





IHE Devices – SDPi Supplement

Introduction & Overview

<date> 2020

SDC is a registered trademark of OR.NET



IHE Germany – SDC / SDPi Plug-a-Thon – Briefing

IHE Basics - Why profile?

From ISO/IEEE 11073 SDC to IHE SDPi TF to PATs & CATs

Orientation Tour: IHE Technical Framework & SDPi Profiles

IHE SDPi Profile Option Specifications

IHE SDPi TF-2 Transactions & MDPWS Messaging

IHE SDPi TF-3 SDC/BICEPS Content Modules & Specializations

First ... Term Usage & Assumptions

SDC Service-oriented Device Connectivity

Family of ISO/IEEE 11073 SDC standards

Assumption: PAT participants have a working understanding of SDC

SDPi Service-oriented Device Point-of-care Interoperability

Set of (4) IHE technical framework profiles based on ISO/IEEE 11073 SDC standards Assumption: PAT participants may have some working knowledge of IHE & TF profiles

PAT Plug-a-thon

IHE testing event intended for early, informal exploration of new tech & new profiles Assumption: PAT participants may have background in "hackathons", plugfests, etc.

CAT Connect**at**hon

IHE formal interoperability testing event for published profiles; includes independent monitors, test management tooling; published results

Assumption: PAT participants may have background in formal test invents

Second ... Profiles? Why?!

IHE Profile

A technical specification that *constrains* a set of general open standards for application to a specific interoperability or integration need (described by a set of use cases) ¹

Why profiles?

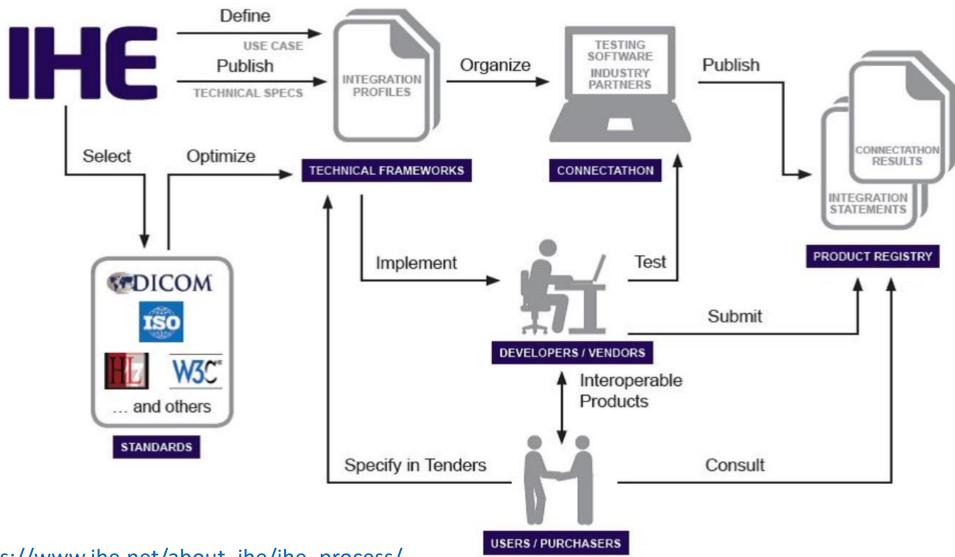
As users and implementers agree how to use standards to address specific integration needs, optionality must be minimized, coordinated usage of multiple standards considered, and national / regional allowances factored

Isn't a well architected family of standards sufficient?

The needs of an implementation community are often both narrower than the set of possible applications that are covered by foundational / core standards, such as ISO/IEEE 11073 SDC, as well as broader in scope requiring additional standards to be integrated.



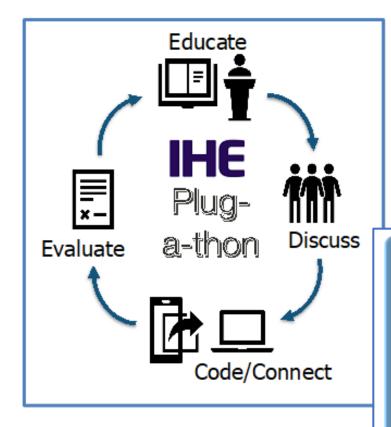
IHE Process Overview



Source: https://www.ihe.net/about_ihe/ihe_process/



IHE Plug-a-thon (PAT) Basics



IHE Testing Events – Pathway to CA & Certification!

HE Plug-a-thons

- Rigor: Low

- Iterative testing process based on

use cases

- Similar to Hackathon
- Standards and code in development
- Code will change on-site

HE Connectathons

- Rigor: Medium

- Structured, Peerto-Peer testing
- Conformance
- Multiple standards
- Established standards
- Code might change on-site

HE Conformity Assessment

- Rigor: High

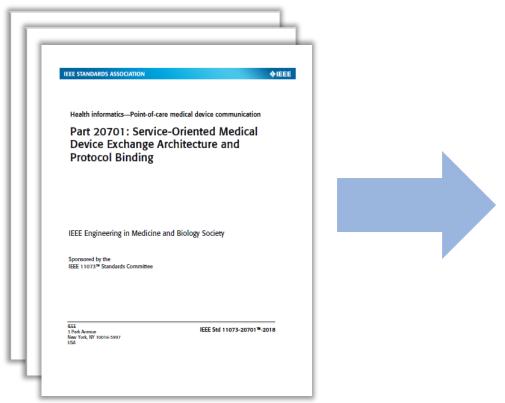
- Selected IHEProfiles in FinalText
- ISO accredited test labs
- Strict version controls of product & tools



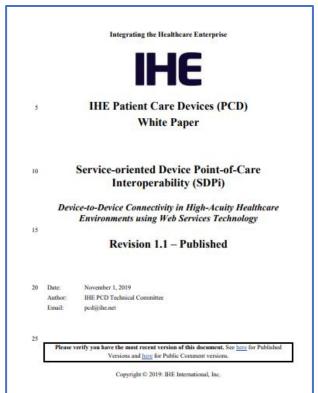
<Add a simple CAT overview slide / graphic>

- SDC / SDPi Distinctives ... SOA / DPI / PnT / SOMDA ... WS*
- Drives CA & Tooling challenges!

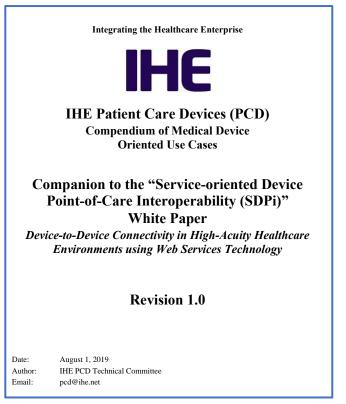
Orientation Tour: IHE TF & SDPi Profiles



2019 SDPi paper established rationale and strategy for profiling ISO/IEEE 11073 SDC in IHE Technical Framework profile specifications.



https://www.ihe.net/uploadedFiles/Documents/PCD/IHE_PCD_WP_SDPi_Rev1-1_Pub_2019-11-01.pdf

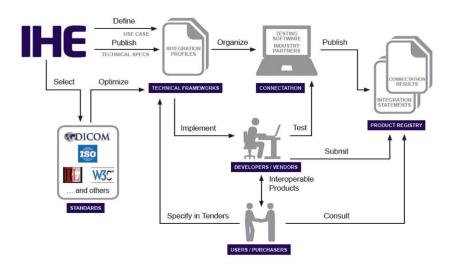


https://wiki.ihe.net/index.php/SDC@IHE_ White_Paper



<from Use Cases/Scenarios to Profiles to Test Scripts>

- Profiles constrained to test scripts (full circle see IHE Process overview)
- Link to detail in SDPi profiles / supplement (from narrative to Gherkin)
- Drives profile requirement => test plan / test cases / scripts ...



Orientation Tour: IHE TF & SDPi Profiles

5 Structure of the IHE Technical Frameworks

The IHE Technical Frameworks define specific use of established standards. They are updated annually and maintained regularly through the identification and correction of errata. The Technical Framework volumes are augmented by supplements and change proposal documents as described in Section 8. The latest versions of Technical Framework documents are always available at http://www.ihe.net/Technical Frameworks.

The Technical Framework for each domain consists of several volumes:

- Volume 1 provides high-level overviews of each profile, the use cases it addresses, the actors involved, and references to the Transactions and Content Modules used.
- Volume 2 provides detailed technical descriptions of each IHE Transaction.
- Volume 3 provides detailed technical descriptions of each IHE Content Module.
- Volume 4 describes National Extensions to the Technical Framework such as countryspecific code sets or national patient privacy requirements.

