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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Please verify you have the most recent version of this document. See here for Trial Implementation and Final Text versions and here for Public Comment versions.

<Instructions to authors are encapsulated in angled brackets as "< ... >" and denoted with italicized text. These instructions should be deleted entirely prior to publication.>

<Use of capitalization: Please follow standard English grammar rules-only proper nouns and names are upper case. For example, "Modality Actor" is upper case, but "an actor which fulfills the role of a modality" is lower case. Do not use upper case to emphasize a word/topic. Examples:

<Note: Before creating a draft supplement, please review the editing conventions, which include information such as section, table and diagram numbering and how to use Microsoft Word tools, at http://wiki.ihe.net/index.php?title=Writing_Technical_Frameworks_and_Supplements. This guidance is especially useful for first time authors.>

<This supplement template is intended for developing new profiles or making significant changes to profiles, such as adding formal options. Simple changes to existing supplements or profiles should be made using the Change Proposal (CP) process. See the Technical Framework Development section at http://wiki.ihe.net/index.php?title=Process#Technical_Framework_Development for more guidance on supplements vs. CPs.>

<All of the sections in this document are required. Sections may not be deleted. The outline numbering is intended to be consistent across profiles and across domains, so do not adjust the outline numbering. If there is no relevant content for a section, simply state "Section not applicable", but leave the numbering intact. Sub-sections may be added for clarity.>

<This supplement template includes templates for Volumes 1 (Profiles), 2 (Transactions), 3 (Content Modules), and 4 (National Extensions).>

<Volumes 1, 2, and/or 3 are developed together for Public Comment and Trial Implementation submission. Volume 4, National Extensions, is typically developed at a later point in time, usually at Trial Implementation or later. Templates for all four volumes are included in this document for the sake of completeness. If you are beginning a new profile, you are strongly discouraged from using National Extensions and should instead focus on optional data sets or other alternatives. For more information, see http://wiki.ihe.net/index.php?title=National_Extensions_Process.>

Foreword

This is a supplement to the IHE Devices Technical Framework Revision 10.0. Each supplement undergoes a process of public comment and trial implementation before being incorporated into the volumes of the Technical Frameworks.

<*For Public Comment:*> This supplement is published on <Month XX, 201x> for Public Comment. Comments are invited and can be submitted at http://www.ihe.net/Public_Comment/#domainname. In order to be considered in development of the Trial Implementation version of the supplement, comments must be received by <Month XX, 201X>.

<*For Trial Implementation:*> This supplement is published on <Month XX, 201X> for Trial Implementation and may be available for testing at subsequent IHE Connectathons. The supplement may be amended based on the results of testing. Following successful testing it will be incorporated into the Devices Technical Framework. Comments are invited and can be submitted at http://www.ihe.net/Public_Comment/#domainname.

This supplement describes changes to the existing technical framework documents.

"Boxed" instructions like the sample below indicate to the Volume Editor how to integrate the relevant section(s) into the relevant Technical Framework volume.

Amend section W.X by the following:

Where the amendment adds text, make the added text **bold underline**. Where the amendment removes text, make the removed text **~~bold strikethrough~~**. When entire new sections are added, introduce with editor's instructions to "add new text" or similar, which for readability are not bolded or underlined.

General information about IHE can be found at www.ihe.net.

Information about the IHE Devices domain can be found at ihe.net/IHE_Domains.

Information about the organization of IHE Technical Frameworks and Supplements and the process used to create them can be found at http://ihe.net/IHE_Process and http://ihe.net/Profiles.

The current version of the IHE DevicesTechnical Framework can be found at http://ihe.net/Technical_Frameworks.

<*Comments may be submitted on IHE Technical Framework templates any time at http://ihe.net/Templates_Public_Comments. Please enter comments/issues as soon as they are found. Do not wait until a future review cycle is announced.*>

CONTENTS

[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] FHIR®[2] specification. HL7 describes FHIR Change Management and Versioning at https://www.hl7.org/fhir/versions.html.

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

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

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

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

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

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

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

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

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, which in turn is linked to the related Gemini HL7 confluence page 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**
    a. Github Issue: ***#33 – Topic: Connect Time Delay Algorithm***
    b.
2. …

IHE Technical Frameworks General Introduction

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

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9.1.2 HL7 (Health Level Seven)

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

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9.1.3 LOINC (Logical Observation Identifiers Names and Codes)

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

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

Amend section 9.1.x by adding the following:

9.1.5 IEEE 11073 (Health Device Interoperability)

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

2020.09.18 Discussion w/ IEEE Staff …

1. Add language to TF-1 Appendix B regarding utilization of the SDC ICS tables (language to be supplied by IEEE)
2. This section could at a minimum declare IEEE & IEEE 11073 as registered trademarks. Etc.

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

]

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IHE Technical Frameworks General Introduction Appendices

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

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*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.*

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

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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*
985 *table below. These will be added to the IHE TF General Introduction Appendix A after publication for trial implementation. Verify that any actors added here are not already contained in the IHE General Introduction Appendix A.>*

New (or modified) Actor Name	Definition
<Verb-Noun format (e.g., Store Image, Register Document Set)>	*If this is a modified actor description, add the original description and use **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.]

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

<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.>*

<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.

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.*

1010

[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

New (or modified) Glossary Term	Definition	Synonyms	Acronyms / Abbreviation
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 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.]

