use case / scenarios analysis will be contained in Appendix C ... for now
2. “ICU Integration” is a PLACE HOLDER TITLE ...

]

10.4.2.2.1 ICU Integration Use Case Description

1595 *<Describe the key use cases addressed by the profile. Limit to a maximum of one page of text or consider an appendix.>*

10.4.2.2.2 ICU Integration Process Flow

<sequence diagram>

1600 **Pre-conditions:**

<Very briefly (typically one sentence) describe the conditions or timing when this content module would be used.>

Main Flow:

1605 *<Typically in an enumerated list, describe the clinical workflow when, where, and how this content module would be used.>*

Post-conditions:

1610 *<Very briefly (typically one sentence) describe the state of the clinical scenario after this content module has been created including examples of potential next steps.>*

10.5 SDPi-P Safety, Effectiveness, Security Considerations and Requirements

1615 *<Describe profile-specific security considerations. This should include the outcomes of a risk assessment. This likely will include profile groupings, and residual risks that need to be assigned to the product design, system administration, or policy. See the ITI document titled ‘Cookbook: Preparing the IHE Profile Security Section’ at http://ihe.net/Technical_Frameworks/#IT for suggestions on risk assessment, risk mitigation, and IT and security profiles.>*

1620 *<If this is not a content module, delete the sentence below. If this is a content module profile, you may want to expound upon the security considerations provided by grouped actors.>*

[Editor’s Note: Updated title per the SES coupling of the SDPi profiles. This section’s organization reflects both the original (very thin) security focus but then allows for the linkages to more specific SES requirements.]

10.5.1 SES General Considerations

1625 *<SDPi content here>*

The security considerations for a content module are dependent upon the security provisions defined by the grouped actor(s).

10.5.2 Safety Requirements & Considerations

1630 **10.5.3 Effectiveness Requirements & Considerations**

10.5.4 Security Requirements & Considerations

10.6 SDPi-P Cross Profile Considerations

- 1635 *<This section is informative, not normative. It is intended to put this profile in context with other profiles. Any required groupings should have already been described above. Brief descriptions can go directly into this section; lengthy descriptions should go into an appendix. Examples of this material include ITI Cross Community Access (XCA) Grouping Rules (Section 18.2.3), the Radiology associated profiles listed at wiki.ihe.net, or ITI Volume 1 Appendix E “Cross Profile Considerations”, and the “See Also” sections Radiology Profile descriptions on the wiki such as http://wiki.ihe.net/index.php/Scheduled_Workflow#See_Also. If this section is left blank, add “Not applicable.” >*
- 1640 *<Consider using a format such as the following:>*
- 1645 *<other profile acronym> - <other profile name>*
- A <other profile actor name> in <other profile name> might be grouped with a <this profile actor name> to <describe benefit/what is accomplished by grouping>.

11 Service-oriented Device Point-of-care Interoperability - Reporting (SDPi-R) Profile

[Editor’s Note: Replicate & adapt content from 10 above]

11.1 SDPi-R Actors, Transactions, and Content Modules

This section defines the actors, transactions, and/or content modules in this profile. General definitions of actors are given in the Technical Frameworks General Introduction Appendix A. IHE Transactions can be found in the Technical Frameworks General Introduction Appendix B. Both appendices are located at http://ihe.net/Technical_Frameworks/#GenIntro

Figure 11.1-1 shows the actors directly involved in the SDPi-R Profile. The relevant transactions between them are detailed in the subsequent Table 11.1-1. Abstract Actors (i.e., those that provide common specifications that are utilized in other “concrete” or implementation actors) are indicated by names in *italics*, and with the actors that inherit their capabilities grouped in boxes with dotted lines and non-*italics* names. Actor groupings, including abstract with concrete are detailed in Section 11.3.

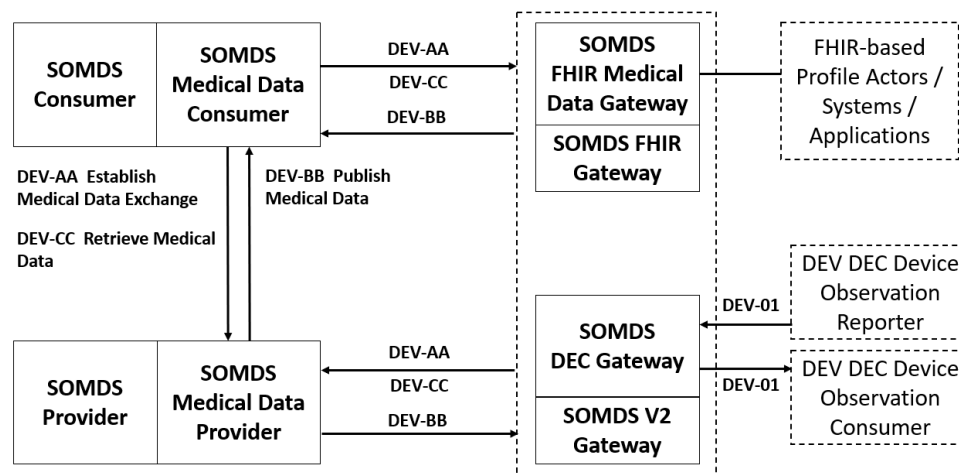


Figure 11.1-1: SDPi-R Actor Diagram ⁹

[Editor’s Notes: Considerations / discussion for the actor diagram above]

⁹ Note that the transaction labeled “DEV-01” is same as “PCD-01”, and is the result of changing the IHE domain name from Patient Care Devices (PCD) to Devices (DEV). This is also true of all other PCD-xyz transactions. See [IHE DEV Technical Framework – Transaction Map](#) for additional detail.

1. NOTE this is a first iteration of the diagram – STARTER!
- 1670 2. Is there a better way of representing the -R transactions to the dotted box that that indicates that a gateway can be EITHER a Provider and / or a Consumer? (it was confusing / not obvious to the IHE DE PAT 10/21 participants)
3. Discussion notes from review slides:
 - 1675 a. DEC can have DOR and DOC actor implementations; indicate HERE or in actor documentation? Or ...
 - b. Document FUTURE DEC FHIR Option could be implemented using <SDPi> actors.
 - 1680 c. Any need to show external FHIR system/application? Or is it obvious here? Added it but discussion can identify various options. Note could also identify IHE FHIR-based Profile Options!
 - d. Include rationale for separate –R actors and transactions (incl. BICEPS requirements / message sequences / SES bindings / Conformance claims)
 - e. Does Medical Reporting have implications on the SOMDS-external connections? Requirements placed on those?
 - 1685 f. Are the transactions truly unique or should we utilize SDPi-P transactions and include different mandatory bindings here?
4. From initial review discussion 2020.09.11:
 - a. Update to show Gateway can play both roles ... CONSUMER & PROVIDER
 - b. Add DEV-DD Retrieve Archived Medical Data ...
- 1690 5.

Table 11.1-1 lists the transactions for each actor directly involved in the SDPi-R Profile. To claim compliance with this profile, an actor shall support all required transactions (labeled “R”) and may support the optional transactions (labeled “O”). Note that “Consumer” is indicated for actors that receive but do not directly respond to a specific transaction.

Table 11.1-1: SDPi-R Profile - Actors and Transactions

Actors	Transactions	Initiator or Responder	Optionality	Reference
	Establish Medical Data Exchange	Responder	R	DEV TF-2:3.35

Actors	Transactions	Initiator or Responder	Optionality	Reference
SOMDS Medical Data Provider	Publish Medical Data	Initiator	R	DEV TF-2:3.36
	Retrieve Medical Data	Responder	O	DEV TF-2:3.37
SOMDS Medical Data Consumer	Establish Medical Data Exchange	Initiator	R	DEV TF-2:3.35
	Publish Medical Data	Responder	R	DEV TF-2:3.36
	Retrieve Medical Data	Initiator	O	DEV TF-2:3.37
SOMDS FHIR Medical Data Gateway	Establish Medical Data Exchange	Initiator / Responder (See Note 1)	R	DEV TF-2:3.35
	Publish Medical Data	Initiator / Responder (See Note 1)	R	DEV TF-2:3.36
	Retrieve Medical Data	Initiator / Responder (See Note 1)	O	DEV TF-2:3.37
SOMDS DEC Gateway	Establish Medical Data Exchange	Initiator / Responder (See Note 1)	R	DEV TF-2:3.35
	Publish Medical Data	Initiator / Responder (See Note 1)	R	DEV TF-2:3.36
	Retrieve Medical Data	Initiator / Responder (See Note 1)	O	DEV TF-2:3.37

Note 1: Gateways may include a SOMDS Medical Data Provider or SOMDS Medical Data Consumer actor, and therefore they may be the “Initiator” or “Responder” or both depending on which actors are implemented.

11.1.1 Actor Descriptions and Actor Profile Requirements

11.1.1.1 SOMDS Medical Data Consumer

Actor Summary Definition: [to be copied to Appendix A – Actor Summary Definitions above]

A SOMDS network participant that supports one or more medical key purposes for retrieving and utilizing data from a SOMDS Medical Data Provider system.

Every SOMDS Medical Data Consumer is paired with a SOMDS Consumer actor that defines all the foundational capabilities for participating in a SOMDS network instance, including system and service discovery, connection establishment and health information retrieval and service invocation from SOMDS Provider actors. Additional capability requirements are defined for this actor to ensure that all medical data is safely, securely, and effectively managed.

See section 11.5 SDPi-R Safety, Effectiveness, Security Considerations and Requirements for details on the “medical” requirements for this actor. Note that these SES requirements include comprehensive support for the ISO/IEEE 11073-10701 Standard for Metric Provisioning by Participants in a Service-Oriented Device Connectivity (SDC) System (draft) standard.

11.1.1.2 SOMDS Medical Data Provider

Actor Summary Definition: [to be copied to Appendix A – Actor Summary Definitions above]

A SOMDS network participant that supports one or more medical key purposes for providing services and data to a SOMDS Medical Data Consumer system.

1720 Every SOMDS Medical Data Provider is paired with a SOMDS Provider actor that defines all the foundational capabilities for participating in a SOMDS network instance, including system and service discovery, connection establishment and health information retrieval and service invocation from SOMDS Consumer actors. Additional capability requirements are defined for this actor to ensure that all medical data is safely, securely, and effectively managed.

1725 See section *11.5 SDPi-R Safety, Effectiveness, Security Considerations and Requirements* for details on the “medical” requirements for this actor. Note that these SES requirements include comprehensive support for the *ISO/IEEE 11073-10701 Standard for Metric Provisioning by Participants in a Service-Oriented Device Connectivity (SDC) System* (draft) standard.

11.1.1.3 SOMDS FHIR Medical Data Gateway

1730 Actor Summary Definition: [to be copied to Appendix A – Actor Summary Definitions above]

A SOMDS network participant that supports the bi-directional exchange of medical data with HL7 FHIR-based non-SOMDS systems and applications.

1735 SOMDS FHIR Medical Data Gateway actors shall be grouped with a SOMDS FHIR Gateway actor to support the core specifications for protocol-level exchange between SOMDS-based and FHIR-based network environments. Generally, this logic is defined in the HL7 Devices on FHIR (DoF) implementation guide for Point-of-Care Devices¹⁰.

1740 This actor shall include SOMDS Medical Data Consumer (for SOMDS-to-FHIR) or SOMDS Medical Data Provider (for FHIR-to-SOMDS) actors to interact with other SOMDS Participant systems. In this way, the actor may support bi-directional communication between the two environments, supporting the access and exchange of medical data to and from a SOMDS network instance.

1745 Since this gateway actor includes at least one of the other SOMDS medical data actors, it also supports the SES requirements detailed in section *11.5 SDPi-R Safety, Effectiveness, Security Considerations and Requirements*, as well as the SES requirements specified in the *ISO/IEEE 11073-10701 Standard for Metric Provisioning by Participants in a Service-Oriented Device Connectivity (SDC) System* (draft) standard.

Given that the HL7 FHIR specification defines several architectural approaches, including HTTP-based RESTful exchange and messaging exchange, there are no constraints on how these gateway actors support the FHIR-based exchange. For example, the gateway may integrate a

¹⁰ See the HL7 Devices on FHIR implementation guide information at <https://confluence.hl7.org/x/k4FE>.

1750 FHIR server that supports query access to snapshot and trended device-sourced medical data. It may support FHIR publication / subscription capabilities to notify (or be notified) when medical data changes and is available. It may simply support FHIR message exchanges to systems and applications based on pre-configured settings.

1755 Note that the gateway may define SOMDS services for querying and retrieving FHIR-based medical data, such as a patient's latest lab results.

The SOMDS FHIR Medical Data Gateway may also be implemented in systems that integrate other gateway actors, such as the SOMDS DEC Gateway.

11.1.1.4 SOMDS DEC Gateway

Actor Summary Definition: [to be copied to Appendix A – Actor Summary Definitions above]

1760 A SOMDS network participant that supports the bi-directional exchange of medical data using IHE Device Enterprise Communication (DEC) messages with non-SOMDS systems and applications.

1765 [Editor's Note: For symmetry we could change the name to "SOMDS DEC Medical Data Gateway" (the same as the FHIR gateway above). This may make sense in that SES MDI requirements COULD be required for all DEC DEV-01 transactions related to this gateway – but that may also be too prescriptive and the SES MDI using DEC could be an OPTION considered for this actor.]

1770 SOMDS DEC Gateway actors shall be grouped with a SOMDS V2 Gateway actor to support the core specifications for protocol-level exchange between SOMDS-based and V2 message-based network environments. This actor supports medical data exchange using the IHE Device Enterprise Communication (DEC) profile, DEV-01 *Communicate Device Data* transaction⁹.

1775 This actor shall include SOMDS Medical Data Consumer (for SOMDS-to-DEC) or SOMDS Medical Data Provider (for DEC-to-SOMDS) actors to interact with other SOMDS Participant systems. In this way, the actor may support bi-directional communication between the two environments, supporting the access and exchange of medical data to and from a SOMDS network instance, sending DEC-01 messages to a DEC Device Observation Consumer (DOC) actor, or receiving messages from a DEC Device Observation Reporter (DOR).

1780 No additional requirements are made on the implementation architecture of the gateway actor beyond those specified in the IHE DEC profile for the DOC and DOR actors. Note that the gateway may define SOMDS services for querying and retrieving DEC-based medical data, such as a snapshot of a patient's trended vital signs information over the preceding 48 hours; however, how that is implemented on the HL7 V2 DEC side of the gateway is out-of-scope for this specification.

1785 Since this gateway actor includes at least one of the other SOMDS medical data actors, it also supports the SES requirements detailed in section 11.5 *SDPi-R Safety, Effectiveness, Security Considerations and Requirements*, as well as the SES requirements specified in the *ISO/IEEE*

11073-10701 Standard for Metric Provisioning by Participants in a Service-Oriented Device Connectivity (SDC) System (draft) standard.

1790 The SOMDS FHIR Medical Data Gateway may also be implemented in systems that integrate other gateway actors, such as the SOMDS FHIR Medical Data Gateway.

11.2 SDPi-R Actor Options

11.2.1 <Option Name>

11.3 SDPi-R Required Actor Groupings

11.4 SDPi-R Overview

1795 11.4.1 Concepts

11.4.2 Use Cases

11.4.2.1 Use Case #1: <simple name>

11.4.2.1.1 <simple name> Use Case Description

1800 11.5 SDPi-R Safety, Effectiveness, Security Considerations and Requirements

11.5.1 SES General Considerations

<SDPi content here>

The security considerations for a content module are dependent upon the security provisions defined by the grouped actor(s).

1805 11.5.2 Safety Requirements & Considerations

11.5.3 Effectiveness Requirements & Considerations

1810 11.5.4 Security Requirements & Considerations

11.6 SDPi-R Cross Profile Considerations

12 Service-oriented Device Point-of-care Interoperability - Alerting (SDPi-A) Profile

[Editor's Note: Replicate & adapt content from 11 above]

12.1 SDPi-A Actors, Transactions, and Content Modules

This section defines the actors, transactions, and/or content modules in this profile. General definitions of actors are given in the Technical Frameworks General Introduction Appendix A. IHE Transactions can be found in the Technical Frameworks General Introduction Appendix B. Both appendices are located at http://ihe.net/Technical_Frameworks/#GenIntro

Figure 12.1-1 shows the actors directly involved in the SDPi-A Profile. The relevant transactions between them are detailed in the subsequent Table 12.1-1. Abstract Actors (i.e., those that provide common specifications that are utilized in other “concrete” or implementation actors) are indicated by names in *italics*, and with the actors that inherit their capabilities grouped in boxes with dotted lines and non-italics names. Actor groupings, including abstract with concrete are detailed in Section 12.3.

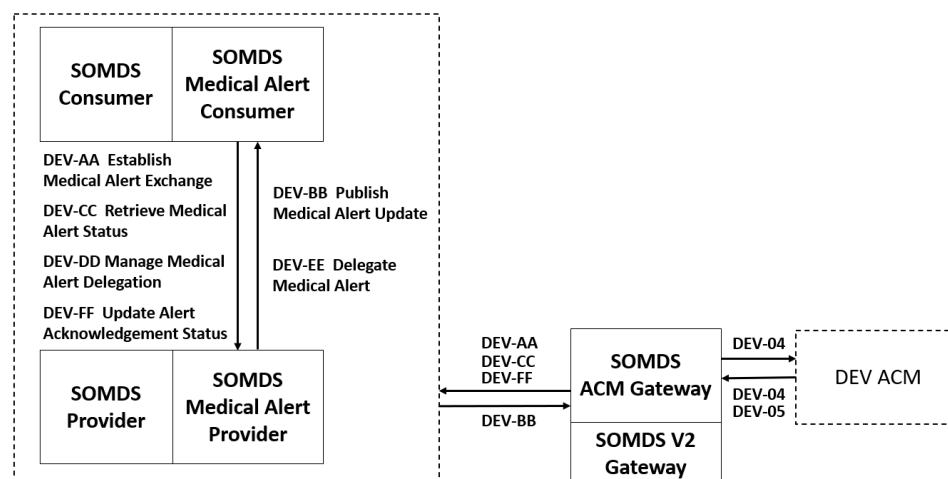


Figure 12.1-1: SDPi-A Actor Diagram

[Editor's Notes: Considerations / discussion for the actor diagram above]

1. NOTE this is a first iteration of the diagram – STARTER!
2. Discussion notes from review slides:

- a. FHIR Gateway goes away until there is a path in DoF IG for medical alerting

- 1840
- b. ACM – instead of showing the various actors (since there are AR & ACON options for example) just showed the external profile w/ in-scope transactions
 - c. SOMDS ACM Gateway can essentially function like a SOMDS Medical Alert Consumer ... should we indicate it as such?
 - d. @ White Paper, PCD-05 was mapped to SDC-DC (delegation confirmation) – however, at this level, a transaction has been defined for Clinician Response Status
3. From initial review discussion 2020.09.11:
- 1845
- a. Review SDC alerting / delegation & PCD-05 purposes and elements to reflect correctly in the right transactions
 - b. Determine if DEV-FF is real ... what it is ... or if it should be “voted of the island”
 - c. Also map to 60601-1-8 constructs, esp. re CDAS
 - d. TF-1 SDPi-A include sections (analogous to SDPi-P) on DIS / DAS / CDAS ...
- 1850
- e. NOTE Gateway would only have AR & ACON capabilities (note in profile)
- 4.

1

1855 Table 12.1-1 lists the transactions for each actor directly involved in the SDPi-A Profile. To claim compliance with this profile, an actor shall support all required transactions (labeled “R”) and may support the optional transactions (labeled “O”). Note that “Consumer” is indicated for actors that receive but do not directly respond to a specific transaction.

1860 **Table 12.1-1: SDPi-R Profile - Actors and Transactions**

Actors	Transactions	Initiator or Responder	Optionality	Reference
SOMDS Medical Alert Provider	Establish Medical Alert Exchange	Responder	R	DEV TF-2:3.38
	Publish Medical Alert Update	Initiator	R	DEV TF-2:3.39
	Retrieve Medical Alert Status	Responder	O	DEV TF-2:3.40
	Manage Medical Alert Delegation	Responder	O	DEV TF-2:3.41
	Delegate Medical Alert	Initiator	O (See note 2)	DEV TF-2:3.42

Actors	Transactions	Initiator or Responder	Optionality	Reference
	Update Alert Acknowledgement Status	Responder	O (See note 3)	DEV TF-2:3.43
SOMDS Medical Alert Consumer	Establish Medical Alert Exchange	Initiator	R	DEV TF-2:3.38
	Publish Medical Alert Update	Responder	R	DEV TF-2:3.39
	Retrieve Medical Alert Status	Initiator	O	DEV TF-2:3.40
	Manage Medical Alert Delegation	Initiator	O	DEV TF-2:3.41
	Delegate Medical Alert	Responder	O (See note 2)	DEV TF-2:3.42
	Update Alert Acknowledgement Status	Initiator	O (See note 3)	DEV TF-2:3.43
SOMDS ACM Gateway	Establish Medical Alert Exchange	Initiator / Responder (See Note 1)	R	DEV TF-2:3.38
	Publish Medical Alert Update	Initiator / Responder (See Note 1)	R	DEV TF-2:3.39
	Retrieve Medical Alert Status	Initiator / Responder (See Note 1)	O	DEV TF-2:3.40
	Update Alert Acknowledgement Status	Initiator / Responder (See Note 1)	O (See note 3)	DEV TF-2:3.43

Note 1: Gateways may include a SOMDS Medical Alert Provider or SOMDS Medical Alert Consumer actor, and therefore they may be the “Initiator” or “Responder” or both depending on which actors are implemented.

Note 2: This transaction is Required if the actor supports alert delegation.

Note 3: This transaction is optional even if the actor supports alert delegation.

1865

12.1.1 Actor Descriptions and Actor Profile Requirements

12.1.1.1 SOMDS Medical Alert Consumer

Actor Summary Definition: [to be copied to Appendix A – Actor Summary Definitions above]

1870

A SOMDS network participant that supports retrieving and utilizing medical alert information from a SOMDS Medical Alert Provider system, including alert delegation.

[Editor’s Note: including some wording about alert delegation is important. Should it also say “optionally including...”? Also note that the key purposes are mentioned in the medical data consumer actor description but seemed redundant / unnecessary here – but could add.]

1875

Every SOMDS Medical Alert Consumer is paired with a SOMDS Consumer actor that defines all the foundational capabilities for participating in a SOMDS network instance, including

system and service discovery, connection establishment and health information retrieval and service invocation from SOMDS Provider actors. Additional capability requirements are defined for this actor to ensure that all medical alert information is safely, securely, and effectively managed.

