SDC Glue

Revision 2
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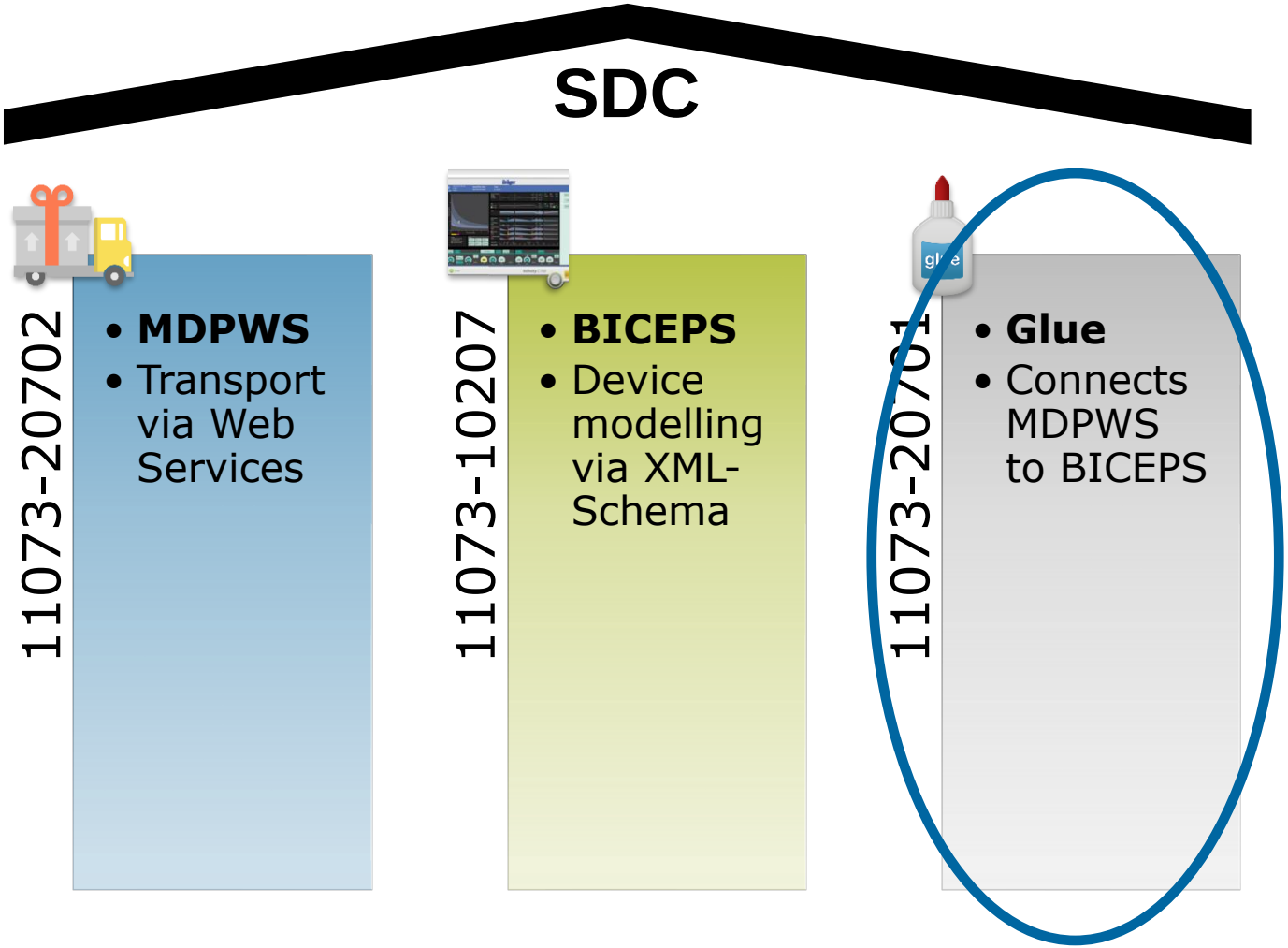
Orientation



At a glance

- Official title: 11073-20701 – Service-Oriented Medical Device Exchange Architecture and Protocol Binding
- Non-normative title: SDC Glue = Service-oriented Device Connectivity Glue
- Defines an architecture to enable connectivity in service-oriented distributed PoC medical devices and medical IT systems
- Binds BICEPS to MDPWS
- Binds to
  - Network Time Protocol (NTP) for time synchronization
  - Differentiated Services (DiffServ) in order to convey QoS information

Participant model binding

- Normatively includes participant model sections from BICEPS
- Defines constraints and supersessions

Participant model binding

Coded values

Coding System

- If applicable, use of ISO/IEEE 11073-1010X nomenclature is mandatory

Context-free codes

- If supported by the coding system, use of context-free numerical codes is mandatory

Participant model binding
Remote control

Semantics of operations

- The meaning of any remote invocation operation is specified by the combination of pm:AbstractOperationDescriptor/pm:Type and pm:AbstractOperationDesriptor/pm:OperationTarget.

