





# 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 C**onnect**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) <sup>1</sup>

### Why profiles?

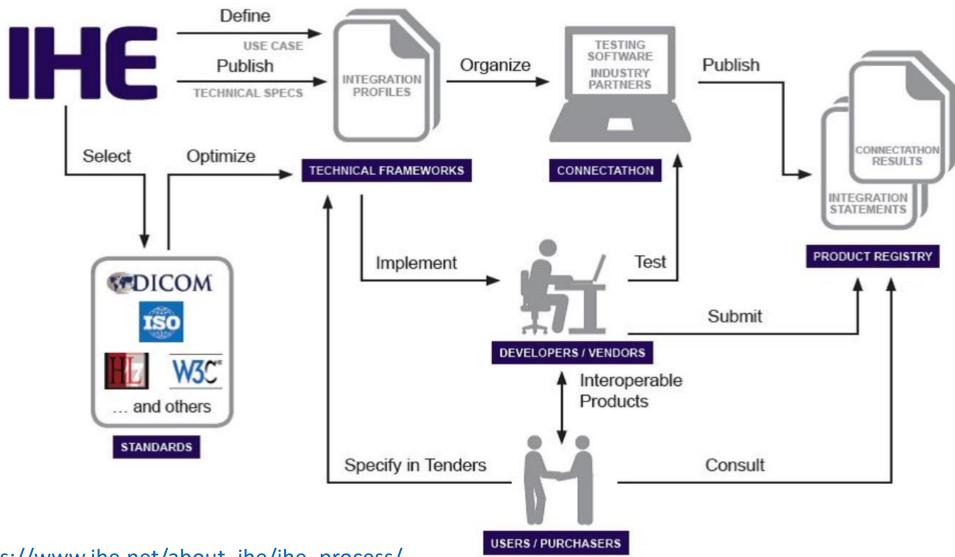
As users and implementers agree how to use standards to address specific integration needs, optionality must be minimized, coordinated usage of multiple standards considered, and national / regional allowances factored

## 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.



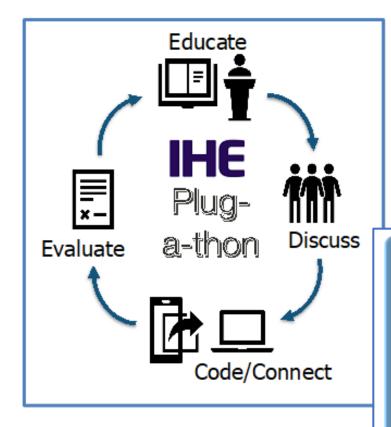
# **IHE Process Overview**



Source: <a href="https://www.ihe.net/about\_ihe/ihe\_process/">https://www.ihe.net/about\_ihe/ihe\_process/</a>



# 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

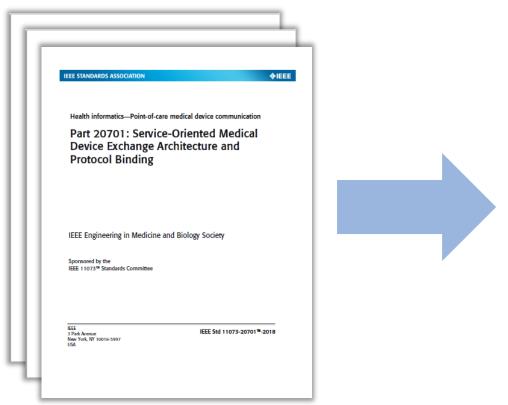
HE Conformity Assessment

- Rigor: High

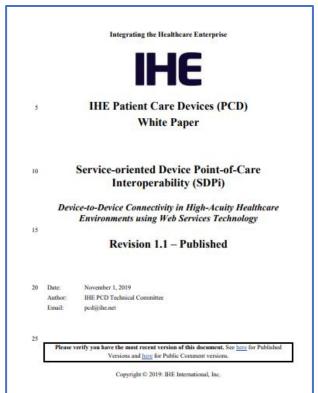
- Selected IHEProfiles in FinalText
- ISO accredited test labs
- Strict version controls of product & tools



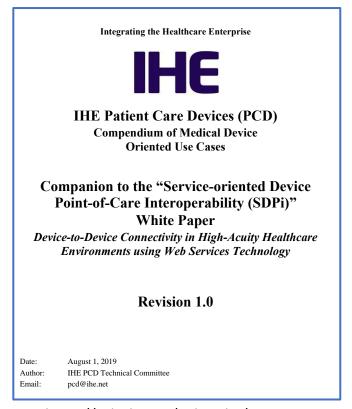
# Orientation Tour: IHE TF & SDPi Profiles



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



# 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 <a href="Section 8">Section 8</a>. The latest versions of Technical Framework documents are always available at <a href="http://www.ihe.net/Technical Frameworks">http://www.ihe.net/Technical Frameworks</a>.

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

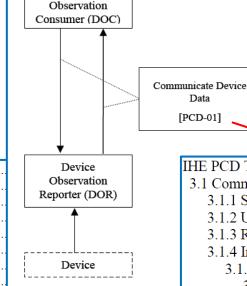
IHE

IHE Patient Care Device (PCD) Technical Framework

Integrating the Healthcare Enterprise

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

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



[PCD-01]

Device

IHE Patient Care Device (PCD) Technical Framework

Integrating the Healthcare Enterprise

IHE

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]	
3.1.1 Scope	
3.1.2 Use Case Roles	
3.1.3 Referenced Standards	
3.1.4 Interaction Diagrams	13
3.1.4.1 DOR communicates with DOC	
3.1.4.1.1 PCD-01 Communicate PCD Data (ORU^R01^ORU	
	 14
3.1.4.1.2 Trigger events	
3.1.4.1.3 Message Semantics	16
3.1.4.1.4 Expected Actions	
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

