Integrating the Healthcare Enterprise

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: August 7, 2020

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

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/indeW.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/indeW.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/indeW.php?title=National_Extensions_Process.>

Foreword

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

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

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

This supplement describes changes to the existing technical framework documents.

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

Amend section W.X by the following:

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

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

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

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

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

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

CONTENTS

Introduction to this Supplement

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

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

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

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

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

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

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

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

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

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

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

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

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

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

TF-1 Integration Profiles

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

TF-2 Transactions

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

TF-3 Content Modules

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

Open Issues and Questions

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

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

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 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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IHE technical documents refer to and make use of a number of standards developed and published by several standards development organizations. All rights for their respective base standards are reserved by these organizations. This agreement does not supersede any copyright provisions applicable to such base standards. Copyright license information for frequently referenced base standards is provided below.

9.1.1 DICOM (Digital Imaging and Communications in Medicine)

DICOM® is the registered trademark of the National Electrical Manufacturers Association for its standards publications relating to digital communications of medical information.

9.1.2 HL7 (Health Level Seven)

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

HL7®, Health Level Seven®, CDA®, FHIR®, and the FHIR [FLAME DESIGN] ® are registered trademarks of Health Level Seven International.

Health Level Seven, Inc. has granted permission to IHE to reproduce tables from the HL7 standard. The HL7 tables in this document are copyrighted by Health Level Seven, Inc. All rights reserved. Material drawn from these documents is credited where used.

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.]

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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.

*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.*

***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.*

Appendix A – Actor Summary Definitions

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

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

New (or modified) Actor Name	Definition
<Verb-Noun format (e.g., Store Image, Register Document Set)>	*If this is a modified actor description, add the original description and use **bold underline** to indicate where the amendment adds text and bold strikethrough. where the amendment removes text*
Service Consumer	[Editor's Note: Add Definition here]
Service 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.]

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

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

Complete List of Existing Actors Utilized in this Profile

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

Appendix B – Transaction Summary Definitions

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

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

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

New (or modified) Transaction Name and Number	Definition
<Verb-Noun formation (e.g., Send Data [DOM-xx]}>	*If this is a modified transaction description, add the original description and use **bold underline** to indicate where the amendment adds text and ~~**bold strikethrough**~~. where the amendment removes text*

Appendix D – Glossary

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

*<Add any **new or updated glossary terms** associated with the profile here. Verify that any new glossary terms added here are not already contained in the IHE Glossary. Also, please review the Glossary Rules for terms that should/should not be added to the IHE Glossary. Please list terms in alphabetical order.>*

New (or modified) Glossary Term	Definition
New or modified glossary term (in alphabetical order)	*If this is a modified glossary term definition, add the original definition and use **bold underline** to indicate where the amendment adds text and ~~**bold strikethrough**~~. where the amendment removes text*

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<Note: The sections following this Introduction will eventually be added as Final Text to Volumes 1 – 4 of the Technical Framework. The material above this note (the Introduction to this Supplement, Open and Closed Issues and General Introduction and Shared Appendices sections) will not be moved when this supplement is moved to Final Text.>

Volume 1 – Profiles

2 Devices Integration Profiles

[Editor's Note:

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

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

Consider adding here:

1. *General IHE Devices Architecture / Use Context section + (4) KIPs*
2. *General SDPi Family of Profiles Overview section.*

]

2.2 Safety, Effectiveness & Security Implications

[Editor's Note: This section is modified from the original template to show SES … "Implications" is maintained, although changing that to "Considerations and Requirements" might be better. Note additional section in Appendix 1]

2.3 Integration Profiles Overview

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

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

<Mary?>

]

W.2.1 <Option Name>

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

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

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

<Sometimes an option requires that the actor be grouped with an actor in another profile. In that case, describe that here and also refer to the Required Grouping table in the next section. E.g., "An Actor-A that supports the Really Secure Option shall be grouped with an Secure Node or Secure Application in the ATNA Profile. See Table W.3-1.">

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

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

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

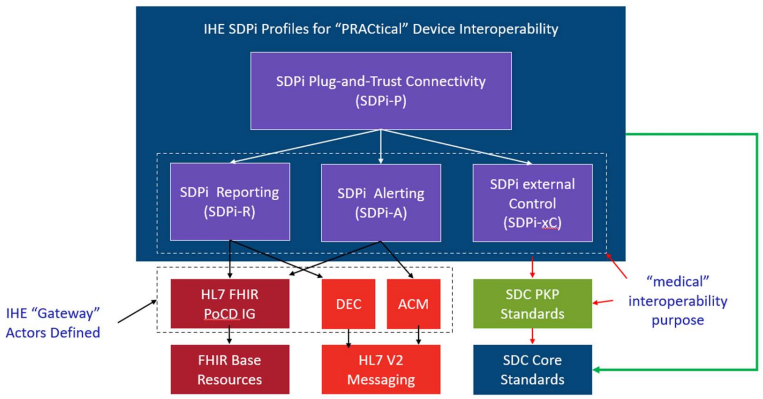


Figure 2.X-1: SDPi Profiles & Foundational Standards

<add caption + explain model>

<give reference to appendix 1>

Add new Section #

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

[Editor's Note: Mary: The section numbers are reserved. When do we update them to this Supplement document?]

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

<Provide an end-user friendly overview of what the profile does for them. Keep it brief (a paragraph or two, up to a page). If extensive detail is needed, it should be included in Section W.4- Use Cases.>

<Explicitly state whether this is a Workflow, Transport, or Content Module (or combination) profile. See the IHE Technical Frameworks General Introduction for definitions of these profile types. The IHE Technical Frameworks General Introduction is published at http://ihe.net/Technical_Frameworks.>

[Editor's Note: This is in section 4 @ https://www.ihe.net/uploadedFiles/Documents/Templates/IHE_TF_General_Introduction.pdf .

Reviewing the descriptions, SDPi would be **primarily Transport**, an implementation of the SOMDA in the Ref Arch layer; Future profiles could be WORKFLOW focused such as OR / ICU / ED device integration with actors such as Central Station, Bedside Cockpit, Alert Distribution, etc. BICEPS CONTENT MODULES will be defined in TF-3, with initial bindings defined in TF-1 and TF-2.]

