**Integrating the Healthcare Enterprise**



**IHE Devices**

**Technical Framework Supplement**

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

**Revision 0.1.12 – Draft in Preparation for Public Comment (*or* Trial Implementation)**

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CONTENTS

[Introduction to this Supplement 23](#_Toc96578077)

[Open Issues and Questions 24](#_Toc96578078)

[Closed Issues 25](#_Toc96578079)

[IHE Technical Frameworks General Introduction 26](#_Toc96578080)

[9 Copyright Licenses 26](#_Toc96578081)

[9.1 Copyright of Base Standards 26](#_Toc96578082)

[9.1.1 DICOM (Digital Imaging and Communications in Medicine) 26](#_Toc96578083)

[9.1.2 HL7 (Health Level Seven) 26](#_Toc96578084)

[9.1.3 LOINC (Logical Observation Identifiers Names and Codes) 27](#_Toc96578085)

[9.1.4 SNOMED CT (Systematized Nomenclature of Medicine -- Clinical Terms) 27](#_Toc96578086)

[9.1.5 IEEE 11073 (Health Device Interoperability) 27](#_Toc96578087)

[10 Trademark 27](#_Toc96578088)

[IHE Technical Frameworks General Introduction Appendices 28](#_Toc96578089)

[Appendix A – Actor Summary Definitions 28](#_Toc96578090)

[Appendix B – Transaction Summary Definitions 29](#_Toc96578091)

[Appendix D – Glossary 30](#_Toc96578092)

[Volume 1 – Profiles 32](#_Toc96578093)

[2 Devices Integration Profiles 32](#_Toc96578094)

[2.2 Safety, Effectiveness & Security Considerations and Requirements 32](#_Toc96578095)

[2.3 Integration Profiles Overview 32](#_Toc96578096)

[10.2.1 <Option Name> 32](#_Toc96578097)

[2.X Service-oriented Device Point-of-care Interoperability (SDPi) – Overview & Framework 33](#_Toc96578098)

[10 Service-oriented Device Point-of-care Interoperability – Plug-and-trust (SDPi-P) Profile 34](#_Toc96578099)

[10.1 SDPi-P Actors, Transactions, and Content Modules 35](#_Toc96578100)

[10.1.1 Actor Descriptions and Actor Profile Requirements 40](#_Toc96578101)

[10.1.1.1 SOMDS Participant 41](#_Toc96578102)

[10.1.1.2 SOMDS Provider 42](#_Toc96578103)

[10.1.1.3 SOMDS Consumer 42](#_Toc96578104)

[10.1.1.4 SOMDS Connector 42](#_Toc96578105)

[10.1.1.5 SOMDS FHIR Gateway 44](#_Toc96578106)

[10.1.1.6 SOMDS V2 Gateway 45](#_Toc96578107)

[10.1.1.7 SOMDS Sensor Gateway 46](#_Toc96578108)

[10.1.1.8 SOMDS Smart App Platform 46](#_Toc96578109)

[10.1.1.9 BICEPS Content Creator 47](#_Toc96578110)

[10.1.1.10 BICEPS Content Consumer 48](#_Toc96578111)

[10.2 SDPi-P Actor Options 48](#_Toc96578112)

[10.2.1 Streaming Option 50](#_Toc96578113)

[10.2.2 Safe Data Transmission Option 50](#_Toc96578114)

[10.2.3 Compact Representation Option 51](#_Toc96578115)

[10.2.4 Patient Context Management Option 51](#_Toc96578116)

[10.2.5 Archive Service Option 51](#_Toc96578117)

[10.2.6 Localization Service Option 52](#_Toc96578118)

[10.2.7 Ensemble Participation Option 52](#_Toc96578119)

[10.3 SDPi-P Required Actor Groupings 52](#_Toc96578120)

[10.4 SDPi-P Overview 55](#_Toc96578121)

[10.4.1 Concepts 55](#_Toc96578122)

[10.4.1.1 SOA & SOMDS Architecture Alignment 55](#_Toc96578123)

[10.4.1.2 General Healthcare vs. Medical Interoperability Purposes 55](#_Toc96578124)

[10.4.1.3 Ensuring Time Synchronization 56](#_Toc96578125)

[10.4.1.3 Aggregators, Proxies, Sensors 56](#_Toc96578126)

[10.4.1.4 Protocol-specific Gateways 56](#_Toc96578127)

[10.4.1.5 Smart App Platforms 56](#_Toc96578128)

[10.4.1.6 Workflow vs. Transport Actors and Interactions 57](#_Toc96578129)

[10.4.1.7 SDC / BICEPS MDIB Versioning Management 57](#_Toc96578130)

[10.4.2 Use Cases 57](#_Toc96578131)

[10.4.2.1 Use Case #1: Functional Endoscopic Sinus Surgery (FESS) 57](#_Toc96578132)

[10.4.2.1.1 FESS Use Case Description 58](#_Toc96578133)

[10.4.2.1.2 FESS Process Flow 58](#_Toc96578134)

[10.4.2.2 Use Case #2: ICU Integration 60](#_Toc96578135)

[10.4.2.2.1 ICU Integration Use Case Description 60](#_Toc96578136)

[10.4.2.2.2 ICU Integration Process Flow 60](#_Toc96578137)

[10.5 SDPi-P Safety, Effectiveness, Security Considerations and Requirements 61](#_Toc96578138)

[10.5.1 SES General Considerations 61](#_Toc96578139)

[10.5.2 Safety Requirements & Considerations 61](#_Toc96578140)

[10.5.3 Effectiveness Requirements & Considerations 61](#_Toc96578141)

[10.5.4 Security Requirements & Considerations 61](#_Toc96578142)

[10.6 SDPi-P Cross Profile Considerations 62](#_Toc96578143)

[11 Service-oriented Device Point-of-care Interoperability - Reporting (SDPi-R) Profile 63](#_Toc96578144)

[11.1 SDPi-R Actors, Transactions, and Content Modules 63](#_Toc96578145)

[11.1.1 Actor Descriptions and Actor Profile Requirements 65](#_Toc96578146)

[11.1.1.1 SOMDS Medical Data Consumer 65](#_Toc96578147)

[11.1.1.2 SOMDS Medical Data Provider 66](#_Toc96578148)

[11.1.1.3 SOMDS FHIR Medical Data Gateway 66](#_Toc96578149)

[11.1.1.4 SOMDS DEC Gateway 67](#_Toc96578150)

[11.2 SDPi-R Actor Options 68](#_Toc96578151)

[11.2.1 <Option Name> 68](#_Toc96578152)

[11.3 SDPi-R Required Actor Groupings 68](#_Toc96578153)

[11.4 SDPi-R Overview 68](#_Toc96578154)

[11.4.1 Concepts 68](#_Toc96578155)

[11.4.2 Use Cases 68](#_Toc96578156)

[11.4.2.1 Use Case #1: <simple name> 68](#_Toc96578157)

[11.4.2.1.1 <simple name> Use Case Description 68](#_Toc96578158)

[11.5 SDPi-R Safety, Effectiveness, Security Considerations and Requirements 68](#_Toc96578159)

[11.5.1 SES General Considerations 68](#_Toc96578160)

[11.5.2 Safety Requirements & Considerations 68](#_Toc96578161)

[11.5.3 Effectiveness Requirements & Considerations 68](#_Toc96578162)

[11.5.4 Security Requirements & Considerations 68](#_Toc96578163)

[11.6 SDPi-R Cross Profile Considerations 69](#_Toc96578164)

[12 Service-oriented Device Point-of-care Interoperability - Alerting (SDPi-A) Profile 70](#_Toc96578165)

[12.1 SDPi-A Actors, Transactions, and Content Modules 70](#_Toc96578166)

[12.1.1 Actor Descriptions and Actor Profile Requirements 72](#_Toc96578167)

[12.1.1.1 SOMDS Medical Alert Consumer 72](#_Toc96578168)

[12.1.1.2 SOMDS Medical Alert Provider 73](#_Toc96578169)

[12.1.1.3 SOMDS ACM Gateway 74](#_Toc96578170)

[12.2 SDPi-A Actor Options 75](#_Toc96578171)

[12.2.1 Alert Delegation 75](#_Toc96578172)

[12.2.1 Alert User Acknowledgement 75](#_Toc96578173)

[12.3 SDPi-A Required Actor Groupings 75](#_Toc96578174)

[12.4 SDPi-A Overview 75](#_Toc96578175)

[12.4.1 Concepts 75](#_Toc96578176)

[12.4.1.1 Medical Alerting and SES MDI Risk Management 75](#_Toc96578177)

[12.4.1.1 Alert Delegation 75](#_Toc96578178)

[12.4.1.2 Acknowledging Alert Conditions 75](#_Toc96578179)

[12.4.1.3 Integration with Alert Communication Management Profile (ACM) 76](#_Toc96578180)

[12.4.1.4 IEC 60601-1-8 DIS / DAS / CDAS Considerations 76](#_Toc96578181)

[12.4.2 Use Cases 76](#_Toc96578182)

[12.4.2.1 Use Case #1: <simple name> 76](#_Toc96578183)

[12.4.2.1.1 <simple name> Use Case Description 76](#_Toc96578184)

[12.4.2.2 Use Case #2: Silent ICU 76](#_Toc96578185)

[12.4.2.2.1 Silent ICU Use Case Description 76](#_Toc96578186)

[12.4.2.2.2 Silent ICU Process Flow 76](#_Toc96578187)

[12.5 SDPi-A Safety, Effectiveness, Security Considerations and Requirements 77](#_Toc96578188)

[12.5.1 SES General Considerations 77](#_Toc96578189)

[12.5.2 Safety Requirements & Considerations 77](#_Toc96578190)

[12.5.3 Effectiveness Requirements & Considerations 77](#_Toc96578191)

[12.5.4 Security Requirements & Considerations 77](#_Toc96578192)

[12.6 SDPi-A Cross Profile Considerations 77](#_Toc96578193)

[13 Service-oriented Device Point-of-care Interoperability – external Control (SDPi-xC) Profile 78](#_Toc96578194)

[13.1 SDPi-xC Actors, Transactions, and Content Modules 78](#_Toc96578195)

[13.1.1 Actor Descriptions and Actor Profile Requirements 80](#_Toc96578196)

[13.1.1.1 SOMDS Medical Control Consumer 80](#_Toc96578197)

[13.1.1.2 SOMDS Medical Control Provider 80](#_Toc96578198)

[13.2 SDPi-xC Actor Options 81](#_Toc96578199)

[13.2.1 <Option Name> 81](#_Toc96578200)

[13.3 SDPi-xC Required Actor Groupings 81](#_Toc96578201)

[13.4 SDPi-xC Overview 81](#_Toc96578202)

[13.4.1 Concepts 81](#_Toc96578203)

[13.4.2 Use Cases 81](#_Toc96578204)

[13.4.2.1 Use Case #1: <simple name> 81](#_Toc96578205)

[13.4.2.1.1 <simple name> Use Case Description 81](#_Toc96578206)

[13.5 SDPi-xC Safety, Effectiveness, Security Considerations and Requirements 81](#_Toc96578207)

[13.5.1 SES General Considerations 81](#_Toc96578208)

[13.5.2 Safety Requirements & Considerations 81](#_Toc96578209)

[13.5.3 Effectiveness Requirements & Considerations 82](#_Toc96578210)

[13.5.4 Security Requirements & Considerations 82](#_Toc96578211)

[13.6 SDPi-xC Cross Profile Considerations 82](#_Toc96578212)

[Appendices to Volume 1 83](#_Toc96578213)

[Appendix A – Requirements Management for Plug-and-Trust Interoperability 84](#_Toc96578214)

[A.1 Requirements: From Narratives to Plug-and-Trust Interfaces 84](#_Toc96578215)

[A.1.1 Hanging Gardens “Layers” Model 84](#_Toc96578216)

[A.1.2 ISO/IEEE 11073 SDC Components 85](#_Toc96578217)

[A.1.3 Reference Frameworks – IHE and MDIRA / ICE 85](#_Toc96578218)

[A.1.4 Assurance Case Integration as Basis of Trust 85](#_Toc96578219)

[A.1.5 <other subsections> 85](#_Toc96578220)

[A.2 Integrating Safety, Effectiveness & Security Requirements & Considerations 85](#_Toc96578221)

[A.2 Requirements Capture, Mapping & Traceability Layer-to-Layer 86](#_Toc96578222)

[A.3 Specifying SystemFunctionContribution (SFC) for Plug-and-Trust Interfaces 86](#_Toc96578223)

[A.4 Requirements Management using Gherkin & ReqIF 86](#_Toc96578224)

[A.4.1 Use Case Formalization using Gherkin 86](#_Toc96578225)

[A.4.2 Requirements Specification using ReqIF 86](#_Toc96578226)

[A.4.3 Mapping ReqIF from Scenarios to Interfaces 86](#_Toc96578227)

[A.5 Approach for integrating ReqIF into the IHE DEV Technical Framework 86](#_Toc96578228)

[Appendix B – Referenced Standards Requirements Conformance Support 88](#_Toc96578229)

[B.1 Mapping Foundational Requirements to SDPi Constructs 88](#_Toc96578230)

[B.2 IEEE Implementation Conformance Statement (ICS) Table Overview 88](#_Toc96578231)

[B.3 ISO/IEC 11073-10207 BICEPS ICS Tables 89](#_Toc96578232)

[B.2.1 General 89](#_Toc96578233)

[B.2.2 Service Provider 90](#_Toc96578234)

[B.2.3 Service Consumer 92](#_Toc96578235)

[B.2.4 Remote Control 92](#_Toc96578236)

[B.2.5 Context Processing 92](#_Toc96578237)

[B.4 ISO/IEC 11073-20701 SOMDA ICS Tables 94](#_Toc96578238)

[B.3.1 MDIB Version 94](#_Toc96578239)

[B.3.2 Handle-based Filtering 94](#_Toc96578240)

[B.3.3 Cyber-Security 94](#_Toc96578241)

[B.3.4 Discovery 95](#_Toc96578242)

[B.3.5 Quality of Service (QoS) 95](#_Toc96578243)

[B.5 ISO/IEC 11073-20702 MDPWS ICS Tables 95](#_Toc96578244)

[B.4.1 General 96](#_Toc96578245)

[B.4.2 Streaming 96](#_Toc96578246)

[B.4.3 Safe Data Transmission 97](#_Toc96578247)

[B.4.4 Compact Representation 97](#_Toc96578248)

[B.4.5 Secured Discovery 98](#_Toc96578249)

[B.6 IEEE 11073-10700 Base PKP ICS Tables 98](#_Toc96578250)

[B.5.1 Support for general concepts and capabilities 99](#_Toc96578251)

[B.5.2 General ICSs applicable to SDC PARTICIPANTSs 99](#_Toc96578252)

[B.5.3 ICSs applicable to SDC SERVICE PROVIDERs only 100](#_Toc96578253)

[B.5.4 ICSs applicable to SDC SERVICE CONSUMERs only 100](#_Toc96578254)

[B.7 ISO/IEC 80001-1:2021 (2nd Edition) 101](#_Toc96578255)

[B.6.1 Support for general concepts and capabilities 103](#_Toc96578256)

[B.6.2 Support for specific requirements 103](#_Toc96578257)

[B.8 JHU/APL MDIRA Specification 104](#_Toc96578258)

[Appendix C – Device Point-of-care Interoperability (DPI) Use Cases 105](#_Toc96578259)

[C.1 Overview of DPI Narratives, Use Cases & Scenarios 105](#_Toc96578260)

[C.1.1 Rich History of Medical Device Interoperability Use Cases 105](#_Toc96578261)

[C.1.2 Overview of Architectural & Business Systems Concepts 105](#_Toc96578262)

[C.1.3 Overview of DIS & DAS Medical Device Alert Distribution Systems 106](#_Toc96578263)

[C.1.4 Use Case Specification Conventions Using Cucumber/Gherkin 109](#_Toc96578264)

[C.2 Use Case Feature: Standalone OR Dashboard (SORD) 110](#_Toc96578265)

[C.2.1 Narrative: 110](#_Toc96578266)

[C.2.2 Background: Technical Pre-Conditions 110](#_Toc96578267)

[C.2.3 Scenario: SORD 1.1 - OR Devices are Accessible to the Dashboard 110](#_Toc96578268)

[C.2.4 Scenario: SORD 1.2 - OR Devices are inaccessible to the Dashboard 111](#_Toc96578269)

[C.2.5 Scenario: SORD 1.3 - One or more OR Devices are inaccessible to the Dashboard 111](#_Toc96578270)

[C.3 Use Case Feature: Standalone OR Cockpit (SORC) 111](#_Toc96578271)

[C.3.1 Narrative: 111](#_Toc96578272)

[C.3.2 Background: Technical Pre-Condition 112](#_Toc96578273)

[C.3.3 Scenario: SORC 2.1 - OR Devices are accessible to the Cockpit 112](#_Toc96578274)

[C.3.4 Scenario: SORC 2.2 - OR Devices are inaccessible to the Cockpit 112](#_Toc96578275)

[C.3.5 Scenario: SORC 2.3 - Some OR Devices are inaccessible to the Cockpit 112](#_Toc96578276)

[C.4 Use Case Feature: Isolation PoC Use Case (IPoC) 113](#_Toc96578277)

[C.4.1 Narrative: 113](#_Toc96578278)

[C.4.2 Background: Technical Pre-Conditions 114](#_Toc96578279)

[C.4.3 Scenario: IPoC 3.1 – Isolation bed & devices need to be configured for patient 114](#_Toc96578280)

[C.5 - Use Case Feature: Silent PoC Alert distribution (SpoC) 114](#_Toc96578281)

[C.5.1 Narrative 114](#_Toc96578282)

[C.5.2 Background: Technical Pre-Condition 115](#_Toc96578283)

[C.5.3 Scenario: SPoC 4.1 - Medical device detects an alert situation and at least one distributed alarm system (xDASxx) is accessible 115](#_Toc96578284)

[C.5.4 Scenario: SPoC 4.2 - Medical device detects an alert situation and all distributed alarm systems (xDASxx) are inaccessible or become inaccessible 116](#_Toc96578285)

[C.5.5 Scenario: SPoC 4.3 - Alert situation has been resolved and at least one distributed alarm system (xDASxx) is accessible 116](#_Toc96578286)