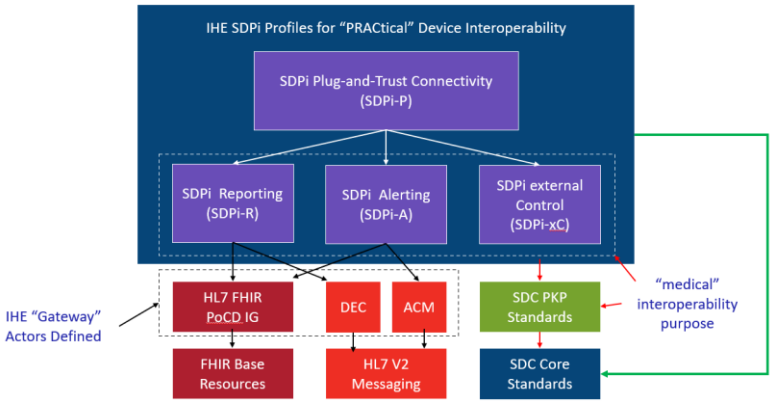


Figure 2.X-1: SDPi Profiles & Foundational Standards

<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] begins at the start of discovery and a secure connection. Therefore, the profile name: Plug-and-Trust.

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

Although all information exchanged between SDPi-P SOMDS participating systems and applications must conform to the basic SDC/BICEPS content module[5] requirements, content modules have been defined for common high-acuity medical devices such as infusion pumps, ventilators and physiologic monitors.

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

[3] Note that SDPi-P supports application interoperability including "Software as a Medical Device" (SaMD).

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

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

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

10.1 SDPi-P Actors, Transactions, and Content Modules

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

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

[Editor's Notes:

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

]

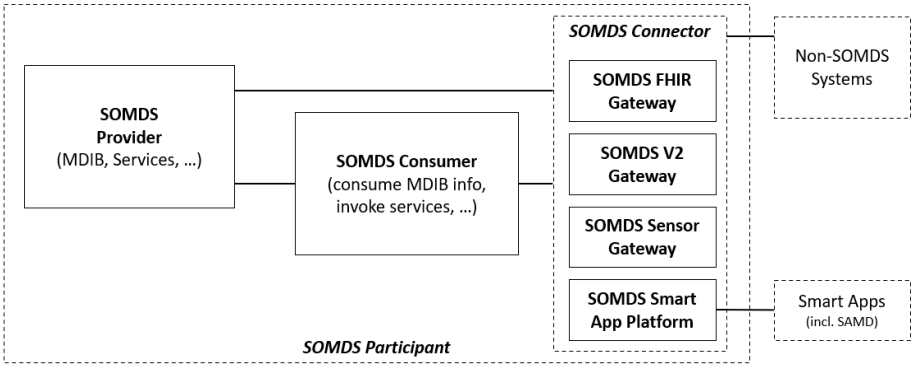


Figure 10.1-1: SDPi-P Actor Diagram

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

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

3. SOMDS is the overarching concept … obviously! But keeps away from SDC (confusion & implementation specific)
4. Three core actors: Participant, Provider, Consumer
    a. Analogous to the ACM profile, these actors could include contained boxes / graphics for the components that are currently listed in text …
    b. OR we can just list them in text!
5. The approach with a Participant being in a dashed box around the others is leveraged from XDS.b for the "Integrated Document Source/Repository Actor" – note that if IHE had the concept of actor specialization / generalization … that would be a good thing
6. SOMDS Connector/Proxy :
    a. Note: XCA has "gateway" actors
    b. Clearly this actor CAN integrate a provider and / or consumer actor
    c. Technically this could be a grouped actor but it would probably be grouped with a Participant … which can be Provider / Consumer / both … In UML this would be easy to capture … and grouping with a Participant when that is the dotted line box is clear-as-mud IMHO
7. Protocol-specific Gateway Actors
    a. SDPi-P will define three gateways: FHIR, V2, IHE DEV PCD (e.g., DEC & ACM); FHIR is called out here since it is a specific instance and currently the top priority
    b. Gateways are indicated as specialized versions of the
    c. A "generic" gateway will also support proprietary or other protocols / adaptors / connectors not otherwise specified here
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

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

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

[Editor's Note:

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

3. *IF we did update the diagram …*
    a. *SDPi MDIB Creator / Reporter?*
    b. *SDPi MDIB Content / Consumer?*
    c. *"Share Content" => ??? [note that this could apply both across a SOMDS and gateway to enterprise … the content would remain the same!]*

]