Source: https://www.ihe.net/uploadedFiles/Documents/Templates/IHE_TF_General_Introduction.pdf

Orientation Tour: Example – IHE DEC Profile

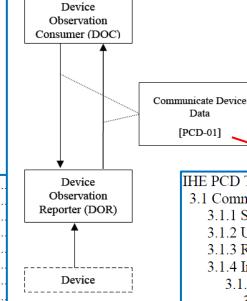
IHE

Integrating the Healthcare Enterprise

IHE Patient Care Device (PCD) Technical Framework

> Volume 1 IHE PCD TF-1 **Profiles**

TF-1 Profile calls out TF-2 Transaction(s) – may add usage constraints



[PCD-01]

IHE

Integrating the Healthcare Enterprise

IHE Patient Care Device (PCD) **Technical Framework**

> Volume 2 IHE PCD TF-2 **Transactions**

3 Device Enterprise Communication (DEC) Profile 3.1 DEC Actors and Transactions.... 3.1.1 Patient Demographics – Recommended Transactions 3.2 DEC Profile Options 3.3 DEC Overview 3.3.1 Note on Patient Identification 3.4 DEC Use Cases 3.4.1 Standard Use Cases 3.4.1.2 Case DEC-2: Communicate validated periodic DEC data to EMR/EHR 16

> **TF-2 Common Transaction Message Elements are Specified Once in Appendices**

NOTE: Only message profiling specifications included, relying on references to base message standards for all additional details.

IHE PCD Transactions	12
3.1 Communicate PCD Data [PCD-01]	12
3.1.1 Scope	
3.1.2 Use Case Roles	
3.1.3 Referenced Standards	
3.1.4 Interaction Diagrams	
3.1.4.1 DOR communicates with DOC	
3.1.4.1.1 PCD-01 Communicate PCD Data (ORU^R01^ORU R	01) static definition
	14
3.1.4.1.2 Trigger events	
3.1.4.1.3 Message Semantics	16
3.1.4.1.4 Expected Actions	16
3.1.5 Security Considerations.	

B.4 NTE - Notes and Comment Segment 84

Appendix A Mapping ISO/IEEE 11073 Domain Information Model to HL7



Orientation Tour: Example – IHE DEC Profile

Integrating the Healthcare Enterprise



IHE Patient Care Device (PCD)
Technical Framework

Volume 3
IHE PCD TF-3
Semantic Content

TF-3 Bindings only generally referenced in DEC profile & DEV-01 Transaction

General semantic content profiling specifications

Device Specializations –
Apply General to –
Specific types

٠.			
1	3	Overview of device semantic content profiling	
		3.1 General device content considerations.	
		3.1.1 Hierarchical containment tree information	1
		3.1.2 Device semantics & controlled terminologies	1
		3.1.3 Overview of the ISO/IEEE 11073 nomenclature/terminology	1
		3.1.4 Private terms and scope	. 1
		3.1.5 New or non-specified terms	
		3.1.6 Episodic vs. periodic data updates	1
		3.1.7 Alternative units of measurement mapping	1
		3.2 Alert and event semantics	
		3.3 Body site semantics	1
		3.4 Basic data type specifications	1
		3.5 MDS semantics	2
		3.6 VMD semantics	2
		3.7 Channel semantics	2
1	4	Reserved	2
	5	Reserved	. 2
	6	Reserved	. 2
1	7	Device specialization content modules	. 2
		7.1 Device: Infusion Pump	. 2
		7.1.1 Containment tree	. 2
		7.1.2 Channel: Source	. 2
		7.1.3 Channel: Delivery	. 2
		7.2 Device: Ventilator	. 2
		7.2.1 Containment tree	. 2
		7.2.2 Channel: Ventilator	. 3
		7.2.3 Channel: Airway Pressure	. 3
		7.2.4 Channel: Airway Volume	. 3
		7.2.5 Channel: Airway Breath Pattern	. 3
		7.3 Device: Physiologic Monitor	
		7.3.1 Containment tree	3
1			

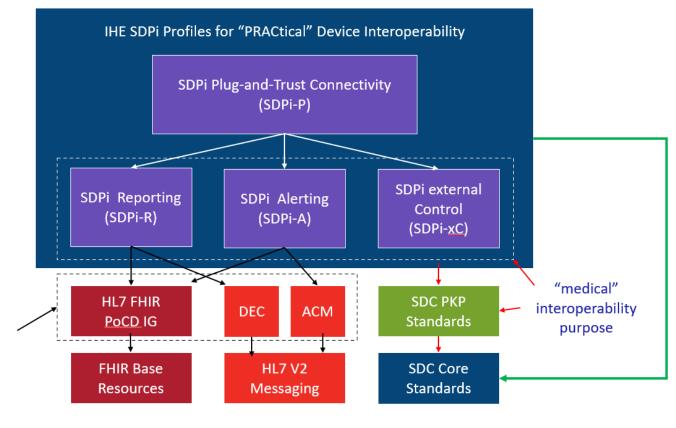
Orientation Tour: IHE TF & SDPi Profiles

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

- **✓** Four profile specifications:
 - SDPi-P for Plug-and-Trust Interoperability
 - SDPi-R for Reporting Medical Information
 - SDPi-A for Alerting
 - SDPi-xC for External Controlling
- IHE "Gateway" Actors Defined

✓ Three IHE DEV TF Volumes:

- TF-1 Profiles / use cases / actors / ...
- TF-2 Transactions / MDPWS messaging
- TF-3 BICEPS content modules / device specializations



See draft SDPi Supplement Word Document for additional content detail & outline (https://github.com/IHE/sdpi-fhir/tree/master/SDPi%20%20Supplement/SDPi%20Rev%201.0)

Orientation Tour: From Volume 1 to 2 to 3

Transactions

SDPi-P Profile Profile Actors & Transactions & Content Modules Profile Actor Options Profile Overview (Concepts & Use Cases) SES Considerations SDPi-Reporting Profile ... SDPi-Alerting Profile ... SDPi-xControl Profile ... M:N Profiles &

Appendix A: Requirements Management for Plug-n-Trust Interoperability

Appendix B: ISO/IEEE 11073 SDC Requirements Coverage <including ISO/IEEE 11073 SDC ICS tables>

Appendix C: Device Point-of-care Interoperability Use Cases <including Gherkin detail & links to Compendium etc.>

SDPi TF Supplement Vol.2 Transactions DEV-23 Announce Network Presence

Scope
Actor Roles & Referenced Standards
Messages (at BICEPS level w/ links to Appendix A)
Protocol Requirements

SES Considerations

MDPWS Message

Detail in Appendix

DEV-24 *Discover Network Participants*

DEV-44 Invoke Medical Control Services

Appendix A: ISO/IEEE 11073 SDC / MDPWS Message Specifications (Normative)

SDC/BICEPS to SDC/MDPWS Message Specifications
Messages for BICEPS Discovery Model
<specific MDPWS message links>
<example exchanges & library calls>

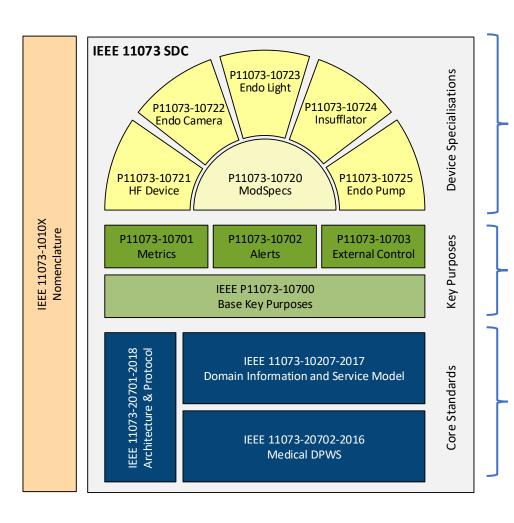
See SDPi Supplement (1.0) document in the IHE sdpi-fhir Github repository for full details.

