Integrating the Healthcare Enterprise

IHE

IHE Devices
Technical Framework Supplement

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

Revision 0.1 – Draft in Preparation for Public Comment (*or* Trial Implementation)

Date: September 18, 2020

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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.>

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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.

60   *<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>.

65   *<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.

70   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
75   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.

80   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.

85   *<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.>*

90 **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

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[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

585 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

590
- 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.

595
- 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.

600

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
605 systems (e.g., GitHub or Confluence or … Jira …); Intent is to migrate the confluence-based Topics to this list and link them to GitHub Issues with summaries only here.]

Closed Issues

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

IHE Technical Frameworks General Introduction

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

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9.1.1 DICOM (Digital Imaging and Communications in Medicine)

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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)

LOINC® is registered United States trademarks of Regenstrief Institute, Inc.

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](#).*

680

> ==*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:*

690

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

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

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

695 *<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

700 *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*
705 *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.

710

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.

715

[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 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
Safe, Effective & Secure	General name given to the requirements, general and specific, derived by the application of medical device and health software quality standards, including ISO 81001-1 and IEC 80001-1.		SES
Service-oriented Device Connectivity	Application of service-oriented architecture to support healthcare device interoperability. (See ISO/IEEE 11073-20701)		SDC

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

Volume 1 – Profiles

2 Devices Integration Profiles

720

[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.*

725 *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

730 [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

735 [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>

740

*<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*
745 *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.">*

750 *<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
755

[Editor's Note: This is the general section on SDPi. An overview of SOA, SOMDS, etc.]
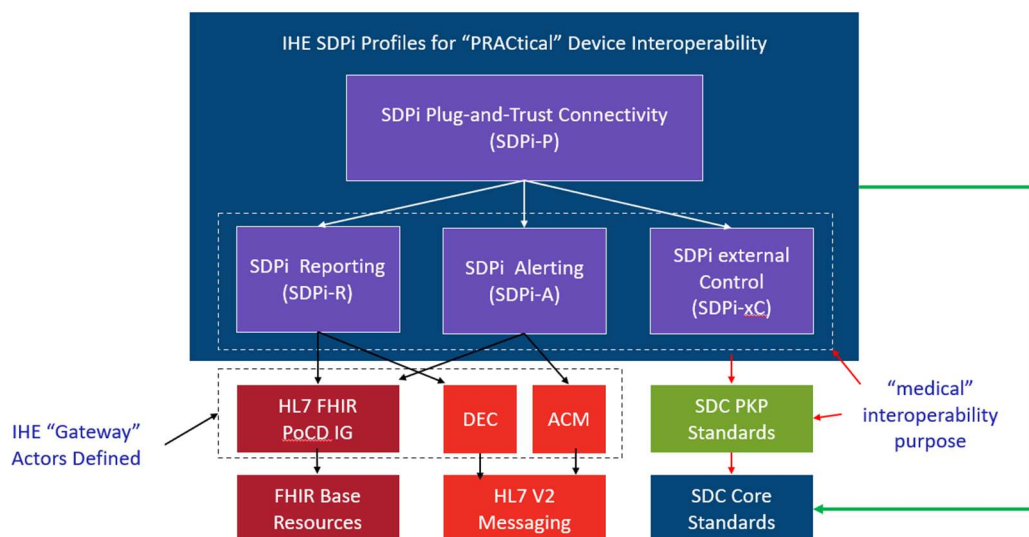
760 **Figure 2.X-1: SDPi Profiles & Foundational Standards**

<add caption + explain model>

<give reference to appendix 1>
765

Add new Section #

770 *<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

775 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 780 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 785 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 790 (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, 795 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

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[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
800 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.
805 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
810 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.
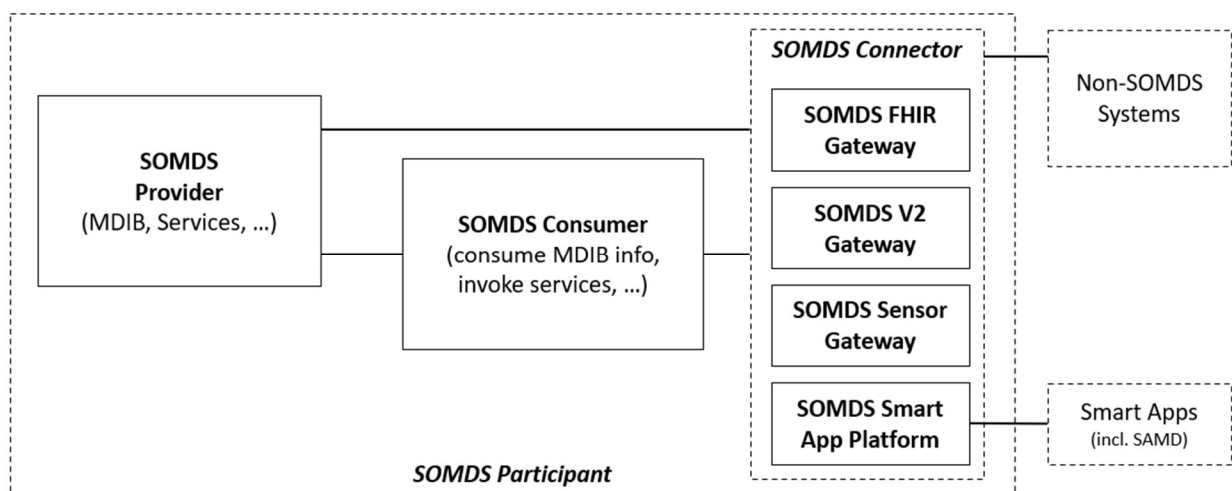
Figure 10.1-1: SDPi-P Actor Diagram

815 [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)

820 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. *...*

]

855

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

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

Actors	Transactions	Initiator or Responder	Optionality	Reference
	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.*

860 *[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*

865 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!]*

870 *]*

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) 875 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*.