- 1880 See section *12.5 SDPi-A Safety, Effectiveness, Security Considerations and Requirements* for details on the “medical” requirements for this actor. Note that these SES requirements include comprehensive support for the *ISO/IEEE 11073-10702 Standard for Alert Provisioning by Participants in a Service-Oriented Device Connectivity (SDC) System* (draft) standard.

- 1885 This alert consumer actor may support, for example, a SOMDS-based “dashboard” application that synthesizes alert conditions reported by multiple provider systems and presents a consolidated view to the clinician.

A SOMDS Medical Alert Consumer may also support alert delegation, allowing the provider system to establish a “contract” with the consumer for the annunciation of its alert conditions. See *12.4.1.1 Alert Delegation* for more information.

- 1890 A consumer system may also provide user alert acknowledgement updates, indicating whether a clinician has (directly or indirectly) received and responded to the alert conditions of a provider actor. See *12.4.1.2 Acknowledging Alert Conditions* below.

12.1.1.2 SOMDS Medical Alert Provider

Actor Summary Definition: [to be copied to Appendix A – Actor Summary Definitions above]

- 1895 A SOMDS network participant that supports services and medical alert status information to a SOMDS Medical Alert Consumer system, including alert delegation.

- 1900 Every SOMDS Medical Alert Provider is paired with a SOMDS Provider actor that defines all the foundational capabilities for participating in a SOMDS network instance, including system and service discovery, connection establishment and health information retrieval and service invocation from SOMDS Provider actors. Additional capability requirements are defined for this actor to ensure that all medical alert information is safely, securely, and effectively managed.

- 1905 See section *12.5 SDPi-A Safety, Effectiveness, Security Considerations and Requirements* for details on the “medical” requirements for this actor. Note that these SES requirements include comprehensive support for the *ISO/IEEE 11073-10702 Standard for Alert Provisioning by Participants in a Service-Oriented Device Connectivity (SDC) System* (draft) standard.

- 1910 A SOMDS Medical Alert Provider actor may simply support reporting of its medical (and non-medical) alert conditions to one or more consumer actors. Additionally, it may also support alert delegation, allowing the actor to establish a “contract” with a SOMDS Medical Alert Consumer system for the annunciation of its alert conditions. See *12.4.1.1 Alert Delegation* for more information.

A single system may support both medical alert provider and consumer actor capabilities. For example, it may consume medical alert information as well as medical data, from multiple

provider systems, analyze the information and then generate its own “smart alert” condition to be provided to other “consumer” systems.

- 1915 A provider system may also support receipt of user alert acknowledgement updates from a SOMDS Medical Alert Consumer system, indicating whether a clinician has (directly or indirectly) received and responded to the alert conditions of a provider actor. See *12.4.1.2 Acknowledging Alert Conditions* below.

12.1.1.3 SOMDS ACM Gateway

- 1920 Actor Summary Definition: **[to be copied to Appendix A – Actor Summary Definitions above]**
- A SOMDS network participant that supports the bi-directional exchange of medical alert information with non-SOMDS systems and applications using IHE Alert Communication Management (ACM) transactions.
- 1925 SOMDS ACM Gateway actors shall be grouped with a SOMDS V2 Gateway actor to support the core specifications for protocol-level exchange between SOMDS-based and V2 message-based network environments. This gateway actor supports medical alert information exchange using IHE Alert Communication Management (ACM) profile transactions⁹.
- The gateway actor shall include SOMDS Medical Alert Consumer (for SOMDS-to-ACM) or SOMDS Medical Alert Provider (for ACM-to-SOMDS) actors to interact with other SOMDS
- 1930 Participant systems. In this way, the actor may support bi-directional communication between the two environments, supporting the access and exchange of medical alert information and services to and from a SOMDS network instance.
- Note that in *Figure 12.1-1: SDPi-A Actor Diagram* above, only DEV-04 and DEV-05 transactions are supported by the SOMDS ACM Gateway; out-of-scope is the communication of alert conditions using ACM Alert Communicator (AC) actor to clinicians in the enterprise. Also support for alert delegation is out-of-scope for this gateway actor.
- 1935 SDPi-A primarily provides for alert “distribution” *within* a single SOMDS network instance (e.g., systems around a single surgery point-of-care); however, the use context may also require the ability to distribute alert conditions *external* to the SOMDS environment. The SOMDS
- 1940 ACM Gateway actor provides support for this SOMDS external alert dissemination requirement.
- Note that the DEC-05 transaction may be received by a SOMDS gateway from an ACM actor; however, generation of DEC-05 transactions from a SOMDS ACM Gateway to ACM actors is out-of-scope for the SDPi-A profile.
- 1945 No additional requirements are made on the implementation architecture of the gateway actor beyond those specified in the IHE ACM profile for the AR and ACON actors. Note that the gateway may define SOMDS services for interacting with ACM-based actors, including registering a gateway-based ACM Alert Consumer (ACON) actor to receive and provide alert information from other non-SOMDS systems to SOMDS Consumer actors.

1950 Since this gateway actor includes at least one of the other SOMDS medical alert actors, it shall also support the SES requirements detailed in section *11.5 SDPi-R Safety, Effectiveness, Security Considerations and Requirements*, as well as the SES requirements specified in the *ISO/IEEE 11073-10702 Standard for Alert Provisioning by Participants in a Service-Oriented Device Connectivity (SDC) System* (draft) standard.

1955 The SOMDS ACM Gateway may also be implemented in systems that integrate other gateway actors, such as the SOMDS DEC Gateway.

12.2 SDPi-A Actor Options

12.2.1 Alert Delegation

<reference possible support for this function>

12.2.1 Alert User Acknowledgement

1960 <include overview of this option and the transactions that it includes + possible PCD-05 to gateway (or FROM gateway!)>

12.3 SDPi-A Required Actor Groupings

12.4 SDPi-A Overview

1965 12.4.1 Concepts

12.4.1.1 Medical Alerting and SES MDI Risk Management

[Editor's Note: Explain the general topic of alerts / alarms in medical devices as a RCM. Integrate with SES MDI below. Indicate related standards including 14971 and 80001-1 and 80001-2-5 etc.]

1970 12.4.1.1 Alert Delegation

[Editor's Note: Explain the general idea (again?) of alert delegation and the role that -A plays but in conjunction with the other three SDPi profiles]

12.4.1.2 Acknowledging Alert Conditions

1975 [Editor's Note: Explain the various ways in which alert conditions may be clinician / user / app acknowledged to an originating device. Include relationship with Alert Delegation as well as Alert Dissemination (DEC-05 below)]

12.4.1.3 Integration with Alert Communication Management Profile (ACM)

[Editor's Note: Explain the use of the SDPi-P SOMDS V2 Gateway actor to integrate with ACM capabilities. This should lead into the next DIS / DAS / CDAS section.]

1980

Also consider this or a related section for addressing “enterprise” vs. bedside alerting and the future use of FHIR and the SOMDS FHIR Gateway.]

12.4.1.4 IEC 60601-1-8 DIS / DAS / CDAS Considerations

1985

[Editor's Note: Capture the mapping of SDPi incl. SDPi-A actors to the DIS / DAS / CDAS 60601-1-8 constructs.]

12.4.2 Use Cases

12.4.2.1 Use Case #1: <simple name>

1990

12.4.2.1.1 <simple name> Use Case Description

12.4.2.2 Use Case #2: Silent ICU

<One or two sentence simple description of this particular use case.>

[Editor's Note: So how do we craft these sections with 20-30 scenarios? !!!!!!!]

1995

Reference separate use case analysis files? Detailed REQUIREMENTS in ReqIF will be contained ... else where]

12.4.2.2.1 Silent ICU Use Case Description

<Describe the key use cases addressed by the profile. Limit to a maximum of one page of text or consider an appendix.>

12.4.2.2.2 Silent ICU Process Flow

2000

<sequence diagram>

Pre-conditions:

<Very briefly (typically one sentence) describe the conditions or timing when this content module would be used.>

2005

Main Flow:

<Typically in an enumerated list, describe the clinical workflow when, where, and how this content module would be used.>

2010 **Post-conditions:**

<Very briefly (typically one sentence) describe the state of the clinical scenario after this content module has been created including examples of potential next steps.>

2015 **12.5 SDPi-A Safety, Effectiveness, Security Considerations and Requirements**

12.5.1 SES General Considerations

<SDPi content here>

The security considerations for a content module are dependent upon the security provisions defined by the grouped actor(s).

2020 **12.5.2 Safety Requirements & Considerations**

12.5.3 Effectiveness Requirements & Considerations

12.5.4 Security Requirements & Considerations

2025

12.6 SDPi-A Cross Profile Considerations

2030 **13 Service-oriented Device Point-of-care Interoperability – external Control (SDPi-xC) Profile**

[Editor’s Note: Replicate & adapt content from 12 above]

13.1 SDPi-xC Actors, Transactions, and Content Modules

2035 This section defines the actors, transactions, and/or content modules in this profile. General definitions of actors are given in the Technical Frameworks General Introduction Appendix A. IHE Transactions can be found in the Technical Frameworks General Introduction Appendix B. Both appendices are located at http://ihe.net/Technical_Frameworks/#GenIntro

2040 Figure 13.1-1 shows the actors directly involved in the SDPi-xC Profile. The relevant transactions between them are detailed in the subsequent Table 13.1-1. Abstract Actors (i.e., those that provide common specifications that are utilized in other “concrete” or implementation actors) are indicated by names in *italics*, and with the actors that inherit their capabilities grouped in boxes with dotted lines and non-italics names. Actor groupings, including abstract with concrete are detailed in Section 13.3.

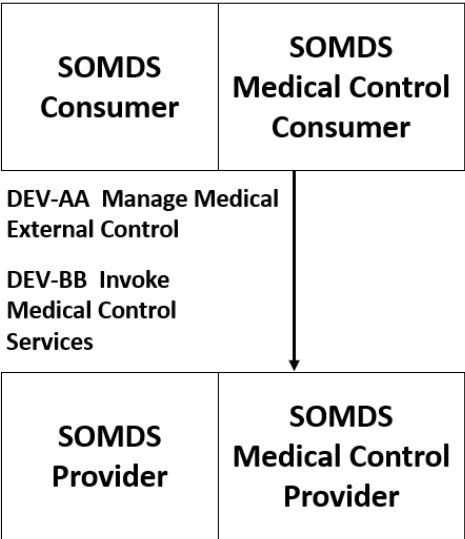


Figure 13.1-1: SDPi-xC Actor Diagram

[Editor’s Notes: Considerations / discussion for the actor diagram above]

- 1. NOTE this is a first iteration of the diagram – STARTER!
- 2. Discussion notes from review slides:

- 2050 a. Control is currently out-of-scope for SOMDS external entities (e.g., V2 / FHIR based)
- b. Question: All of these have “Establish...” what about “Manage ...” similar to SDPi-P’s manage subscription labeling
- 2055 c. DEV-BB sequence will be in TF-2, namely Retrieve Current Device State => Invoke Device Control => Verify Invocation
- d. Question: What about non-Medical Control? Should foundational transactions be added to SDPi-P or only here? SCO-related logic HERE only or also in SDPi-P?
- e. NOTE: SDPi-P has a basic “set” service transaction, but that is not intended for “MEDICAL” applications
- 2060 f. NOTE: That ALL the external control sequences in David G’s PlantUML World will get allocated in TF-2 Appendix A, reflected in TF-2 transaction descriptions and linked to actors ... here
- g. Is it “Service” or “Services”?

3. From initial review discussion 2020.09.11:

- 2065 a. Include safety class / “rejection” discussion from Confluence Topic page(s)
- 4.

Note: External control of SOMDS Medical Control Provider actors from outside a SOMDS network environment (e.g., via a gateway actor) is out-of-scope for the SDPi-xC actor.

- 2070 Table 13.1-1 lists the transactions for each actor directly involved in the SDPi-xC Profile. To claim compliance with this profile, an actor shall support all required transactions (labeled “R”) and may support the optional transactions (labeled “O”). Note that “Consumer” is indicated for actors that receive but do not directly respond to a specific transaction.

2075 **Table 13.1-1: SDPi-xC Profile - Actors and Transactions**

Actors	Transactions	Initiator or Responder	Optionality	Reference
SOMDS Medical Control Provider	Manage Medical External Control	Responder	R	DEV TF-2:3.44
	Invoke Medical Control Services	Responder	R	DEV TF-2:3.45
SOMDS Medical Control Consumer	Manage Medical External Control	Initiator	R	DEV TF-2:3.44
	Invoke Medical Control Services	Initiator	R	DEV TF-2:3.45

13.1.1 Actor Descriptions and Actor Profile Requirements

13.1.1.1 SOMDS Medical Control Consumer

2080 Actor Summary Definition: [to be copied to Appendix A – Actor Summary Definitions above]

A SOMDS network participant that supports one or more medical key purposes for managing and invoking external control services from a SOMDS Medical Control Provider system.

2085 Every SOMDS Medical Control Consumer is paired with a SOMDS Consumer actor that defines all the foundational capabilities for participating in a SOMDS network instance, including system and service discovery, connection establishment and health information retrieval and service invocation from SOMDS Provider actors. Additional capability requirements are defined for this actor to ensure that all SOMDS participant external control capabilities are safely, securely, and effectively managed.

2090 <seems like there should be additional descriptive info here ... ??? Or in the 13.4.1 Concepts section?>

See section *13.5 SDPi-xC Safety, Effectiveness, Security Considerations and Requirements* for details on the “medical” requirements for this actor. Note that these SES requirements include comprehensive support for the *ISO/IEEE 11073-10703 Standard for External Control Provisioning by Participants in a Service-Oriented Device Connectivity (SDC) System* (draft) standard.

2095

13.1.1.2 SOMDS Medical Control Provider

Actor Summary Definition: [to be copied to Appendix A – Actor Summary Definitions above]

2100 A SOMDS network participant that supports one or more medical key purposes for providing external control services to a SOMDS Medical Control Consumer system.

2105 Every SOMDS Medical Control Provider is paired with a SOMDS Provider actor that defines all the foundational capabilities for participating in a SOMDS network instance, including system and service discovery, connection establishment and health information retrieval and service invocation from SOMDS Consumer actors. Additional capability requirements are defined for this actor to ensure that all medical control services are safely, securely, and effectively managed.

See section *13.5 SDPi-xC Safety, Effectiveness, Security Considerations and Requirements* for details on the “medical” requirements for this actor. Note that these SES requirements include comprehensive support for the *ISO/IEEE 11073-10703 Standard for External Control*

- 2110 *Provisioning by Participants in a Service-Oriented Device Connectivity (SDC) System* (draft) standard.

13.2 SDPi-xC Actor Options

13.2.1 <Option Name>

- 2115 **13.3 SDPi-xC Required Actor Groupings**

13.4 SDPi-xC Overview

13.4.1 Concepts

13.4.2 Use Cases

- 2120 [Editor's Note: consider including ICE 2700 safety interlock use cases ... + Synchronization with safety interlock <e.g., pause vent while taking image> in Compendium]

13.4.2.1 Use Case #1: <simple name>

13.4.2.1.1 <simple name> Use Case Description

13.5 SDPi-xC Safety, Effectiveness, Security Considerations and Requirements

- 2125 **13.5.1 SES General Considerations**

<SDPi content here>

The security considerations for a content module are dependent upon the security provisions defined by the grouped actor(s).

13.5.2 Safety Requirements & Considerations

2130

13.5.3 Effectiveness Requirements & Considerations

13.5.4 Security Requirements & Considerations

2135

13.6 SDPi-xC Cross Profile Considerations

Appendices to Volume 1

- 2140 *<Add appendices to Volume 1 for this profile here. Examples of an appendix include HITSP mapping to IHE Use Cases or long use case definitions.>*
- <If there are no Volume 1 appendices, enter “Not applicable” and delete the Appendix A and Appendix B placeholder sections.>*
- 2145 *<Volume 1 appendices are informational only. No “SHALL” language is allowed in a Volume 1 Appendix.>*

Appendix A – Requirements Management for Plug-and-Trust Interoperability

[Editor’s Note: The content for this section is primarily from the CA & Tooling sections of the SDPi+FHIR confluence site.

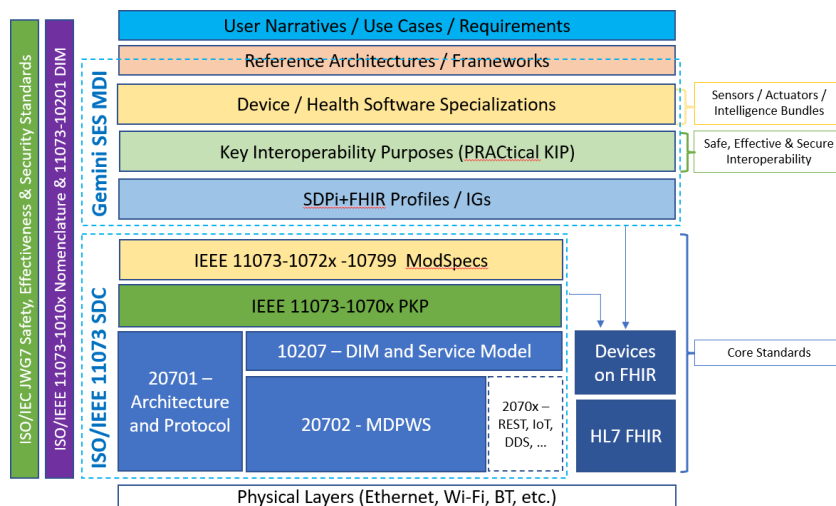
AND A NOTE ABOUT SECTIONLESS CONTENT – Although the IHE Template allows – typically encourages – content after a section title and before subsection titles, this is generally not a style that other standards bodies have – and will not be supported here ... hopefully]

A.1 Requirements: From Narratives to Plug-and-Trust Interfaces

A.1.1 Hanging Gardens “Layers” Model

<include content from confluence pages>

<include Hanging Gardens Model – content from slide deck>



[UPDATE TO LATEST VERSION!]

Figure A.1.1-1: Hanging Gardens Model

<explain the model>

2165 **A.1.2 ISO/IEEE 11073 SDC Components**

A.1.3 Reference Frameworks – IHE and MDIRA / ICE

A.1.4 Assurance Case Integration as Basis of Trust

2170 <leverage the assurance case strategy from the SES MDI WP>

A.1.5 <other subsections>

2175 **A.2 Integrating Safety, Effectiveness & Security Requirements & Considerations**

<provide perspective on SES MDI requirements>

<KIP Layer linkage>

<Ecosystem of SES trusted interoperable DECOUPLED products>

<Dynamic TRUSTED product coupling at Plug-and-Trust logical connection establishment>

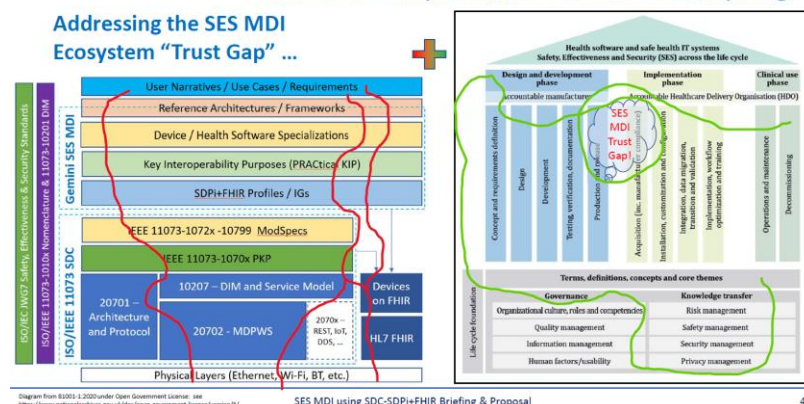
2180 <Reference the SES MDI white paper>

<???include SES MDI problem graphic?>

<Note: where does the Assurance Case component integrate into this appendix?>

A Framework for *Trusted Interoperable Product Decoupling*

Addressing the SES MDI Ecosystem “Trust Gap” ...



2185

Figure A.2-1: SES MDI Trust Gap Framework Proposal

A.2 Requirements Capture, Mapping & Traceability Layer-to-Layer

2190 <explain need and general strategy>

A.3 Specifying SystemFunctionContribution (SFC) for Plug-and-Trust Interfaces

<mention assurance case integration / results support>

<interlinking of plug-and-trust assurance cases to achieve clinical level integrated assurance>

2195 A.4 Requirements Management using Gherkin & ReqIF

A.4.1 Use Case Formalization using Gherkin

A.4.2 Requirements Specification using ReqIF

2200

A.4.3 Mapping ReqIF from Scenarios to Interfaces

A.5 Approach for integrating ReqIF into the IHE DEV Technical Framework

2205 <detail strategy for integrating the above into this DEV TF>

<include what is in separate companion specification files>

<Note SDPi requirements primary requirements application:

SDC Standards	Primary TF Volume	Linked / Secondary Volumes
BICEPS	TF-3	TF-1
SOMDA	TF-2	TF-1
MDPWS	TF-2	
PKP	TF-1 ???	

ModSpec	Tf-1	TF-3

>

2210

Appendix B – ISO/IEEE 11073 SDC Requirements Coverage

B.1 Implementation Conformance Statement (ICS) Table Overview

2215 Each of the ISO/IEEE 11073 SDC standards utilized in the SDPi profiles defines a set of Implementation Conformance Statement (ICS) tables that provide a common way to declare what capabilities of the standard are included in an implementation. This is especially true for conditional or optional capabilities or alternatives and extensions that are defined.

2220 The ICS tables included in this appendix are copied from the indicated published version of the standard (e.g., 2017), and have an added column indicating how each row is addressed in the SDPi profiles. When appropriate, the specific IHE Devices technical framework sections are linked to facilitate review and use.

Additional IEEE 11073 SDC standards are currently in development, as indicated in the *A.1.1 Hanging Gardens “Layers” Model* above, namely:

IEEE 11073-1070x SDC Participant Key Purposes (PKP) Standards

IEEE 11073-1072x SDC Device Specialization “Module Specifications” (ModSpecs)

2225 When these standards are published and their capabilities and requirements integrated into the SDPi profiles, their ICS tables will added to this appendix as well.

[Editor’s Notes:

1. Is there a computable representation for these tables?
2. Is there a linkage to the SFC or CA/test tooling etc.?
- 2230 3. Will these standards have ReqIF representations that we can then map to the SDPi Capabilities & Requirement provisions?
4. Is there any issue with including ALL the text from the conformance tables?

]

2235 NOTE: Some of the ICS table rows are designated as the subject of errata for the related standard. Change “tickets” have been opened for each of these and will be addressed either in the next revision of the standard or in a companion corrigenda or addendum document.