Orientation Tour: From Volume 1 to 2 to 3

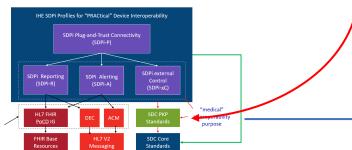
SDPi TF Supplement Vol.1 Integration Profiles SDPi TF Supplement Vol.3 Content Modules SDPi-P Profile **DEV Semantic Content Modules** Profile Actors & Transactions & Content Modules **General Device Content Considerations** Profile Actor Options Profile Overview (Concepts & Use Cases) SDC / BICEPS Semantic Content **SES Considerations DEV Specialization Content Modules Device: Infusion Pump** SDPi-Reporting Profile ... SDC / BICEPS Content Module **SDPi TF Supplement Vol.2 Transactions** Device: Ventilator ... Bindings -Device: Physiologic Monitor ... **DEV-23** Announce Network Presence **General & Specific** Devices: Surgery ... (new) Scope Devices: Anesthesia ... (new) Actor Roles & Referenced Standards Devices: Dialysis ... (new) Messages (at BICEPS level w/ links to Appendix A) **Protocol Requirements SES Considerations DEV-24** *Discover Network Participants*

See SDPi Supplement (1.0) document in the IHE sdpi-fhir Github repository for full details.

Orientation Tour: From 11073 SDC to SDPi



- ✓ Initially, map to **TF-3 DEV** Content Modules / Device Specializations
- ✓ Can include content before specializations published
- ✓ Eventually, may inform IHE DEV Device-Specific Profiles
- ✓ Pre-publication, will reference in SDPi SES sections (TF-1, -2 & -3)
- ✓ Post-publication, can fully integrate requirements into SDPi (incl. TF-1 Appendix B conformance)
- ✓ NOTE: (4) profiles are aligned with these (4) key purposes
- ✓ SDC/BICEPS (-10207) Referenced in all (3) volumes (TF-1, -2 & 3)
- ✓ SDC/SOMDA (-20701) Referenced in TF-1 & TF-2
- ✓ SDC/MDPWS (-20702) Referenced primarily in TF-2 (esp. Apdx. A)



<add SES in SDPi TF slide here>



Orientation Tour: IHE Profile Actor Diagrams

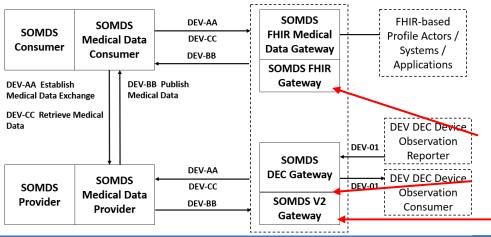
IHE Actor

"information systems or components of information systems that produce, manage, or act on health information"

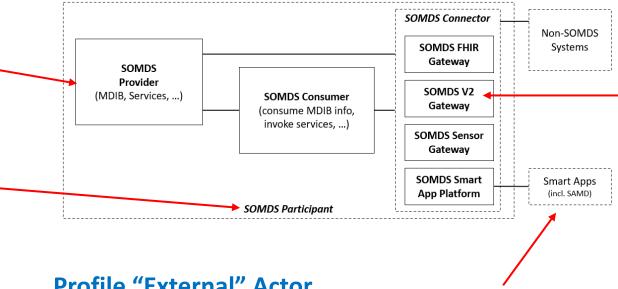
IHE Abstract Actor

Specifies behavior that is shared across / inherited by a set of IHE Actors (actor name in italics & dotted line around concrete actors)

SDPi-A Actor Diagram



SDPi-P Actor Diagram



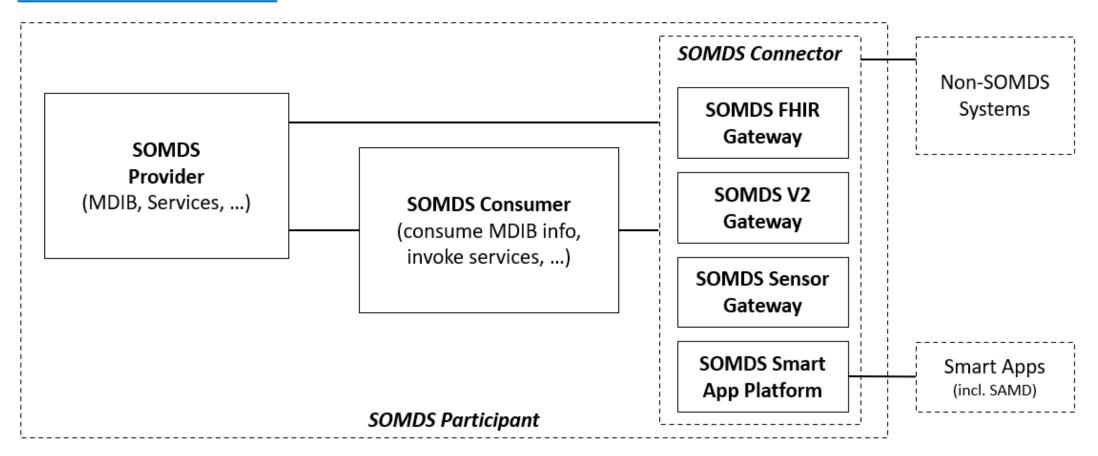
Profile "External" Actor

Indicates actors that are outside the scope of the profile but interact with profile actors (dotted box) Note: actor may be defined in other profiles

IHE Grouped Actor

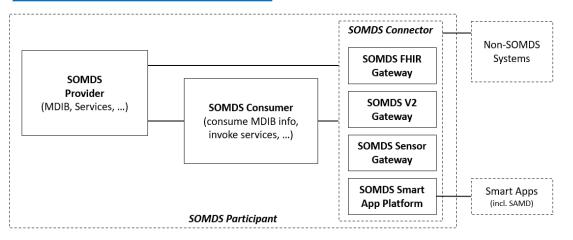
Indicates actors that integrate with other actors to provide their functionality (two rectangles joined side-by-side)

SDPi-P Actor Model



NOTE: SOMDS Participant actors may be devices, system applications, SAMD, "smart apps" ...

SDPi-P Actor Model



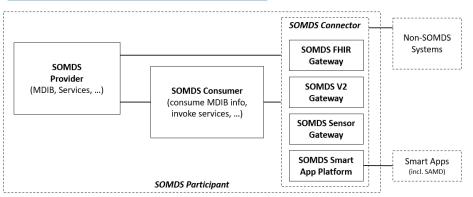
See SDPI Profile Option Specifications section for detail on each

SDPi-P Options (partial)

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
Current	Safe Data Transmission Option	DEV TF-1 10.2.2 Safe Data Transmission Option
Proposed -	Compact Representation Option	DEV TF-1 10.2.3 Compact Representation Option
Options	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	Streaming Option	DEV TF-1 10.2.1 Streaming Option
(See Note 1)	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

SDPi-P Actor Model



SDPi-P Transactions

See SDPI Transaction Specifications section for detail on each

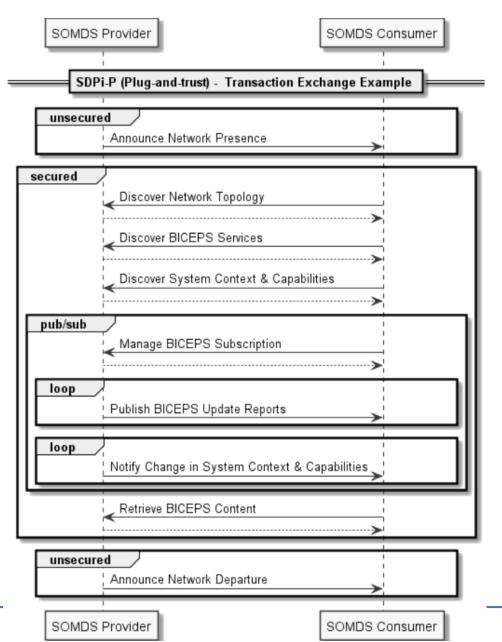
Table 10.1-1: SDPi-P Profile - Actors and Transactions

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
\neg	Publish BICEPS Update Reports	Initiator	R	DEV TF-2:3.29
	Retrieve BICEPS Content	Responder	0	DEV TF-2:3.30
	Set Provider State	Responder	0	DEV TF-2:3.31
	Retrieve Archive Data	Responder	0	DEV TF-2:3.32
	Retrieve Localization Information	Responder	0	DEV TF-2:3.33
	Announce Network Departure	Initiator	R	DEV TF-2:3.34
SOMDS Consumer	Announce Network Presence	Consumer	0	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



Example of an SDPi-P transaction exchange ...

NOTE: Definition of "BICEPS" abstraction level for SDPi transactions.