880
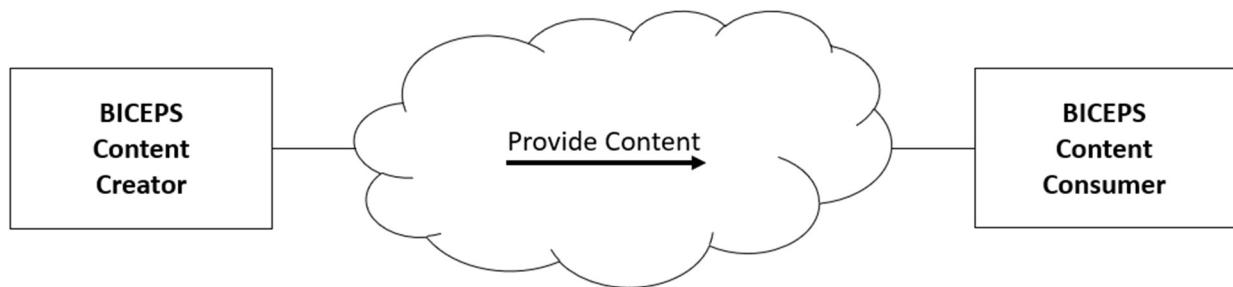
Figure 10.1-2: SDPi-P BICEPS Content Actor Diagram

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 885 optional content modules (labeled "O").

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

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

Actors	Content Modules	Optionality	Reference
BICEPS Content Creator	SDC/BICEPS Content Module	R See Note 1	DEV TF-3: 8.2.8.1
	Infusion Pump SDC/BICEPS Content Module	O	DEV TF-3: 8.3.1.4
	Ventilator SDC/BICEPS Content Module	O	DEV TF-3: 8.3.2.4

Actors	Content Modules	Optionality	Reference
	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

890

Note 1: *All content exchanged on a SOMDS shall conform to the general SDPi "BICEPS Content Module". 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.

895 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:

900
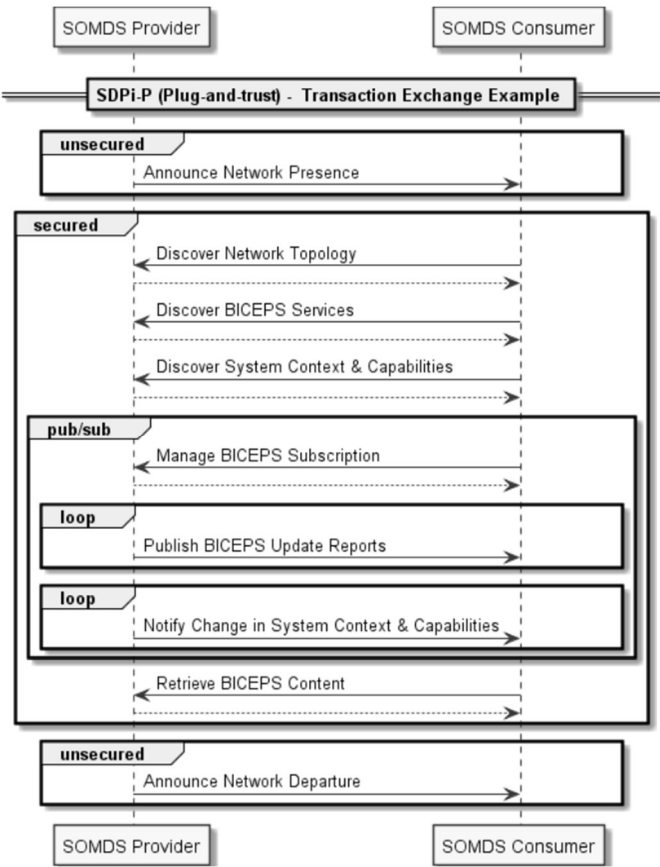
Figure W.1.1-1: SDPi-P Example Sequence Diagram

905 [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]

910 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.

915 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.

920 **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.

925 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]

930 > 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.

935 **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
940 > SOMDS Provider, with a specific SOMDS instance, as the foundation for protocol-specific gateway and platform actors.

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

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

---

[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*.

945 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
950 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.

955 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
960 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
965 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
970 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
975 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
980 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 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

---

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

1050   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

1055   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]

1060   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

1065   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

1070   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

1075   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

1080   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.

1085   ]

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

1090   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

1095   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).

1100   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.

1105   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-

1110   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

1115   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.

1120   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.

1125   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-
1130   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.

1135   [Editor's Note:

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

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

1140   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.*

1145   5. *Consider also:*

a. *Archive Service Support*

b. *Locationalization Service Support*

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

d. *Ensemble Support*

1150   6. *Note also that some OPTIONS that are allowed here may be mandatory in the medical
profiles.*

---

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

a.   *SDPi-A Alert Delegation Option*

b.   *SDPi-A Alert Confirmation Option*

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

1155   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*
	Localization Service Option	DEV TF-1 *10.2.6 Localization Service Option*
	Ensemble Participation Option	DEV TF-1 *10.2.7 Ensemble Participation Option*

Actor	Option Name	Reference
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?

1180 3. And/or does it apply to compression of streams / waveforms, specific bulky data?

]

10.2.4 Patient Context Management Option

[Editor's Note:

1185 1. Indicates that a SOMDS Provider not only supplies BICEPS PatientContext information but that it also allows a SOMDS Consumer to update / "manage" that patient context.

2. NOTE: This directly supports patient-device association management or the IHE DEV PCIM profile constructs.

3. And/or does it apply to compression of streams / waveforms, specific bulky data?

1190]

10.2.5 Archive Service Option

[Editor's Note:

1. Indicates support for a SOMDS Provider to archived information to a SOMDS Consumer
1195 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

]

1200 ### 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

1205 3. This will be detailed in a post 1.0 version of the SDPi Supplement

]

10.2.7 Ensemble Participation Option

[Editor's Note:

1210
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.]

1220 *<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
1225 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.

1230 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.