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

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

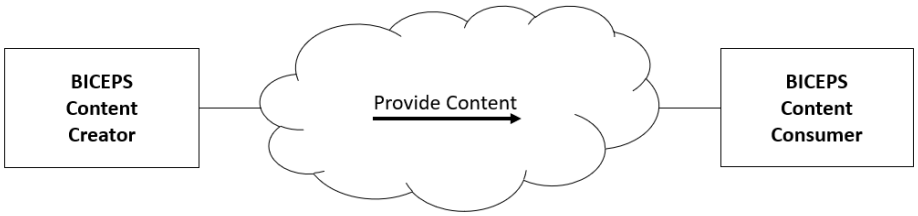


Figure 10.1-2: SDPi-P BICEPS Content Actor Diagram

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

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

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

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

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

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

10.1.1 Actor Descriptions and Actor Profile Requirements

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

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

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

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

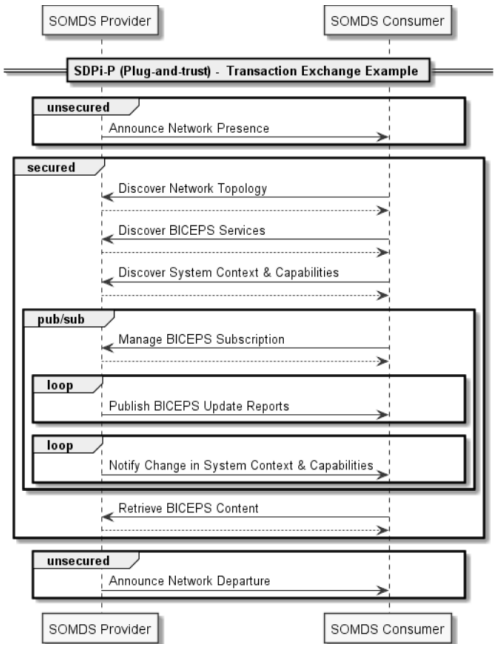


Figure W.1.1-1: SDPi-P Example Sequence Diagram

[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] 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.

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

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

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

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!
    a. 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].

[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

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

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

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

10.1.1.7 SOMDS Sensor Gateway

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

> A *SOMDS Connector* that supports integration of sensors external to a SOMDS network

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

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

10.1.1.8 SOMDS Smart App Platform

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

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

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

[Editor's Note:

1. Need to define "smart app" … where?
2. Need to reference SAMD … which of the volumes of documents?!
3. Differentiate here (or in Concept below) the difference between a SOMD "local" app platform (e.g., within a dashboard application) and a "remote" (like within a SMART on FHIR EHR app that consumes real-time device-sourced data)

4. Discuss "intelligence" and levels of interaction + how app requirements (SES MDI) are aggregated by a platform actor
5.

]

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]

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:*
    a. *Archive Service Support*
    b. *Locationalization Service Support*
    c. *SystemContext (and related contexts) Configuration Support*

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

d. Ensemble Support

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

a. SDPi-A Alert Delegation Option

b. SDPi-A Alert Confirmation Option

c. SDPi-xC "You Could Kill Someone" Option

d. SDPi-xC Closed-Loop Control Ensemble Option

e. …

]

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

Actor	Option Name	Reference
SOMDS Participant	No options defined	
SOMDS Provider (See Note 1)	Streaming Option [Editor's Note: Which can be waveform or other content; but is that in SDPi-R vs. here? And should we have a waveform option? What about SCO or polling mode type support options?]	DEV TF-1 *10.2.1 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*

Actor	Option Name	Reference
	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:
    a. Topic: Discovery Proxy Actors
    b. Topic: SystemContext Profiling & Use
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

SDPi-P Actor	Actor(s) to be grouped with	Reference	Content Bindings Reference
	<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; 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

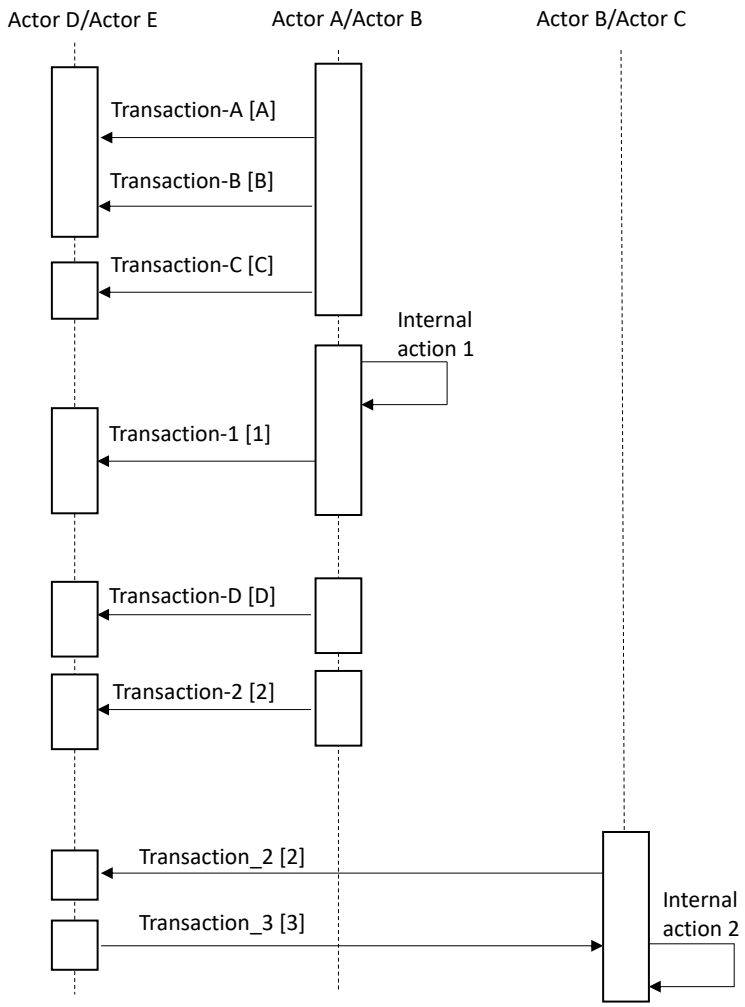
<Diagram and describe the process flow(s) covered by this profile in order to satisfy the use cases. Demonstrate how the profile transactions are combined/sequenced. To provide context and demonstrate how the profile interacts with other profiles, feel free to include transactions and events that are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



1675

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>.

