Integrating the Healthcare Enterprise

IHE

**IHE Devices
Technical Framework Supplement**

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

**Revision 0.1.7 – Draft in Preparation for Public
Comment (*or* Trial Implementation)**

Date: January 15, 2021
Author: Devices Technical Committee
Email: devices@ihe.net
[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

30 *the role of a modality" is lower case. Do not use upper case to emphasize a word/topic. Examples:*

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

35 *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

40 *http://wiki.ihe.net/index.php?title=Process#Technical_Framework_Development for more guidance on supplements vs. CPs.>*

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

45 *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,

50 *usually at Trial Implementation or later. Templates for all four volumes are included in this document for the sake of completeness. If you are beginning a new profile, you are strongly discouraged from using National Extensions and should instead focus on optional data sets or other alternatives. For more information, see http://wiki.ihe.net/index.php?title=National_Extensions_Process.>*

55

_____

_____

Foreword

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

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

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

70 This supplement describes changes to the existing technical framework documents.

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

Amend section W.X by the following:

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

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

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

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

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

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

_____

_____

90 **CONTENTS**

_____

_____

_____

_____

_____

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

_____

_____

220
225
230
235
240
245
250
255

_____

_____

_____

_____

345

350

355

360

365

370

375

380

_____

_____

_____

_____

_____

_____

510

515

520

525

530

535

540

545

550

_____

_____

555

560

565

570

575

580

585

590

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

765

770

775

780

785

790

795

800

_____

_____

_____

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

1. Glossary Table & First Mentions – make sure they are sync'd and descriptions / definitions properly attributed.

2. Review all "?" marks and either resolve OR convert to Public Comment / Future Consideration designations.

3. Section & Figure & Table #'ing – especially references to Tables that are hard coded! (e.g., Table W.2-1)

4. …

]

_____

Introduction to this Supplement

825 *<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.]

830 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.

835 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.

840 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>*

845

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:

850 • 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:

855   **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
860   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

865   **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.

870 ## 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
875 Topics to this list and link them to GitHub Issues with summaries only here.

2020.11.16 @ Github Issue linkages

1. Can we simply include a link from this section to the repository and not list the open /
   closed issues?

880 2. Should we have issue titles, list them in open & closed and THEN provide the Github
   link to the specific issue?

3. …

_____

==highlight==]==

Closed Issues

885 *<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

890 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.

9 Copyright Licenses

IHE International hereby grants to each Member Organization, and to any other user of these
895 documents, an irrevocable, worldwide, perpetual, royalty-free, nontransferable, nonexclusive,
non-sublicensable license under its copyrights in any IHE profiles and Technical Framework
documents, as well as any additional copyrighted materials that will be owned by IHE
International and will be made available for use by Member Organizations, to reproduce and
distribute (in any and all print, electronic or other means of reproduction, storage or
900 transmission) such IHE Technical Documents.

The licenses covered by this Copyright License are only to those copyrights owned or controlled
by IHE International itself. If parts of the Technical Framework are included in products that also
include materials owned or controlled by other parties, licenses to use those products are beyond
the scope of this IHE document and would have to be obtained from that other party.

905 ### 9.1 Copyright of Base Standards

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
910 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)

915 *<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
920 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)

925 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:

930 ### 9.1.5 IEEE 11073 (Health Device Interoperability)

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

2020.09.18 Discussion w/ IEEE Staff …

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

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

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

940]

10 Trademark

IHE® and the IHE logo are trademarks of the Healthcare Information Management Systems
Society in the United States and trademarks of IHE Europe in the European Community. They
may only be used with the written consent of the IHE International Board Operations
945 Committee, which may be given to a Member Organization in broad terms for any use that is
consistent with the IHE mission and operating principles.

_____

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*
BICEPS Content Consumer	[Editor's Note: Move Definitions here from Actor Description sections below]
BICEPS Content Creator	[Editor's Note: Move Definitions here from Actor Description sections below]
SOMDS Connector	[Editor's Note: Move Definitions here from Actor Description sections below]
SOMDS Consumer	[Editor's Note: Move Definitions here from Actor Description sections below]
SOMDS FHIR Gateway	[Editor's Note: Move Definitions here from Actor Description sections below]
SOMDS Participant	[Editor's Note: Move Definitions here from Actor Description sections below]
SOMDS Provider	[Editor's Note: This is defined in the Actor list BUT is defined as "Service Provider" (100% self referential!!!). This probably has two definitions: one as a clinical service provider and the other here as a SOA actor.]

_____

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

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

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

975 **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:

980 *<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,
985 *see the IHE wiki at http://wiki.ihe.net/indeW.php/IHE_Profile_Design_Principles_and_Conventions#Transactions.*

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

_____

Appendix D – Glossary

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

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

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

_____

New (or modified) Glossary Term	Definition	Synonyms	Acronyms / Abbreviation
Service-oriented Device Connectivity	Application of service-oriented architecture to support healthcare device interoperability. (See ISO/IEEE 11073-20701)		SDC
Service-Oriented Medical Device System	A point-of-care system of products that implements a service-oriented SDC architecture composed of service providers and service consumers. (See ISO/IEEE 11073-10207)		SOMDS
System Function Contribution	A detailed specification of the capabilities of a SOMDS network participant		SFC

995

_____

_____

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.

1000 *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.*

1005 *]*

2.2 Safety, Effectiveness & Security Considerations and Requirements

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

1010

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?>

1015]

<NUMBERING??? 10.2.1???>

10.2.1 <Option Name>

<First, include a sentence with a high-level description of the option. What capability does this option enable in the profile? Then, enumerate the specific requirements for the actor(s) that
1020 *support this option.>*

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

<Sometimes an option requires that an optional transaction becomes mandatory. In that case, list the transaction as Optional in Table 10.1-1, but indicate in this section that it is required,
1025 *e.g., Transaction [DOM-Y4 is required for Actor-B that supports this option.">*

_____

_____

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

1030   *<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.]

1035
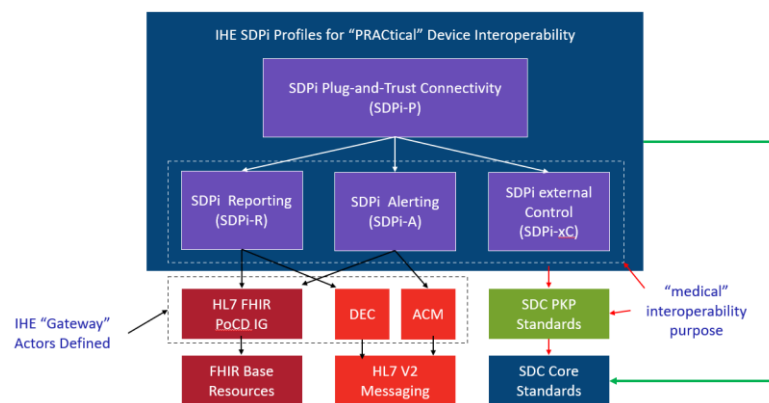
Figure 2.X-1: SDPi Profiles & Foundational Standards

<add caption + explain model>

1040

<give reference to appendix 1>

_____

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

_____

1045 <*Reserve a subsequent section number in the current domain Technical Framework Volume 1 (DOM TF-1). Replace the letter "X" with that section heading number. This number should not change when this supplement is added to the Final Text Technical Framework. In this manner, references should be able to be maintained going forward.>*

10 Service-oriented Device Point-of-care Interoperability – Plug-and-
1050 ## trust (SDPi-P) Profile

The SDPi-Plug-and-trust (SDPi-P) profile supports foundational seamless connectivity, information exchange and service invocation as defined in the SDPi architecture detailed in section *2.X Service-oriented Device Point-of-care Interoperability (SDPi) – Overview & Framework* above. Whereas the related SPDI profiles for reporting, alerting and external control
1055 are explicitly intended to support medical care capabilities, the SDPi-P profile focuses on healthcare interoperability. All the capabilities defined in SDPi-P are leveraged by and extended in the medically focused profiles. This foundational profile not only supports medical device interoperability ("MDI"), providing for "plug-and-play" capabilities, but also with a tightly integrated "trust" framework (see *Appendix A – Requirements Management for Plug-and-Trust*
1060 *Interoperability*). The establishment of a trusted ecosystem of medical and non-medical devices and applications[3] begins at the start of discovery and a secure connection. Therefore, the profile name: Plug-and-Trust.

This is primarily an IHE *transport profile*[4], although it does define several content modules detailed in IHE Devices TF-3. It supports the transactions and information exchanged in
1065 accordance to a Service-Oriented Architecture (SOA) specialized for high-acuity points of care (e.g., operating table or ICU bed), defined as a Service-Oriented Medical Device System (SOMDS). All the SDPi-P actors are therefore scoped with "SOMDS" to clearly identify their application context and scope.

Although all information exchanged between SDPi-P SOMDS participating systems and
1070 applications must conform to the basic SDC/BICEPS content module[5] requirements, content modules have been defined for common high-acuity medical devices such as infusion pumps, ventilators and physiologic monitors.

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

---

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

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

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

_____

1075 Point-of-Care Integration, ICU Point-of-Care Integration, or more service-focused profiles such
as Silent ICU or Quiet Hospital where the acute point-of-care is integrated with enterprise
systems around device alerting and alert distribution to provide an improved environment of care
(reduced noise level and improved safety) and clinician interaction.

10.1 SDPi-P Actors, Transactions, and Content Modules

1080 This section defines the actors, transactions, and/or content modules in this profile. General
definitions of actors are given in the Technical Frameworks General Introduction Appendix A.
IHE Transactions can be found in the Technical Frameworks General Introduction Appendix B.
Both appendices are located at http://ihe.net/Technical_Frameworks/#GenIntro

Figure 10.1-1 shows the actors directly involved in the SDPi-P Profile. The relevant transactions
1085 between them are detailed in the subsequent Table 10.1-1. Abstract Actors (i.e., those that
provide common specifications that are utilized in other "concrete" or implementation actors) are
indicated by names in *italics*, and with the actors that inherit their capabilities grouped in boxes
with dotted lines and non-italics names. Actor groupings, including abstract with concrete are
detailed in Section 10.3.

1090 [Editor's Notes:

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

]
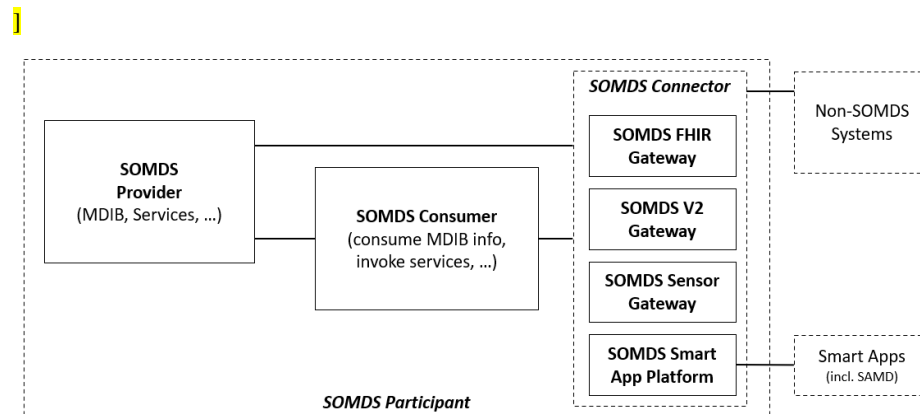
1095 **Figure 10.1-1: SDPi-P Actor Diagram**

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

1. See notes around line #545 …

2. Descriptions of these actors are in the sections below

_____

_____

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

4. Three core actors: Participant, Provider, Consumer

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

   b. OR we can just list them in text!

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

6. SOMDS Connector/Proxy :

   a. Note: XCA has "gateway" actors

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

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

7. Protocol-specific Gateway Actors

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

   b. Gateways are indicated as specialized versions of the

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

8. …

]

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

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

1. waveform service negotiation and streaming.

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

_____

_____

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

4. *…*

1135   *]*

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

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

_____

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

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

1140

[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

1145   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*
1150   *gateway to enterprise … the content would remain the same!]*

]

Figure 10.1-2 shows the content-related actors defined in the SDPi-P Profile and the direction
that the content is exchanged. In general, a SOMDS Provider actor will create content for
consumption by a SOMDS Consumer actor; however, in the case of external control where a
1155   SOMDS Provider actor is creating and sending content (e.g., patient demographics information)
to a SOMDS Provider actor, the content module creator / consumer roles will be reversed.

A product implementation using this profile may group actors from this profile with actors from
a workflow or transport profile to be functional. The grouping of the content module described in
this profile to specific actors is described in more detail in *10.3 SDPi-P Required Actor*
1160   *Groupings* or in *10.6 SDPi-P Cross Profile Considerations*.
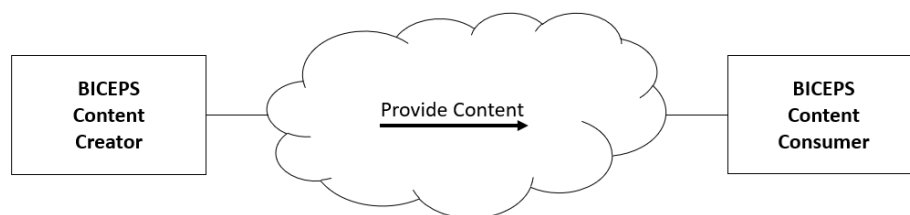
Figure 10.1-2: SDPi-P BICEPS Content Actor Diagram

Table 10.1-2 lists the content module(s) defined in the SDPi-P Profile. To claim support with this
1165   profile, an actor shall support all required content modules (labeled "R") and may support
optional content modules (labeled "O").

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

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

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

_____

_____

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

1170   Note 1: *All content exchanged on a SOMDS shall conform to the general SDPi "BICEPS Content Module" (see 8.2.8 SDC/BICEPS semantic content). SOMDS Provider-specific content modules (e.g., infusion pumps) may be optionally supported as indicated.*

10.1.1 Actor Descriptions and Actor Profile Requirements

1175   SDPi-P actor roles and responsibilities are described in the subsections below.

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

_____

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

1180 The following sequence diagram illustrates a typical (not comprehensive) exchange scenarios
between SDPi-P actors:
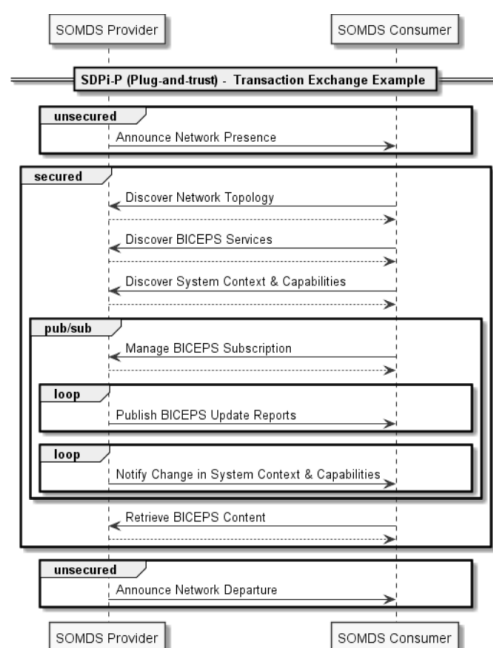
1185

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

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

10.1.1.1 SOMDS Participant

1190 Actor Summary Definition: [to be copied to Appendix A – Actor Summary Definitions above]

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

_____

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

1195   All systems participating in a SOMDS network instance must implement this abstract actor.

All SDPi profiles actors are grouped (inherit from) this actor, including both transport /
transaction actors and content module actors. This required grouping ensures that all systems
connecting to a SOMDS network support the SES MDI[6] requirements necessary for establishing
a plug-and-trust ecosystem, including the secure and dynamic provision of an implementation's
1200   system function contribution (SFC). See *A.3 Specifying SystemFunctionContribution (SFC) for
Plug-and-Trust Interfaces* for more information.

10.1.1.2 SOMDS Provider

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

A *SOMDS Participant* that provides at least one service to the other participant systems.
1205   (See ISO/IEEE 11073-10201 "SERVICE PROVIDER" definition)

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

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

10.1.1.3 SOMDS Consumer

1210   Actor Summary Definition: [to be copied to Appendix A – Actor Summary Definitions above]

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

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

1215   A system that participates in a SOMDS network instance can include both SOMDS Consumer
and SOMDS Provider actors.

10.1.1.4 SOMDS Connector

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

A *SOMDS Participant* that enables seamless interaction with systems and software
1220   applications that are outside the scope of the SOMDS network instance. This abstract
actor provides a consistent method for interacting, as a SOMDS Consumer and / or
SOMDS Provider, with a specific SOMDS instance, as the foundation for protocol-
specific gateway and platform actors.

_____

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

_____

Every abstract *SOMDS Connector* actor is grouped with (inherits from) the abstract *SOMDS*
1225 *Provider* actor.

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

In the case of a connector implementing a SOMDS Consumer actor, it is able to interact with
other SOMDS Provider actors to either obtain information that is then made available to Non-
SOMDS Systems or invoke services that are requested from the external Non-SOMDS Systems.
1230 For example, forwarding patient respiratory rate readings to an external "flow sheet" application
or invoking a device's "pause alert audio" service when a clinician indicates they are responding
to a physiological alert condition (e.g., high respiratory rate).

In the case of a connector implementing a SOMDS Provider actor, service capabilities for
interacting with Non-SOMDS Systems are provided to the other networked SOMDS Consumer
1235 actors. For example, an application that wants to retrieve patient information from an EHR or
check the latest patient laboratory results.