[C.5.6 Scenario: SPoC 4.4 - Medical device detects an alert situation, initially xDASxx is accessible but fails 116](#_Toc96578287)

[C.6 Use Case Feature: Silent ICU Alert Distribution (SICU) 116](#_Toc96578288)

[C.6.1 Narrative: 117](#_Toc96578289)

[C.6.2 Background: Technical Pre-Condition 117](#_Toc96578290)

[C.6.3 Scenario: SICU 5.1 - Medical device detects an alert situation and the distributed alarm system CDAScg is accessible 118](#_Toc96578291)

[C.6.4 Scenario: SICU 5.2 - Medical device detects an alert situation and the distributed alarm system CDAScg is inaccessible 118](#_Toc96578292)

[C.6.5 Scenario: SICU 5.3 - Medical device detects an alert situation and all distributed alarm systems (xDASxx) are or become inaccessible 118](#_Toc96578293)

[C.6.6 Scenario: SICU 5.4 - Alert situation has been resolved and at least one distributed alarm system (xDASxx) is accessible 119](#_Toc96578294)

[C.6.7 Scenario: SICU 5.5 - Medical device detects an alert situation, initially DAS is accessible but fails 119](#_Toc96578295)

[C.7 Use Case Feature: Remote Alert Management (RAM) 119](#_Toc96578296)

[C.7.1 Narrative 119](#_Toc96578297)

[C.7.2 Background: Technical Pre-Condition 120](#_Toc96578298)

[C.7.3 Scenario: RAM 6.1 - Caregiver adjusts alarm limit at their Mobile Device 120](#_Toc96578299)

[C.7.4 Scenario: RAM 6.2 - Caregiver attempts to adjust alarm limit at their CDAScg mobile device but the respective CDAScg is not accessible 121](#_Toc96578300)

[C.8 Use Case Feature: Smart Alerting System (SAS) 121](#_Toc96578301)

[C.8.1 Narrative: 121](#_Toc96578302)

[C.8.2 Background: Technical Pre-Conditions 122](#_Toc96578303)

[C.8.3 Scenario Outline: SAS 7.1 - Local device generates alerts, Smart Alerting System is accessible, and xDASmp and/or xDAScg is accessible 122](#_Toc96578304)

[C.8.4 Scenario Outline: SAS 7.2 - Local device generates alerts, Smart Alerting System is inaccessible, and xDASmp and/or xDAScg is accessible 123](#_Toc96578305)

[C.8.5 Scenario: SAS 7.3 - Local device generates alerts, and xDASmp and/or xDAScg is inaccessible 123](#_Toc96578306)

[C.8.6 Scenario: SAS 7.4 -Smart Alerting generates an alert and an xDASxx is accessible 124](#_Toc96578307)

[C.8.7 Scenario: SAS 7.5 - Smart Alerting generates an alert and an xDASxx is inaccessible 124](#_Toc96578308)

[C.8.8 Scenario: SAS 7.6 - Smart Alerting System is inaccessible from devices and an xDASxx is accessible 124](#_Toc96578309)

[C.8.9 Scenario: SAS 7.7 - Smart Alerting System is inaccessible from devices and an xDASxx is inaccessible 124](#_Toc96578310)

[C.8.10 Scenario: SAS 7.8: Devices, CDASxx and Smart Alerting System are accessible, and SAS generates an alert 125](#_Toc96578311)

[C.9 Use Case Feature: <xyz> 125](#_Toc96578312)

[Volume 2 – Transactions 126](#_Toc96578313)

[3.23 Announce Network Presence [DEV-23] 126](#_Toc96578314)

[3.23.1 Scope 126](#_Toc96578315)

[3.23.2 Actor Roles 126](#_Toc96578316)

[3.23.3 Referenced Standards 126](#_Toc96578317)

[3.23.4 Messages 127](#_Toc96578318)

[3.23.4.1 BICEPS Announce Network Presence Message 127](#_Toc96578319)

[3.23.4.1.1 Trigger Events 127](#_Toc96578320)

[3.23.4.1.2 Message Semantics 128](#_Toc96578321)

[3.23.4.1.3 Expected Actions 128](#_Toc96578322)

[3.23.5 Protocol Requirements 129](#_Toc96578323)

[3.23.6 Safety, Effectiveness, Security Requirements & Considerations 129](#_Toc96578324)

[3.23.6.1 SES General Considerations 129](#_Toc96578325)

[3.23.6.2 Safety Requirements & Considerations 129](#_Toc96578326)

[3.23.6.3 Effectiveness Requirements & Considerations 129](#_Toc96578327)

[3.23.6.4 Security Requirements & Considerations 129](#_Toc96578328)

[3.23.6.4.1 Security Audit Considerations 129](#_Toc96578329)

[3.23.6.4.1.(z) <Actor> Specific Security Considerations 130](#_Toc96578330)

[3.24 Discover Network Topology [DEV-24] 130](#_Toc96578331)

[3.24.1 Scope 130](#_Toc96578332)

[3.24.2 Actor Roles 130](#_Toc96578333)

[3.24.3 Referenced Standards 130](#_Toc96578334)

[3.24.4 Messages 130](#_Toc96578335)

[3.24.4.1 BICEPS DiscoverNetworkProviders() Message 131](#_Toc96578336)

[3.24.4.1.1 Trigger Events 131](#_Toc96578337)

[3.24.4.1.2 Message Semantics 132](#_Toc96578338)

[3.24.4.1.3 Expected Actions 132](#_Toc96578339)

[3.24.4.2 BICEPS DiscoverNetworkProvidersResponse() Message 132](#_Toc96578340)

[3.24.4.2.1 Trigger Events 132](#_Toc96578341)

[3.24.4.2.2 Message Semantics 132](#_Toc96578342)

[3.24.4.2.3 Expected Actions 133](#_Toc96578343)

[3.24.5 Protocol Requirements 133](#_Toc96578344)

[3.24.6 Safety, Effectiveness, Security Requirements & Considerations 133](#_Toc96578345)

[3.24.6.1 SES General Considerations 133](#_Toc96578346)

[3.24.6.2 Safety Requirements & Considerations 134](#_Toc96578347)

[3.24.6.3 Effectiveness Requirements & Considerations 134](#_Toc96578348)

[3.24.6.4 Security Requirements & Considerations 134](#_Toc96578349)

[3.24.6.4.1 Security Audit Considerations 134](#_Toc96578350)

[3.24.6.4.1.(z) <Actor> Specific Security Considerations 134](#_Toc96578351)

[3.25 Discover BICEPS Services [DEV-25] 134](#_Toc96578352)

[3.25.1 Scope 134](#_Toc96578353)

[3.25.2 Actor Roles 134](#_Toc96578354)

[3.25.3 Referenced Standards 134](#_Toc96578355)

[3.25.4 Messages 134](#_Toc96578356)

[3.25.4.1 “SDC Hello” Message 135](#_Toc96578357)

[3.25.4.1.1 Trigger Events 135](#_Toc96578358)

[3.25.4.1.2 Message Semantics 135](#_Toc96578359)

[3.25.4.1.3 Expected Actions 135](#_Toc96578360)

[3.25.5 Protocol Requirements 135](#_Toc96578361)

[3.25.6 Safety, Effectiveness, Security Requirements & Considerations 136](#_Toc96578362)

[3.25.6.1 SES General Considerations 136](#_Toc96578363)

[3.25.6.2 Safety Requirements & Considerations 136](#_Toc96578364)

[3.25.6.3 Effectiveness Requirements & Considerations 136](#_Toc96578365)

[3.25.6.4 Security Requirements & Considerations 136](#_Toc96578366)

[3.25.6.4.1 Security Audit Considerations 136](#_Toc96578367)

[3.25.6.4.1.(z) <Actor> Specific Security Considerations 136](#_Toc96578368)

[3.26 Discover System Context and Capabilities [DEV-26] 136](#_Toc96578369)

[3.26.1 Scope 136](#_Toc96578370)

[3.26.2 Actor Roles 137](#_Toc96578371)

[3.26.3 Referenced Standards 137](#_Toc96578372)

[3.26.4 Messages 137](#_Toc96578373)

[3.26.4.1 “SDC Hello” Message 137](#_Toc96578374)

[3.26.4.1.1 Trigger Events 137](#_Toc96578375)

[3.26.4.1.2 Message Semantics 137](#_Toc96578376)

[3.26.4.1.3 Expected Actions 137](#_Toc96578377)

[3.26.5 Protocol Requirements 138](#_Toc96578378)

[3.26.6 Safety, Effectiveness, Security Requirements & Considerations 138](#_Toc96578379)

[3.26.6.1 SES General Considerations 138](#_Toc96578380)

[3.26.6.2 Safety Requirements & Considerations 138](#_Toc96578381)

[3.26.6.3 Effectiveness Requirements & Considerations 138](#_Toc96578382)

[3.26.6.4 Security Requirements & Considerations 139](#_Toc96578383)

[3.26.6.4.1 Security Audit Considerations 139](#_Toc96578384)

[3.26.6.4.1.(z) <Actor> Specific Security Considerations 139](#_Toc96578385)

[3.27 Manage BICEPS Subscription [DEV-27] 139](#_Toc96578386)

[3.27.1 Scope 139](#_Toc96578387)

[3.27.2 Actor Roles 139](#_Toc96578388)

[3.27.3 Referenced Standards 139](#_Toc96578389)

[3.27.4 Messages 139](#_Toc96578390)

[3.27.4.1 “SDC Hello” Message 139](#_Toc96578391)

[3.27.4.1.1 Trigger Events 140](#_Toc96578392)

[3.27.4.1.2 Message Semantics 140](#_Toc96578393)

[3.27.4.1.3 Expected Actions 140](#_Toc96578394)

[3.27.5 Protocol Requirements 140](#_Toc96578395)

[3.27.6 Safety, Effectiveness, Security Requirements & Considerations 140](#_Toc96578396)

[3.27.6.1 SES General Considerations 140](#_Toc96578397)

[3.27.6.2 Safety Requirements & Considerations 141](#_Toc96578398)

[3.27.6.3 Effectiveness Requirements & Considerations 141](#_Toc96578399)

[3.27.6.4 Security Requirements & Considerations 141](#_Toc96578400)

[3.27.6.4.1 Security Audit Considerations 141](#_Toc96578401)

[3.27.6.4.1.(z) <Actor> Specific Security Considerations 141](#_Toc96578402)

[3.28 Notify Change in System Context and Capabilities [DEV-28] 141](#_Toc96578403)

[3.28.1 Scope 141](#_Toc96578404)

[3.28.2 Actor Roles 141](#_Toc96578405)

[3.28.3 Referenced Standards 141](#_Toc96578406)

[3.28.4 Messages 141](#_Toc96578407)

[3.28.4.1 “SDC Hello” Message 142](#_Toc96578408)

[3.28.4.1.1 Trigger Events 142](#_Toc96578409)

[3.28.4.1.2 Message Semantics 142](#_Toc96578410)

[3.28.4.1.3 Expected Actions 142](#_Toc96578411)

[3.28.5 Protocol Requirements 142](#_Toc96578412)

[3.28.6 Safety, Effectiveness, Security Requirements & Considerations 143](#_Toc96578413)

[3.28.6.1 SES General Considerations 143](#_Toc96578414)

[3.28.6.2 Safety Requirements & Considerations 143](#_Toc96578415)

[3.28.6.3 Effectiveness Requirements & Considerations 143](#_Toc96578416)

[3.28.6.4 Security Requirements & Considerations 143](#_Toc96578417)

[3.28.6.4.1 Security Audit Considerations 143](#_Toc96578418)

[3.28.6.4.1.(z) <Actor> Specific Security Considerations 143](#_Toc96578419)

[3.29 Publish BICEPS Update Reports [DEV-29] 143](#_Toc96578420)

[3.29.1 Scope 143](#_Toc96578421)

[3.29.2 Actor Roles 144](#_Toc96578422)

[3.29.3 Referenced Standards 144](#_Toc96578423)

[3.29.4 Messages 144](#_Toc96578424)

[3.29.4.1 “SDC Hello” Message 144](#_Toc96578425)

[3.29.4.1.1 Trigger Events 144](#_Toc96578426)

[3.29.4.1.2 Message Semantics 144](#_Toc96578427)

[3.29.4.1.3 Expected Actions 144](#_Toc96578428)

[3.29.5 Protocol Requirements 145](#_Toc96578429)

[3.29.6 Safety, Effectiveness, Security Requirements & Considerations 145](#_Toc96578430)

[3.29.6.1 SES General Considerations 145](#_Toc96578431)

[3.29.6.2 Safety Requirements & Considerations 145](#_Toc96578432)

[3.29.6.3 Effectiveness Requirements & Considerations 145](#_Toc96578433)

[3.29.6.4 Security Requirements & Considerations 145](#_Toc96578434)

[3.29.6.4.1 Security Audit Considerations 145](#_Toc96578435)

[3.29.6.4.1.(z) <Actor> Specific Security Considerations 146](#_Toc96578436)

[3.30 Retrieve BICEPS Content [DEV-30] 146](#_Toc96578437)

[3.30.1 Scope 146](#_Toc96578438)

[3.30.2 Actor Roles 146](#_Toc96578439)

[3.30.3 Referenced Standards 146](#_Toc96578440)

[3.30.4 Messages 146](#_Toc96578441)

[3.30.4.1 “SDC Hello” Message 146](#_Toc96578442)

[3.30.4.1.1 Trigger Events 146](#_Toc96578443)

[3.30.4.1.2 Message Semantics 146](#_Toc96578444)

[3.30.4.1.3 Expected Actions 147](#_Toc96578445)

[3.30.5 Protocol Requirements 147](#_Toc96578446)

[3.30.6 Safety, Effectiveness, Security Requirements & Considerations 147](#_Toc96578447)

[3.30.6.1 SES General Considerations 147](#_Toc96578448)

[3.30.6.2 Safety Requirements & Considerations 147](#_Toc96578449)

[3.30.6.3 Effectiveness Requirements & Considerations 147](#_Toc96578450)

[3.30.6.4 Security Requirements & Considerations 148](#_Toc96578451)

[3.30.6.4.1 Security Audit Considerations 148](#_Toc96578452)

[3.30.6.4.1.(z) <Actor> Specific Security Considerations 148](#_Toc96578453)

[3.31 Set Provider State [DEV-31] 148](#_Toc96578454)

[3.31.1 Scope 148](#_Toc96578455)

[3.31.2 Actor Roles 148](#_Toc96578456)

[3.31.3 Referenced Standards 148](#_Toc96578457)

[3.31.4 Messages 148](#_Toc96578458)

[3.31.4.1 “SDC Hello” Message 148](#_Toc96578459)

[3.31.4.1.1 Trigger Events 148](#_Toc96578460)

[3.31.4.1.2 Message Semantics 149](#_Toc96578461)

[3.31.4.1.3 Expected Actions 149](#_Toc96578462)

[3.31.5 Protocol Requirements 149](#_Toc96578463)

[3.31.6 Safety, Effectiveness, Security Requirements & Considerations 149](#_Toc96578464)

[3.31.6.1 SES General Considerations 149](#_Toc96578465)

[3.31.6.2 Safety Requirements & Considerations 150](#_Toc96578466)

[3.31.6.3 Effectiveness Requirements & Considerations 150](#_Toc96578467)

[3.31.6.4 Security Requirements & Considerations 150](#_Toc96578468)

[3.31.6.4.1 Security Audit Considerations 150](#_Toc96578469)

[3.31.6.4.1.(z) <Actor> Specific Security Considerations 150](#_Toc96578470)

[3.32 Retrieve Archive Data [DEV-32] 150](#_Toc96578471)

[3.32.1 Scope 150](#_Toc96578472)

[3.32.2 Actor Roles 151](#_Toc96578473)

[3.32.3 Referenced Standards 151](#_Toc96578474)

[3.32.4 Messages 151](#_Toc96578475)

[3.32.4.1 “SDC Hello” Message 151](#_Toc96578476)

[3.32.4.1.1 Trigger Events 151](#_Toc96578477)

[3.32.4.1.2 Message Semantics 151](#_Toc96578478)

[3.32.4.1.3 Expected Actions 152](#_Toc96578479)

[3.32.5 Protocol Requirements 152](#_Toc96578480)

[3.32.6 Safety, Effectiveness, Security Requirements & Considerations 152](#_Toc96578481)

[3.32.6.1 SES General Considerations 152](#_Toc96578482)

[3.32.6.2 Safety Requirements & Considerations 152](#_Toc96578483)

[3.32.6.3 Effectiveness Requirements & Considerations 152](#_Toc96578484)

[3.32.6.4 Security Requirements & Considerations 152](#_Toc96578485)

[3.32.6.4.1 Security Audit Considerations 153](#_Toc96578486)

[3.32.6.4.1.(z) <Actor> Specific Security Considerations 153](#_Toc96578487)

[3.33 Retrieve Localization Information [DEV-33] 153](#_Toc96578488)

[3.33.1 Scope 153](#_Toc96578489)

[3.33.2 Actor Roles 153](#_Toc96578490)

[3.33.3 Referenced Standards 153](#_Toc96578491)

[3.33.4 Messages 153](#_Toc96578492)

[3.33.4.1 “SDC Hello” Message 153](#_Toc96578493)

[3.33.4.1.1 Trigger Events 153](#_Toc96578494)

[3.33.4.1.2 Message Semantics 153](#_Toc96578495)

[3.33.4.1.3 Expected Actions 154](#_Toc96578496)

[3.33.5 Protocol Requirements 154](#_Toc96578497)

[3.33.6 Safety, Effectiveness, Security Requirements & Considerations 154](#_Toc96578498)

[3.33.6.1 SES General Considerations 154](#_Toc96578499)

[3.33.6.2 Safety Requirements & Considerations 154](#_Toc96578500)

[3.33.6.3 Effectiveness Requirements & Considerations 155](#_Toc96578501)

[3.33.6.4 Security Requirements & Considerations 155](#_Toc96578502)

[3.33.6.4.1 Security Audit Considerations 155](#_Toc96578503)

[3.33.6.4.1.(z) <Actor> Specific Security Considerations 155](#_Toc96578504)

[3.34 Announce Network Departure [DEV-34] 155](#_Toc96578505)