1235 *<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.*

1240

- *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.]

1245
<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*
1250 *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.
1255 *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
1260 *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*		

SDPi-P Actor	Actor(s) to be grouped with	Reference	Content Bindings Reference
SOMDS V2 Gateway	*SDPi-P/SOMDS Connector*		
SOMDS Sensor Gateway	*SDPi-P/SOMDS Connector*		
SOMDS Smart App Platform	*SDPi-P/SOMDS Connector*		
BICEPS Content Creator	See Note 2		*DEV TF-3 8.2.8.1 SDC/BICEPS Content Module*
BICEPS Content Consumer	See Note 2		*DEV TF-3 8.2.8.1 SDC/BICEPS Content Module*
Actor A	*<external Domain Acronym or blank>* *SDPi-P/<Actor>* *<e.g., ITI CT / Time Client>*	*<TF Reference; typically from Vol 1>* *<e.g., ITI-TF-1: 7.1>*	--
Actor B	None	--	--
Actor C *<In this example, Actor C shall be grouped with all three actors listed in column 2>*	*<external Domain Acronym or blank>* *SDPi-P/<Actor>*	--	See Note 1
	<external Domain Acronym or blank> SDPi-P/<Actor>	--	See Note 1
	<external Domain Acronym or blank> *SDPi-P/<Actor>*	--	See Note 1
Actor D *(See note 1)* *<In this example, the note is used to indicate that the Actor D shall be grouped with one or more of the two actors of the two actors in column 2.>*	*<external Domain Acronym or blank>* *SDPi-P/<Actor>*	--	See Note 1
	<external Domain Acronym or blank> *SDPi-P/<Actor>*	--	See Note 1
Actor E *<In rare cases, the actor to be grouped with must implement an option. An example is in column 2.)*	*<external Domain Acronym or blank>* *SDPi-P <Actor>* *<e.g., ITI RFD Form Filler with the Archive Form Option>*	*<TF Reference to the Option definition; typically from Vol 1>* *<(e.g., ITI TF-1: 17.3.11)>*	
<e.g., Content Consumer (See Note 1)	ITI XDS.b / Document Consumer	ITI TF-1: 10.1	*PCC TF-2:4.1 (See Note 2)>*

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

1265

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

1270 *<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

1275 *<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.>

1280 #### 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
1285 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
1290 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 …

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.]

1330

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

1335

[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

1340

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

1345

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

1350

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

1355

<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.)*

1360

*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.>*

1365

*<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".>

1370   **Figure 10.4.2.2-1: Basic Process Flow in SDPi-P Profile**
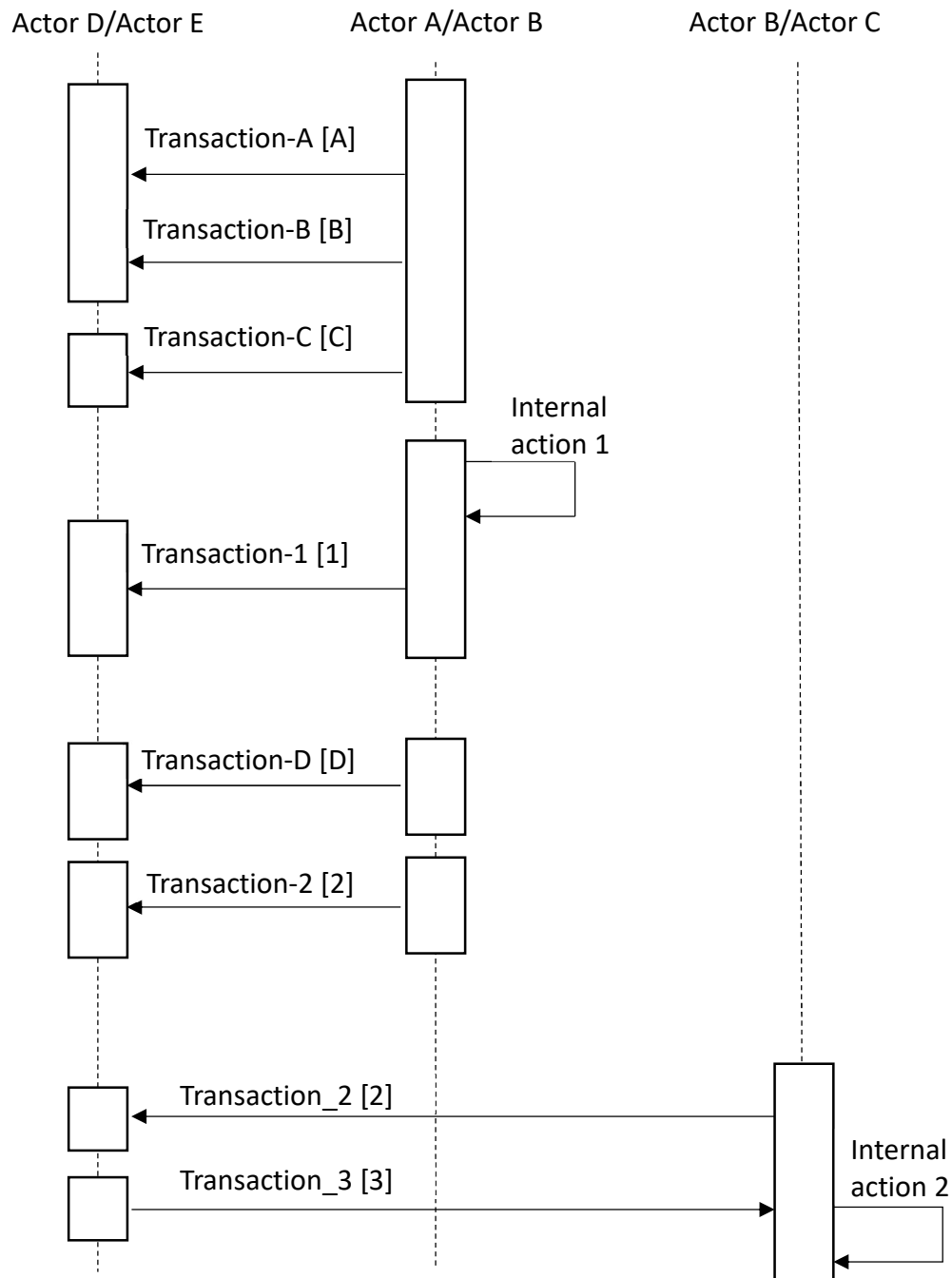
<If process flow "swimlane" diagrams require additional explanation to clarify conditional flows, or flow variations need to be described where alternate systems may be playing different actor roles, document those conditional flows here.>

<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.>

10.4.2.1 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]

10.4.2.1.1 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.>

10.4.2.1.2 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.>

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

1435

<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

1440

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>

1445

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

1450   [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.