B.2 ISO/IEC 11073-10207 BICEPS ICS Tables

Standard Version: IEEE 11073-10207:2017

[Editor’s Notes:

- 2240 1. Should this Appendix be made a section and shifted to landscape to better accommodate the additional columns?
2. The content below should be updated for a more general audience – some of the notes are more editorial than appropriate for the published version of the TF supplement.

2245

3. The Word Style for the copy & pasted tables below has to be normalized to the IHE TF Style Guide.]

B.2.1 General

NOTE: GEN-1 & GEN-4 are broken references, GEN-2 and GEN-3 are satisfied by Glue, GEN-4 should be mandatory as extensions.

2250

[Editor's Note: Update style and format of table below and review before updating rest.

Also note that THIS is the actual table from the standard ... hmmm ...

Table 20—General ICSSs

Index	Feature	Reference	Status	Support	Comment
GEN-1	pm:ComponentActivation state	5.4.5	m		Support required to increase interoperability
GEN-2	Authorization capabilities	R0083	n/a		Requirement that addresses authorization binding in another standard that is used by a comprehensive implementation
GEN-3	Quality-of-Service metrics	R0092	n/a		Requirement that addresses authorization binding in another standard that is used by a comprehensive implementation
GEN-4	Wrapped extension elements	ext:Extension	o		Does not affect interoperability.

]

2255

Index	Feature	Reference	Text	SDPi Profiles
GEN-1	pm:ComponentActivation state	Clause 5.3.4	A pm:MdDescription MAY possess zero or more pm:MdsDescriptor objects. The pm:MdsDescriptor object is depicted in Figure 3 as MDS.	
GEN-2	Authorization capabilities	R0083	A BICEPS BINDING SHOULD provide means to enable authorization capabilities between PARTICIPANTs.	
GEN-3	Quality-of-Service metrics	R0092	A BICEPS BINDING SHOULD provide means to define Quality-of-Service metrics for communication between two PARTICIPANTs.	
GEN-4	Wrapped extension elements	ext:Extension	Optional element definition for extensions.	

B.2.2 Service Provider

Optional requirements for the service provider side excluding contexts and external control.

Index	Feature	Reference	Text
PROV-1	Same handle on same object	R0099	If a SERVICE PROVIDER removes and reinserts the same CONTAINMENT TREE ENTRY of an element in the CONTAINMENT TREE beyond one MDIB sequence, it SHOULD use the same HANDLE for that CONTAINMENT TREE ENTRY.
PROV-2	Only standardized CODED VALUES used	R0008	A SERVICE PROVIDER SHOULD use standardized values for CODE and CODING SYSTEM in order to specialize a CONTAINMENT TREE ENTRY if available.
PROV-3	ISO/IEEE 11073-10101 nomenclature	R0128	A SERVICE PROVIDER SHOULD use the ISO/IEEE 11073-10101 and IEEE 11073-10101a-2015 nomenclature whenever there is an appropriate CODE available.
PROV-4	Provide remote capabilities	R0011	A SERVICE PROVIDER SHOULD describe all offered remote invocation capabilities using the pm:ScoDescriptor structure in pm:MdsDescriptor/pm:Sco.
PROV-5	Reject remote control if reports are not subscribed	R0057	A SERVICE PROVIDER SHOULD reject an incoming request-response SERVICE OPERATION call on the SET SERVICE if the SERVICE CONSUMER has not subscribed to msg:OperationInvokedReport MESSAGES in advance.
PROV-6	Announce absence, i.e., SERVICE PROVIDER does not send MESSAGES for a certain time	R0074	A SERVICE PROVIDER SHOULD announce its upcoming absence if it is switching to a mode where it is not ready to exchange MESSAGES with a SERVICE CONSUMER temporarily. <i>[will be resolved in Base PKP]</i>
PROV-7	Non-functional requirements	R0082	An MDIB SHOULD include nonfunctional requirements in its descriptive part.
PROV-8	Include parent MDS descriptor in result	msg:GetMdDescriptionResponse/ msg:MdDescription	<i>[important if multiple MDSs per MDIB exist; but: multiple MDSs per MDIB should be forbidden and realized by multiple device instead]</i>
PROV-9	Include METRIC retrievability as extension	msg:Retrievability	<i>[was made mandatory in Glue]</i>
PROV-10	Increase of instance identifier	pm:MdibVersionGroup/ pm:InstanceId	<i>[if demanded; no significant effect on interoperability]</i>

PROV-11	Slot usage	pm:AlertSignalState/ pm:Slot	<i>[if demanded; no significant effect on interoperability]</i>
PROV-12	Body site states	pm:AbstractMetricState/ pm:BodySite	<i>[if demanded; no significant effect on interoperability]</i>

2260

B.2.3 Service Consumer

CONS-1 is broken; R0115 is not optional in the released document.

Index	Feature	Reference	Text
CONS-1	Interpretation of pm:AlertSignalState/@Presence	R0115	While pm:AlertSignalState/@ActivationState is “Off,” a SERVICE CONSUMER SHALL NOT interpret pm:AlertSignalState/@Presence.

2265

B.2.4 Remote Control

Index	Feature	Reference	Text
SCO-1	Provide remote capabilities	R0011	<i>[Same as PROV-4 – if remote control is supported, R0011 should be mandatory]</i>
SCO-2	Context state create and update.	msg:SetContextState/ msg:ProposedContextState	ProposedContextState comprises the context states that have to be inserted or updated: — If ProposedContextState/@Handle is equal ProposedContextState/@DescriptorHandle, the proposed object SHOULD be created as a new context state. — If ProposedContextState/@Handle is not equal ProposedContextState/@DescriptorHandle, the proposed object SHOULD be modified. <i>[if demanded; significant effect on interoperability]</i>

B.2.5 Context Processing

2270

Context processing pertains to effective utilization of context information like workflow (e.g., orders) info, patient demographics and locations. A general concept should be described how to cope with contexts in terms of SDPi, i.e. device coupling mechanisms should be described informally in TF-1 and formally in TF-2 (as transaction?).

Index	Feature	Reference	Text
CTXT-1	Patient context	R0014	If a SERVICE PROVIDER or POC MEDICAL DEVICE is, e.g., capable of determining to which patient the POC MEDICAL DEVICE is currently connected to, this capability SHOULD be expressed in the MDS context with a <code>pm:PatientContextDescriptor</code> .
CTXT-2	Location context	R0015	If a SERVICE PROVIDER or POC MEDICAL DEVICE is, e.g., capable of determining in which location the POC MEDICAL DEVICE is currently operated, this capability SHOULD be expressed in the MDS context with a <code>pm:LocationContextDescriptor</code> .
CTXT-3	Workflow context	R0016	If a SERVICE PROVIDER or POC MEDICAL DEVICE is, e.g., capable of determining in which clinical workflow the POC MEDICAL DEVICE is currently participating, this capability SHOULD be expressed in the MDS context with a <code>pm:WorkflowContextDescriptor</code> .
CTXT-4	Operator context	R0017	If a SERVICE PROVIDER or POC MEDICAL DEVICE is, e.g., capable of determining who is currently operating the POC MEDICAL DEVICE, this capability SHOULD be expressed in the MDS context with a <code>pm:OperatorContextDescriptor</code> .
CTXT-5	Means context	R0018	If a SERVICE PROVIDER or POC MEDICAL DEVICE is, e.g., capable of determining which virtual or physical means the POC MEDICAL DEVICE is using, this capability SHOULD be expressed in the MDS context with a <code>pm:MeansContextDescriptor</code> .
CTXT-6	Ensemble context	R0019	If a SERVICE PROVIDER or POC MEDICAL DEVICE is, e.g., capable of determining in which logical group the POC MEDICAL DEVICE is currently operated, this capability SHOULD be expressed in the MDS context with a <code>pm:EnsembleContextDescriptor</code> .
CTXT-7	Context state create and update.	<code>msg:SetContextState/</code> <code>msg:ProposedContextState</code>	[See SCO-2]
CTXT-8	Express quality of measurements regarding patient context related information	R5012	If the POC MEDICAL DEVICE itself has patient-related observations (e.g., weight, height) as in- or output, these SHOULD be modelled as METRICS. <i>[is validated patient context data good enough from the quality perspective or not?]</i>

2275

B.3 ISO/IEC 11073-20701 SOMDA ICS Tables

Standard Version: IEEE 11073-10207:2018

B.3.1 MDIB Version

2280

<...>

Index	Feature	Reference	Text
MDIBV-1	UUIDv5 Algorithm	Clause 7.5	An SDC SERVICE PROVIDER SHOULD determine the pm:MdibVersionGroup/@SequenceId using the UUIDv5 algorithm when the PoC MEDICAL DEVICE possesses at least one UDI

B.3.2 Handle-based Filtering

<...>

Index	Feature	Reference	Text
HBF-1	Handle-based Filtering Support for SDC SERVICE CONSUMER	R0037	An SDC SERVICE CONSUMER SHOULD subscribe to EVENT SOURCES using the Handle-based Filter Dialect in a wse:Subscribe MESSAGE if it is interested only in certain CONTAINMENT TREE ENTRY changes with a defined set of pm:Handle.
HBF-2	Handle-based Filtering Support for SDC SERVICE PROVIDER	R0039	An SDC SERVICE PROVIDER SHOULD support filtering by the Handle-based Filter Dialect.

2285

B.3.3 Cyber-Security

<...>

Index	Feature	Reference	Text
CS-1	Common Name in X.509 certificates	R0045	As Common Name of the Distinguished Name in X.509 certificates an SDC PARTICIPANT SHOULD use the PRIMARY UDI of the PoC MEDICAL DEVICE in UUIDv5 form as described in 7.5. <i>[should be mandatory, if an SDC PARTICIPANT has a UDI]</i>
CS-2	Integrity Protection for Header Field MESSAGEs	R0046	An SDC PARTICIPANT SHOULD NOT send a SOAP ENVELOPE without protecting the integrity of any Message Information Header blocks matching the following XPath expressions
CS-3	Utilize the highest TLS version	R0064	An SDC PARTICIPANT SHOULD utilize the highest TLS version.

B.3.4 Discovery

<...>

Index	Feature	Reference	Text
DIS-1	Location Context Details	Clause Error! Reference source not found.	An SDC SERVICE PROVIDER SHOULD provide the following ATTRIBUTES in pm:LocationContextState/pm:LocationDetail if the SDC SERVICE PROVIDER is providing pm:LocationContextState/pm:LocationDetail. - LocationDetail/@Facility - LocationDetail/@PoC - LocationDetail/@Bed
DIS-2	Announce Absence	R0004	
DIS-3	MDS-Based Discovery	Error! Reference source not found.	For every instance derived from pm:AbstractComplexDeviceComponentDescriptor in the MDIB an SDC SERVICE PROVIDER SHOULD include a URI-encoded pm:AbstractComplexDeviceComponentDescriptor/pm:Type as dpws:Scope of the MDPWS discovery messages. <i>[should be made mandatory for MDS, optional for VMDs]</i>
DIS-4	Context-Based Discovery	9.4	For every associated context in the MDIB an SDC SERVICE PROVIDER SHOULD include a URI-encoded pm:AbstractContextState/pm:Identification as dpws:Scope of the MDPWS discovery messages. <i>[Mandatory for locations and ensembles if that's in accordance with privacy laws]</i>
DIS-5	SDC Participant Key Purpose based Discovery	9.3	For every SDC PARTICIPANT KEY PURPOSE that is also defined using the mechanisms for Trust Establishment (see 10.2.3), an SDC SERVICE PROVIDER SHOULD include a URI-encoded SDC PARTICIPANT KEY PURPOSE as dpws:Scope of the MDPWS discovery messages. <i>[should be made mandatory for SDC Provider purpose only]</i>

2290

B.3.5 Quality of Service (QoS)

<...>

Index	Feature	Reference	Text
QoS-1	No Expedited Forwarding	R0016	An SDC PARTICIPANT SHOULD NOT mark any MESSAGE with Expedited Forwarding (EF) PHB. <i>[should be made mandatory]</i>
QoS-2	Assured Forwarding	R0017	
QoS-3	Alerts PHB Class	R0020	
QoS-4	Metrics PHB Class	R0021	
QoS-6	Information only CONTAINMENT TREE ELEMENTs Default PHB	R0023	

B.4 ISO/IEC 11073-20702 MDPWS ICS Tables

2295 Standard Version: IEEE 11073-10207:2016

B.4.1 General

General MDPWS optional requirements. None of them are mandatory and don't need to be mandatory in order to be interoperable.

2300

Index	Feature	Reference	Text
GEN-1	SOAP-over-UDP messaging	R0002	A SERVICE MAY reject a SOAP ENVELOPE received over UDP that has more than MAX_ _UDP_ENVELOPE_SIZE octets if it is received via the discovery port. Otherwise, it SHOULD NOT be rejected.
GEN-2	SOAP-over-UDP messaging	R0003	A CLIENT MAY reject a SOAP ENVELOPE received over UDP that has more than MAX_ _UDP_ENVELOPE_SIZE octets if it is received via the discovery port. Otherwise, it SHOULD NOT be rejected.
GEN-3	SOAP-over-HTTP messaging	R0006	A SERVICE SHOULD NOT send a TEXT SOAP ENVELOPE with more than MAX_LARGE_ENVELOPE_SIZE octets.
GEN-4	Service Description	R0012	If a HOSTED SERVICE receives a MESSAGE that is inconsistent with its WSDL description, the HOSTED SERVICE SHOULD generate a SOAP Fault with a Code Value of "Sender", unless a "MustUnderstand" or "VersionMismatch" Fault is generated.

B.4.2 Streaming

Streaming is a feature of MDPWS to allow sending waveform streams via UDP multicast. Streaming is an optional feature that is not recommended to be used as the data is conveyed using an unsecured channel, and securing the channel requires extra, non-standard-conforming efforts (establishing a shared key between participants in the UDP multicast cast group). If streaming needs to be supported, every ICS statement except for STRM-4 should be made mandatory.

2305

Index	Feature	Reference	Text
STRM-1	SOAP-over-UDP messaging	R0002	A SERVICE MAY reject a SOAP ENVELOPE received over UDP that has more than MAX_UDP_ENVELOPE_SIZE octets if it is received via the discovery port. Otherwise, it SHOULD NOT be rejected.
STRM-2	SOAP-over-UDP messaging	R0003	A CLIENT MAY reject a SOAP ENVELOPE received over UDP that has more than MAX_UDP_ENVELOPE_SIZE octets if it is received via the discovery port. Otherwise, it SHOULD NOT be rejected.
STRM-3	Message sequencing	R0027	If the AppSequence header from [WS-Discovery] is used to establish MESSAGE sequence numbering, the SequenceId attribute SHOULD be set to the wsa:action URI of the transmitted MESSAGE and the MessageNumber attribute SHALL be incremented by 1.
STRM-4	Ability of dereferencing target namespace	Clause Error! Reference source not found.	ATTRIBUTE defines the namespace affiliation of the Stream Types declared within the StreamDescriptions. Its value SHALL be an absolute IRI [RFC 3987]. It SHOULD be dereferenceable .

2310

B.4.3 Safe Data Transmission

Safe data transmission pertains to single-fault safety and safety contexts. Safe data transmission is an optional feature that requires implementations to process and expose XML on their APIs, hence it is recommended to only be used in very specific scenarios with pre-defined attribution.

2315 If dual-channel (single-fault safety) is used, SAFE-2 and SAFE-3 ought to be mandatory.

Index	Feature	Reference	Text
SAFE-1	Safety Requirements Advertising	R0029	A DEVICE SHOULD indicate its feature support of clause 9 of this standard by including the SafetyReqAssertion within its WSDL.
SAFE-2	Representation Generation Algorithms	R0036	A DEVICE SHOULD support mdpws:HexSHA1 if safety-related transmission with a second channel is required.
SAFE-3	Transformation Algorithms	R0039	A DEVICE SHOULD support mdpws:xml-exc-c14n if safety-related transmission with a second channel is required.

B.4.4 Compact Representation

2320 An efficient representation of XML is called EXI. EXI is an optional feature, potentially being a candidate for effective and efficient compression. Unfortunately, there is barely any support for EXI in the market and a custom implementation comes at tremendous costs. Hence, it is not recommended to use EXI, but rather switch to gzip or LZ4 which can be negotiated by means of HTTP. HTTP-based compression is not XML-aware and hence XML needs to be serialized first, then to be compressed, whereas EXI instantly generates a compressed data stream from XML

2325 infosets.

If EXI is used, CP-1 and CP-2 are completely free to support or not as this only affects the resulting compression rate.

Index	Feature	Reference	Text
CP-1	EXI	R0022	If a DEVICE supports EXI, then it SHOULD support schema-informed EXI streams with compressed option set to true and default values for the other Options [EXI10].
CP-2	EXI	R0023	If a CLIENT supports EXI, then it SHOULD support schema-informed EXI streams with compressed option set to true and default values for the other Options [EXI10].

2330 B.4.5 Secured Discovery

WS-Discovery comes with a mode that supports message integrity, called compact signatures. Compact signatures facilitate participants to trust any information that is received over multicast. However, computing compact signatures is expensive and hence might be out of scope for resource constrained devices. Compact signature should never be a mandatory feature.

2335

Index	Feature	Reference	Text
SEC-1	Security of Probe MESSAGES	R0015	A DEVICE SHOULD support receiving and responding to a Probe SOAP ENVELOPE over HTTP using a SECURE CHANNEL.

Appendix C – Device Point-of-care Interoperability (DPI) Use Cases

[Editor's Notes:

- 2340 1. This is a PLACE HOLDER TBD Appendix ... MAY BE DELETED BEFORE END
2. Detailed use case / scenario analysis w/ Gherkin details & ReqIF linkage would be HERE vs. elsewhere
3. Question: Should this be an MDI Appendix or DPI?
- 2345 4. Question: Should this detail be in collateral files for this SDPi Supplement vs. in the actual document? [note from above that ReqIF detail would be in a separate file]

]

C.1 Overview of DPI Narratives, Use Cases & Scenarios

[Editor's Notes:

- 2350 1. Note this section should reference Appendix A + the profiles use case sections
2. It should address supplement 1.0 detailed use cases (in subsequent sections) as well as ...
3. Identify use cases that might be used in the future for SDPi revisions after 1.0
4. Include by reference / directly the process for formalizing use case based requirements (per the Editor's Notes section above)
- 2355 5. Identify ICE-related use cases that may be integrated in SDPi or in the forthcoming MDIRA profile

]

C.2 <specific groupings of use cases w/ Gherkin detail>

2360

Volume 2 – Transactions

Add Section 3.23 and subsequent transactions for SDPi profiles

3.23 Announce Network Presence [DEV-23]

2365 3.23.1 Scope

This transaction is used to notify all SOMDS Consumer that a service provider system is connected to the network and ready to exchange messages with other SOMDS Participants.

3.23.2 Actor Roles

The actors in this transaction play the following roles:

2370 **Table 3.23.2-1: Actor Roles**

Actor:	SOMDS Provider
Role:	Broadcasts the transaction to all listing consumer systems.
Actor:	SOMDS Consumer
Role:	Listens for this transaction to identify any provider systems that it may want to establish a connection with and further discover a provider's service capabilities.

3.23.3 Referenced Standards

- ISO/IEEE 11073-10207 (2017), Section 9.2 Implicit Discovery

2375 [NOTE: These are just captured for ease of integration ... will be deleted once complete:

- R0073: A SERVICE PROVIDER SHALL announce its presence if it is ready to exchange MESSAGEs with a SERVICE CONSUMER.
- R0074: A SERVICE PROVIDER SHOULD announce its upcoming absence if it is switching to a

2380 mode where it is not ready to exchange MESSAGEs with a SERVICE CONSUMER temporarily.

- R0075: A SERVICE PROVIDER SHALL include a *unique identifier* in a discovery MESSAGE that allows a SERVICE CONSUMER to identify the SERVICE PROVIDER.

- 2385
- R0076: A SERVICE PROVIDER SHALL include a *discovery type* in a discovery MESSAGE that allows a SERVICE CONSUMER to identify if the SERVICE PROVIDER is compliant with BICEPS.
- R0078: A BICEPS BINDING SHALL provide means for implicit discovery.
- 2390
- ISO/IEEE 11073-20701 (2018), section 9.1
 - ISO/IEEE 11073-20702 (2016), section 5

3.23.4 Messages

The following sequence diagram overviews the message(s) exchange in this transaction:

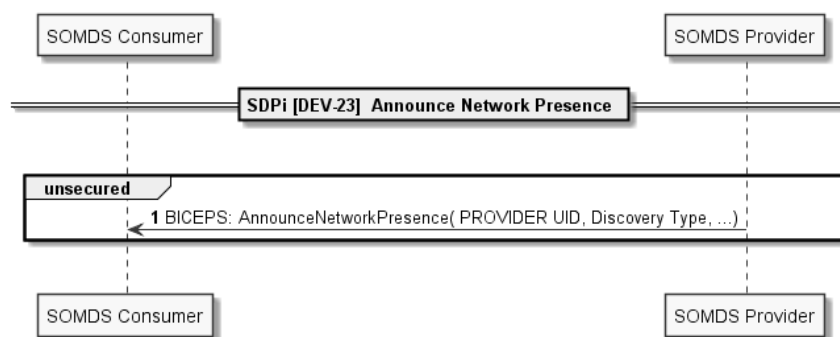


Figure 3.23.4-1: DEV-23 Messaging Interaction Diagram

[Editor’s Note: This BICEPS “message” is not explicitly defined in the standard, but the text and parameters are “extracted” from the text. TBD if the semantics should be extended in BICEPS or SOMDA]

3.23.4.1 BICEPS Announce Network Presence Message

The AnnounceNetworkPresence() message is part of the SDC/BICEPS “implicit discovery” protocol for allowing SOMDS Consumer systems to receive a notification when a SOMDS Provider system is ready to receive messages from other SOMDS Consumer systems. This is a broadcast message that is sent from each provider system to all listening consumer systems (zero to many). Limited but sufficient information is provided with the message to enable consumer systems to determine if they are interested in connecting with the provider discovering additional information. Note that additional information may be provided to better facilitate the discovery process.

3.23.4.1.1 Trigger Events

This message is sent whenever

- (1) a SOMDS Provider system is connected to a network, or
- (2) when it is returning to normal “on-line” operation after having indicated temporary suspension of SOMDA exchanges (e.g., issuing a 3.34 *Announce Network Departure* [DEV-34] transaction).

2415 **3.23.4.1.2 Message Semantics**

<Detailed description of the meaning, structure and contents of the message, including any IHE specific clarifications of the message format, attributes, etc.>

2420 *<Start by describing the standard underlying the message and how the participating actors are mapped (e.g., “This message is a DICOM C-FIND Request. Actor A is the SCU. Actor D is the SCP.”)>*

<Continue profiling the message by providing guidance or constraints on how the message parameters are populated, how the payload is encoded, how the message is structured and what the contents mean. These message semantics should both help the sender to construct the message and the receiver to interpret the message.>

2425 **Provider UID**

Discovery Type

Additional info (“...”)