[3.34.1 Scope 155](#_Toc96578506)

[3.34.2 Actor Roles 155](#_Toc96578507)

[3.34.3 Referenced Standards 155](#_Toc96578508)

[3.34.4 Messages 155](#_Toc96578509)

[3.34.4.1 “SDC Hello” Message 155](#_Toc96578510)

[3.34.4.1.1 Trigger Events 156](#_Toc96578511)

[3.34.4.1.2 Message Semantics 156](#_Toc96578512)

[3.34.4.1.3 Expected Actions 156](#_Toc96578513)

[3.34.5 Protocol Requirements 156](#_Toc96578514)

[3.34.6 Safety, Effectiveness, Security Requirements & Considerations 156](#_Toc96578515)

[3.34.6.1 SES General Considerations 156](#_Toc96578516)

[3.34.6.2 Safety Requirements & Considerations 157](#_Toc96578517)

[3.34.6.3 Effectiveness Requirements & Considerations 157](#_Toc96578518)

[3.34.6.4 Security Requirements & Considerations 157](#_Toc96578519)

[3.34.6.4.1 Security Audit Considerations 157](#_Toc96578520)

[3.34.6.4.1.(z) <Actor> Specific Security Considerations 157](#_Toc96578521)

[3.35 Establish Medical Data Exchange [DEV-35] 157](#_Toc96578522)

[3.35.1 Scope 157](#_Toc96578523)

[3.35.2 Actor Roles 157](#_Toc96578524)

[3.35.3 Referenced Standards 157](#_Toc96578525)

[3.35.4 Messages 158](#_Toc96578526)

[3.35.4.1 “SDC Hello” Message 158](#_Toc96578527)

[3.35.4.1.1 Trigger Events 158](#_Toc96578528)

[3.35.4.1.2 Message Semantics 158](#_Toc96578529)

[3.35.4.1.3 Expected Actions 158](#_Toc96578530)

[3.35.5 Protocol Requirements 159](#_Toc96578531)

[3.35.6 Safety, Effectiveness, Security Requirements & Considerations 159](#_Toc96578532)

[3.35.6.1 SES General Considerations 159](#_Toc96578533)

[3.35.6.2 Safety Requirements & Considerations 159](#_Toc96578534)

[3.35.6.3 Effectiveness Requirements & Considerations 159](#_Toc96578535)

[3.35.6.4 Security Requirements & Considerations 159](#_Toc96578536)

[3.35.6.4.1 Security Audit Considerations 159](#_Toc96578537)

[3.35.6.4.1.(z) <Actor> Specific Security Considerations 159](#_Toc96578538)

[3.36 Publish Medical Data [DEV-36] 159](#_Toc96578539)

[3.36.1 Scope 160](#_Toc96578540)

[3.36.2 Actor Roles 160](#_Toc96578541)

[3.36.3 Referenced Standards 160](#_Toc96578542)

[3.36.4 Messages 160](#_Toc96578543)

[3.36.4.1 “SDC Hello” Message 160](#_Toc96578544)

[3.36.4.1.1 Trigger Events 160](#_Toc96578545)

[3.36.4.1.2 Message Semantics 160](#_Toc96578546)

[3.36.4.1.3 Expected Actions 161](#_Toc96578547)

[3.36.5 Protocol Requirements 161](#_Toc96578548)

[3.36.6 Safety, Effectiveness, Security Requirements & Considerations 161](#_Toc96578549)

[3.36.6.1 SES General Considerations 161](#_Toc96578550)

[3.36.6.2 Safety Requirements & Considerations 161](#_Toc96578551)

[3.36.6.3 Effectiveness Requirements & Considerations 161](#_Toc96578552)

[3.36.6.4 Security Requirements & Considerations 161](#_Toc96578553)

[3.36.6.4.1 Security Audit Considerations 162](#_Toc96578554)

[3.36.6.4.1.(z) <Actor> Specific Security Considerations 162](#_Toc96578555)

[3.37 Retrieve Medical Data [DEV-37] 162](#_Toc96578556)

[3.37.1 Scope 162](#_Toc96578557)

[3.37.2 Actor Roles 162](#_Toc96578558)

[3.37.3 Referenced Standards 162](#_Toc96578559)

[3.37.4 Messages 162](#_Toc96578560)

[3.37.4.1 “SDC Hello” Message 162](#_Toc96578561)

[3.37.4.1.1 Trigger Events 162](#_Toc96578562)

[3.37.4.1.2 Message Semantics 163](#_Toc96578563)

[3.37.4.1.3 Expected Actions 163](#_Toc96578564)

[3.37.5 Protocol Requirements 163](#_Toc96578565)

[3.37.6 Safety, Effectiveness, Security Requirements & Considerations 163](#_Toc96578566)

[3.37.6.1 SES General Considerations 163](#_Toc96578567)

[3.37.6.2 Safety Requirements & Considerations 164](#_Toc96578568)

[3.37.6.3 Effectiveness Requirements & Considerations 164](#_Toc96578569)

[3.37.6.4 Security Requirements & Considerations 164](#_Toc96578570)

[3.37.6.4.1 Security Audit Considerations 164](#_Toc96578571)

[3.37.6.4.1.(z) <Actor> Specific Security Considerations 164](#_Toc96578572)

[3.38 Establish Medical Alert Exchange [DEV-38] 164](#_Toc96578573)

[3.38.1 Scope 164](#_Toc96578574)

[3.38.2 Actor Roles 164](#_Toc96578575)

[3.38.3 Referenced Standards 164](#_Toc96578576)

[3.38.4 Messages 164](#_Toc96578577)

[3.38.4.1 “SDC Hello” Message 164](#_Toc96578578)

[3.38.4.1.1 Trigger Events 165](#_Toc96578579)

[3.38.4.1.2 Message Semantics 165](#_Toc96578580)

[3.38.4.1.3 Expected Actions 165](#_Toc96578581)

[3.38.5 Protocol Requirements 165](#_Toc96578582)

[3.38.6 Safety, Effectiveness, Security Requirements & Considerations 166](#_Toc96578583)

[3.38.6.1 SES General Considerations 166](#_Toc96578584)

[3.38.6.2 Safety Requirements & Considerations 166](#_Toc96578585)

[3.38.6.3 Effectiveness Requirements & Considerations 166](#_Toc96578586)

[3.38.6.4 Security Requirements & Considerations 166](#_Toc96578587)

[3.38.6.4.1 Security Audit Considerations 166](#_Toc96578588)

[3.38.6.4.1.(z) <Actor> Specific Security Considerations 166](#_Toc96578589)

[3.39 Publish Medical Alert Update [DEV-39] 166](#_Toc96578590)

[3.39.1 Scope 166](#_Toc96578591)

[3.39.2 Actor Roles 167](#_Toc96578592)

[3.39.3 Referenced Standards 167](#_Toc96578593)

[3.39.4 Messages 167](#_Toc96578594)

[3.39.4.1 “SDC Hello” Message 167](#_Toc96578595)

[3.39.4.1.1 Trigger Events 167](#_Toc96578596)

[3.39.4.1.2 Message Semantics 167](#_Toc96578597)

[3.39.4.1.3 Expected Actions 167](#_Toc96578598)

[3.39.5 Protocol Requirements 168](#_Toc96578599)

[3.39.6 Safety, Effectiveness, Security Requirements & Considerations 168](#_Toc96578600)

[3.39.6.1 SES General Considerations 168](#_Toc96578601)

[3.39.6.2 Safety Requirements & Considerations 168](#_Toc96578602)

[3.39.6.3 Effectiveness Requirements & Considerations 168](#_Toc96578603)

[3.39.6.4 Security Requirements & Considerations 168](#_Toc96578604)

[3.39.6.4.1 Security Audit Considerations 168](#_Toc96578605)

[3.39.6.4.1.(z) <Actor> Specific Security Considerations 169](#_Toc96578606)

[3.40 Retrieve Medical Alert Status [DEV-40] 169](#_Toc96578607)

[3.40.1 Scope 169](#_Toc96578608)

[3.40.2 Actor Roles 169](#_Toc96578609)

[3.40.3 Referenced Standards 169](#_Toc96578610)

[3.40.4 Messages 169](#_Toc96578611)

[3.40.4.1 “SDC Hello” Message 169](#_Toc96578612)

[3.40.4.1.1 Trigger Events 169](#_Toc96578613)

[3.40.4.1.2 Message Semantics 169](#_Toc96578614)

[3.40.4.1.3 Expected Actions 170](#_Toc96578615)

[3.40.5 Protocol Requirements 170](#_Toc96578616)

[3.40.6 Safety, Effectiveness, Security Requirements & Considerations 170](#_Toc96578617)

[3.40.6.1 SES General Considerations 170](#_Toc96578618)

[3.40.6.2 Safety Requirements & Considerations 170](#_Toc96578619)

[3.40.6.3 Effectiveness Requirements & Considerations 171](#_Toc96578620)

[3.40.6.4 Security Requirements & Considerations 171](#_Toc96578621)

[3.40.6.4.1 Security Audit Considerations 171](#_Toc96578622)

[3.40.6.4.1.(z) <Actor> Specific Security Considerations 171](#_Toc96578623)

[3.41 Manage Medical Alert Delegation [DEV-41] 171](#_Toc96578624)

[3.41.1 Scope 171](#_Toc96578625)

[3.41.2 Actor Roles 171](#_Toc96578626)

[3.41.3 Referenced Standards 171](#_Toc96578627)

[3.41.4 Messages 171](#_Toc96578628)

[3.41.4.1 “SDC Hello” Message 171](#_Toc96578629)

[3.41.4.1.1 Trigger Events 172](#_Toc96578630)

[3.41.4.1.2 Message Semantics 172](#_Toc96578631)

[3.41.4.1.3 Expected Actions 172](#_Toc96578632)

[3.41.5 Protocol Requirements 172](#_Toc96578633)

[3.41.6 Safety, Effectiveness, Security Requirements & Considerations 172](#_Toc96578634)

[3.41.6.1 SES General Considerations 172](#_Toc96578635)

[3.41.6.2 Safety Requirements & Considerations 173](#_Toc96578636)

[3.41.6.3 Effectiveness Requirements & Considerations 173](#_Toc96578637)

[3.41.6.4 Security Requirements & Considerations 173](#_Toc96578638)

[3.41.6.4.1 Security Audit Considerations 173](#_Toc96578639)

[3.41.6.4.1.(z) <Actor> Specific Security Considerations 173](#_Toc96578640)

[3.42 Delegate Medical Alert [DEV-42] 173](#_Toc96578641)

[3.42.1 Scope 173](#_Toc96578642)

[3.42.2 Actor Roles 173](#_Toc96578643)

[3.42.3 Referenced Standards 173](#_Toc96578644)

[3.42.4 Messages 174](#_Toc96578645)

[3.42.4.1 “SDC Hello” Message 174](#_Toc96578646)

[3.42.4.1.1 Trigger Events 174](#_Toc96578647)

[3.42.4.1.2 Message Semantics 174](#_Toc96578648)

[3.42.4.1.3 Expected Actions 174](#_Toc96578649)

[3.42.5 Protocol Requirements 175](#_Toc96578650)

[3.42.6 Safety, Effectiveness, Security Requirements & Considerations 175](#_Toc96578651)

[3.42.6.1 SES General Considerations 175](#_Toc96578652)

[3.42.6.2 Safety Requirements & Considerations 175](#_Toc96578653)

[3.42.6.3 Effectiveness Requirements & Considerations 175](#_Toc96578654)

[3.42.6.4 Security Requirements & Considerations 175](#_Toc96578655)

[3.42.6.4.1 Security Audit Considerations 175](#_Toc96578656)

[3.42.6.4.1.(z) <Actor> Specific Security Considerations 175](#_Toc96578657)

[3.43 Update Alert Acknowledgement Status [DEV-43] 175](#_Toc96578658)

[3.43.1 Scope 176](#_Toc96578659)

[3.43.2 Actor Roles 176](#_Toc96578660)

[3.43.3 Referenced Standards 176](#_Toc96578661)

[3.43.4 Messages 176](#_Toc96578662)

[3.43.4.1 “SDC Hello” Message 176](#_Toc96578663)

[3.43.4.1.1 Trigger Events 176](#_Toc96578664)

[3.43.4.1.2 Message Semantics 176](#_Toc96578665)

[3.43.4.1.3 Expected Actions 177](#_Toc96578666)

[3.43.5 Protocol Requirements 177](#_Toc96578667)

[3.43.6 Safety, Effectiveness, Security Requirements & Considerations 177](#_Toc96578668)

[3.43.6.1 SES General Considerations 177](#_Toc96578669)

[3.43.6.2 Safety Requirements & Considerations 177](#_Toc96578670)

[3.43.6.3 Effectiveness Requirements & Considerations 177](#_Toc96578671)

[3.43.6.4 Security Requirements & Considerations 177](#_Toc96578672)

[3.43.6.4.1 Security Audit Considerations 178](#_Toc96578673)

[3.43.6.4.1.(z) <Actor> Specific Security Considerations 178](#_Toc96578674)

[3.44 Manage Medical External Control [DEV-44] 178](#_Toc96578675)

[3.44.1 Scope 178](#_Toc96578676)

[3.44.2 Actor Roles 178](#_Toc96578677)

[3.44.3 Referenced Standards 178](#_Toc96578678)

[3.44.4 Messages 178](#_Toc96578679)

[3.44.4.1 “SDC Hello” Message 178](#_Toc96578680)

[3.44.4.1.1 Trigger Events 178](#_Toc96578681)

[3.44.4.1.2 Message Semantics 179](#_Toc96578682)

[3.44.4.1.3 Expected Actions 179](#_Toc96578683)

[3.44.5 Protocol Requirements 179](#_Toc96578684)

[3.44.6 Safety, Effectiveness, Security Requirements & Considerations 179](#_Toc96578685)

[3.44.6.1 SES General Considerations 179](#_Toc96578686)

[3.44.6.2 Safety Requirements & Considerations 180](#_Toc96578687)

[3.44.6.3 Effectiveness Requirements & Considerations 180](#_Toc96578688)

[3.44.6.4 Security Requirements & Considerations 180](#_Toc96578689)

[3.44.6.4.1 Security Audit Considerations 180](#_Toc96578690)

[3.44.6.4.1.(z) <Actor> Specific Security Considerations 180](#_Toc96578691)

[3.45 Invoke Medical Control Services [DEV-45] 180](#_Toc96578692)

[3.45.1 Scope 180](#_Toc96578693)

[3.45.2 Actor Roles 180](#_Toc96578694)

[3.45.3 Referenced Standards 180](#_Toc96578695)

[3.45.4 Messages 180](#_Toc96578696)

[3.45.4.1 “SDC Hello” Message 180](#_Toc96578697)

[3.45.4.1.1 Trigger Events 181](#_Toc96578698)

[3.45.4.1.2 Message Semantics 181](#_Toc96578699)

[3.45.4.1.3 Expected Actions 181](#_Toc96578700)

[3.45.5 Protocol Requirements 181](#_Toc96578701)

[3.45.6 Safety, Effectiveness, Security Requirements & Considerations 182](#_Toc96578702)

[3.45.6.1 SES General Considerations 182](#_Toc96578703)

[3.45.6.2 Safety Requirements & Considerations 182](#_Toc96578704)

[3.45.6.3 Effectiveness Requirements & Considerations 182](#_Toc96578705)

[3.45.6.4 Security Requirements & Considerations 182](#_Toc96578706)

[3.45.6.4.1 Security Audit Considerations 182](#_Toc96578707)

[3.45.6.4.1.(z) <Actor> Specific Security Considerations 182](#_Toc96578708)

[Appendices to Volume 2 183](#_Toc96578709)

[Appendix A – ISO/IEEE 11073 SDC / MDPWS Message Specifications (Normative) 184](#_Toc96578710)

[A.1 SDC/BICEPS to SDC/MDPWS Message Specifications 185](#_Toc96578711)

[A.1.1 <Title> 185](#_Toc96578712)

[A.2 SDC Messages for BICEPS Discovery Model 186](#_Toc96578713)

[A.2.1 MDPWS: Hello() 187](#_Toc96578714)

[A.2.2 MDPWS: Probe () 188](#_Toc96578715)

[A.2.3 MDPWS: ProbeMatches() 188](#_Toc96578716)

[A.241 MDPWS: Bye() 189](#_Toc96578717)

[A.3 SDC Messages for Secure Connections 189](#_Toc96578718)

[A.4 SDC Messages for PROVIDER MDIB Discovery 189](#_Toc96578719)

[A.5 SDC Messages for Update Publication / Subscription Services 190](#_Toc96578720)

[A.6 SDC Messages for <…> 190](#_Toc96578721)

[A.7 SDC Messages for PARTICIPANT Context Management 190](#_Toc96578722)

[Appendix B – <Appendix Title> 191](#_Toc96578723)

[B.1 <Title> 191](#_Toc96578724)

[B.1.1 <Title> 191](#_Toc96578725)

[Namespace Additions for Volume 2 192](#_Toc96578726)

[Volume 3 – Content Modules 193](#_Toc96578727)

[5 IHE Namespaces, Concept Domains and Vocabularies 194](#_Toc96578728)

[5.1 IHE Devices Namespaces 194](#_Toc96578729)

[5.2 IHE Devices Concept Domains 194](#_Toc96578730)

[5.3 IHE Devices Format Codes and Vocabularies 195](#_Toc96578731)

[5.3.1 IHE Format Codes 195](#_Toc96578732)

[5.3.2 IHEActCode Vocabulary 195](#_Toc96578733)

[5.3.3 IHERoleCode Vocabulary 196](#_Toc96578734)

[6 DEV HL7 V3 CDA Content Modules 197](#_Toc96578735)

[7 DEV DICOM Content Definitions 198](#_Toc96578736)

[8 DEV Semantic Content Modules 199](#_Toc96578737)

[8.1 Overview of device semantic content 199](#_Toc96578738)

[8.2 General device content considerations 199](#_Toc96578739)

[8.2.8 SDC/BICEPS semantic content 199](#_Toc96578740)

[8.2.8.1 SDC/BICEPS Content Module 199](#_Toc96578741)

[8.2.8.2 SDC/BICEPS Descriptive Model 199](#_Toc96578742)