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

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

11.1 SDPi-R Actors, Transactions, and Content Modules

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

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

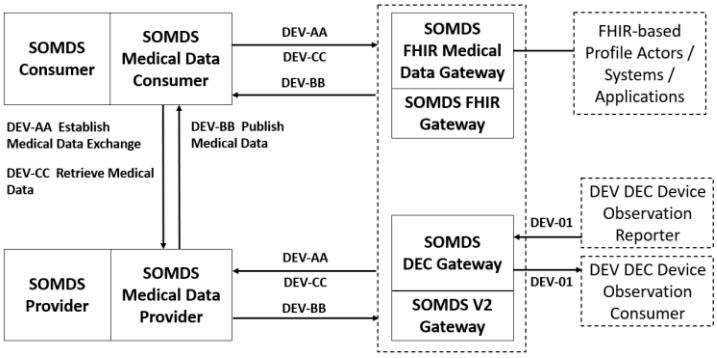


Figure 11.1-1: SDPi-R Actor Diagram [9]

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

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

1. NOTE this is a first iteration of the diagram – STARTER!
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:
    a. DEC can have DOR and DOC actor implementations; indicate HERE or in actor documentation? Or …
    b. Document FUTURE DEC FHIR Option could be implemented using <SDPi> actors.
    c. Any need to show external FHIR system/application? Or is it obvious here? Added it but discussion can identify various options. Note could also identify IHE FHIR-based Profile Options!
    d. Include rationale for separate –R actors and transactions (incl. BICEPS requirements / message sequences / SES bindings / Conformance claims)
    e. Does Medical Reporting have implications on the SOMDS-external connections? Requirements placed on those?
    f. Are the transactions truly unique or should we utilize SDPi-P transactions and include different mandatory bindings here?
4. From initial review discussion 2020.09.11:
    a. Update to show Gateway can play both roles … CONSUMER & PROVIDER
    b. Add DEV-DD Retrieve Archived Medical Data …
5.

]

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

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

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

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

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

11.1.1 Actor Descriptions and Actor Profile Requirements

11.1.1.1 SOMDS Medical Data Consumer

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

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

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

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

11.1.1.2 SOMDS Medical Data Provider

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

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

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].

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

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

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* transaction[9].

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

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

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

12.1 SDPi-A Actors, Transactions, and Content Modules

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

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

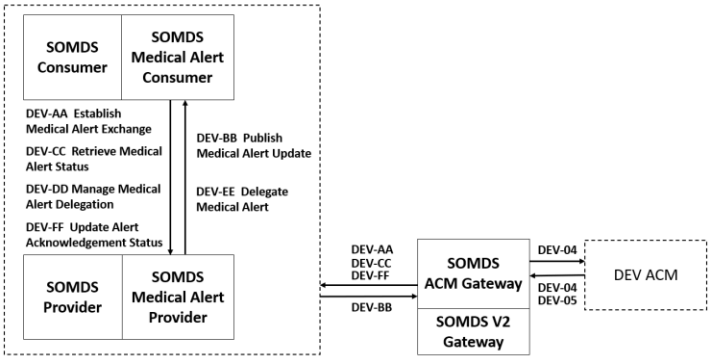


Figure 12.1-1: SDPi-A Actor Diagram

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

1. NOTE this is a first iteration of the diagram – STARTER!
2. Discussion notes from review slides:
    a. FHIR Gateway goes away until there is a path in DoF IG for medical alerting

b. ACM – instead of showing the various actors (since there are AR & ACON options for example) just showed the external profile w/ in-scope transactions

c. SOMDS ACM Gateway can essentially function like a SOMDS Medical Alert Consumer … should we indicate it as such?

d. @ White Paper, PCD-05 was mapped to SDC-DC (delegation confirmation) – however, at this level, a transaction has been defined for Clinician Response Status

3. From initial review discussion 2020.09.11:

a. Review SDC alerting / delegation & PCD-05 purposes and elements to reflect correctly in the right transactions

b. Determine if DEV-FF is real … what it is … or if it should be "voted of the island"

c. Also map to 60601-1-8 constructs, esp. re CDAS

d. TF-1 SDPi-A include sections (analogous to SDPi-P) on DIS / DAS / CDAS …

e. NOTE Gateway would only have AR & ACON capabilities (note in profile)

4.

]

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

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

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

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

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

12.1.1 Actor Descriptions and Actor Profile Requirements

12.1.1.1 SOMDS Medical Alert Consumer

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

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 transactions[9].

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

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

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

13.1 SDPi-xC Actors, Transactions, and Content Modules

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.