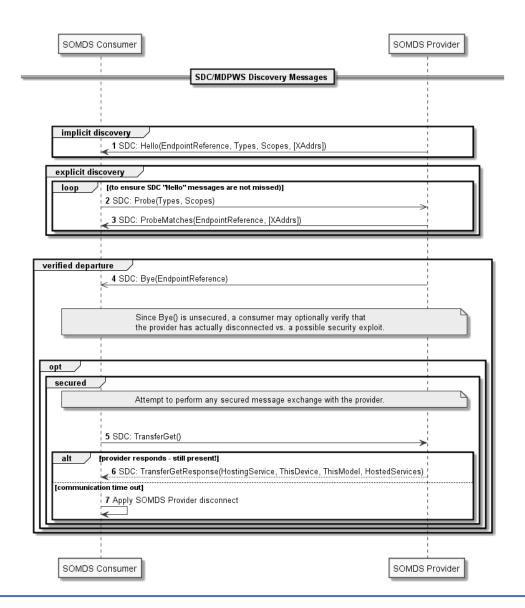


For a full set of profilespecific MDPWS sequence exchanges, see:

https://confluence.hl7.org/display/GP/SDPi+Technical+Framework+Models



Example of an SDPi-P transaction MDPWS sequence



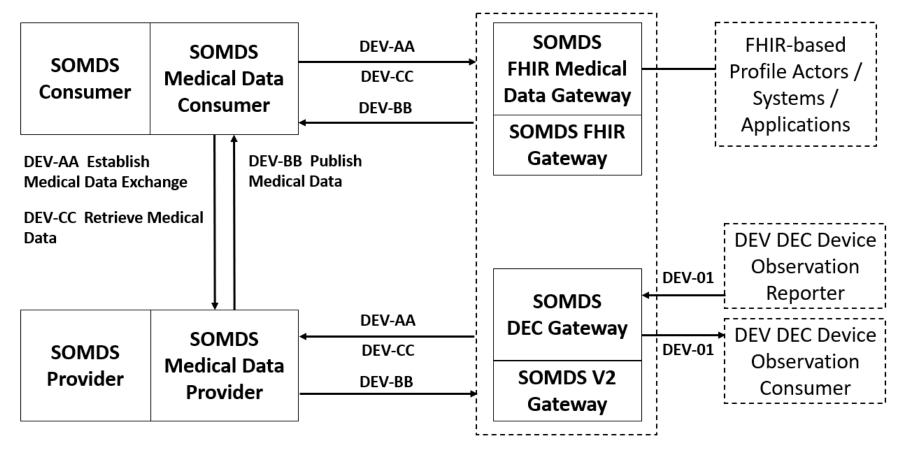
For a full set of profilespecific MDPWS sequence exchanges, see:

https://confluence.hl7.org/display/GP/SDPi+Technical+Framework+Models



Orientation Tour: SDPi-R (Reporting)

SDPi-R Actor Model



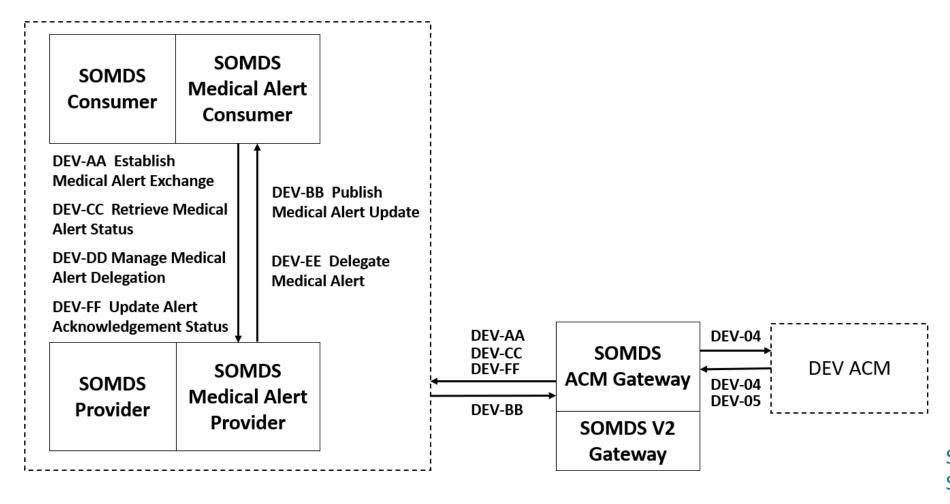
NOTE: Transactions are drawn to the dotted box around the gateways, indicating that they can be either Provider and / or Consumer SDPi-R actors

See SDPI Transaction
Specifications section for detail on each



Orientation Tour: SDPi-A (Alerting)

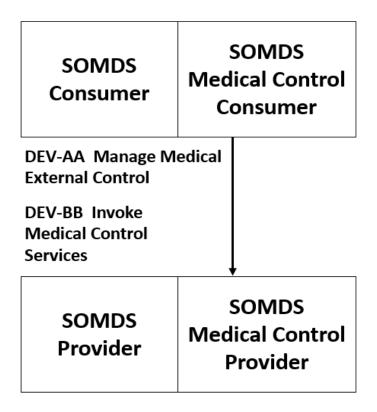
SDPi-A Actor Model



See SDPI Transaction Specifications section for detail on each

Orientation Tour: SDPi-xC (External Control)

SDPi-xC Actor Model



See SDPI Transaction
Specifications section for detail on each

SDPi-P Option Specifications

SDPi-P Options: Streaming

Define related:

- transactions,
- MDPWS sequences,
- SOMDA Constraints,
- Content Module Bindings
- SDPi 1.0 or subsequent?
- ...
- Transactions are the same as for SDPi-R -> only transport layer is different!
- Out of scope for SDPi 1.0 securing the waveform channel is extra-challenging; adds unnessecary complexity with questionable performance benefit

- 1. Secured waveforms in 1.0 (default) ... MDPWS out-of-the-box;
- 2. Consider unsecured UDP streaming for 1.x (upon request only)
- 3. OR as an alternative transport HTTP/2 gRPC in 1.x
- ADD UML version of <u>THIS SDPi-R</u> & add to Appendix A Waveform Service section

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	Streaming Option	DEV TF-1 10.2.1 Streaming Option
(See Note 1)	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

SDPi-P Options: Safe Data Transmission

Define related:

- transactions,
- MDPWS sequences,
- SOMDA Constraints,
- Content Module Bindings
- SDPi 1.0 or subsequent?
- ...
- Transactions are the same except for the message payload
- Out of scope for SDPi 1.0 unless a party claims
 need safe data transmission is conceptually fuzzy
 and brittle. Would require very specific profiling

- 1. Message Payload is the only difference ... & relies on XML;
- 2. @ gRPC is fundamentally different & challenges (e.g., not using xpath)
- 3. Wait for -10703 for specific value proposition (incremental over baseline) +
- 4. May use this or alternative to current MDPWS (ambiguity)

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
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SOMDS Consumer	Streaming Option	DEV TF-1 10.2.1 Streaming Option
(See Note 1)	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

SDPi-P Options: Compact Representation

Define related:

- transactions,
- MDPWS sequences,
- SOMDA Constraints,
- Content Module Bindings
- SDPi 1.0 or subsequent?
- •
- Transactions are the same except for the message serialization
- There are no serious EXI implementations on the market; SDPi should recommend/require use of HTTP compression; which is not optimal but widely adopted

- 1. EXI is a "beast" of a spec; SDC libraries do not support little market support either
- 2. HTTP/2 + gRPC would address out of the box
- 3. HTTP/1.1 ... good enough , but ...gzip for example FOR SDPi 1.0 for every transaction w/ option; in every transaction section
- 4. NOTE: Sequence of serialization & compression of message content varies per approach
- 5. NOTE: A key application need is for performance at scale e.g., streaming 100's of beds with 12 lead per bed
- 6. Consider whole SOMDS running in "compressed" mode
- 7. Add note to MDPWS Appendix A + as TBD @ EXI use; call out the HTTP/1.1 approach

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

Actor	Option Name	Reference
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	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

SDPi-P Options: Patient Context Management

Define related:

- transactions,
- MDPWS sequences,
- SOMDA Constraints,
- Content Module Bindings
- SDPi 1.0 or subsequent?
- ...
- I guess I need more *context* here (hihi). Let's talk about that on Wednesday

- 1. Defer (?) to SDPi 1.x what is needed NOW vs. when connecting to enterprise applications
- 2. MUST do something in 1.0 to ensure safety of all exchanges IOW what is IN this option vs. must be supported by the base SDPi-x profiles? In SDPi-P vs. –R / -A / -xC require it
- 3. What use cases NOW will rely on this? A Patient-Device Association Management Source of Truth within a System of Products / SOMDS implementation
- 4. What will be baked into the related PKP standards? the preconditions are baked into the PKP, not how you can make sure the data is the needed Quality (e.g., reliability)