[8.2.8.3 SDC/BICEPS Relationship to Classic DIM 199](#_Toc96578743)

[8.2.8.4 Nomenclature Considerations – Private Extensions & External Systems 199](#_Toc96578744)

[8.2.8.4 Safety, Effectiveness, Security Content Requirements & Considerations 199](#_Toc96578745)

[8.2.8.5 SDC/BICEPS Conventions for device specialization content modules 200](#_Toc96578746)

[8.2.8.6 Device Aggregators & Proxies Modeling 200](#_Toc96578747)

[8.2.8.7 SDC/BICEPS Mapping of SOMDS Connector Content Modules 200](#_Toc96578748)

[8.2.8.8 SOMDA System Function Contribution Content Module 200](#_Toc96578749)

[8.2.8.8 SDC / BICEPS Extension Provisions 200](#_Toc96578750)

[8.3 Device specialization content modules 200](#_Toc96578751)

[8.3.1 Device: Infusion Pump 201](#_Toc96578752)

[8.3.1.4 SDC/BICEPS content module 201](#_Toc96578753)

[8.3.2 Device: Ventilator 201](#_Toc96578754)

[8.3.2.4 SDC/BICEPS content module 201](#_Toc96578755)

[8.3.3 Device: Physiologic monitor 202](#_Toc96578756)

[8.3.3.4 SDC/BICEPS content module 202](#_Toc96578757)

[8.3.4 Devices: Surgery 203](#_Toc96578758)

[8.3.5 Devices: Anesthesia 203](#_Toc96578759)

[8.3.6 Devices: Dialysis 203](#_Toc96578760)

[Appendices to Volume 3 205](#_Toc96578761)

[Appendix A – <Appendix Title> 206](#_Toc96578762)

[A.1 <Title> 206](#_Toc96578763)

[A.1.1 <Title> 206](#_Toc96578764)

[Appendix B – <Appendix Title> 207](#_Toc96578765)

[B.1 <Title> 207](#_Toc96578766)

[B.1.1 <Title> 207](#_Toc96578767)

[Volume 4 – National Extensions 208](#_Toc96578768)

[3 National Extensions for <Country Name or IHE Organization> 209](#_Toc96578769)

[3.1 Comments 209](#_Toc96578770)

[3.2 IHE <Country Name> Scope of Changes 209](#_Toc96578771)

[3.3 <Profile Name> <(Profile Acronym)> 210](#_Toc96578772)

[3.3.1 <Profile Acronym> Value Set Binding for <Country Name or IHE Organization> Realm Concept Domains 210](#_Toc96578773)

[3.3.2 <Profile Acronym> <Type of Change> 210](#_Toc96578774)

[4 National Extensions for <Country Name or IHE Organization> 211](#_Toc96578775)

[Appendices to Volume 4 212](#_Toc96578776)

[Appendix A – <Appendix Title> 213](#_Toc96578777)

[A.1 <Title> 213](#_Toc96578778)

[A.1.1 <Title> 213](#_Toc96578779)

[Appendix B – <Appendix Title> 214](#_Toc96578780)

[B.1 <Title> 214](#_Toc96578781)

[B.1.1 <Title> 214](#_Toc96578782)

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

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.
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]](#footnote-2) FHIR®[[2]](#footnote-3) 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
* SDPi-Reporting (**SDPi-R**) Profile
* SDPi-Alerting (**SDPi-A**) Profile
* SDPi-external Control (**SDPi-xC**) Profile

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

**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

**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.

## 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.>

[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.

2020.11.16 @ Github Issue linkages

1. Can we simply include a link from this section to the repository and not list the open / closed issues?
2. Should we have issue titles, list them in open & closed and THEN provide the Github link to the specific issue?
3. …

]

## Closed Issues

The following issues have been resolved and integrated into the supplement document.

Note: Issues that include “Topic: …” are the result of Gemini SES+MDI project team discussions. They are linked to a specific [sdpi-fhir github issue](https://github.com/IHE/sdpi-fhir/issues), which in turn is linked to the related [Gemini HL7 confluence page](https://confluence.hl7.org/pages/viewpage.action?pageId=82912211#TopicsofInterest-TopicsontheTable) that provides the full details leading up to the resolution listed below.

[Ed. Note: Look at how these are formatted in other recently published supplements How did I do issue identification / naming for some of the others … I forget!!! ALSO add high priority open issues to the Open Issues list above]

1. **Issue: Topic: Connect Time Delay Algorithm**
   1. Github Issue: [***#33 – Topic: Connect Time Delay Algorithm***](https://github.com/IHE/sdpi-fhir/issues/33)
2. …

# IHE Technical Frameworks General Introduction

The [IHE Technical Framework General Introduction](http://ihe.net/Technical_Frameworks/#GenIntro) 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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Amend section 9.1.x by adding the following:

### 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.

]

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# IHE Technical Frameworks General Introduction Appendices

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

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](https://www.ihe.net/resources/technical_frameworks/#GenIntro).

**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](https://wiki.ihe.net/index.php/Approval_Process_for_IHE_Actors,_Transactions_and_Glossary_Terms) for additional guidance and links to the forms for approval submission.

# Appendix A – Actor Summary Definitions

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

<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](http://ihe.net/Technical_Frameworks/#GenIntro).>

| 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* ***bold underline*** *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. ] |
| 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] |
|  |  |
|  |  |

*<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

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

<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](http://ihe.net/Technical_Frameworks/#GenIntro).>

<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](http://wiki.ihe.net/index.php/IHE_Profile_Design_Principles_and_Conventions#Transactions).

| 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* ***bold underline*** *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.

[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 *Point of Care Devices*. |  | 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 | [Where in the IHE DEV TF defined?] |  | PoC |
| Point of Care Cockpit | [See TF-1 Appendix C description language] |  | PoCC |
| Point of Care Device | A healthcare device that is used at a *point of care*, typically at a patient’s clinical bedside. May include patient-connected mobile devices, such as telemetry monitors. |  | PoCD |
| Point of Care Dashboard | [See TF-1 Appendix C description language] |  |  |
| 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 |
| 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

## 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.*

*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

[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

[Editor’s Note: The template only has a reference to the [http://www.ihe.net/Profiles](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???>

### 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.>

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. ]

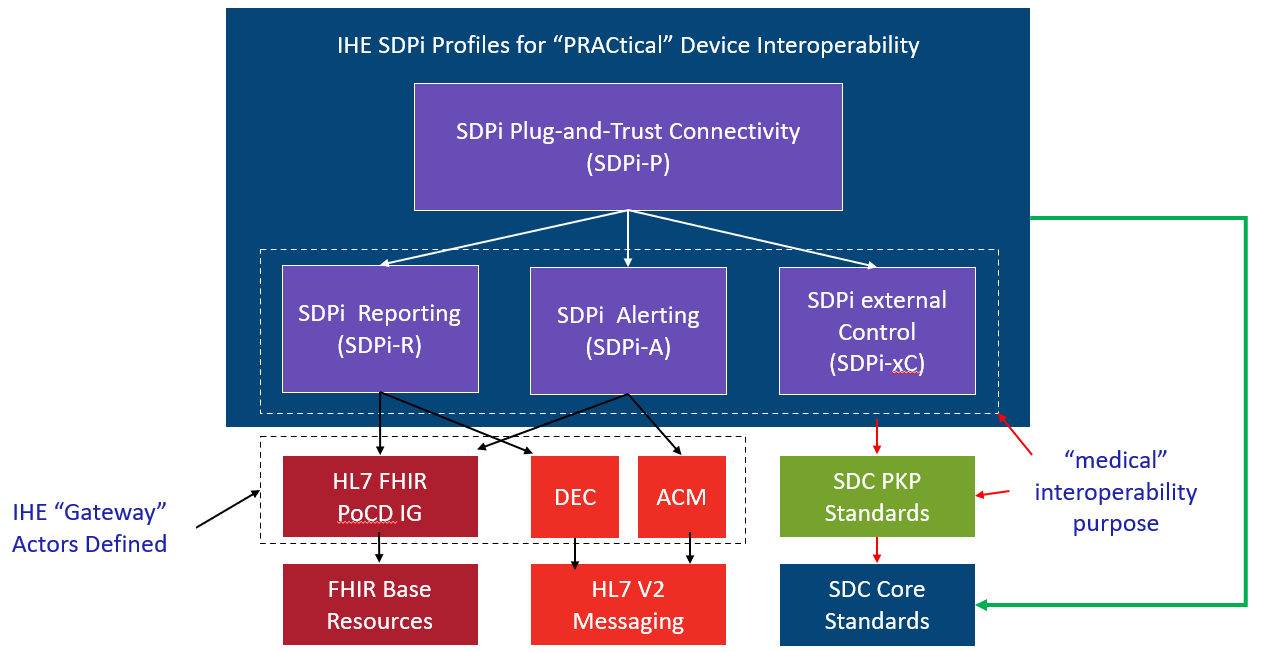


Figure 2.X-1: SDPi Profiles & Foundational Standards

<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 applications[[3]](#footnote-4) 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]](#footnote-5), 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 module[[5]](#footnote-6) 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 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?

]

A screenshot of a social media post

Description automatically generated

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
   1. Analogous to the ACM profile, these actors could include contained boxes / graphics for the components that are currently listed in text …
   2. OR we can just list them in text!
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 :
   1. Note: XCA has “gateway” actors
   2. Clearly this actor CAN integrate a provider and / or consumer actor
   3. 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
   1. 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
   2. Gateways are indicated as specialized versions of the
   3. A “generic” gateway will also support proprietary or other protocols / adaptors / connectors not otherwise specified here
8. …

]

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.

[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)
3. Time Synchronization … and leveraging CT or profiling CT for use with SDC-enabled systems?
4. …

]

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

| Actors | Transactions | Initiator or Responder | Optionality | Reference |
| --- | --- | --- | --- | --- |
| *SOMDS Participant* | [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 |
| 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:

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 …
   1. SDPi MDIB Creator / Reporter?
   2. SDPi MDIB Content / Consumer?
   3. “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*.

A screenshot of a cell phone

Description automatically generated

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 |
| 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:

A screenshot of a cell phone

Description automatically generated

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

[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]

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.

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 MDI[[6]](#footnote-7) 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.

#### 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.

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]

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.

#### 10.1.1.4 SOMDS Connector

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

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.

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.

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.

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.

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*.

[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.]

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*

*[*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 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.

*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?
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?
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!
   1. Perhaps it would be good to define that just to push the point and get feedback one way or the other.

]

#### 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.

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.

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 Devices[[7]](#footnote-8).

[Editor’s Note:

1. Include reference / example to **QEDm profile** … and those FHIR transactions being supported by SOMDS Provider service definitions.
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.

]

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.

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

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.

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 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

]

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.

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.

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).

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.

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.

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.

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.

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.

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]](#footnote-9)

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.

## 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.

[Editor’s Note:

1. Sync with the SDC ICS Options in DEV TF-1 *Appendix B –*
2. *Note that not all SDC options will be carried over as SDPi options … specialization by constraint! (e.g., new Secured Discovery included here)*
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.*
5. *Consider also:*
   1. *Archive Service Support*
   2. *Locationalization Service Support*
   3. *SystemContext (and related contexts) Configuration Support*
   4. *Ensemble Support*
6. *Note also that some OPTIONS that are allowed here may be mandatory in the medical profiles.*
   1. *SDPi-A Alert Delegation Option*
   2. *SDPi-A Alert Confirmation Option*
   3. *SDPi-xC “You Could Kill Someone” Option*
   4. *SDPi-xC Closed-Loop Control Ensemble Option*
   5. *…*

]

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 Streaming Option* |
| Safe Data Transmission Option | DEV TF-1 *10.2.2 Safe Data Transmission Option* |
| Compact Representation Option | DEV TF-1 *10.2.3 Compact Representation Option* |
| Patient Context Management Option | DEV TF-1 *10.2.4 Patient Context Management Option* |
| 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 Consumer  (See Note 1) | Streaming Option | DEV TF-1 *10.2.1 Streaming Option* |
| Safe Data Transmission Option | DEV TF-1 *10.2.2 Safe Data Transmission Option* |
| Compact Representation Option | DEV TF-1 *10.2.3 Compact Representation Option* |
| Patient Context Management Option | DEV TF-1 *10.2.4 Patient Context Management Option* |
| 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?

]

### 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?

]

### 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. May include a SOMDS Connector / Gateway for the PCIM profile transactions
3. And/or does it apply to compression of streams / waveforms, specific bulky data?
4. Topics of Interest pages related to this include:
   1. [Topic: Discovery Proxy Actors](https://confluence.hl7.org/display/GP/Topic%3A+Discovery+Proxy+Actors)
   2. [Topic: SystemContext Profiling & Use](https://confluence.hl7.org/pages/viewpage.action?pageId=86970701)
5. See also HL7 FHIR CAT IPoC discussions that included PCIM mentions + DoF discussions on this topic

]

### 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

]

### 10.2.6 Localization Service Option

[Editor’s Note:

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.

<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.>

[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.]

<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.>

<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. 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.>

| 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]*** |
| SOMDS Provider | *SDPi-P/SOMDS Participant* |  |  |
| SOMDS Consumer | *SDPi-P/SOMDS Participant* |  |  |
| *SOMDS Connector*  (See Note 1) | *SDPi-P/SOMDS Provider* |  |  |
| *SDPi-P/SOMDS Consumer* |  |  |
| SOMDS FHIR Gateway | *SDPi-P/SOMDS Connector* |  |  |
| SOMDS V2 Gateway | *SDPi-P/SOMDS Connector* |  |  |
| SOMDS Sensor Gateway | *SDPi-P/SOMDS Connector* |  |  |
| SOMDS Smart App Platform | *SDPi-P/SOMDS Connector* |  |  |
| BICEPS Content Creator | See Note 2 |  | *DEV TF-3 8.2.8.1 SDC/BICEPS Content Module* |
| BICEPS Content Consumer | See Note 2 |  | *DEV TF-3 8.2.8.1 SDC/BICEPS Content Module* |
|  |  |  |  |
| Actor A | *<external Domain Acronym or blank>*  *SDPi-P/<Actor>*  *<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>*  *SDPi-P/<Actor>* | -- | See Note 1 |
|  | *<external Domain Acronym or blank> SDPi-P/<Actor>* | -- | See Note 1 |
|  | *<external Domain Acronym or blank>*  *SDPi-P/<Actor>* | -- | 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>*  *SDPi-P/<Actor>* | -- | See Note 1 |
|  | *<external Domain Acronym or blank>*  *SDPi-P/<Actor>* | -- | See Note 1 |
| 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>* | -- |

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

*<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

<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

[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

[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

[Editor’s Note: Include single / multiple patient variations. See [Topic on confluence](https://confluence.hl7.org/x/QSsvBQ); 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 …

NOTE: This is not defined in 11073-20701 beyond clause 3. Definitions

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

#### 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.

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:

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.
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.
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.)?

]

#### 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.]

#### 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

[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.

**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 … ???

**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.>

<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

<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.)

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.>

<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”.>

Transaction-A [A]

Actor D/Actor E

Actor A/Actor B

Actor B/Actor C

Internal action 1

Internal action 2

Transaction-B [B]

Transaction-C [C]

Transaction\_2 [2]

Transaction\_3 [3]

Transaction-1 [1]

Transaction-D [D]

Transaction-2 [2]

Figure 10.4.2.2-1: Basic Process Flow in SDPi-P Profile

<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.>

<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.>

**Main Flow**:

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

**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.>

[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

<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>

**Pre-conditions**:

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

**Main Flow**:

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

**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.>

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

<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.>

<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

<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

### 10.5.3 Effectiveness Requirements & Considerations

### 10.5.4 Security Requirements & Considerations

## 10.6 SDPi-P Cross Profile Considerations

<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.” >

*<Consider using a format such as the following:>*

<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>.

# 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.

A screenshot of a cell phone

Description automatically generated

Figure 11.1-1: SDPi-R Actor Diagram [[9]](#footnote-10)

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

1. NOTE this is a first iteration of the diagram – STARTER!
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:
   1. DEC can have DOR and DOC actor implementations; indicate HERE or in actor documentation? Or …
   2. Document FUTURE DEC FHIR Option could be implemented using <SDPi> actors.
   3. 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!
   4. Include rationale for separate –R actors and transactions (incl. BICEPS requirements / message sequences / SES bindings / Conformance claims)
   5. Does Medical Reporting have implications on the SOMDS-external connections? Requirements placed on those?
   6. 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:
   1. Update to show Gateway can play both roles … CONSUMER & PROVIDER
   2. Add DEV-DD Retrieve Archived Medical Data …

]

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 |
| --- | --- | --- | --- | --- |
| SOMDS Medical Data Provider | Establish Medical Data Exchange | Responder | R | DEV TF-2:3.35 |
| 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.*

### 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.

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.

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

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.

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 Devices[[10]](#footnote-11).

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.

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 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.

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]

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.

[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. ]

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.

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).

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.

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.

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

### 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

## 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).

### 11.5.2 Safety Requirements & Considerations

### 11.5.3 Effectiveness Requirements & Considerations

### 11.5.4 Security Requirements & Considerations

## 11.6 SDPi-R Cross Profile Considerations

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

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

## 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.

A screenshot of a cell phone

Description automatically generated

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:
   1. FHIR Gateway goes away until there is a path in DoF IG for medical alerting
   2. ACM – instead of showing the various actors (since there are AR & ACON options for example) just showed the external profile w/ in-scope transactions
   3. SOMDS ACM Gateway can essentially function like a SOMDS Medical Alert Consumer … should we indicate it as such?
   4. @ 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:
   1. Review SDC alerting / delegation & PCD-05 purposes and elements to reflect correctly in the right transactions
   2. Determine if DEV-FF is real … what it is … or if it should be “voted of the island”
   3. Also map to 60601-1-8 constructs, esp. re CDAS
   4. TF-1 SDPi-A include sections (analogous to SDPi-P) on DIS / DAS / CDAS …
   5. NOTE Gateway would only have AR & ACON capabilities (note in profile)

]

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.

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 |
|  | 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.*

### 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]

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.]

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.

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.

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.

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]

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

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.

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.

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.

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

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.

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 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.

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 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.

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.

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.

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

<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

### 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.]

#### 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

[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.