1455   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

1460   with dotted lines and non-italics names. Actor groupings, including abstract with concrete are detailed in Section 11.3.
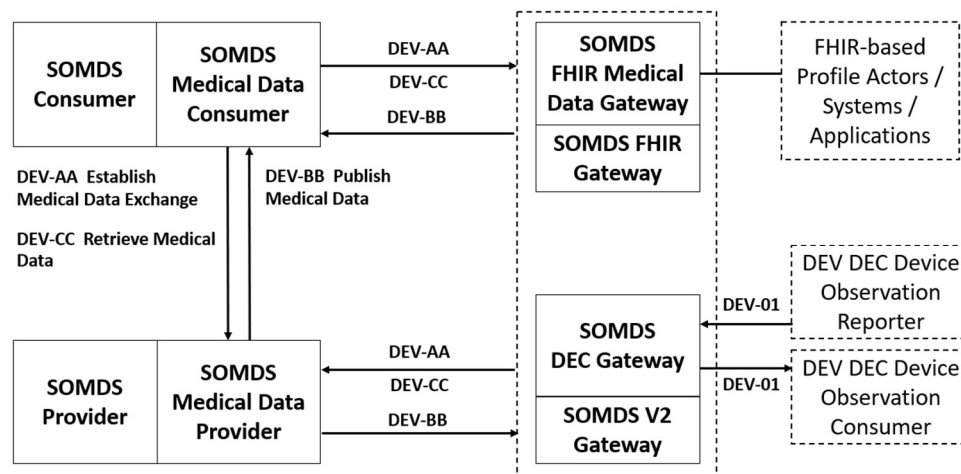

1465   **Figure 11.1-1: SDPi-R Actor Diagram**

[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.   DEC can have DOR and DOC actor implementations; indicate HERE or in actor

1470   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!

1475

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?

1480

f. Are the transactions truly unique or should we utilize SDPi-P transactions and include different mandatory bindings here?

3. 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 …

1485

4.

]

11.1.1 Actor Descriptions and Actor Profile Requirements

11.1.1.1 SOMDS Medical Data Consumer

1490 Actor Summary Definition: [to be copied to Appendix A – Actor Summary Definitions above]

      <short description>

<more detailed actor description>

11.1.1.2 SOMDS Medical Data Provider

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

1495   <short description>

<more detailed actor description>

11.1.1.3 SOMDS FHIR Medical Data Gateway

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

      <short description>

1500 <more detailed actor description>

11.1.1.4 SOMDS DEC Gateway

Actor Summary Definition: <mark>[to be copied to Appendix A – Actor Summary Definitions above]</mark>

<short description>

<more detailed actor description>

1505

11.2 SDPi-R Actor Options

11.2.1 <Option Name>

11.3 SDPi-R Required Actor Groupings

11.4 SDPi-R Overview

1510 ### 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
1515 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).

1520 ### 11.5.2 Safety Requirements & Considerations

11.5.3 Effectiveness Requirements & Considerations

11.5.4 Security Requirements & Considerations

1525

11.6 SDPi-R Cross Profile Considerations

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

1530

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

12.1 SDPi-A Actors, Transactions, and Content Modules

1535

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.,

1540

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.
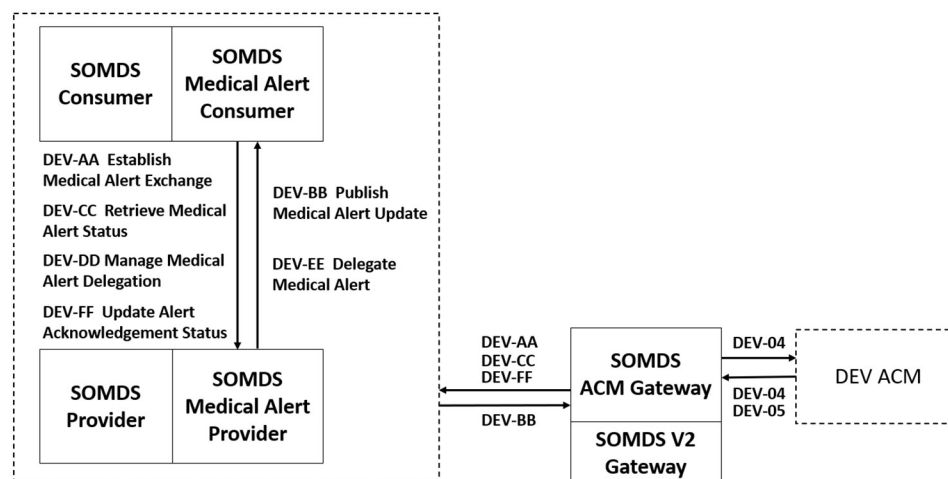

Figure 12.1-1: SDPi-A Actor Diagram

1545

[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:

1550

    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.

]

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]

   <short description>

<more detailed actor description>

12.1.1.2 SOMDS Medical Alert Provider

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

   <short description>

<more detailed actor description>

12.1.1.3 SOMDS ACM Gateway

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

   <short description>

12.2 SDPi-A Actor Options

12.2.1 <Option Name>

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]

12.4.1.1 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.]

