IHE Change Proposal

Tracking information:

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| IHE Domain | Patient Care Device (PCD) |
| Change Proposal ID: | CP-PCD-NN0 |
| Change Proposal Status: | Draft |
| Date of last update: | 2022-12-02 |
| Person assigned: | Eldon Metz |

Change Proposal Summary information:

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| PCIM Foundational Changes | |
| Submitter’s Name(s) and e-mail address(es): | Eldon Metz, emetz@innovisionmedical.com |
| Submission Date: | TBD |
| Integration Profile(s) affected: | Point-of-Care Identity Management (PCIM) |
| Actor(s) affected: | Device-Patient Association Consumer  Device-Patient Association Manager  Device-Patient Association Reporter  Device Registrant |
| IHE Technical Framework or Supplement modified: | PCIM Profile TI revision 1.1, dated 2018-12-07 |
| Volume(s) and Section(s) affected: | Trial Implementation, Multiple Sections |
| Rationale for Change:  After completing the HIMSS showcase demonstration and Connectathon Testing events for PCIM in 2022, the working group members arrived at consensus at the October F2F in Cape Canaveral, Florida on foundational changes to transaction numbering and semantics that enhance design simplicity and clarity, patient safety and device security. The following changes are proposed:   * PCD-17 (assert association) and PCD-18 (assert disassociation) transactions to be deprecated and instead combining them into a single PCD-21 (assert association state) transaction. The OBX for indicating association or disassociation, or even something like a “update” in the future is fully covered within the single transaction. * A PCD-22 (report association state) transaction to reflect the manager to consumer reporting of real-time association status events. A separate transaction between the manager and consumer actors than that between the reporter and manager actors is consistent with IHE assignments and it allows for different message content and constraints. * The PCD-19 (query associations) transaction semantics are updated to indicate it represents the initial query transaction only, as the PCD-22 transaction represents the real time reporting. The PCD-19 query response always includes an accurate snapshot of active associations for the specified filter irregardless of whether a continuing real-time subscription is requested. * To simplify networking, eliminate burdensome configuration for Healthcare IT staff all while simultaneously increasing security for the consumer via threat surface minimization (no open ports), the PCD-19 query transaction real-time option specification is updated such that the manager uses the same incoming connection from the consumer for the initial query to deliver PCD-22 messages.   This Change Proposal (CP) proposes changes to implement profile clarifications and positions for the above. | |
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Section **Appendix A – Actor Summary Definitions,** modify the definitions in the table on line 213 as shown below and also adding the acroynm text in the name column and a new OID column.

Original Table

A picture containing table

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Proposed Table

|  |  |  |
| --- | --- | --- |
| **Actor Name and Acronym** | **Definition** | **Actor OID** |
| Device-Patient Association Reporter (DPAR) | A system that asserts a device-patient association, disassociation, or attributes related to either such as location, starting and ending times, and observers involved. The system may be fully automated or require human machine interaction (HMI). Provisions are made so systems may report assertions that are final or those that require additional user validation. | 1.3.6.1.4.1.19376.1.6.3.22 |
| Device-Patient Association Consumer (DPAC) | A system that queries for active device-patient association records with the option to establish a subscription to receive ongoing updates in real-time. | 1.3.6.1.4.1.19376.1.6.3.23 |
| Device-Patient Association Manager (DPAM) | A system that receives and manages association assertions and active association state and coordinates conflict resolution. The system serves records that match device-patient association queries in snapshot and real-time modalities. The system is required to provide an HMI to allow observers to validate assertions that require it. | 1.3.6.1.4.1.19376.1.6.3.24 |
| Device Registrant (DREG) | A system (which could be the medical device itself) that registers a device by uniquely identifying a device instance with the device-patient association manager along with a registration state. The system may manage the complete device instance registration lifecycle. | 1.3.6.1.4.1.19376.1.6.3.25 |

Section **Appendix B – Transaction Summary Definitions,** modify the table on line 218 to update the transaction names, definitions and numbers