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

[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>

##### 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? !!!!!!!!

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

<sequence diagram>

**Pre-conditions**:

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

**Main Flow**:

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

**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.>

## 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).

### 12.5.2 Safety Requirements & Considerations

### 12.5.3 Effectiveness Requirements & Considerations

### 12.5.4 Security Requirements & Considerations

## 12.6 SDPi-A Cross Profile Considerations

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

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

## SDPi-xC 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 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.

A screenshot of a cell phone

Description automatically generated

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:
   1. Control is currently out-of-scope for SOMDS external entities (e.g., V2 / FHIR based)
   2. Question: All of these have “Establish…” what about “Manage …” similar to SDPi-P’s manage subscription labeling
   3. DEV-BB sequence will be in TF-2, namely Retrieve Current Device State => Invoke Device Control => Verify Invocation
   4. 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?
   5. NOTE: SDPi-P has a basic “set” service transaction, but that is not intended for “MEDICAL” applications
   6. 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
   7. Is it “Service” or “Services”?
3. From initial review discussion 2020.09.11:
   1. Include safety class / “rejection” discussion from Confluence Topic page(s)

]

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.

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.

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 |

### Actor Descriptions and Actor Profile Requirements

#### 13.1.1.1 SOMDS Medical Control 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 managing and invoking external control services from a SOMDS Medical Control Provider system.

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.

<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.

#### 13.1.1.2 SOMDS Medical Control 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 external control services to a SOMDS Medical Control Consumer system.

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

## 13.2 SDPi-xC Actor Options

### 13.2.1 <Option Name>

## 13.3 SDPi-xC Required Actor Groupings

## 13.4 SDPi-xC Overview

### 13.4.1 Concepts

### 13.4.2 Use Cases

[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

### 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

### 13.5.3 Effectiveness Requirements & Considerations

### 13.5.4 Security Requirements & Considerations

## 13.6 SDPi-xC Cross Profile Considerations

Appendices to Volume 1

<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.>

<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>

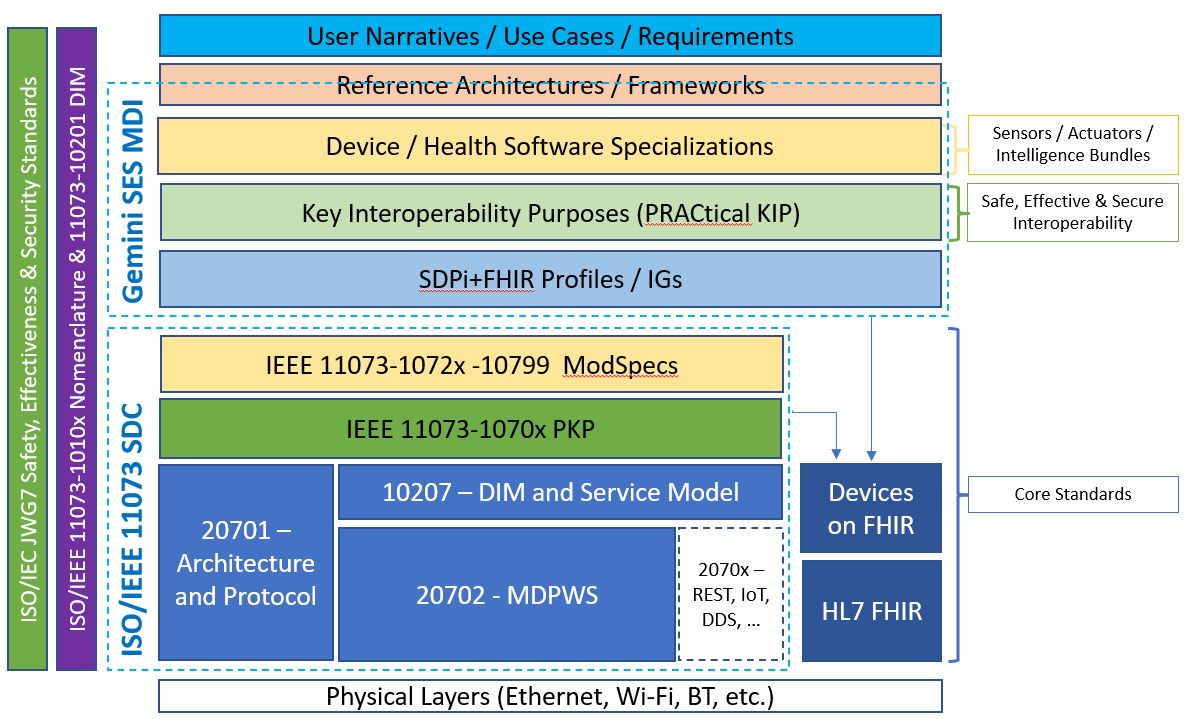
[UPDATE TO LATEST VERSION!]

Figure A.1.1-1: Hanging Gardens Model

<explain the model>

### 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

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

### A.1.5 <other subsections>

## 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>

<Reference the SES MDI white paper>

<???include SES MDI problem graphic?>

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

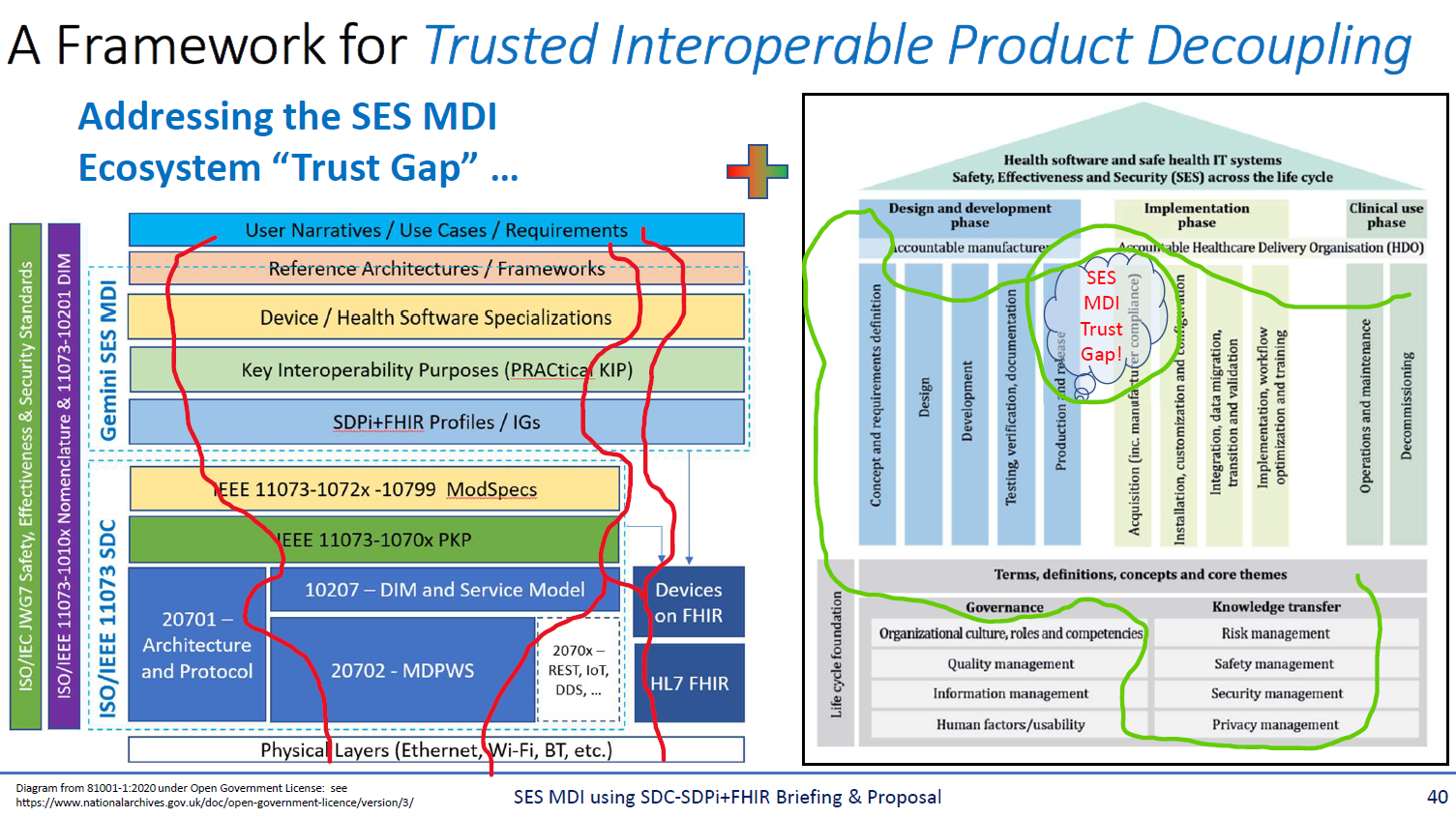


Figure A.2-1: SES MDI Trust Gap Framework Proposal

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

<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>

## A.4 Requirements Management using Gherkin & ReqIF

### A.4.1 Use Case Formalization using Gherkin

### A.4.2 Requirements Specification using ReqIF

### A.4.3 Mapping ReqIF from Scenarios to Interfaces

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

<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 |
|  |  |  |

>

# Appendix B – Referenced Standards Requirements Conformance Support

## B.1 Mapping Foundational Requirements to SDPi Constructs

[Editor’s Notes:

1. Provide overview of both MDI and SES standards mapping
2. ROLE of this ‘mapping” appendix, namely to identify if and what form requirements from various standards are addressed in the SDPi specification.
3. RI in this Appendix provides ***THE primary pivot point*** for coverage and traceability from standard requirement (e.g., 11073-10701) to verification & product CA
4. Plays a key role in RR as well .. identifying WHAT is included in the SES+MDI space and what has to be provided by plug-and-trust product developers / manufacturers

]

## B.2 IEEE Implementation Conformance Statement (ICS) Table Overview

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.

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 a*bove, namely:

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

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

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.?
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?

]

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.3 ISO/IEC 11073-10207 BICEPS ICS Tables

Standard Version: IEEE 11073-10207:2017

[Editor’s Notes:

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.
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.

[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 … hmmmm …



]

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 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.  *[will be resolved in Base PKP]* |
| 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 | *[important if multiple MDSs per MDIB exist; but: multiple MDSs per MDIB should be forbidden and realized by multiple device instead]* |
| ~~PROV-9~~ | Include METRIC retrievability as extension | msg:Retrievability | *[was made mandatory in Glue]* |
| PROV-10 | Increase of instance identifier | pm:MdibVersionGroup/ pm:InstanceId | *[if demanded; no significant effect on interoperability]* |
| PROV-11 | Slot usage | pm:AlertSignalState/ pm:Slot | *[if demanded; no significant effect on interoperability]* |
| PROV-12 | Body site states | pm:AbstractMetricState/ pm:BodySite | *[if demanded; no significant effect on interoperability]* |

### 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. |

### B.2.4 Remote Control

|  |  |  |  |
| --- | --- | --- | --- |
| Index | Feature | Reference | Text |
| SCO-1 | Provide remote capabilities | R0011 | *[Same as PROV-4 – if remote control is supported, R0011 should be mandatory]* |
| 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.  *[if demanded; significant effect on interoperability]* |

### B.2.5 Context Processing

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 pm:PatientContextDescriptor. |
| 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 pm:LocationContextDescriptor. |
| 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 pm:WorkflowContextDescriptor. |
| 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 pm:OperatorContextDescriptor. |
| 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 pm:MeansContextDescriptor. |
| 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 pm:EnsembleContextDescriptor. |
| CTXT-7 | Context state create and update. | msg:SetContextState/ msg:ProposedContextState | *[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.  *[is validated patient context data good enough from the quality perspective or not?]* |

## B.4 ISO/IEC 11073-20701 SOMDA ICS Tables

Standard Version: IEEE 11073-10207:2018

### B.3.1 MDIB Version

<…>

|  |  |  |  |
| --- | --- | --- | --- |
| 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. |

### 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.  *[should be mandatory, if an SDC PARTICIPANT has a UDI]* |
| ~~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.  *[should be made mandatory for MDS, optional for VMDs]* |
| 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.  *[Mandatory for locations and ensembles if that’s in accordance with privacy laws]* |
| 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.  *[should be made mandatory for SDC Provider purpose only]* |

### 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.  *[should be made mandatory]* |
| 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.5 ISO/IEC 11073-20702 MDPWS ICS Tables

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.

|  |  |  |  |
| --- | --- | --- | --- |
| 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.

|  |  |  |  |
| --- | --- | --- | --- |
| 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 . |

### 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. 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

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 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]. |

### 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.

|  |  |  |  |
| --- | --- | --- | --- |
| 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. |

## B.6 IEEE 11073-10700 Base PKP ICS Tables

Standard Version: **IEEE 11073-10700:2021** (**DRAFT**)

Standard Title: P11073-10700™/D3 ***Draft Standard for Base Requirements for Participants in a Service-Oriented Device Connectivity (SDC) System***

[Editor’s Notes:

1. The tables below are based on the DRAFT Base PKP standard and are included here to understand how the PKPs can be implemented
2. Only a subset of each table is included … until they are completed
3. The approach for the -1070x ICS tables is different from that of the “core” SDC standards above, in that ALL Rxxxx are included somewhere in these tables + general requirements at the start of the Conformance section about having to meet ALL “shall” statements + explain any “should” / options that were not included
4. **ALSO it is TBD how much of the content from the original standard we recreate here and what we require people to go back and get the standard for.**
5. **ADDITIONALLY think about “computable IfU” + SF/SFC formalization … like … where are the OIDs specified? And how does the user know that they have all the functions connected and operational that are needed for the CLINICAL FUNCTION of taking out Joe’s appendix?!**

]

### B.5.1 Support for general concepts and capabilities

[Editor’s Notes:

This section should include defined terms from 11073-10700, whether they are in scope in general or how they are supported … in general … as a “preamble” if you will for the ICS table sections below.

]

### B.5.2 General ICSs applicable to SDC PARTICIPANTSs

General Base PKP requirements for all SDC PARTICIPANT systems. For the SDPi profiles, this is represented as the SDPi-P “SOMDS Participant” actor.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Index | Reference | Status | Requirement Text | SDPi Support |
| ICS-1285 | **Error! Reference source not found.** | m | Where there is potential of injury or death resulting from the use of an SDC PARTICIPANT, the MANUFACTURER SHALL use a risk management process and a usability engineering process conforming to recognized standards. | <link to the SES section for SDC Participant> |
| ICS-1005 | **Error! Reference source not found.** | m | When the MANUFACTURER of an SDC PARTICIPANT reveals deficiencies of another SDC PARTICIPANT, the MANUFACTURER SHALL provide information about the deficiency to the MANUFACTURER of the other SDC PARTICIPANT, unless the deficiency is already disclosed in the MEDICAL DEVICE's list of non-conformities. | <out-of-scope for SDPi?> |
| ICS-1241 | RR1241 | m | The MANUFACTURER of an SDC PARTICIPANT SHALL provide a list of OIDs in the accompanying documentation to express which sets of requirements the SDC PARTICIPANT satisfies. | <is this “CA by inspection” + linkage to OIDs list in this document & how discovered dynamically; see Note under requirement that this is to help RO’s identify potential incompatibilities> |
|  |  |  |  |  |

### B.5.3 ICSs applicable to SDC SERVICE PROVIDERs only

Base PKP requirements for all SDC SERVICE PROVIDER systems. For the SDPi profiles, this is represented as the SDPi-P “SOMDS Provider” actor.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Index | Reference | Status | Text | SDPi Support |
| ICS-845 | **Error! Reference source not found.** | m | If an SDC SERVICE PROVIDER declares conformance of a CONTAINMENT TREE ENTRY to a given set of requirements, the SDC SERVICE PROVIDER SHALL be implemented in a way that the CONTAINMENT SUBTREE that has the CONTAINMENT TREE ENTRY as its root conforms to these requirements. | <what in the world do we say to this requirement?! Link to the SES section in TF-3 and related XML files?> |
| ICS-1035 | **Error! Reference source not found.** | m | The MANUFACTURER of an SDC SERVICE PROVIDER SHALL consider the RISK of executing SYSTEM FUNCTIONs with an SDC SERVICE CONSUMER that does not contain the Base Consumer PKP OID in the EKU extension of its X.509 certificate. | <link to SES section in sections where these OIDs are quired? Describe the real-time compute scenarios (e.g., in the related transactions) where the problem might be mitigated or identified? “Testable Assertion” would be document inspection? Drive to test cases that cover the scenarios foreseen here and any real-time mitigations that may / shall be put into place?> |
| ICS-1113 | **Error! Reference source not found.** | m | In the accompanying documentation the MANUFACTURER of an SDC SERVICE PROVIDER SHALL declare for each group of messages having the same DiffServ PHB:   * the factory-configured default PHB, * the required NETWORK BANDWIDTH under MAXIMUM LOAD CONDITIONs (outbound and inbound) | <note: PHB = “per-hop behaviour”; how will the manufacturer “declare” conformity to this requirement? Can we reflect PHB in the MDIB? Can we reflect default PHB in the MDIB? Where is the best place to formalize the SES requirements like bandwidth requirements in the MDIB? For example, to support dynamic network SES monitoring using performance metrics> |
|  |  |  |  |  |

### B.5.4 ICSs applicable to SDC SERVICE CONSUMERs only

General Base PKP requirements for all SDC CONSUMER systems. For the SDPi profiles, this is represented as the SDPi-P “SOMDS Consumer” actor.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Index | Reference | Status | Text | SDPi Support |
| ICS-1210 | **Error! Reference source not found.** | m | For each SYSTEM FUNCTION CONTRIBUTION of an SDC SERVICE CONSUMER, its MANUFACTURER SHALL evaluate which standards are applicable. | <obviously this is an inspection of documentation of the ***evaluation*** BUT “applicable standards” could also be derived from the RI aspects and included in the CA test summary report; ALSO link to each SFC – where FORMALIZED in SDC & SDPi? This will be linked to the SES in general for the SOMDS Consumer.> |
| ICS-1239 | **Error! Reference source not found.** | m | If an SDC SERVICE PROVIDER attaches to a CONTAINMENT TREE ENTRY an extension with @ext:MustUnderstand = true containing a pm:InstanceIdentifier that conveys an OID indicating a set of requirements and an SDC SERVICE CONSUMER does not conform to this set of requirements, the SDC SERVICE CONSUMER SHALL NOT use elements from the CONTAINMENT SUBTREE that has the CONTAINMENT TREE ENTRY as its root for functions where unacceptable RISKs can result from disregarding such requirements. | <link to SES for BICEPS MDIB for Provider use etc. Test cases can both assert the positive and explore the negative side of this requirement> |
| ICS-1215 | **Error! Reference source not found.** | m | The MANUFACTURER of an SDC SERVICE CONSUMER SHALL state an INTEROPERABLE USE SPECIFICATION for the SYSTEM FUNCTION provided by the SDC SERVICE CONSUMER. | <how much of this IUS can be extracted and / or explicitly included in the devices MDIB + verified dynamicly for SOMDS participants> |
|  |  |  |  |  |