12.4.1.1 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

12.5 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

1625

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

13.1 SDPi-xC Actors, Transactions, and Content Modules

1630 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.,

1635 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.


1640
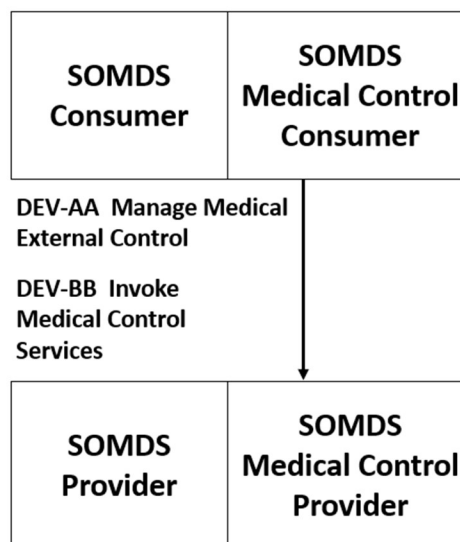
Figure 13.1-1: SDPi-xC Actor Diagram

[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:

1645

    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

1650

    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

1655

    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:

1660

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

4.

]

13.1.1 Actor Descriptions and Actor Profile Requirements

1665

13.1.1.1 SOMDS Medical Control Consumer

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

       \<short description>

\<more detailed actor description>

13.1.1.2 SOMDS Medical Control Provider

1670   Actor Summary Definition: [to be copied to Appendix A – Actor Summary Definitions above]

       \<short description>

\<more detailed actor description>

13.2 SDPi-xC Actor Options

13.2.1 <Option Name>

13.3 SDPi-xC Required Actor Groupings

13.4 SDPi-xC Overview

13.4.1 Concepts

13.4.2 Use Cases

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

13.4.2.1 Use Case #1: <simple name>

13.4.2.1.1 <simple name> Use Case Description

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

13.5.1 SES General Considerations

<SDPi content here>

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

13.5.2 Safety Requirements & Considerations

13.5.3 Effectiveness Requirements & Considerations

13.5.4 Security Requirements & Considerations

13.6 SDPi-xC Cross Profile Considerations

1700

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.>

1705 *<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

1710 [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]

1715

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

A.1.1 Hanging Gardens "Layers" Model

<include content from confluence pages>

1720 <include Hanging Gardens Model – content from slide deck>
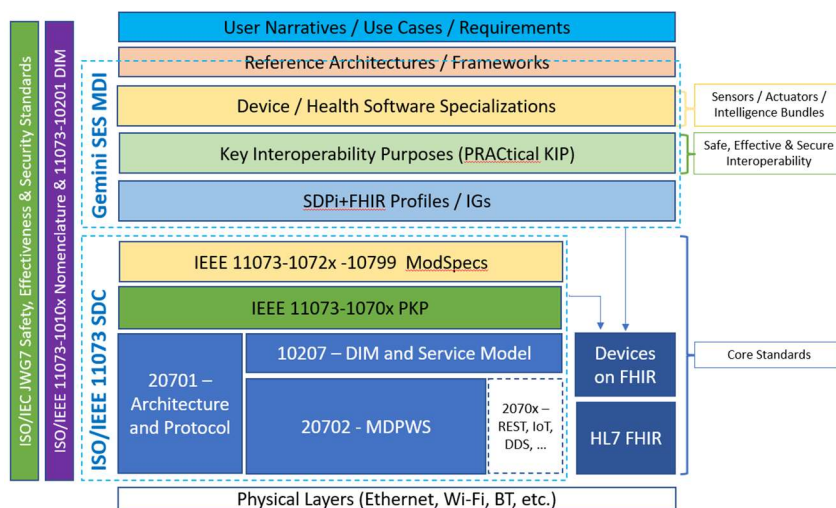
[UPDATE TO LATEST VERSION!]

Figure A.1.1-1: Hanging Gardens Model

1725 <explain the model>

A.1.2 ISO/IEEE 11073 SDC Components

A.1.3 Reference Frameworks – IHE and MDIRA / ICE

1730 ## 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>

1735 # A.2 Integrating Safety, Effectiveness & Security Requirements & Considerations

<provide perspective on SES MDI requirements>

<KIP Layer linkage>

<Ecosystem of SES trusted interoperable DECOUPLED products>

1740 <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?>

1745
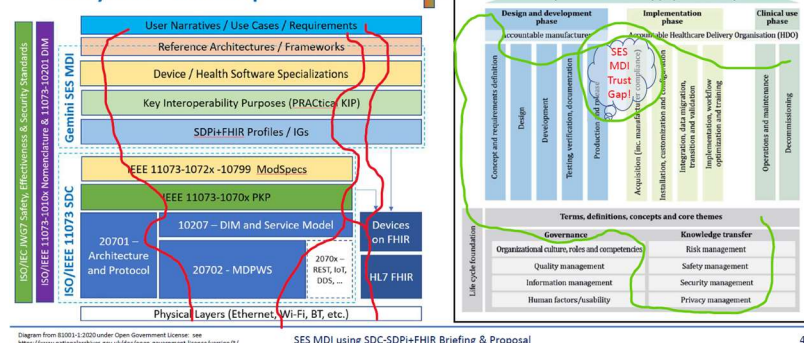
Figure A.2-1: SES MDI Trust Gap Framework Proposal

1750 ## 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>

1755 <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

1760 ### 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
1765 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

1770 >

Appendix B – ISO/IEEE 11073 SDC Requirements Coverage

B.1 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.2 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.

1805   3. The Word Style for the copy & pasted tables below has to be normalized to the IHE TF Style Guide.]

B.2.1 General

1810   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.

]

1815

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

B.2.2 Service Provider

1820   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.

1825

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

1830   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?]*

1835

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

Standard Version: IEEE 11073-10207:2018

1840 **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.

1845

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

1850   <...>

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	

1855   # B.4 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].

1890

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
1895   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.