1	3	Overview of device semantic content profiling	
ı		3.1 General device content considerations	1
ı		3.1.1 Hierarchical containment tree information	10
ı		3.1.2 Device semantics & controlled terminologies	12
ı		3.1.3 Overview of the ISO/IEEE 11073 nomenclature/terminology	1
ı		3.1.4 Private terms and scope	1
ı		3.1.5 New or non-specified terms	1
ı		3.1.6 Episodic vs. periodic data updates	14
ı		3.1.7 Alternative units of measurement mapping	1
ı		3.2 Alert and event semantics	1
ı		3.3 Body site semantics	19
ı		3.4 Basic data type specifications	19
ı		3.5 MDS semantics	2
ı		3.6 VMD semantics	2
		3.7 Channel semantics	2
	4	Reserved	20
ı	5	Reserved	20
ı	6	Reserved	20
1	7	Device specialization content modules	2′
ı		7.1 Device: Infusion Pump	
ı		7.1.1 Containment tree	
ı		7.1.2 Channel: Source	2
ı		7.1.3 Channel: Delivery	
ı		7.2 Device: Ventilator	29
ı		7.2.1 Containment tree	
ı		7.2.2 Channel: Ventilator	
ı		7.2.3 Channel: Airway Pressure	
ı		7.2.4 Channel: Airway Volume	
		7.2.5 Channel: Airway Breath Pattern	
		7.3 Device: Physiologic Monitor	3
		7.3.1 Containment tree	3

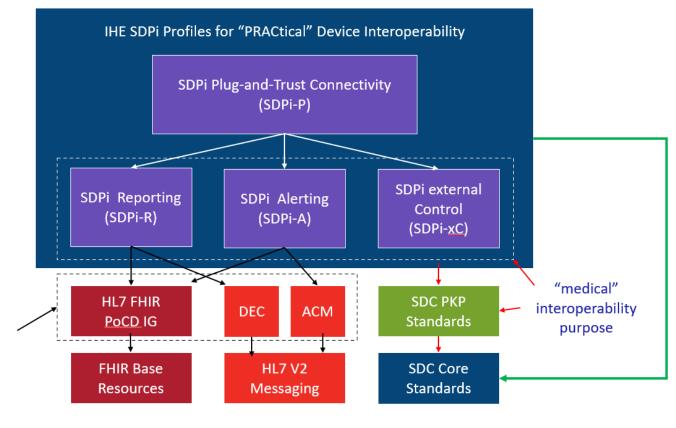
# Orientation Tour: IHE TF & SDPi Profiles

## 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

# 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 ... Transactions

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 <a href="mailto:linksuper-care"><including Gherkin detail & links to Compendium</a> etc.>

# 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 <a href="https://example.com/linearing-supplement">IHE sdpi-fhir Github repository</a> for full details.



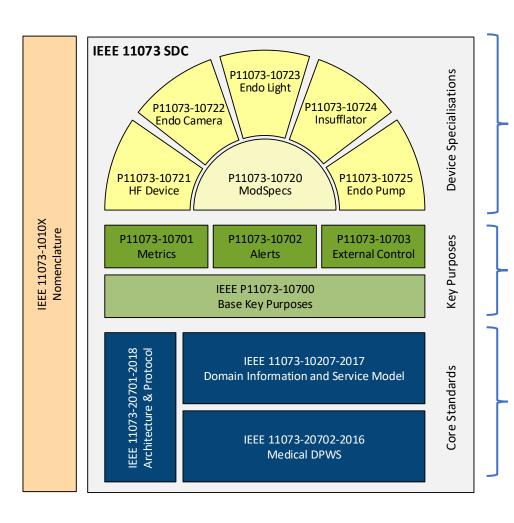
# Orientation Tour: From Volume 1 to 2 to 3

### **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 <a href="https://example.com/linearing-supplement">IHE sdpi-fhir Github repository</a> 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)