Note that these general BICEPS semantics shall be bound to specific protocol elements as indicated below.

2430 **3.23.4.1.3 Expected Actions**

<Description of the actions expected to be taken as a result of sending or receiving this message.>

<Describe what the receiver is expected/required to do upon receiving this message. >

2435 *<Avoid re-iterating the transaction sequencing specified in the Profile Process Flows as expected actions internal to the transaction. Doing so prevents this transaction being re-used in other contexts.>*

<Explicitly define any expected action based on the multiplicity of an actor(s), if applicable.>

2440 When a SOMDS Provider sends this message, there is no expected or required responses. This is due to the fact that either there are no SOMDS Consumer systems listening for announcement messages, or the information in the message (e.g., Discovery Type) is not of interest to any receiving consumers.

When a

3.23.5 Protocol Requirements

[Editor's Note:

- 2445 1. Note a “loop” algorithm is implemented in DEV-24 because DEV-23 is UNSECURED and may be spoofed!

]

2450 *<In this section, the selected protocol bindings of the transactions are explained in detail (like SOAP or HTTP bindings). For an example, see the QRPH DEX Profile or ITI TF-2b:3.34.5, 3.35.5. Indicate NA if not used.>*

As part of the SDC/BICEPS Implicit Discovery mechanism

By default, this message shall be bound to the MDPWS: Hello() message (see Appendix

3.23.6 Safety, Effectiveness, Security Requirements & Considerations

3.23.6.1 SES General Considerations

2455 *<Address any SES requirements & considerations that need to be managed; include linkages to assurance case template entries>*

[Editor's Note: The security below includes <Actor> specific considerations .. should that also be included in the SES components? What about message specific considerations?]

2460 [Editor's Note: This transaction is in UNSECURED mode ... need to call that out in general here and then add ??? to the .4 section below?]

3.23.6.2 Safety Requirements & Considerations

<Requirements for this transaction relating to safety (e.g., risk analysis)>

2465 3.23.6.3 Effectiveness Requirements & Considerations

<Requirements for this transaction relating to effectiveness (e.g., Quality of Service, Quality of Data, etc.)>

3.23.6.4 Security Requirements & Considerations

<Description of the transaction specific security consideration; such as use of security profiles.>

2470 3.23.6.4.1 Security Audit Considerations

<This section should identify any specific ATNA security audit event that is associated with this transaction and requirements on the encoding of that audit event. >

3.23.6.4.1.(z) <Actor> Specific Security Considerations

<This section should specify any specific security considerations on an actor-by-actor basis.>

2475 3.24 Discover Network Topology [DEV-24]

3.24.1 Scope

This transaction is used by SOMDS Consumers to explicitly search the network to identify any SOMDS Provider systems that match specified discovery criteria.

2480 3.24.2 Actor Roles

The actors in this transaction play the following roles:

Table 3.23.2-1: Actor Roles

Actor:	SOMDS Consumer
Role:	Broadcasts the discovery message to all listening SOMDS Provider systems.
Actor:	SOMDS Provider
Role:	Listens for these explicit discovery search messages, and if the discovery criteria match the provider system, it responds to the SOMDS Consumer indicating the matched criteria and providing information needed to establish a connection and further discover a provider's service capabilities.

3.24.3 Referenced Standards

- 2485
- ISO/IEEE 11073-10207 (2017), Section 9.3 Explicit Discovery
 - ISO/IEEE 11073-20701 (2018), section 9.1
 - ISO/IEEE 11073-20702 (2016), section 5

[Editor's Note:

- 2490
1. What about SOMDA 9.2ff for complex component-based discovery, PKP discovery, Context Based Discovery (Location, Patient, etc.)

]

3.24.4 Messages

The following sequence diagram overviews the message(s) exchange in this transaction:

2495

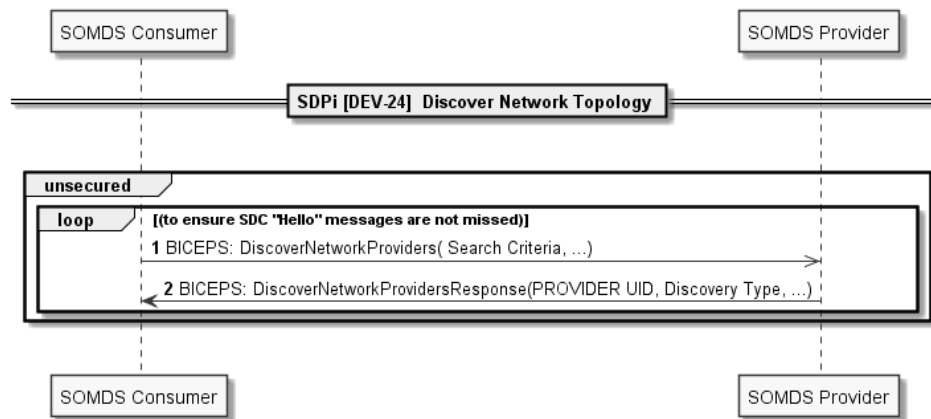


Figure 3.24.4-1: DEV-24 Discover Network Topology Interaction Diagram

2500

[Editor’s Note: This BICEPS “message” is not explicitly defined in the standard, but the text and parameters are “extracted” from the text. TBD if the semantics should be extended in BICEPS or SOMDA]

3.24.4.1 BICEPS DiscoverNetworkProviders() Message

2505

[Editor’s Note: The message name above “SDC Hello” is one approach for addressing the specific names of messages without tying them to the transaction (e.g., DEV23). These can then be addressed in detail in the appendix A, referenced to the SDC standards requirements numbers, matched with a specific SDC Library service, etc. etc. etc.]

2510

<One or two sentence summary of what Message 1 accomplishes typically relating the message to the relevant standard. Avoid shall language in this upper level section. Do not duplicate the triggers, encoding, semantics, standards used, or expected actions. Those belong in the following sections.>

<Explicitly state if the multiplicity of an actor may be greater than one; i.e., if an actor (whether it is a client or server) can expect this message from a single source or multiple sources.>

2515

3.24.4.1.1 Trigger Events

<Description of the real world events that cause the sender (Actor A) to send Message 1 (e.g., an operator or an automated function determines that a new workitem is needed).>

3.24.4.1.2 Message Semantics

2520 <Detailed description of the meaning, structure and contents of the message, including any IHE specific clarifications of the message format, attributes, etc.>

<Start by describing the standard underlying the message and how the participating actors are mapped (e.g., “This message is a DICOM C-FIND Request. Actor A is the SCU. Actor D is the SCP.”).>

2525 <Continue profiling the message by providing guidance or constraints on how the message parameters are populated, how the payload is encoded, how the message is structured and what the contents mean. These message semantics should both help the sender to construct the message and the receiver to interpret the message.>

3.24.4.1.3 Expected Actions

2530 <Description of the actions expected to be taken as a result of sending or receiving this message.>

<Describe what the receiver is expected/required to do upon receiving this message. >

<Avoid re-iterating the transaction sequencing specified in the Profile Process Flows as expected actions internal to the transaction. Doing so prevents this transaction being re-used in other contexts.>

2535 <Explicitly define any expected action based on the multiplicity of an actor(s), if applicable.>

3.24.4.2 BICEPS DiscoverNetworkProvidersResponse() Message

2540 <One or two sentence summary of what Message 2 accomplishes typically relating the message to the relevant standard. Avoid shall language in this upper level section. Do not duplicate the triggers, encoding, semantics, standards used, or expected actions. Those belong in the following sections.>

<Explicitly state if the multiplicity of an actor may be greater than one; i.e., if an actor (whether it is a client or server) can expect this message from a single source or multiple sources.>

<Repeat this section as necessary based on the number of messages in the interaction diagram.>

3.24.4.2.1 Trigger Events

2545 <Description of the real world events that cause the sender (Actor A) to send Message 1(e.g., an operator or an automated function determines that a new workitem is needed).>

3.24.4.2.2 Message Semantics

<Detailed description of the meaning, structure and contents of the message, including any IHE specific clarifications of the message format, attributes, etc.>

- 2550 <Start by describing the standard underlying the message and how the participating actors are mapped (e.g., “This message is a DICOM C-FIND Request. Actor A is the SCU. Actor D is the SCP.”).>
- <Continue profiling the message by providing guidance or constraints on how the message parameters are populated, how the payload is encoded, how the message is structured and what the contents mean. These message semantics should both help the sender to construct the message and the receiver to interpret the message.>
- 2555

3.24.4.2.3 Expected Actions

- <Description of the actions expected to be taken as a result of sending or receiving this message.>
- 2560 <Describe what the receiver is expected/required to do upon receiving this message. >
- <Avoid re-iterating the transaction sequencing specified in the Profile Process Flows as expected actions internal to the transaction. Doing so prevents this transaction being re-used in other contexts.>
- <Explicitly define any expected action based on the multiplicity of an actor(s), if applicable.>

2565 3.24.5 Protocol Requirements

<In this section, the selected protocol bindings of the transactions are explained in detail (like SOAP or HTTP bindings). For an example, see the QRPH DEX Profile or ITI TF-2b:3.34.5, 3.35.5. Indicate NA if not used.>

[Editor’s Note:

- 2570
2. Note Confluence Topic about potentially missed SDC “Hello” implicit messages and the need to run an algorithm to ensure “discovered” topology is still true.
 3. NOTE: This loop is in DEV-24 and not DEV-25 because the Announce message is UNSECURED!

I

2575 3.24.6 Safety, Effectiveness, Security Requirements & Considerations

3.24.6.1 SES General Considerations

<Address any SES requirements & considerations that need to be managed; include linkages to assurance case template entries>

- 2580 [Editor’s Note: The security below includes <Actor> specific considerations .. should that also be included in the SES components? What about message specific considerations?]

[Editor's Note: This transaction is in UNSECURED mode ... need to call that out in general here and then add ??? to the .4 section below?]

2585 **3.24.6.2 Safety Requirements & Considerations**

<Requirements for this transaction relating to safety (e.g., risk analysis)>

3.24.6.3 Effectiveness Requirements & Considerations

<Requirements for this transaction relating to effectiveness (e.g., Quality of Service, Quality of Data, etc.)>

2590 **3.24.6.4 Security Requirements & Considerations**

<Description of the transaction specific security consideration; such as use of security profiles.>

3.24.6.4.1 Security Audit Considerations

<This section should identify any specific ATNA security audit event that is associated with this transaction and requirements on the encoding of that audit event. >

2595 **3.24.6.4.1.(z) <Actor> Specific Security Considerations**

<This section should specify any specific security considerations on an actor-by-actor basis.>

3.25 Discover BICEPS Services [DEV-25]

2600 **3.25.1 Scope**

This transaction is used to *<...describe what is accomplished by using the transaction. Remember that by keeping transactions general/abstract, they can be re-used in a variety of profiles>*

3.25.2 Actor Roles

2605

3.25.3 Referenced Standards

- *<e.g., HL7 2.3.1 Chapters 2, 3>*

3.25.4 Messages

[Editor's Note: interaction diagram here]

2610 **3.25.4.1 “SDC Hello” Message**

<One or two sentence summary of what Message 1 accomplishes typically relating the message to the relevant standard. Avoid shall language in this upper level section. Do not duplicate the triggers, encoding, semantics, standards used, or expected actions. Those belong in the following sections.>

2615 *<Explicitly state if the multiplicity of an actor may be greater than one; i.e., if an actor (whether it is a client or server) can expect this message from a single source or multiple sources.>*

3.25.4.1.1 Trigger Events

<Description of the real world events that cause the sender (Actor A) to send Message 1 (e.g., an operator or an automated function determines that a new workitem is needed).>

2620 **3.25.4.1.2 Message Semantics**

<Detailed description of the meaning, structure and contents of the message, including any IHE specific clarifications of the message format, attributes, etc.>

2625 *<Start by describing the standard underlying the message and how the participating actors are mapped (e.g., “This message is a DICOM C-FIND Request. Actor A is the SCU. Actor D is the SCP.”).>*

<Continue profiling the message by providing guidance or constraints on how the message parameters are populated, how the payload is encoded, how the message is structured and what the contents mean. These message semantics should both help the sender to construct the message and the receiver to interpret the message.>

2630 **3.25.4.1.3 Expected Actions**

<Description of the actions expected to be taken as a result of sending or receiving this message.>

<Describe what the receiver is expected/required to do upon receiving this message. >

2635 *<Avoid re-iterating the transaction sequencing specified in the Profile Process Flows as expected actions internal to the transaction. Doing so prevents this transaction being re-used in other contexts.>*

<Explicitly define any expected action based on the multiplicity of an actor(s), if applicable.>

3.25.5 Protocol Requirements

2640 *<In this section, the selected protocol bindings of the transactions are explained in detail (like SOAP or HTTP bindings). For an example, see the QRPH DEX Profile or ITI TF-2b:3.34.5, 3.35.5. Indicate NA if not used.>*

3.25.6 Safety, Effectiveness, Security Requirements & Considerations

3.25.6.1 SES General Considerations

2645 <Address any SES requirements & considerations that need to be managed; include linkages to assurance case template entries>

[Editor's Note: The security below includes <Actor> specific considerations .. should that also be included in the SES components? What about message specific considerations?]

2650 [Editor's Note: This transaction is in UNSECURED mode ... need to call that out in general here and then add ??? to the .4 section below?]

3.25.6.2 Safety Requirements & Considerations

<Requirements for this transaction relating to safety (e.g., risk analysis)>

2655 3.25.6.3 Effectiveness Requirements & Considerations

<Requirements for this transaction relating to effectiveness (e.g., Quality of Service, Quality of Data, etc.)>

3.25.6.4 Security Requirements & Considerations

<Description of the transaction specific security consideration; such as use of security profiles.>

2660 3.25.6.4.1 Security Audit Considerations

<This section should identify any specific ATNA security audit event that is associated with this transaction and requirements on the encoding of that audit event. >

3.25.6.4.1.(z) <Actor> Specific Security Considerations

<This section should specify any specific security considerations on an actor-by-actor basis.>

2665 3.26 Discover System Context and Capabilities [DEV-26]

3.26.1 Scope

2670 This transaction is used to <...describe what is accomplished by using the transaction. Remember that by keeping transactions general/abstract, they can be re-used in a variety of profiles>

3.26.2 Actor Roles

3.26.3 Referenced Standards

- <e.g., HL7 2.3.1 Chapters 2, 3>

2675 3.26.4 Messages

[Editor's Note: interaction diagram here]

3.26.4.1 “SDC Hello” Message

2680 <One or two sentence summary of what Message 1 accomplishes typically relating the message to the relevant standard. Avoid shall language in this upper level section. Do not duplicate the triggers, encoding, semantics, standards used, or expected actions. Those belong in the following sections.>

<Explicitly state if the multiplicity of an actor may be greater than one; i.e., if an actor (whether it is a client or server) can expect this message from a single source or multiple sources.>

3.26.4.1.1 Trigger Events

2685 <Description of the real world events that cause the sender (Actor A) to send Message 1 (e.g., an operator or an automated function determines that a new workitem is needed).>

3.26.4.1.2 Message Semantics

<Detailed description of the meaning, structure and contents of the message, including any IHE specific clarifications of the message format, attributes, etc.>

2690 <Start by describing the standard underlying the message and how the participating actors are mapped (e.g., “This message is a DICOM C-FIND Request. Actor A is the SCU. Actor D is the SCP.”).>

2695 <Continue profiling the message by providing guidance or constraints on how the message parameters are populated, how the payload is encoded, how the message is structured and what the contents mean. These message semantics should both help the sender to construct the message and the receiver to interpret the message.>

3.26.4.1.3 Expected Actions

<Description of the actions expected to be taken as a result of sending or receiving this message.>

2700 <Describe what the receiver is expected/required to do upon receiving this message. >

<Avoid re-iterating the transaction sequencing specified in the Profile Process Flows as expected actions internal to the transaction. Doing so prevents this transaction being re-used in other contexts.>

<Explicitly define any expected action based on the multiplicity of an actor(s), if applicable.>

2705

3.26.5 Protocol Requirements

[Editor's Note:

1. Original sequence included the following “optional” section:

2710

- a. opt conditional if context states were empty in GetMdbResponse
- b. sdpi_somds_consumer -> sdpi_somds_provider: SDC: GetContextStates()
- c. sdpi_somds_consumer <-- sdpi_somds_provider: SDC: GetContextStatesResponse(ContextStates)
- d. end

2. BUT this was only used if GetMdb() is used for non-secured communication – which is profiled out for SDPi use – note that here somewhere

2715

3. Context States MUST be included in GetMdbResponse ... by SDPi profile

]

3.26.6 Safety, Effectiveness, Security Requirements & Considerations

3.26.6.1 SES General Considerations

2720

<Address any SES requirements & considerations that need to be managed; include linkages to assurance case template entries>

[Editor's Note: The security below includes <Actor> specific considerations .. should that also be included in the SES components? What about message specific considerations?]

2725

[Editor's Note: This transaction is in UNSECURED mode ... need to call that out in general here and then add ??? to the .4 section below?]

3.26.6.2 Safety Requirements & Considerations

<Requirements for this transaction relating to safety (e.g., risk analysis)>

3.26.6.3 Effectiveness Requirements & Considerations

2730

<Requirements for this transaction relating to effectiveness (e.g., Quality of Service, Quality of Data, etc.)>

3.26.6.4 Security Requirements & Considerations

<Description of the transaction specific security consideration; such as use of security profiles.>

3.26.6.4.1 Security Audit Considerations

2735 *<This section should identify any specific ATNA security audit event that is associated with this transaction and requirements on the encoding of that audit event. >*

3.26.6.4.1.(z) <Actor> Specific Security Considerations

<This section should specify any specific security considerations on an actor-by-actor basis.>

2740 3.27 Manage BICEPS Subscription [DEV-27]

3.27.1 Scope

2745 This transaction is used to *<...describe what is accomplished by using the transaction. Remember that by keeping transactions general/abstract, they can be re-used in a variety of profiles>*

3.27.2 Actor Roles

3.27.3 Referenced Standards

- *<e.g., HL7 2.3.1 Chapters 2, 3>*

2750 3.27.4 Messages

[Editor's Note: interaction diagram here]

3.27.4.1 "SDC Hello" Message

2755 *<One or two sentence summary of what Message 1 accomplishes typically relating the message to the relevant standard. Avoid shall language in this upper level section. Do not duplicate the triggers, encoding, semantics, standards used, or expected actions. Those belong in the following sections.>*

<Explicitly state if the multiplicity of an actor may be greater than one; i.e., if an actor (whether it is a client or server) can expect this message from a single source or multiple sources.>

3.27.4.1.1 Trigger Events

2760 <Description of the real world events that cause the sender (Actor A) to send Message 1 (e.g., an operator or an automated function determines that a new workitem is needed).>

3.27.4.1.2 Message Semantics

<Detailed description of the meaning, structure and contents of the message, including any IHE specific clarifications of the message format, attributes, etc.>

2765 <Start by describing the standard underlying the message and how the participating actors are mapped (e.g., “This message is a DICOM C-FIND Request. Actor A is the SCU. Actor D is the SCP.”).>

2770 <Continue profiling the message by providing guidance or constraints on how the message parameters are populated, how the payload is encoded, how the message is structured and what the contents mean. These message semantics should both help the sender to construct the message and the receiver to interpret the message.>

3.27.4.1.3 Expected Actions

<Description of the actions expected to be taken as a result of sending or receiving this message.>

2775 <Describe what the receiver is expected/required to do upon receiving this message. >

<Avoid re-iterating the transaction sequencing specified in the Profile Process Flows as expected actions internal to the transaction. Doing so prevents this transaction being re-used in other contexts.>

2780 <Explicitly define any expected action based on the multiplicity of an actor(s), if applicable.>

3.27.5 Protocol Requirements

<In this section, the selected protocol bindings of the transactions are explained in detail (like SOAP or HTTP bindings). For an example, see the QRPH DEX Profile or ITI TF-2b:3.34.5, 3.35.5. Indicate NA if not used.>

2785 3.27.6 Safety, Effectiveness, Security Requirements & Considerations

3.27.6.1 SES General Considerations

<Address any SES requirements & considerations that need to be managed; include linkages to assurance case template entries>

2790 [Editor’s Note: The security below includes <Actor> specific considerations .. should that also be included in the SES components? What about message specific considerations?]

[Editor's Note: This transaction is in UNSECURED mode ... need to call that out in general here and then add ??? to the .4 section below?]

2795 **3.27.6.2 Safety Requirements & Considerations**

<Requirements for this transaction relating to safety (e.g., risk analysis)>

3.27.6.3 Effectiveness Requirements & Considerations

<Requirements for this transaction relating to effectiveness (e.g., Quality of Service, Quality of Data, etc.)>

2800 **3.27.6.4 Security Requirements & Considerations**

<Description of the transaction specific security consideration; such as use of security profiles.>

3.27.6.4.1 Security Audit Considerations

<This section should identify any specific ATNA security audit event that is associated with this transaction and requirements on the encoding of that audit event. >

2805 **3.27.6.4.1.(z) <Actor> Specific Security Considerations**

<This section should specify any specific security considerations on an actor-by-actor basis.>

3.28 Notify Change in System Context and Capabilities [DEV-28]

3.28.1 Scope

2810 This transaction is used to *<...describe what is accomplished by using the transaction. Remember that by keeping transactions general/abstract, they can be re-used in a variety of profiles>*

3.28.2 Actor Roles

2815 **3.28.3 Referenced Standards**

- *<e.g., HL7 2.3.1 Chapters 2, 3>*

3.28.4 Messages

[Editor's Note: interaction diagram here]

3.28.4.1 “SDC Hello” Message

2820 *<One or two sentence summary of what Message 1 accomplishes typically relating the message to the relevant standard. Avoid shall language in this upper level section. Do not duplicate the triggers, encoding, semantics, standards used, or expected actions. Those belong in the following sections.>*

2825 *<Explicitly state if the multiplicity of an actor may be greater than one; i.e., if an actor (whether it is a client or server) can expect this message from a single source or multiple sources.>*

3.28.4.1.1 Trigger Events

<Description of the real world events that cause the sender (Actor A) to send Message 1 (e.g., an operator or an automated function determines that a new workitem is needed).>

3.28.4.1.2 Message Semantics

2830 *<Detailed description of the meaning, structure and contents of the message, including any IHE specific clarifications of the message format, attributes, etc.>*

<Start by describing the standard underlying the message and how the participating actors are mapped (e.g., “This message is a DICOM C-FIND Request. Actor A is the SCU. Actor D is the SCP.”).>

2835 *<Continue profiling the message by providing guidance or constraints on how the message parameters are populated, how the payload is encoded, how the message is structured and what the contents mean. These message semantics should both help the sender to construct the message and the receiver to interpret the message.>*

3.28.4.1.3 Expected Actions

2840 *<Description of the actions expected to be taken as a result of sending or receiving this message.>*

<Describe what the receiver is expected/required to do upon receiving this message. >

2845 *<Avoid re-iterating the transaction sequencing specified in the Profile Process Flows as expected actions internal to the transaction. Doing so prevents this transaction being re-used in other contexts.>*

<Explicitly define any expected action based on the multiplicity of an actor(s), if applicable.>

3.28.5 Protocol Requirements

2850 *<In this section, the selected protocol bindings of the transactions are explained in detail (like SOAP or HTTP bindings). For an example, see the QRPH DEX Profile or ITI TF-2b:3.34.5, 3.35.5. Indicate NA if not used.>*

3.28.6 Safety, Effectiveness, Security Requirements & Considerations

3.28.6.1 SES General Considerations

2855 *<Address any SES requirements & considerations that need to be managed; include linkages to assurance case template entries>*

[Editor's Note: The security below includes <Actor> specific considerations .. should that also be included in the SES components? What about message specific considerations?]