W.1 SDPi-P Actors, Transactions, and Content Modules

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

<Workflow/Transport Instructions>

<If this profile does not define workflow or transport transactions, delete the following text and diagram until the "Content Module Instructions" below.>

[Editor's Note: Modeling approach will leverage constructs from XDS.b, SWF & ACM.

The actor diagram below will be analogous to ACM where it shows actors and general connection but not specific transaction detail. The transactions will be included in the subsequent table with linkages to TF-2]

<Continue here for workflow and/or transport profiles:>

Figure W.1-1 shows the actors directly involved in the SDPi-P Profile and the relevant transactions between them. If needed for context, other actors that may be indirectly involved due to their participation in other related profiles are shown in dotted lines. Actors which have a required grouping are shown in conjoined boxes (see Section W.3).

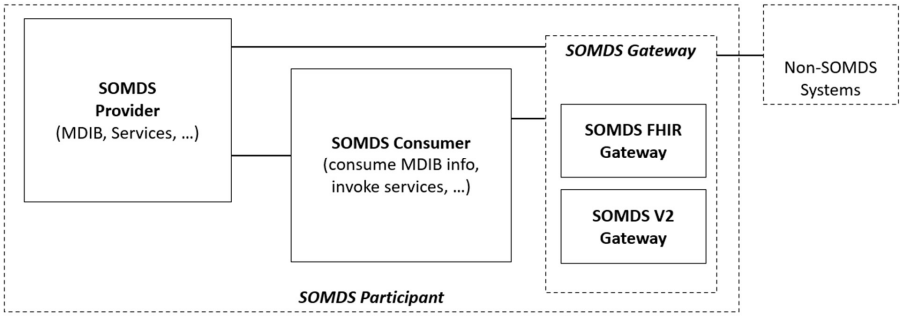


Figure W.1-1: SDPi-P Actor Diagram

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

1. See notes around line #545 …
2. Descriptions of these actors are in the sections below
3. SOMDS is the overarching concept … obviously!
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 Gateway/Proxy :
   a. Clearly this actor CAN integrate a provider and / or consumer actor
   b. 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 W.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").

<Actors from other profiles represented in dotted boxes, such as Actor C in the example above, should not be listed in Table W.1-1. They are documented in Section W.3.>

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

1. *waveform service negotiation and streaming.*
2. *Set for SystemContext type stuff for example (localization / patient info)*
3. *Time Synchronization … and leveraging CT or profiling CT for use with SDC-enabled systems?*
4. *…*

]

Table W.1-1: SDPi-P Profile - Actors and Transactions

Commented [TC1]: TABLE NEEDS TO BE NORMALIZED TO LATEST TRANSACTION SEQUENCES … SOMEWHERE!

Actors	Transactions	Initiator or Responder	Optionality	Reference
SOMDS Participant	<TBD specific transactions / abstract actor!>			DEV TF-2:3.xyz
SOMDS Provider	Announce Network Presence	Initiator	R	DEV TF-2:3.xyz
	Discover Network Topology	Responder	R	
	Discover System Context and Capabilities	Responder		DEV TF-2:3.xyz
	Discover BICEPS Services	Responder		DEV TF-2:3.xyz
	Subscribe to MDIB Reports	Responder		DEV TF-2:3.xyz
	Notify Change in System Context and Capabilities	Initiator	O (See Note 1)	DEV TF-2:3.xyz
	Publish Update Reports		R	DEV TF-2:3.xyz
	Retrieve Update Reports	Responder	O	DEV TF-2:3.xyz
	Retrieve Archive Data	Responder	O	DEV TF-2:3.xyz
	Retrieve Localization Information	Responder	O	DEV TF-2:3.xyz
	Announce Network Departure	Initiator	R	DEV TF-2:3.xyz
SOMDS Consumer	Discover Network Topology	Initiator	R	DEV TF-2:3.23
	Discover BICEPS Services	Initiator		DEV TF-2:3.xyz
	Subscribe to MDIB Reports	Initiator		DEV TF-2:3.xyz
	Discover System Context and Capabilities	Initiator		DEV TF-2:3.xyz
	Retrieve Update Reports	Initiator		DEV TF-2:3.xyz
	Retrieve Archive Data	Initiator		DEV TF-2:3.xyz
	Retrieve Localization Information	Initiator		DEV TF-2:3.xyz
	Publish Update Reports	Responder / "Consumer"		DEV TF-2:3.xyz

Actors	Transactions	Initiator or Responder	Optionality	Reference
	Notify Change in System Context and Capabilities	Responder / "consumer"		DEV TF-2:3.xyz
SOMDS Gateway	<TBD specific transactions / abstract actor! See actor description below>			
SOMDS FHIR Gateway	<TBD specific transactions; see actor description below>			
SOMDS V2 Gateway	<TBD specific transactions; see actor description below>			
Actor E	Transaction 2		R	<Domain Acronym> TF-2: 3.Y2
	Transaction 3		O (See Note 1)	<Domain Acronym> TF-2: 3.Y3
	Transaction 4		O (See Note 1)	<Domain Acronym> TF-2: 3.Y4
Actor B	Transaction 3		R	<Domain Acronym> TF-2: 3.Y3
	Transaction 4		O (See Note 2)	<Domain Acronym> TF-2: 3.Y4

Note 1: *<For example, a note could specify that at least one of the transactions shall be supported by an actor or other variations. For example: Note: Either Transaction Y3 or Transaction Y4 shall be implemented for Actor E. >*

Note 2: *<For example, could specify that Transaction Y4 is required if Actor B supports XYZ Option, see Section W.3.W.>*

<Content Module Instructions:>

<If this profile does not define Content Modules, delete the following diagram, text, and table. <Note that this figure number has to change if this profile describes both transactions and content modules (or there will be two figures entitled W.1-1).>

[Editor's Note:

1. *Should we include a description of SOMDS Participant MDIB & device specializations etc. here?*
2. *We have loosely talked about Content Modules in the past; however, not explicitly integrated them in any serious way*
3. *IF we did update the diagram …*
    a. *SDPi MDIB Creator / Reporter?*
    b. *SDPi MDIB Content / Consumer?*

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

]

The recommended Content Creator/Content Consumer diagram is given below. If this is not applicable to this profile, it is up to the author's discretion to modify/replace. Authors are encouraged to maintain the neutrality of the content modules and incorporate transport by specifying grouping of the actors in the content module with actors from transport transactions.>

Figure W.1-1 shows the actors directly involved in the SDPi-P Profile and the direction that the content is exchanged.