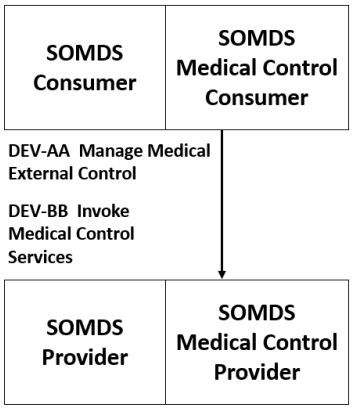


Figure 13.1-1: SDPi-xC Actor Diagram

[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:

a. Control is currently out-of-scope for SOMDS external entities (e.g., V2 / FHIR based)

b. Question: All of these have "Establish…" what about "Manage …" similar to SDPi-P's manage subscription labeling

c. DEV-BB sequence will be in TF-2, namely Retrieve Current Device State => Invoke Device Control => Verify Invocation

d. Question: What about non-Medical Control? Should foundational transactions be added to SDPi-P or only here? SCO-related logic HERE only or also in SDPi-P?

e. NOTE: SDPi-P has a basic "set" service transaction, but that is not intended for "MEDICAL" applications

f. NOTE: That ALL the external control sequences in David G's PlantUML World will get allocated in TF-2 Appendix A, reflected in TF-2 transaction descriptions and linked to actors … here

g. Is it "Service" or "Services"?

3. From initial review discussion 2020.09.11:

a. Include safety class / "rejection" discussion from Confluence Topic page(s)

4.

]

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

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

13.1.1 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

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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.

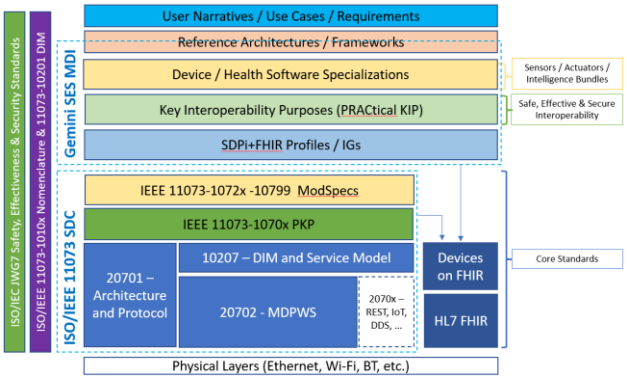
AND A NOTE ABOUT SECTIONLESS CONTENT – Although the IHE Template allows – typically encourages – content after a section title and before subsection titles, this is generally not a style that other standards bodies have – and will not be supported here … hopefully]

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?>

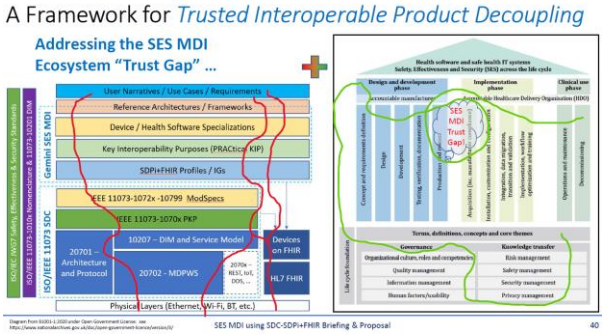


Figure A.2-1: SES MDI Trust Gap Framework Proposal

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 …

Table 20 —General ICSs

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

]

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.	

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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?]*

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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
    a. **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

    b. **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)**
6. **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**
7. **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]
    a. 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

]

Commented [TC1]: Todd will provide initial content

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!

]

Commented [TC2]: Ken Fuchs will provide initial language

C.1.2 Overview of Architectural & Business Systems Concepts

[Editor's Notes:

Commented [TC3]: Ken Fuchs will craft initial language

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. …

]

Commented [TC4]: Todd to update with ACM reference / relationship

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 Confirmation[1]	Operator Delivery Confirmation[2]	Optional Alarm Management	Examples
Reports alerts from a Single Patient (sp)	DISsp	No	No	Local	Single-Pt. information Dashboard
	CDISsp	No	Yes[3]	Remote[3]	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	Yes[3]	Remote[3]	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	Yes[3]	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.

Commented [TC5]: John Rhoads will craft initial language for this section

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

Commented [KP6]: What is the relevant difference between 1.2 and 1.3?

Commented [KF7R6]: In one case it would seem the network is down, while in the other case it would seem specific devices are just not available. Can we specify different error messages in Gherkin?

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]

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

[11] Source: Adapted from AAMI CR Proposal: "Emergency Use Guidance for Remote Control of Medical Devices".

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 …

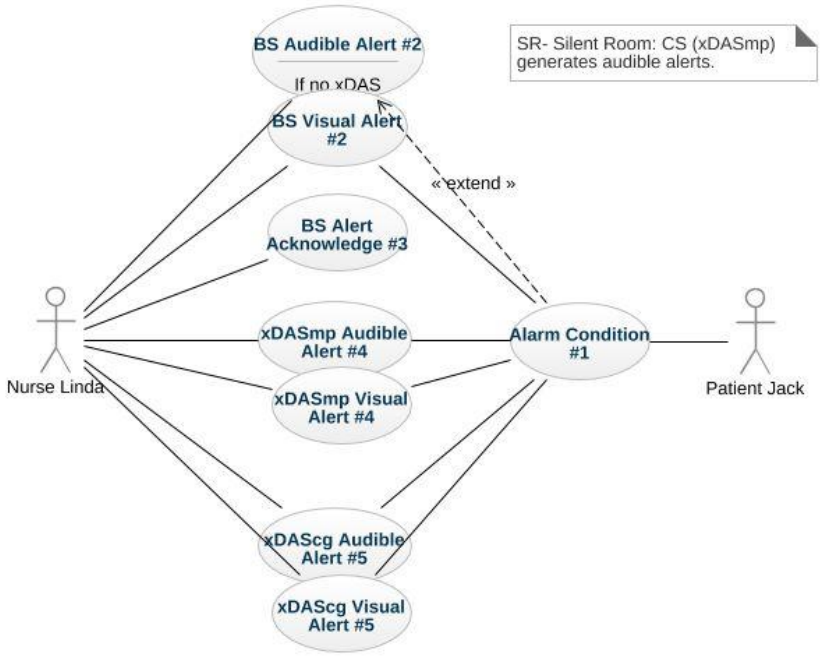
Then …

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).