2860 [Editor's Note: This transaction is in UNSECURED mode ... need to call that out in general here and then add ??? to the .4 section below?]

3.28.6.2 Safety Requirements & Considerations

<Requirements for this transaction relating to safety (e.g., risk analysis)>

3.28.6.3 Effectiveness Requirements & Considerations

2865 *<Requirements for this transaction relating to effectiveness (e.g., Quality of Service, Quality of Data, etc.)>*

3.28.6.4 Security Requirements & Considerations

<Description of the transaction specific security consideration; such as use of security profiles.>

3.28.6.4.1 Security Audit Considerations

2870 *<This section should identify any specific ATNA security audit event that is associated with this transaction and requirements on the encoding of that audit event. >*

3.28.6.4.1.(z) <Actor> Specific Security Considerations

<This section should specify any specific security considerations on an actor-by-actor basis.>

3.29 Publish BICEPS Update Reports [DEV-29]

2875

3.29.1 Scope

This transaction is used to *<...describe what is accomplished by using the transaction. Remember that by keeping transactions general/abstract, they can be re-used in a variety of profiles>*

2880 **3.29.2 Actor Roles**

3.29.3 Referenced Standards

- <e.g., HL7 2.3.1 Chapters 2, 3>

3.29.4 Messages

2885 [Editor's Note: interaction diagram here]

3.29.4.1 “SDC Hello” Message

2890 <One or two sentence summary of what Message 1 accomplishes typically relating the message to the relevant standard. Avoid shall language in this upper level section. Do not duplicate the triggers, encoding, semantics, standards used, or expected actions. Those belong in the following sections.>

<Explicitly state if the multiplicity of an actor may be greater than one; i.e., if an actor (whether it is a client or server) can expect this message from a single source or multiple sources.>

3.29.4.1.1 Trigger Events

2895 <Description of the real world events that cause the sender (Actor A) to send Message 1 (e.g., an operator or an automated function determines that a new workitem is needed).>

3.29.4.1.2 Message Semantics

<Detailed description of the meaning, structure and contents of the message, including any IHE specific clarifications of the message format, attributes, etc.>

2900 <Start by describing the standard underlying the message and how the participating actors are mapped (e.g., “This message is a DICOM C-FIND Request. Actor A is the SCU. Actor D is the SCP.”).>

2905 <Continue profiling the message by providing guidance or constraints on how the message parameters are populated, how the payload is encoded, how the message is structured and what the contents mean. These message semantics should both help the sender to construct the message and the receiver to interpret the message.>

3.29.4.1.3 Expected Actions

<Description of the actions expected to be taken as a result of sending or receiving this message.>

<Describe what the receiver is expected/required to do upon receiving this message. >

2910 *<Avoid re-iterating the transaction sequencing specified in the Profile Process Flows as expected actions internal to the transaction. Doing so prevents this transaction being re-used in other contexts.>*

<Explicitly define any expected action based on the multiplicity of an actor(s), if applicable.>

2915 **3.29.5 Protocol Requirements**

<In this section, the selected protocol bindings of the transactions are explained in detail (like SOAP or HTTP bindings). For an example, see the QRPH DEX Profile or ITI TF-2b:3.34.5, 3.35.5. Indicate NA if not used.>

3.29.6 Safety, Effectiveness, Security Requirements & Considerations

2920 **3.29.6.1 SES General Considerations**

<Address any SES requirements & considerations that need to be managed; include linkages to assurance case template entries>

[Editor's Note: The security below includes <Actor> specific considerations .. should that also be included in the SES components? What about message specific considerations?]

2925

[Editor's Note: This transaction is in UNSECURED mode ... need to call that out in general here and then add ??? to the .4 section below?]

3.29.6.2 Safety Requirements & Considerations

2930 *<Requirements for this transaction relating to safety (e.g., risk analysis)>*

3.29.6.3 Effectiveness Requirements & Considerations

<Requirements for this transaction relating to effectiveness (e.g., Quality of Service, Quality of Data, etc.)>

3.29.6.4 Security Requirements & Considerations

2935 *<Description of the transaction specific security consideration; such as use of security profiles.>*

3.29.6.4.1 Security Audit Considerations

<This section should identify any specific ATNA security audit event that is associated with this transaction and requirements on the encoding of that audit event. >

3.29.6.4.1.(z) <Actor> Specific Security Considerations

2940 *<This section should specify any specific security considerations on an actor-by-actor basis.>*

3.30 Retrieve BICEPS Content [DEV-30]

3.30.1 Scope

2945 This transaction is used to *<...describe what is accomplished by using the transaction. Remember that by keeping transactions general/abstract, they can be re-used in a variety of profiles>*

3.30.2 Actor Roles

3.30.3 Referenced Standards

2950

- *<e.g., HL7 2.3.1 Chapters 2, 3>*

3.30.4 Messages

[Editor's Note: interaction diagram here]

3.30.4.1 “SDC Hello” Message

2955 *<One or two sentence summary of what Message 1 accomplishes typically relating the message to the relevant standard. Avoid shall language in this upper level section. Do not duplicate the triggers, encoding, semantics, standards used, or expected actions. Those belong in the following sections.>*

<Explicitly state if the multiplicity of an actor may be greater than one; i.e., if an actor (whether it is a client or server) can expect this message from a single source or multiple sources.>

3.30.4.1.1 Trigger Events

2960 *<Description of the real world events that cause the sender (Actor A) to send Message 1 (e.g., an operator or an automated function determines that a new workitem is needed).>*

3.30.4.1.2 Message Semantics

2965 *<Detailed description of the meaning, structure and contents of the message, including any IHE specific clarifications of the message format, attributes, etc.>*

<Start by describing the standard underlying the message and how the participating actors are mapped (e.g., “This message is a DICOM C-FIND Request. Actor A is the SCU. Actor D is the SCP.”).>

2970 *<Continue profiling the message by providing guidance or constraints on how the message parameters are populated, how the payload is encoded, how the message is structured and what the contents mean. These message semantics should both help the sender to construct the message and the receiver to interpret the message.>*

3.30.4.1.3 Expected Actions

2975 *<Description of the actions expected to be taken as a result of sending or receiving this message.>*

<Describe what the receiver is expected/required to do upon receiving this message. >

<Avoid re-iterating the transaction sequencing specified in the Profile Process Flows as expected actions internal to the transaction. Doing so prevents this transaction being re-used in other contexts.>

2980 *<Explicitly define any expected action based on the multiplicity of an actor(s), if applicable.>*

3.30.5 Protocol Requirements

2985 *<In this section, the selected protocol bindings of the transactions are explained in detail (like SOAP or HTTP bindings). For an example, see the QRPH DEX Profile or ITI TF-2b:3.34.5, 3.35.5. Indicate NA if not used.>*

3.30.6 Safety, Effectiveness, Security Requirements & Considerations

3.30.6.1 SES General Considerations

<Address any SES requirements & considerations that need to be managed; include linkages to assurance case template entries>

2990 [Editor's Note: The security below includes <Actor> specific considerations .. should that also be included in the SES components? What about message specific considerations?]

[Editor's Note: This transaction is in UNSECURED mode ... need to call that out in general here and then add ??? to the .4 section below?]

2995

3.30.6.2 Safety Requirements & Considerations

<Requirements for this transaction relating to safety (e.g., risk analysis)>

3.30.6.3 Effectiveness Requirements & Considerations

3000 *<Requirements for this transaction relating to effectiveness (e.g., Quality of Service, Quality of Data, etc.)>*

3.30.6.4 Security Requirements & Considerations

<Description of the transaction specific security consideration; such as use of security profiles.>

3.30.6.4.1 Security Audit Considerations

3005 *<This section should identify any specific ATNA security audit event that is associated with this transaction and requirements on the encoding of that audit event. >*

3.30.6.4.1.(z) <Actor> Specific Security Considerations

<This section should specify any specific security considerations on an actor-by-actor basis.>

3.31 Set Provider State [DEV-31]

3010 3.31.1 Scope

This transaction is used to *<...describe what is accomplished by using the transaction. Remember that by keeping transactions general/abstract, they can be re-used in a variety of profiles>*

3.31.2 Actor Roles

3015

3.31.3 Referenced Standards

- *<e.g., HL7 2.3.1 Chapters 2, 3>*

3.31.4 Messages

[Editor's Note: interaction diagram here]

3020 3.31.4.1 "SDC Hello" Message

<One or two sentence summary of what Message 1 accomplishes typically relating the message to the relevant standard. Avoid shall language in this upper level section. Do not duplicate the triggers, encoding, semantics, standards used, or expected actions. Those belong in the following sections.>

3025 *<Explicitly state if the multiplicity of an actor may be greater than one; i.e., if an actor (whether it is a client or server) can expect this message from a single source or multiple sources.>*

3.31.4.1.1 Trigger Events

<Description of the real world events that cause the sender (Actor A) to send Message 1 (e.g., an operator or an automated function determines that a new workitem is needed).>

3030 **3.31.4.1.2 Message Semantics**

<Detailed description of the meaning, structure and contents of the message, including any IHE specific clarifications of the message format, attributes, etc.>

3035 *<Start by describing the standard underlying the message and how the participating actors are mapped (e.g., “This message is a DICOM C-FIND Request. Actor A is the SCU. Actor D is the SCP.”)>*

<Continue profiling the message by providing guidance or constraints on how the message parameters are populated, how the payload is encoded, how the message is structured and what the contents mean. These message semantics should both help the sender to construct the message and the receiver to interpret the message.>

3040 **3.31.4.1.3 Expected Actions**

<Description of the actions expected to be taken as a result of sending or receiving this message.>

<Describe what the receiver is expected/required to do upon receiving this message. >

3045 *<Avoid re-iterating the transaction sequencing specified in the Profile Process Flows as expected actions internal to the transaction. Doing so prevents this transaction being re-used in other contexts.>*

<Explicitly define any expected action based on the multiplicity of an actor(s), if applicable.>

3.31.5 Protocol Requirements

3050 *<In this section, the selected protocol bindings of the transactions are explained in detail (like SOAP or HTTP bindings). For an example, see the QRPH DEX Profile or ITI TF-2b:3.34.5, 3.35.5. Indicate NA if not used.>*

3.31.6 Safety, Effectiveness, Security Requirements & Considerations

3.31.6.1 SES General Considerations

3055 *<Address any SES requirements & considerations that need to be managed; include linkages to assurance case template entries>*

[Editor’s Note: The security below includes <Actor> specific considerations .. should that also be included in the SES components? What about message specific considerations?]

3060 [Editor’s Note: This transaction is in UNSECURED mode ... need to call that out in general here and then add ??? to the .4 section below?]

3.31.6.2 Safety Requirements & Considerations

<Requirements for this transaction relating to safety (e.g., risk analysis)>

3065 3.31.6.3 Effectiveness Requirements & Considerations

<Requirements for this transaction relating to effectiveness (e.g., Quality of Service, Quality of Data, etc.)>

3.31.6.4 Security Requirements & Considerations

<Description of the transaction specific security consideration; such as use of security profiles.>

3070 3.31.6.4.1 Security Audit Considerations

<This section should identify any specific ATNA security audit event that is associated with this transaction and requirements on the encoding of that audit event. >

3.31.6.4.1.(z) <Actor> Specific Security Considerations

<This section should specify any specific security considerations on an actor-by-actor basis.>

3075 3.32 Retrieve Archive Data [DEV-32]

3.32.1 Scope

This transaction is used to *<...describe what is accomplished by using the transaction. Remember that by keeping transactions general/abstract, they can be re-used in a variety of profiles>*

3080

[Editor's Note: From discussion with David G.:

1. This archive service has “never been implemented” ... !!!

2. Intended for “backfilling” missed updates ... over minutes and hours ... not days – weeks etc.

3085

3. Not a data logger or device historical archive service

4. Primarily intended for temporary disconnections (e.g., communication link down OR patient transport, etc.)

5. Problem is that DescriptorRevisions VERSION (state) sequence numbers may be reset with power cycling or system reset.

3090

6. BUT what about using TimeFrame for retrieval and detecting if there has been a sequence # change and if so, marking the gap or accessing the known good retrieval and reconcile the two????

7. AND is this behavior undefined in SDC/BICEPS or SOMDA or MDPWS?

8. ...

3095]

3.32.2 Actor Roles

3.32.3 Referenced Standards

- 3100 • <e.g., HL7 2.3.1 Chapters 2, 3>

3.32.4 Messages

[Editor's Note: interaction diagram here]

3.32.4.1 "SDC Hello" Message

3105 <One or two sentence summary of what Message 1 accomplishes typically relating the message to the relevant standard. Avoid shall language in this upper level section. Do not duplicate the triggers, encoding, semantics, standards used, or expected actions. Those belong in the following sections.>

<Explicitly state if the multiplicity of an actor may be greater than one; i.e., if an actor (whether it is a client or server) can expect this message from a single source or multiple sources.>

3110 3.32.4.1.1 Trigger Events

<Description of the real world events that cause the sender (Actor A) to send Message 1 (e.g., an operator or an automated function determines that a new workitem is needed).>

3.32.4.1.2 Message Semantics

3115 <Detailed description of the meaning, structure and contents of the message, including any IHE specific clarifications of the message format, attributes, etc.>

<Start by describing the standard underlying the message and how the participating actors are mapped (e.g., "This message is a DICOM C-FIND Request. Actor A is the SCU. Actor D is the SCP.").>

3120 <Continue profiling the message by providing guidance or constraints on how the message parameters are populated, how the payload is encoded, how the message is structured and what the contents mean. These message semantics should both help the sender to construct the message and the receiver to interpret the message.>

3.32.4.1.3 Expected Actions

- 3125 <Description of the actions expected to be taken as a result of sending or receiving this message.>
- <Describe what the receiver is expected/required to do upon receiving this message. >
- <Avoid re-iterating the transaction sequencing specified in the Profile Process Flows as expected actions internal to the transaction. Doing so prevents this transaction being re-used in other contexts.>
- 3130 <Explicitly define any expected action based on the multiplicity of an actor(s), if applicable.>

3.32.5 Protocol Requirements

- 3135 <In this section, the selected protocol bindings of the transactions are explained in detail (like SOAP or HTTP bindings). For an example, see the QRPH DEX Profile or ITI TF-2b:3.34.5, 3.35.5. Indicate NA if not used.>

3.32.6 Safety, Effectiveness, Security Requirements & Considerations

3.32.6.1 SES General Considerations

- <Address any SES requirements & considerations that need to be managed; include linkages to assurance case template entries>
- 3140 [Editor's Note: The security below includes <Actor> specific considerations .. should that also be included in the SES components? What about message specific considerations?]

[Editor's Note: This transaction is in UNSECURED mode ... need to call that out in general here and then add ??? to the .4 section below?]

3145

3.32.6.2 Safety Requirements & Considerations

<Requirements for this transaction relating to safety (e.g., risk analysis)>

3.32.6.3 Effectiveness Requirements & Considerations

- 3150 <Requirements for this transaction relating to effectiveness (e.g., Quality of Service, Quality of Data, etc.)>

3.32.6.4 Security Requirements & Considerations

<Description of the transaction specific security consideration; such as use of security profiles.>

3.32.6.4.1 Security Audit Considerations

3155 *<This section should identify any specific ATNA security audit event that is associated with this transaction and requirements on the encoding of that audit event. >*

3.32.6.4.1.(z) <Actor> Specific Security Considerations

<This section should specify any specific security considerations on an actor-by-actor basis.>

3.33 Retrieve Localization Information [DEV-33]

3160 3.33.1 Scope

This transaction is used to *<...describe what is accomplished by using the transaction. Remember that by keeping transactions general/abstract, they can be re-used in a variety of profiles>*

3.33.2 Actor Roles

3165

3.33.3 Referenced Standards

- *<e.g., HL7 2.3.1 Chapters 2, 3>*

3.33.4 Messages

[Editor's Note: interaction diagram here]

3170 3.33.4.1 "SDC Hello" Message

<One or two sentence summary of what Message 1 accomplishes typically relating the message to the relevant standard. Avoid shall language in this upper level section. Do not duplicate the triggers, encoding, semantics, standards used, or expected actions. Those belong in the following sections.>

3175 *<Explicitly state if the multiplicity of an actor may be greater than one; i.e., if an actor (whether it is a client or server) can expect this message from a single source or multiple sources.>*

3.33.4.1.1 Trigger Events

<Description of the real world events that cause the sender (Actor A) to send Message 1 (e.g., an operator or an automated function determines that a new workitem is needed).>

3180 3.33.4.1.2 Message Semantics

<Detailed description of the meaning, structure and contents of the message, including any IHE specific clarifications of the message format, attributes, etc.>

3185 <Start by describing the standard underlying the message and how the participating actors are mapped (e.g., “This message is a DICOM C-FIND Request. Actor A is the SCU. Actor D is the SCP.”).>

<Continue profiling the message by providing guidance or constraints on how the message parameters are populated, how the payload is encoded, how the message is structured and what the contents mean. These message semantics should both help the sender to construct the message and the receiver to interpret the message.>

3190 **3.33.4.1.3 Expected Actions**

<Description of the actions expected to be taken as a result of sending or receiving this message.>

<Describe what the receiver is expected/required to do upon receiving this message. >

3195 <Avoid re-iterating the transaction sequencing specified in the Profile Process Flows as expected actions internal to the transaction. Doing so prevents this transaction being re-used in other contexts.>

<Explicitly define any expected action based on the multiplicity of an actor(s), if applicable.>

3.33.5 Protocol Requirements

3200 <In this section, the selected protocol bindings of the transactions are explained in detail (like SOAP or HTTP bindings). For an example, see the QRPH DEX Profile or ITI TF-2b:3.34.5, 3.35.5. Indicate NA if not used.>

3.33.6 Safety, Effectiveness, Security Requirements & Considerations

3.33.6.1 SES General Considerations

3205 <Address any SES requirements & considerations that need to be managed; include linkages to assurance case template entries>

[Editor’s Note: The security below includes <Actor> specific considerations .. should that also be included in the SES components? What about message specific considerations?]

3210 [Editor’s Note: This transaction is in UNSECURED mode ... need to call that out in general here and then add ??? to the .4 section below?]

3.33.6.2 Safety Requirements & Considerations

<Requirements for this transaction relating to safety (e.g., risk analysis)>

3215 **3.33.6.3 Effectiveness Requirements & Considerations**

<Requirements for this transaction relating to effectiveness (e.g., Quality of Service, Quality of Data, etc.)>

3.33.6.4 Security Requirements & Considerations

<Description of the transaction specific security consideration; such as use of security profiles.>

3220 **3.33.6.4.1 Security Audit Considerations**

<This section should identify any specific ATNA security audit event that is associated with this transaction and requirements on the encoding of that audit event. >

3.33.6.4.1.(z) <Actor> Specific Security Considerations

<This section should specify any specific security considerations on an actor-by-actor basis.>

3225 **3.34 Announce Network Departure [DEV-34]**

3.34.1 Scope

This transaction is used to *<...describe what is accomplished by using the transaction. Remember that by keeping transactions general/abstract, they can be re-used in a variety of profiles>*

3230

3.34.2 Actor Roles

3.34.3 Referenced Standards

- *<e.g., HL7 2.3.1 Chapters 2, 3>*

3235 **3.34.4 Messages**

[Editor's Note: interaction diagram here]

3.34.4.1 "SDC Hello" Message

<One or two sentence summary of what Message 1 accomplishes typically relating the message to the relevant standard. Avoid shall language in this upper level section. Do not duplicate the triggers, encoding, semantics, standards used, or expected actions. Those belong in the following sections.>

3240

<Explicitly state if the multiplicity of an actor may be greater than one; i.e., if an actor (whether it is a client or server) can expect this message from a single source or multiple sources.>

3.34.4.1.1 Trigger Events

3245 *<Description of the real world events that cause the sender (Actor A) to send Message 1 (e.g., an operator or an automated function determines that a new workitem is needed).>*

3.34.4.1.2 Message Semantics

<Detailed description of the meaning, structure and contents of the message, including any IHE specific clarifications of the message format, attributes, etc.>

3250 *<Start by describing the standard underlying the message and how the participating actors are mapped (e.g., “This message is a DICOM C-FIND Request. Actor A is the SCU. Actor D is the SCP.”).>*

3255 *<Continue profiling the message by providing guidance or constraints on how the message parameters are populated, how the payload is encoded, how the message is structured and what the contents mean. These message semantics should both help the sender to construct the message and the receiver to interpret the message.>*

3.34.4.1.3 Expected Actions

<Description of the actions expected to be taken as a result of sending or receiving this message.>

3260 *<Describe what the receiver is expected/required to do upon receiving this message. >*

<Avoid re-iterating the transaction sequencing specified in the Profile Process Flows as expected actions internal to the transaction. Doing so prevents this transaction being re-used in other contexts.>

3265 *<Explicitly define any expected action based on the multiplicity of an actor(s), if applicable.>*

3.34.5 Protocol Requirements

<In this section, the selected protocol bindings of the transactions are explained in detail (like SOAP or HTTP bindings). For an example, see the QRPH DEX Profile or ITI TF-2b:3.34.5, 3.35.5. Indicate NA if not used.>

3270 3.34.6 Safety, Effectiveness, Security Requirements & Considerations

3.34.6.1 SES General Considerations

<Address any SES requirements & considerations that need to be managed; include linkages to assurance case template entries>

3275 **[Editor’s Note: The security below includes <Actor> specific considerations .. should that also be included in the SES components? What about message specific considerations?]**

[Editor's Note: This transaction is in UNSECURED mode ... need to call that out in general here and then add ??? to the .4 section below?]