Volume 2 – Transactions

1900 | *Add Section 3.23 and subsequent transactions for SDPi profiles*

3.23 Announce Network Presence [DEV-23]

3.23.1 Scope

1905 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.

1910 ### 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:

1915
   - 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.

1920
   - 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:
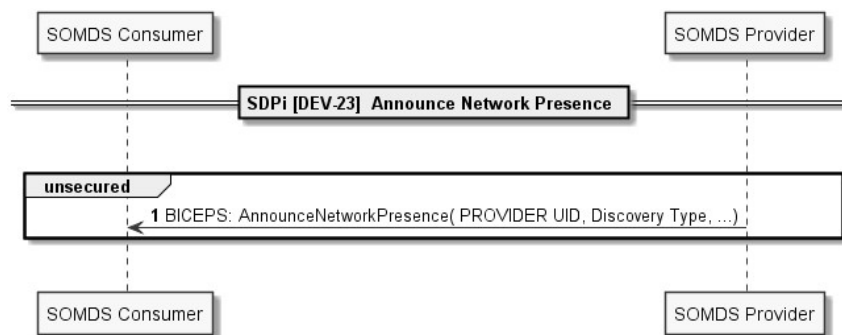
Figure 3.23.4-1: DEV-23 Messaging Interaction Diagram

[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

1950 (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

1955 *<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.").>

1960 *<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

1965 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

1970 *<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.>

1975 *<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.

1980 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!

1985]

<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

1990 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>

1995 [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?]

2000

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
2005 *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
2010 *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:

2035
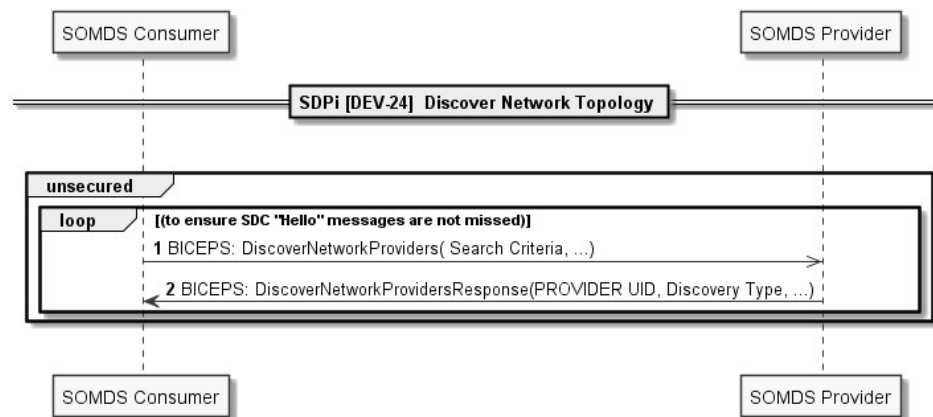
Figure 3.24.4-1: DEV-24 Discover Network Topology Interaction Diagram

[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]

2040

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.]

2045

<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.>

2050

<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).>

2055

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.>

2060 *<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 2065 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. >

2070 *<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

2075 *<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 2080 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).>

2085 ### 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.>

2090 *<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.>

2095 ### 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. >

2100 *<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

2105 *<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.

2110   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

2115 *<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?]

2120 <mark>[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?]</mark>

3.24.6.2 Safety Requirements & Considerations

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

2125 ### 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.>

2130 ### 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.>

2135

3.25 Discover BICEPS Services [DEV-25]

3.25.1 Scope

This transaction is used to *<...describe what is accomplished by using the transaction.*
2140 *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

2145 • *<e.g., HL7 2.3.1 Chapters 2, 3>*

3.25.4 Messages

<mark>[Editor's Note: interaction diagram here]</mark>

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>

2185 [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?]

2190

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
2195 *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
2200 *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]

2205 ### 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

2210

3.26.3 Referenced Standards

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

3.26.4 Messages

[Editor's Note: interaction diagram here]

2215 **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.>

2220 *<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).>

2225 **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
2230 *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.>

2235 **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?]

2330 <mark>[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?]</mark>

3.27.6.2 Safety Requirements & Considerations

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

2335 ### 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.>

2340 ### 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.>

2345 ## 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*
2350 *profiles>*

3.28.2 Actor Roles

3.28.3 Referenced Standards

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

2355 ### 3.28.4 Messages

<mark>[Editor's Note: interaction diagram here]</mark>

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.>

2390 **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>

2395 [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?]

2400 **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.)>

2405 **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. >

2410 **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

2415 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

2420 ### 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

2425 *<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
2430 *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

2435 *<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.").>

2440 *<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

2445 *<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]

2480

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>*

2485 ### 3.30.2 Actor Roles

3.30.3 Referenced Standards

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

3.30.4 Messages

2490 [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
2495 *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
2500 *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
2505 *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

2540 *<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

2545 *<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.*
2550 *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

2555 • *<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
2560 *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.>

2565 **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. >

2665 *<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.>

2670 ### 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

2675 ### 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?]

2680

[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

2685 *<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

2690 *<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

2695 *<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.*
2700 *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

2705 • *<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
2710 *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.>

2715 **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
2720 *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.").>

2725

<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.>

2730

<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.>

2735 *<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,
2740 *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>

2745 [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?]

2750

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).>

2785
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.").>

2790

<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.>

2795
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.>

2800

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

3.34.5 Protocol Requirements

2805 *<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

2810 *<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?]

2815 <mark>[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?]</mark>

3.34.6.2 Safety Requirements & Considerations

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

2820 ### 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.>

2825 ### 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.>

2830

Appendices to Volume 2

2835 *<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.>

2840

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[9]

2875

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.