2870

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.

2875

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

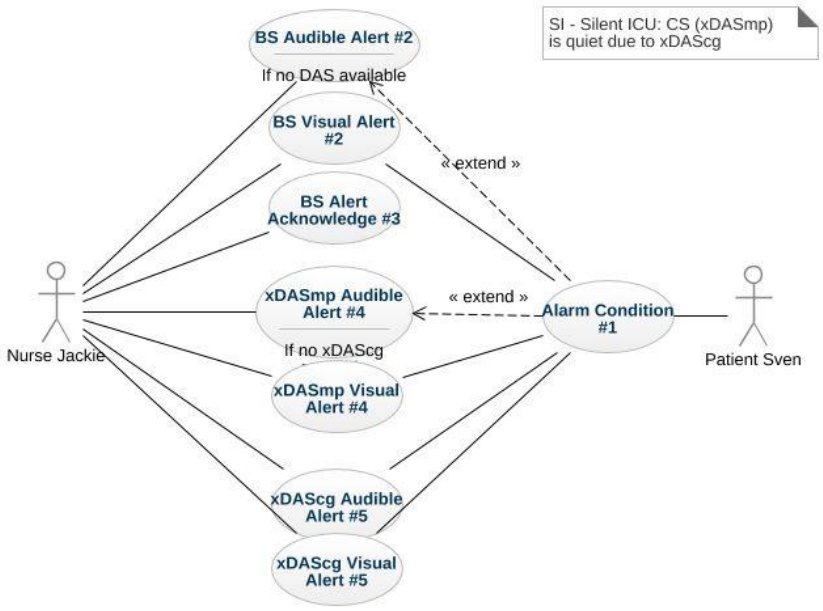
C.5.6 Scenario: SPoC 4.4 - Medical device detects an alert situation, initially xDASxx is accessible but fails

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

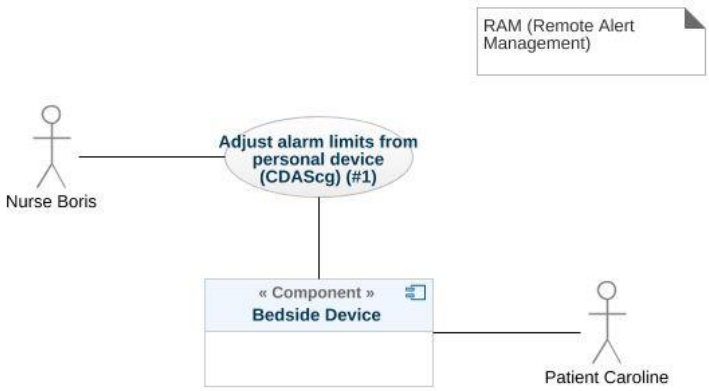
C.6.7 Scenario: SICU 5.5 - Medical device detects an alert situation, initially DAS is accessible but fails

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]

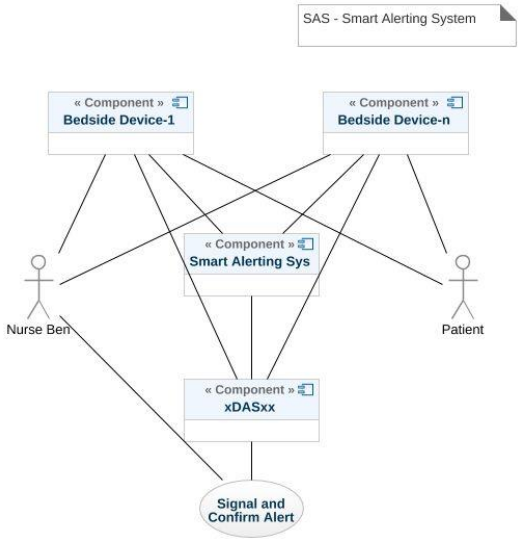
C.8.1 Narrative:

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

Commented [KF8]: Could it be an xDASxx?

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

Commented [KF9]: The Scenario Outline is only used in 2 places. Here and in the next Section. Can we just use Scenarios?