## B.7 ISO/IEC 80001-1:2021 (2nd Edition)

Standard Version: **ISO/IEC 80001-1:2021** (2nd Edition)

Standard Title: IEC 80001-1:2021 **Safety, effectiveness and security in the implementation and use of connected medical devices or connected health software — Part 1: Application of risk management**

[Editor’s Notes:

1. This 2nd edition of the 80001-1 risk management standard is significantly modified from the 2010 edition, and it aggregates all requirements into Annex A (informative) IEC 80001-1 requirements mapping table.
2. The table below reflects those summary requirements
3. **ONE OF THE KEY issues for realizing implementation of 80001-1 managed systems (e.g., SOMDS) is that the activities required on the HDO / RO are such that they never have the bandwidth to actually do them, even though every stakeholder recognizes the value of doing so; QUESTION is how we can architect SDPi capabilities and “SES” implementation so as to provide the information (out of the box) that is needed for 80001-1 RM + to ensure the robustness (e.g., auto-SES resilient system configuiration & monitoring (a la MDIRA)) desired**
4. **INITIALLY this section may be more advisory than normative; however, the end goal is to achieve SES MDI robust systems and ease the life for EVERYONE and impacting the lives of patients #1;**
5. Note that the 11073-10700 bPKP standard above references (non-normatively) the 1st 2010 edition, which is far more prescriptive
   1. **ALSO the 2010 edition defines MEDICAL IT-NETWORK but this term has been replaced in the 2nd edition by the more general “Health IT infrastructure” & “health IT networks”**

*…* IEC 80001-1 used the term “medical *IT-network*” to describe the network that hosted and supported the *medical device(s)* within the hospital. In the search for a term that can apply to the broader scope of *medical devices*, *health software*, and other supporting infrastructure, this document uses the term “*health IT infrastructure*” to identify the infrastructure that not only supports but includes *health software*. The health IT infrastructure can include one of more medical devices, software as a medical device (SaMD), health IT systems, as well as other IT infrastructure *components* and cloud-based solutions. It is important to identify and manage this infrastructure for the purposes of maintaining the *safety*, *effectiveness*, and *security* of its *components* and the connected *health software*, *medical devices* and *health IT systems* that leverage them. Figure 2 provides a visual representation of

* 1. **ALSO the implementation of SF / SFC is critical throughout the bPKP standards but is clear as mud when it comes to how to actually implement it in an Ecosystem of PnT Decoupled Products (see B.5 comments above)**

1. **NOTE THE TEXT BELOW IS OK BUT HALF BAKED AT BEST; remember that this is a right-side standard (vs. for a manufacturer) – perhaps there is good content to be found in linking what the RO needs with what SDPi provides … sourced from the systems manufacturer or configured by implementers / end users / RO’s**
2. **CONSIDER addition of a “terms” section General intro to the 80001-1 mapping that identifies topics such as ASSURANCE CASE, HEALTH IT INFRASTRUCTURE, etc. and how that does / does not map to SDPi stuff; ditto for classes of “stakeholders” / actors in the definitions section / documentation inspection vs. documentation generation or verification etc.**

]

### B.6.1 Support for general concepts and capabilities

[Editor’s Notes:

This section should include defined terms from 11073-10700, whether they are in scope in general or how they are supported … in general … as a “preamble” if you will for the subsequent requirements

]

### B.6.2 Support for specific requirements

The following requirements from the 80001-1:2021 standard are from the informative Annex A, Table A.1 that identifies requirements based on the sections of the standard in which they appear. Note that many requirements of this standard are completely out-of-scope for this specification, such as those that pertain to organizational management. When that is the case, the requirement scope is appropriately indicated. In other cases, the risk mitigation requirement may be reflected in a specific SDPi specification element, or may be verified based on capabilities contained in the specification.

|  |  |  |
| --- | --- | --- |
| Section | Requirement | SDPi Support |
| 6.1.2.3  HAZARD identification | **The ORGANIZATION shall:**  a) identify and document known, and foreseeable HAZARDS associated with deployment of the HEALTH IT SYSTEM and its use under both normal and foreseeable operating conditions;  b) review HAZARDS identified in any ACCOMPANYING DOCUMENTS supplied by the HEALTH SOFTWARE or MEDICAL DEVICE MANUFACTURER for applicability in the context of deployment, use or decommissioning of the HEALTH IT SYSTEM; and  c) where no HAZARDS are identified, record the justification for this conclusion within the RISK MANAGEMENT FILE. | <support in SDPi for identifying HAZARDS and their mitigations? Support for ACCOMPANYING DOCUMENTS … info that RO needs for RM?  Links from 80001-1 requirements to PKP ICS table entries to SDPi risk management SES constructs?> |
| 6.1.4.3  VERIFICATION of RISK CONTROL  measures | **The ORGANIZATION shall:**  a) implement the RISK CONTROL measures identified in accordance with 6.1.4.1;  b) verify the ***EFFECTIVENESS*** of each RISK CONTROL measure; and  c) incorporate the results of the RISK MANAGEMENT activities undertaken through the requirements in this subclause in the ***ASSURANCE CASE*** and record them in the RISK MANAGEMENT FILE. | <how does a connected system support verification of RCM effectiveness – both during initial implementation and during use?  How can SDPi + IHE CA support both verification & ASSURANCE CASE content (evidence)? See TF-1 Appendix A section above> |
|  |  |  |
|  |  |  |

## B.8 JHU/APL MDIRA Specification

Specification Version: **MDIRA Version 2.1 (June 2021)**

Specification Title: **Medical Device Interoperability Reference Architecture (MDIRA)**

[Editor’s Notes:

1. This is a PLACE HOLDER section for the anticipated requirements from the Gemini MDIRA profile. That profile will include an Appendix B section like this, capturing the conformity model from the 2.1 specification and indicating how the profile supports those provisions.
2. The MDIRA Profile will also place requirements on SDPi; so those requirements MAY be reflected in this table once MDIRA Supplement 1.0 is published (or being prepared)
3. NOTE: That the IHE TF has provisions for requirements from other IHE profiles (dependencies, grouped actors, etc.). Depending on the requirements from the MDRIA Profile and the mapping of those to one or more SDPi profiles, this “mapping” appendix may / may not be needed. (odds are, it will play a crucial role supporting inter-profile RI!).
4. Include links like: <https://secwww.jhuapl.edu/mdira/documents>, or the github profile location
5. …

]

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

[Editor’s Notes:

1. ~~Detailed use case / scenario analysis w/ Gherkin details & ReqIF linkage would be HERE vs. elsewhere~~
2. ~~Question: Should this be an MDI Appendix or DPI?~~
3. 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]
   1. DECISION: “Feature” files will be validated (e.g., in CucumberStudio) and persisted in the github repo

]

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

[Editor’s Notes:

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)
5. Identify ICE-related use cases that may be integrated in SDPi or in the forthcoming MDIRA profile

]

### C.1.1 Rich History of Medical Device Interoperability Use Cases

[Editor’s Notes:

1. Shout out to the Compendium
2. Connect the HISTORIC dots from use cases in the SDPi White Paper to the Confluence pages to the specific Features below.
3. For example, FESS is now “renamed” as “Standalone OR Cockpit” … all still there but clearer concepts!

]

### C.1.2 Overview of Architectural & Business Systems Concepts

[Editor’s Notes:

1. Include common concepts like Central Station, Cockpit, Dashboard, etc.
2. NOTE: These may be called out in subsequent profiles (e.g., ICU Integration); so language here should both be clear for the subsequent use in
3. Consider including MDIRA / ICE actors within the use case + for a subsequent MDIRA/ICE Profile being proposed (see above C.1.1)
4. Mention also the TF-3 device specializations that may be defined related back to these items

]

### C.1.3 Overview of DIS & DAS Medical Device Alert Distribution Systems

[Editor’s Notes:

1. ~~These concepts are based on established standards such as 60601-1-8~~
2. Intent is to not duplicate ACM actors … and thus engender confusion … but to identify a method of characterizing the various systems more clearly that may also be mapped onto ACM Actors such as AlertManager, AlertSource or AlertCommunicator. NOTE: The SDPi-A profile has defined ACM gateway to support this type of bi-directional interaction.
3. …

]

While IEC 60601-1-8 is focused on alarm and alert functionality, it also provides some very useful system concepts such as the Distributed Information System (DIS) and Distributed Alarm System (DAS). We use these concepts in many of our use cases, so we have included the following is a quick guide to the functionality of DIS, CDIS, DAS and CDAS systems.

**DIS – Distributed Information System**

* DIS is a system for reporting alarm signals with no technical confirmation (of receipt).
  + Cannot rely on it for alarm signaling as a risk control
  + Optional support operator alarm management\* response locally
  + Examples:
    - “Dashboard” - display which integrates the data from one patient. Dashboards do not support audible alerts or remote control.
    - “View Station” - display which integrates the data from multiple patients. View Stations do not support audible alerts or remote control.

**CDIS – Distributed Information System with Confirmation**

* CDIS is a system for reporting alarm signals with no technical confirmation and operator confirmation (accept/reject). (Note it is not recognized in 60601-1-8)
  + Cannot rely on it for alarm signaling as a risk control
  + Optional support operator alarm management\* response locally and remotely
  + Example – two-way pager (open loop)

**xDIS – Connotes a system that can be either a DIS or CDIS**

**DAS – Distributed Alarm System**

* DAS is a system for reporting alarm signals with technical confirmation (of receipt).
  + Can rely on it for alarm signaling as a risk control
  + Supports local alert confirmation
  + A communications failure or failure in any remote component of the DAS must initiate a technical alarm.
  + Examples:
    - “Cockpit”- display which integrates the data from one patient and support audible alerts. The DAS Cockpit only supports local operations while the CDAS cockpit supports operator confirmation and optional remote control.
    - “Central Station” - display which integrates the data from one patient and support audible alerts. The DAS Central Station only supports local operations while the CDAS Central Station supports operator confirmation and optional remote control.

**CDAS - Distributed Information System with Confirmation**

* CDAS is a system for reporting alarm signals with technical and operator confirmation (accept/reject) (of receipt).
  + Can rely on it for alarm signaling as a risk control
  + Supports operator confirmation (accept/reject); It may redirect…
  + Optionally support local/remote alarm management (acknowledgement)
  + A communications failure or failure in any remote component of the DAS must initiate a technical alarm.
  + Examples:
    - Cockpit and/or Central Station with remote confirmation and optional alarm management.
    - System that sends alarm to caregiver mobile device with accept / reject. Integrator may redirect

**xDAS – Connotes a system that can be either a DAS or CDAS**

In addition to the various types of xDIS and xDAS, we have also distinguished between various types of xDIS and xDAS as follows:

* xDxSsp – forms of DxS that are for *single patients*.
* xDxSmp – forms of DxS that are for *multiple patients*
* xDxScg – forms of DxS that communicated directly to the *caregiver*.

The following table provides examples and summarizes the various types of information/alarm systems.

Table C.1.3-1 Alert Distribution System Types

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Description** | **Type** | **Technical Delivery Confirmation1** | **Operator Delivery Confirmation2** | **Optional Alarm Management** | **Examples** |
| Reports alerts from a Single Patient (sp) | DISsp | No | No | Local | Single-Pt. information Dashboard |
| CDISsp | No | Yes3 | Remote3 | Single-Pt. Remote View w/ accept/reject |
| DASsp | Yes | No | Local | Single Pt. Cockpit w/audible alarms |
| CDASsp | Yes | Yes | Remote | Single Pt. Cockpit w/ accept/reject |
| Reports alerts from Multiple Patients (mp) | DISmp | No | No | Local | Multiple-Pt. info. View Station |
| CDISmp | No | Yes3 | Remote3 | Multiple-Pt. info. View Station w/ accept/reject |
| DASmp | Yes | No | Local | Multiple Pt. Central Station w/ audible alarms |
| CDASmp | Yes | Yes | Remote | Multiple Pt. Central Station w/ accept/reject |
| Reports and directs alerts to responsible Caregiver (cg) | DIScg | No | No | Local | Alert Distribution System (ADS) to caregiver pager, Mobile viewer |
| CDIScg | No | Yes3 | Remote | ADS to caregiver pager, w/ accept/reject |
| DAScg | Yes | No | Local | ADS to caregiver w/ audible/haptic alarms |
| CDAScg | Yes | Yes | Remote | ADS to caregiver w/ accept/reject |
| 1 In each communication step the receiving device provides a technical response to the sending device that it received and is taking responsibility for the alert  2 Operator can, at their choice, use the receiving device (communicator) UI to accept or reject responsibility for the alert  3 Not recommended since there is no confirmation that the Source has received the commands | | | | | |

[Editor’s Note: The table above needs to be “converted” to IHE style for Notes. See any of the tables in the profiles sections above.]

### C.1.4 Use Case Specification Conventions Using Cucumber/Gherkin

[Editor’s Notes:

1. Provide overview (why, what, how) for using Gherkin
2. Gherkin usage considerations / conventions (improved clarity & specificity but short of complexity.
3. References to related IHE materials & links, etc.
4. Feature files to be persisted in the sdpi-fhir Github repository
5. Feature naming convention including acronym + Relevant Profiles (-R/-A/-xC … all assume -P)
6. …

]

[Editor’s Notes:

1. SHOULD THE Use Cases Below be organized by top-level “feature” or general “use case topic”? **ANSWER**: Title Use Case … “Feature” can be added in CStudio etc.
2. This would push most of the detail down a level BUT would be much easier to navigate at the top!

]

## C.2 Use Case Feature: Standalone OR Dashboard (SORD)

### C.2.1 Narrative:

Dr. Presky is in the Operating Room performing an operation to remove cancerous tumors from the patient’s abdominal area. He can view previous radiology results, electrosurgical equipment settings, patient readings such as HR, Blood Pressure, SpO2 and associated waveforms integrated on his real-time ‘Dashboard’ display. The dashboard display can display visual alarms but does not sound alerts or provide any remote-control capabilities. (This display can be considered an xDISsp.)

### C.2.2 Background: Technical Pre-Conditions

Given all devices communicate using SDC

**And** at least one OR Dashboard display

### C.2.3 Scenario: SORD 1.1 - OR Devices are Accessible to the Dashboard

**Given** dashboard detected at least one accessible OR device

**When** one or more OR Devices are operational

**Then** the Cockpit shall display parameter, waveform, setting, alarm, imaging, etc. information from those devices (based on configuration)

### C.2.4 Scenario: SORD 1.2 - OR Devices are inaccessible to the Dashboard

**Given** dashboard did not detect any accessible OR devices

**When** no OR Devices are detected or accessible

**Then** the Dashboard shall display an error message

### C.2.5 Scenario: SORD 1.3 - One or more OR Devices are inaccessible to the Dashboard

**Given** dashboard did not detect configured OR devices (based on configuration)

**When** no configured OR Devices are detected

**Then** the Dashboard shall display an error message

## C.3 Use Case Feature: Standalone OR Cockpit (SORC)

[Editor’s Note: Old title - : Use Case 2 - SDPi-R/A/xC Standalone OR Cockpit – SORC]

### C.3.1 Narrative:

John Miller (13yrs, m) has chronic rhinosinusitis, which is an inflammatory condition in which the nose and his left maxillary sinus is swollen and the drainage of the mucus is prevented. John’s chronic rhinosinusitis doesn’t respond to medication anymore. After consulting with his physician, he and his parents decide to resolve the issue with Functional Endoscopic Sinus Surgery (FESS). The FESS will be done as a day surgery, so that John can get home in the evening.

Before the day of the surgery, a CT scan is taken that is used to guide the surgeon during the surgery.

In order for the surgery to start, John is put under general anesthesia and monitored with a patient monitor by a pediatric anesthesiologist, especially his mean arterial blood pressure which has been lowered in order reduce capillary bleeding to provide optimal visibility of the surgical field.

During the intervention, the Surgeon has a constant view, using his Surgical Cockpit of the patient's vitals (including MABP), CT imaging results, real-time endoscope camera output and has access to the control functions to execute the intervention. The anesthesiologist can also view relevant patient real-time information such as ECG, blood pressure, anesthesia agent, depth of anesthesia, allergies, etc. using the Anesthesia Cockpit where he/she can manage alarms and control device settings as needed.

{During the procedure one of the surgical devices has a technical issue. It generates a technical alert which notifies the responsible biomedical technician. He/she decides to replace the device and connects it to the network where it is automatically discovered and configured allowing the intervention to continue.}

There are no additional technical or clinical problems, the surgery is a success and John can go home with his parents.

### C.3.2 Background: Technical Pre-Condition

**Given** all devices communicate using SDC

**And** at least one Anesthesia Cockpit and/or Surgical Cockpit

### C.3.3 Scenario: SORC 2.1 - OR Devices are accessible to the Cockpit

**Given** Cockpit detected at least one accessible OR device

**When** the one or more OR Devices are operational

**And** audio alarms are enabled on the Cockpit

**And** remote control is enabled on the Cockpit

**Then** the Cockpit shall display parameter, waveform, setting, alarm, etc. information from those devices (based on configuration)

**And** the audio alarm shall be disabled on the source devices associated with the Cockpit (based on configuration)

**And** the user shall be able to control device settings at the source device or at the Cockpit

### C.3.4 Scenario: SORC 2.2 - OR Devices are inaccessible to the Cockpit

**Given** Cockpit did not detect any accessible OR devices

**When** any OR Device detects an alert condition

**Then** the Cockpit will display an error message

**And** the audio alarm shall be signaled at that source device in the OR

### C.3.5 Scenario: SORC 2.3 - Some OR Devices are inaccessible to the Cockpit

**Given** Cockpit did not detect some configured OR devices (based on configuration)

**When** the OR Device detects an alert condition

**Then** the Cockpit will display an error message

**And** the audio alarm shall be signaled at that source device in the OR for the devices not detected by the cockpit

## C.4 Use Case Feature: Isolation PoC Use Case (IPoC)

[Editor’s Notes:

1. Old title - : Use Case 3 - SDPi-R/xC ICU Isolation PoC Use Case – IIPoC]
2. This use case has been the focus of the IHE FHIR CAT events in 2021 and is being considered for a public demonstration in 2023. See the related content on the Gemini confluence pages <https://confluence.hl7.org/x/m2PPBQ>. The starter content below is from those pages
3. Question: Dropped the “ICU” from the front and retitled IPoC … sync’d with what is on the confluence page. Confirm.