Safety requirements

- Safety requirements as defined in MDPWS are hooked into operation descriptors as ext:Extension elements.

XPath expression root elements

- Safety information XPath expressions point to the pm:Mdib root element
- Dual channel XPath expressions point to the SOAP message's Body element

Operation invoked reports

- Final successful operation invoked reports shall carry the same MDIB version as the modification report that is the result of the operation

Participant model binding

Remote control

Anonymous SDC participant

- An instance identifier that can be used in case an SDC participant does not possess any identifying information
  - Root: http://standards.ieee.org/downloads/11073/11073-20701-2018
  - Extension: AnonymousSdcParticipant

Instance identifier encoding of an SDC participant's identity

- If an SDC participant has an X.509 certificate to identify itself, the instance identifier is encoded by
  - Root: http://standards.ieee.org/downloads/11073/11073-20701-2018/DistinguishedName
  - Extension: the *Common Name* of the *Distinguished Name* of the x.509 Certificate

Participant model binding

Dynamic containment tree changes

Description modification reports

- Description modification reports with “Update” indicate changes that can negatively influence the utilization of the affected containment tree entries
- In order to announce changes that do not negatively influence the affected containment tree entries, SDC service providers are obliged to insert reports deleted entries followed by inserted entries.

Metrics with more than one unit

- If a device is capable of determining the value of a metric with more than one unit, there shall be separate containment tree entries of the metric for each unit

Participant model binding
Types

- Type definitions (pm:AbstractDescriptor/pm:Type) are required for elements of the following XML types or any XML types derived from these types:
  - pm:AbstractComplexDeviceComponentDescriptor
  - pm:ChannelDescriptor
  - pm:AbstractOperationDescriptor
  - pm:AlertConditionDescriptor
  - pm:AbstractMetricDescriptor

Communication model binding

- Normatively includes message and service model sections from BICEPS
- Defines constraints and supersessions

→ Recommends port 6464 for communication (IANA reserved port)

Communication model binding
Subscription handling

BICEPS services

- Implement the following BICEPS services in one MDPWS hosted service in order to allow report subscription with one WS-Eventing subscribe message:
  - Description Event Service
  - State Event Service
  - Context Service
  - Waveform Service

Subscribe messages

- Subscribe to all desired reports by using a single subscribe message for all services mentioned above.

Purpose: only use one socket to retrieve all reports in the right order – no re-ordering on client side required

Communication model binding
Subscription handling

Description modification reports

- As description modification reports are not required to be subscribed, any change to the description shall first create the description modification report followed by respective state reports

Delivery error

- Devices shall stop sending notifications to a receiver on the first delivery error

Communication model binding
Large payloads & description event service

- *Large payloads*
  if the response to a request message is going to exceed the maximum message size defined in MDPWS, then the sender shall respond with HTTP status code 413 (payload too large) (~4MB)
- *Description event service*
  if a device is capable of being extended by removable subsystems, then a description event service is mandatory

Communication model binding
Localization service

- If an SDC service provider provides more than one language, then it shall also provide a BICEPS localization service

→ Why? Avoid inflating the MDIB with multiple languages / translations

Communication model binding
Prioritization of connection establishment

- In order to reduce peak CPU and network loads for an SDC service provider when it joins the network and announces itself, SDC Glue defines priority groups (PG) for SDC service consumers
  - 10 groups with 0 lowest and 9 highest priority
  - Implicit discovery messages are sent out depending on the priority group of the service consumer (with random T): PG*5[s] < T < (PG*5[s])+15 [s]
- T may be random, but fixed

Discovery binding

- Normatively includes discovery clauses from BICEPS
- Defines constraints and supersessions

Discovery binding
Complex device component based discovery

- 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
- Format: sdc.cdc.type:/<CODING-SYSTEM>/<VERSION>/<CODE>
- Example ventilator MDS: sdc.cdc.type:///70001
  - 70001 is the context-free code from 1::4465 from ISO/IEEE Std 11073-10101
  - As ISO/IEEE Std 11073-10101 is the default CODING-SYSTEM, CODING-SYSTEM and VERSION are empty

Discovery binding
SDC participant key purpose based discovery

- For every SDC participant key purpose an SDC service provider include a URI-encoded SDC participant key purpose as dpws:Scope of the MDPWS discovery messages.
- Format: sdc.mds.pkp:<OID>
- Example: sdc.mds.pkp:1.2.840.10004.20701.1.1

Discovery binding
Context-based discovery

- 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.
- Format: sdc.ctxt.<CONTEXT-TYPE>:/<ROOT>/<EXTENSION>?<QUERY>
- Example: sdc.ctxt.loc:/any-root/any-extension?fac=any-facility&flr=any-floor

Discovery binding
Fallback instance identifier algorithm

- SDC Glue provides a mandatory algorithm to derive locations from location detail
- Format: <FACILITY>/<BUILDING>/<FLOOR>/<POINT-OF-CARE>/<ROOM>/<BED>
- Example: sdc.ctxt.loc:/sdc.ctxt.loc.detail/fac//poc/room/