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 Required Actor Groupings <DOM> TF-1: W.6 or in Cross Profile Considerations <DOM> TF-1: W.6.

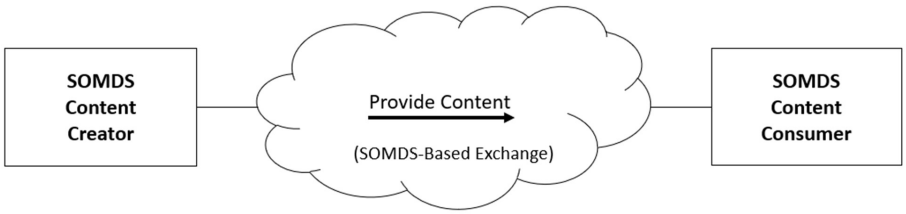


Figure W.1-2: SDPi-P Content Actor Diagram

Table W.1-1 lists the content module(s) defined in the SDPi-P Profile. To claim support with this profile, an actor shall support all required content modules (labeled "R") and may support optional content modules (labeled "O").

<Note that this table number has to change if this profile describes both transactions and content modules (or there will be two tables entitled W.1-1).>

<Note that the abbreviation in the column "Reference" the letter "D" will be incremented for every content module document defined in this profile (e.g., For example D1, D2).>

<In general, one supplement template will only contain one required content module document, but the example here shows multiple with one optional, just for illustration purposes.>

Table W.1-2 SDPi-P – Actors and Content Modules

Actors	Content Modules	Optionality	Reference
SOMDS Content Creator	Content Module 1 Name and Template ID	R	<Domain Acronym> TF-3: 6.3.1.D
	Content Module 2 Name and Template ID	O See Note 1	<Domain Acronym> TF-3: 6.3.1.D
SOMDS Content Consumer	Content Module 1 Name and Template ID	O See Note 1	<Domain Acronym> TF-3: 6.3.1.D
	Content Module 2 Name and Template ID	R	<Domain Acronym> TF-3: 6.3.1.D

Note 1: *<For example, a note could describe that one of two possible transactions could be supported by an actor or other variations.*

For example - Note 1: Either Content Module 2 or Content Module 3 shall be implemented for the Content Creator or Content Consumer.

For example- Note 1: At least one of Content Module 2, Content Module 3, or Content Module 4 shall be implemented for Content Consumer.>

W.1.1 Actor Descriptions and Actor Profile Requirements

<For Workflow Profile:>

Most requirements are documented in <DOM> TF-2 Transactions. This section documents any additional requirements on profile's actors.

<Enter here "No additional requirements needed.", if none.>

<For Content Module Profile:>

Most requirements are documented in <DOM> TF-3 T Content Modules. This section documents any additional requirements on profile's actors.

<Enter here "No additional requirements needed.", if none.>

*<**Do not repeat** the definitions of the actors that are maintained in the Technical Frameworks General Introduction Appendix A (Actors). Include text in this section to describe the actor in the context of this profile.>*

*<**This section is empty unless there is a need for specific descriptions or requirements. Actors without additional requirements or elaborate descriptions need not be listed here.** >*

<If this is a Workflow Profile the sequence of transactions often require data from an inbound transaction to be carried forward to subsequent transactions . Individual transactions, which are designed to be reusable, do not define this data mapping and it must be documented here. If this

is a long technical mapping, consider including this material in an appendix to Volume 2. For an example, see Radiology Scheduled Workflow RAD TF-2: Appendix A.>

<This section may also define system behavior. For example, in the PIX Profile, an ADT message is first received by the PIX Manager. The PIX Manager should then use this data to respond to subsequent queries. Although this may be implied, it should be explicitly documented in this section.>

<Note that for actors in, bindings to other transport or workflow modules are referenced in the Required Actor Groupings section below. >

W.1.1.1 SOMDS Participant

[Editor's Note: This is an Abstract Actor and thus the italics on the diagram above]

W.1.1.2 SOMDS Provider

<If the summary description of the actor in Appendix A is insufficient to understand its role in this profile, elaborate here.>

<Requirements on actors are predominantly contained inside transactions in Volume 2. The main requirement on actors contained in Volume 1 is to support the transactions identified in Table W.1-1 and the content modules identified in Table Z. Requirements that do not fit in those locations may be placed here.>

W.1.1.3 SOMDS Consumer

[Editor's Note: alternative SDC Provider or … ???]

W.1.1.4 SOMDS Gateway

[Editor's Note: Abstract actor …]

W.1.1.5 SOMDS FHIR Gateway

[Editor's Note: Specialized version of SDC Gateway above.]

W.1.1.6 SOMDS V2 Gateway

[Editor's Note: Specialized version of SOMDS Gateway above.

1. Are there unique transactions at the -P level or only when grouped with -R/-A?
2. Are there unique transactions on the non-SOMDS exchange?
3. 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?

4. Or does the gateway have an SDC Consumer sucking in the world and then internally push out PCD-1 based on pre-configuration?

]

W.2 SDPi-P Actor Options

<Modify the following table, listing all the actors in this profile, the options available for each, and references to sections that state requirements for compliance to each option. For actors with no options, state "No options defined" in column 2.>

<Note: Options are directly carried over to the integration statements which are published by vendors for review by buyers. Too many options can be confusing for readers, so try to ***minimize*** *options for actors and only use if necessary.>*

<Several options for Content Consumers are defined in PCC TF-2: 3.1.1-3.1.4. It is recommended that these options are reused, if applicable, but read the option definitions thoroughly to be certain that they apply. If they do not apply in their entirety, you will need to define a corresponding option in this profile. The recommended naming convention for a similar, but different, option is, for example, "View Option - SDPi-P, etc., "View Option – CIRC".>

Options that may be selected for each actor in this profile, if any, are listed in the Table W.2-1. Dependencies between options, when applicable, are specified in notes.