Note that the term "connector" is used to allow for SOMDS interaction with other systems that
do not require protocol "gateway" adaptation, but do require a consistent interface to the other
participants within a SOMDS environment. See *10.1.1.7 SOMDS Sensor Gateway* and *10.1.1.8*
1240 *SOMDS Smart App Platform* for examples.

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

1245 [Editor's Note: One question is whether SDC should be explicitly named here or not? THE
protocol for SOMDS is SDC but it also creates confusion on the non-SDPi front with "structured
data capture" for example. These actors could be an SDC Gateway and an SDC-FHIR Gateway
etc. The approach chosen here keeps the focus on SOMDS and non-SOMDS, relegating SDC
specific content to TF-2.]

1250 Although the SDPi-P profile SOMDS Connector actor provides for non-SOMDS *protocol-*
specific adaptors, they establish the foundation for specifying system and application-specific
interfaces such as for EHR or decision support systems (e.g., sepsis determination).   See
10.4.1.3 Ensuring Time Synchronization

[Editor's Note: This is a key topic for all health information exchange, and especially that of
1255 medical data. A consuming system has to know, for example, that the time stamps provided in
the BICEPS content or in the messages is accurate (and to what degree). Requirements will be
included HERE for SOMDS Participant & all other actors including BICEPS Content <xyz>.
Additional requirements may be added to the TF-3 BICEPS Content Module section as well.

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

1260]

_____

_____

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

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

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

[Editor's Note: Specialized versions of SOMDS Connector …

1. Are there unique transactions at the -P level or only when grouped with -R/-A?

2. Does the abstract SOMDS Connector / SOMDS Provider define core services as well?
   For example, discovery of the protocols and protocol-specific capabilities and content?

3. Are there unique transactions on the non-SOMDS exchange?

4. For example: Service to "Send V2 Message (ORU, R01, <header info>, etc.) OR is most
   of that pre-configured in the gateway actor separately? And only the end point and
   BICEPS content provided?

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

6. NOTE: That the SOMDS V2 Gateway, for example, could define a generic V2 message
   service (for stuff that isn't part of an IHE DEV PCD profile), and that transaction would
   be included here at the -P level!

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

]

10.1.1.5 SOMDS FHIR Gateway

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

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

_____

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

1300 The SOMDS FHIR Gateway actor identifies and specifies the logic necessary for connecting a SOMDS network environment with Non-SOMDS Systems that utilize HL7 FHIR for their interoperability protocol. Generally, this logic is defined in the HL7 Devices on FHIR (DoF) implementation guide for Point-of-Care Devices[7].

[Editor's Note:

1305
1. Include reference / example to **QEDm profile** … and those FHIR transactions being supported by SOMDS Provider service definitions.

2. Include SOMEWHERE utilization of Inferno & Asbestos … in the supplement document as examples in a testing section?

3. Other IHE FHIR-based profiles to also integrate? MHD (for SOMDS Consumer systems that want to retrieve (or supply!) documents. PDQm / PIXm for demographic info. Etc.

1310]

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

1315 Alternatively, the SOMDS FHIR Gateway could implement a FHIR server and provide support for systems to discover and retrieve information asynchronously, including the use of FHIR publication / subscription ("pub/sub") services.

The SOMDS FHIR Gateway can also support SOMDS services invoked by FHIR-based systems, such as requesting a snapshot of the latest vital signs measurements for a specific
1320 patient and triggering a blood-pressure cuff reading.

10.1.1.6 SOMDS V2 Gateway

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

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

1325 SOMDS V2 Gateway actors shall be grouped with (inherit from) the abstract *SOMDS Connector* actor. They shall implement either a SOMDS Provider and / or SOMDS Consumer actor.

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

_____

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

_____

interoperability protocol. Since V2 is a message-based protocol, the primary implementation
1330 guide logic is defined in the IHE DEV TF-2 appendices for V2 messaging, such as *Appendix B
Common Segment Descriptions* and *Appendix C Common Data Types*. The logic for semantic
content modules is detailed in IHE DEV TF-3, including *8.2.8.3 SDC/BICEPS Relationship to
Classic* DIM.

Generally, the SOMDS V2 Gateway actor supports messaging *from* a SOMDS environment to
1335 V2-enabled systems, utilizing a SOMDS Consumer actor to collect information from SOMDS
Provider systems and translate them to V2 messages sent to other Non-SOMDS Systems. There
are cases, though, where information may be sent to a SOMDS-based system such as an alert
conformation utilizing a DEV-05 (i.e., PCD-05) transaction (see the *Service-oriented Device
Point-of-care Interoperability - Alerting (SDPi-A) Profile* below).

1340 ## 10.1.1.7 SOMDS Sensor Gateway

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

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

SOMDS Sensor Gateway actors shall be grouped with (inherit from) the abstract *SOMDS
Connector* actor. They shall implement either a SOMDS Provider and / or SOMDS Consumer
1345 actor.

The SOMDS V2 Gateway actor identifies and specifies the logic necessary for integration of
signals and controls from small sensor and actuator devices that do not have the resources to
support direct integration into a SOMDS network. This includes integration of both wired and
wireless sensor networks ("WSN"). This also includes SOMDS integration of IoT ("Internet of
1350 Things") architectures / networks.

10.1.1.8 SOMDS Smart App Platform

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

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

1355 SOMDS Smart App Platform actors shall be grouped with (inherit from) the abstract *SOMDS
Connector* actor. They shall implement either a SOMDS Provider and / or SOMDS Consumer
actor.

[Editor's Note:

1. Need to define "smart app" … where?

1360 2. Need to reference SAMD … which of the volumes of documents?!

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

_____

_____

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

5.

]

1365

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

1370

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

1375

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

1380

See *10.4.1.5 Smart App Platforms* for additional discussion.

10.1.1.9 BICEPS Content Creator

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

1385

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

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

1390

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

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

1395

_____

_____

10.1.1.10 BICEPS Content Consumer

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

1400   Processes MDIB information conformant to ISO/IEEE 11073-10207 BICEPS specifications provided by BICEPS Content Creator systems.

A BICEPS Content Consumer actor shall be capable of processing information provided by a BICEPS Content Creator, in accordance to the BICEPS content module specifications in DEV TF-3 *8.2.8.1 SDC/BICEPS Content Module* and related sections. The supported BICEPS

1405 content processing shall include one or more of the options identified for this actor in *Table 10.2-1: SDPi-P – Actors and Options* below.

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

1410 Note that although this SDPi-P content actor primarily supports information exchange between systems participating in a SOMDS network environment, they may be referenced by other non-SDPi profiles that utilize other non-SOMDS exchange architectures, transactions and technologies.

10.2 SDPi-P Actor Options

1415 Options that may be selected for each actor in this profile, if any, are listed in the Table 10.2-1. Dependencies between options, when applicable, are specified in notes.

<mark>[Editor's Note:</mark>

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

1420 <mark>2. Note that not all SDC options will be carried over as SDPi options … specialization by constraint! (e.g., new Secured Discovery included here)</mark>

<mark>3. No SOMDA options are included in the table below … OK? For example, what about handle-based filtering?</mark>

<mark>4. Trick is identifying what should be specified as a formal OPTION (and thus tested as a</mark>
1425 <mark>bundle and called out on SDOC / IHE Conformance Statements) and what should be simply left for runtime discovery per "Note 1" after the table below.</mark>

<mark>5. Consider also:</mark>

<mark>a. Archive Service Support</mark>

<mark>b. Locationalization Service Support</mark>

_____

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

_____

_____

1430
       c. *SystemContext (and related contexts) Configuration Support*

       d. *Ensemble Support*

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

       a. *SDPi-A Alert Delegation Option*

1435
       b. *SDPi-A Alert Confirmation Option*

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

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

       e. *…*

]

1440
Table 10.2-1: SDPi-P – Actors and Options

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

_____

_____

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

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

10.2.1 Streaming Option

1445 [Editor's Note:

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

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

3. See ICS Appendix B below

1450]

10.2.2 Safe Data Transmission Option

[Editor's Note:

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

2. Involves implementation of the dual-path design construct

_____

_____

1455   3. Will this be mandatory or an option for the medical profiles?

]

10.2.3 Compact Representation Option

[Editor's Note:

1460   1. Compression enablement

2. NOTE: This applies to a compressed XML representation … right?

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

]

1465   ### 10.2.4 Patient Context Management Option

[Editor's Note:

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

2. NOTE: This directly supports patient-device association management or the IHE DEV
1470   PCIM profile constructs. May include a SOMDS Connector / Gateway for the PCIM
    profile transactions

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

]

1475   ### 10.2.5 Archive Service Option

[Editor's Note:

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

2. NOTE: This includes support for the BICEPS Archive Service

1480   3. This will be detailed in a post 1.0 version of the SDPi Supplement

]

10.2.6 Localization Service Option

[Editor's Note:

_____

_____

1485
1. Indicates support for a SOMDS Provider to supply natural language specific strings to SOMDS Consumer systems

2. NOTE: This includes support for the BICEPS Localization Service

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

]

1490

10.2.7 Ensemble Participation Option

[Editor's Note:

1. Bundle of capabilities related to the establishment & operation of an Ensemble Context

2. NOTE: This includes support for CLC systems

1495
3. This will be detailed in a post 1.0 version of the SDPi Supplement

]

10.3 SDPi-P Required Actor Groupings

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

1500
[Editor's Note: Actors from OTHER profiles. These would include -R -A -xC … "… may be grouped with…" forward looking? What about CT? This would be grouped with SOMDS Participant actors.]

<This section specifies all REQUIRED Actor Groupings (although "required" sometimes allows for a selection of one of several). To SUGGEST other profile groupings or helpful references for
1505
other profiles to consider, use Section 10.6 Cross Profile Considerations. Use Section 10.5 for security profile recommendations.>

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

1510
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
1515
grouped actors. Notes are used to highlight this situation.

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

_____

_____

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

- *If there are no required groupings for any actor in this profile, use alternative 1 as a template.*

- *If an actor in this profile (with no option), has a required grouping, use alternative 1.*

- *If any required grouping is associated with an actor/option combination in this profile, use alternative 2.>*

1520

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

1525

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

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

1530

<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>

1535

<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.>

1540

1545

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

_____

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

_____

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

_____

_____

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

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

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

10.4 SDPi-P Overview

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

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

10.4.1 Concepts

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

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

10.4.1.1 SOA & SOMDS Architecture Alignment

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

10.4.1.2 General Healthcare vs. Medical Interoperability Purposes

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

_____

_____

10.4.1.3 Ensuring Time Synchronization

1570 [Editor's Note: This is a key topic for all health information exchange, and especially that of medical data. A consuming system has to know, for example, that the time stamps provided in the BICEPS content or in the messages is accurate (and to what degree). Requirements will be included HERE for SOMDS Participant & all other actors including BICEPS Content <xyz>. Additional requirements may be added to the TF-3 BICEPS Content Module section as well.

1575 Integration of CT and ATNA (TBD) below in required groupings is assumed.

]

10.4.1.3 Aggregators, Proxies, Sensors

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

1580 Mention SENSORS and WSN referencing SOMDS Sensor Gateways w/ rationale.

Include CLINICAL WORKPLACE SOMDS PROXY SERVICE …

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

10.4.1.4 Protocol-specific Gateways

1585 [Editor's Note: External interfaces "gateways" defined in the abstract and in the protocol-specific. These actors are leveraged in other profiles such as SDPi-Reporting for a DEC Gateway or in SDPi-Alerting for an ACM gateway. Include proprietary protocols as well.

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

1590 ### 10.4.1.5 Smart App Platforms

[Editor's Note:

1. This section enhances the short actor description above to describe in more detail the various aspects of an application "platform"

2. Include forward looking applications such as for a MDIRA / ICE, incl. Supervisor actors,
1595 Central Station, Bedside Cockpit, etc.

3. Include "simple" reporting apps to DSS (running a specific algorithm) to CLC App.

4. Note analogous to SMART on FHIR (or whatever the new name is) for launching apps from within a FHIR-enabled EHR +

5. SoF apps that want to consume medical device & include diagram of a possible DSS app
1600 that utilizes the Platform actor to integrate with and access information from a SOMDS

_____

_____

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

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

]

10.4.1.6 Workflow vs. Transport Actors and Interactions

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

10.4.1.7 SDC / BICEPS MDIB Versioning Management

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

]

10.4.2 Use Cases

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

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

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

]

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

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

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

_____

_____

10.4.2.1.1 FESS Use Case Description

1635 *<Describe the key use cases addressed by the profile. Limit to a maximum of one page of text or consider an appendix.>*

10.4.2.1.2 FESS Process Flow

<Diagram and describe the process flow(s) covered by this profile in order to satisfy the use cases. Demonstrate how the profile transactions are combined/sequenced. To provide context
1640 *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).

1645 *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".>

1650

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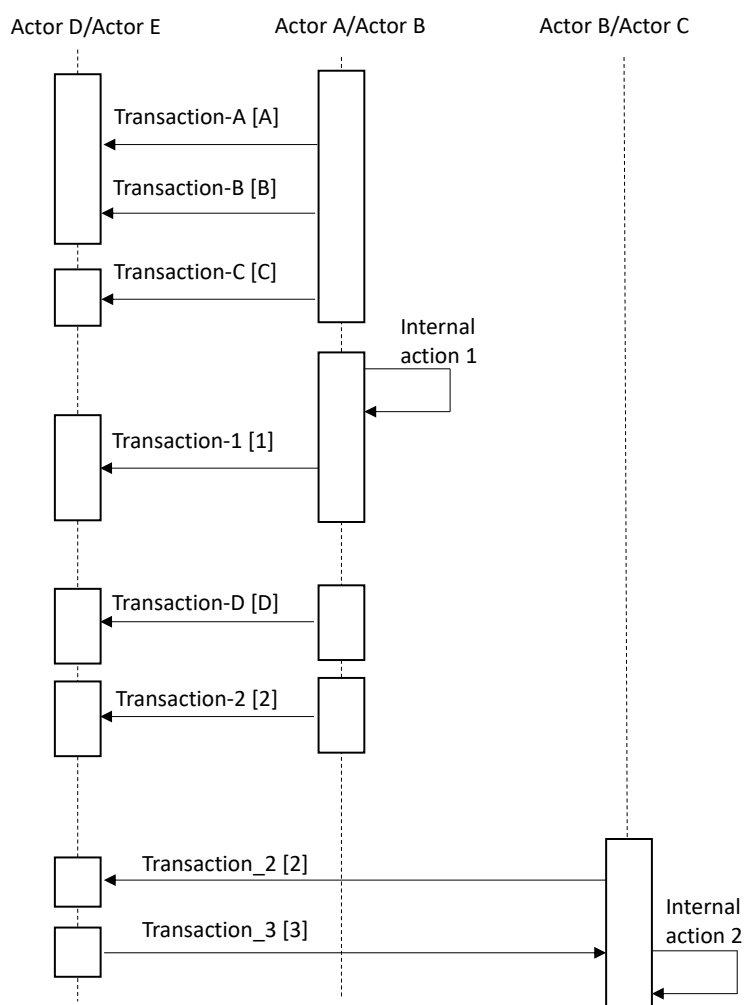
Figure 10.4.2.2-1: Basic Process Flow in SDPi-P Profile

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

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

Pre-conditions:

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

Main Flow:

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

Post-conditions:

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

10.4.2.2 Use Case #2: ICU Integration

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

[Editor's Notes:

1. Detailed use case / scenarios analysis will be contained in Appendix C … for now

2. "ICU Integration" is a PLACE HOLDER TITLE …

]

10.4.2.2.1 ICU Integration Use Case Description

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

10.4.2.2.2 ICU Integration Process Flow

<sequence diagram>

Pre-conditions:

_____

_____

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

Main Flow:

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

Post-conditions:

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

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

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

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

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

10.5.1 SES General Considerations

<SDPi content here>

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

10.5.2 Safety Requirements & Considerations

10.5.3 Effectiveness Requirements & Considerations

10.5.4 Security Requirements & Considerations

_____

_____

10.6 SDPi-P Cross Profile Considerations

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

<Consider using a format such as the following:>

<other profile acronym> - <other profile name>

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

_____

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

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

11.1 SDPi-R Actors, Transactions, and Content Modules

1735

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

1740

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

1745

detailed in Section 11.3.
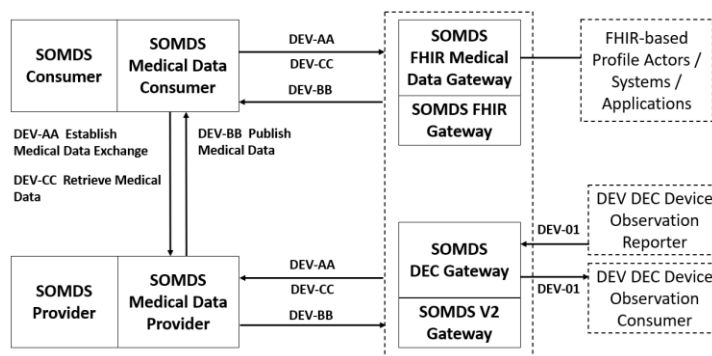
Figure 11.1-1: SDPi-R Actor Diagram [9]

1750

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

_____

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

_____

1. NOTE this is a first iteration of the diagram – STARTER!

2. Is there a better way of representing the -R transactions to the dotted box that that
indicates that a gateway can be EITHER a Provider and / or a Consumer? (it was
confusing / not obvious to the IHE DE PAT 10/21 participants)

3. Discussion notes from review slides:

   a. DEC can have DOR and DOC actor implementations; indicate HERE or in actor
   documentation? Or …

   b. Document FUTURE DEC FHIR Option could be implemented using <SDPi>
   actors.

   c. Any need to show external FHIR system/application? Or is it obvious here?
   Added it but discussion can identify various options. Note could also identify
   IHE FHIR-based Profile Options!

   d. Include rationale for separate –R actors and transactions (incl. BICEPS
   requirements / message sequences / SES bindings / Conformance claims)

   e. Does Medical Reporting have implications on the SOMDS-external connections?
   Requirements placed on those?