3280 **3.34.6.2 Safety Requirements & Considerations**

<Requirements for this transaction relating to safety (e.g., risk analysis)>

3.34.6.3 Effectiveness Requirements & Considerations

<Requirements for this transaction relating to effectiveness (e.g., Quality of Service, Quality of Data, etc.)>

3285 **3.34.6.4 Security Requirements & Considerations**

<Description of the transaction specific security consideration; such as use of security profiles.>

3.34.6.4.1 Security Audit Considerations

<This section should identify any specific ATNA security audit event that is associated with this transaction and requirements on the encoding of that audit event. >

3290 **3.34.6.4.1.(z) <Actor> Specific Security Considerations**

<This section should specify any specific security considerations on an actor-by-actor basis.>

3.35 Establish Medical Data Exchange [DEV-35]

3295 **3.35.1 Scope**

This transaction is used to *<...describe what is accomplished by using the transaction. Remember that by keeping transactions general/abstract, they can be re-used in a variety of profiles>*

3.35.2 Actor Roles

3300

3.35.3 Referenced Standards

- *<e.g., HL7 2.3.1 Chapters 2, 3>*

3.35.4 Messages

[Editor's Note: interaction diagram here]

3305 3.35.4.1 "SDC Hello" Message

<One or two sentence summary of what Message 1 accomplishes typically relating the message to the relevant standard. Avoid shall language in this upper level section. Do not duplicate the triggers, encoding, semantics, standards used, or expected actions. Those belong in the following sections.>

3310 *<Explicitly state if the multiplicity of an actor may be greater than one; i.e., if an actor (whether it is a client or server) can expect this message from a single source or multiple sources.>*

3.35.4.1.1 Trigger Events

<Description of the real world events that cause the sender (Actor A) to send Message 1 (e.g., an operator or an automated function determines that a new workitem is needed).>

3315 3.35.4.1.2 Message Semantics

<Detailed description of the meaning, structure and contents of the message, including any IHE specific clarifications of the message format, attributes, etc.>

3320 *<Start by describing the standard underlying the message and how the participating actors are mapped (e.g., "This message is a DICOM C-FIND Request. Actor A is the SCU. Actor D is the SCP.")>*

<Continue profiling the message by providing guidance or constraints on how the message parameters are populated, how the payload is encoded, how the message is structured and what the contents mean. These message semantics should both help the sender to construct the message and the receiver to interpret the message.>

3325 3.35.4.1.3 Expected Actions

<Description of the actions expected to be taken as a result of sending or receiving this message.>

<Describe what the receiver is expected/required to do upon receiving this message. >

3330 *<Avoid re-iterating the transaction sequencing specified in the Profile Process Flows as expected actions internal to the transaction. Doing so prevents this transaction being re-used in other contexts.>*

<Explicitly define any expected action based on the multiplicity of an actor(s), if applicable.>

3.35.5 Protocol Requirements

- 3335 <In this section, the selected protocol bindings of the transactions are explained in detail (like SOAP or HTTP bindings). For an example, see the QRPH DEX Profile or ITI TF-2b:3.35.5, 3.35.5. Indicate NA if not used.>

3.35.6 Safety, Effectiveness, Security Requirements & Considerations

3.35.6.1 SES General Considerations

- 3340 <Address any SES requirements & considerations that need to be managed; include linkages to assurance case template entries>

[Editor's Note: The security below includes <Actor> specific considerations .. should that also be included in the SES components? What about message specific considerations?]

- 3345 [Editor's Note: This transaction is in UNSECURED mode ... need to call that out in general here and then add ??? to the .4 section below?]

3.35.6.2 Safety Requirements & Considerations

<Requirements for this transaction relating to safety (e.g., risk analysis)>

- 3350 **3.35.6.3 Effectiveness Requirements & Considerations**

<Requirements for this transaction relating to effectiveness (e.g., Quality of Service, Quality of Data, etc.)>

3.35.6.4 Security Requirements & Considerations

<Description of the transaction specific security consideration; such as use of security profiles.>

- 3355 **3.35.6.4.1 Security Audit Considerations**

<This section should identify any specific ATNA security audit event that is associated with this transaction and requirements on the encoding of that audit event. >

3.35.6.4.1.(z) <Actor> Specific Security Considerations

<This section should specify any specific security considerations on an actor-by-actor basis.>

3360

3.36 Publish Medical Data [DEV-36]

3.36.1 Scope

3365 This transaction is used to *<...describe what is accomplished by using the transaction. Remember that by keeping transactions general/abstract, they can be re-used in a variety of profiles>*

3.36.2 Actor Roles

3.36.3 Referenced Standards

3370

- *<e.g., HL7 2.3.1 Chapters 2, 3>*

3.36.4 Messages

[Editor's Note: interaction diagram here]

3.36.4.1 "SDC Hello" Message

3375 *<One or two sentence summary of what Message 1 accomplishes typically relating the message to the relevant standard. Avoid shall language in this upper level section. Do not duplicate the triggers, encoding, semantics, standards used, or expected actions. Those belong in the following sections.>*

<Explicitly state if the multiplicity of an actor may be greater than one; i.e., if an actor (whether it is a client or server) can expect this message from a single source or multiple sources.>

3380 3.36.4.1.1 Trigger Events

<Description of the real world events that cause the sender (Actor A) to send Message 1 (e.g., an operator or an automated function determines that a new workitem is needed).>

3.36.4.1.2 Message Semantics

3385 *<Detailed description of the meaning, structure and contents of the message, including any IHE specific clarifications of the message format, attributes, etc.>*

<Start by describing the standard underlying the message and how the participating actors are mapped (e.g., "This message is a DICOM C-FIND Request. Actor A is the SCU. Actor D is the SCP.").>

3390 *<Continue profiling the message by providing guidance or constraints on how the message parameters are populated, how the payload is encoded, how the message is structured and what the contents mean. These message semantics should both help the sender to construct the message and the receiver to interpret the message.>*

3.36.4.1.3 Expected Actions

- 3395 <Description of the actions expected to be taken as a result of sending or receiving this message.>
- <Describe what the receiver is expected/required to do upon receiving this message. >
- <Avoid re-iterating the transaction sequencing specified in the Profile Process Flows as expected actions internal to the transaction. Doing so prevents this transaction being re-used in other contexts.>
- 3400 <Explicitly define any expected action based on the multiplicity of an actor(s), if applicable.>

3.36.5 Protocol Requirements

- <In this section, the selected protocol bindings of the transactions are explained in detail (like SOAP or HTTP bindings). For an example, see the QRPH DEX Profile or ITI TF-2b:3.36.5, 3.35.5. Indicate NA if not used.>

3.36.6 Safety, Effectiveness, Security Requirements & Considerations

3.36.6.1 SES General Considerations

- <Address any SES requirements & considerations that need to be managed; include linkages to assurance case template entries>
- 3410 [Editor's Note: The security below includes <Actor> specific considerations .. should that also be included in the SES components? What about message specific considerations?]

[Editor's Note: This transaction is in UNSECURED mode ... need to call that out in general here and then add ??? to the .4 section below?]

3415

3.36.6.2 Safety Requirements & Considerations

<Requirements for this transaction relating to safety (e.g., risk analysis)>

3.36.6.3 Effectiveness Requirements & Considerations

- <Requirements for this transaction relating to effectiveness (e.g., Quality of Service, Quality of Data, etc.)>

3420

3.36.6.4 Security Requirements & Considerations

<Description of the transaction specific security consideration; such as use of security profiles.>

3.36.6.4.1 Security Audit Considerations

3425 *<This section should identify any specific ATNA security audit event that is associated with this transaction and requirements on the encoding of that audit event. >*

3.36.6.4.1.(z) <Actor> Specific Security Considerations

<This section should specify any specific security considerations on an actor-by-actor basis.>

3.37 Retrieve Medical Data [DEV-37]

3430

3.37.1 Scope

This transaction is used to *<...describe what is accomplished by using the transaction. Remember that by keeping transactions general/abstract, they can be re-used in a variety of profiles>*

3435 3.37.2 Actor Roles

3.37.3 Referenced Standards

- *<e.g., HL7 2.3.1 Chapters 2, 3>*

3.37.4 Messages

3440 [Editor's Note: interaction diagram here]

3.37.4.1 "SDC Hello" Message

3445 *<One or two sentence summary of what Message 1 accomplishes typically relating the message to the relevant standard. Avoid shall language in this upper level section. Do not duplicate the triggers, encoding, semantics, standards used, or expected actions. Those belong in the following sections.>*

<Explicitly state if the multiplicity of an actor may be greater than one; i.e., if an actor (whether it is a client or server) can expect this message from a single source or multiple sources.>

3.37.4.1.1 Trigger Events

3450 *<Description of the real world events that cause the sender (Actor A) to send Message 1 (e.g., an operator or an automated function determines that a new workitem is needed).>*

3.37.4.1.2 Message Semantics

<Detailed description of the meaning, structure and contents of the message, including any IHE specific clarifications of the message format, attributes, etc.>

3455 *<Start by describing the standard underlying the message and how the participating actors are mapped (e.g., “This message is a DICOM C-FIND Request. Actor A is the SCU. Actor D is the SCP.”)>*

3460 *<Continue profiling the message by providing guidance or constraints on how the message parameters are populated, how the payload is encoded, how the message is structured and what the contents mean. These message semantics should both help the sender to construct the message and the receiver to interpret the message.>*

3.37.4.1.3 Expected Actions

<Description of the actions expected to be taken as a result of sending or receiving this message.>

<Describe what the receiver is expected/required to do upon receiving this message. >

3465 *<Avoid re-iterating the transaction sequencing specified in the Profile Process Flows as expected actions internal to the transaction. Doing so prevents this transaction being re-used in other contexts.>*

<Explicitly define any expected action based on the multiplicity of an actor(s), if applicable.>

3470 3.37.5 Protocol Requirements

<In this section, the selected protocol bindings of the transactions are explained in detail (like SOAP or HTTP bindings). For an example, see the QRPH DEX Profile or ITI TF-2b:3.37.5, 3.35.5. Indicate NA if not used.>

3.37.6 Safety, Effectiveness, Security Requirements & Considerations

3475 3.37.6.1 SES General Considerations

<Address any SES requirements & considerations that need to be managed; include linkages to assurance case template entries>

[Editor’s Note: The security below includes <Actor> specific considerations .. should that also be included in the SES components? What about message specific considerations?]

3480

[Editor’s Note: This transaction is in UNSECURED mode ... need to call that out in general here and then add ??? to the .4 section below?]

3.37.6.2 Safety Requirements & Considerations

3485 <Requirements for this transaction relating to safety (e.g., risk analysis)>

3.37.6.3 Effectiveness Requirements & Considerations

<Requirements for this transaction relating to effectiveness (e.g., Quality of Service, Quality of Data, etc.)>

3.37.6.4 Security Requirements & Considerations

3490 <Description of the transaction specific security consideration; such as use of security profiles.>

3.37.6.4.1 Security Audit Considerations

<This section should identify any specific ATNA security audit event that is associated with this transaction and requirements on the encoding of that audit event. >

3.37.6.4.1.(z) <Actor> Specific Security Considerations

3495 <This section should specify any specific security considerations on an actor-by-actor basis.>

3.38 Establish Medical Alert Exchange [DEV-38]

3.38.1 Scope

3500 This transaction is used to <...describe what is accomplished by using the transaction. Remember that by keeping transactions general/abstract, they can be re-used in a variety of profiles>

3.38.2 Actor Roles

3.38.3 Referenced Standards

- <e.g., HL7 2.3.1 Chapters 2, 3>

3.38.4 Messages

[Editor's Note: interaction diagram here]

3.38.4.1 "SDC Hello" Message

3510 <One or two sentence summary of what Message 1 accomplishes typically relating the message to the relevant standard. Avoid shall language in this upper level section. Do not duplicate the

triggers, encoding, semantics, standards used, or expected actions. Those belong in the following sections.>

3515 *<Explicitly state if the multiplicity of an actor may be greater than one; i.e., if an actor (whether it is a client or server) can expect this message from a single source or multiple sources.>*

3.38.4.1.1 Trigger Events

<Description of the real world events that cause the sender (Actor A) to send Message 1 (e.g., an operator or an automated function determines that a new workitem is needed).>

3.38.4.1.2 Message Semantics

3520 *<Detailed description of the meaning, structure and contents of the message, including any IHE specific clarifications of the message format, attributes, etc.>*

<Start by describing the standard underlying the message and how the participating actors are mapped (e.g., “This message is a DICOM C-FIND Request. Actor A is the SCU. Actor D is the SCP.”).>

3525 *<Continue profiling the message by providing guidance or constraints on how the message parameters are populated, how the payload is encoded, how the message is structured and what the contents mean. These message semantics should both help the sender to construct the message and the receiver to interpret the message.>*

3.38.4.1.3 Expected Actions

3530 *<Description of the actions expected to be taken as a result of sending or receiving this message.>*

<Describe what the receiver is expected/required to do upon receiving this message. >

3535 *<Avoid re-iterating the transaction sequencing specified in the Profile Process Flows as expected actions internal to the transaction. Doing so prevents this transaction being re-used in other contexts.>*

<Explicitly define any expected action based on the multiplicity of an actor(s), if applicable.>

3.38.5 Protocol Requirements

3540 *<In this section, the selected protocol bindings of the transactions are explained in detail (like SOAP or HTTP bindings). For an example, see the QRPH DEX Profile or ITI TF-2b:3.38.5, 3.35.5. Indicate NA if not used.>*

3.38.6 Safety, Effectiveness, Security Requirements & Considerations

3.38.6.1 SES General Considerations

3545 *<Address any SES requirements & considerations that need to be managed; include linkages to assurance case template entries>*

[Editor's Note: The security below includes <Actor> specific considerations .. should that also be included in the SES components? What about message specific considerations?]

3550 [Editor's Note: This transaction is in UNSECURED mode ... need to call that out in general here and then add ??? to the .4 section below?]

3.38.6.2 Safety Requirements & Considerations

<Requirements for this transaction relating to safety (e.g., risk analysis)>

3.38.6.3 Effectiveness Requirements & Considerations

3555 *<Requirements for this transaction relating to effectiveness (e.g., Quality of Service, Quality of Data, etc.)>*

3.38.6.4 Security Requirements & Considerations

<Description of the transaction specific security consideration; such as use of security profiles.>

3.38.6.4.1 Security Audit Considerations

3560 *<This section should identify any specific ATNA security audit event that is associated with this transaction and requirements on the encoding of that audit event. >*

3.38.6.4.1.(z) <Actor> Specific Security Considerations

<This section should specify any specific security considerations on an actor-by-actor basis.>

3565 3.39 Publish Medical Alert Update [DEV-39]

3.39.1 Scope

3570 This transaction is used to *<...describe what is accomplished by using the transaction. Remember that by keeping transactions general/abstract, they can be re-used in a variety of profiles>*

3.39.2 Actor Roles

3.39.3 Referenced Standards

- *<e.g., HL7 2.3.1 Chapters 2, 3>*

3575 3.39.4 Messages

[Editor's Note: interaction diagram here]

3.39.4.1 “SDC Hello” Message

3580 *<One or two sentence summary of what Message 1 accomplishes typically relating the message to the relevant standard. Avoid shall language in this upper level section. Do not duplicate the triggers, encoding, semantics, standards used, or expected actions. Those belong in the following sections.>*

<Explicitly state if the multiplicity of an actor may be greater than one; i.e., if an actor (whether it is a client or server) can expect this message from a single source or multiple sources.>

3.39.4.1.1 Trigger Events

3585 *<Description of the real world events that cause the sender (Actor A) to send Message 1 (e.g., an operator or an automated function determines that a new workitem is needed).>*

3.39.4.1.2 Message Semantics

3590 *<Detailed description of the meaning, structure and contents of the message, including any IHE specific clarifications of the message format, attributes, etc.>*

<Start by describing the standard underlying the message and how the participating actors are mapped (e.g., “This message is a DICOM C-FIND Request. Actor A is the SCU. Actor D is the SCP.”).>

3595 *<Continue profiling the message by providing guidance or constraints on how the message parameters are populated, how the payload is encoded, how the message is structured and what the contents mean. These message semantics should both help the sender to construct the message and the receiver to interpret the message.>*

3.39.4.1.3 Expected Actions

<Description of the actions expected to be taken as a result of sending or receiving this message.>

3600 *<Describe what the receiver is expected/required to do upon receiving this message. >*

<Avoid re-iterating the transaction sequencing specified in the Profile Process Flows as expected actions internal to the transaction. Doing so prevents this transaction being re-used in other contexts.>

<Explicitly define any expected action based on the multiplicity of an actor(s), if applicable.>

3605

3.39.5 Protocol Requirements

<In this section, the selected protocol bindings of the transactions are explained in detail (like SOAP or HTTP bindings). For an example, see the QRPH DEX Profile or ITI TF-2b:3.39.5, 3.35.5. Indicate NA if not used.>

3610

3.39.6 Safety, Effectiveness, Security Requirements & Considerations

3.39.6.1 SES General Considerations

<Address any SES requirements & considerations that need to be managed; include linkages to assurance case template entries>

3615

[Editor's Note: The security below includes <Actor> specific considerations .. should that also be included in the SES components? What about message specific considerations?]

[Editor's Note: This transaction is in UNSECURED mode ... need to call that out in general here and then add ??? to the .4 section below?]

3620

3.39.6.2 Safety Requirements & Considerations

<Requirements for this transaction relating to safety (e.g., risk analysis)>

3.39.6.3 Effectiveness Requirements & Considerations

<Requirements for this transaction relating to effectiveness (e.g., Quality of Service, Quality of Data, etc.)>

3625

3.39.6.4 Security Requirements & Considerations

<Description of the transaction specific security consideration; such as use of security profiles.>

3.39.6.4.1 Security Audit Considerations

<This section should identify any specific ATNA security audit event that is associated with this transaction and requirements on the encoding of that audit event. >

3630 **3.39.6.4.1.(z) <Actor> Specific Security Considerations**

<This section should specify any specific security considerations on an actor-by-actor basis.>

3.40 Retrieve Medical Alert Status [DEV-40]

3635 **3.40.1 Scope**

This transaction is used to <...describe what is accomplished by using the transaction. Remember that by keeping transactions general/abstract, they can be re-used in a variety of profiles>

3.40.2 Actor Roles

3640

3.40.3 Referenced Standards

- *<e.g., HL7 2.3.1 Chapters 2, 3>*

3.40.4 Messages

[Editor's Note: interaction diagram here]

3645 **3.40.4.1 "SDC Hello" Message**

<One or two sentence summary of what Message 1 accomplishes typically relating the message to the relevant standard. Avoid shall language in this upper level section. Do not duplicate the triggers, encoding, semantics, standards used, or expected actions. Those belong in the following sections.>

3650 *<Explicitly state if the multiplicity of an actor may be greater than one; i.e., if an actor (whether it is a client or server) can expect this message from a single source or multiple sources.>*

3.40.4.1.1 Trigger Events

<Description of the real world events that cause the sender (Actor A) to send Message 1 (e.g., an operator or an automated function determines that a new workitem is needed).>

3655 **3.40.4.1.2 Message Semantics**

<Detailed description of the meaning, structure and contents of the message, including any IHE specific clarifications of the message format, attributes, etc.>

3660 <Start by describing the standard underlying the message and how the participating actors are mapped (e.g., “This message is a DICOM C-FIND Request. Actor A is the SCU. Actor D is the SCP.”).>

<Continue profiling the message by providing guidance or constraints on how the message parameters are populated, how the payload is encoded, how the message is structured and what the contents mean. These message semantics should both help the sender to construct the message and the receiver to interpret the message.>

3665 **3.40.4.1.3 Expected Actions**

<Description of the actions expected to be taken as a result of sending or receiving this message.>

<Describe what the receiver is expected/required to do upon receiving this message. >

3670 <Avoid re-iterating the transaction sequencing specified in the Profile Process Flows as expected actions internal to the transaction. Doing so prevents this transaction being re-used in other contexts.>

<Explicitly define any expected action based on the multiplicity of an actor(s), if applicable.>

3.40.5 Protocol Requirements

3675 <In this section, the selected protocol bindings of the transactions are explained in detail (like SOAP or HTTP bindings). For an example, see the QRPH DEX Profile or ITI TF-2b:3.40.5, 3.35.5. Indicate NA if not used.>

3.40.6 Safety, Effectiveness, Security Requirements & Considerations

3.40.6.1 SES General Considerations

3680 <Address any SES requirements & considerations that need to be managed; include linkages to assurance case template entries>

[Editor’s Note: The security below includes <Actor> specific considerations .. should that also be included in the SES components? What about message specific considerations?]

3685 [Editor’s Note: This transaction is in UNSECURED mode ... need to call that out in general here and then add ??? to the .4 section below?]

3.40.6.2 Safety Requirements & Considerations

<Requirements for this transaction relating to safety (e.g., risk analysis)>

3690 **3.40.6.3 Effectiveness Requirements & Considerations**

<Requirements for this transaction relating to effectiveness (e.g., Quality of Service, Quality of Data, etc.)>

3.40.6.4 Security Requirements & Considerations

<Description of the transaction specific security consideration; such as use of security profiles.>

3695 **3.40.6.4.1 Security Audit Considerations**

<This section should identify any specific ATNA security audit event that is associated with this transaction and requirements on the encoding of that audit event. >

3.40.6.4.1.(z) <Actor> Specific Security Considerations

<This section should specify any specific security considerations on an actor-by-actor basis.>

3700

3.41 Manage Medical Alert Delegation [DEV-41]

3.41.1 Scope

3705 This transaction is used to *<...describe what is accomplished by using the transaction. Remember that by keeping transactions general/abstract, they can be re-used in a variety of profiles>*

3.41.2 Actor Roles

3.41.3 Referenced Standards

- 3710
 - *<e.g., HL7 2.3.1 Chapters 2, 3>*

3.41.4 Messages

[Editor's Note: interaction diagram here]

3.41.4.1 "SDC Hello" Message

3715 *<One or two sentence summary of what Message 1 accomplishes typically relating the message to the relevant standard. Avoid shall language in this upper level section. Do not duplicate the triggers, encoding, semantics, standards used, or expected actions. Those belong in the following sections.>*

<Explicitly state if the multiplicity of an actor may be greater than one; i.e., if an actor (whether it is a client or server) can expect this message from a single source or multiple sources.>

3720 **3.41.4.1.1 Trigger Events**

<Description of the real world events that cause the sender (Actor A) to send Message 1 (e.g., an operator or an automated function determines that a new workitem is needed).>

3.41.4.1.2 Message Semantics

3725 *<Detailed description of the meaning, structure and contents of the message, including any IHE specific clarifications of the message format, attributes, etc.>*

<Start by describing the standard underlying the message and how the participating actors are mapped (e.g., “This message is a DICOM C-FIND Request. Actor A is the SCU. Actor D is the SCP.”).>

3730 *<Continue profiling the message by providing guidance or constraints on how the message parameters are populated, how the payload is encoded, how the message is structured and what the contents mean. These message semantics should both help the sender to construct the message and the receiver to interpret the message.>*

3.41.4.1.3 Expected Actions

3735 *<Description of the actions expected to be taken as a result of sending or receiving this message.>*

<Describe what the receiver is expected/required to do upon receiving this message. >

<Avoid re-iterating the transaction sequencing specified in the Profile Process Flows as expected actions internal to the transaction. Doing so prevents this transaction being re-used in other contexts.>

3740 *<Explicitly define any expected action based on the multiplicity of an actor(s), if applicable.>*

3.41.5 Protocol Requirements

3745 *<In this section, the selected protocol bindings of the transactions are explained in detail (like SOAP or HTTP bindings). For an example, see the QRPH DEX Profile or ITI TF-2b:3.41.5, 3.35.5. Indicate NA if not used.>*

3.41.6 Safety, Effectiveness, Security Requirements & Considerations

3.41.6.1 SES General Considerations

<Address any SES requirements & considerations that need to be managed; include linkages to assurance case template entries>

3750 [Editor's Note: The security below includes <Actor> specific considerations .. should that also be included in the SES components? What about message specific considerations?]