Table W.2-1: SDPi-P – Actors and Options

Actor	Option Name	Reference
Actor A	*<Option 1 name>* Option	*<reference to applicable W.2.x sub-section below table>*
Actor B	No options defined	--
Actor C	*<Option 2 name>* Option	*<reference to applicable W.2.x sub-section below table>*
Actor D	*<Option 1 name>* Option *<Note that it is OK to have the same option apply to more than one actor. The option adds specific functionality in a profile. The actors will have different requirements identified in Section W.2.X to enable that functionality.>*	*<reference to applicable sub-section below table, e.g., Section W.2.1>*
Actor E, *<e.g., Content Consume>* (See Note)	View Option	PCC TF-2: 3.1.1
	Document Import Option	PCC TF-2: 3.1.2
	Section Import Option	PCC TF-2: 3.1.3
	Discrete Data Import Option	PCC TF-2: 3.1.4

Note: *<Conditional or required options must be described in this short note, for longer notes use Section W.2.1.>*

<Add a sub-section below for every new option defined in Table W.2-1.>

W.3 SDPi-P Required Actor Groupings

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

<Note that this section effectively combines sections from previous versions of the template: "Profile Dependencies" section (formerly Vol. 1, Section 2.1) and the "Groupings" section.>

<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 W.6 Cross Profile Considerations. Use Section W.5 for security profile recommendations.>

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

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

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

Section W.5 describes some optional groupings that may be of interest for security considerations and Section W.6 describes some optional groupings in other related profiles.

<Two alternatives for Table W.3-1 are presented below.

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

<alternative 1> Table W.3-1: SDPi-P - Required Actor Groupings

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

<In some cases, required groupings are defined as at least one of an enumerated set of possible actors; to designate this, create a row for each potential actor grouping and merge column one to form a single cell containing the profile actor which should be grouped with at least one of the actors in the spanned rows. In addition, a note should be included to explain the enumerated set. See example below showing Document Consumer needing to be grouped with at least one of XDS.b Document Consumer, XDR Document Recipient or XDM Portable Media Importer>

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

<this Profile Acronym> Actor	Actor(s) to be grouped with	Reference	Content Bindings Reference
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

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

Note 1: *<This is a short note. It may be used to describe situations where an actor from this profile may be grouped with one of several other profiles/actors.*

Note 2: *<A note could also be used to explain why the grouping is required, if that is still not clear from the text above.>*

<alternative 2> Table W.3-1: SDPi-P Profile - Required Actor Groupings

<All actors from this profile should be listed in Column 1. If no required grouping exists, "None" should be indicated in Column 3. >

<Guidance on using the "Grouping Condition" column:

- *If an actor has no required grouping, Column 2 should contain "--". See Actor A below.*
- *If an actor has a required grouping that is not associated with a profile option (i.e., it has no condition), column 2 should contain "Required". See Actor B below.*
- *Sometimes an option requires that an actor in this profile be grouped with an actor in another profile. That condition is specified in Column 2. See Actor C below.>*

SDPi-P Actor	Grouping Condition	Actor(s) to be grouped with	Reference
Actor A	--	None	--
Actor B	Required	*<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 C	With the *<Option name in this profile>* Option	*<external Domain Acronym or blank> SDPi-P/<Actor>*	*Where the Option is defined in this profile <Section W.3 z>*

SDPi-P Actor	Grouping Condition	Actor(s) to be grouped with	Reference
Actor D *<if an actor has both required and conditional groupings, list the Required grouping first>*	Required	*<external Domain Acronym or blank> SDPi-P/<Actor>*	*<TF Reference; typically from Vol 1>*
	If the *<Option name in this profile>* Option is supported.	*<external Domain Acronym or blank> SDPi-P/<Actor>*	*<TF Reference; typically from Vol 1>*
	If the *<other Option name in this profile>* Option is supported.	*<external Domain Acronym or blank> SDPi-P/<Actor>*	*<TF Reference; typically from Vol 1>*
Actor E *(In rare cases, the actor to be grouped with must implement an option, an example is in column 3)*	Required	*<external Domain Acronym or blank> SDPi-P/<Actor>* with the *<option name>* *<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)>*

W.4 SDPi-P Overview

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

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

W.4.1 Concepts

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

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

W.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]

W.4.1.2 General Healthcare vs. Medical Interoperability Purposes

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

W.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.]

W.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.]

W.4.1.5 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.]

W.4.2 Use Cases

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

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

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

]

W.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 W.4.2.1 repeats in its entirety for additional use cases (replicate as Section W.4.2.2, W.4.2.3, etc.).>

W.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 appendiW.>

W.4.2.1.2 FESS Process Flow

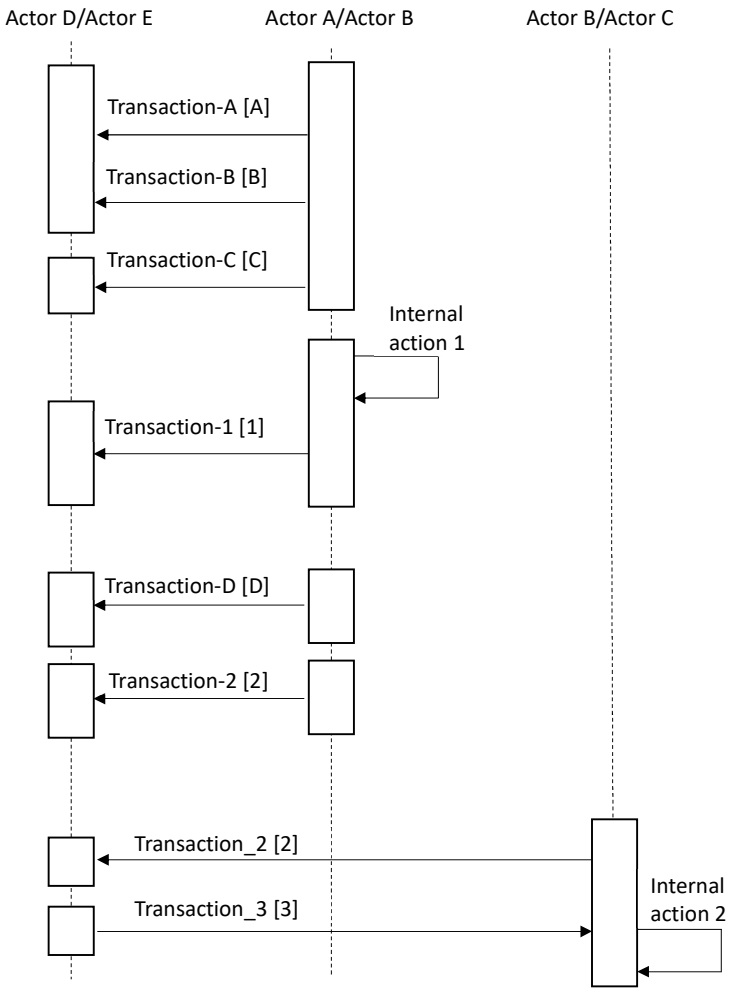
<Diagram and describe the process flow(s) covered by this profile in order to satisfy the use cases. Demonstrate how the profile transactions are combined/sequenced. To provide context and demonstrate how the profile interacts with other profiles, feel free to include transactions and events that are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