# Orientation Tour: IHE Profile Actor Diagrams

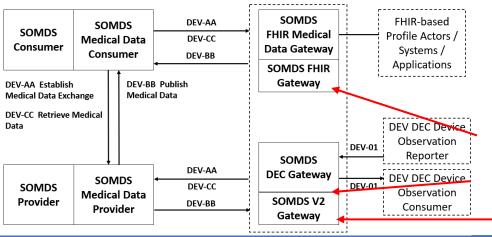
### **IHE Actor**

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

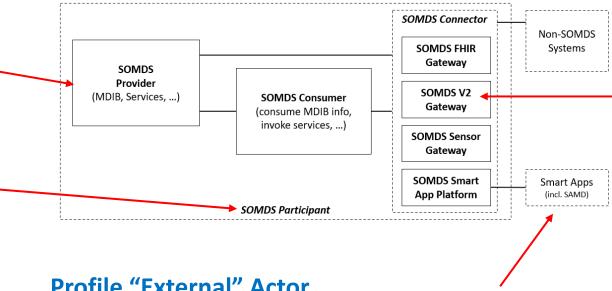
### **IHE Abstract Actor**

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



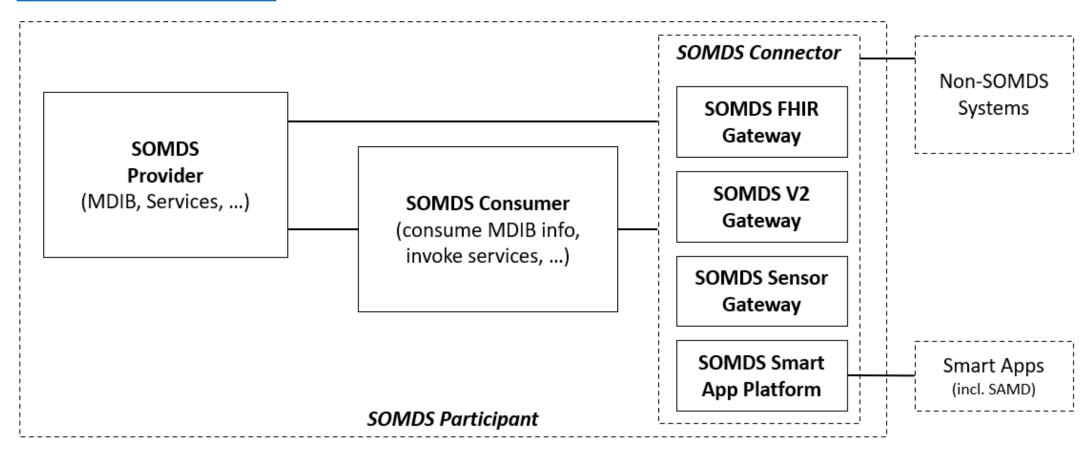
### **Profile "External" Actor**

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**

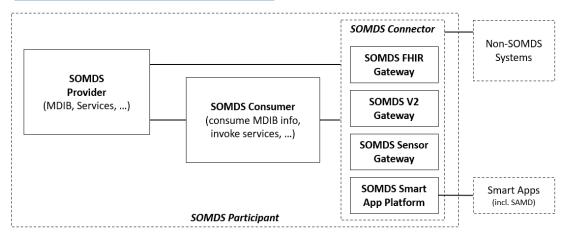
Indicates actors that integrate with other actors to provide their functionality (two rectangles joined side-by-side)

### **SDPi-P Actor Model**



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

### **SDPi-P Actor Model**



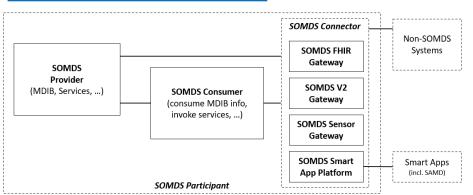
See SDPI Profile Option Specifications section for detail on each

### **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

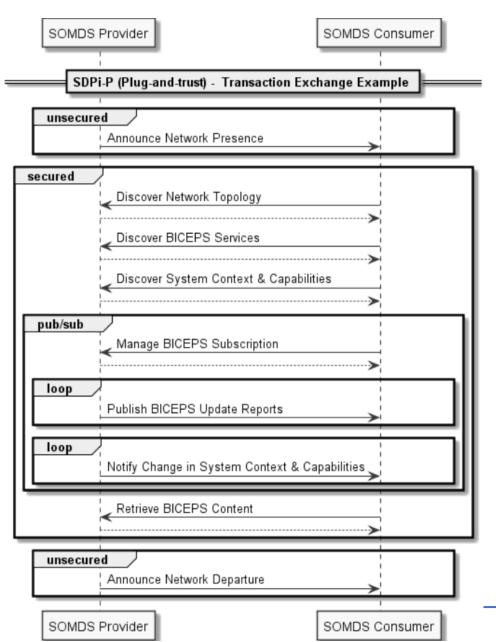
Table 10.1-1: SDPi-P Profile - Actors and Transactions

Actors	Transactions	Initiator or Responder	Optionality	Reference
OMDS Participant	[Editor's Note: TBD specific transactions / abstract actor!]			DEV TF-2:3.xyz
OMDS rovider	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
$\exists$	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
OMDS 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.

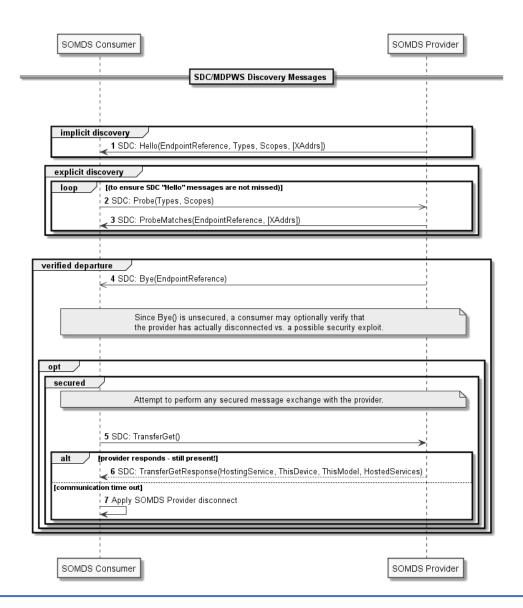


For a full set of profilespecific MDPWS sequence exchanges, see:

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



**Example of an SDPi-P transaction MDPWS sequence** 



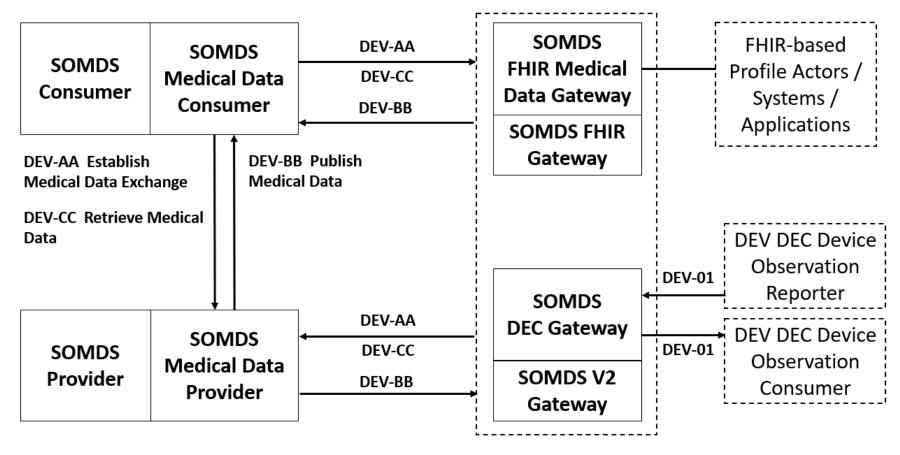
For a full set of profilespecific MDPWS sequence exchanges, see:

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



# Orientation Tour: SDPi-R (Reporting)

### **SDPi-R Actor Model**



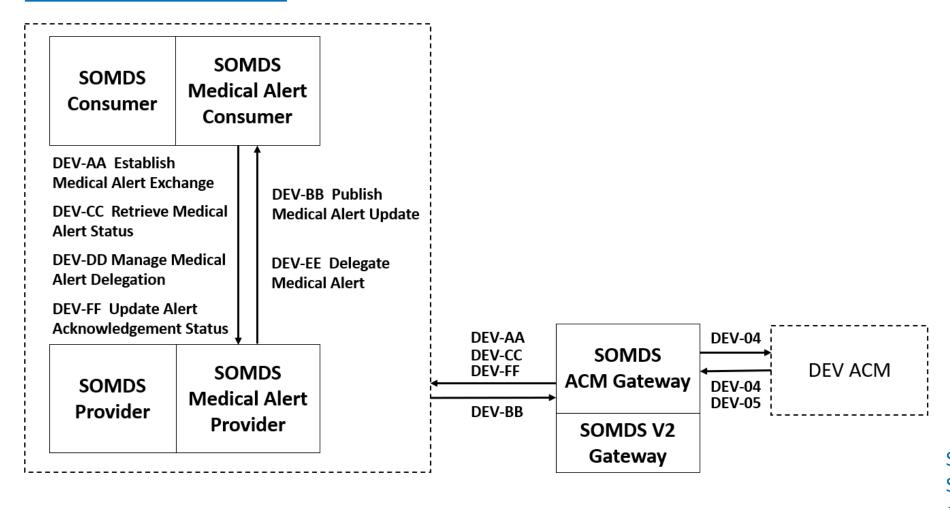
NOTE: Transactions are drawn to the dotted box around the gateways, indicating that they can be either Provider and / or Consumer SDPi-R actors

See SDPI Transaction
Specifications section for detail on each



# Orientation Tour: SDPi-A (Alerting)

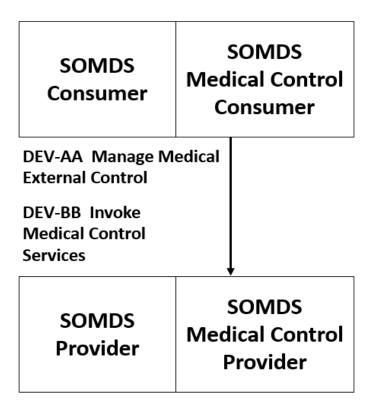
### **SDPi-A Actor Model**



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

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

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

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

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

Actor	Option Name	Reference
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	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
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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

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

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: Patient Context Management

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

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

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

# SDPi-P Options: Archive Service

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

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

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

# SDPi-P Options: Localization Service

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

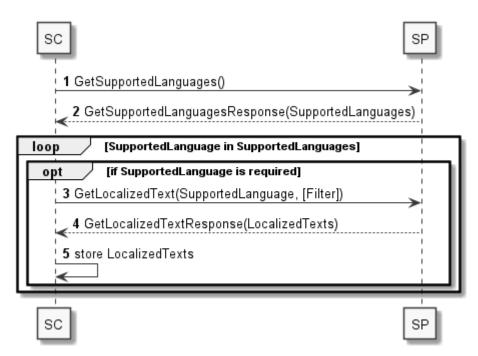


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	Patient Context Management Option	DEV TF-1 10.2.4 Patient Context Management Option
	Archive Service Option	DEV TF-1 10.2.5 Archive Service Option
	Localization Service Option	DEV TF-1 10.2.6 Localization Service Option
	Ensemble Participation Option	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

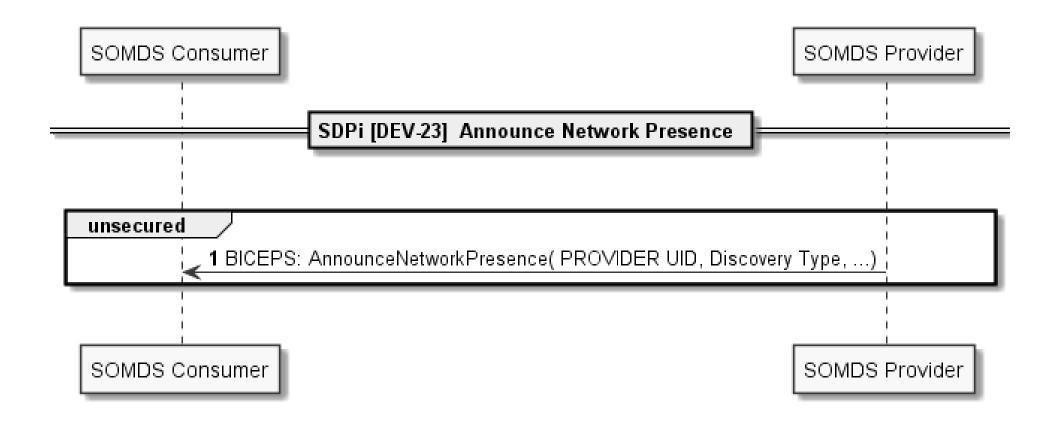
# SDPi-P Options: Ensemble Participation

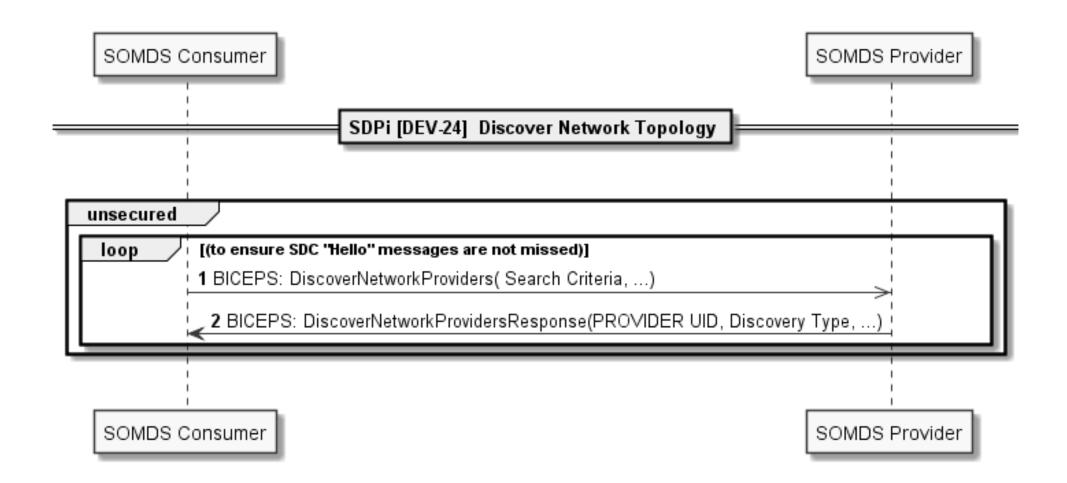
- transactions,
- MDPWS sequences,
- SOMDA Constraints,
- Content Module Bindings
- SDPi 1.0 or subsequent?
- •