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

4. From initial review discussion 2020.09.11:

   a. Update to show Gateway can play both roles … CONSUMER & PROVIDER

   b. Add DEV-DD Retrieve Archived Medical Data …

5.

]

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

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

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

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

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

11.1.1 Actor Descriptions and Actor Profile Requirements

11.1.1.1 SOMDS Medical Data Consumer

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

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

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

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

_____

_____

11.1.1.2 SOMDS Medical Data Provider

1800   Actor Summary Definition: [to be copied to Appendix A – Actor Summary Definitions above]

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

Every SOMDS Medical Data Provider is paired with a SOMDS Provider actor that defines all
the foundational capabilities for participating in a SOMDS network instance, including system
1805   and service discovery, connection establishment and health information retrieval and service
invocation from SOMDS Consumer actors. Additional capability requirements are defined for
this actor to ensure that all medical data is safely, securely, and effectively managed.

See section *11.5 SDPi-R Safety, Effectiveness, Security Considerations and Requirements* for
details on the "medical" requirements for this actor. Note that these SES requirements include
1810   comprehensive support for the *ISO/IEEE 11073-10701 Standard for Metric Provisioning by
Participants in a Service-Oriented Device Connectivity (SDC) System* (draft) standard.

11.1.1.3 SOMDS FHIR Medical Data Gateway

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

A SOMDS network participant that supports the bi-directional exchange of medical data
1815   with HL7 FHIR-based non-SOMDS systems and applications.

SOMDS FHIR Medical Data Gateway actors shall be grouped with a SOMDS FHIR Gateway
actor to support the core specifications for protocol-level exchange between SOMDS-based and
FHIR-based network environments. Generally, this logic is defined in the HL7 Devices on FHIR
(DoF) implementation guide for Point-of-Care Devices[10].

1820   This actor shall include SOMDS Medical Data Consumer (for SOMDS-to-FHIR) or SOMDS
Medical Data Provider (for FHIR-to-SOMDS) actors to interact with other SOMDS Participant
systems. In this way, the actor may support bi-directional communication between the two
environments, supporting the access and exchange of medical data to and from a SOMDS
network instance.

1825   Since this gateway actor includes at least one of the other SOMDS medical data actors, it also
supports the SES requirements detailed in section *11.5 SDPi-R Safety, Effectiveness, Security
Considerations and Requirements*, as well as the SES requirements specified in the *ISO/IEEE
11073-10701 Standard for Metric Provisioning by Participants in a Service-Oriented Device
Connectivity (SDC) System* (draft) standard.

1830   Given that the HL7 FHIR specification defines several architectural approaches, including
HTTP-based RESTful exchange and messaging exchange, there are no constraints on how these
gateway actors support the FHIR-based exchange. For example, the gateway may integrate a

_____

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

_____

FHIR server that supports query access to snapshot and trended device-sourced medical data. It
may support FHIR publication / subscription capabilities to notify (or be notified) when medical
1835   data changes and is available. It may simply support FHIR message exchanges to systems and
applications based on pre-configured settings.

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

The SOMDS FHIR Medical Data Gateway may also be implemented in systems that integrate
1840   other gateway actors, such as the SOMDS DEC Gateway.

11.1.1.4 SOMDS DEC Gateway

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

> A SOMDS network participant that supports the bi-directional exchange of medical data
> using IHE Device Enterprise Communication (DEC) messages with non-SOMDS
1845   > systems and applications.

[Editor's Note: For symmetry we could change the name to "SOMDS DEC Medical Data
Gateway" (the same as the FHIR gateway above). This may make sense in that SES MDI
requirements COULD be required for all DEC DEV-01 transactions related to this gateway – but
that may also be too prescriptive and the SES MDI using DEC could be an OPTION considered
1850   for this actor.]

SOMDS DEC Gateway actors shall be grouped with a SOMDS V2 Gateway actor to support the
core specifications for protocol-level exchange between SOMDS-based and V2 message-based
network environments.   This actor supports medical data exchange using the IHE Device
Enterprise Communication (DEC) profile, DEV-01 *Communicate Device Data* transaction[9].

1855   This actor shall include SOMDS Medical Data Consumer (for SOMDS-to-DEC) or SOMDS
Medical Data Provider (for DEC-to-SOMDS) actors to interact with other SOMDS Participant
systems. In this way, the actor may support bi-directional communication between the two
environments, supporting the access and exchange of medical data to and from a SOMDS
network instance, sending DEC-01 messages to a DEC Device Observation Consumer (DOC)
1860   actor, or receiving messages from a DEC Device Observation Reporter (DOR).

No additional requirements are made on the implementation architecture of the gateway actor
beyond those specified in the IHE DEC profile for the DOC and DOR actors.   Note that the
gateway may define SOMDS services for querying and retrieving DEC-based medical data, such
as a snapshot of a patient's trended vital signs information over the preceding 48 hours; however,
1865   how that is implemented on the HL7 V2 DEC side of the gateway is out-of-scope for this
specification.

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

1870 *11073-10701 Standard for Metric Provisioning by Participants in a Service-Oriented Device Connectivity (SDC) System (draft) standard.*

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

11.2 SDPi-R Actor Options

1875 ### 11.2.1 <Option Name>

11.3 SDPi-R Required Actor Groupings

11.4 SDPi-R Overview

11.4.1 Concepts

11.4.2 Use Cases

1880 #### 11.4.2.1 Use Case #1: <simple name>

11.4.2.1.1 <simple name> Use Case Description

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

11.5.1 SES General Considerations

1885 <SDPi content here>

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

11.5.2 Safety Requirements & Considerations

1890 ### 11.5.3 Effectiveness Requirements & Considerations

11.5.4 Security Requirements & Considerations

1895 **11.6 SDPi-R Cross Profile Considerations**

_____

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

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

1900

12.1 SDPi-A Actors, Transactions, and Content Modules

This section defines the actors, transactions, and/or content modules in this profile. General definitions of actors are given in the Technical Frameworks General Introduction Appendix A. IHE Transactions can be found in the Technical Frameworks General Introduction Appendix B.
1905   Both appendices are located at http://ihe.net/Technical_Frameworks/#GenIntro

Figure 12.1-1 shows the actors directly involved in the SDPi-A Profile. The relevant transactions between them are detailed in the subsequent Table 12.1-1. Abstract Actors (i.e., those that provide common specifications that are utilized in other "concrete" or implementation actors) are indicated by names in *italics*, and with the actors that inherit their capabilities grouped
1910   in boxes with dotted lines and non-italics names. Actor groupings, including abstract with concrete are detailed in Section 12.3.
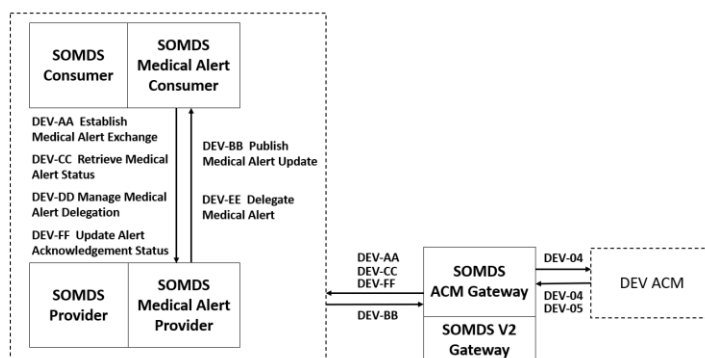
Figure 12.1-1: SDPi-A Actor Diagram

1915   [Editor's Notes: Considerations / discussion for the actor diagram above

    1. NOTE this is a first iteration of the diagram – STARTER!

    2. Discussion notes from review slides:

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

_____

1920

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

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

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

1925

3. From initial review discussion 2020.09.11:

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

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

1930

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

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

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

4.

1935

]

Table 12.1-1 lists the transactions for each actor directly involved in the SDPi-A Profile. To
claim compliance with this profile, an actor shall support all required transactions (labeled "R")
1940   and may support the optional transactions (labeled "O"). Note that "Consumer" is indicated for
actors that receive but do not directly respond to a specific transaction.

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

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

_____

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

1945

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

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

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

12.1.1 Actor Descriptions and Actor Profile Requirements

1950 **12.1.1.1 SOMDS Medical Alert Consumer**

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

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

[Editor's Note: including some wording about alert delegation is important. Should it also say
1955 "optionally including…"? Also note that the key purposes are mentioned in the medical data consumer actor description but seemed redundant / unnecessary here – but could add.]

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

_____

1960 system and service discovery, connection establishment and health information retrieval and
service invocation from SOMDS Provider actors. Additional capability requirements are defined
for this actor to ensure that all medical alert information is safely, securely, and effectively
managed.

See section *12.5 SDPi-A Safety, Effectiveness, Security Considerations and Requirements* for
details on the "medical" requirements for this actor. Note that these SES requirements include
1965 comprehensive support for the *ISO/IEEE 11073-10702 Standard for Alert Provisioning by
Participants in a Service-Oriented Device Connectivity (SDC) System* (draft) standard.

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

1970 A SOMDS Medical Alert Consumer may also support alert delegation, allowing the provider
system to establish a "contract" with the consumer for the annunciation of its alert conditions.
See *12.4.1.1 Alert Delegation* for more information.

A consumer system may also provide user alert acknowledgement updates, indicating whether a
clinician has (directly or indirectly) received and responded to the alert conditions of a provider
1975 actor. See *12.4.1.2 Acknowledging Alert Conditions* below.

12.1.1.2 SOMDS Medical Alert Provider

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

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

1980 Every SOMDS Medical Alert Provider is paired with a SOMDS Provider actor that defines all
the foundational capabilities for participating in a SOMDS network instance, including system
and service discovery, connection establishment and health information retrieval and service
invocation from SOMDS Provider actors. Additional capability requirements are defined for this
actor to ensure that all medical alert information is safely, securely, and effectively managed.

1985 See section *12.5 SDPi-A Safety, Effectiveness, Security Considerations and Requirements* for
details on the "medical" requirements for this actor. Note that these SES requirements include
comprehensive support for the *ISO/IEEE 11073-10702 Standard for Alert Provisioning by
Participants in a Service-Oriented Device Connectivity (SDC) System* (draft) standard.

A SOMDS Medical Alert Provider actor may simply support reporting of its medical (and non-
1990 medical) alert conditions to one or more consumer actors. Additionally, it may also support alert
delegation, allowing the actor to establish a "contract" with a SOMDS Medical Alert Consumer
system for the annunciation of its alert conditions. See *12.4.1.1 Alert Delegation* for more
information.

A single system may support both medical alert provider and consumer actor capabilities. For
1995 example, it may consume medical alert information as well as medical data, from multiple

_____

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

A provider system may also support receipt of user alert acknowledgement updates from a
SOMDS Medical Alert Consumer system, indicating whether a clinician has (directly or
2000   indirectly) received and responded to the alert conditions of a provider actor. See *12.4.1.2
Acknowledging Alert Conditions* below.

12.1.1.3 SOMDS ACM Gateway

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

2005   A SOMDS network participant that supports the bi-directional exchange of medical alert
information with non-SOMDS systems and applications using IHE Alert Communication
Management (ACM) transactions.

SOMDS ACM Gateway actors shall be grouped with a SOMDS V2 Gateway actor to support the
core specifications for protocol-level exchange between SOMDS-based and V2 message-based
network environments.   This gateway actor supports medical alert information exchange using
2010   IHE Alert Communication Management (ACM) profile transactions[9].

The gateway actor shall include SOMDS Medical Alert Consumer (for SOMDS-to-ACM) or
SOMDS Medical Alert Provider (for ACM-to-SOMDS) actors to interact with other SOMDS
Participant systems. In this way, the actor may support bi-directional communication between
the two environments, supporting the access and exchange of medical alert information and
2015   services to and from a SOMDS network instance.

Note that in *Figure 12.1-1: SDPi-A Actor Diagram* above, only DEV-04 and DEV-05
transactions are supported by the SOMDS ACM Gateway; out-of-scope is the communication of
alert conditions using ACM Alert Communicator (AC) actor to clinicians in the enterprise. Also
support for alert delegation is out-of-scope for this gateway actor.

2020   SDPi-A primarily provides for alert "distribution" *within* a single SOMDS network instance
(e.g., systems around a single surgery point-of-care); however, the use context may also require
the ability to distribute alert conditions *external* to the SOMDS environment. The SOMDS
ACM Gateway actor provides support for this SOMDS external alert dissemination requirement.

Note that the DEC-05 transaction may be received by a SOMDS gateway from an ACM actor;
2025   however, generation of DEC-05 transactions from a SOMDS ACM Gateway to ACM actors is
out-of-scope for the SDPi-A profile.

No additional requirements are made on the implementation architecture of the gateway actor
beyond those specified in the IHE ACM profile for the AR and ACON actors.   Note that the
gateway may define SOMDS services for interacting with ACM-based actors, including
2030   registering a gateway-based ACM Alert Consumer (ACON) actor to receive and provide alert
information from other non-SOMDS systems to SOMDS Consumer actors.

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

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

12.2 SDPi-A Actor Options

12.2.1 Alert Delegation

<reference possible support for this function>

12.2.1 Alert User Acknowledgement

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

12.3 SDPi-A Required Actor Groupings

12.4 SDPi-A Overview

12.4.1 Concepts

12.4.1.1 Medical Alerting and SES MDI Risk Management

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

12.4.1.1 Alert Delegation

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

12.4.1.2 Acknowledging Alert Conditions

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

2060 **12.4.1.3 Integration with Alert Communication Management Profile (ACM)**

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

2065 Also consider this or a related section for addressing "enterprise" vs. bedside alerting and the
future use of FHIR and the SOMDS FHIR Gateway.]

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

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

2070 **12.4.2 Use Cases**

12.4.2.1 Use Case #1: <simple name>

12.4.2.1.1 <simple name> Use Case Description

12.4.2.2 Use Case #2: Silent ICU

2075 *<One or two sentence simple description of this particular use case.>*

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

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

12.4.2.2.1 Silent ICU Use Case Description

2080 *<Describe the key use cases addressed by the profile. Limit to a maximum of one page of text or
consider an appendix.>*

12.4.2.2.2 Silent ICU Process Flow

<sequence diagram>

2085 **Pre-conditions**:

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

_____

Main Flow:

2090 *<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
2095 *module has been created including examples of potential next steps.>*

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

12.5.1 SES General Considerations

2100 <SDPi content here>

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

12.5.2 Safety Requirements & Considerations

2105 ### 12.5.3 Effectiveness Requirements & Considerations

12.5.4 Security Requirements & Considerations

2110 ## 12.6 SDPi-A Cross Profile Considerations

_____

_____

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

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

2115

13.1 SDPi-xC Actors, Transactions, and Content Modules

This section defines the actors, transactions, and/or content modules in this profile. General
definitions of actors are given in the Technical Frameworks General Introduction Appendix A.
IHE Transactions can be found in the Technical Frameworks General Introduction Appendix B.
2120   Both appendices are located at http://ihe.net/Technical_Frameworks/#GenIntro

Figure 13.1-1 shows the actors directly involved in the SDPi-xC Profile. The relevant
transactions between them are detailed in the subsequent Table 13.1-1. Abstract Actors (i.e.,
those that provide common specifications that are utilized in other "concrete" or implementation
actors) are indicated by names in *italics*, and with the actors that inherit their capabilities grouped
2125   in boxes with dotted lines and non-italics names. Actor groupings, including abstract with
concrete are detailed in Section 13.3.
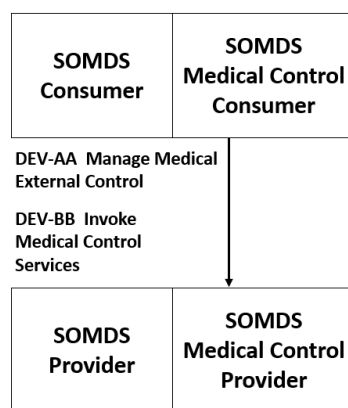
Figure 13.1-1: SDPi-xC Actor Diagram

2130   [Editor's Notes: Considerations / discussion for the actor diagram above

    1.   NOTE this is a first iteration of the diagram – STARTER!

    2.   Discussion notes from review slides:

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

2135

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

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

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

2140

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

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

2145

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

3. From initial review discussion 2020.09.11:

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

4.

2150   ]

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

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

2155

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

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

2160

13.1.1 Actor Descriptions and Actor Profile Requirements

13.1.1.1 SOMDS Medical Control Consumer

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

2165
> A SOMDS network participant that supports one or more medical key purposes for
> managing and invoking external control services from a SOMDS Medical Control
> Provider system.

Every SOMDS Medical Control Consumer is paired with a SOMDS Consumer actor that defines
all the foundational capabilities for participating in a SOMDS network instance, including
system and service discovery, connection establishment and health information retrieval and
2170 service invocation from SOMDS Provider actors. Additional capability requirements are defined
for this actor to ensure that all SOMDS participant external control capabilities are safely,
securely, and effectively managed.