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

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

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

<Modify the following "Swimlane Diagram".>



850

Figure W.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.>

W.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]

W.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 appendiW.>

W.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.>

W.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.]

W.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).

W.5.2 Safety Requirements & Considerations

W.5.3 Effectiveness Requirements & Considerations

W.5.4 Security Requirements & Considerations

W.6 SDPi-P Cross Profile Considerations

<This section is informative, not normative. It is intended to put this profile in context with other profiles. Any required groupings should have already been described above. Brief descriptions can go directly into this section; lengthy descriptions should go into an appendix. Examples of this material include ITI Cross Community Access (XCA) Grouping Rules (Section 18.2.3), the Radiology associated profiles listed at wiki.ihe.net, or ITI Volume 1 Appendix E "Cross Profile Considerations", and the "See Also" sections Radiology Profile descriptions on the wiki such as http://wiki.ihe.net/indeW.php/Scheduled_Workflow#See_Also. If this section is left blank, add "Not applicable." >

<Consider using a format such as the following:>

<other profile acronym> - <other profile name>

A <other profile actor name> in <other profile name> might be grouped with a <this profile actor name> to <describe benefit/what is accomplished by grouping>.

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

X.1 SDPi-R Actors, Transactions, and Content Modules

X.1.1 Actor Descriptions and Actor Profile Requirements

X.2 SDPi-R Actor Options

X.2.1 <Option Name>

X.3 SDPi-R Required Actor Groupings

X.4 SDPi-R Overview

X.4.1 Concepts

X.4.2 Use Cases

X.4.2.1 Use Case #1: <simple name>

X.4.2.1.1 <simple name> Use Case Description

X.5 SDPi-R Safety, Effectiveness, Security Considerations and Requirements

X.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).

X.5.2 Safety Requirements & Considerations

X.5.3 Effectiveness Requirements & Considerations

X.5.4 Security Requirements & Considerations

X.6 SDPi-R Cross Profile Considerations

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

Y.1 SDPi-A Actors, Transactions, and Content Modules

Y.1.1 Actor Descriptions and Actor Profile Requirements

Y.2 SDPi-A Actor Options

Y.2.1 <Option Name>

Y.3 SDPi-A Required Actor Groupings

Y.4 SDPi-A Overview

Y.4.1 Concepts

Y.4.2 Use Cases

Y.4.2.1 Use Case #1: <simple name>

Y.4.2.1.1 <simple name> Use Case Description

Y.5 SDPi-A Safety, Effectiveness, Security Considerations and Requirements

Y.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).

Y.5.2 Safety Requirements & Considerations

Y.5.3 Effectiveness Requirements & Considerations

Y.5.4 Security Requirements & Considerations

Y.6 SDPi-A Cross Profile Considerations

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

Z.1 SDPi-xC Actors, Transactions, and Content Modules

Z.1.1 Actor Descriptions and Actor Profile Requirements

Z.2 SDPi-xC Actor Options

Z.2.1 <Option Name>

Z.3 SDPi-xC Required Actor Groupings

Z.4 SDPi-xC Overview

Z.4.1 Concepts

Z.4.2 Use Cases

Z.4.2.1 Use Case #1: <simple name>

Z.4.2.1.1 <simple name> Use Case Description

Z.5 SDPi-xC Safety, Effectiveness, Security Considerations and Requirements

Z.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).

Z.5.2 Safety Requirements & Considerations

Z.5.3 Effectiveness Requirements & Considerations

Z.5.4 Security Requirements & Considerations

Z.6 SDPi-xC Cross Profile Considerations

1010

Appendices to Volume 1

<Add appendices to Volume 1 for this profile here. Examples of an appendix include HITSP mapping to IHE Use Cases or long use case definitions.>

<If there are no Volume 1 appendices, enter "Not applicable" and delete the Appendix A and Appendix B placeholder sections.>

<Volume 1 appendices are informational only. No "SHALL" language is allowed in a Volume 1 AppendiW.>

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

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

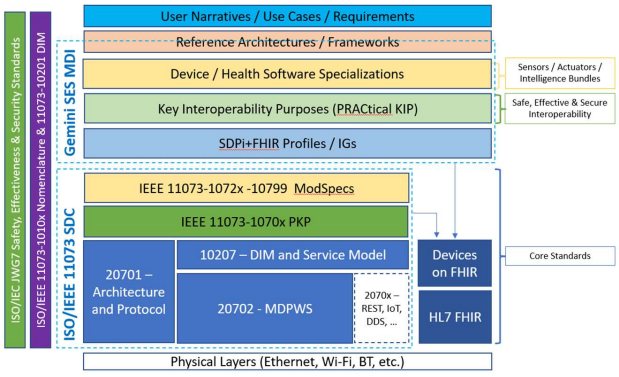
AND A NOTE ABOUT SECTIONLESS CONTENT – Although the IHE Template allows – typically encourages – content after a section title and before subsection titles, this is generally not a style that other standards bodies have – and will not be supported here … hopefully]

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

A.1.1 Hanging Gardens "Layers" Model

<include content from confluence pages>

<include Hanging Gardens Model – content from slide deck>



[UPDATE TO LATEST VERSION!]