Non-functional quality attributes

- Normatively includes non-functional requirement clauses from BICEPS
- Defines constraints and supersessions

Non-functional quality attributes
Cybersecurity

- Do not use
  - SSL2.0 (Hickman [B2])
  - SSL3.0 (IETF RFC 6101 [B6])
  - TLS 1.0 (IETF RFC 2246 [B4])
  - TLS1.1 (IETF RFC 4346 [B5])
- Use highest TLS version if possible
- Only transmit contextual information on secured channel
- The Common Name of the Distinguished Name in X.509 certificates should be settled with the primary UDI in a UUIDv5 form

Non-functional quality attributes
Patient safety / trust establishment

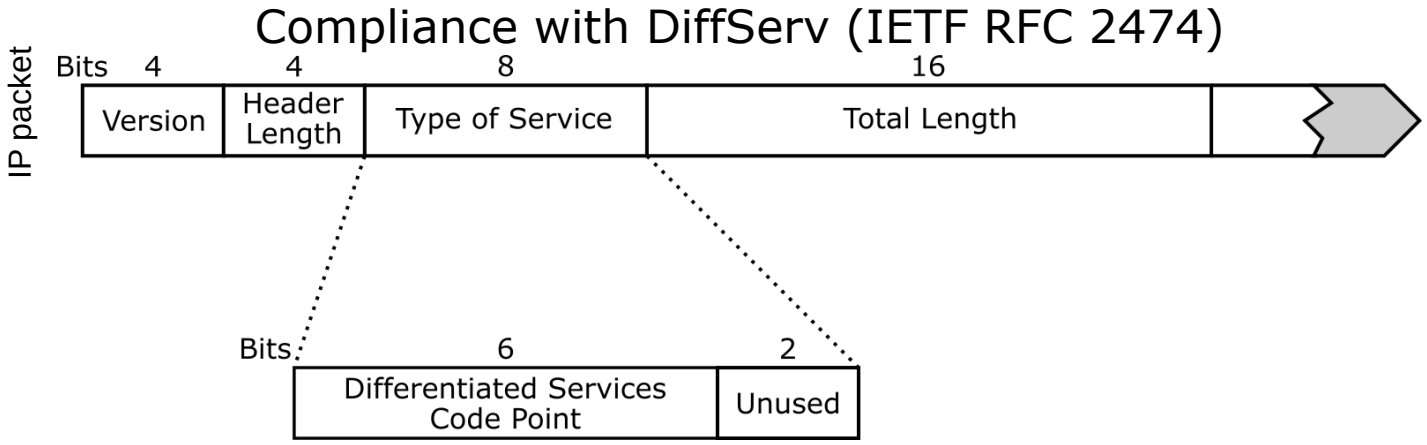
- An SDC participant shall utilize the Extended Key Usage (EKU) extension of the x.509 certificate of a service consumer to restrict modifications that modify performance characteristics if necessary to achieve freedom from unacceptable RISK
- An SDC participant shall include SDC participant key purposes for declaring its certified capabilities. Base key purposes:
  - SDC SERVICE PROVIDER (OID: 1.2.840.10004.20701.1.1)
  - SDC SERVICE CONSUMER (OID: 1.2.840.10004.20701.1.2)

Non-functional quality attributes
Clinical effectiveness

- NTP usage: version 3 (IETF RFC 1305) or any compatible version
- Clock descriptor and state are mandatory
- Mandatory timestamps:
  - Metrics (if applicable)
  - Required and executed calibrations are mandatory
  - pm:AlertConditionState/@DeterminationTime and pm:AlertSystemState/@LastSelfCheck
  - pm:AbstractContextState/@BindingStartTime and pm:AbstractContextState/@BindingEndTime
  - pm:ClockState/@LastSet (every time the clock is synchronized)

Non-functional quality attributes

Transmission of quality of service attributes



- No Expedited Forwarding (EF) per-hop behavior (PHB)
- Assured Forwarding (AF) PHB encouraged
  - for data where delay could result in a patient risk
- If any alerts with safety classification are communicated, use a low drop preference
- If any metrics with safety classification are communicated, use low or medium drop preference
- Data without safety classification should be marked with default PHB

Non-functional quality attributes
IP Packet qualification

						Description
0	0	0	0	0	0	Default PHB
0	0	1	y_1	y_2	0	AF PHB Class 1
0	1	0	y_1	y_2	0	AF PHB Class 2
0	1	1	y_1	y_2	0	AF PHB Class 3
1	0	0	y_1	y_2	0	AF PHB Class 4
~~1~~	~~0~~	~~1~~	~~1~~	~~1~~	~~0~~	~~EF~~ (not recommended)

y_{12} = 01 → Low Drop Preference (e.g., alerts)
y_{12} = 10 → Medium Drop Preference (e.g., metrics)
y_{12} = 11 → High Drop Preference

Thank you for your attention!

Contact information

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