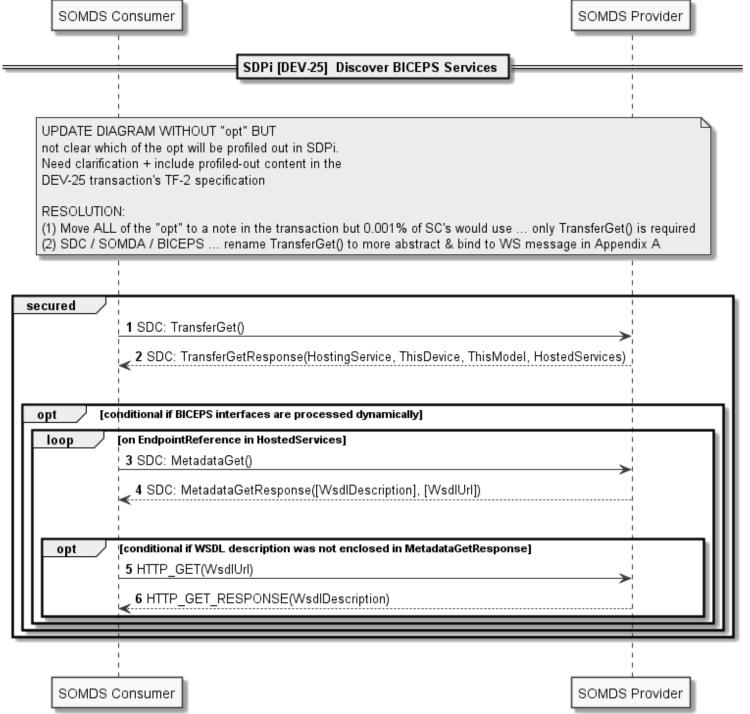
Table 10.2-1: SDPi-P - Actors and Options

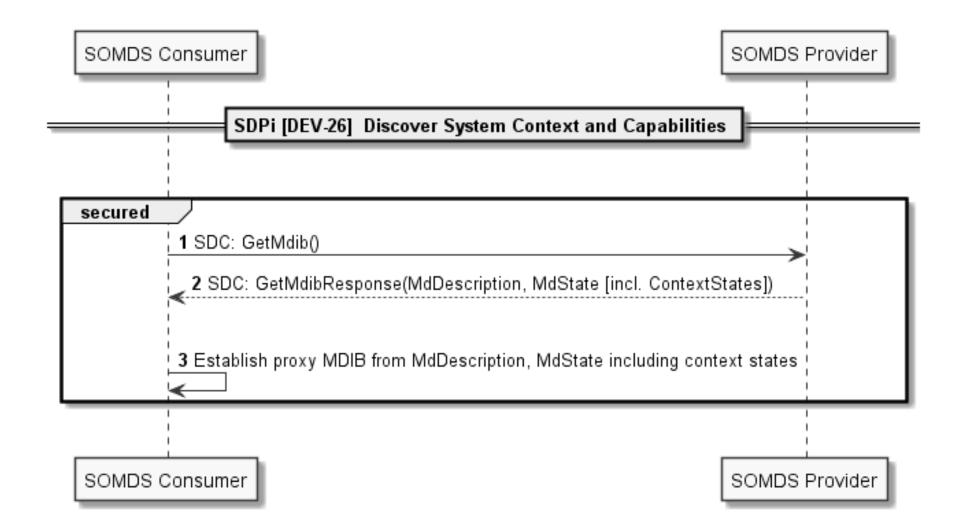
Actor	Option Name	Reference
SOMDS Participant	No options defined	
SOMDS Provider (See Note 1)	Streaming Option  [Editor's Note: Which can be waveform or other content; but is that in SDPi-R vs. here? And should we have a waveform option?  What about SCO or polling mode type support options?	DEV TF-1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

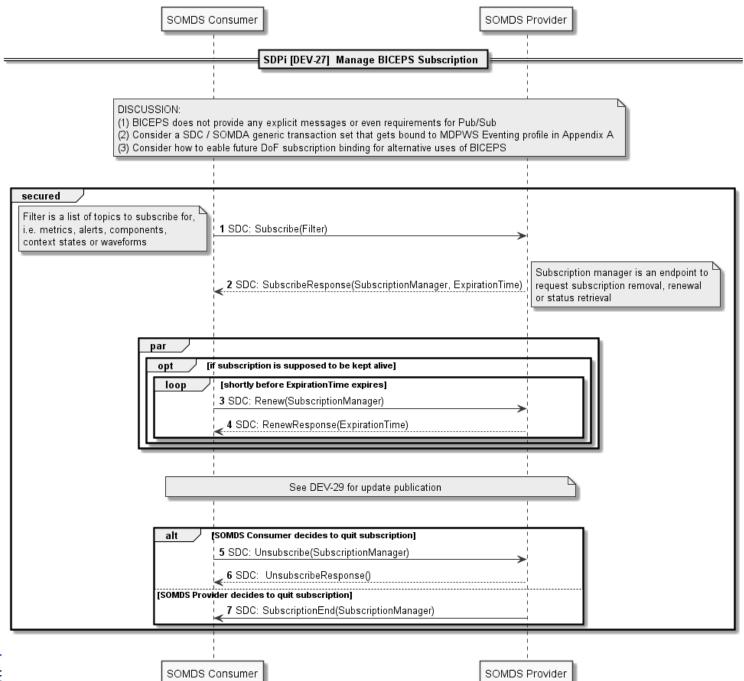
# SDPi TF-2 Transactions & MDPWS Messaging