Figure A.1.1-1: Hanging Gardens Model

<explain the model>

A.1.2 ISO/IEEE 11073 SDC Components

A.1.3 Reference Frameworks – IHE and MDIRA / ICE

A.1.4 Assurance Case Integration as Basis of Trust

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

A.1.5 <other subsections>

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

<provide perspective on SES MDI requirements>

<KIP Layer linkage>

<Ecosystem of SES trusted interoperable DECOUPLED products>

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

<Reference the SES MDI white paper>

<???include SES MDI problem graphic?>

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

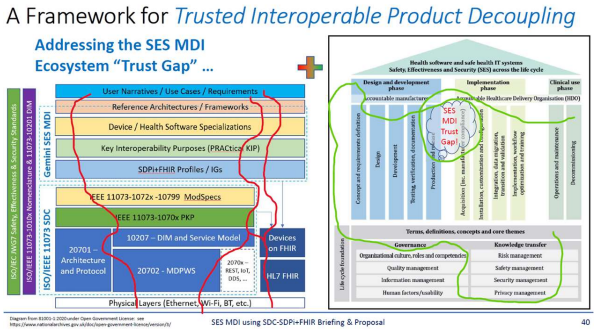


Figure A.2-1: SES MDI Trust Gap Framework Proposal

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

<explain need and general strategy>

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

<mention assurance case integration / results support>

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

A.4 Requirements Management using Gherkin & ReqIF

A.4.1 Use Case Formalization using Gherkin

A.4.2 Requirements Specification using ReqIF

A.4.3 Mapping ReqIF from Scenarios to Interfaces

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

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

<include what is in separate companion specification files>

<Note SDPi requirements primary requirements application:

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

ModSpec	Tf-1	TF-3

>

Appendix B – 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.

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

B.2.1 General

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

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

Also note that THIS is the actual table from the standard … hmmmm …

Table 20 —General ICSs

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

]

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

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B.2.2 Service Provider

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

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

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

B.2.3 Service Consumer

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

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

B.2.4 Remote Control

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

B.2.5 Context Processing

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

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

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

Standard Version: IEEE 11073-10207:2018

B.3.1 MDIB Version

<…>

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

B.3.2 Handle-based Filtering

<…>

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

B.3.3 Cyber-Security

<…>

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

B.3.4 Discovery

<…>

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

B.3.5 Quality of Service (QoS)

<…>

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

B.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].

B.4.5 Secured Discovery

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

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

Volume 2 – Transactions

Add Section 3.23

3.23 Discover Network Topology [DEV-23]

[Editor's Note: Strategy for Transactions to Message Sequences to SDC/MDPWS Messages

1.

]

3.23.1 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*>

3.23.2 Actor Roles

<*Alternative 1*> Table 3.23.2-1: Actor Roles

Actor:	<Official actor name; list every actor in this transaction.>
Role:	<Very brief, one phrase, description of the role that this actor plays in this transaction.>
Actor:	
Role:	
Actor:	
Role:	

<The assignment and use of role names in transaction specifications has proved to be very effective/efficient in Radiology, especially when existing transactions are re-used by additional actors. Following is an alternative example of the Role section. Delete whichever form of the role section you choose not to use.>

The roles in this transaction are defined in the following table and may be played by the actors shown here:

<*Alternative 2*>Table 3.23.2-1 Actor Roles

Role:	*<Role Name:><Only unique within this transaction. Typically one word. The Role Name is analogous to SCU or SCP in DICOM Services.>*

Actor(s):	The following actors may play the role of <*Role Name*>: <*Actor Name*>: <*optionally, the situation where the actor would play this role if needed for clarity.*>"
Role:	<*e.g., Requestor:* *Submits the relevant details and requests the creation of a new workitem.*>
Actor(s):	<*e.g., The following actors may play the role of Requestor:* *Workitem Creator: when requesting workitems* *Workitem Performer: when performing unscheduled workitems*>
Role:	<*e.g., Manager:* *Creates and manages a Unified Procedure Step instance for the requested workitem.*>
Actor(s):	<*e.g., The following actors may play the role of Manager:* *Workitem Manager: when receiving a new workitem for its worklist.*>

Transaction text specifies behavior for each role. The behavior of specific actors may also be specified when it goes beyond that of the general role.

3.23.3 Referenced Standards

- <*e.g., HL7 2.3.1 Chapters 2, 3*>
- <*e.g., DICOM 2008 PS 3.3: A.35.8 X-Ray Radiation Dose SR IOD*>
- <*e.g., applicable sub-sections in ITI TF-2x: Appendix Z on HL7 FHIR*>

3.23.4 Messages

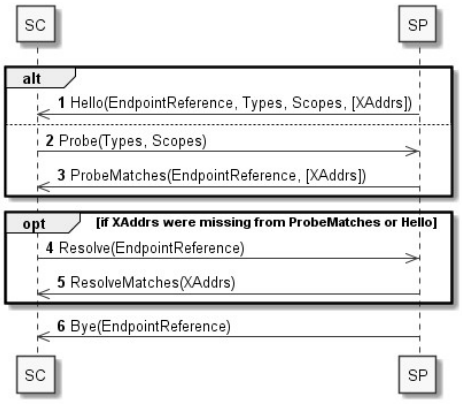

Figure 3.23.4-1: DEV-23 Discover Network Topology Interaction Diagram

3.23.4.1 "SDC Hello" Message

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

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

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

3.23.4.1.1 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).>

3.23.4.1.2 Message Semantics

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

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

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

3.23.4.1.3 Expected Actions

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

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

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

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

3.23.4.2 SDC Probe Message

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

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

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

3.23.4.2.1 Trigger Events

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

3.23.4.2.2 Message Semantics

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

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

<Continue profiling the message by providing guidance or constraints on how the message parameters are populated, how the payload is encoded, how the message is structured and what

the contents mean. These message semantics should both help the sender to construct the message and the receiver to interpret the message.>

3.23.4.2.3 Expected Actions

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

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

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

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

3.23.5 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.>

3.23.6 Safety, Effectiveness, Security Requirements & Considerations

3.23.6.1 SES General Considerations

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

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

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

3.23.6.2 Safety Requirements & Considerations

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

3.23.6.3 Effectiveness Requirements & Considerations

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

3.23.6.4 Security Requirements & Considerations

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

3.23.6.4.1 Security Audit Considerations

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

3.23.6.4.1.(z) <Actor> Specific Security Considerations

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

Appendices to Volume 2

<Detailed cross transaction relationships or mapping details are described in an appendix in Volume 2W. Volume 2 appendices may be informational or normative. Immediately after the title of a Volume 2 appendix, provide a very explicit statement defining whether this new appendix is informative or normative.