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

2175 See section *13.5 SDPi-xC Safety, Effectiveness, Security Considerations and Requirements* for
details on the "medical" requirements for this actor. Note that these SES requirements include
comprehensive support for the *ISO/IEEE 11073-10703 Standard for External Control
Provisioning by Participants in a Service-Oriented Device Connectivity (SDC) System* (draft)
standard.

2180 #### 13.1.1.2 SOMDS Medical Control Provider

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

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

Every SOMDS Medical Control Provider is paired with a SOMDS Provider actor that defines all
2185 the foundational capabilities for participating in a SOMDS network instance, including system
and service discovery, connection establishment and health information retrieval and service
invocation from SOMDS Consumer actors. Additional capability requirements are defined for
this actor to ensure that all medical control services are safely, securely, and effectively
managed.

2190 See section *13.5 SDPi-xC Safety, Effectiveness, Security Considerations and Requirements* for
details on the "medical" requirements for this actor. Note that these SES requirements include
comprehensive support for the *ISO/IEEE 11073-10703 Standard for External Control*

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

2195

13.2 SDPi-xC Actor Options

13.2.1 <Option Name>

13.3 SDPi-xC Required Actor Groupings

13.4 SDPi-xC Overview

2200 ### 13.4.1 Concepts

13.4.2 Use Cases

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

13.4.2.1 Use Case #1: <simple name>

2205 ##### 13.4.2.1.1 <simple name> Use Case Description

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

13.5.1 SES General Considerations

<SDPi content here>

2210 The security considerations for a content module are dependent upon the security provisions
defined by the grouped actor(s).

13.5.2 Safety Requirements & Considerations

13.5.3 Effectiveness Requirements & Considerations

2215

13.5.4 Security Requirements & Considerations

_____

13.6 SDPi-xC Cross Profile Considerations

2220

_____

_____

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.>

2225 *<If there are no Volume 1 appendices, enter "Not applicable" and delete the Appendix A and Appendix B placeholder sections.>*

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

_____

2230 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.

2235 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

2240

<include content from confluence pages>

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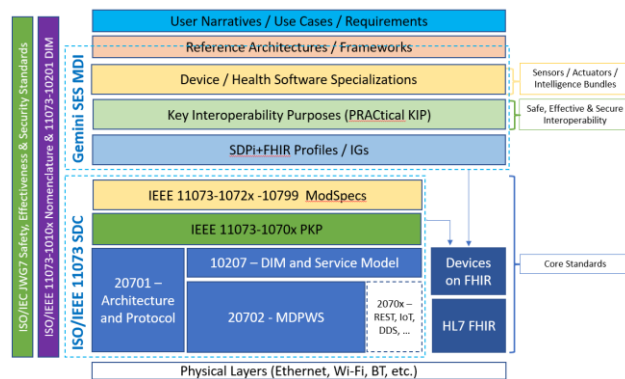
[UPDATE TO LATEST VERSION!]

2245 **Figure A.1.1-1: Hanging Gardens Model**

<explain the model>

_____

_____

A.1.2 ISO/IEEE 11073 SDC Components

2250 ### 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>

2255 ### A.1.5 <other subsections>

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

<provide perspective on SES MDI requirements>

2260 <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?>

2265 <Note: where does the Assurance Case component integrate into this appendix?>

_____

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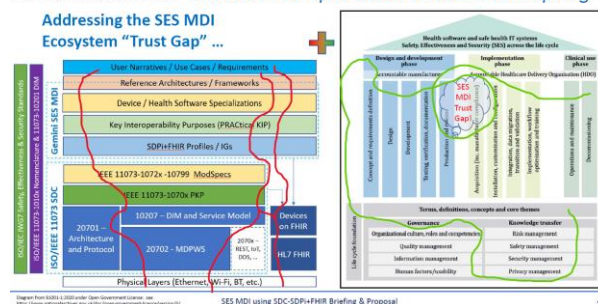
Figure A.2-1: SES MDI Trust Gap Framework Proposal

2270

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

<explain need and general strategy>

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

2275

<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

2280

A.4.1 Use Case Formalization using Gherkin

A.4.2 Requirements Specification using ReqIF

A.4.3 Mapping ReqIF from Scenarios to Interfaces

2285

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>

2290 <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

2295 ### 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.

2300 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*
2305 *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.

2310 [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?

2315 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.

2320 ### 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?

2325 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.

_____

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

_____

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.	

2340

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

2345   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]*

2350

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
2355   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

2360 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

2365 ### 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.

2370

_____

B.3.4 Discovery

<…>

Index	Feature	Reference	Text
DIS-1	Location Context Details	Clause **Error! R eference source not found.**	An SDC SERVICE PROVIDER SHOULD provide the following ATTRIBUTEs in pm:LocationContextState\pm:LocationDetail if the SDC SERVICE PROVIDER is providing pm:LocationContextState\pm:LocationDetail. - LocationDetail/@Facility - LocationDetail/@PoC - LocationDetail/@Bed
DIS-2	Announce Absence	R0004	
DIS-3	MDS-Based Discovery	**Error! R eference 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)

2375   <…>

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

_____

2380 **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.

2385 **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
2390 streaming needs to be supported, every ICS statement except for STRM-4 should be made mandatory.

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

_____

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! R eference 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

2395   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.

2400

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
2405   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.

_____

2410   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.
2415   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.

2420

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

[Editor's Notes:

1. Detailed use case / scenario analysis w/ Gherkin details & ReqIF linkage would be HERE vs. elsewhere

2425   2. Question: Should this be an MDI Appendix or DPI?

3. Question: Should this detail be in collateral files for this SDPi Supplement vs. in the actual document? [note from above that ReqIF detail would be in a separate file]

    a. DECISION: "Feature" files will be validated (e.g., in CucumberStudio) and persisted in the github repo

2430   ]

C.1.1 Overview of DPI Narratives, Use Cases & Scenarios

[Editor's Notes:

1. Note this section should reference Appendix A + the profiles use case sections

2. It should address supplement 1.0 detailed use cases (in subsequent sections) as well as …

2435   3. Identify use cases that might be used in the future for SDPi revisions after 1.0

4. Include by reference / directly the process for formalizing use case based requirements (per the Editor's Notes section above)

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

2440   ]

C.1.2 Overview of Architectural & Business Systems Concepts

[Editor's Notes:

1. Include common concepts like Central Station, Cockpit, Dashboard, etc.

2445   2. NOTE: These may be called out in subsequent profiles (e.g., ICU Integration); so language here should both be clear for the subsequent use in

3. Consider including MDIRA / ICE actors within the use case + for a subsequent MDIRA/ICE Profile being proposed (see above C.1.1)

4. Mention also the TF-3 device specializations that may be defined related back to these
2450   items

]

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

[Editor's Notes:

2455   1. These concepts are based on established standards such as 60601-1-8

2. Intent is to not duplicate ACM actors … and thus engender confusion … but to identify a method of characterizing the various systems more clearly that may also be mapped onto ACM Actors such as AlertManager, AlertSource or AlertCommunicator. NOTE: The SDPi-A profile has defined ACM gateway to support this type of bi-directional
2460   interaction.

3. …

]

While IEC 60601-1-8 is focused on alarm and alert functionality, it also provides some very useful system concepts such as the Distributed Information System (DIS) and Distributed Alarm
2465   System (DAS). We use these concepts in many of our use cases, so we have included the following is a quick guide to the functionality of DIS, CDIS, DAS and CDAS systems.

DIS – Distributed Information System
- DIS is a system for reporting alarm signals with no technical confirmation (of receipt).
2470   o Cannot rely on it for alarm signaling as a risk control
        o Optional support operator alarm management* response locally
        o Examples:
            ▪ "Dashboard" - display which integrates the data from one patient. Dashboards do not support audible alerts or remote control.
2475   ▪ "View Station" - display which integrates the data from multiple patients. View Stations do not support audible alerts or remote control.

CDIS – Distributed Information System with Confirmation
- CDIS is a system for reporting alarm signals with no technical confirmation and operator
2480   confirmation (accept/reject). (Note it is not recognized in 60601-1-8)
        o Cannot rely on it for alarm signaling as a risk control
        o Optional support operator alarm management* response locally and remotely
        o Example – two-way pager (open loop)

2485 **xDIS – Connotes a system that can be either a DIS or CDIS**

_____

_____

DAS – Distributed Alarm System

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

CDAS - Distributed Information System with Confirmation

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

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

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

- xDxSsp – forms of DxS that are for *single patients*.

- xDxSmp – forms of DxS that are for *multiple patients*

- xDxScg – forms of DxS that communicated directly to the *caregiver*.

_____

The following table provides examples and summarizes the various types of information/alarm
2525   systems.

Table C.1.3-1 Alert Distribution System Types

Description	Type	Technical Delivery Confirmation[1]	Operator Delivery Confirmation[2]	Optional Alarm Management	Examples
Reports alerts from a Single Patient (sp)	DISsp	No	No	Local	Single-Pt. information Dashboard
	CDISsp	No	Yes[3]	Remote[3]	Single-Pt. Remote View w/ accept/reject
	DASsp	Yes	No	Local	Single Pt. Cockpit w/audible alarms
	CDASsp	Yes	Yes	Remote	Single Pt. Cockpit w/ accept/reject
Reports alerts from Multiple Patients (mp)	DISmp	No	No	Local	Multiple-Pt. info. View Station
	CDISmp	No	Yes[3]	Remote[3]	Multiple-Pt. info. View Station w/ accept/reject
	DASmp	Yes	No	Local	Multiple Pt. Central Station w/ audible alarms
	CDASmp	Yes	Yes	Remote	Multiple Pt. Central Station w/ accept/reject
Reports and directs alerts to responsible Caregiver (cg)	DIScg	No	No	Local	Alert Distribution System (ADS) to caregiver pager, Mobile viewer
	CDIScg	No	Yes[3]	Remote[3]	ADS to caregiver pager, w/ accept/reject
	DAScg	Yes	No	Local	ADS to caregiver w/ audible/haptic alarms
	CDAScg	Yes	Yes	Remote	ADS to caregiver w/ accept/reject

[1] In each communication step the receiving device provides a technical response to the sending device that it received and is taking responsibility for the alert
[2] Operator can, at their choice, use the receiving device (communicator) UI to accept or reject responsibility for the alert
[3] Not recommended since there is no confirmation that the Source has received the commands

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

2530

C.1.3 Use Case Specification Conventions Using Cucumber/Gherkin

[Editor's Notes:

1. Provide overview (why, what, how) for using Gherkin

2. Gherkin usage considerations / conventions (improved clarity & specificity but short of complexity.

3. References to related IHE materials & links, etc.

4. Feature files to be persisted in the sdpi-fhir Github repository

5. Feature naming convention including acronym + Relevant Profiles (-R/-A/-xC … all assume -P)

6. …

]

[Editor's Notes:

1. SHOULD THE Use Cases Below be organized by top-level "feature" or general "use case topic"?

2. This would push most of the detail down a level BUT would be much easier to navigate at the top!

]

C.2 Use Case: Functional Endoscopic Sinus Surgery

[Editor's Notes:

1. Pull in content from SDPi White Paper and any subsequent

2.

3. Sync with PoCSpeC project participants to ensure that the systems here support work that they will want to do in the near future!

4. …

]

C.2.1 Narrative:

2560 **C.2.2 Background: Technical Pre-Conditions**

Given …

And …

C.2.3 Scenario: FESS 1.1 - OR …

Given …

2565 **When** …

Then …

C.3 Feature: Use Case 1 - SDPi-R Standalone OR Dashboard – SORD

<mark>[Editor's Note: Is it better to have the SDPi-R as above OR to have the name then – acronym –</mark>
2570 <mark>then "(SDPi-R/-A/-xC)"?]</mark>

C.3.1 Narrative:

Dr. Presky is in the Operating Room performing an operation to remove cancerous tumors from the patient's abdominal area. He can view previous radiology results, electrosurgical equipment settings, patient readings such as HR, Blood Pressure, SpO2 and associated waveforms
2575 integrated on his real-time 'Dashboard' display. The dashboard display can display visual alarms but does not sound alerts or provide any remote-control capabilities. (This display can be considered an xDISsp.)

C.3.2 Background: Technical Pre-Conditions

2580 **Given** all devices communicate using SDC

And at least one OR Dashboard display

C.3.3 Scenario: SORD 1.1 - OR Devices are Accessible to the Dashboard

Given dashboard detected at least one accessible OR device

2585 **When** one or more OR Devices are operational

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

_____

C.3.4 Scenario: SORD 1.2 - OR Devices are inaccessible to the Dashboard

2590   **Given** dashboard did not detect any accessible OR devices

Then the Dashboard shall display an error message

C.3.5 Scenario: SORD 1.3 - One or more OR Devices are inaccessible to the Dashboard

2595   **Given** dashboard did not detect configured OR devices (based on configuration)

Then the Dashboard shall display an error message

Commented [KP1]: What is the relevant difference between 1.2 and 1.3?
Commented [KF2R1]: In one case it would seem the network is down, while in the other case it would seem specific devices are just not available. Can we specify different error messages in Gherkin?

C.3 Feature: Use Case 2 - SDPi-R/A/xC Standalone OR Cockpit - SORC

2600   ### C.3.1 Narrative:

John Miller (13yrs, m) has chronic rhinosinusitis, which is an inflammatory condition in which the nose and his left maxillary sinus is swollen and the drainage of the mucus is prevented. John's chronic rhinosinusitis doesn't respond to medication anymore. After consulting with his physician, he and his parents decide to resolve the issue with Functional Endoscopic Sinus
2605   Surgery (FESS). The FESS will be done as a day surgery, so that John can get home in the evening.

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

In order for the surgery to start, John is put under general anesthesia and monitored with a patient
2610   monitor by a pediatric anesthesiologist, especially his mean arterial blood pressure which has been lowered in order reduce capillary bleeding to provide optimal visibility of the surgical field.

During the intervention, the Surgeon has a constant view, using his Surgical Cockpit of the patient's vitals (including MABP), CT imaging results, real-time endoscope camera output and has access to the control functions to execute the intervention. The anesthesiologist can also
2615   view relevant patient real-time information such as ECG, blood pressure, anesthesia agent, depth of anesthesia, allergies, etc. using the Anesthesia Cockpit where he/she can manage alarms and control device settings as needed.

{During the procedure one of the surgical devices has a technical issue. It generates a technical alert which notifies the responsible biomedical technician. He/she decides to replace the device
2620   and connects it to the network where it is automatically discovered and configured allowing the intervention to continue.}

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

2625 **C.3.2 Background: Technical Pre-Condition**

Given all devices communicate using SDC

And at least one Anesthesia Cockpit and/or Surgical Cockpit

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

2630 **Given** Cockpit detected at least one accessible OR device

When the one or more OR Devices are operational

And audio alarms are enabled on the Cockpit

And remote control is enabled on the Cockpit

Then the Cockpit shall display parameter, waveform, setting, alarm, etc. information from those
2635 devices (based on configuration)

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

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

2640 **C.3.4 Scenario: SORC 2.2 - OR Devices are inaccessible to the Cockpit**

Given Cockpit did not detect any accessible OR devices

When any OR Device detects an alert condition

Then the Cockpit will display an error message

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

2645

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

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

When the OR Device detects an alert condition

Then the Cockpit will display an error message

2650 **And** the audio alarm shall be signaled at that source device in the OR for the devices not detected by the cockpit

_____

_____

C.4 Feature: Use Case 3 - SDPi-R/xC ICU Isolation PoC Use Case - IIPoC

2655 **13.1.2 Narrative:**

13.1.3 Background: Technical Pre-Condition

Coming soon…

2660

C.5 - Feature: Use Case 4 - SDPI-A - Silent PoC Alert distribution - SPoC

C.5.1 Narrative

2665 Linda is an ICU nurse responsible for 4 patients. While she is updating documentation at the
nursing station Jack's (one of her patients) condition deteriorates and his ventilator goes into an
alarm state (#1). The ventilator alarm sounds are quite loud and jarring which usually disturbs
the patient in the room and nearby rooms. In this case the alert only generates visual alerts and
does not generate an audible tone in the patient room (#2). It does generate an alarm tone at the
2670 central station (xDASmp) (#3) and her mobile device (xDAScg) (#4). As a result, Linda must
acknowledge or otherwise handle the alert at the bedside (#5).