[Editor's Note: This transaction is in UNSECURED mode ... need to call that out in general here and then add ??? to the .4 section below?]

3755

3.41.6.2 Safety Requirements & Considerations

<Requirements for this transaction relating to safety (e.g., risk analysis)>

3.41.6.3 Effectiveness Requirements & Considerations

3760 *<Requirements for this transaction relating to effectiveness (e.g., Quality of Service, Quality of Data, etc.)>*

3.41.6.4 Security Requirements & Considerations

<Description of the transaction specific security consideration; such as use of security profiles.>

3.41.6.4.1 Security Audit Considerations

3765 *<This section should identify any specific ATNA security audit event that is associated with this transaction and requirements on the encoding of that audit event. >*

3.41.6.4.1.(z) <Actor> Specific Security Considerations

<This section should specify any specific security considerations on an actor-by-actor basis.>

3.42 Delegate Medical Alert [DEV-42]

3770

3.42.1 Scope

This transaction is used to *<...describe what is accomplished by using the transaction. Remember that by keeping transactions general/abstract, they can be re-used in a variety of profiles>*

3775 **3.42.2 Actor Roles**

3.42.3 Referenced Standards

- *<e.g., HL7 2.3.1 Chapters 2, 3>*

3.42.4 Messages

3780 [Editor's Note: interaction diagram here]

3.42.4.1 "SDC Hello" Message

3785 *<One or two sentence summary of what Message 1 accomplishes typically relating the message to the relevant standard. Avoid shall language in this upper level section. Do not duplicate the triggers, encoding, semantics, standards used, or expected actions. Those belong in the following sections.>*

<Explicitly state if the multiplicity of an actor may be greater than one; i.e., if an actor (whether it is a client or server) can expect this message from a single source or multiple sources.>

3.42.4.1.1 Trigger Events

3790 *<Description of the real world events that cause the sender (Actor A) to send Message 1 (e.g., an operator or an automated function determines that a new workitem is needed).>*

3.42.4.1.2 Message Semantics

<Detailed description of the meaning, structure and contents of the message, including any IHE specific clarifications of the message format, attributes, etc.>

3795 *<Start by describing the standard underlying the message and how the participating actors are mapped (e.g., "This message is a DICOM C-FIND Request. Actor A is the SCU. Actor D is the SCP.")>*

3800 *<Continue profiling the message by providing guidance or constraints on how the message parameters are populated, how the payload is encoded, how the message is structured and what the contents mean. These message semantics should both help the sender to construct the message and the receiver to interpret the message.>*

3.42.4.1.3 Expected Actions

<Description of the actions expected to be taken as a result of sending or receiving this message.>

<Describe what the receiver is expected/required to do upon receiving this message. >

3805 *<Avoid re-iterating the transaction sequencing specified in the Profile Process Flows as expected actions internal to the transaction. Doing so prevents this transaction being re-used in other contexts.>*

<Explicitly define any expected action based on the multiplicity of an actor(s), if applicable.>

3810 **3.42.5 Protocol Requirements**

<In this section, the selected protocol bindings of the transactions are explained in detail (like SOAP or HTTP bindings). For an example, see the QRPH DEX Profile or ITI TF-2b:3.42.5, 3.35.5. Indicate NA if not used.>

3.42.6 Safety, Effectiveness, Security Requirements & Considerations

3815 **3.42.6.1 SES General Considerations**

<Address any SES requirements & considerations that need to be managed; include linkages to assurance case template entries>

[Editor's Note: The security below includes <Actor> specific considerations .. should that also be included in the SES components? What about message specific considerations?]

3820

[Editor's Note: This transaction is in UNSECURED mode ... need to call that out in general here and then add ??? to the .4 section below?]

3.42.6.2 Safety Requirements & Considerations

3825 *<Requirements for this transaction relating to safety (e.g., risk analysis)>*

3.42.6.3 Effectiveness Requirements & Considerations

<Requirements for this transaction relating to effectiveness (e.g., Quality of Service, Quality of Data, etc.)>

3.42.6.4 Security Requirements & Considerations

3830 *<Description of the transaction specific security consideration; such as use of security profiles.>*

3.42.6.4.1 Security Audit Considerations

<This section should identify any specific ATNA security audit event that is associated with this transaction and requirements on the encoding of that audit event. >

3.42.6.4.1.(z) <Actor> Specific Security Considerations

3835 *<This section should specify any specific security considerations on an actor-by-actor basis.>*

3.43 Update Alert Acknowledgement Status [DEV-43]

3.43.1 Scope

- 3840 This transaction is used to *<...describe what is accomplished by using the transaction. Remember that by keeping transactions general/abstract, they can be re-used in a variety of profiles>*

3.43.2 Actor Roles

3845 3.43.3 Referenced Standards

- *<e.g., HL7 2.3.1 Chapters 2, 3>*

3.43.4 Messages

[Editor's Note: interaction diagram here]

3.43.4.1 "SDC Hello" Message

- 3850 *<One or two sentence summary of what Message 1 accomplishes typically relating the message to the relevant standard. Avoid shall language in this upper level section. Do not duplicate the triggers, encoding, semantics, standards used, or expected actions. Those belong in the following sections.>*
- 3855 *<Explicitly state if the multiplicity of an actor may be greater than one; i.e., if an actor (whether it is a client or server) can expect this message from a single source or multiple sources.>*

3.43.4.1.1 Trigger Events

<Description of the real world events that cause the sender (Actor A) to send Message 1 (e.g., an operator or an automated function determines that a new workitem is needed).>

3.43.4.1.2 Message Semantics

- 3860 *<Detailed description of the meaning, structure and contents of the message, including any IHE specific clarifications of the message format, attributes, etc.>*
- <Start by describing the standard underlying the message and how the participating actors are mapped (e.g., "This message is a DICOM C-FIND Request. Actor A is the SCU. Actor D is the SCP.").>*
- 3865 *<Continue profiling the message by providing guidance or constraints on how the message parameters are populated, how the payload is encoded, how the message is structured and what the contents mean. These message semantics should both help the sender to construct the message and the receiver to interpret the message.>*

3.43.4.1.3 Expected Actions

- 3870 <Description of the actions expected to be taken as a result of sending or receiving this message.>
- <Describe what the receiver is expected/required to do upon receiving this message. >
- <Avoid re-iterating the transaction sequencing specified in the Profile Process Flows as expected actions internal to the transaction. Doing so prevents this transaction being re-used in other contexts.>
- 3875 <Explicitly define any expected action based on the multiplicity of an actor(s), if applicable.>

3.43.5 Protocol Requirements

- 3880 <In this section, the selected protocol bindings of the transactions are explained in detail (like SOAP or HTTP bindings). For an example, see the QRPH DEX Profile or ITI TF-2b:3.43.5, 3.35.5. Indicate NA if not used.>

3.43.6 Safety, Effectiveness, Security Requirements & Considerations

3.43.6.1 SES General Considerations

- 3885 <Address any SES requirements & considerations that need to be managed; include linkages to assurance case template entries>

[Editor's Note: The security below includes <Actor> specific considerations .. should that also be included in the SES components? What about message specific considerations?]

- 3890 [Editor's Note: This transaction is in UNSECURED mode ... need to call that out in general here and then add ??? to the .4 section below?]

3.43.6.2 Safety Requirements & Considerations

<Requirements for this transaction relating to safety (e.g., risk analysis)>

3.43.6.3 Effectiveness Requirements & Considerations

- 3895 <Requirements for this transaction relating to effectiveness (e.g., Quality of Service, Quality of Data, etc.)>

3.43.6.4 Security Requirements & Considerations

<Description of the transaction specific security consideration; such as use of security profiles.>

3.43.6.4.1 Security Audit Considerations

3900 <This section should identify any specific ATNA security audit event that is associated with this transaction and requirements on the encoding of that audit event. >

3.43.6.4.1.(z) <Actor> Specific Security Considerations

<This section should specify any specific security considerations on an actor-by-actor basis.>

3905 3.44 Manage Medical External Control [DEV-44]

3.44.1 Scope

3910 This transaction is used to <...describe what is accomplished by using the transaction. Remember that by keeping transactions general/abstract, they can be re-used in a variety of profiles>

3.44.2 Actor Roles

3.44.3 Referenced Standards

- <e.g., HL7 2.3.1 Chapters 2, 3>

3915 3.44.4 Messages

[Editor's Note: interaction diagram here]

3.44.4.1 "SDC Hello" Message

3920 <One or two sentence summary of what Message 1 accomplishes typically relating the message to the relevant standard. Avoid shall language in this upper level section. Do not duplicate the triggers, encoding, semantics, standards used, or expected actions. Those belong in the following sections.>

<Explicitly state if the multiplicity of an actor may be greater than one; i.e., if an actor (whether it is a client or server) can expect this message from a single source or multiple sources.>

3.44.4.1.1 Trigger Events

3925 <Description of the real world events that cause the sender (Actor A) to send Message 1 (e.g., an operator or an automated function determines that a new workitem is needed).>

3.44.4.1.2 Message Semantics

<Detailed description of the meaning, structure and contents of the message, including any IHE specific clarifications of the message format, attributes, etc.>

3930 *<Start by describing the standard underlying the message and how the participating actors are mapped (e.g., “This message is a DICOM C-FIND Request. Actor A is the SCU. Actor D is the SCP.”).>*

3935 *<Continue profiling the message by providing guidance or constraints on how the message parameters are populated, how the payload is encoded, how the message is structured and what the contents mean. These message semantics should both help the sender to construct the message and the receiver to interpret the message.>*

3.44.4.1.3 Expected Actions

<Description of the actions expected to be taken as a result of sending or receiving this message.>

3940 *<Describe what the receiver is expected/required to do upon receiving this message. >*

<Avoid re-iterating the transaction sequencing specified in the Profile Process Flows as expected actions internal to the transaction. Doing so prevents this transaction being re-used in other contexts.>

3945 *<Explicitly define any expected action based on the multiplicity of an actor(s), if applicable.>*

3.44.5 Protocol Requirements

<In this section, the selected protocol bindings of the transactions are explained in detail (like SOAP or HTTP bindings). For an example, see the QRPH DEX Profile or ITI TF-2b:3.44.5, 3.35.5. Indicate NA if not used.>

3950 3.44.6 Safety, Effectiveness, Security Requirements & Considerations

3.44.6.1 SES General Considerations

<Address any SES requirements & considerations that need to be managed; include linkages to assurance case template entries>

3955 [Editor’s Note: The security below includes <Actor> specific considerations .. should that also be included in the SES components? What about message specific considerations?]

[Editor’s Note: This transaction is in UNSECURED mode ... need to call that out in general here and then add ??? to the .4 section below?]

3960 **3.44.6.2 Safety Requirements & Considerations**

<Requirements for this transaction relating to safety (e.g., risk analysis)>

3.44.6.3 Effectiveness Requirements & Considerations

<Requirements for this transaction relating to effectiveness (e.g., Quality of Service, Quality of Data, etc.)>

3965 **3.44.6.4 Security Requirements & Considerations**

<Description of the transaction specific security consideration; such as use of security profiles.>

3.44.6.4.1 Security Audit Considerations

<This section should identify any specific ATNA security audit event that is associated with this transaction and requirements on the encoding of that audit event. >

3970 **3.44.6.4.1.(z) <Actor> Specific Security Considerations**

<This section should specify any specific security considerations on an actor-by-actor basis.>

3.45 Invoke Medical Control Services [DEV-45]

3975 **3.45.1 Scope**

This transaction is used to <...describe what is accomplished by using the transaction. Remember that by keeping transactions general/abstract, they can be re-used in a variety of profiles>

3.45.2 Actor Roles

3980

3.45.3 Referenced Standards

- *<e.g., HL7 2.3.1 Chapters 2, 3>*

3.45.4 Messages

[Editor's Note: interaction diagram here]

3985 **3.45.4.1 "SDC Hello" Message**

<One or two sentence summary of what Message 1 accomplishes typically relating the message to the relevant standard. Avoid shall language in this upper level section. Do not duplicate the

triggers, encoding, semantics, standards used, or expected actions. Those belong in the following sections.>

- 3990 *<Explicitly state if the multiplicity of an actor may be greater than one; i.e., if an actor (whether it is a client or server) can expect this message from a single source or multiple sources.>*

3.45.4.1.1 Trigger Events

<Description of the real world events that cause the sender (Actor A) to send Message 1 (e.g., an operator or an automated function determines that a new workitem is needed).>

- 3995 **3.45.4.1.2 Message Semantics**

<Detailed description of the meaning, structure and contents of the message, including any IHE specific clarifications of the message format, attributes, etc.>

- 4000 *<Start by describing the standard underlying the message and how the participating actors are mapped (e.g., “This message is a DICOM C-FIND Request. Actor A is the SCU. Actor D is the SCP.”).>*

<Continue profiling the message by providing guidance or constraints on how the message parameters are populated, how the payload is encoded, how the message is structured and what the contents mean. These message semantics should both help the sender to construct the message and the receiver to interpret the message.>

- 4005 **3.45.4.1.3 Expected Actions**

<Description of the actions expected to be taken as a result of sending or receiving this message.>

<Describe what the receiver is expected/required to do upon receiving this message. >

- 4010 *<Avoid re-iterating the transaction sequencing specified in the Profile Process Flows as expected actions internal to the transaction. Doing so prevents this transaction being re-used in other contexts.>*

<Explicitly define any expected action based on the multiplicity of an actor(s), if applicable.>

3.45.5 Protocol Requirements

- 4015 *<In this section, the selected protocol bindings of the transactions are explained in detail (like SOAP or HTTP bindings). For an example, see the QRPH DEX Profile or ITI TF-2b:3.45.5, 3.35.5. Indicate NA if not used.>*

3.45.6 Safety, Effectiveness, Security Requirements & Considerations

3.45.6.1 SES General Considerations

4020 *<Address any SES requirements & considerations that need to be managed; include linkages to assurance case template entries>*

[Editor's Note: The security below includes <Actor> specific considerations .. should that also be included in the SES components? What about message specific considerations?]

4025 [Editor's Note: This transaction is in UNSECURED mode ... need to call that out in general here and then add ??? to the .4 section below?]

3.45.6.2 Safety Requirements & Considerations

<Requirements for this transaction relating to safety (e.g., risk analysis)>

3.45.6.3 Effectiveness Requirements & Considerations

<Requirements for this transaction relating to effectiveness (e.g., Quality of Service, Quality of Data, etc.)>

3.45.6.4 Security Requirements & Considerations

<Description of the transaction specific security consideration; such as use of security profiles.>

3.45.6.4.1 Security Audit Considerations

<This section should identify any specific ATNA security audit event that is associated with this transaction and requirements on the encoding of that audit event. >

3.45.6.4.1.(z) <Actor> Specific Security Considerations

<This section should specify any specific security considerations on an actor-by-actor basis.>

4040

4045

Appendices to Volume 2

4050 <Detailed cross transaction relationships or mapping details are described in an appendix in Volume 2. Volume 2 appendices may be informational or normative. Immediately after the title of a Volume 2 appendix, provide a very explicit statement defining whether this new appendix is informative or normative.

If there are no Volume 2 appendices, enter “Not applicable” and delete the Appendix A and Appendix B placeholder sections.>

Appendix A – ISO/IEEE 11073 SDC / MDPWS Message Specifications (Normative)

[Editor's Note: this section includes "general" messages that may be used in one or more SDPi Transactions earlier in the document. For example, Pub/Sub messages. Specific message usages in a transaction will be handled above, along with appropriate semantic bindings. This section should be used to manage the level of detail in TF-2 specifications, linking to the detailed requirements in the 11073 SDC standards messaging models (incl. MDPWS) and aligned with implementation library (e.g., Python) APIs.

2020.09.07 Note: From Andres Besting

In order to make SDC available in other programming languages, there has recently been an open API specification that is intended to facilitate cross-language use. The specification is based on the OpenAPI standard (<https://www.openapis.org>). The principle of OpenAPI is to specify REST API functions and data types in a machine-readable manner in order to generate client, server code and documentation from this specification.

An example of a possible SDC specification can be found here: <https://bitbucket.org/besting-it/sdcapispec>

You will also find further links here, on the one hand to SDCLib / J, which implements the server side for this, and a C # demo client, which implements the client side. The C # client is also available as a complete NuGet package (for further information see <https://bitbucket.org/besting-it/sdcapisharp>).

To test other languages, I would like to invite you to create additional clients and test them. Information about supported languages and code generators can be found at <https://github.com/OpenAPITools/openapi-generator> .

]

The ISO/IEEE 11073-20702 Medical Device Profile for Web Services (MDPWS) provides transport-level messaging for implementing SDC/BICEPS and SOMDA exchange over a web services infrastructure. Extensive information is provided in both the MDPWS standard as well as the web services standards that it normatively references from IETF, OASIS and W3C including:

OASIS Devices Profile for Web Services (DPWS) Version 1.1, 1 July 2009¹¹

A.1 SDC/BICEPS to SDC/MDPWS Message Specifications

4090 [Editor's Note: Explain the relationship and traceability between general BICEPS message model and specific WS messages called out in the 11073-20702 Medical Device Profile for Web Services (MDPWS) standard.

"Connection" – clarify topic ... note that this annex is very WS-* technically focused]

4095 UPDATE / PROFILE THE BICEPS 7.3.1 Service Model GLUE! for organization of the messages here?

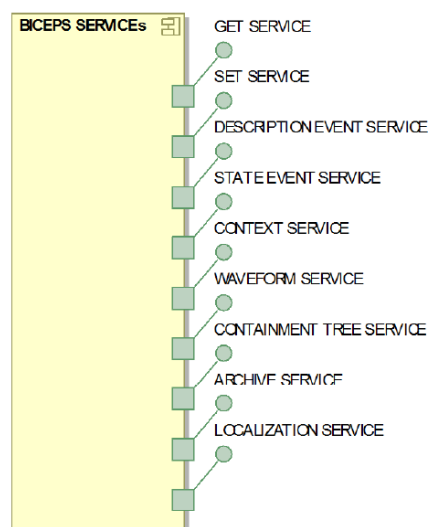


Figure 12—SERVICES defined to let SERVICE CONSUMERS gain access to the MDIB

4100 A.1.1 <Title>

Appendix A.1.1 text.

¹¹ Available at <http://docs.oasis-open.org/ws-dd/dpws/wsdd-dpws-1.1-spec.html>. (Accessed 2020.08.24)

4105 [Editor’s Note: The following subsections A.xyz are intended to be illustrative and NOT reflecting specific organizations of messages. It is assumed that SDC library APIs have considered organizations that provide appropriate groupings. These should be a primary organizing factor for the remaining message sections.]

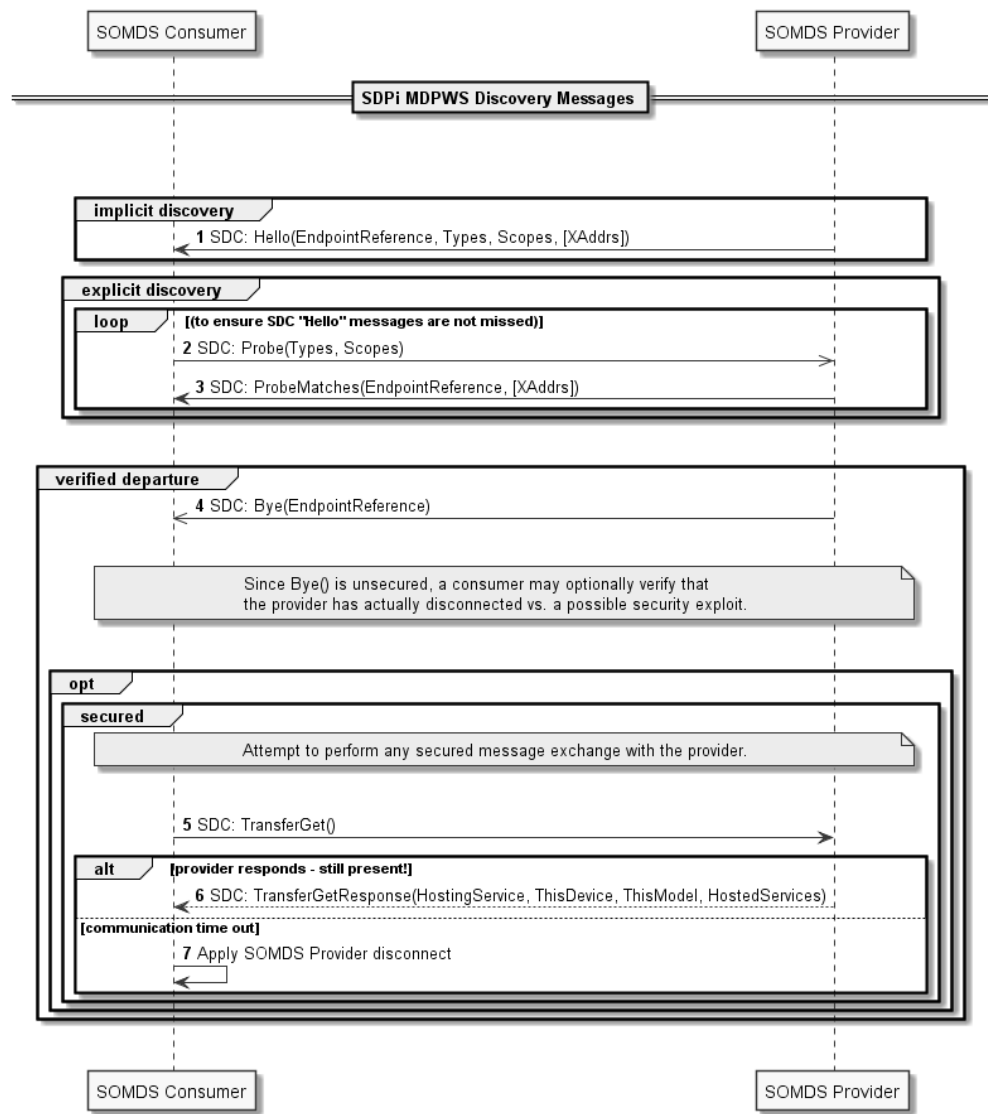
A.2 SDC Messages for BICEPS Discovery Model

4110 The messages in this section relate to the SDC/BICEPS Dynamic Discovery capabilities, including both implicit and explicit discovery.