If there are no Volume 2 appendices, enter "Not applicable" and delete the Appendix A and Appendix B placeholder sections.>

Appendix A – ISO/IEEE 11073 SDC Message Specifications

[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.]

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

[Editor's Note: Explain the relationship and traceability between general BICEPS message model and specific WS messages called out in the 11073-20702 Medical Device Profile for Web Services (MDPWS) standard.

"Connection" – clarify topic … note that this annex is very WS-* technically focused]

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

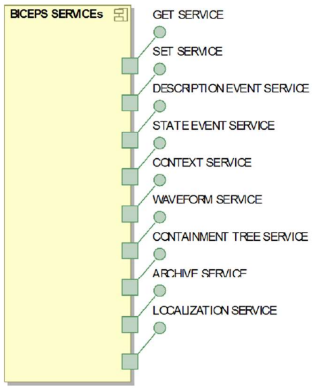

Figure 12—SERVICEs defined to let SERVICE CONSUMERs gain access to the MDIB

A.1.1 <Title>

Appendix A.1.1 text.

[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 PARTICIPANT Discovery, etc.

A.3 SDC Messages for Secure Connections

A.4 SDC Messages for PROVIDER MDIB Discovery

A.5 SDC Messages for Update Publication / Subscription Services

A.6 SDC Messages for <…>

A.7 SDC Messages for PARTICIPANT Context Management

Appendix B – <Appendix Title>

Appendix B text.

B.1 <Title>

Appendix B.1 text.

B.1.1 <Title>

Appendix B.1.1 text.

Namespace Additions for Volume 2

<For Public Comment, please explicitly identify all new OIDs, UIDs, URNs, etc., defined specifically for this profile. These items should be collected from the sections above, and listed here as additions to the applicable domain OID Registry. This section will be deleted prior to inclusion into the Technical Framework as Final Text, but should be present for publication of Public Comment and Trial Implementation.>

*At Trial Implementation publication, the domain technical committee **must** ensure that all new OIDs, UIDs, URNs, etc., defined specifically for this profile have been recorded in their OID Registry. This section will be deleted prior to inclusion into the Technical Framework Volumes as Final Text but should be present for publication of Public Comment and Trial Implementation.>*

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

Volume 2 additions to the Devices OID Registry are:

Volume 3 – Content Modules

<The current version of the supplement template only addresses HL7 v3 CDA Content Modules and DICOM Content. All CDA Content Modules (Document, Header, Section and Entry) will go in Section 6 of Volume 3 of each domain's Technical Framework document and DICOM Content Definitions will go in Section 7. In the future, this supplement template may have additional sections for other types of Content Modules (Section 8, etc., of Volume 3).

<Please note that prior to the release of the new template set, some domains may have defined CDA Content Modules in Volume 2 (e.g., PCC); however, going forward, CDA Content Modules will be defined in Volume 3.>

5 IHE Namespaces, Concept Domains and Vocabularies

Add to Section 5 IHE Namespaces, Concept Domains and Vocabularies

[Editor: Sync this section with the content in IHE DEV TF-3 Rev. 10.0, recognizing that SDC may bring in some additional semantics over those generally "not applicable" in Rev. 10]

5.1 IHE Devices Namespaces

*<**For Public Comment publication**, please explicitly identify all **new** OIDs, UIDs, URNs, etc., defined specifically for this profile. These items should be collected from the sections within this supplement and listed here as additions to the applicable domain OID Registry. The tables within this section will be deleted prior to inclusion into the Technical Framework as Final Text, but should be present for publication for Public Comment.>*

*<**For Trial Implementation publication**, the domain technical committee **must** ensure that all new OIDs, UIDs, URNs, etc., defined specifically for this profile (and listed here for public comment publication have now been recorded in their OID Registry. The tables within this section will be deleted prior to inclusion into the Technical Framework Volumes as Final Text but should be present for publication for Trial Implementation.>*

<Ensure the domain's registry of OIDs is linked to from the following wiki page. It may be another wiki page, a document on the ftp site, etc.>

The Devices registry of OIDs is located at
http://wiki.ihe.net/indeW.php/OID_Registration#IHE_Domain_Namespaces

Additions to the Devices OID Registry are:

codeSystem	codeSystemName	Description
<oid or uid>	<code system name>	<short description or pointer to more detailed description>
<oid or uid>	<code system name>	<short description or pointer to more detailed description>
<oid or uid>	<code system name>	<short description or pointer to more detailed description>

5.2 IHE Devices Concept Domains

<Concept Domains are named categories of things that are used when it isn't possible to bind to a specific set of codes. There are a number of reasons you might not be able to define and bind to a specific set of codes, one of the most common being that the codes set needs to vary depending on locale or context.>

For a listing of the <Domain Acronym> Concept Domains see *<enter location of the domains Concept Domains or NA if none>*

conceptDomain	conceptDomainName	Description
<oid or uid>	<code system name>	<short description or pointer to more detailed description>
<oid or uid>	<code system name>	<short description or pointer to more detailed description>
<oid or uid>	<code system name>	<short description or pointer to more detailed description>

5.3 IHE Devices Format Codes and Vocabularies

5.3.1 IHE Format Codes

*List in the table below any **new** format codes to be added to the IHE Format Codes wiki page at http://wiki.ihe.net/indeW.php/IHE_Format_Codes. For public comment, the additions must be listed in the table below. The domain technical committee must ensure any new codes are also added to the wiki page prior to publication for trial implementation.*