2880   "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?
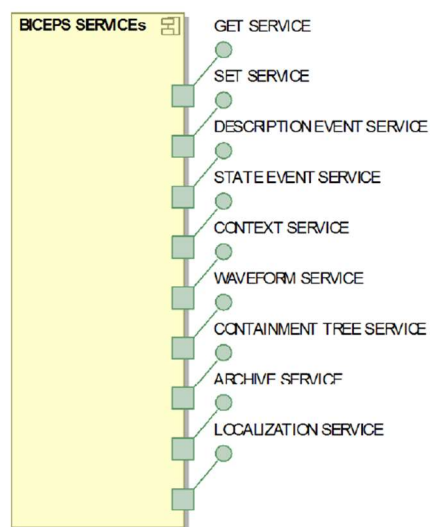
Figure 12—SERVICEs defined to let SERVICE CONSUMERs
gain access to the MDIB

2885

A.1.1 <Title>

Appendix A.1.1 text.

---

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

2890 [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

2895

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?

2900 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?

]

2905
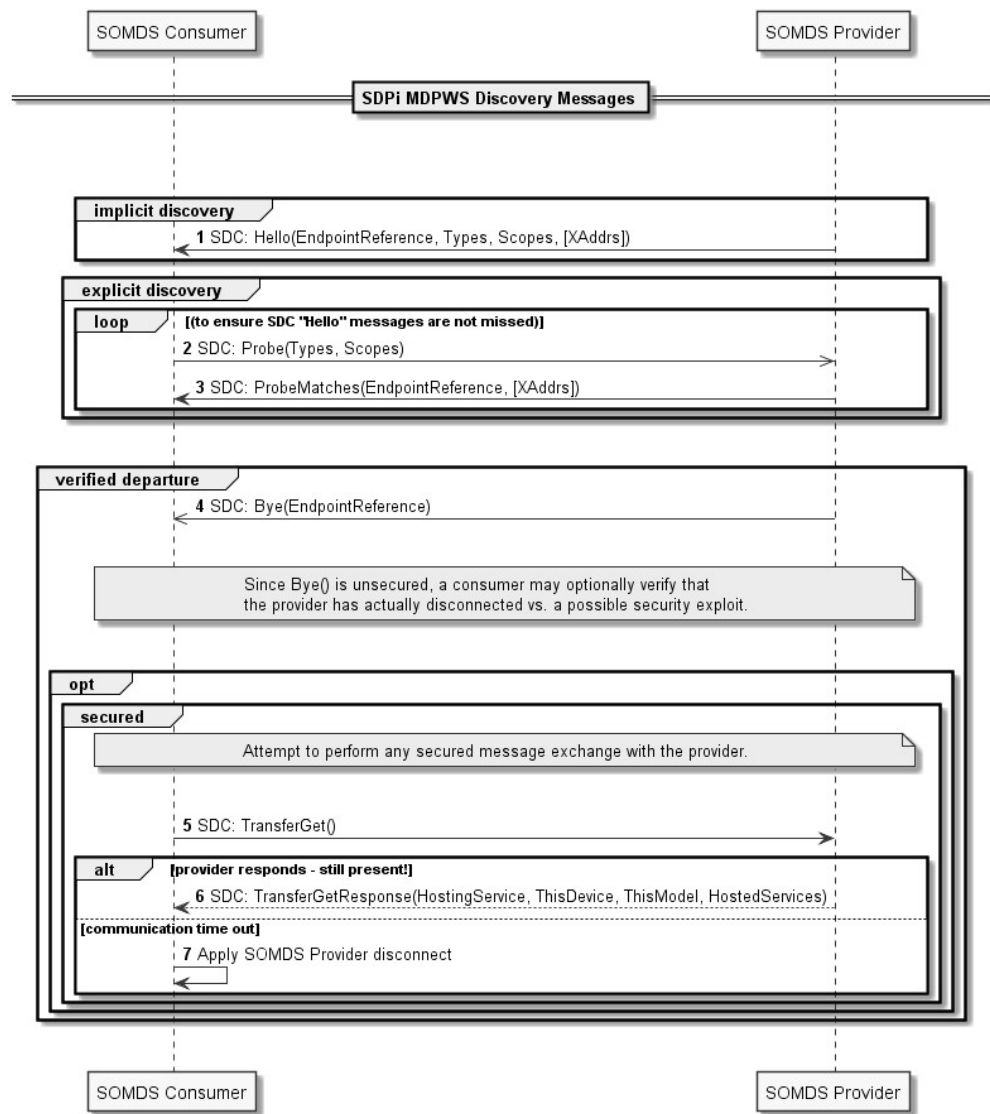
A.2.1 MDPWS: Hello()

2910   xyz.

[Editor's Note: Add standardized section content for:
  • Binding references (BICEPS, MDPWS,…)

2915
- Parameter semantics
- SES & Other Considerations
- Profiling & Usage Notes
- …

]

A.2.2 MDPWS: Probe ()

2920

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.

2925
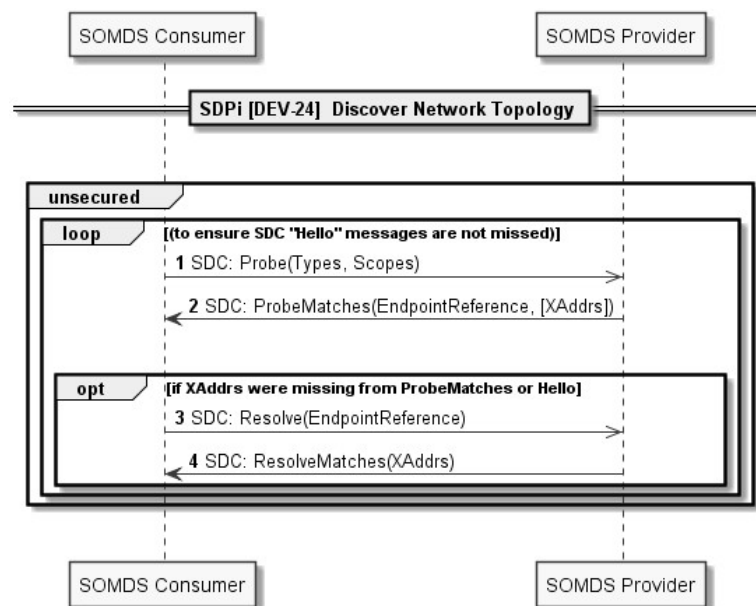
[Editor's Note: Remove "opt" section and indicate WHY this is profiled out in SDPi; then remove diagram.]