_____

_____
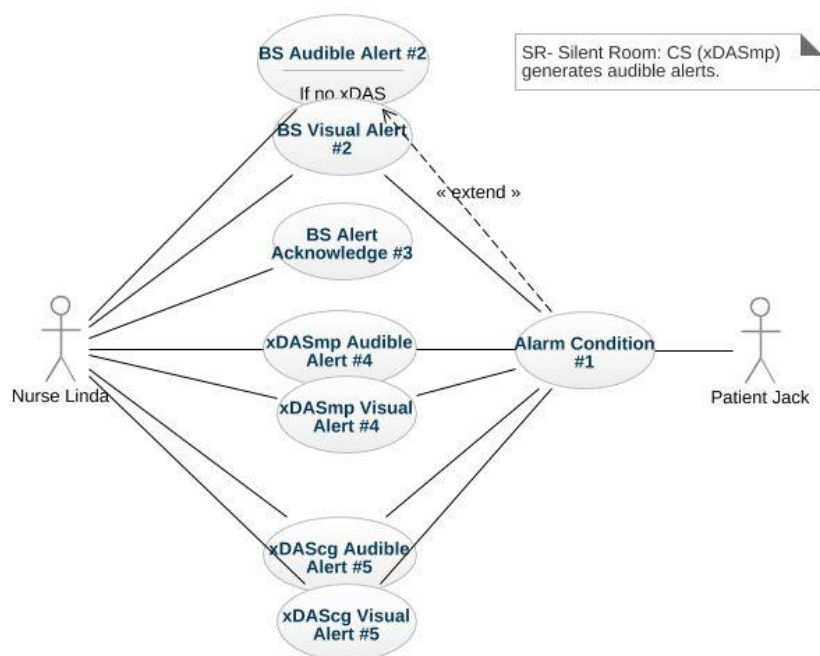
2675

C.5.2 Background: Technical Pre-Condition

Given all devices communicate using SDC

And at least one xDASmp

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

2680

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

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

_____

_____

When at least one remote alert system is accessible

2685   **Then** the alert shall be shown on all accessible remote alerting devices

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

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

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

2690   **C.5.4 Scenario: SPoC 4.2 - Medical device detects an alert situation and all distributed alarm systems (xDASxx) are inaccessible or become inaccessible**

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

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

2695   **Then** active device alert events shall be shown on the medical devices locally

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

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

2700   **Given** medical device detected that the alert situation has been resolved

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

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

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

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

2705   **And** the audio alarm shall be disabled on all accessible remote alerting device for this alert event

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

2710   **C.6 Feature: Use Case 5 - SDPi-A: Silent ICU Alert Distribution - SICU**

_____

C.6.1 Narrative:

Jackie is an ICU nurse responsible for 4 patients. While she is updating documentation at the
nursing station Sven's (one of her patients) condition deteriorates and his ventilator goes into an
2715   alarm state (#1). The ventilator alarm sounds are quite loud and jarring which usually disturbs
the patient in the room and nearby rooms. Jackie's ICU uses personal mobile devices to alert the
nurses about patient alarms so in this case the alert only generates visual alerts in the patient
room (#2) and central station (#3). It does generate an audible alert on her mobile device
(xDAScg) (#4).

2720
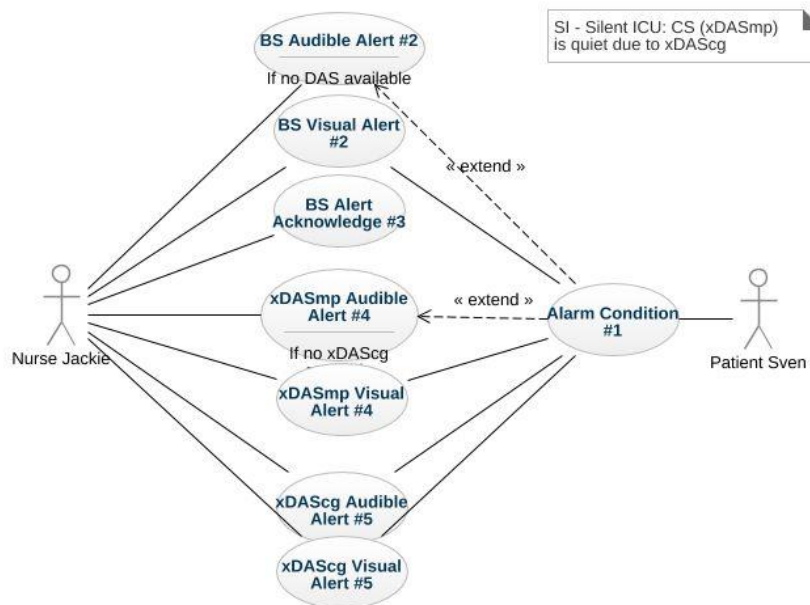
C.6.2 Background: Technical Pre-Condition

Given all devices communicate using SDC

2725   **And** at least one xDAScg

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

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

2730   **Given** alert event was detected by a medical device attached to the patient

When at least one remote alert system is accessible

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

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

2735   **And** the audio alarm shall be disabled on all accessible non-CDAScg remote alerting devices

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

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

C.6.4 Scenario: SICU 5.2 - Medical device detects an alert situation and the
2740   distributed alarm system CDAScg is inaccessible

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

When at least one remote alert system is accessible

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

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

2745   **And** active device alert events shall be shown on the medical devices locally

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

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

2750   **Given** alert event was detected by a medical device attached to the patient

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

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

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

_____

C.7.2 Background: Technical Pre-Condition

2780

Given all devices communicate using SDC

And at least one CDAScg

And all devices in room enable remote control

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

2785

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

And remote alerting device is part of the CDAScg

When caregiver confirms the alert at a remote alerting device

And CDAScg is accessible

2790 **Then** the alert shall be shown as acknowledged at the medical device

And the audio alarm shall be disabled on the medical device

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

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

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

And remote alerting device is part of the DIS

When caregiver confirms the alert at a remote alerting device

But DAS is inaccessible

Then ???

C.8 Feature: Use Case 7 - SDPi-A Smart Alerting System - SAS

C.8.1 Narrative:

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

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

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

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

SAS - Smart Alerting System

« Component »
Bedside Device-1

« Component »
Bedside Device-n

« Component »
Smart Alerting Sys

Nurse Ben

Patient

« Component »
xDASxx

Signal and
Confirm Alert

2825
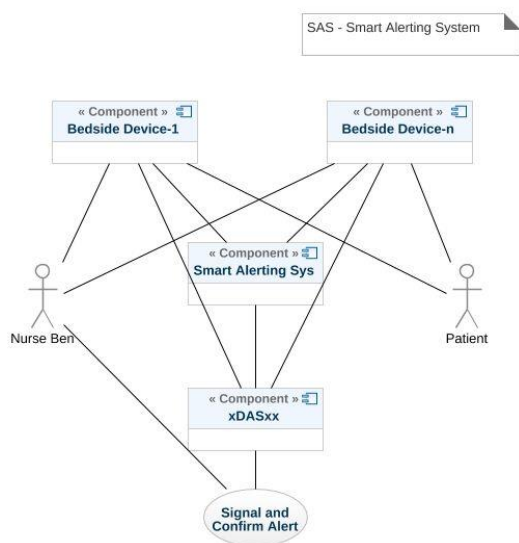
C.8.2 Background: Technical Pre-Conditions

Given bedside devices are SDC compliant

2830 **And** a single smart alert system (SAS) that is SDC compliant

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

And an xDASmp and/or xDAScg that is SDC compliant

> **Commented [KF3]:** Could it be an xDASxx?

C.8.3 Scenario Outline: SAS 7.1 - Local device generates alerts, Smart Alerting
2835 ### System is accessible, and xDASmp and/or xDAScg is accessible

> **Commented [KF4]:** The Scenario Outline is only used in 2 places. Here and in the next Section. Can we just use Scenarios?

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

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

And smart alerting system is accessible

And xDASmp and/or xDAScg is accessible

_____

2840 **Then** the alerts on the medical devices in the patient room shall be delegated to the SAS

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

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

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

2845 Examples:

state	action
disabled	disabled
enabled	enabled

2850 **C.8.3 Scenario Outline: SAS 7.2 - Local device generates alerts, Smart Alerting System is inaccessible, and xDASmp and/or xDAScg is accessible**

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

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

And smart alerting system is inaccessible

2855 **And** xDASmp and/or xDAScg is accessible

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

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

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

2860

Examples:

state	action
disabled	disabled
enabled	enabled

2865

C.8.4 Scenario: SAS 7.3 - Local device generates alerts, and xDASmp and/or xDAScg is inaccessible

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

And xDASmp and/or xDAScg is inaccessible

2870   **Then** active device alert events shall be shown on the medical devices locally

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

C.8.5 Scenario: SAS 7.4 -Smart Alerting generates an alert and an xDASxx is accessible

2875   **When** SAS is accessible
And there is an alert event detected by the SAS (e.g. derived from vital signs data)
And an xDASxx is accessible
Then the alerts on the SAS shall be delegated to the xDASxx
And the xDASxx shall signal the SAS audio and visual alerts
2880   ~~**And** a CDASxx can confirm the alert back to the SAS~~

> **Commented [KP5]:** I would describe this in a separate scenario

C.8.6 Scenario: SAS 7.5 - Smart Alerting generates an alert and an xDASxx is inaccessible

When SAS is accessible
2885   **And** there is an alert event detected by the SAS
And an xDASxx is inaccessible
Then any device alert signal delegation shall be disabled
And any active alerts (audio and visual) shall be signaled on the originating device

2890   ### C.8.6 Scenario: SAS 7.6 - Smart Alerting System is inaccessible from devices and an xDASxx is accessible

When SAS is inaccessible
And an alert event was detected by a bedside device
And an xDASxx is accessible
2895   **Then** the alerts on the device shall be delegated to the xDASxx
And the xDASxx shall signal the device audio and visual alerts
And a CDASxx can confirm the alert back to the device

C.8.7 Scenario: SAS 7.7 - Smart Alerting System is inaccessible from devices
2900   ### and an xDASxx is inaccessible

When SAS is inaccessible
And an alert event was detected by a bedside device
And an xDASxx is inaccessible
Then any device alert signal delegation shall be disabled

2905 **And** any active alerts (audio and visual) shall be signaled on the originating device

C.8.8 SAS Scenario 7.8: Devices, CDASxx and Smart Alerting System are accessible, and SAS generates an alert

When a CDASxx is accessible
2910 **And** an alert event was detected by the SAS
And the operator confirms the alert at the CDASxx
Then the confirmation will be sent to the SAS
And the SAS will send the confirmation to the appropriate Devices

2915

C.5 Use Case: <xyz>

2920

Volume 2 – Transactions

Add Section 3.23 and subsequent transactions for SDPi profiles

3.23 Announce Network Presence [DEV-23]

2925 **3.23.1 Scope**

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

3.23.2 Actor Roles

The actors in this transaction play the following roles:

2930 **Table 3.23.2-1: Actor Roles**

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

3.23.3 Referenced Standards

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

2935 [NOTE: These are just captured for ease of integration … will be deleted once
complete:

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

2940 mode where it is not ready to exchange MESSAGEs with a SERVICE CONSUMER
temporarily.

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

_____

2945
- R0076: A SERVICE PROVIDER SHALL include a *discovery type* in a discovery MESSAGE that allows a SERVICE CONSUMER to identify if the SERVICE PROVIDER is compliant with BICEPS.

  R0078: A BICEPS BINDING SHALL provide means for implicit discovery.

- ISO/IEEE 11073-20701 (2018), section 9.1

2950
- ISO/IEEE 11073-20702 (2016), section 5

3.23.4 Messages

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

2955
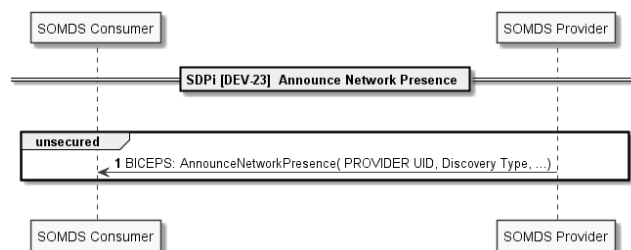
Figure 3.23.4-1: DEV-23 Messaging Interaction Diagram

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

2960 **3.23.4.1 BICEPS Announce Network Presence Message**

The AnnounceNetworkPresence() message is part of the SDC/BICEPS "implicit discovery" protocol for allowing SOMDS Consumer systems to receive a notification when a SOMDS Provider system is ready to receive messages from other SOMDS Consumer systems. This is a broadcast message that is sent from each provider system to all listening consumer systems (zero 2965 to many). Limited but sufficient information is provided with the message to enable consumer systems to determine if they are interested in connecting with the provider discovering additional information. Note that additional information may be provided to better facilitate the discovery process.

3.23.4.1.1 Trigger Events

2970 This message is sent whenever

_____

_____

(1) a SOMDS Provider system is connected to a network, or

(2) when it is returning to normal "on-line" operation after having indicated temporary
suspension of SOMDA exchanges (e.g., issuing a *3.34 Announce Network Departure
[DEV-34]* transaction).

2975 **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*
2980 *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.>*

2985 Provider UID

Discovery Type

Additional info ("…")

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

2990 **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
2995 *expected actions internal to the transaction. Doing so prevents this transaction being re-used in
other contexts.>*

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

When a SOMDS Provider sends this message, there is no expected or required responses. This is
due to the fact that either there are no SOMDS Consumer systems listening for announcement
3000 messages, or the information in the message (e.g., Discovery Type) is not of interest to any
receiving consumers.

When a

_____

3.23.5 Protocol Requirements

[Editor's Note:

3005   1. Note a "loop" algorithm is implemented in DEV-24 because DEV-23 is UNSECURED and may be spoofed!

]

<In this section, the selected protocol bindings of the transactions are explained in detail (like SOAP or HTTP bindings).For an example, see the QRPH DEX Profile or ITI TF-2b:3.34.5,
3010 *3.35.5. Indicate NA if not used.>*

As part of the SDC/BICEPS Implicit Discovery mechanism

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

3.23.6 Safety, Effectiveness, Security Requirements & Considerations

3.23.6.1 SES General Considerations

3015 *<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?]

3020 [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)>

3025 #### 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.>

3030 #### 3.23.6.4.1 Security Audit Considerations

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

3.23.6.4.1.(z) <Actor> Specific Security Considerations

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

3.24 Discover Network Topology [DEV-24]

3.24.1 Scope

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

3.24.2 Actor Roles

The actors in this transaction play the following roles:

Table 3.23.2-1: Actor Roles

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

3.24.3 Referenced Standards

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

[Editor's Note:

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

]

3.24.4 Messages

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

3055
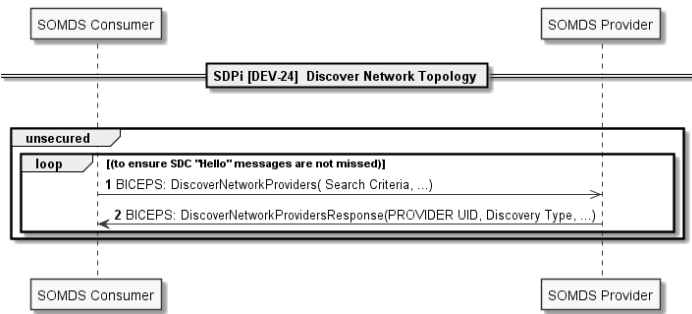
Figure 3.24.4-1: DEV-24 Discover Network Topology Interaction Diagram

3060 <mark>[Editor's Note: This BICEPS "message" is not explicitly defined in the standard, but the text
and parameters are "extracted" from the text. TBD if the semantics should be extended in
BICEPS or SOMDA]</mark>

3.24.4.1 BICEPS DiscoverNetworkProviders() Message

3065 <mark>[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.]</mark>

3070 *<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.>*

3075 #### 3.24.4.1.1 Trigger Events

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

_____

3.24.4.1.2 Message Semantics

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

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

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

3.24.4.1.3 Expected Actions

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

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

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

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

3.24.4.2 BICEPS DiscoverNetworkProvidersResponse() Message

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

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

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

3.24.4.2.1 Trigger Events

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

3.24.4.2.2 Message Semantics

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

_____

3110 *<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
3115 *the contents mean. These message semantics should both help the sender to construct the message and the receiver to interpret the message.>*

3.24.4.2.3 Expected Actions

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

3120 *<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.>

3125 **3.24.5 Protocol Requirements**

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

[Editor's Note:

3130   2.   Note Confluence Topic about potentially missed SDC "Hello" implicit messages and the need to run an algorithm to ensure "discovered" topology is still true.

   3.   NOTE: This loop is in DEV-24 and not DEV-25 because the Announce message is UNSECURED!

]

3135 **3.24.6 Safety, Effectiveness, Security Requirements & Considerations**

3.24.6.1 SES General Considerations

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

[Editor's Note: The security below includes <Actor> specific considerations .. should that also
3140 be included in the SES components? What about message specific considerations?]