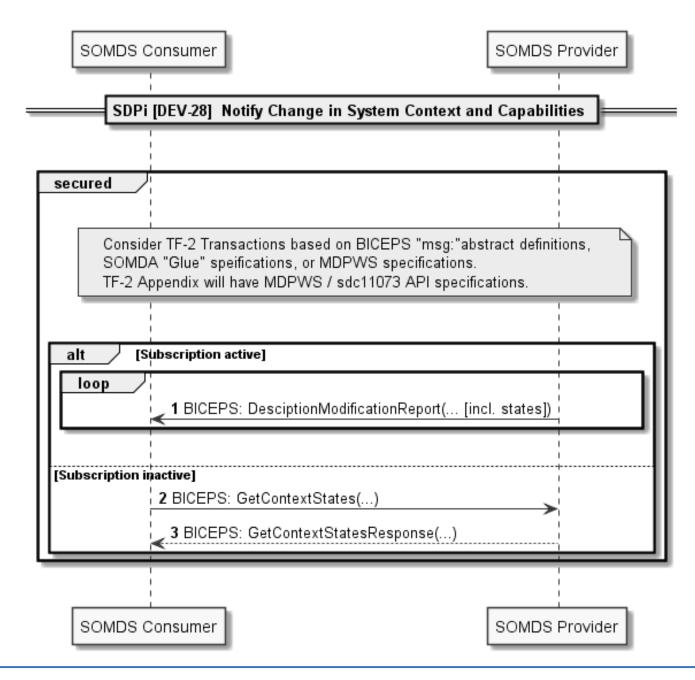


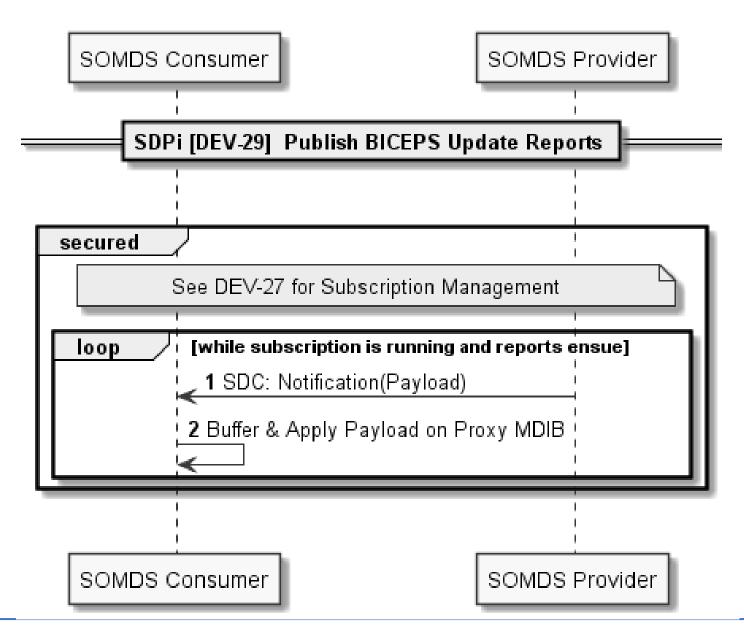


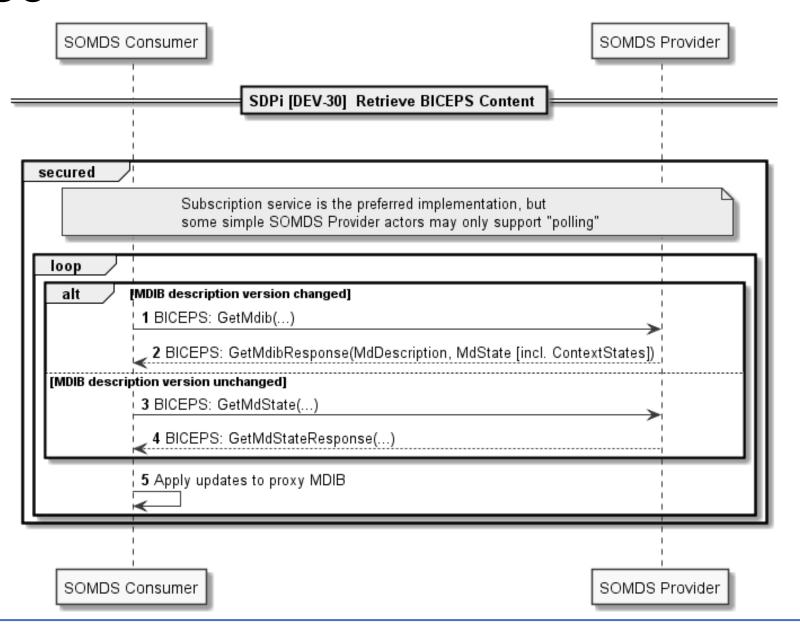


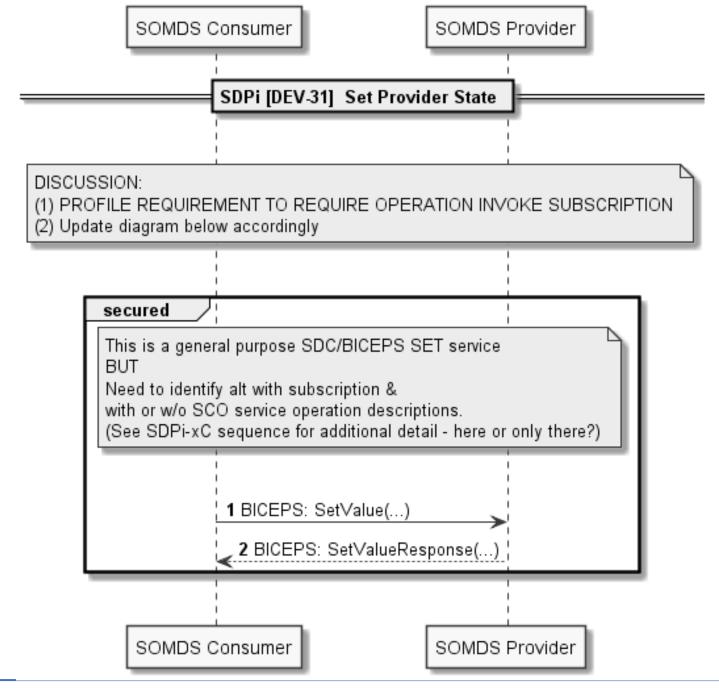


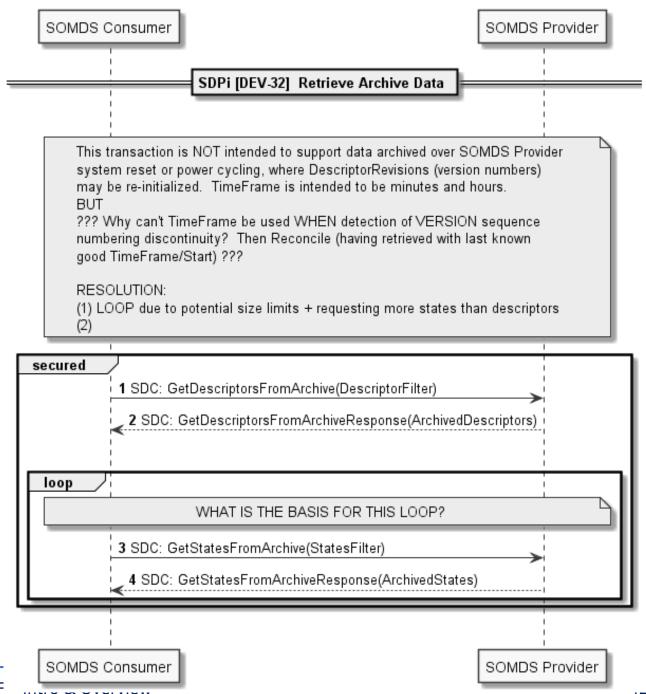


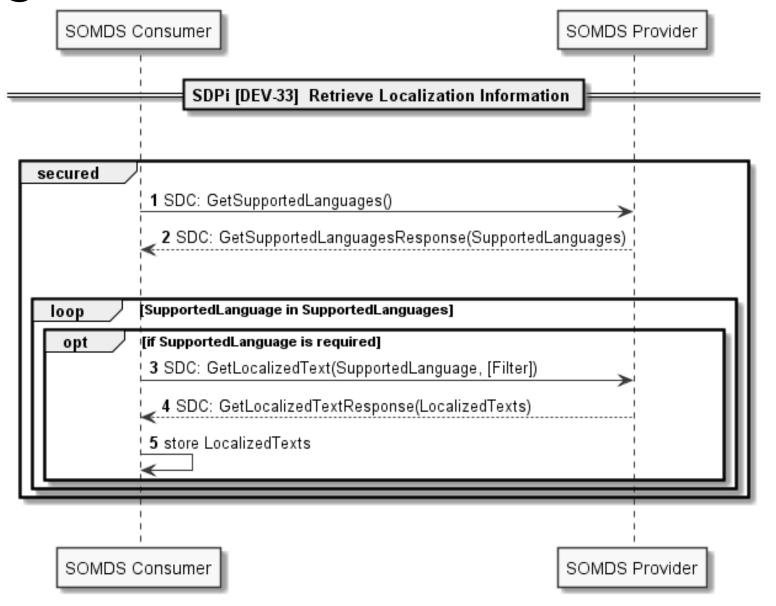


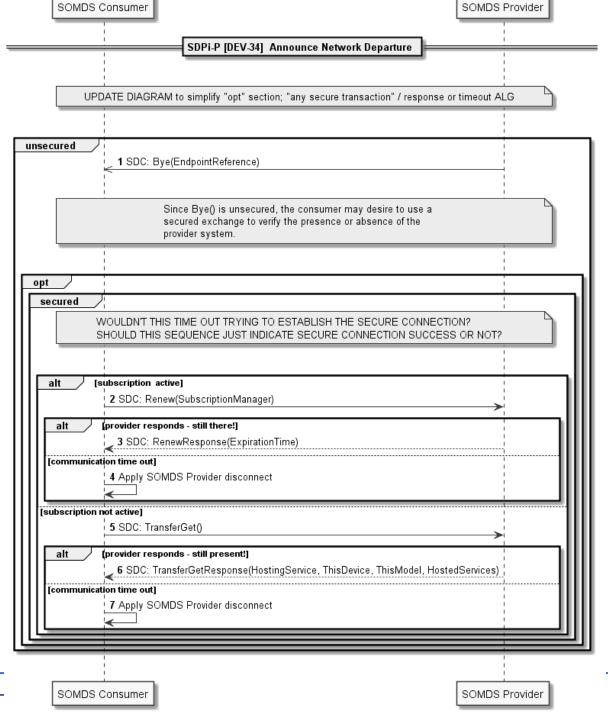