Original Table

Table

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Table

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Proposed Table

|  |  |  |
| --- | --- | --- |
| **Transaction Name and Number** | **Definition** | **Transaction**  **OID** |
| Query Associations  (PCD-19) | A Device-Patient Association Consumer sends a query to a Device-Patient Association Manager with filter criteria. The Device-Patient Association Manager responds with the filtered active association status and optionally sets up a real-time subscription on the same connection. | 1.3.6.1.4.1.19376.1.6.1.19.1 |
| Register Device  (PCD-20) | A Device Registrant registers, updates, or deletes a record of identifying information on a device instance for storage and use by the Device-Patient Association Manager. | 1.3.6.1.4.1.19376.1.6.1.20.1 |
| Assert Association State  (PCD-21) | A Device-Patient Association Reporter asserts to a Device-Patient Association Manager that a device has been associated or disassociated with a patient and optional location. It may also report updated data for a previously reported assertion. | 1.3.6.1.4.1.19376.1.6.1.21.1 |
| Report Association State  (PCD-22) | A Device-Patient Association Manager reports to a Device-Patient Association Consumer that a device has been associated or disassociated with a patient with optional location. It may also report an update for an existing association. | 1.3.6.1.4.1.19376.1.6.1.22.1 |

**7.1 PCIM Actors, Transactions, and Content Modules,** replace Figure 7.1-1 on page 13 with updated actor name, number and definitions:

Original Figure

Diagram

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Proposed Figure

Diagram

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**7.1 PCIM Actors, Transactions, and Content Modules,** replace **Table 7.1-1 PCIM Profile – Actors and Transactions** on page 14 with updated actor names, transactions and optionality value:

Original Table

Calendar

Description automatically generated

Proposed Table

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Actors** | **Transactions** | **Initiator or Responder** | **Optionality** | **Reference** |
| Device-Patient Association Consumer (DPAC) | Query Associations  (PCD-19) | Initiator | R | PCD TF-2: 3.19 |
| Report Association State  (PCD-22) | Responder | O | PCD TF-2: 3.22 |
| Device Registrant (DREG) | Register Device  (PCD-20) | Initiator | R | PCD TF-2: 3.20 |
| Device-Patient Association Reporter (DPAR) | Assert Association State  (PCD-21) | Initiator | R | PCD TF-2: 3.21 |
| Device-Patient Association Manager (DPAM) | Query Associations  (PCD-19) | Responder | R | PCD TF-2: 3.19 |
| Register Device  (PCD-20) | Responder | R | PCD TF-2: 3.20 |
| Assert Association State  (PCD-21) | Responder | R | PCD TF-2: 3.21 |
| Report Association State  (PCD-22) | Initiator | R | PCD TF-2: 3.22 |

Section **7.1.1.1 Device-Patient Association Reporter,** change the paragraph on line 270:

Original Text

The Device-Patient Association Reporter represents a system or person that is asserts that a given device is attached or removed from a specific patient. For each such event, the unique Patient ID, Device ID, and timestamp must be reported.

Proposed Text

The Device-Patient Association Reporter represents a system that asserts that a given device is associated or disassociated with a specific patient. For each such event, the unique Patient ID, Device ID, and timestamp of the beginning of association or end of association shall be reported. If a location is known, it should be included in the report. If the report is validated, the report observation shall be marked final, otherwise it shall be marked as requiring validation.

Section 7.1.1.2 **Device-Patient Association Manager**, change the paragraph on line 274.

Original Text

The Device-Patient Association Manager represents a system that collects and persists  
information on what devices are currently or were connected to patients within a defined scope, such as a clinical unit, at a given time, and can communicate these associations as query responses, event notifications, or both.

Proposed Text

The Device-Patient Association Manager represents a system that collects and persists  
information on devices currently associated with patients within a defined scope, such as a clinical unit and shall communicate validated associations as query responses, event notifications, or both if requested. The system is responsible for resolving conflicts and shall provide an HMI for validating association assertions that require validation and resolving conflicts. **(NOTE: Add an out-of-scope statement that describes the possibility of an actor that provides retrospective capabilities and why that makes sense)**

Section 7.1.1.3 **Device-Patient Association Consumer**, change the paragraph on line 279.