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 an xDASxx 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~~

Commented [KP10]: I would describe this in a separate scenario

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 an xDASxx 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 an xDASxx 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 an xDASxx 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:

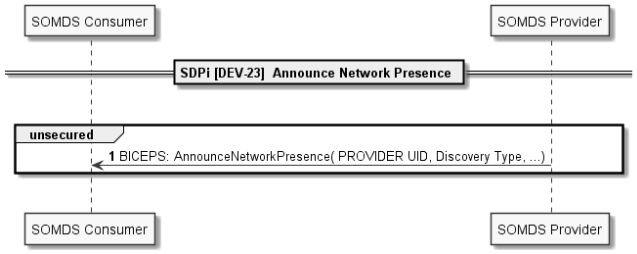


Figure 3.23.4-1: DEV-23 Messaging Interaction Diagram

[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:

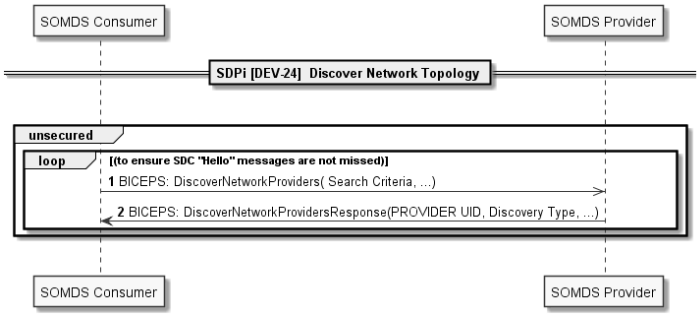


Figure 3.24.4-1: DEV-24 Discover Network Topology Interaction Diagram

[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:

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

]

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:
    a. opt conditional if context states were empty in GetMdibResponse
    b. sdpi_somds_consumer -> sdpi_somds_provider: SDC: GetContextStates()
    c. sdpi_somds_consumer <-- sdpi_somds_provider: SDC: GetContextStatesResponse(ContextStates)
    d. end
2. BUT this was only used if 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]

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?

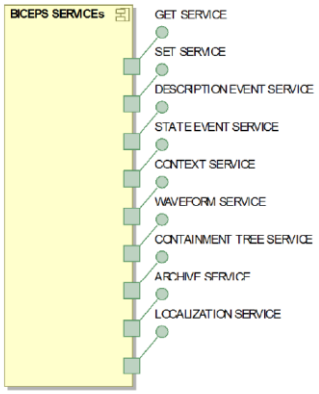


Figure 12—SERVICEs defined to let SERVICE CONSUMERs gain access to the MDIB

A.1.1 <Title>

Appendix A.1.1 text.

[12] Available at http://docs.oasis-open.org/ws-dd/dpws/wsdd-dpws-1.1-spec.html. (Accessed 2020.08.24)

[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

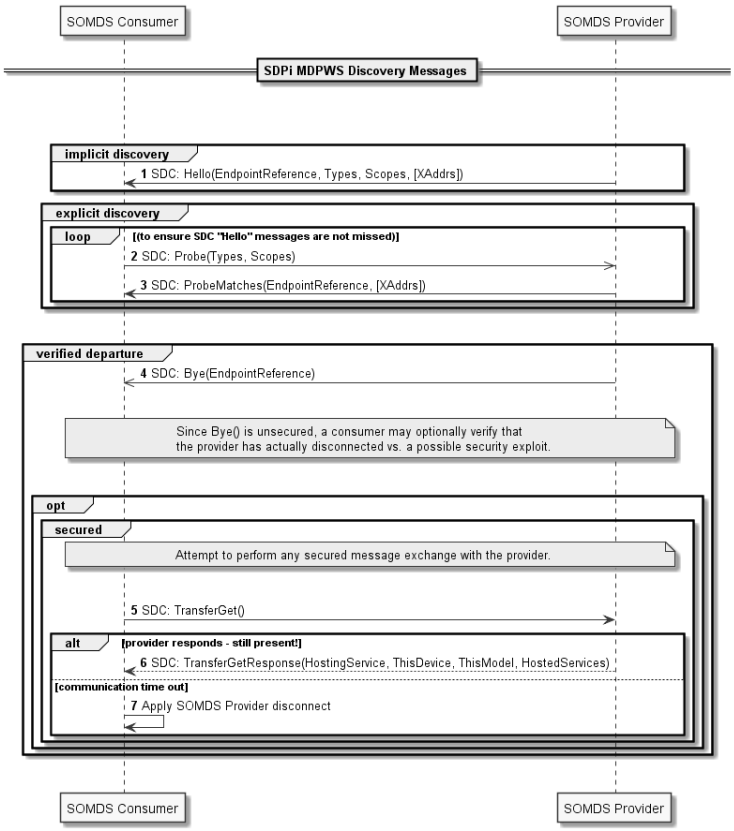
The messages in this section relate to the SDC/BICEPS Dynamic Discovery capabilities, including both implicit and explicit discovery.

[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.2.1 MDPWS: Hello()

4880 xyz.

[Editor's Note: Add standardized section content for:

- Binding references (BICEPS, MDPWS,…)

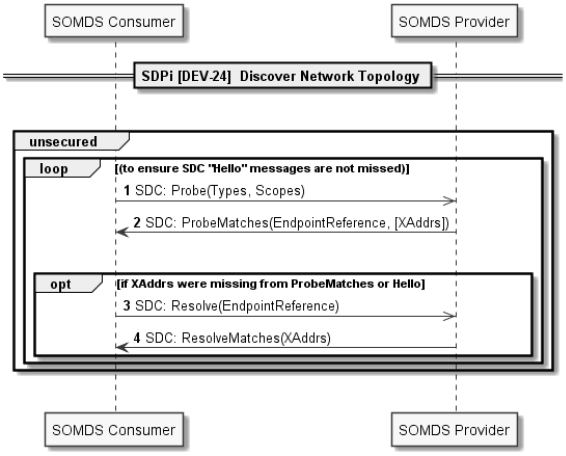
- Parameter semantics
- SES & Other Considerations
- Profiling & Usage Notes
- …

]

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.