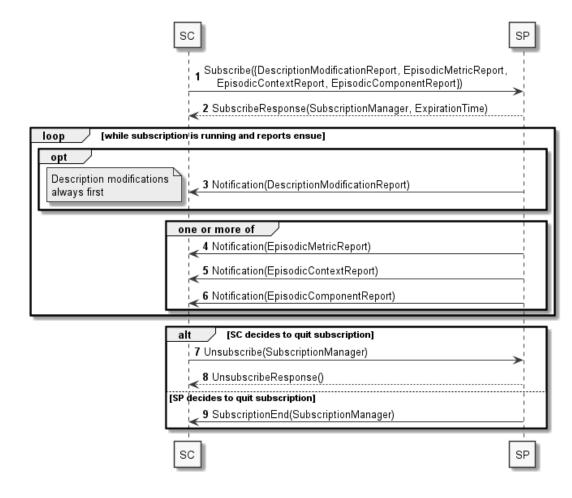




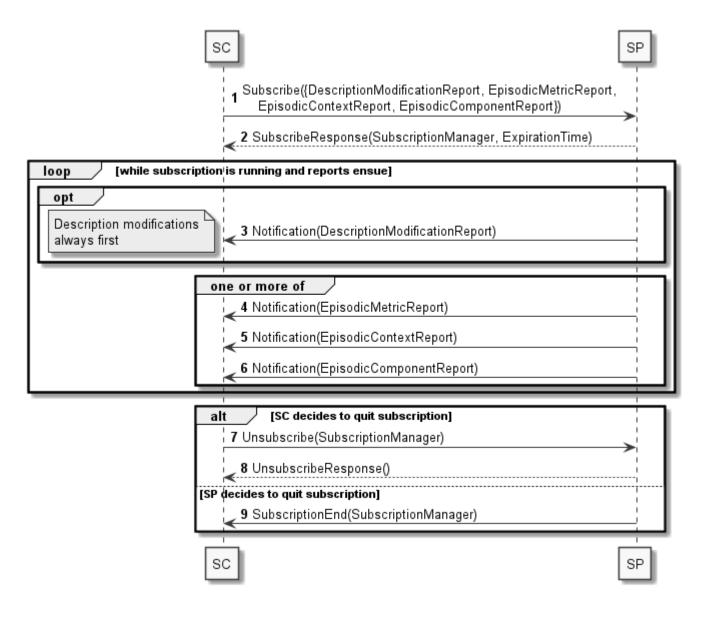




3.35 Establish Medical Data Exchange [DEV-35]



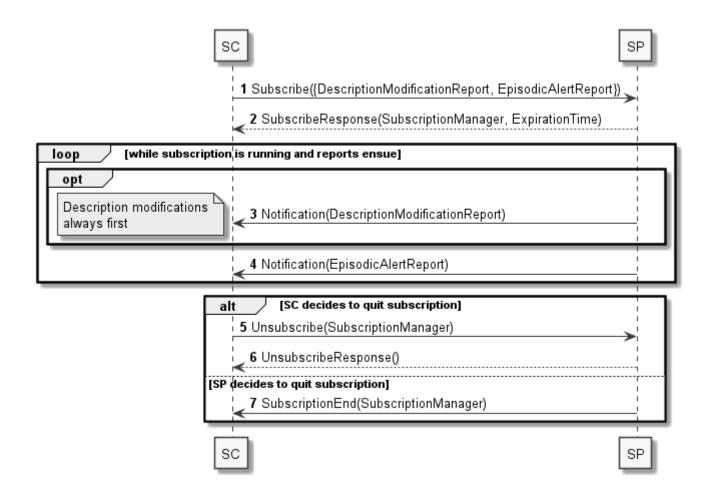
3.36 Publish Medical Data [DEV-36]



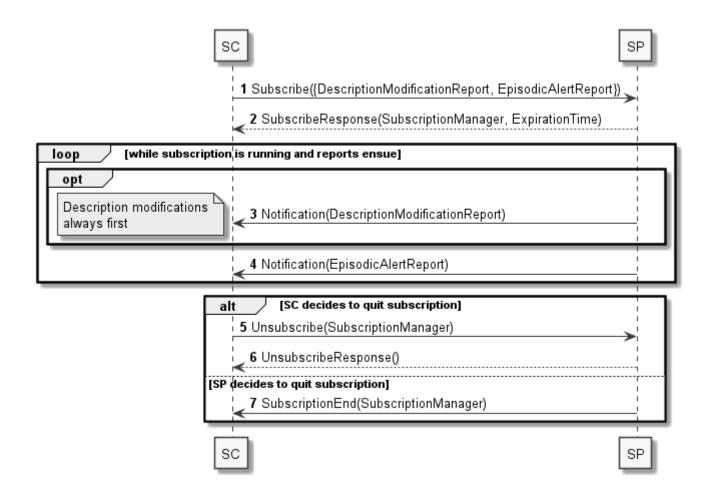
3.37 Retrieve Medical Data [DEV-37]

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]