]

### C.4.1 Narrative:

**Pandemic Patient in Isolation ICU [[11]](#footnote-12)**

In dealing with severely infectious patients, healthcare workers (HCWs) are at a significantly greater risk of infection than the overall population due to their frequency and time in contact with the infected patients. The HCWs will enter the patient room to administer care to the patient and manage the therapeutic equipment. This management of the patient’s therapy may require frequent device adjustments which may be delayed due to the need for the HCWs to protect themselves by donning PPE prior to entering the patient room and doffing the PPE upon leaving. This donning and doffing processes can exceed 15 minutes depending on the specific PPEs used. A recent study (Suen, 2018) reported times of 7 minutes for donning and 10 minutes for doffing, with the doffing process providing the opportunity for “considerable” self-contamination.

Infectious diseases confer a synergistic burden on and risk to the patient due to the requirements for isolating the patient (Abad et al., 2010) including poorer care and impaired coordination of care, (Mehrotra et al., 2013), significantly fewer HCW and family visits (relative to patients not on precautions) (Morgan et al., 2013), increased rate of adverse events (Stelfox et al., 2003) and increased depression (compared to other inpatients). (Day et al., 2011). The use of remote control and monitoring can be used to eliminate some treatment delays, reduce the infection risk to the HCW, and help preserve the limited supplies of PPE and improve patient care.

Critically ill patients with an infectious disease will often require monitoring with physiologic monitors and therapeutic support with ventilators and infusion pumps. As previously explained, entering the room to view parameters or adjust any settings can require 15 minutes for something that may take less than 1 minute. Medical devices that support open interoperability technology can provide remote access to view parameters and adjust settings thereby increasing efficiency, saving the costs of the PPE and most importantly increasing the safety of the HCW.

### C.4.2 Background: Technical Pre-Conditions

**Given** all devices communicate using SDC

**And** an isolation point-of-care “bed” / room is being utilized

### C.4.3 Scenario: IPoC 3.1 – Isolation bed & devices need to be configured for patient

**Given** …

**When** …

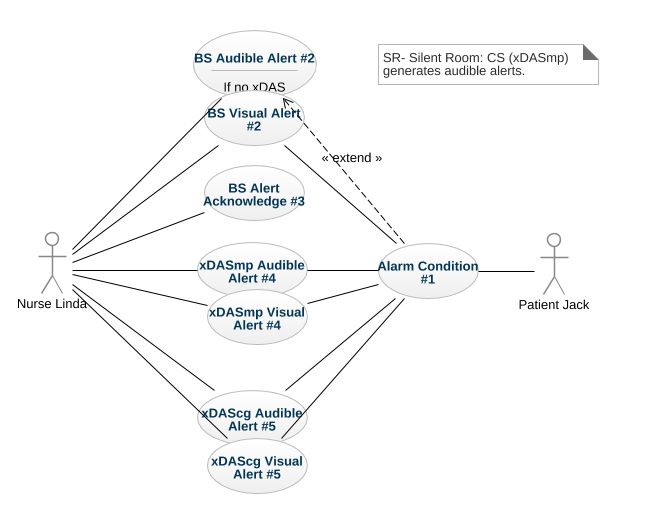
**Then** …

## C.5 - Use Case Feature: Silent PoC Alert distribution (SpoC)

[Editor’s Note: Old title - : Use Case 4 - SDPI-A - Silent PoC Alert distribution - SPoC]

### C.5.1 Narrative

Linda is an ICU nurse responsible for 4 patients. While she is updating documentation at the nursing station Jack’s (one of her patients) condition deteriorates and his ventilator goes into an alarm state (#1). The ventilator alarm sounds are quite loud and jarring which usually disturbs the patient in the room and nearby rooms. In this case the alert only generates visual alerts and does not generate an audible tone in the patient room (#2). It does generate an alarm tone at the central station (xDASmp) (#3) and her mobile device (xDAScg) (#4). As a result, Linda must acknowledge or otherwise handle the alert at the bedside (#5).



### C.5.2 Background: Technical Pre-Condition

**Given** all devices communicate using SDC

**And** at least one xDASmp

**And** all devices in room delegate their alerts to one or more xDASmp.

### C.5.3 Scenario: SPoC 4.1 - Medical device detects an alert situation and at least one distributed alarm system (xDASxx) is accessible

**Given** alert event was detected by a medical device attached to the patient

**When** at least one remote alert system is accessible

**Then** the alert shall be shown on all accessible remote alerting devices

**And** the audio alarm shall be enabled on all accessible remote alerting devices

**And** active device alert events shall be shown on the medical devices locally

**And** the audio alarm shall be disabled on all medical devices in the patient room

### C.5.4 Scenario: SPoC 4.2 - Medical device detects an alert situation and all distributed alarm systems (xDASxx) are inaccessible or become inaccessible

**Given** alert event was detected by a medical device attached to the patient

**When** distributed alarm systems (DAS/DIS) are inaccessible or become inaccessible

**Then** active device alert events shall be shown on the medical devices locally

**And** the audio alarm shall be enabled on all medical devices in the patient room

### C.5.5 Scenario: SPoC 4.3 - Alert situation has been resolved and at least one distributed alarm system (xDASxx) is accessible

**Given** medical device detected that the alert situation has been resolved

**When** at least one distributed alarm system (DAS/DIS) is accessible

**Then** the alert shall be shown as inactive/ended at the medical device locally

**And** the audio alarm shall be disabled on the medical device in the patient room

**And** the alert shall be shown as inactive/ended on all accessible remote alerting devices

**And** the audio alarm shall be disabled on all accessible remote alerting device for this alert event

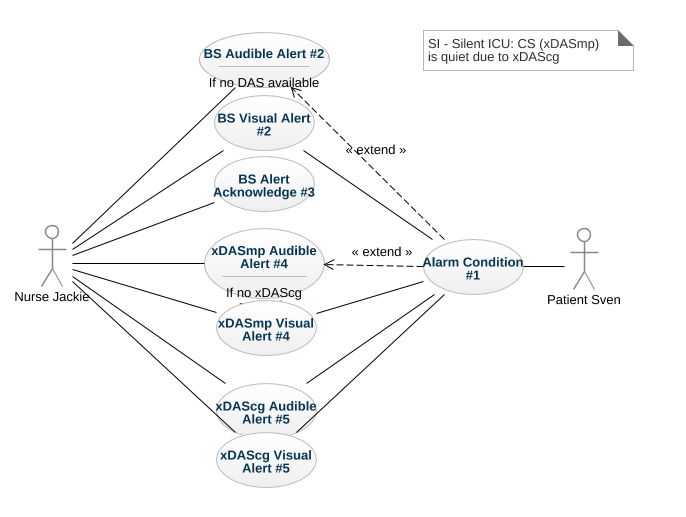
### C.5.6 Scenario: SPoC 4.4 - Medical device detects an alert situation, initially xDASxx is accessible but fails

## C.6 Use Case Feature: Silent ICU Alert Distribution (SICU)

[Editor’s Note: Old title - : Use Case 5 - SDPi-A: Silent ICU Alert Distribution - SICU]

### C.6.1 Narrative:

Jackie is an ICU nurse responsible for 4 patients. While she is updating documentation at the nursing station Sven’s (one of her patients) condition deteriorates and his ventilator goes into an alarm state (#1). The ventilator alarm sounds are quite loud and jarring which usually disturbs the patient in the room and nearby rooms. Jackie’s ICU uses personal mobile devices to alert the nurses about patient alarms so in this case the alert only generates visual alerts in the patient room (#2) and central station (#3). It does generate an audible alert on her mobile device (xDAScg) (#4).



### C.6.2 Background: Technical Pre-Condition

**Given** all devices communicate using SDC

**And** at least one xDAScg

And all devices in room delegate their alerts to one or more xDASxx

### C.6.3 Scenario: SICU 5.1 - Medical device detects an alert situation and the distributed alarm system CDAScg is accessible

**Given** alert event was detected by a medical device attached to the patient

**When** at least one remote alert system is accessible

**Then** the alert shall be shown on all accessible remote alerting devices

**And** the audio alarm shall be enabled on the caregiver’s accessible CDAScg remote alerting devices

**And** the audio alarm shall be disabled on all accessible non-CDAScg remote alerting devices

**And** active device alert events shall be shown on the medical devices locally

**And** the audio alarm shall be disabled on all medical devices in the patient room

### C.6.4 Scenario: SICU 5.2 - Medical device detects an alert situation and the distributed alarm system CDAScg is inaccessible

**Given** alert event was detected by a medical device attached to the patient

**When** at least one remote alert system is accessible

**Then** the alert shall be shown on all accessible remote alerting devices

**And** the audio alarm shall be enabled on all accessible remote alerting devices

**And** active device alert events shall be shown on the medical devices locally

**And** the audio alarm shall be disabled on all medical devices in the patient room

### C.6.5 Scenario: SICU 5.3 - Medical device detects an alert situation and all distributed alarm systems (xDASxx) are or become inaccessible

**Given** alert event was detected by a medical device attached to the patient

**When** distributed alarm systems (DAS/DIS) are inaccessible or become inaccessible

**Then** active device alert events shall be shown on the medical devices locally

**And** the audio alarm shall be enabled on all medical devices in the patient room

### C.6.6 Scenario: SICU 5.4 - Alert situation has been resolved and at least one distributed alarm system (xDASxx) is accessible

**Given** medical device detected that the alert situation has been resolved

**When** at least one distributed alarm system (DAS/DIS) is accessible

**Then** the alert shall be shown as inactive/ended at the medical device locally

**And** the audio alarm shall be disabled on the medical device in the patient room

**And** the alert shall be shown as inactive/ended on all accessible remote alerting devices

**And** the audio alarm shall be disabled on all accessible remote alerting device for this alert event

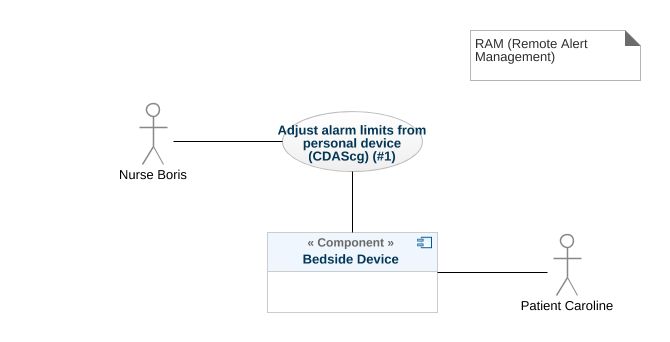
### C.6.7 Scenario: SICU 5.5 - Medical device detects an alert situation, initially DAS is accessible but fails

## C.7 Use Case Feature: Remote Alert Management (RAM)

[Editor’s Note: Old title - : Use Case 6 - SDPi-A/xC: Remote Alert Management - RAM]

### C.7.1 Narrative

Boris is an ICU nurse responsible for 4 patients. His ICU has a central station but also uses personal devices for alert notification and management. He needs to adjust the upper heart rate limit for Caroline, one of his patients. Even though Boris is near the central station, he decides to use his personal device to adjust the limit (#1).



### C.7.2 Background: Technical Pre-Condition

**Given** all devices communicate using SDC

**And** at least one CDAScg

**And** all devices in room enable remote control

### C.7.3 Scenario: RAM 6.1 - Caregiver adjusts alarm limit at their Mobile Device

**Given** alert event was detected by a medical device attached to the patient

**And** remote alerting device is part of the CDAScg

**When** caregiver confirms the alert at a remote alerting device

**And** CDAScg is accessible

**Then** the alert shall be shown as acknowledged at the medical device

**And** the audio alarm shall be disabled on the medical device

**And** the alert shall be shown as acknowledged on all accessible remote alerting devices

### C.7.4 Scenario: RAM 6.2 - Caregiver attempts to adjust alarm limit at their CDAScg mobile device but the respective CDAScg is not accessible

**Given** alert event was detected by a medical device attached to the patient

**And** remote alerting device is part of the DIS

**When** caregiver confirms the alert at a remote alerting device

**But** DAS is inaccessible

**Then** ???

## C.8 Use Case Feature: Smart Alerting System (SAS)

[Editor’s Note: Old title - : Use Case 7 - SDPi-A Smart Alerting System - SAS]

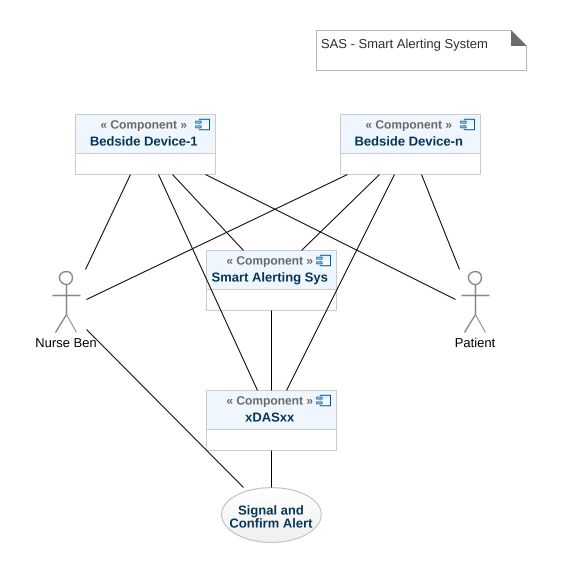
### C.8.1 Narrative:

Ben is an ICU nurse. Suddenly, he gets a “Check Ventilation Hose!” alert for one of the patients he is responsible for. In addition, the alert suggests possible root causes to the caregiver (i.e. obstruction (sputum/kinked hose)). This leads to a quicker, more adequate intervention.

The alert was generated by a smart alerting system that collects all the data from the point-of-care devices such as vital signs, alerts, settings, waves, etc., and combines them to create more actionable information for the care giver to guide care, intervention and treatment. In the example above, an algorithm combines a “Low SPO2” alarm from the patient monitor and a “Peak Pressure” alarm and “Minute Volume low” alarm from the ventilator into one alarm superseding the individual alarms.

The original alerts generated by the patient monitor and the ventilator are shown at the devices but the audio alarm is enabled or disabled on both devices dependent on other rules such as configuration or presence of caregiver in patient room.

Note that the smart alerting system is seen as a separate entity independent of an xDxSxx in this Feature. However, a combination of a xDxSxx with a smart alerting system is a typical configuration.



### C.8.2 Background: Technical Pre-Conditions

**Given** bedside devices are SDC compliant

**And** a single smart alert system (SAS) that is SDC compliant

**And** the SAS is a component with no visual or audible alert output

**And** an xDASmp and/or xDAScg that is SDC compliant

### C.8.3 Scenario Outline: SAS 7.1 - Local device generates alerts, Smart Alerting System is accessible, and xDASmp and/or xDAScg is accessible

**Given** local device audio alarm state was set to <state>

**When** there is an alert event on one or more medical devices in the patient room

**And** smart alerting system is accessible

**And** xDASmp and/or xDAScg is accessible

**Then** the alerts on the medical devices in the patient room shall be delegated to the SAS

**And** active device alert events shall be shown on the medical devices locally

**And** the audio alarm shall be <action> on all medical devices in the patient room

**And** smart alerts from the SAS shall be delegated to the xDASmp and/or xDAScg

Examples:

| state | action |

| disabled | disabled |

| enabled | enabled |

### C.8.4 Scenario Outline: SAS 7.2 - Local device generates alerts, Smart Alerting System is inaccessible, and xDASmp and/or xDAScg is accessible

**Given** local device audio alarm state was set to <state>

**When** there is an alert event on one or more medical devices in the patient room

**And** smart alerting system is inaccessible

**And** xDASmp and/or xDAScg is accessible

**Then** the alerts on the medical devices in the patient room shall be delegated to the xDASmp and/or xDAScg

**And** active device alert events shall be shown on the medical devices locally

**And** the audio alarm shall be <action> on all medical devices in the patient room

Examples:

| state | action |

| disabled | disabled |

| enabled | enabled |

### C.8.5 Scenario: SAS 7.3 - Local device generates alerts, and xDASmp and/or xDAScg is inaccessible

**When** there is an alert event on one or more medical devices in the patient room

**And** xDASmp and/or xDAScg is inaccessible

**Then** active device alert events shall be shown on the medical devices locally

**And** the audio alarm shall be enabled on all medical devices in the patient room

### C.8.6 Scenario: SAS 7.4 -Smart Alerting generates an alert and an xDASxx is accessible

**When** SAS is accessible

**And** there is an alert event detected by the SAS (e.g. derived from vital signs data)

**And**anxDASxx is accessible

**Then** the alerts on the SAS shall be delegated to the xDASxx

**And** the xDASxx shall signal the SAS audio and visual alerts

**~~And~~** ~~a CDASxx can confirm the alert back to the SAS~~

### C.8.7 Scenario: SAS 7.5 - Smart Alerting generates an alert and an xDASxx is inaccessible

**When** SAS is accessible

**And** there is an alert event detected by the SAS

**And**anxDASxx is inaccessible

**Then** any device alert signal delegation shall be disabled

**And** any active alerts (audio and visual) shall be signaled on the originating device

### C.8.8 Scenario: SAS 7.6 - Smart Alerting System is inaccessible from devices and an xDASxx is accessible

**When** SAS is inaccessible

And an alert event was detected by a bedside device

**And**anxDASxx is accessible

**Then** the alerts on the device shall be delegated to the xDASxx

**And** the xDASxx shall signal the device audio and visual alerts

**And** a CDASxx can confirm the alert back to the device

### C.8.9 Scenario: SAS 7.7 - Smart Alerting System is inaccessible from devices and an xDASxx is inaccessible

**When** SAS is inaccessible

And an alert event was detected by a bedside device

**And**anxDASxx is inaccessible

**Then** any device alert signal delegation shall be disabled

**And** any active alerts (audio and visual) shall be signaled on the originating device

### C.8.10 Scenario: SAS 7.8: Devices, CDASxx and Smart Alerting System are accessible, and SAS generates an alert

**When** a CDASxx is accessible

**And** an alert event was detected by the SAS

**And** the operator confirms the alert at the CDASxx

**Then** the confirmation will be sent to the SAS

**And** the SAS will send the confirmation to the appropriate Devices

## C.9 Use Case Feature: <xyz>

Volume 2 – Transactions

Add Section 3.23 and subsequent transactions for SDPi profiles

## 3.23 Announce Network Presence [DEV-23]

### 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:

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

[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

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.
* 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.