_____

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

3145 **3.24.6.2 Safety Requirements & Considerations**

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

3.24.6.3 Effectiveness Requirements & Considerations

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

3150 **3.24.6.4 Security Requirements & Considerations**

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

3.24.6.4.1 Security Audit Considerations

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

3155 **3.24.6.4.1.(z) <Actor> Specific Security Considerations**

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

3.25 Discover BICEPS Services [DEV-25]

3160 **3.25.1 Scope**

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

3.25.2 Actor Roles

3165

3.25.3 Referenced Standards

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

3.25.4 Messages

[Editor's Note: interaction diagram here]

_____

3.25.4.1 "SDC Hello" Message

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

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

3.25.4.1.1 Trigger Events

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

3.25.4.1.2 Message Semantics

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

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

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

3.25.4.1.3 Expected Actions

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

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

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

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

3.25.5 Protocol Requirements

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

3.25.6 Safety, Effectiveness, Security Requirements & Considerations

3.25.6.1 SES General Considerations

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

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

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

3.25.6.2 Safety Requirements & Considerations

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

3215 #### 3.25.6.3 Effectiveness Requirements & Considerations

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

3.25.6.4 Security Requirements & Considerations

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

3220 #### 3.25.6.4.1 Security Audit Considerations

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

3.25.6.4.1.(z) <Actor> Specific Security Considerations

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

3225 ## 3.26 Discover System Context and Capabilities [DEV-26]

3.26.1 Scope

This transaction is used to *<…describe what is accomplished by using the transaction. Remember that by keeping transactions general/abstract, they can be re-used in a variety of*
3230 *profiles>*

_____

_____

3.26.2 Actor Roles

3.26.3 Referenced Standards

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

3235　### 3.26.4 Messages

[Editor's Note: interaction diagram here]

3.26.4.1 "SDC Hello" Message

<One or two sentence summary of what Message 1 accomplishes typically relating the message to the relevant standard. Avoid shall language in this upper level section. Do not duplicate the
3240　*triggers, encoding, semantics, standards used, or expected actions. Those belong in the following sections.>*

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

3.26.4.1.1 Trigger Events

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

3.26.4.1.2 Message Semantics

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

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

<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
3255　*the contents mean. These message semantics should both help the sender to construct the message and the receiver to interpret the message.>*

3.26.4.1.3 Expected Actions

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

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

_____

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

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

3.26.5 Protocol Requirements

[Editor's Note:

1. Original sequence included the following "optional" section:

    a. opt conditional if context states were empty in GetMdibResponse

    b.   sdpi_somds_consumer -> sdpi_somds_provider: SDC: GetContextStates()

    c.   sdpi_somds_consumer <-- sdpi_somds_provider: SDC: GetContextStatesResponse(ContextStates)

    d.   end

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

3. Context States MUST be included in GetMdibResponse … by SDPi profile

]

3.26.6 Safety, Effectiveness, Security Requirements & Considerations

3.26.6.1 SES General Considerations

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

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

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

3.26.6.2 Safety Requirements & Considerations

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

3.26.6.3 Effectiveness Requirements & Considerations

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

_____

_____

3.26.6.4 Security Requirements & Considerations

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

3.26.6.4.1 Security Audit Considerations

3295 *<This section should identify any specific ATNA security audit event that is associated with this
transaction and requirements on the encoding of that audit event. >*

3.26.6.4.1.(z) <Actor> Specific Security Considerations

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

3300 3.27 Manage BICEPS Subscription [DEV-27]

3.27.1 Scope

This transaction is used to *<...describe what is accomplished by using the transaction.
Remember that by keeping transactions general/abstract, they can be re-used in a variety of*
3305 *profiles>*

3.27.2 Actor Roles

3.27.3 Referenced Standards

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

3310 3.27.4 Messages

[Editor's Note: interaction diagram here]

3.27.4.1 "SDC Hello" Message

*<One or two sentence summary of what Message 1 accomplishes typically relating the message
to the relevant standard. Avoid shall language in this upper level section. Do not duplicate the*
3315 *triggers, encoding, semantics, standards used, or expected actions. Those belong in the following
sections.>*

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

_____

3.27.4.1.1 Trigger Events

3320 *<Description of the real world events that cause the sender (Actor A) to send Message 1 (e.g., an operator or an automated function determines that a new workitem is needed).>*

3.27.4.1.2 Message Semantics

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

3325 *<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
3330 *the contents mean. These message semantics should both help the sender to construct the message and the receiver to interpret the message.>*

3.27.4.1.3 Expected Actions

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

3335 *<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.>

3340

3.27.5 Protocol Requirements

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

3345 ### 3.27.6 Safety, Effectiveness, Security Requirements & Considerations

3.27.6.1 SES General Considerations

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

[Editor's Note: The security below includes <Actor> specific considerations .. should that also
3350 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?]

3355 ### 3.27.6.2 Safety Requirements & Considerations

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

3.27.6.3 Effectiveness Requirements & Considerations

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

3360 ### 3.27.6.4 Security Requirements & Considerations

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

3.27.6.4.1 Security Audit Considerations

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

3365 ### 3.27.6.4.1.(z) <Actor> Specific Security Considerations

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

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

3.28.1 Scope

3370 This transaction is used to *<...describe what is accomplished by using the transaction. Remember that by keeping transactions general/abstract, they can be re-used in a variety of profiles>*

3.28.2 Actor Roles

3375 ### 3.28.3 Referenced Standards

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

3.28.4 Messages

[Editor's Note: interaction diagram here]

_____

3.28.4.1 "SDC Hello" Message

3380 *<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
3385 *it is a client or server) can expect this message from a single source or multiple sources.>*

3.28.4.1.1 Trigger Events

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

3.28.4.1.2 Message Semantics

3390 *<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.").>

3395 *<Continue profiling the message by providing guidance or constraints on how the message parameters are populated, how the payload is encoded, how the message is structured and what the contents mean. These message semantics should both help the sender to construct the message and the receiver to interpret the message.>*

3.28.4.1.3 Expected Actions

3400 *<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
3405 *other contexts.>*

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

3.28.5 Protocol Requirements

<In this section, the selected protocol bindings of the transactions are explained in detail (like
3410 *SOAP or HTTP bindings).For an example, see the QRPH DEX Profile or ITI TF-2b:3.34.5, 3.35.5. Indicate NA if not used.>*

_____

3.28.6 Safety, Effectiveness, Security Requirements & Considerations

3.28.6.1 SES General Considerations

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

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

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

3.28.6.2 Safety Requirements & Considerations

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

3.28.6.3 Effectiveness Requirements & Considerations

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

3.28.6.4 Security Requirements & Considerations

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

3.28.6.4.1 Security Audit Considerations

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

3.28.6.4.1.(z) <Actor> Specific Security Considerations

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

3.29 Publish BICEPS Update Reports [DEV-29]

3.29.1 Scope

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

3440 **3.29.2 Actor Roles**

3.29.3 Referenced Standards

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

3.29.4 Messages

3445 [Editor's Note: interaction diagram here]

3.29.4.1 "SDC Hello" Message

<One or two sentence summary of what Message 1 accomplishes typically relating the message to the relevant standard. Avoid shall language in this upper level section. Do not duplicate the triggers, encoding, semantics, standards used, or expected actions. Those belong in the following
3450 *sections.>*

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

3.29.4.1.1 Trigger Events

<Description of the real world events that cause the sender (Actor A) to send Message 1 (e.g., an
3455 *operator or an automated function determines that a new workitem is needed).>*

3.29.4.1.2 Message Semantics

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

<Start by describing the standard underlying the message and how the participating actors are
3460 *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
3465 *message and the receiver to interpret the message.>*

3.29.4.1.3 Expected Actions

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

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

3470 *<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.>

3475 **3.29.5 Protocol Requirements**

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

3.29.6 Safety, Effectiveness, Security Requirements & Considerations

3480 **3.29.6.1 SES General Considerations**

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

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

3485

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

3.29.6.2 Safety Requirements & Considerations

3490 *<Requirements for this transaction relating to safety (e.g., risk analysis)>*

3.29.6.3 Effectiveness Requirements & Considerations

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

3.29.6.4 Security Requirements & Considerations

3495 *<Description of the transaction specific security consideration; such as use of security profiles.>*

3.29.6.4.1 Security Audit Considerations

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

_____

3.29.6.4.1.(z) <Actor> Specific Security Considerations

3500 *<This section should specify any specific security considerations on an actor-by-actor basis.>*

3.30 Retrieve BICEPS Content [DEV-30]

3.30.1 Scope

This transaction is used to *<...describe what is accomplished by using the transaction.*
3505 *Remember that by keeping transactions general/abstract, they can be re-used in a variety of*
profiles>

3.30.2 Actor Roles

3.30.3 Referenced Standards

3510 • *<e.g., HL7 2.3.1 Chapters 2, 3>*

3.30.4 Messages

[Editor's Note: interaction diagram here]

3.30.4.1 "SDC Hello" Message

<One or two sentence summary of what Message 1 accomplishes typically relating the message
3515 *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.>

3520 ### 3.30.4.1.1 Trigger Events

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

3.30.4.1.2 Message Semantics

<Detailed description of the meaning, structure and contents of the message, including any IHE
3525 *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.").>

_____

_____

3530 *<Continue profiling the message by providing guidance or constraints on how the message parameters are populated, how the payload is encoded, how the message is structured and what the contents mean. These message semantics should both help the sender to construct the message and the receiver to interpret the message.>*

3.30.4.1.3 Expected Actions

<Description of the actions expected to be taken as a result of sending or receiving this
3535 *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.>

3540 *<Explicitly define any expected action based on the multiplicity of an actor(s), if applicable.>*

3.30.5 Protocol Requirements

<In this section, the selected protocol bindings of the transactions are explained in detail (like SOAP or HTTP bindings).For an example, see the QRPH DEX Profile or ITI TF-2b:3.34.5,
3545 *3.35.5. Indicate NA if not used.>*

3.30.6 Safety, Effectiveness, Security Requirements & Considerations

3.30.6.1 SES General Considerations

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

3550 [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?]

3555

3.30.6.2 Safety Requirements & Considerations

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

3.30.6.3 Effectiveness Requirements & Considerations

<Requirements for this transaction relating to effectiveness (e.g., Quality of Service, Quality of
3560 *Data, etc.)>*

_____

_____

3.30.6.4 Security Requirements & Considerations

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

3.30.6.4.1 Security Audit Considerations

3565 *<This section should identify any specific ATNA security audit event that is associated with this transaction and requirements on the encoding of that audit event. >*

3.30.6.4.1.(z) <Actor> Specific Security Considerations

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

3.31 Set Provider State [DEV-31]

3570 ### 3.31.1 Scope

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

3.31.2 Actor Roles

3575

3.31.3 Referenced Standards

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

3.31.4 Messages

[Editor's Note: interaction diagram here]

3580 ### 3.31.4.1 "SDC Hello" Message

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

3585 *<Explicitly state if the multiplicity of an actor may be greater than one; i.e., if an actor (whether it is a client or server) can expect this message from a single source or multiple sources.>*

3.31.4.1.1 Trigger Events

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

_____

3590 **3.31.4.1.2 Message Semantics**

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

<Start by describing the standard underlying the message and how the participating actors are mapped (e.g., "This message is a DICOM C-FIND Request. Actor A is the SCU. Actor D is the
3595 *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.>

3600 **3.31.4.1.3 Expected Actions**

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

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

<Avoid re-iterating the transaction sequencing specified in the Profile Process Flows as
3605 *expected actions internal to the transaction. Doing so prevents this transaction being re-used in other contexts.>*

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

3.31.5 Protocol Requirements

3610 *<In this section, the selected protocol bindings of the transactions are explained in detail (like SOAP or HTTP bindings).For an example, see the QRPH DEX Profile or ITI TF-2b:3.34.5, 3.35.5. Indicate NA if not used.>*

3.31.6 Safety, Effectiveness, Security Requirements & Considerations

3.31.6.1 SES General Considerations

3615 *<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?]

3620 [Editor's Note: This transaction is in UNSECURED mode … need to call that out in general here and then add ??? to the .4 section below?]

3.31.6.2 Safety Requirements & Considerations

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

3625
3.31.6.3 Effectiveness Requirements & Considerations

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

3.31.6.4 Security Requirements & Considerations

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

3630
3.31.6.4.1 Security Audit Considerations

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

3.31.6.4.1.(z) <Actor> Specific Security Considerations

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

3635
3.32 Retrieve Archive Data [DEV-32]

3.32.1 Scope

This transaction is used to *<…describe what is accomplished by using the transaction. Remember that by keeping transactions general/abstract, they can be re-used in a variety of*
3640 *profiles>*

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

1. This archive service has "never been implemented" … !!!
2. Intended for "backfilling" missed updates … over minutes and hours … not days – weeks etc.
3645
3. Not a data logger or device historical archive service
4. Primarily intended for temporary disconnections (e.g., communication link down OR patient transport, etc.)
5. Problem is that DescriptorRevisions VERSION (state) sequence numbers may be reset with power cycling or system reset.
3650
6. **BUT what about using TimeFrame for retrieval and detecting if there has been a sequence # change and if so, marking the gap or accessing the known good retrieval and reconcile the two????**

_____

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

8. …

3655]

3.32.2 Actor Roles

3.32.3 Referenced Standards

3660 • *<e.g., HL7 2.3.1 Chapters 2, 3>*

3.32.4 Messages

[Editor's Note: interaction diagram here]

3.32.4.1 "SDC Hello" Message

<One or two sentence summary of what Message 1 accomplishes typically relating the message
3665 *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.>

3670 #### 3.32.4.1.1 Trigger Events

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

3.32.4.1.2 Message Semantics

<Detailed description of the meaning, structure and contents of the message, including any IHE
3675 *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
3680 *parameters are populated, how the payload is encoded, how the message is structured and what*
the contents mean. These message semantics should both help the sender to construct the
message and the receiver to interpret the message.>

_____

_____

3.32.4.1.3 Expected Actions

3685 *<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.>

3690 *<Explicitly define any expected action based on the multiplicity of an actor(s), if applicable.>*

3.32.5 Protocol Requirements

<In this section, the selected protocol bindings of the transactions are explained in detail (like SOAP or HTTP bindings).For an example, see the QRPH DEX Profile or ITI TF-2b:3.34.5, 3695 *3.35.5. Indicate NA if not used.>*

3.32.6 Safety, Effectiveness, Security Requirements & Considerations

3.32.6.1 SES General Considerations

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

3700 [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?]

3705

3.32.6.2 Safety Requirements & Considerations

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

3.32.6.3 Effectiveness Requirements & Considerations

<Requirements for this transaction relating to effectiveness (e.g., Quality of Service, Quality of 3710 *Data, etc.)>*

3.32.6.4 Security Requirements & Considerations

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

_____

_____

3.32.6.4.1 Security Audit Considerations

<This section should identify any specific ATNA security audit event that is associated with this
3715 *transaction and requirements on the encoding of that audit event. >*

3.32.6.4.1.(z) <Actor> Specific Security Considerations

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

3.33 Retrieve Localization Information [DEV-33]

3720 ### 3.33.1 Scope

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

3.33.2 Actor Roles

3725

3.33.3 Referenced Standards

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

3.33.4 Messages

[Editor's Note: interaction diagram here]

3730 ### 3.33.4.1 "SDC Hello" Message

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

3735 *<Explicitly state if the multiplicity of an actor may be greater than one; i.e., if an actor (whether*
it is a client or server) can expect this message from a single source or multiple sources.>

3.33.4.1.1 Trigger Events

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

3740 ### 3.33.4.1.2 Message Semantics

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

_____

_____

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

3745

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

3.33.4.1.3 Expected Actions

3750

<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.>

3755

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

3.33.5 Protocol Requirements

3760

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

3.33.6 Safety, Effectiveness, Security Requirements & Considerations

3.33.6.1 SES General Considerations

3765

<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?]

3770

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

3.33.6.2 Safety Requirements & Considerations

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

_____

_____

3.33.6.3 Effectiveness Requirements & Considerations

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

3.33.6.4 Security Requirements & Considerations

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

3.33.6.4.1 Security Audit Considerations

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

3.33.6.4.1.(z) <Actor> Specific Security Considerations

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

3.34 Announce Network Departure [DEV-34]

3.34.1 Scope

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

3.34.2 Actor Roles

3.34.3 Referenced Standards

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

3.34.4 Messages

[Editor's Note: interaction diagram here]

3.34.4.1 "SDC Hello" Message

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

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

_____

_____

3.34.4.1.1 Trigger Events

3805 *<Description of the real world events that cause the sender (Actor A) to send Message 1 (e.g., an operator or an automated function determines that a new workitem is needed).>*

3.34.4.1.2 Message Semantics

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

3810 *<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
3815 *the contents mean. These message semantics should both help the sender to construct the message and the receiver to interpret the message.>*

3.34.4.1.3 Expected Actions

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

3820 *<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.>

3825

3.34.5 Protocol Requirements

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

3830 ### 3.34.6 Safety, Effectiveness, Security Requirements & Considerations

3.34.6.1 SES General Considerations

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

[Editor's Note: The security below includes <Actor> specific considerations .. should that also
3835 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?]

3840 **3.34.6.2 Safety Requirements & Considerations**

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

3.34.6.3 Effectiveness Requirements & Considerations

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

3845 **3.34.6.4 Security Requirements & Considerations**

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

3.34.6.4.1 Security Audit Considerations

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

3850 **3.34.6.4.1.(z) <Actor> Specific Security Considerations**

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

3.35 Establish Medical Data Exchange [DEV-35]

3855 **3.35.1 Scope**

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

3.35.2 Actor Roles

3860

3.35.3 Referenced Standards

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

3.35.4 Messages

[Editor's Note: interaction diagram here]

3865 **3.35.4.1 "SDC Hello" Message**

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

3870 *<Explicitly state if the multiplicity of an actor may be greater than one; i.e., if an actor (whether
it is a client or server) can expect this message from a single source or multiple sources.>*

3.35.4.1.1 Trigger Events

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

3875 #### 3.35.4.1.2 Message Semantics

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

*<Start by describing the standard underlying the message and how the participating actors are
mapped (e.g., "This message is a DICOM C-FIND Request. Actor A is the SCU. Actor D is the*
3880 *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.>*

3885 #### 3.35.4.1.3 Expected Actions

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

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

<Avoid re-iterating the transaction sequencing specified in the Profile Process Flows as
3890 *expected actions internal to the transaction. Doing so prevents this transaction being re-used in
other contexts.>*

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

3.35.5 Protocol Requirements

3895 *<In this section, the selected protocol bindings of the transactions are explained in detail (like SOAP or HTTP bindings).For an example, see the QRPH DEX Profile or ITI TF-2b:3.35.5, 3.35.5. Indicate NA if not used.>*

3.35.6 Safety, Effectiveness, Security Requirements & Considerations

3.35.6.1 SES General Considerations

3900 *<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?]

3905 [Editor's Note: This transaction is in UNSECURED mode … need to call that out in general here and then add ??? to the .4 section below?]