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

5.3.2 IHEActCode Vocabulary

*List in the table below, any **new** additions to the IHEActCode Vocabulary wiki page at http://wiki.ihe.net/indeW.php/IHEActCode_Vocabulary. For public comment, the additions must be listed in the table below. The domain technical committee must ensure any new codes are also added to the wiki page prior to publication for trial implementation.*

Code	Description
<Code name>	<short one sentence description or reference to longer description (not preferred)>

<Code name>	<short one sentence description or reference to longer description (not preferred)>
<Code name>	<short one sentence description or reference to longer description (not preferred)>

5.3.3 IHERoleCode Vocabulary

*List in the table below any **new** additions to the IHERoleCode Vocabulary wiki page at http://wiki.ihe.net/indeW.php/IHERoleCode_Vocabulary. For public comment, the additions must be listed in the table below. The domain technical committee must ensure any new codes are also added to the wiki page prior to publication for trial implementation.*

Code	Description
<name of role>	<Short, one sentence description of role or reference to more info.>
<name of role>	<Short, one sentence description of role or reference to more info.>
<name of role>	<Short, one sentence description of role or reference to more info.>

6 DEV HL7 V3 CDA Content Modules

[Editor: This section left blank in IHE DEV TF-3 Rev. 10.0]

7 DEV DICOM Content Definitions

[Editor: This section left blank in IHE DEV TF-3 Rev. 10.0]

8 DEV Semantic Content Modules

8.1 Overview of device semantic content

8.2 General device content considerations

8.2.8 Overview of SDC/BICEPS semantic content

[Editor: Include:

- BICEPS Standard overview
- Reference TF-1 SDC overview
- Include SES section + Assurance Case
- Quality of Data requirements; RM Alerting considerations / requirements
- Look forward to device specialization profiles
- Consider links / bindings to transactions

]

8.2.8.1 SDC/BICEPS Descriptive Model

8.2.8.2 BICEPS Relationship to Classic DIM

8.2.8.3 Safety, Effectiveness, Security Content Requirements & Considerations

8.2.8.4 BICEPS Conventions for device specialization content modules

8.2.8.5 Device Aggregators & Proxies Modeling

[Editor:

1. Capture the discussion from "Topic: MDIB/MDS Modeling for Device Aggregators:"
2. NOTE: TBD how much of that discussion is formalized in this section and how much should be covered in other Supplement sections
3. The topic will be included in the Open / Closed Issues section at the start of the supplement.

]

8.3 Device specialization content modules

[Editor:

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

]

8.3.1 Device: Infusion Pump

8.3.1.4 SDC/BICEPS content module

8.3.2 Device: Ventilator

8.3.2.4 SDC/BICEPS content module

8.3.3 Device: Physiologic monitor

8.3.3.4 SDC/BICEPS content module

Appendices to Volume 3

<Add any applicable Volume 3 appendices below.

<If there are no Volume 3 appendices, enter "Not applicable" and delete the Appendix A and Appendix B placeholder sections.>

Appendix A – <Appendix Title>

Appendix A text.

A.1 <Title>

Appendix A.1 text.

A.1.1 <Title>

Appendix A.1.1 text.

Appendix B – <Appendix Title>

Appendix B text.

B.1 <Title>

Appendix B.1 text.

B.1.1 <Title>

Appendix B.1.1 text.

Volume 4 – National Extensions

Add appropriate Country section

3 National Extensions for <Country Name or IHE Organization>

<A template for Volume 4 is included in this document for completeness; however, National Extensions are typically developed after a profile has been published for Trial Implementation. If you are developing a new profile for Public Comment, it is recommended that this section be marked "Not Applicable".>

<Avoid using this section if you can, this is "only if absolutely necessary". Differences add cost to implementation and testing and can reduce interoperability. Review carefully to determine if the national use case truly requires a difference in the profile mechanisms rather than just differences in system configuration.>

<National Extensions can add requirements above and beyond IHE, but ***not*** *relax requirements. This would prevent Connectathon results based on national testing being recognized elsewhere. For more information, see* http://wiki.ihe.net/indeW.php?title=National_Extensions_Process.*>*

The format of this section is not strongly specified due to the varying nature of national extensions. For an example of National Extensions, see the RAD TF 4 or ITI TF-4 documents.>

*<**This section should be repeated for each set of additional extensions. Instructions may be given in both English and the native language**.>*

The national extensions documented in this section shall be used in conjunction with the definitions of integration profiles, actors and transactions provided in Volumes 1 through 3 of the IHE <Domain Acronym> Technical Framework. This section includes extensions and restrictions to effectively support the regional practice of healthcare in <Country Name>. It also translates a number of English terms to ensure correct interpretation of requirements of the <Domain Acronym> Technical Framework.

3.1 Comments

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

Name:

Organization/Title:

Email:

3.2 IHE <Country Name> Scope of Changes

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

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

- Etc.

3.3 <Profile Name> <(Profile Acronym)>

<Add info or tables>

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

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

<Add info or tables>

<Delete the example below prior to publication for Public Comment.>

<Beginning of example

e.g., 3.3.1CARD Value Set Binding for US Realm Concept Domains

UV Concept Domain	US Realm Vocabulary Binding or Single Code Binding	Value Set OID
UV_CardiacProcedureDrugClasses	US_CardiacProcedureDrugClasses	1.3.6.1.4.1.19376.1.4.1.5.15

e.g., 3.3.2.1 US_CardiacProcedureDrugClasses (1.3.6.1.4.1.19376.1.4.1.5.15)

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

end of example>

3.3.2 <Profile Acronym> <Type of Change>

<Add info or tables>

4 National Extensions for <Country Name or IHE Organization>

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

Appendices to Volume 4

<Add any applicable Volume 4 appendices below>

<If there are no Volume 4 appendices, enter "Not applicable" and delete the Appendix A and Appendix B placeholder sections.>

Appendix A – <Appendix Title>

Appendix A text.

A.1 <Title>

Appendix A.1 text.

A.1.1 <Title>

Appendix A.1.1 text.

Appendix B – <Appendix Title>

Appendix B text.

B.1 <Title>

Appendix B.1 text.

B.1.1 <Title>

Appendix B.1.1 text.