[Editor’s Note: Include sequence diagram here with MDPWS detailed exchanges?

Also, what about excluded messages, such as Resolve()/ResolveMatches()? Free text here OR in an “Excluded SDC/MDPWS discovery messages” or similar section at the end?

4115 Also, where to identify the BICEPS and SOMDA Rxxxx addressed by the bindings?
]



4120

A.2.1 MDPWS: Hello()

xyz.

4125

[Editor’s Note: Add standardized section content for:

- Binding references (BICEPS, MDPWS,...)

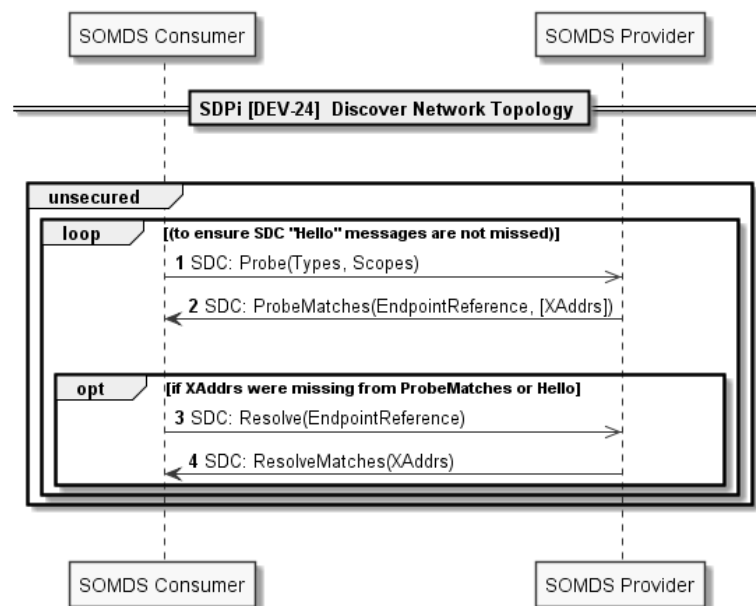
- Parameter semantics
- SES & Other Considerations
- Profiling & Usage Notes
- ...

]

A.2.2 MDPWS: Probe ()

xyz.

[Editor's Note: Or a Probe() / ProbeMatches() section? My assumption is that it is simpler to just keep each message in a separate section.]



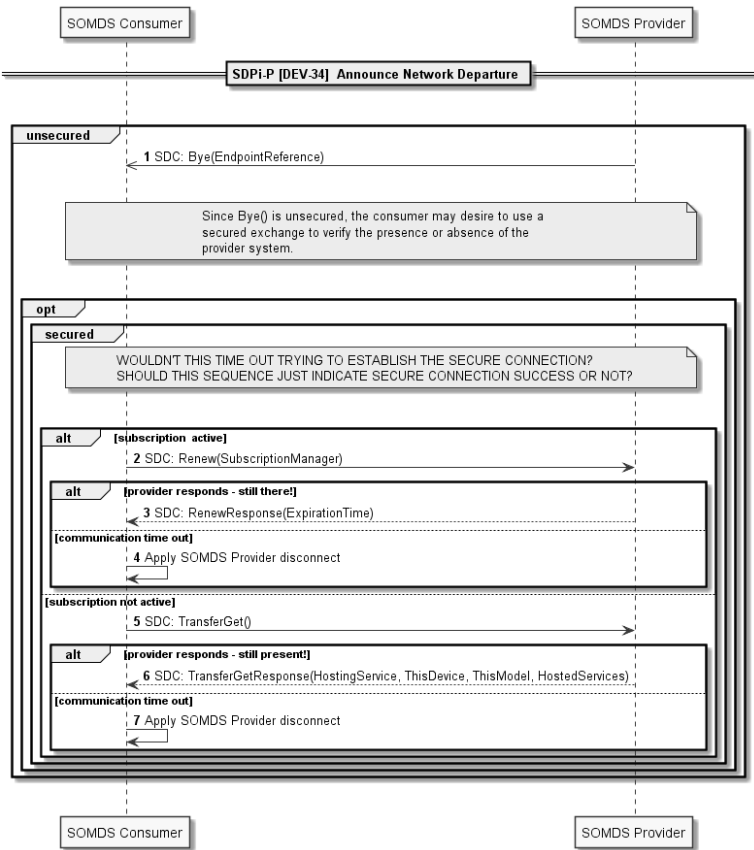
[Editor's Note: Remove "opt" section and indicate WHY this is profiled out in SDPi; then remove diagram.]

A.2.3 MDPWS: ProbeMatches()

xyz.

A.241 MDPWS: Bye()

xyz.



4150

[Editor’s Note: Simplify (per instructions in 8/24 PlantUML; Add in Profiling / Usage Notes]

A.3 SDC Messages for Secure Connections

4155

A.4 SDC Messages for PROVIDER MDIB Discovery

A.5 SDC Messages for Update Publication / Subscription Services

4160 **A.6 SDC Messages for <...>**

A.7 SDC Messages for PARTICIPANT Context Management

4165 **Appendix B – <Appendix Title>**

Appendix B text.

B.1 <Title>

Appendix B.1 text.

B.1.1 <Title>

4170 Appendix B.1.1 text.

Namespace Additions for Volume 2

4175 *<For Public Comment, please explicitly identify all new OIDs, UUIDs, URNs, etc., defined specifically for this profile. These items should be collected from the sections above, and listed here as additions to the applicable domain OID Registry. This section will be deleted prior to inclusion into the Technical Framework as Final Text, but should be present for publication of Public Comment and Trial Implementation.>*

4180 *At Trial Implementation publication, the domain technical committee **must** ensure that all new OIDs, UUIDs, URNs, etc., defined specifically for this profile have been recorded in their OID Registry. This section will be deleted prior to inclusion into the Technical Framework Volumes as Final Text but should be present for publication of Public Comment and Trial Implementation.>*

4185 The Devices registry of OIDs is located at <link to your OID registry(ies)>

Volume 2 additions to the Devices OID Registry are:

Volume 3 – Content Modules

- 4190 *<The current version of the supplement template only addresses HL7 v3 CDA Content Modules and DICOM Content. All CDA Content Modules (Document, Header, Section and Entry) will go in Section 6 of Volume 3 of each domain's Technical Framework document and DICOM Content Definitions will go in Section 7. In the future, this supplement template may have additional sections for other types of Content Modules (Section 8, etc., of Volume 3).*
- 4195 *<Please note that prior to the release of the new template set, some domains may have defined CDA Content Modules in Volume 2 (e.g., PCC); however, going forward, CDA Content Modules will be defined in Volume 3.>*

5 IHE Namespaces, Concept Domains and Vocabularies

Add to Section 5 IHE Namespaces, Concept Domains and Vocabularies

4200 [Editor: Sync this section with the content in IHE DEV TF-3 Rev. 10.0, recognizing that SDC may bring in some additional semantics over those generally “not applicable” in Rev. 10]

5.1 IHE Devices Namespaces

4205 <For Public Comment publication, please explicitly identify all **new** *OIDs, UUIDs, URNs, etc.*, defined specifically for this profile. These items should be collected from the sections within this supplement and listed here as additions to the applicable domain *OID Registry*. The tables within this section will be deleted prior to inclusion into the *Technical Framework as Final Text*, but should be present for publication for *Public Comment*.>

4210 <For Trial Implementation publication, the domain technical committee **must** ensure that all new *OIDs, UUIDs, URNs, etc.*, defined specifically for this profile (and listed here for public comment publication have now been recorded in their *OID Registry*. The tables within this section will be deleted prior to inclusion into the *Technical Framework Volumes as Final Text* but should be present for publication for *Trial Implementation*.>

<Ensure the domain’s registry of *OIDs* is linked to from the following wiki page. It may be another wiki page, a document on the ftp site, etc.>

4215 The Devices registry of *OIDs* is located at
http://wiki.ihe.net/index.php/OID_Registration#IHE_Domain_Namespaces

Additions to the Devices *OID Registry* are:

codeSystem	codeSystemName	Description
<oid or uid>	<code system name>	<short description or pointer to more detailed description>
<oid or uid>	<code system name>	<short description or pointer to more detailed description>
<oid or uid>	<code system name>	<short description or pointer to more detailed description>

4220

5.2 IHE Devices Concept Domains

4225 <Concept Domains are named categories of things that are used when it isn’t possible to bind to a specific set of codes. There are a number of reasons you might not be able to define and bind to a specific set of codes, one of the most common being that the codes set needs to vary depending on locale or context.>

For a listing of the <Domain Acronym> Concept Domains see <enter location of the domains Concept Domains or NA if none>

conceptDomain	conceptDomainName	Description
<oid or uid>	<code system name>	<short description or pointer to more detailed description>
<oid or uid>	<code system name>	<short description or pointer to more detailed description>
<oid or uid>	<code system name>	<short description or pointer to more detailed description>

4230

5.3 IHE Devices Format Codes and Vocabularies

5.3.1 IHE Format Codes

4235

List in the table below any **new** format codes to be added to the IHE Format Codes wiki page at http://wiki.ihe.net/index.php/IHE_Format_Codes. For public comment, the additions must be listed in the table below. The domain technical committee must ensure any new codes are also added to the wiki page prior to publication for trial implementation.

Profile	Format Code	Media Type	Template ID
<Profile name (profile acronym)>	<urn:ihe: >		<oids>

4240

5.3.2 IHEActCode Vocabulary

4245

List in the table below, any **new** additions to the IHEActCode Vocabulary wiki page at http://wiki.ihe.net/index.php/IHEActCode_Vocabulary. For public comment, the additions must be listed in the table below. The domain technical committee must ensure any new codes are also added to the wiki page prior to publication for trial implementation.

Code	Description
<Code name>	<short one sentence description or reference to longer description (not preferred)>

<Code name>	<short one sentence description or reference to longer description (not preferred)>
<Code name>	<short one sentence description or reference to longer description (not preferred)>

5.3.3 IHERoleCode Vocabulary

4250

List in the table below any **new** additions to the *IHERoleCode Vocabulary* wiki page at http://wiki.ihe.net/index.php/IHERoleCode_Vocabulary. For public comment, the additions must be listed in the table below. The domain technical committee must ensure any new codes are also added to the wiki page prior to publication for trial implementation.

Code	Description
<name of role>	<Short, one sentence description of role or reference to more info.>
<name of role>	<Short, one sentence description of role or reference to more info.>
<name of role>	<Short, one sentence description of role or reference to more info.>

6 DEV HL7 V3 CDA Content Modules

4255 [Editor: This section left blank in IHE DEV TF-3 Rev. 10.0]

7 DEV DICOM Content Definitions

[Editor: This section left blank in IHE DEV TF-3 Rev. 10.0]

4260 **8 DEV Semantic Content Modules**

8.1 Overview of device semantic content

8.2 General device content considerations

8.2.8 SDC/BICEPS semantic content

[Editor: Include:

4265 BICEPS Standard overview

Reference TF-1 SDC overview

Include SES section + Assurance Case

Quality of Data requirements; RM Alerting considerations / requirements

Look forward to device specialization profiles

4270 Consider links / bindings to transactions

KEY DIFFERENTIATOR – ALERTING & CONTROL BICEPS elements

]

8.2.8.1 SDC/BICEPS Content Module

4275 [Editor's Note: This subsection defines the overarching “content module” that is required for all SDPi transaction exchanges, namely use of 11073-1010x & -10207 etc. This is referenced in the SDPi-P Content Modules section

Subsequent subsections provide additional descriptive detail for implementers.]

8.2.8.2 SDC/BICEPS Descriptive Model

4280 **8.2.8.3 SDC/BICEPS Relationship to Classic DIM**

8.2.8.4 Safety, Effectiveness, Security Content Requirements & Considerations

8.2.8.5 SDC/BICEPS Conventions for device specialization content modules

4285

8.2.8.6 Device Aggregators & Proxies Modeling

[Editor:

1. Capture the discussion from “[Topic: MDIB/MDS Modeling for Device Aggregators:](#)”
2. NOTE: TBD how much of that discussion is formalized in this section and how much should be covered in other Supplement sections
3. The topic will be included in the Open / Closed Issues section at the start of the supplement.

]

8.2.8.7 SDC/BICEPS Mapping of SOMDS Connector Content Modules

[Editor:

1. General discussion about the need to and how to specify the mapping of content from one system / protocol to SOMDS / SDC / BICEPS ... per the SOMDS Connector Actor
2. If / how these GATWAY CONTENT MODULES will be specified
3. For example, mapping of FHIR Content into a BICEPS WorkflowContext. OR the DoF PoCD IG mappings from -10201 and -10207.
4. OR XCS-I imaging info (metadata & images) into BICEPS ... ???
5. OR when you really shouldn't do such mapping to BICEPS and just have a different extension / API based on the established protocol!

]

8.2.8.8 SOMDA System Function Contribution Content Module

[Editor: Formal definition of the SFC content specification required for PnT connectivity]

8.3 Device specialization content modules

[Editor:

1. Note that for each specialization, the current 9.0 version content will remain unchanged and a specific SDC/BICEPS section will be added to the end;
2. Since OR integration and High-Frequency Surgery devices may be the focus of the SDPi 1.0 supplement, these specializations may also be added to the end.

]

4315 **8.3.1 Device: Infusion Pump**

8.3.1.4 SDC/BICEPS content module

[Editor's Note: This content module will include a detailed "from the device interface" specification:

1. Supporting all (4) PKP functions.
- 4320 2. Aligned with the "enterprise" focused definitions in the preceding sections, but explaining differences & extensions along with rationale
3. Aligned with any 11073 device specialization standard (summarizing approach & referencing detailed conformance XML specification file)
4. Include the high-level containment w/ example & key metrics etc.
- 4325 5. Reference detailed value sets (e.g., via OID) & files, etc.
6. NOTE: This is a CONTENT module; whereas BICEPS uses the descriptive MDIB "content" to also define a specialized set of services. In the case of device-specific services, it is anticipated that this will be addressed in device specialization profile specifications (e.g., profiles that build upon the interoperability foundation of SDPi profiles, but define device-specific architecture / workflow transactions & appropriately
- 4330 scoped content.

]

8.3.2 Device: Ventilator

4335 **8.3.2.4 SDC/BICEPS content module**

[Editor's Note: This content module will include a detailed "from the device interface" specification:

1. Supporting all (4) PKP functions.
- 4340 2. Aligned with the "enterprise" focused definitions in the preceding sections, but explaining differences & extensions along with rationale
3. Aligned with any 11073 device specialization standard (summarizing approach & referencing detailed conformance XML specification file)
4. Include the high-level containment w/ example & key metrics etc.
5. Reference detailed value sets (e.g., via OID) & files, etc.
- 4345 6. NOTE: This is a CONTENT module; whereas BICEPS uses the descriptive MDIB "content" to also define a specialized set of services. In the case of device-specific services, it is anticipated that this will be addressed in device specialization profile

4350 specifications (e.g., profiles that build upon the interoperability foundation of SDPi profiles, but define device-specific architecture / workflow transactions & appropriately scoped content.

]

8.3.3 Device: Physiologic monitor

8.3.3.4 SDC/BICEPS content module

4355 [Editor's Note: This content module will include a detailed "from the device interface" specification:

7. Supporting all (4) PKP functions.
8. Aligned with the "enterprise" focused definitions in the preceding sections, but explaining differences & extensions along with rationale
- 4360 9. Aligned with any 11073 device specialization standard (summarizing approach & referencing detailed conformance XML specification file)
10. Include the high-level containment w/ example & key metrics etc.
11. Reference detailed value sets (e.g., via OID) & files, etc.
- 4365 12. NOTE: This is a CONTENT module; whereas BICEPS uses the descriptive MDIB "content" to also define a specialized set of services. In the case of device-specific services, it is anticipated that this will be addressed in device specialization profile specifications (e.g., profiles that build upon the interoperability foundation of SDPi profiles, but define device-specific architecture / workflow transactions & appropriately scoped content.

4370]

8.3.4 Devices: Surgery

4375 [Editor's Note: This is a place holder section for additional device specializations based on the 11073-1072x projects under way, primarily focused on endoscopic procedures. These include specializations for: HF Device, Endoscopy Camera, Endoscopy Light, Insufflator & Endoscopy Pump. Will also need a Surgery Table, etc.

TBD whether these are grouped under a heading like this OR (more probably) spelled out individually. The need for these – near term – will be to support the Surgery use case.

4380 Ultimately, this will link to normative BICEPS content module specifications that are published in GitHub or the .io space or similar registry.

NOTE: Infusion Pumps are a CLASS of devices ... just like Surgery?

]

8.3.5 Devices: Anesthesia

4385 [Editor's Note: This is a place holder section for additional device specializations based on the 11073-1072x projects under way + real-world products that support SDC interoperability. These include specializations for: Anesthesia Workstation + integration with other general-purpose & specialized anesthesia devices such as syringe pumps or BIS monitors.

See notes for infusion pumps above for additional detail.

]

4390

8.3.6 Devices: Dialysis

4395 [Editor's Note: This is a place holder section for additional device specializations based on the 11073-1072x projects under way + real-world products that support SDC interoperability + other 11073 device specialization specification projects.. These include specializations for both chronic and acute care renal therapy systems.

See notes for infusion pumps above for additional detail.

]

4400

Appendices to Volume 3

<Add any applicable Volume 3 appendices below.

4405 *<If there are no Volume 3 appendices, enter “Not applicable” and delete the Appendix A and Appendix B placeholder sections.>*

Appendix A – <Appendix Title>

Appendix A text.

A.1 <Title>

4410 Appendix A.1 text.

A.1.1 <Title>

Appendix A.1.1 text.

Appendix B – <Appendix Title>

Appendix B text.

4415 **B.1 <Title>**

Appendix B.1 text.

B.1.1 <Title>

Appendix B.1.1 text.

4420

Volume 4 – National Extensions

<i>Add appropriate Country section</i>
--

3 National Extensions for <Country Name or IHE Organization>

4425 *<A template for Volume 4 is included in this document for completeness; however, National Extensions are typically developed after a profile has been published for Trial Implementation. If you are developing a new profile for Public Comment, it is recommended that this section be marked “Not Applicable”.>*

4430 *<Avoid using this section if you can, this is “only if absolutely necessary”. Differences add cost to implementation and testing and can reduce interoperability. Review carefully to determine if the national use case truly requires a difference in the profile mechanisms rather than just differences in system configuration.>*

*<National Extensions can add requirements above and beyond IHE, but **not** relax requirements. This would prevent Connectathon results based on national testing being recognized elsewhere. For more information, see http://wiki.ihe.net/index.php?title=National_Extensions_Process.>*

4435 *The format of this section is not strongly specified due to the varying nature of national extensions. For an example of National Extensions, see the RAD TF 4 or ITI TF-4 documents.>*

<This section should be repeated for each set of additional extensions. Instructions may be given in both English and the native language.>

4440 The national extensions documented in this section shall be used in conjunction with the definitions of integration profiles, actors and transactions provided in Volumes 1 through 3 of the IHE <Domain Acronym> Technical Framework. This section includes extensions and restrictions to effectively support the regional practice of healthcare in <Country Name>. It also translates a number of English terms to ensure correct interpretation of requirements of the <Domain Acronym> Technical Framework.

4445 3.1 Comments

This <Domain Acronym> national extension document was authored under the sponsorship and supervision of <sponsor name> who welcomes comments on this document and the IHE <country> initiative. Comments should be directed to:

Name:

4450 Organization/Title:

Email:

3.2 IHE <Country Name> Scope of Changes

The extensions, restrictions and translations specified apply to the following IHE <Domain Acronym> Integration profiles:

- 4455
- <Domain Acronym>:Profile Name
 - <Domain Acronym>:Profile Name

- Etc.

3.3 <Profile Name> <(Profile Acronym)>

<Add info or tables>

4460 3.3.1 <Profile Acronym> Value Set Binding for <Country Name or IHE Organization> Realm Concept Domains

<This section defines the actual value sets and code systems for any coded concepts that were described by concept domains in the main profile and binds the value set to the coded concepts.>

<Add info or tables>

4465

<Delete the example below prior to publication for Public Comment.>

<Beginning of example

e.g., 3.3.1CARD Value Set Binding for US Realm Concept Domains

UV Concept Domain	US Realm Vocabulary Binding or Single Code Binding	Value Set OID
UV_CardiacProcedureDrugClasses	US_CardiacProcedureDrugClasses	1.3.6.1.4.1.19376.1.4.1.5.15

4470

e.g., 3.3.2.1 US_CardiacProcedureDrugClasses (1.3.6.1.4.1.19376.1.4.1.5.15)

Concept	Coding Scheme	SNOMED CT	NDF-RT
Calcium channel blockers		48698004	N0000029119
Beta-blockers		33252009	N0000029118
Nitrates		31970009	N0000007647
Aminophylline		55867006	N0000146397

end of example>

3.3.2 <Profile Acronym> <Type of Change>

4475 <Add info or tables>

4 National Extensions for <Country Name or IHE Organization>

<Repeat (and increment) the sections above as needed for additional National Extensions>

4480

Appendices to Volume 4

<Add any applicable Volume 4 appendices below>

<If there are no Volume 4 appendices, enter “Not applicable” and delete the Appendix A and Appendix B placeholder sections.>

Appendix A – <Appendix Title>

4485 Appendix A text.

A.1 <Title>

Appendix A.1 text.

A.1.1 <Title>

Appendix A.1.1 text.

4490 **Appendix B – <Appendix Title>**

Appendix B text.

B.1 <Title>

Appendix B.1 text.

B.1.1 <Title>

4495 Appendix B.1.1 text.