3.35.6.2 Safety Requirements & Considerations

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

3910 ### 3.35.6.3 Effectiveness Requirements & Considerations

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

3.35.6.4 Security Requirements & Considerations

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

3915 ### 3.35.6.4.1 Security Audit Considerations

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

3.35.6.4.1.(z) <Actor> Specific Security Considerations

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

3920

3.36 Publish Medical Data [DEV-36]

_____

3.36.1 Scope

This transaction is used to *<…describe what is accomplished by using the transaction.*
3925 *Remember that by keeping transactions general/abstract, they can be re-used in a variety of*
profiles>

3.36.2 Actor Roles

3.36.3 Referenced Standards

3930 • *<e.g., HL7 2.3.1 Chapters 2, 3>*

3.36.4 Messages

[Editor's Note: interaction diagram here]

3.36.4.1 "SDC Hello" Message

<One or two sentence summary of what Message 1 accomplishes typically relating the message
3935 *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.>

3940 **3.36.4.1.1 Trigger Events**

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

3.36.4.1.2 Message Semantics

<Detailed description of the meaning, structure and contents of the message, including any IHE
3945 *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
3950 *parameters are populated, how the payload is encoded, how the message is structured and what*
the contents mean. These message semantics should both help the sender to construct the
message and the receiver to interpret the message.>

_____

3.36.4.1.3 Expected Actions

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

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

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

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

3.36.5 Protocol Requirements

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

3.36.6 Safety, Effectiveness, Security Requirements & Considerations

3.36.6.1 SES General Considerations

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

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

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

3.36.6.2 Safety Requirements & Considerations

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

3.36.6.3 Effectiveness Requirements & Considerations

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

3.36.6.4 Security Requirements & Considerations

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

_____

_____

3.36.6.4.1 Security Audit Considerations

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

3.36.6.4.1.(z) <Actor> Specific Security Considerations

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

3.37 Retrieve Medical Data [DEV-37]

3.37.1 Scope

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

3.37.2 Actor Roles

3.37.3 Referenced Standards

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

3.37.4 Messages

[Editor's Note: interaction diagram here]

3.37.4.1 "SDC Hello" Message

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

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

3.37.4.1.1 Trigger Events

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

_____

_____

3.37.4.1.2 Message Semantics

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

4015 *<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
4020 message and the receiver to interpret the message.>*

3.37.4.1.3 Expected Actions

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

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

4025 *<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.>

4030 ### 3.37.5 Protocol Requirements

*<In this section, the selected protocol bindings of the transactions are explained in detail (like
SOAP or HTTP bindings).For an example, see the QRPH DEX Profile or ITI TF-2b:3.37.5,
3.35.5. Indicate NA if not used.>*

3.37.6 Safety, Effectiveness, Security Requirements & Considerations

4035 ### 3.37.6.1 SES General Considerations

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

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

4040

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

_____

_____

3.37.6.2 Safety Requirements & Considerations

4045 *<Requirements for this transaction relating to safety (e.g., risk analysis)>*

3.37.6.3 Effectiveness Requirements & Considerations

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

3.37.6.4 Security Requirements & Considerations

4050 *<Description of the transaction specific security consideration; such as use of security profiles.>*

3.37.6.4.1 Security Audit Considerations

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

3.37.6.4.1.(z) <Actor> Specific Security Considerations

4055 *<This section should specify any specific security considerations on an actor-by-actor basis.>*

3.38 Establish Medical Alert Exchange [DEV-38]

3.38.1 Scope

4060 This transaction is used to *<...describe what is accomplished by using the transaction. Remember that by keeping transactions general/abstract, they can be re-used in a variety of profiles>*

3.38.2 Actor Roles

4065 ### 3.38.3 Referenced Standards

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

3.38.4 Messages

[Editor's Note: interaction diagram here]

3.38.4.1 "SDC Hello" Message

4070 *<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.>*

4075 *<Explicitly state if the multiplicity of an actor may be greater than one; i.e., if an actor (whether
it is a client or server) can expect this message from a single source or multiple sources.>*

3.38.4.1.1 Trigger Events

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

3.38.4.1.2 Message Semantics

4080 *<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.").>*

4085 *<Continue profiling the message by providing guidance or constraints on how the message
parameters are populated, how the payload is encoded, how the message is structured and what
the contents mean. These message semantics should both help the sender to construct the
message and the receiver to interpret the message.>*

3.38.4.1.3 Expected Actions

4090 *<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
4095 other contexts.>*

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

3.38.5 Protocol Requirements

*<In this section, the selected protocol bindings of the transactions are explained in detail (like
4100 SOAP or HTTP bindings).For an example, see the QRPH DEX Profile or ITI TF-2b:3.38.5,
3.35.5. Indicate NA if not used.>*

3.38.6 Safety, Effectiveness, Security Requirements & Considerations

3.38.6.1 SES General Considerations

4105 *<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?]

4110 [Editor's Note: This transaction is in UNSECURED mode … need to call that out in general here and then add ??? to the .4 section below?]

3.38.6.2 Safety Requirements & Considerations

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

3.38.6.3 Effectiveness Requirements & Considerations

4115 *<Requirements for this transaction relating to effectiveness (e.g., Quality of Service, Quality of Data, etc.)>*

3.38.6.4 Security Requirements & Considerations

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

3.38.6.4.1 Security Audit Considerations

4120 *<This section should identify any specific ATNA security audit event that is associated with this transaction and requirements on the encoding of that audit event. >*

3.38.6.4.1.(z) <Actor> Specific Security Considerations

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

4125 3.39 Publish Medical Alert Update [DEV-39]

3.39.1 Scope

This transaction is used to *<…describe what is accomplished by using the transaction. Remember that by keeping transactions general/abstract, they can be re-used in a variety of*
4130 *profiles>*

_____

3.39.2 Actor Roles

3.39.3 Referenced Standards

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

4135 ### 3.39.4 Messages

[Editor's Note: interaction diagram here]

3.39.4.1 "SDC Hello" Message

<One or two sentence summary of what Message 1 accomplishes typically relating the message to the relevant standard. Avoid shall language in this upper level section. Do not duplicate the
4140 *triggers, encoding, semantics, standards used, or expected actions. Those belong in the following sections.>*

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

3.39.4.1.1 Trigger Events

4145 *<Description of the real world events that cause the sender (Actor A) to send Message 1 (e.g., an operator or an automated function determines that a new workitem is needed).>*

3.39.4.1.2 Message Semantics

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

4150 *<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
4155 *the contents mean. These message semantics should both help the sender to construct the message and the receiver to interpret the message.>*

3.39.4.1.3 Expected Actions

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

4160 *<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.>

4165

3.39.5 Protocol Requirements

*<In this section, the selected protocol bindings of the transactions are explained in detail (like
SOAP or HTTP bindings).For an example, see the QRPH DEX Profile or ITI TF-2b:3.39.5,
3.35.5. Indicate NA if not used.>*

4170 ### 3.39.6 Safety, Effectiveness, Security Requirements & Considerations

3.39.6.1 SES General Considerations

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

[Editor's Note: The security below includes <Actor> specific considerations .. should that also
4175 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?]

4180 #### 3.39.6.2 Safety Requirements & Considerations

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

3.39.6.3 Effectiveness Requirements & Considerations

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

4185 #### 3.39.6.4 Security Requirements & Considerations

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

3.39.6.4.1 Security Audit Considerations

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

_____

_____

4190 **3.39.6.4.1.(z) <Actor> Specific Security Considerations**

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

3.40 Retrieve Medical Alert Status [DEV-40]

4195 **3.40.1 Scope**

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

3.40.2 Actor Roles

4200

3.40.3 Referenced Standards

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

3.40.4 Messages

[Editor's Note: interaction diagram here]

4205 **3.40.4.1 "SDC Hello" Message**

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

4210 *<Explicitly state if the multiplicity of an actor may be greater than one; i.e., if an actor (whether it is a client or server) can expect this message from a single source or multiple sources.>*

3.40.4.1.1 Trigger Events

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

4215 **3.40.4.1.2 Message Semantics**

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

_____

_____

<Start by describing the standard underlying the message and how the participating actors are mapped (e.g., "This message is a DICOM C-FIND Request. Actor A is the SCU. Actor D is the
4220   *SCP.").>*

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

3.40.4.1.3 Expected Actions

4225

<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
4230   *expected actions internal to the transaction. Doing so prevents this transaction being re-used in other contexts.>*

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

3.40.5 Protocol Requirements

4235   *<In this section, the selected protocol bindings of the transactions are explained in detail (like SOAP or HTTP bindings).For an example, see the QRPH DEX Profile or ITI TF-2b:3.40.5, 3.35.5. Indicate NA if not used.>*

3.40.6 Safety, Effectiveness, Security Requirements & Considerations

3.40.6.1 SES General Considerations

4240   *<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?]

4245   [Editor's Note: This transaction is in UNSECURED mode … need to call that out in general here and then add ??? to the .4 section below?]

3.40.6.2 Safety Requirements & Considerations

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

_____

4250 **3.40.6.3 Effectiveness Requirements & Considerations**

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

3.40.6.4 Security Requirements & Considerations

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

4255 **3.40.6.4.1 Security Audit Considerations**

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

3.40.6.4.1.(z) <Actor> Specific Security Considerations

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

4260

3.41 Manage Medical Alert Delegation [DEV-41]

3.41.1 Scope

This transaction is used to *<...describe what is accomplished by using the transaction.*
4265 *Remember that by keeping transactions general/abstract, they can be re-used in a variety of profiles>*

3.41.2 Actor Roles

3.41.3 Referenced Standards

4270 • *<e.g., HL7 2.3.1 Chapters 2, 3>*

3.41.4 Messages

[Editor's Note: interaction diagram here]

3.41.4.1 "SDC Hello" Message

<One or two sentence summary of what Message 1 accomplishes typically relating the message
4275 *to the relevant standard. Avoid shall language in this upper level section. Do not duplicate the triggers, encoding, semantics, standards used, or expected actions. Those belong in the following sections.>*

_____

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

3.41.4.1.1 Trigger Events

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

3.41.4.1.2 Message Semantics

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

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

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

3.41.4.1.3 Expected Actions

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

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

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

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

3.41.5 Protocol Requirements

<In this section, the selected protocol bindings of the transactions are explained in detail (like SOAP or HTTP bindings).For an example, see the QRPH DEX Profile or ITI TF-2b:3.41.5, 3.35.5. Indicate NA if not used.>

3.41.6 Safety, Effectiveness, Security Requirements & Considerations

3.41.6.1 SES General Considerations

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

_____

4310 [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?]

4315

3.41.6.2 Safety Requirements & Considerations

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

3.41.6.3 Effectiveness Requirements & Considerations

<Requirements for this transaction relating to effectiveness (e.g., Quality of Service, Quality of
4320 *Data, etc.)>*

3.41.6.4 Security Requirements & Considerations

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

3.41.6.4.1 Security Audit Considerations

<This section should identify any specific ATNA security audit event that is associated with this
4325 *transaction and requirements on the encoding of that audit event. >*

3.41.6.4.1.(z) <Actor> Specific Security Considerations

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

3.42 Delegate Medical Alert [DEV-42]

4330

3.42.1 Scope

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

4335 ### 3.42.2 Actor Roles

3.42.3 Referenced Standards

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

_____

3.42.4 Messages

4340 <mark>[Editor's Note: interaction diagram here]</mark>

3.42.4.1 "SDC Hello" Message

*<One or two sentence summary of what Message 1 accomplishes typically relating the message
to the relevant standard. Avoid shall language in this upper level section. Do not duplicate the
triggers, encoding, semantics, standards used, or expected actions. Those belong in the following*
4345 *sections.>*

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

3.42.4.1.1 Trigger Events

<Description of the real world events that cause the sender (Actor A) to send Message 1 (e.g., an
4350 *operator or an automated function determines that a new workitem is needed).>*

3.42.4.1.2 Message Semantics

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

<Start by describing the standard underlying the message and how the participating actors are
4355 *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*
4360 *message and the receiver to interpret the message.>*

3.42.4.1.3 Expected Actions

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

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

4365 *<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.>

_____

4370 **3.42.5 Protocol Requirements**

*<In this section, the selected protocol bindings of the transactions are explained in detail (like
SOAP or HTTP bindings).For an example, see the QRPH DEX Profile or ITI TF-2b:3.42.5,
3.35.5. Indicate NA if not used.>*

3.42.6 Safety, Effectiveness, Security Requirements & Considerations

4375 **3.42.6.1 SES General Considerations**

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

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

4380

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

3.42.6.2 Safety Requirements & Considerations

4385 *<Requirements for this transaction relating to safety (e.g., risk analysis)>*

3.42.6.3 Effectiveness Requirements & Considerations

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

3.42.6.4 Security Requirements & Considerations

4390 *<Description of the transaction specific security consideration; such as use of security profiles.>*

3.42.6.4.1 Security Audit Considerations

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

3.42.6.4.1.(z) <Actor> Specific Security Considerations

4395 *<This section should specify any specific security considerations on an actor-by-actor basis.>*

3.43 Update Alert Acknowledgement Status [DEV-43]

_____

3.43.1 Scope

4400   This transaction is used to *<…describe what is accomplished by using the transaction. Remember that by keeping transactions general/abstract, they can be re-used in a variety of profiles>*

3.43.2 Actor Roles

4405   ### 3.43.3 Referenced Standards

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

3.43.4 Messages

[Editor's Note: interaction diagram here]

3.43.4.1 "SDC Hello" Message

4410   *<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
4415   *it is a client or server) can expect this message from a single source or multiple sources.>*

3.43.4.1.1 Trigger Events

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

3.43.4.1.2 Message Semantics

4420   *<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.").>

4425   *<Continue profiling the message by providing guidance or constraints on how the message parameters are populated, how the payload is encoded, how the message is structured and what the contents mean. These message semantics should both help the sender to construct the message and the receiver to interpret the message.>*

_____

_____

3.43.4.1.3 Expected Actions

4430 *<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 4435 *other contexts.>*

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

3.43.5 Protocol Requirements

<In this section, the selected protocol bindings of the transactions are explained in detail (like 4440 *SOAP or HTTP bindings).For an example, see the QRPH DEX Profile or ITI TF-2b:3.43.5, 3.35.5. Indicate NA if not used.>*

3.43.6 Safety, Effectiveness, Security Requirements & Considerations

3.43.6.1 SES General Considerations

<Address any SES requirements & considerations that need to be managed; include linkages to 4445 *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 4450 here and then add ??? to the .4 section below?]

3.43.6.2 Safety Requirements & Considerations

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

3.43.6.3 Effectiveness Requirements & Considerations

4455 *<Requirements for this transaction relating to effectiveness (e.g., Quality of Service, Quality of Data, etc.)>*

3.43.6.4 Security Requirements & Considerations

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

_____

3.43.6.4.1 Security Audit Considerations

4460 *<This section should identify any specific ATNA security audit event that is associated with this transaction and requirements on the encoding of that audit event. >*

3.43.6.4.1.(z) <Actor> Specific Security Considerations

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

3.44 Manage Medical External Control [DEV-44]
4465

3.44.1 Scope

This transaction is used to *<...describe what is accomplished by using the transaction. Remember that by keeping transactions general/abstract, they can be re-used in a variety of*
4470 *profiles>*

3.44.2 Actor Roles

3.44.3 Referenced Standards

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

4475 ### 3.44.4 Messages

[Editor's Note: interaction diagram here]

3.44.4.1 "SDC Hello" Message

<One or two sentence summary of what Message 1 accomplishes typically relating the message to the relevant standard. Avoid shall language in this upper level section. Do not duplicate the
4480 *triggers, encoding, semantics, standards used, or expected actions. Those belong in the following sections.>*

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

3.44.4.1.1 Trigger Events

4485 *<Description of the real world events that cause the sender (Actor A) to send Message 1 (e.g., an operator or an automated function determines that a new workitem is needed).>*

_____

_____

3.44.4.1.2 Message Semantics

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

4490 *<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
4495 *the contents mean. These message semantics should both help the sender to construct the message and the receiver to interpret the message.>*

3.44.4.1.3 Expected Actions

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

4500 *<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.>

4505

3.44.5 Protocol Requirements

<In this section, the selected protocol bindings of the transactions are explained in detail (like SOAP or HTTP bindings).For an example, see the QRPH DEX Profile or ITI TF-2b:3.44.5, 3.35.5. Indicate NA if not used.>

4510 ### 3.44.6 Safety, Effectiveness, Security Requirements & Considerations

3.44.6.1 SES General Considerations

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

[Editor's Note: The security below includes <Actor> specific considerations .. should that also
4515 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?]

_____

4520 **3.44.6.2 Safety Requirements & Considerations**

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

3.44.6.3 Effectiveness Requirements & Considerations

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

4525 **3.44.6.4 Security Requirements & Considerations**

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

3.44.6.4.1 Security Audit Considerations

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

4530 **3.44.6.4.1.(z) <Actor> Specific Security Considerations**

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

3.45 Invoke Medical Control Services [DEV-45]

4535 **3.45.1 Scope**

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

3.45.2 Actor Roles

4540

3.45.3 Referenced Standards

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

3.45.4 Messages

[Editor's Note: interaction diagram here]

4545 **3.45.4.1 "SDC Hello" Message**

<One or two sentence summary of what Message 1 accomplishes typically relating the message to the relevant standard. Avoid shall language in this upper level section. Do not duplicate the

_____

*triggers, encoding, semantics, standards used, or expected actions. Those belong in the following
sections.>*

4550 *<Explicitly state if the multiplicity of an actor may be greater than one; i.e., if an actor (whether
it is a client or server) can expect this message from a single source or multiple sources.>*

3.45.4.1.1 Trigger Events

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

4555 ### 3.45.4.1.2 Message Semantics

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

*<Start by describing the standard underlying the message and how the participating actors are
mapped (e.g., "This message is a DICOM C-FIND Request. Actor A is the SCU. Actor D is the*
4560 *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.>*

4565 ### 3.45.4.1.3 Expected Actions

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

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

<Avoid re-iterating the transaction sequencing specified in the Profile Process Flows as
4570 *expected actions internal to the transaction. Doing so prevents this transaction being re-used in
other contexts.>*

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

3.45.5 Protocol Requirements

4575 *<In this section, the selected protocol bindings of the transactions are explained in detail (like
SOAP or HTTP bindings).For an example, see the QRPH DEX Profile or ITI TF-2b:3.45.5,
3.35.5. Indicate NA if not used.>*

_____

3.45.6 Safety, Effectiveness, Security Requirements & Considerations

3.45.6.1 SES General Considerations

4580 *<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?]