A.2.3 MDPWS: ProbeMatches()

2930

xyz.

A.241 MDPWS: Bye()

xyz.

2935
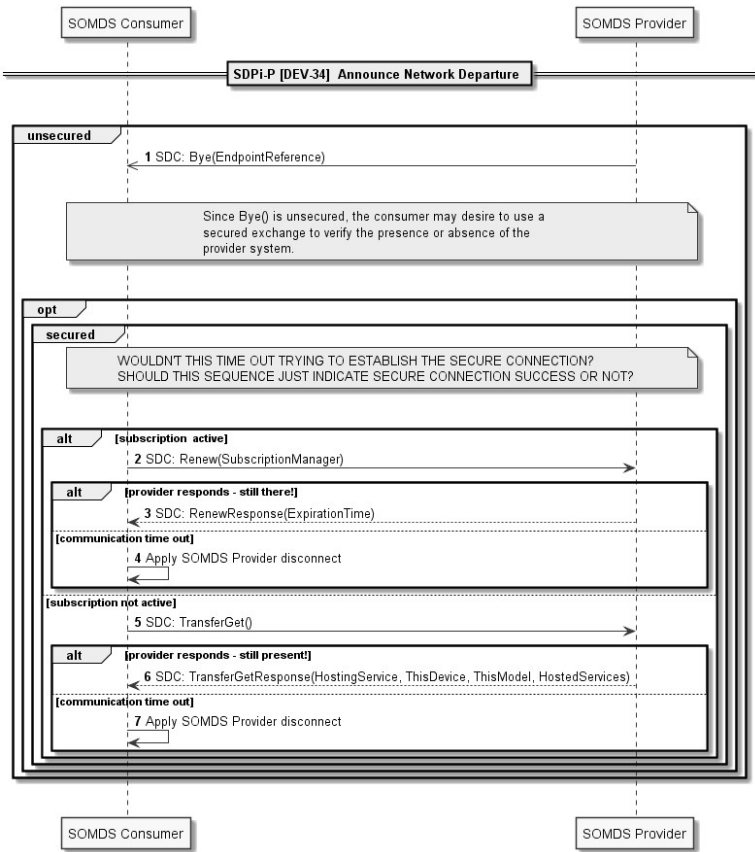
[Editor's Note: Simplify (per instructions in 8/24 PlantUML; Add in Profiling / Usage Notes]

2940

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>

2955   Appendix B.1 text.

B.1.1 <Title>

Appendix B.1.1 text.

Namespace Additions for Volume 2

2960 *<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.>*

2965 *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.>*

2970

The Devices registry of OIDs is located at <link to your OID registry(ies)

Volume 2 additions to the Devices OID Registry are:

2975

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.>

2980

5 IHE Namespaces, Concept Domains and Vocabularies

2985

> *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

2990 *<**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.>*

2995 *<**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.>*

3000 *<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

3005 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

3010 *<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*
3015 *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

3020

*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.

3025

Profile	Format Code	Media Type	Template ID
<Profile name (profile acronym)>	<urn:ihe: >		<oids>

5.3.2 IHEActCode Vocabulary

3030 *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

3035

*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.*

3040

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]

3045

8 DEV Semantic Content Modules

8.1 Overview of device semantic content

8.2 General device content considerations

3050   ### 8.2.8 SDC/BICEPS semantic content

[Editor: Include:

> BICEPS Standard overview
>
> Reference TF-1 SDC overview
>
> Include SES section + Assurance Case

3055
> Quality of Data requirements; RM Alerting considerations / requirements
>
> Look forward to device specialization profiles
>
> Consider links / bindings to transactions

]

8.2.8.1 SDC/BICEPS Content Module

3060   [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

3065

8.2.8.3 SDC/BICEPS Relationship to Classic DIM

8.2.8.4 Safety, Effectiveness, Security Content Requirements & Considerations

3070   ### 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:"

3075
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.

]

3080
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

3085
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!

3090
]

8.2.8.8 SOMDA System Function Contribution Content Module

[Editor: Formal definition of the SFC content specification required for PnT connectivity]

8.3 Device specialization content modules

3095
[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.

3100
]

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:

3105
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)

3110
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

3115
specifications (e.g., profiles that build upon the interoperability foundation of SDPi profiles, but define device-specific architecture / workflow transactions & appropriately scoped content.

]

3120
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.

3125
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.

3130
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

3170   [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.

3175   ]

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

3180   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.

]

3185

Appendices to Volume 3

3190 *<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>

3195

Appendix A.1 text.

A.1.1 <Title>

Appendix A.1.1 text.

Appendix B – <Appendix Title>

3200   Appendix B text.

B.1 <Title>

Appendix B.1 text.

B.1.1 <Title>

Appendix B.1.1 text.

3205

Volume 4 – National Extensions

Add appropriate Country section

3 National Extensions for <Country Name or IHE Organization>

3210 *<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
3215 *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.*
3220 *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**.>*

3225 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
3230 <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:

3235 Name:

Organization/Title:

Email:

3.2 IHE <Country Name> Scope of Changes

The extensions, restrictions and translations specified apply to the following IHE <Domain
3240 Acronym> Integration profiles:

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

- Etc.

3.3 \<Profile Name> \<(Profile Acronym)>

3245 *\<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.>

3250 *\<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

3255

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)

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

end of example>

3260 ### 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>

3265

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>

3270

Appendix A text.

A.1 <Title>

Appendix A.1 text.

A.1.1 <Title>

3275 Appendix A.1.1 text.

Appendix B – <Appendix Title>

Appendix B text.

B.1 <Title>

Appendix B.1 text.

3280
B.1.1 <Title>

Appendix B.1.1 text.