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

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	Ensemble Participation Option	DEV TF-1 10.2.7 Ensemble Participation Option
SOMDS Consumer	Streaming Option	DEV TF-1 10.2.1 Streaming Option
(See Note 1)	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

SDPi-P Options: Archive Service

Define related:

- transactions,
- MDPWS sequences,
- SOMDA Constraints,
- Content Module Bindings
- SDPi 1.0 or subsequent?
- •
- I can prepare best-practice sequences;
 nevertheless the Archive Service as specified in BICEPS does not cover all variations of archival access – backfilling yes, full closure no

- 1. No real experience / use case that drives the message exchanges ...
- 2. Therefore, no way to VALIDATE that what is supported is sufficient
- 3. Supports 5-10 minutes / *off-line period* for "backfilling" ... network connection loss only no Provider restart etc.
- 4. Not 100+ hours of full disclosure ... this would require a different persistence layer & ...
- 5. Relationship with (MDIRA/ICE) DataLogger Actor specification?
- 6. SDPi 1.0 will be narrow Provider off-line backfilling & SDPi 1.x / MDIRA for Full-Disclosure of a forensics data logging capability TBD

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	Streaming Option	DEV TF-1 10.2.1 Streaming Option
(See Note 1)	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

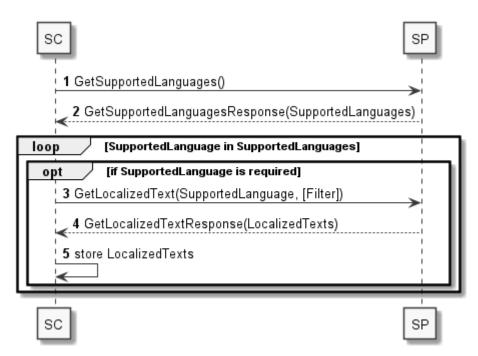


SDPi-P Options: Localization Service

our productive implementation

Define related:

- transactions,
- MDPWS sequences,
- SOMDA Constraints,
- Content Module Bindings
- SDPi 1.0 or subsequent?
- •



2020.11.04

I can prepare best-practice sequences by inspecting

- 1. Change option name to Language Service
- 2. Use in SDPi 1.0
- 3. NOTE: different from LocationContext support
- 4. Example message content is the interesting part!

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
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(See Note 1)	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

SDPi-P Options: Ensemble Participation

Define related:

- transactions,
- MDPWS sequences,
- SOMDA Constraints,
- Content Module Bindings
- SDPi 1.0 or subsequent?
- ...

2020.11.04

- 1. Need to establish INITIAL base use cases for SDPi 1.0 ...
- 2. This is closely related to the SFC definition / management
- 3. Identify basic use of SystemContext objects for this use
- 4. Basic "fixed" workplace ... establish base sequence / approach w/ constraints
- 5. NOTE: SES & clinical workflow / personnel "understanding" is key
- 6. TBD use of mobile devices or multi-patient (spot check) devices, etc.
- 7. Related to Patient-Device Association (Patient Context) Option
- 8. Advanced could factor in:
 - Mobile devices
 - Patient centric devices (e.g., blood gas measurement or telemetry)
 - CLC actors
 - ...

This is a hard nut to crack – we'll have general rules

 We don't have any experiences right now, just some learnings from Dräger's CAP leveraging the location context... much room for development here

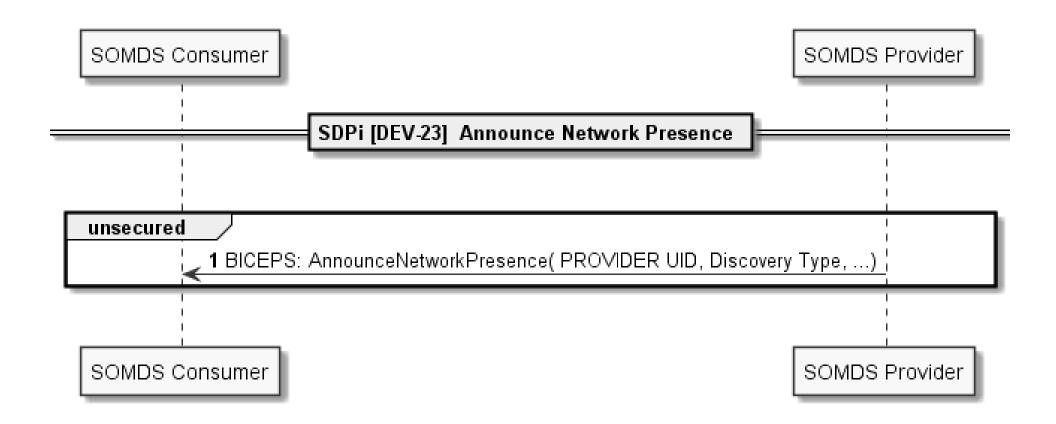
in PKP, but the magic happens beyond that ruleset.

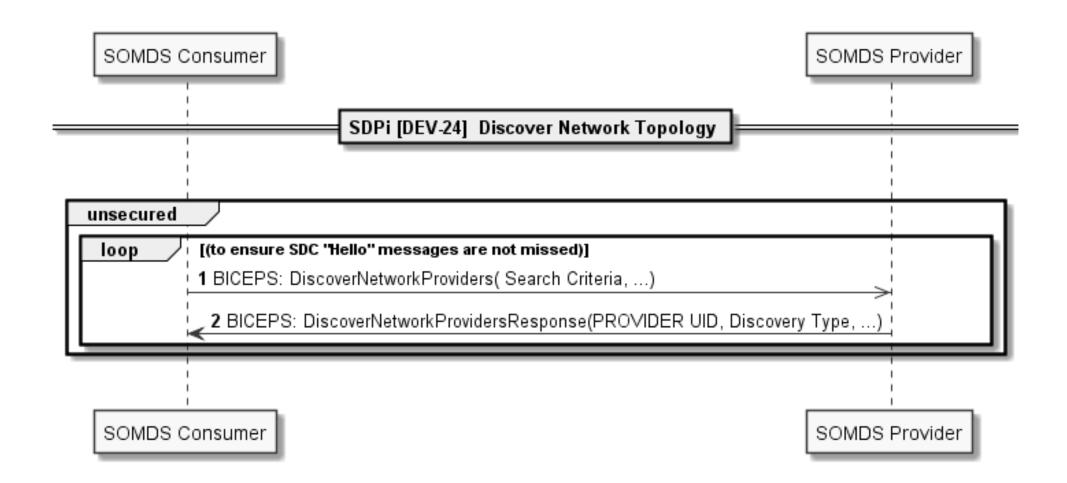
Table 10.2-1: SDPi-P – Actors and Options

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
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	Patient Context Management Option	DEV TF-1 10.2.4 Patient Context Management Option