4585 [Editor's Note: This transaction is in UNSECURED mode … need to call that out in general here and then add ??? to the .4 section below?]

3.45.6.2 Safety Requirements & Considerations

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

4590 #### 3.45.6.3 Effectiveness Requirements & Considerations

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

3.45.6.4 Security Requirements & Considerations

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

4595 #### 3.45.6.4.1 Security Audit Considerations

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

3.45.6.4.1.(z) <Actor> Specific Security Considerations

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

4600

4605

_____

_____

Appendices to Volume 2

*<Detailed cross transaction relationships or mapping details are described in an appendix in
Volume 2. Volume 2 appendices may be informational or normative. Immediately after the title
of a Volume 2 appendix, provide a very explicit statement defining whether this new appendix is
4610   informative or normative.*

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

_____

Appendix A – ISO/IEEE 11073 SDC / MDPWS Message Specifications (Normative)

4615

[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.

4620

2020.09.07 Note: From Andres Besting

In order to make SDC available in other programming languages, there has recently been an open API specification that is intended to facilitate cross-language use. The specification is based on the OpenAPI standard (https://www.openapis.org). The principle of OpenAPI is to specify REST API functions and data types in a machine-readable manner in order to generate client, server code and documentation from this specification.

4625

An example of a possible SDC specification can be found here: https://bitbucket.org/besting-it/sdcapispec

4630

You will also find further links here, on the one hand to SDCLib / J, which implements the server side for this, and a C # demo client, which implements the client side. The C # client is also available as a complete NuGet package (for further information see https://bitbucket.org/besting-it/sdcapisharp).

4635

To test other languages, I would like to invite you to create additional clients and test them. Information about supported languages and code generators can be found at https://github.com/OpenAPITools/openapi-generator .

4640

]

The ISO/IEEE 11073-20702 Medical Device Profile for Web Services (MDPWS) provides transport-level messaging for implementing SDC/BICEPS and SOMDA exchange over a web services infrastructure. Extensive information is provided in both the MDPWS standard as well as the web services standards that it normatively references from IETF, OASIS and W3C including:

4645

_____

OASIS Devices Profile for Web Services (DPWS) Version 1.1, 1 July 2009[11]

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

4650 [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]

4655 UPDATE / PROFILE THE BICEPS 7.3.1 Service Model GLUE! for organization of the messages here?
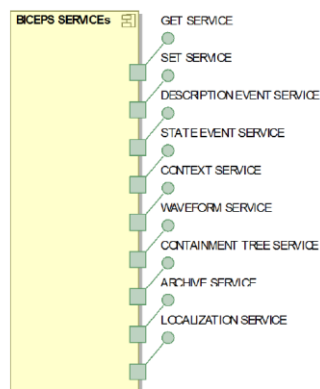

Figure 12—SERVICEs defined to let SERVICE CONSUMERs
gain access to the MDIB

4660 **A.1.1 <Title>**

Appendix A.1.1 text.

_____

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

_____

_____

[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
4665   considered organizations that provide appropriate groupings. These should be a primary
organizing factor for the remaining message sections.]

A.2 SDC Messages for BICEPS Discovery Model

The messages in this section relate to the SDC/BICEPS Dynamic Discovery capabilities,
4670   including both implicit and explicit discovery.

[Editor's Note: Include sequence diagram here with MDPWS detailed exchanges?

Also, what about excluded messages, such as Resolve()/ResolveMatches()? Free text here OR in
an "Excluded SDC/MDPWS discovery messages" or similar section at the end?

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

4675   ]

_____

_____

4680
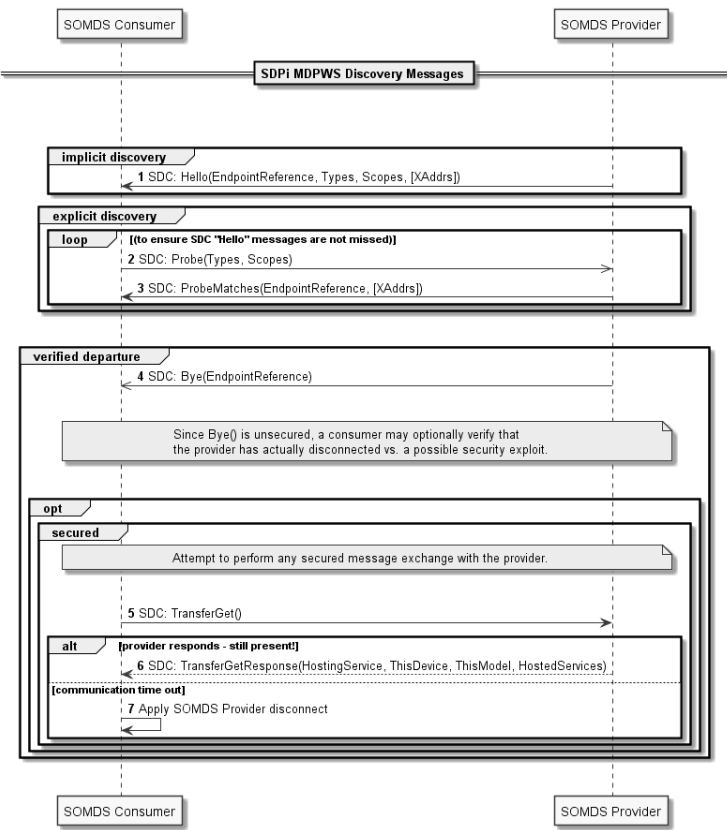
A.2.1 MDPWS: Hello()

xyz.

4685

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

_____

_____

- Parameter semantics
- SES & Other Considerations
4690
- Profiling & Usage Notes
- …
]

A.2.2 MDPWS: Probe ()

xyz.

4695

[Editor's Note: Or a Probe() / ProbeMatches() section? My assumption is that it is simpler to just keep each message in a separate section.
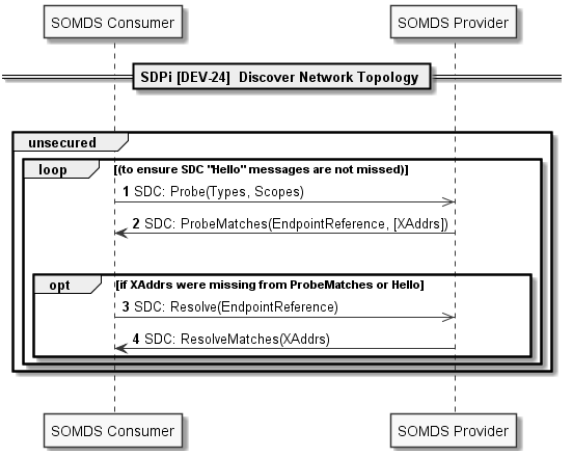
4700 [Editor's Note: Remove "opt" section and indicate WHY this is profiled out in SDPi; then remove diagram.]

A.2.3 MDPWS: ProbeMatches()

xyz.

4705

_____

_____

A.241 MDPWS: Bye()

xyz.

4710
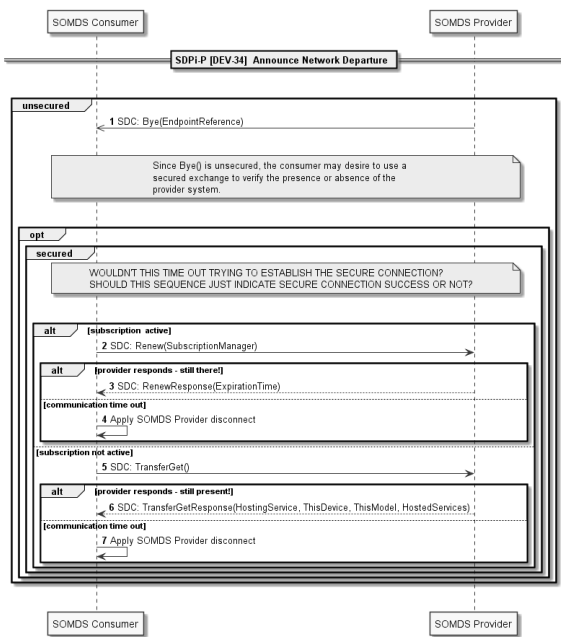
[Editor's Note: Simplify (per instructions in 8/24 PlantUML; Add in Profiling / Usage Notes]

A.3 SDC Messages for Secure Connections

4715

A.4 SDC Messages for PROVIDER MDIB Discovery

_____

A.5 SDC Messages for Update Publication / Subscription Services

4720 **A.6 SDC Messages for <…>**

A.7 SDC Messages for PARTICIPANT Context Management

_____

4725   Appendix B – <Appendix Title>

Appendix B text.

B.1 <Title>

Appendix B.1 text.

B.1.1 <Title>

4730   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
4735 *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*
4740 *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)

4745

Volume 2 additions to the Devices OID Registry are:

_____

_____

Volume 3 – Content Modules

4750   *<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).*

4755   *<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

4760 [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*
4765 *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*
4770 *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.>

4775 The Devices registry of OIDs is located at
http://wiki.ihe.net/index.php/OID_Registration#IHE_Domain_Namespaces

Additions to the Devices OID Registry are:

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

4780

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
4785 *depending on locale or context.>*

_____

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

_____

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>

4790

5.3 IHE Devices Format Codes and Vocabularies

5.3.1 IHE Format Codes

4795

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

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

4800 ### 5.3.2 IHEActCode Vocabulary

4805

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

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

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

5.3.3 IHERoleCode Vocabulary

4810

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

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

_____

6 DEV HL7 V3 CDA Content Modules

4815 [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]

_____

4820
8 DEV Semantic Content Modules

8.1 Overview of device semantic content

8.2 General device content considerations

8.2.8 SDC/BICEPS semantic content
[Editor: Include:

4825   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

4830   Consider links / bindings to transactions

         KEY DIFFERENTIATOR – ALERTING & CONTROL BICEPS elements

]

8.2.8.1 SDC/BICEPS Content Module
[Editor's Note: This subsection defines the overarching "content module" that is required for all
4835 SDPi transaction exchanges, namely use of 11073-1010x & -10207 etc. This is referenced in the
SDPi-P Content Modules section

Subsequent subsections provide additional descriptive detail for implementers.]

8.2.8.2 SDC/BICEPS Descriptive Model

4840
8.2.8.3 SDC/BICEPS Relationship to Classic DIM

8.2.8.4 Nomenclature Considerations – Private Extensions & External Systems

8.2.8.4 Safety, Effectiveness, Security Content Requirements & Considerations
4845

_____

8.2.8.5 SDC/BICEPS Conventions for device specialization content modules

8.2.8.6 Device Aggregators & Proxies Modeling

[Editor:

4850
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.

4855]

8.2.8.7 SDC/BICEPS Mapping of SOMDS Connector Content Modules

[Editor:
1. General discussion about the need to and how to specify the mapping of content from one system / protocol to SOMDS / SDC / BICEPS … per the SOMDS Connector Actor
4860
2. If / how these GATWAY CONTENT MODULES will be specified
3. For example, mapping of FHIR Content into a BICEPS WorkflowContext. OR the DoF PoCD IG mappings from -10201 and -10207.
4. OR XCS-I imaging info (metadata & images) into BICEPS … ???
5. OR when you really shouldn't do such mapping to BICEPS and just have a different
4865
extension / API based on the established protocol!
]

8.2.8.8 SOMDA System Function Contribution Content Module

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

4870 #### 8.2.8.8 SDC / BICEPS Extension Provisions

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

8.3 Device specialization content modules

[Editor:

_____

4875
1. Note that for each specialization, the current 9.0 version content will remain unchanged and a specific SDC/BICEPS section will be added to the end;

2. Since OR integration and High-Frequency Surgery devices may be the focus of the SDPi 1.0 supplement, these specializations may also be added to the end.

]

8.3.1 Device: Infusion Pump

8.3.1.4 SDC/BICEPS content module

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

1. Supporting all (4) PKP functions.

2. Aligned with the "enterprise" focused definitions in the preceding sections, but explaining differences & extensions along with rationale

3. Aligned with any 11073 device specialization standard (summarizing approach & referencing detailed conformance XML specification file)

4. Include the high-level containment w/ example & key metrics etc.

5. Reference detailed value sets (e.g., via OID) & files, etc.

6. NOTE: This is a CONTENT module; whereas BICEPS uses the descriptive MDIB "content" to also define a specialized set of services. In the case of device-specific services, it is anticipated that this will be addressed in device specialization profile specifications (e.g., profiles that build upon the interoperability foundation of SDPi profiles, but define device-specific architecture / workflow transactions & appropriately scoped content.

]

8.3.2 Device: Ventilator

8.3.2.4 SDC/BICEPS content module

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

1. Supporting all (4) PKP functions.

2. Aligned with the "enterprise" focused definitions in the preceding sections, but explaining differences & extensions along with rationale

_____

3. Aligned with any 11073 device specialization standard (summarizing approach & referencing detailed conformance XML specification file)

4. Include the high-level containment w/ example & key metrics etc.

5. Reference detailed value sets (e.g., via OID) & files, etc.

4910   6. NOTE: This is a CONTENT module; whereas BICEPS uses the descriptive MDIB "content" to also define a specialized set of services. In the case of device-specific services, it is anticipated that this will be addressed in device specialization profile specifications (e.g., profiles that build upon the interoperability foundation of SDPi profiles, but define device-specific architecture / workflow transactions & appropriately

4915   scoped content.

]

8.3.3 Device: Physiologic monitor

8.3.3.4 SDC/BICEPS content module

4920   [Editor's Note: This content module will include a detailed "from the device interface" specification:

7. Supporting all (4) PKP functions.

8. Aligned with the "enterprise" focused definitions in the preceding sections, but explaining differences & extensions along with rationale

4925   9. Aligned with any 11073 device specialization standard (summarizing approach & referencing detailed conformance XML specification file)

10. Include the high-level containment w/ example & key metrics etc.

11. Reference detailed value sets (e.g., via OID) & files, etc.

12. NOTE: This is a CONTENT module; whereas BICEPS uses the descriptive MDIB "content" to also define a specialized set of services. In the case of device-specific

4930   services, it is anticipated that this will be addressed in device specialization profile specifications (e.g., profiles that build upon the interoperability foundation of SDPi profiles, but define device-specific architecture / workflow transactions & appropriately scoped content.

4935   ]

8.3.4 Devices: Surgery

4940

[Editor's Note: This is a place holder section for additional device specializations based on the 11073-1072x projects under way, primarily focused on endoscopic procedures. These include specializations for: HF Device, Endoscopy Camera, Endoscopy Light, Insufflator & Endoscopy Pump. Will also need a Surgery Table, etc.

TBD whether these are grouped under a heading like this OR (more probably) spelled out individually. The need for these – near term – will be to support the Surgery use case.

4945

Ultimately, this will link to normative BICEPS content module specifications that are published in GitHub or the .io space or similar registry.

NOTE: Infusion Pumps are a CLASS of devices … just like Surgery?

]

8.3.5 Devices: Anesthesia

4950

[Editor's Note: This is a place holder section for additional device specializations based on the 11073-1072x projects under way + real-world products that support SDC interoperability. These include specializations for: Anesthesia Workstation + integration with other general-purpose & specialized anesthesia devices such as syringe pumps or BIS monitors.

See notes for infusion pumps above for additional detail.

]

4955

8.3.6 Devices: Dialysis

[Editor's Note: This is a place holder section for additional device specializations based on the 11073-1072x projects under way + real-world products that support SDC interoperability + other 11073 device specialization specification projects.. These include specializations for both

4960

chronic and acute care renal therapy systems.

See notes for infusion pumps above for additional detail.

]

4965

_____

Appendices to Volume 3

<Add any applicable Volume 3 appendices below.

4970 *<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>

4975   Appendix A.1 text.

A.1.1 <Title>

Appendix A.1.1 text.

_____

_____

Appendix B – <Appendix Title>

Appendix B text.

4980 ### B.1 <Title>

Appendix B.1 text.

B.1.1 <Title>

Appendix B.1.1 text.

4985

_____

_____

Volume 4 – National Extensions

Add appropriate Country section

_____

_____

3 National Extensions for <Country Name or IHE Organization>

4990 *<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
4995 the national use case truly requires a difference in the profile mechanisms rather than just
differences in system configuration.>*

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

5000 *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
5005 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.

5010 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:

5015 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:

5020 • <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)

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

end of example>

3.3.2 <Profile Acronym> <Type of Change>

<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>

_____

5045

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>

5050 Appendix A text.

A.1 <Title>

Appendix A.1 text.

A.1.1 <Title>

Appendix A.1.1 text.

_____

5055 Appendix B – <Appendix Title>

Appendix B text.

B.1 <Title>

Appendix B.1 text.

B.1.1 <Title>

5060 Appendix B.1.1 text.