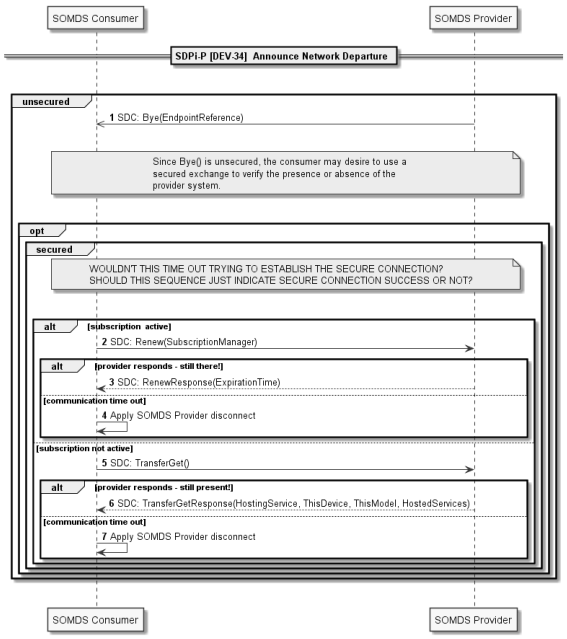
[Editor's Note: Remove "opt" section and indicate WHY this is profiled out in SDPi; then remove diagram.]

A.2.3 MDPWS: ProbeMatches()

xyz.

A.241 MDPWS: Bye()

xyz.



[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]

8 DEV Semantic Content Modules

8.1 Overview of device semantic content

8.2 General device content considerations

8.2.8 SDC/BICEPS semantic content

[Editor: Include:

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:"
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.]

8.3 Device specialization content modules

[Editor:

1. Note that for each specialization, the current 9.0 version content will remain unchanged and a specific SDC/BICEPS section will be added to the end;
2. Since OR integration and High-Frequency Surgery devices may be the focus of the SDPi 1.0 supplement, these specializations may also be added to the end.

]

8.3.1 Device: Infusion Pump

8.3.1.4 SDC/BICEPS content module

[Editor's Note: This content module will include a detailed "from the device interface" specification:

1. Supporting all (4) PKP functions.
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.

]

8.3.2 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.

]

8.3.3 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:

7. Supporting all (4) PKP functions.
8. Aligned with the "enterprise" focused definitions in the preceding sections, but explaining differences & extensions along with rationale
9. Aligned with any 11073 device specialization standard (summarizing approach & referencing detailed conformance XML specification file)
10. Include the high-level containment w/ example & key metrics etc.
11. Reference detailed value sets (e.g., via OID) & files, etc.
12. NOTE: This is a CONTENT module; whereas BICEPS uses the descriptive MDIB "content" to also define a specialized set of services. In the case of device-specific services, it is anticipated that this will be addressed in device specialization profile specifications (e.g., profiles that build upon the interoperability foundation of SDPi profiles, but define device-specific architecture / workflow transactions & appropriately scoped content.

]

8.3.4 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?

]

8.3.5 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 based on prior SDC/OR.NET work. Connections being made to integrate and help advance that work.

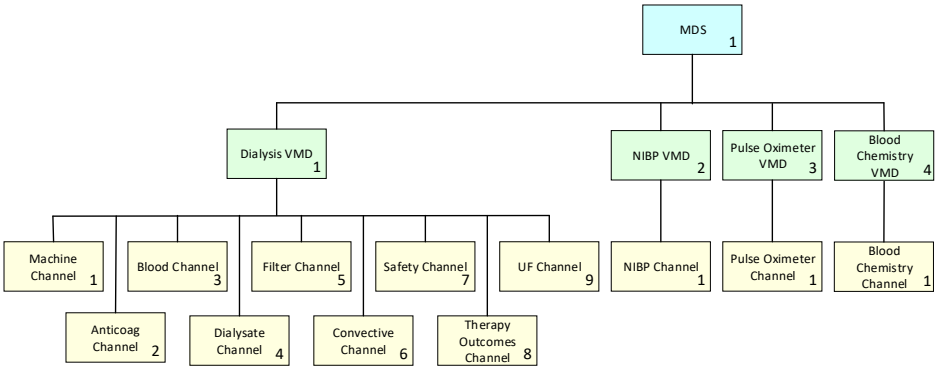
]

8.3.6 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**



]

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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

3 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.

3.1 Comments

This <Domain Acronym> national extension document was authored under the sponsorship and supervision of <sponsor name> who welcomes comments on this document and the IHE <country> initiative. Comments should be directed to:

Name:

Organization/Title:

Email:

3.2 IHE <Country Name> Scope of Changes

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

- <Domain Acronym>:Profile Name
- <Domain Acronym>:Profile Name

- Etc.

3.3 <Profile Name> <(Profile Acronym)>

<Add info or tables>

3.3.1 <Profile Acronym> Value Set Binding for <Country Name or IHE Organization> Realm Concept Domains

<This section defines the actual value sets and code systems for any coded concepts that were described by concept domains in the main profile and binds the value set to the coded concepts.>

<Add info or tables>

<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>

3.3.2 <Profile Acronym> <Type of Change>

<Add info or tables>

4 National Extensions for <Country Name or IHE Organization>

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

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.