SDPi TF-2 Transactions & MDPWS Messaging

SDPi TF-2: DEV-23

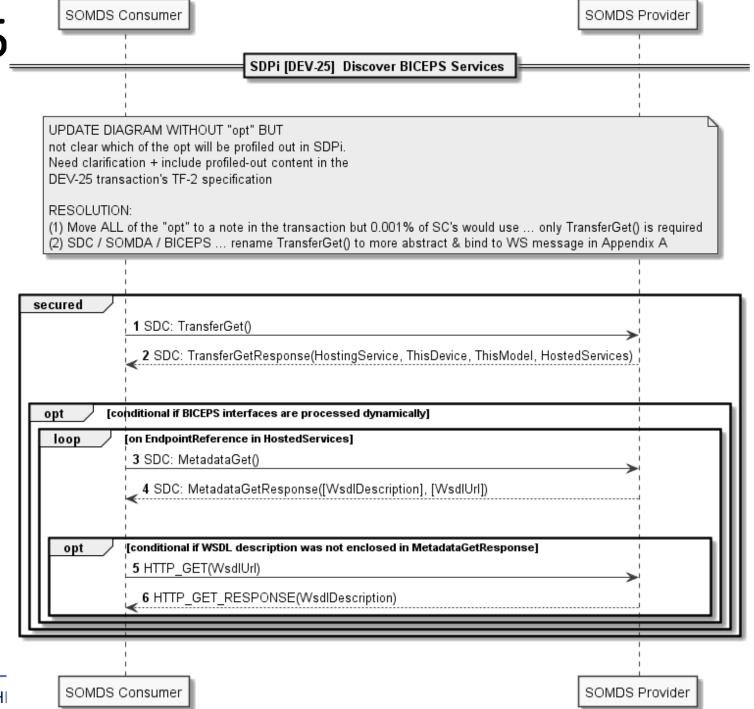


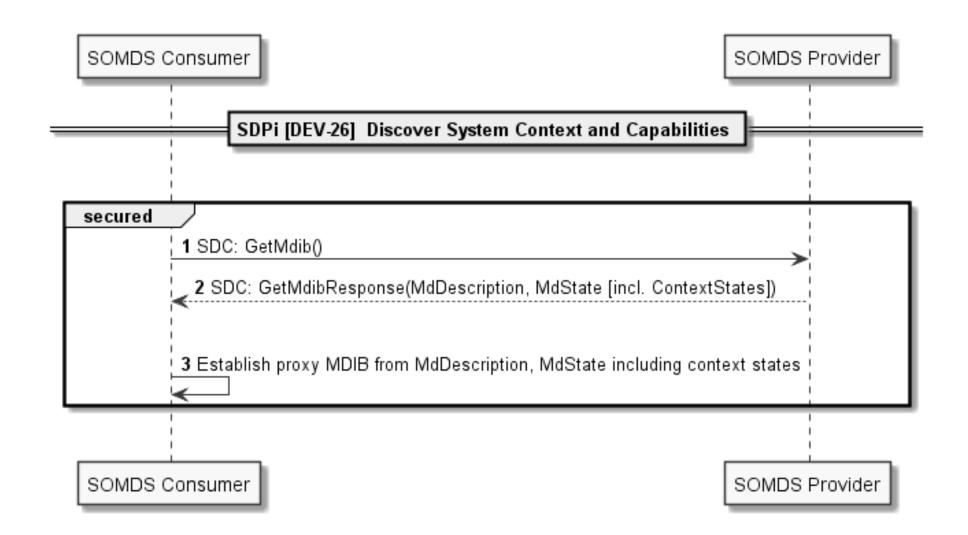


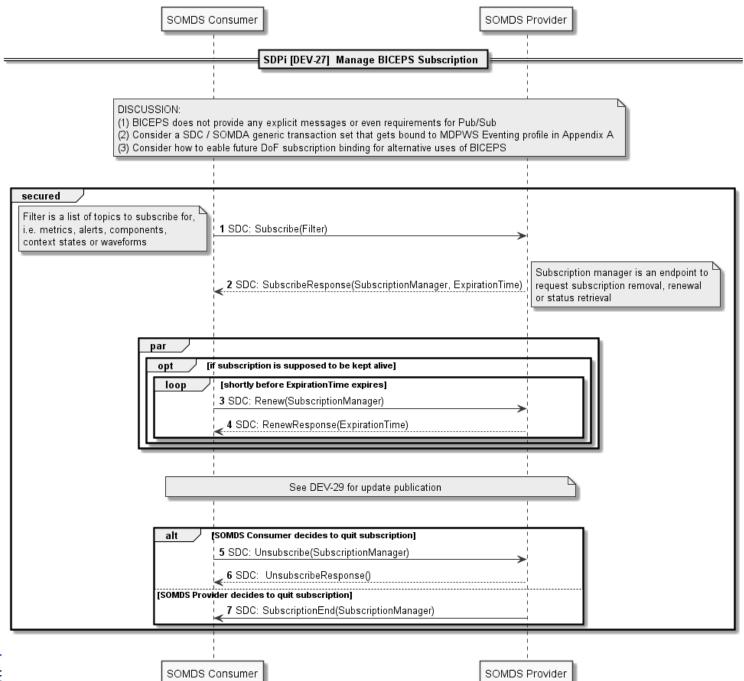
- Both opts are unnecessary if the BICEPS interface is known a-priori which it is partially → we might need some additional profiling to unambigiously determing BICEPS service actions. I'll double-check that
- Only highly dynamic implementations would require to resolve hosted services and WSDLs – unlikely for medical devices

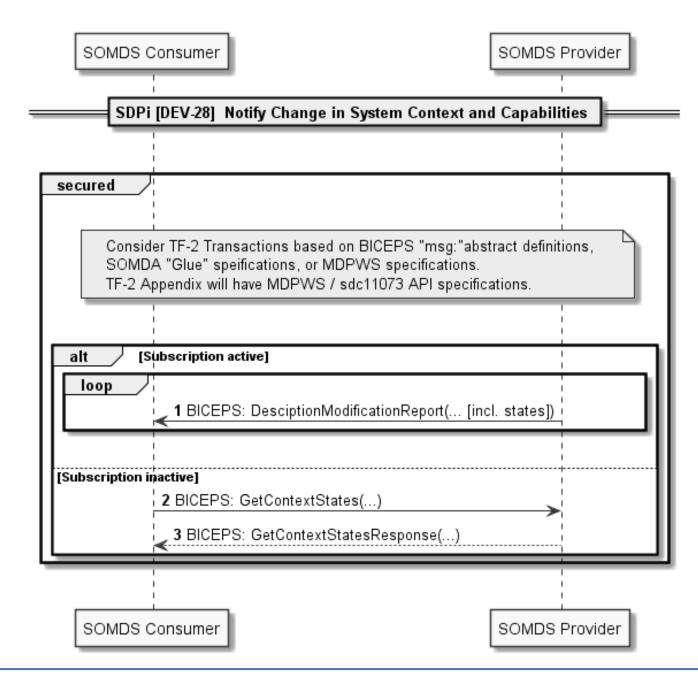
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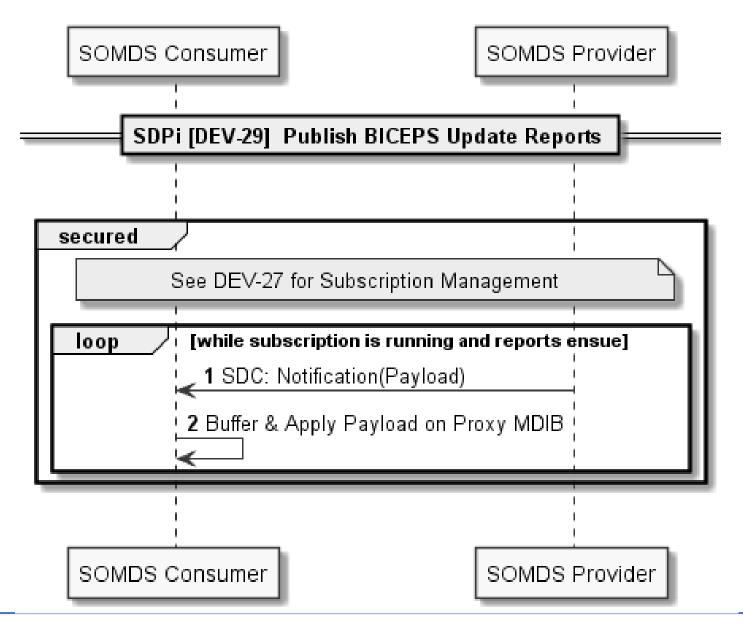
- 1. For SDPi: Normatively reference WSDL file from <XYZ> (e.g., IHE Github IO?) ADD to repo etc.
- 2. Make WSDL file mandatory for all SDPi Providers
- 3. ACTION: David G. will update WSDL to remove optionality & ambiguity − cleaner & nicer ☺
- 4. Include note & future option (???) for retrieving WSDL for each service IF Provider & services are new.