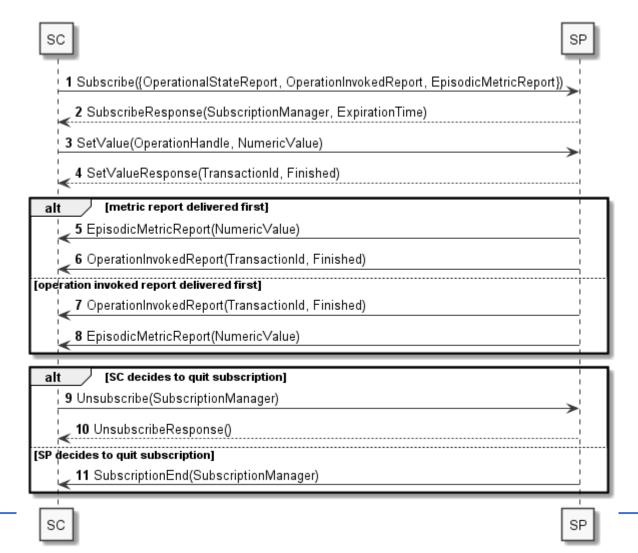
3.41 Manage Medical Alert Delegation [DEV-41]



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?

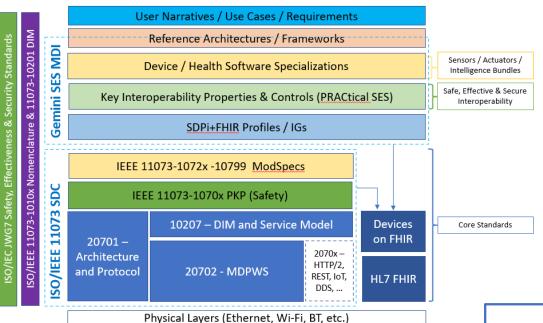
For the purposes of this PAT, what scenarios are of greatest interest?

- 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?