Original Text

The Device-Patient Association Consumer represents a system or person that is has a  
requirement to receive information on what devices are or were connected to which patients. A common example is a critical care system that charts device observations for a patient.

Proposed Text

The Device-Patient Association Consumer represents a system that needs to receive information on what devices are associated with which patients. Common examples are a medical device or critical care system that charts device observations for a patient. The system may receive association updates in real-time, if desired. **(NOTE: Multiple devices attached to a patient through other devices, e.g. Physio Mon with a EtCO2, Ventilator connection)**

Section 7.1.1.4 **Device Registrant**, change the paragraph on line 283.

Original Text

The Device Registrant represents a system or person that maintains the list of medical devices that can be connected to a patient. The list entry for each device typically includes the device type, location (may not apply if the device is mobile), and unique identity.

Proposed Text

The Device Registrant represents a system that contributes to the list of medical devices that can be associated with a patient. The list entry for each device typically includes the device type, location (may not apply if the device is mobile), model, manufacturer and unique identity.

Section 7.1.1.4 **Device Registrant**, change the two paragraphs starting at line 287.

Original Text

Where this is a person, it is most likely hospital staff that is interacting directly with the Device- Patient Association Manager through its user interface.

Where it is a system, it may be a comprehensive device inventory system, a “gateway” system, or even the device itself.

Proposed Text

The Device Registrant system may be automated, such as a “gateway” system or medical device itself, or it may be driven by an HMI that a user interacts with directly.

Section 7.2 **PCIM Actor Options**, change the first two paragraphs starting at line 293 to address the change in options.

Original Text

The Device-Patient Association Consumer has two options available for receiving data from the Device-Patient Association Manager. The first option is to query the Manager for a snapshot of current associations, either by sending a patient identifier and receiving back the associated device(s) or by sending a device identifier and receiving back the associated patient. The second option is to receive an unsolicited continuous stream of association and disassociation events from the Manager as they occur. The Device-Patient Association Manager should support sending data via both methods, and the Device-Patient Association Consumer may support one or both methods.

Options that may be selected for each actor in this profile, if any, are listed in the Table 7.2-1. Dependencies between options, when applicable, are specified in notes.

Proposed Text

The Device-Patient Association Consumer queries the Device-Patient Association Manager for patient association status. The Consumer has the option of subscribing to and receiving association reports from the Device-Patient Association Manager in real-time. The initial query to the Manager results in an immediate snapshot response of the active associations based on the query filter criteria. The real-time option is enabled by specifying a query parameter and allows the Consumer to receive an unsolicited continuous stream of association and disassociation events as they occur on the same connection the original query was sent on to the Manager. The Device-Patient Association Manager shall support the snapshot query and real-time subscription option. The Device-Patient Association Consumer may support the real-time option.

Options that may be selected for each actor in this profile, if any, are listed in the Table 7.2-1. Dependencies between options, when applicable, are specified in notes.

Table 7.2-1 **PCIM - Actor and Options**, change the table near line 303.

Existing Table

Table

Description automatically generated

Proposed Table

|  |  |  |
| --- | --- | --- |
| **Actor** | **Option Name** | **Reference** |
| Device-Patient Consumer | Real-Time Subscription Option | 7.2.1 |
| Device-Patient Association Manager | No options defined |  |
| Device-Patient Association Reporter | No options defined |  |
| Device Registrant | No options defined |  |

Section 7.2.1 **Snapshot Option**, move and alter text to address change in option status in section 3.19, addressed later in this CP.

Section 7.2.2 **Subscription Option**, re-number to 7.2.1.

Original Text

The snapshot option applies to query and response interactions between Device-Patient Association Consumer and Device-Patient Association Manager and specifies that the query response desired is a continuing subscription to changes in device-patient associations.

A Device-Patient Association Consumer that supports this option shall formulate its request in the form described in Section 3.19.