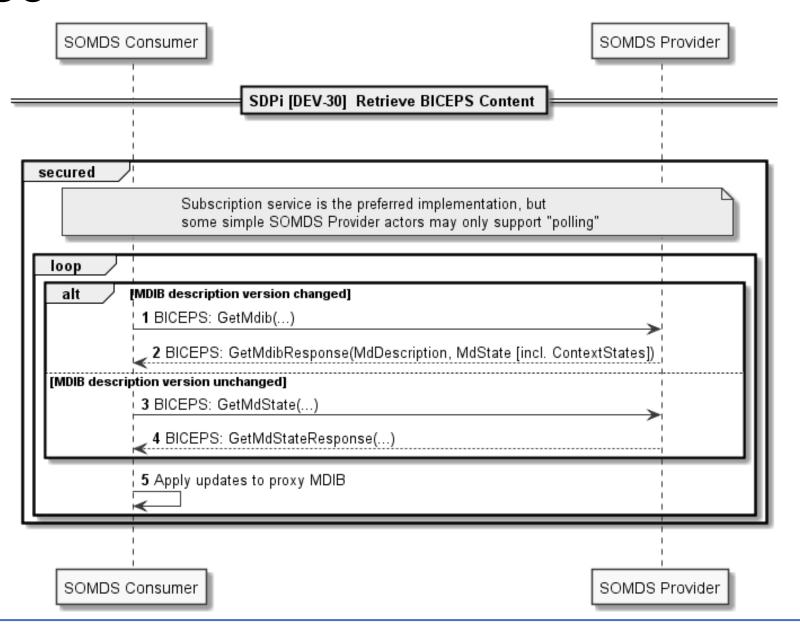


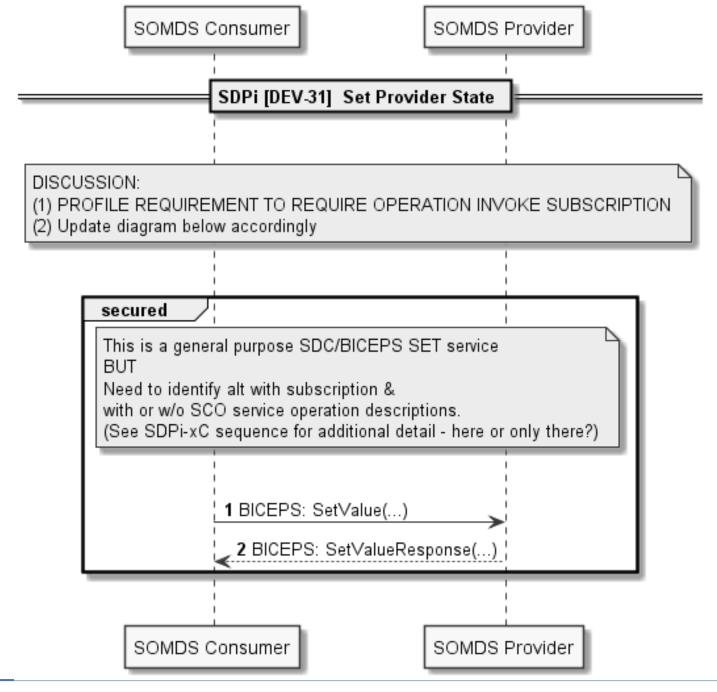








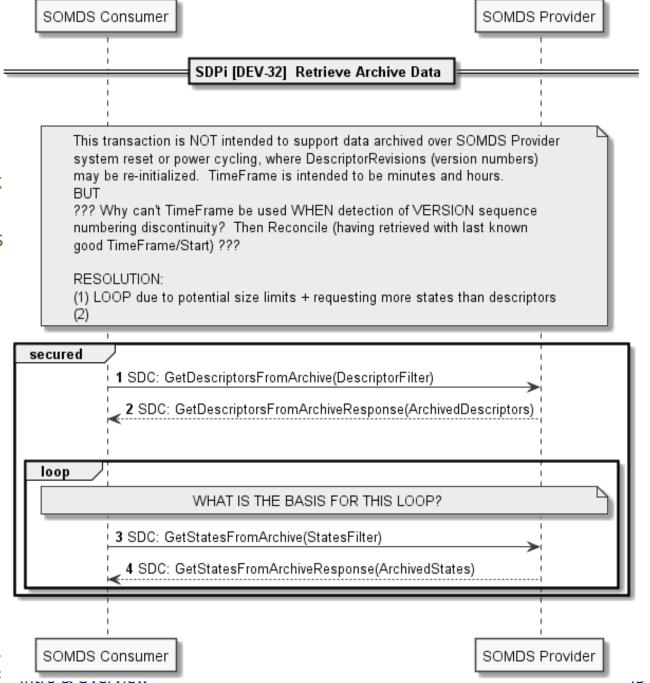


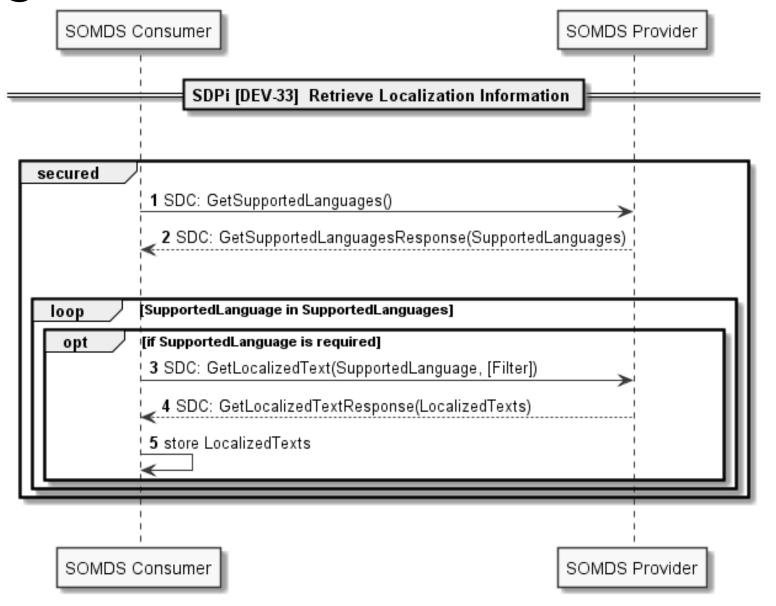


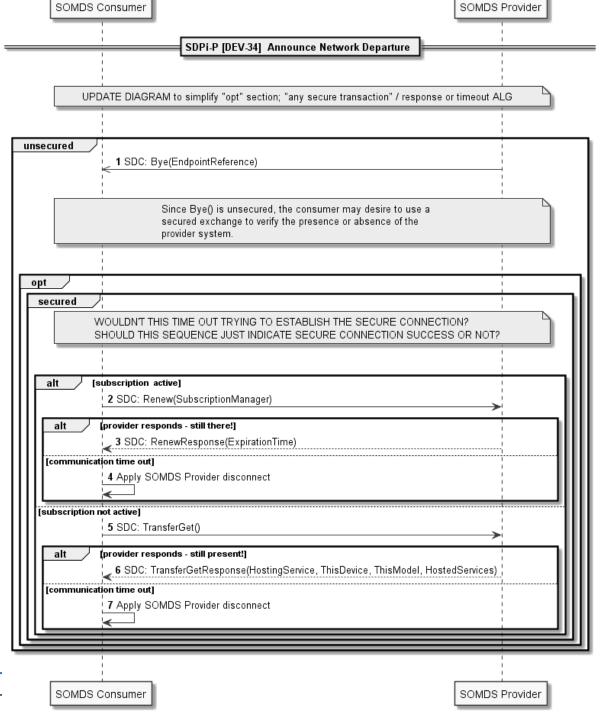
- The loop is based on try-and-error one could request "nested intervals" (is that the right term, I only know the German one... and the translators suck sometimes.
- The whole ArchiveService as already mentioned is wonky and insufficient. Hard to profile, but partially better with HTTP/2

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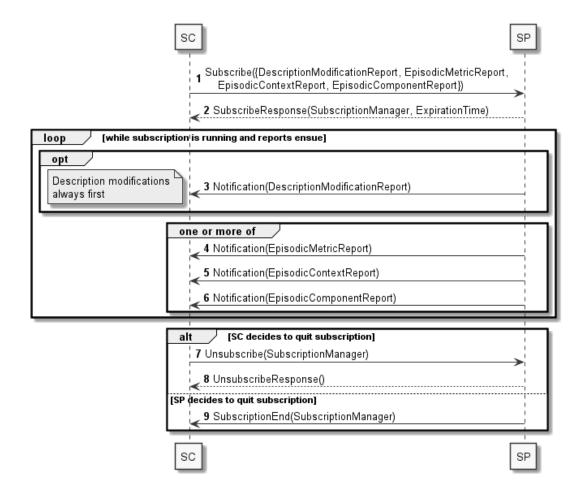
- 1. Sync with the earlier *Option slide context & constraints*
- 2. Descriptors will have time frame (e.g., 4 hours) ...
- 3. States may be overrun by high frequency data
- 4. Strategy: Approximation by try/fail/try again @ ½ size
- 5. Challenge is staying under the 4MB limit ...
- 6. No support now for a "stream" of archive data only request / response and need to approximate in REAL TIME optimal data frame size.
- 7. NOTE: At HTTP/2 provides simple stream for bi-directional exchange
- 8. Archive 2.0 service may address / or alternative transport etc.