* 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:

A screenshot of a cell phone

Description automatically generated

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).

##### 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.>

<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.>

Provider UID

Discovery Type

Additional info (“…”)

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

##### 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. >

<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.>

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:

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

]

<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

<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?]

[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)>

#### 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.>

##### 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.>

## 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.

### 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

* 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:

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:

A screenshot of a social media post

Description automatically generated

Figure 3.24.4-1: DEV-24 Discover Network Topology 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]

#### 3.24.4.1 BICEPS DiscoverNetworkProviders() Message

[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.]

<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.>

##### 3.24.4.1.1 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

<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.”).>

<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

<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.>

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

#### 3.24.4.2 BICEPS DiscoverNetworkProvidersResponse() Message

<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

<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.>

<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.>

##### 3.24.4.2.3 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. >

<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.>

### 3.24.5 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:

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

]

### 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>

[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?]

#### 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.)>

#### 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. >

##### 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]

### 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

### 3.25.3 Referenced Standards

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

### 3.25.4 Messages

[Editor’s Note: interaction diagram here]

#### 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.>

<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).>

##### 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.>

<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.>

##### 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. >

<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

<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

<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?]

[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)>

#### 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.>

##### 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.>

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

### 3.26.1 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>*

### 3.26.2 Actor Roles

### 3.26.3 Referenced Standards

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

### 3.26.4 Messages

[Editor’s Note: interaction diagram here]

#### 3.26.4.1 “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.>

<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

<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.>

<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.>

##### 3.26.4.1.3 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. >

<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.>

### 3.26.5 Protocol Requirements

[Editor’s Note:

1. Original sequence included the following “optional” section:
   1. opt conditional if context states were empty in GetMdibResponse
   2. sdpi\_somds\_consumer -> sdpi\_somds\_provider: SDC: GetContextStates()
   3. sdpi\_somds\_consumer <-- sdpi\_somds\_provider: SDC: GetContextStatesResponse(ContextStates)
   4. end
2. BUT this was only used if GetMdib() is used for non-secured communication – which is profiled out for SDPi use – note that here somewhere
3. Context States MUST be included in GetMdibResponse … by SDPi profile

]

### 3.26.6 Safety, Effectiveness, Security Requirements & Considerations

#### 3.26.6.1 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?]

[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

<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

<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.>

## 3.27 Manage BICEPS Subscription [DEV-27]

### 3.27.1 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>*

### 3.27.2 Actor Roles

### 3.27.3 Referenced Standards

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

### 3.27.4 Messages

[Editor’s Note: interaction diagram here]

#### 3.27.4.1 “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.>

<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

<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.>

<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.>

##### 3.27.4.1.3 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. >

<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.>

### 3.27.5 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.>

### 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>

[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?]

#### 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.)>

#### 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. >

##### 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

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

### 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

<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.>

##### 3.28.4.1.1 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

<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.”).>

<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

<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.>

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

### 3.28.5 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.>

### 3.28.6 Safety, Effectiveness, Security Requirements & Considerations

#### 3.28.6.1 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?]

[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

<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

<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]

### 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>*

### 3.29.2 Actor Roles

### 3.29.3 Referenced Standards

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

### 3.29.4 Messages

[Editor’s Note: interaction diagram here]

#### 3.29.4.1 “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.>

<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

<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.>

<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.>

##### 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. >

<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.>

### 3.29.5 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

#### 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?]

[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

<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

<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

<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

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

* *<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

<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

<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

<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.”).>

<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

<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.>

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

### 3.30.5 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.>

### 3.30.6 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>

[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?]

#### 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

<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

<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]

### 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

### 3.31.3 Referenced Standards

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

### 3.31.4 Messages

[Editor’s Note: interaction diagram here]

#### 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.>

<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).>

##### 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.>

<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.>

##### 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. >

<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

<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

<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?]

[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)>

#### 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.>

##### 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.>

## 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>*

[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.
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.
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. …

]

### 3.32.2 Actor Roles

### 3.32.3 Referenced Standards

* *<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

<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.>

##### 3.32.4.1.1 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

<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.”).>

<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

<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.>

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

### 3.32.5 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.>

### 3.32.6 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>

[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?]

#### 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

<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

<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]

### 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

### 3.33.3 Referenced Standards

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

### 3.33.4 Messages

[Editor’s Note: interaction diagram here]

#### 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.>

<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).>

##### 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.>

<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.>

##### 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. >

<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

<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

<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?]

[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)>

#### 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.>

##### 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.>

## 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>*

### 3.34.2 Actor Roles

### 3.34.3 Referenced Standards

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

### 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.>

<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

<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.>

<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.>

##### 3.34.4.1.3 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. >

<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.>

### 3.34.5 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.>

### 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>

[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?]

#### 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.)>

#### 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. >

##### 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]

### 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

### 3.35.3 Referenced Standards

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

### 3.35.4 Messages

[Editor’s Note: interaction diagram here]

#### 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.>

<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).>

##### 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.>

<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.>

##### 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. >

<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

<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

<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?]

[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)>

#### 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.>

##### 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.>

## 3.36 Publish Medical Data [DEV-36]

### 3.36.1 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>*

### 3.36.2 Actor Roles

### 3.36.3 Referenced Standards

* *<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

<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.>

##### 3.36.4.1.1 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

<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.”).>

<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

<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.>

<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>

[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?]

#### 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.)>

#### 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

<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]

### 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>*

### 3.37.2 Actor Roles

### 3.37.3 Referenced Standards

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

### 3.37.4 Messages

[Editor’s Note: interaction diagram here]

#### 3.37.4.1 “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.>

<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

<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.>

<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.>

##### 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. >

<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.>

### 3.37.5 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

#### 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?]

[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

<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

<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

<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

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

<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.>

##### 3.38.4.1.1 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

<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.”).>

<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

<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.>

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

### 3.38.5 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:3.38.5, 3.35.5. Indicate NA if not used.>

### 3.38.6 Safety, Effectiveness, Security Requirements & Considerations

#### 3.38.6.1 SES General Considerations

<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?]

[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

<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

<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.>

## 3.39 Publish Medical Alert Update [DEV-39]

### 3.39.1 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>*

### 3.39.2 Actor Roles

### 3.39.3 Referenced Standards

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

### 3.39.4 Messages

[Editor’s Note: interaction diagram here]

#### 3.39.4.1 “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.>

<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

<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

<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.”).>

<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.>

<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.>

### 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.>

### 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>

[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?]

#### 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.)>

#### 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. >

##### 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]

### 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

### 3.40.3 Referenced Standards

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

### 3.40.4 Messages

[Editor’s Note: interaction diagram here]

#### 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.>

<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).>

##### 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.>

<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.>

##### 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. >

<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

<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

<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?]

[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)>

#### 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.>

##### 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.>

## 3.41 Manage Medical Alert Delegation [DEV-41]

### 3.41.1 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>*

### 3.41.2 Actor Roles

### 3.41.3 Referenced Standards

* *<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

<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.>

##### 3.41.4.1.1 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

<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.”).>

<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

<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.>

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

### 3.41.5 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:3.41.5, 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>

[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?]

#### 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

<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

<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]

### 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>*

### 3.42.2 Actor Roles

### 3.42.3 Referenced Standards

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

### 3.42.4 Messages

[Editor’s Note: interaction diagram here]

#### 3.42.4.1 “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.>

<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

<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.>

<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.>

##### 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. >

<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.>

### 3.42.5 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

#### 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?]

[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

<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

<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

<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

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

### 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

<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.>

##### 3.43.4.1.1 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

<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.”).>

<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

<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.>

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

### 3.43.5 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:3.43.5, 3.35.5. Indicate NA if not used.>

### 3.43.6 Safety, Effectiveness, Security Requirements & Considerations

#### 3.43.6.1 SES General Considerations

<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?]

[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

<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

<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.>

## 3.44 Manage Medical External Control [DEV-44]

### 3.44.1 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>*

### 3.44.2 Actor Roles

### 3.44.3 Referenced Standards

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

### 3.44.4 Messages

[Editor’s Note: interaction diagram here]

#### 3.44.4.1 “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.>

<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

<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.>

<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.>

##### 3.44.4.1.3 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. >

<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.>

### 3.44.5 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.>

### 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>

[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?]

#### 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.)>

#### 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. >

##### 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]

### 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

### 3.45.3 Referenced Standards

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

### 3.45.4 Messages

[Editor’s Note: interaction diagram here]

#### 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.>

<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).>

##### 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.>

<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.>

##### 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. >

<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

<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

<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?]

[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.>

Appendices to Volume 2

<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:

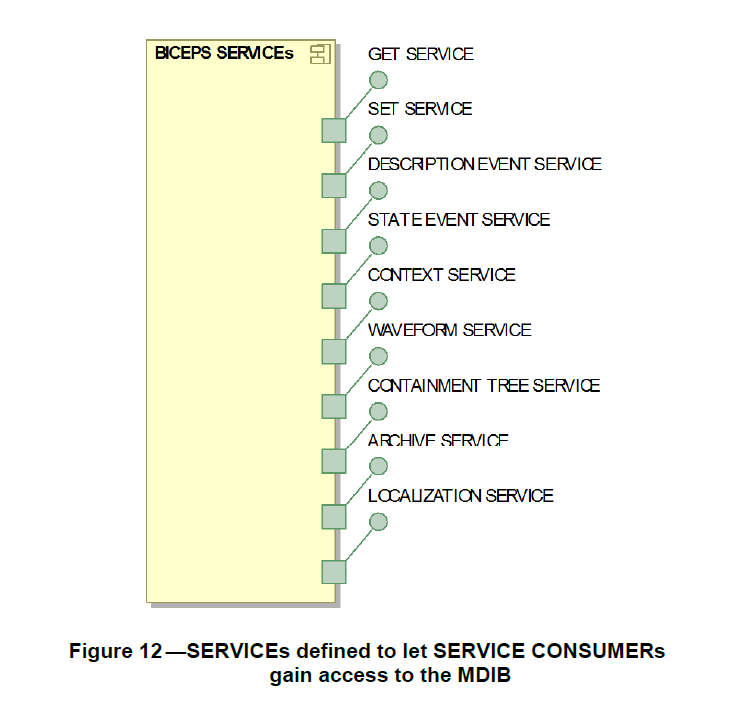
OASIS Devices Profile for Web Services (DPWS) Version 1.1, 1 July 2009[[12]](#footnote-13)

## A.1 SDC/BICEPS to SDC/MDPWS Message Specifications

[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 ]

UPDATE / PROFILE THE BICEPS 7.3.1 Service Model GLUE! for organization of the messages here?



### A.1.1 <Title>

Appendix A.1.1 text.

[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

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?

Also, where to identify the BICEPS and SOMDA Rxxxx addressed by the bindings?

]

A screenshot of a cell phone

Description automatically generated

### A.2.1 MDPWS: Hello()

xyz.

[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.

A screenshot of a cell phone

Description automatically generated

[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.

A screenshot of a cell phone

Description automatically generated

[Editor’s Note: Simplify (per instructions in 8/24 PlantUML; Add in Profiling / Usage Notes]

## A.3 SDC Messages for Secure Connections

## A.4 SDC Messages for PROVIDER MDIB Discovery

## A.5 SDC Messages for Update Publication / Subscription Services

## A.6 SDC Messages for <…>

## A.7 SDC Messages for PARTICIPANT Context Management

# Appendix B – <Appendix Title>

Appendix B text.

## B.1 <Title>

Appendix B.1 text.

### B.1.1 <Title>

Appendix B.1.1 text.

# Namespace Additions for Volume 2

<For Public Comment, please explicitly identify all new OIDs, UIDs, 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.>

At Trial Implementation publication, the domain technical committee **must** ensure that all new OIDs, UIDs, 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.>

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

<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).

<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

[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

<**For Public Comment publication**, please explicitly identify all **new** OIDs, UIDs, 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.>

<**For Trial Implementation publication**, the domain technical committee **must** ensure that all new OIDs, UIDs, 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.>

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> |

## 5.2 IHE Devices Concept Domains

<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> |

## 5.3 IHE Devices Format Codes and Vocabularies

### 5.3.1 IHE Format Codes

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> |
|  |  |  |  |
|  |  |  |  |

### 5.3.2 IHEActCode Vocabulary

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

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

[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]

# DEV Semantic Content Modules

## Overview of device semantic content

## General device content considerations

### SDC/BICEPS semantic content

[Editor: Include:

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

Consider links / bindings to transactions

KEY DIFFERENTIATOR – ALERTING & CONTROL BICEPS elements

]

#### 8.2.8.1 SDC/BICEPS Content Module

[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

#### 8.2.8.3 SDC/BICEPS Relationship to Classic DIM

#### 8.2.8.4 Nomenclature Considerations – Private Extensions & External Systems

#### 8.2.8.4 Safety, Effectiveness, Security Content Requirements & Considerations

#### 8.2.8.5 SDC/BICEPS Conventions for device specialization content modules

#### 8.2.8.6 Device Aggregators & Proxies Modeling

[Editor:

1. Capture the discussion from “[Topic: MDIB/MDS Modeling for Device Aggregators:](https://confluence.hl7.org/x/QSsvBQ)”
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]

#### 8.2.8.8 SDC / BICEPS Extension Provisions

[Editor: Description of how SDPi profiles usage of the SDC (private) extensions model.]

## 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.

]

### 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.
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.
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 scoped content.

]

### Device: Ventilator

#### 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.
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.
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 scoped content.

]

### Device: Physiologic monitor

#### 8.3.3.4 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.
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.
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 scoped content.

]

### Devices: Surgery

[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.

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?

]

### Devices: Anesthesia

[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.

2021-01-2x WGM Discussions: Provided by Martin K. for the [PriMed project](https://www.meditec.hia.rwth-aachen.de/en/research/current-projects/primed) based on prior SDC/OR.NET work. Connections being made to integrate and help advance that work.

]

### Devices: Dialysis

[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.

2021-01 Paul Schluter provided the following diagram related to a content profile for dialysis devices forthcoming: **NEED TO ADD A URL LINK HERE**



]

Appendices to Volume 3

*<Add any applicable Volume 3 appendices below.*

*<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>

Appendix A.1 text.

### A.1.1 <Title>

Appendix A.1.1 text.

# Appendix B – <Appendix Title>

Appendix B text.

## B.1 <Title>

Appendix B.1 text.

### B.1.1 <Title>

Appendix B.1.1 text.

Volume 4 – National Extensions

Add appropriate Country section

# National Extensions for <Country Name or IHE Organization>

<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”.>

<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>.>

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**.>

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.

## 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:

Organization/Title:

Email:

## IHE <Country Name> Scope of Changes

The extensions, restrictions and translations specified apply to the following IHE <Domain Acronym> Integration profiles:

* <Domain Acronym>:Profile Name
* <Domain Acronym>:Profile Name
* Etc.

## <Profile Name> <(Profile Acronym)>

<Add info or tables>

### <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>*

*<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 |

**e.g., 3.3.2.1 US\_CardiacProcedureDrugClasses (1.3.6.1.4.1.19376.1.4.1.5.15)**

|  |  |  |
| --- | --- | --- |
| Coding Scheme  Concept | SNOMED CT | NDF-RT |
| Calcium channel blockers | 48698004 | N0000029119 |
| Beta-blockers | 33252009 | N0000029118 |
| Nitrates | 31970009 | N0000007647 |
| Aminophylline | 55867006 | N0000146397 |

end of example>

### <Profile Acronym> <Type of Change>

<Add info or tables>

# National Extensions for <Country Name or IHE Organization>

<Repeat (and increment) the sections above as needed for additional National Extensions>

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>

Appendix A text.

## A.1 <Title>

Appendix A.1 text.

### A.1.1 <Title>

Appendix A.1.1 text.

# Appendix B – <Appendix Title>

Appendix B text.

## B.1 <Title>

Appendix B.1 text.

### B.1.1 <Title>

Appendix B.1.1 text.

1. HL7 is the registered trademark of Health Level Seven International. [↑](#footnote-ref-2)
2. FHIR is the registered trademark of Health Level Seven International. [↑](#footnote-ref-3)
3. Note that SDPi-P supports application interoperability including “Software as a Medical Device” (SaMD). [↑](#footnote-ref-4)
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> . [↑](#footnote-ref-5)
5. See DEV TF-3 *8.2.8.1 SDC/BICEPS Content Module*. [↑](#footnote-ref-6)
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*. [↑](#footnote-ref-7)
7. See the HL7 Devices on FHIR implementation guide information at <https://confluence.hl7.org/x/k4FE>. [↑](#footnote-ref-8)
8. Apply Postel’s Law: Send conservatively, Accept liberally. [↑](#footnote-ref-9)
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](https://wiki.ihe.net/index.php/DEV_Technical_Framework) for additional detail. [↑](#footnote-ref-10)
10. See the HL7 Devices on FHIR implementation guide information at <https://confluence.hl7.org/x/k4FE>. [↑](#footnote-ref-11)
11. Source: Adapted from AAMI CR Proposal: “Emergency Use Guidance for Remote Control of Medical Devices". [↑](#footnote-ref-12)
12. Available at <http://docs.oasis-open.org/ws-dd/dpws/wsdd-dpws-1.1-spec.html>. (Accessed 2020.08.24) [↑](#footnote-ref-13)