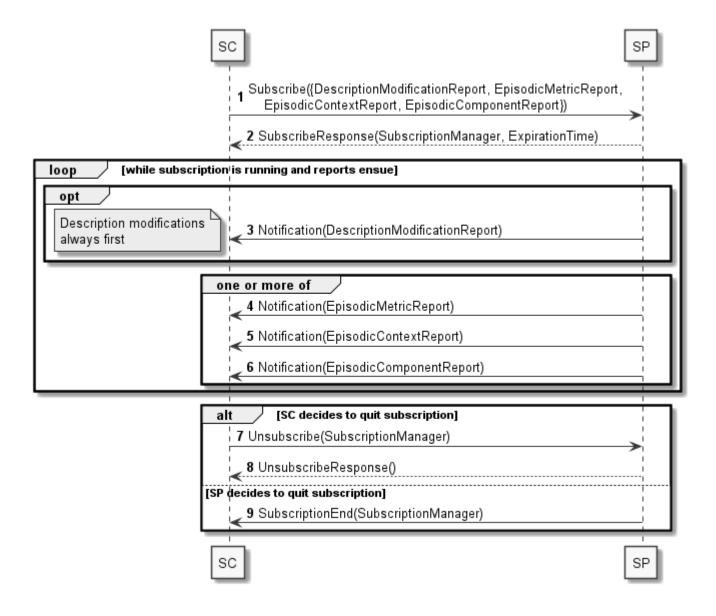




3.35 Establish Medical Data Exchange [DEV-35]



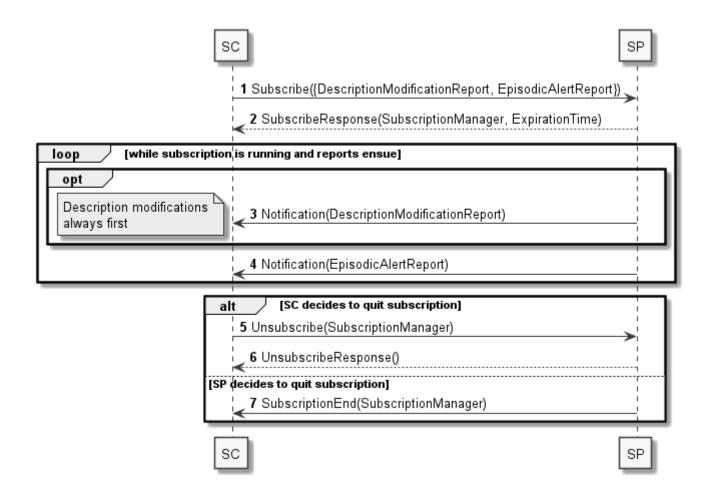
3.36 Publish Medical Data [DEV-36]



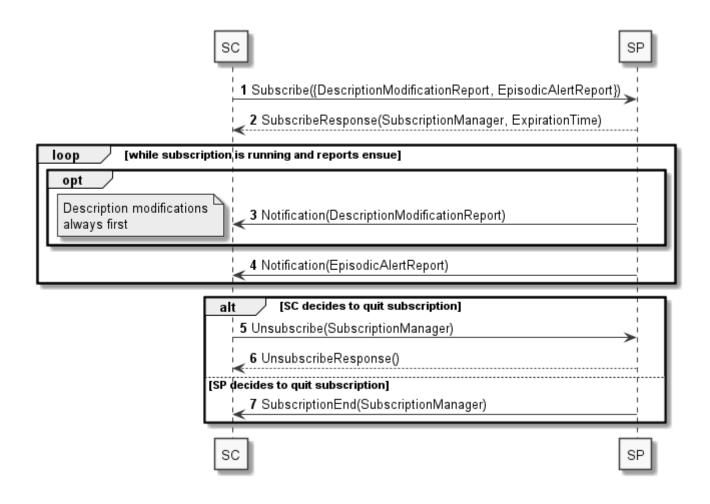
3.37 Retrieve Medical Data [DEV-37]

Note this is a polled retrieve vs. pub/sub eventing

3.38 Establish Medical Alert Exchange [DEV-38]



3.39 Publish Medical Alert Update [DEV-39]



3.40 Retrieve Medical Alert Status [DEV-40]

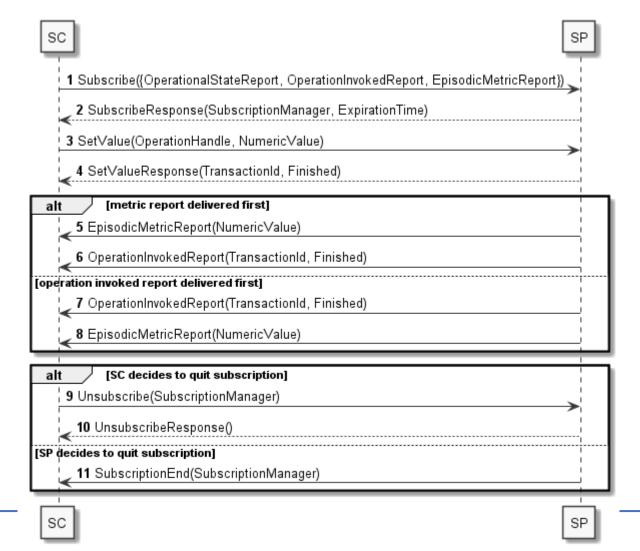
3.41 Manage Medical Alert Delegation [DEV-41]



3.42 Delegate Medical Alert [DEV-42]

3.43 Update Alert Acknowledgement Status [DEV-43]

3.44 Manage Medical External Control [DEV-44]



3.45 Invoke Medical Control Services [DEV-45]

SDPi TF-3 SDC/BICEPS Content Modules & Specializations

SDPi TF-3: SDC/BICEPS Content Modules - General

Topics to be covered in the General BICEPS semantic profiling section:

- 1. Link to TF-1 SDPi-P Content Modules & same for other profiles?
- 2. Extension model
- 3. General (all device specializations)
- 4. SDPi 1.0 or subsequent?
- 5. ... (see subsections in outline)

SDPi TF-3: SDC/BICEPS – Infusion Pumps

Topics to be covered in the BICEPS infusion pump profile section



SDPi TF-3: SDC/BICEPS — Physiologic Monitor

Topics to be covered in the BICEPS physiologic monitor profile section



SDPi TF-3: SDC/BICEPS — Ventilator

Topics to be covered in the BICEPS ventilator profile section

SDPi TF-3: SDC/BICEPS — Surgery Devices

Topics to be covered in the BICEPS surgery devices profile section

Additional Information



Real-world Narrative: Isolation ICU

Pandemic Patients in an Isolation ICU – EUA Remote Control Narrative

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

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

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

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



Real-world Narrative: Isolation ICU

Pandemic Patients in an Isolation ICU – Scenarios?

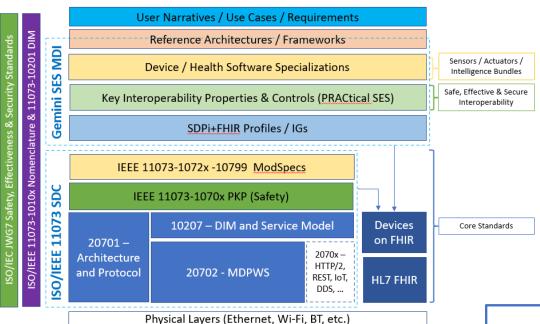
For the purposes of this PAT, what scenarios are of greatest interest?

- 1. Participant Discovery / Security / Service Exchange?
- 2. Patient / Participant Association (Patient & Location & Workflow context establishment)?
- 3. Alert delegation / Alert Limit Adjustment / Alert confirmation / Silence ...?
- 4. Which devices, systems, applications? Monitors, vents, pumps, central ... others?
- 5. Integration with EHR or other system?
- 6. Use of IHE-based FHIR profiles for integration with non-SDPi / non-SDC SOMDS systems?
- 7. ...

Other Use Cases / Scenarios? (e.g., surgery focused)

Hanging Gardens: After SDPi 1.0 ...

NOTE: Profile Titles are notional – hopefully useful too!



Devices-In-Care (PDP) Profile

Device Specialization Profile

Surgery PoC Profile

ICU PoC Profile

MDIRA ICE Profile

SOMDS@home Profile

IHE (Official) Profile Types:

Transport, Content, Workflow Or a combination of all (3)

Other types?

Architecture (SOA, MDIRA, SDC,? Single domain / multi-domain?

