**Integrating the Healthcare Enterprise**



**IHE Patient Care Device Domain**

**Technical Framework Supplement**

**Point-of-Care Identity Management
(PCIM)**

**Draft in preparation for Public Comment**

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**Foreword**

This is a supplement to the IHE Patient Care Device Domain Technical Framework <V5.0>. Each supplement undergoes a process of public comment and trial implementation before being incorporated into the volumes of the Technical Frameworks.

This supplement is published on**Error! Unknown document property name.** for Public Comment. Comments are invited and may be submitted at [http://www.ihe.net/<domain>/<domain>comments.cfm](http://www.ihe.net/Technical_Framework/public_comment.cfm). In order to be considered in development of the Trial Implementation version of the supplement, comments must be received by <Month XX, 201X>.

This supplement describes changes to the existing technical framework documents.

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

Amend section X.X by the following:

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

General information about IHE can be found at: [www.ihe.net](http://www.ihe.net).

Information about the IHE Patient Care Device Domain domain can be found at: <http://www.ihe.net/Domains/index.cfm>.

Information about the organization of IHE Technical Frameworks and Supplements and the process used to create them can be found at: <http://www.ihe.net/About/process.cfm> and <http://www.ihe.net/profiles/index.cfm>.

The current version of the IHE Patient Care Device DomainTechnical Framework can be found at: <http://www.ihe.net/Technical_Framework/index.cfm>.

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

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# Introduction to this Supplement

This Supplement to the IHE Patient Care Device Technical Frameworks adds the rationale and implementation details of the Point-of-Care Identity Management Profile to the Framework, providing a means for standards-based exchange between systems of information collected and confirmed at the point of care tracking the set of medical devices originating observations about each patient.

## Open Issues and Questions

1. The work group solicits feedback on workflow effects and problems found in analyzing the profile and in trial implementation.

## Closed Issues

 <List the closed issues/questions with their resolutions. These are particularly useful for recording the rationale for closed issues to forestall unnecessary rehashing in the future and/or to make it easier to identify when a closed issue should be re-opened due to new information.>

1. Discuss differences from previous approaches based on ADT messages: will be faster, closer to the actual events than ADT feeds, which have a different purpose and are often not well synchronized with actual events at the point-of-care. Will enable devices, device controllers and a variety of other hospital to flexibly exchange information, publish or subscribe change notifications.
2. Include security information and recommendations in the profile.

# General Introduction

Update the following Appendices to the General Introduction as indicated below. Note that these are not appendices to Volume 1.

Appendix A - Actor Summary Definitions

Add the following actors to the IHE Technical Frameworks General Introduction list of Actors:

|  |  |
| --- | --- |
| Actor | Definition |
| Device-Patient Association Reporter | A system or person that asserts a device-patient association, disassociation, or attributes related to either. |
| Device-Patient Association Manager | A system that records, manages, and serves records of device-patient associations. |
| Device-Patient Association Consumer | A system or person that queries a Device-Patient Association Manager for device-patient association records |
| Device Registrant | A system (including the device itself) or person that identifies a device that may participate in device-patient associations. |
| Device Registration System | A system that registers devices and serves device identity information to a Device-Patient Association Manager. May be grouped with that Manager. |
| Patient Registration System | A system that identifies patients that may participate in device-patient associations, typically a master patient index (MPI) or other ADT system. |

Appendix B - Transaction Summary Definitions

Add the following transactions to the IHE Technical Frameworks General Introduction list of Transactions:

|  |  |
| --- | --- |
| Transaction | Definition |
| Assert Device-Patient Association | A Device-Patient Association Reporter asserts to a Device-Patient Association Manager that a device has been associated with a patient, or updates data concerning a reported assertion. |
| Assert Device-Patient Disassociation | A Device-Patient Association Reporter asserts to a Device-Patient Association Manager that the association between a device and a patient has been terminated.. |
| Query Device-Patient Associations | A Device-Patient Association Consumer sends a query to a Device-Patient Association Manager concerning the devices associated with a patient or set of patients currently or at a stated past time. |
| Register Device | A Device Registrant sends, updates, or deletes a record of identifying information on a device instance for storage and use by the Device-Patient Association Manager. |

Glossary

Add the following glossary terms to the IHE Technical Frameworks General Introduction Glossary:

|  |  |
| --- | --- |
| Glossary Term | Definition |
| Assertion | A statement that a certain premise is true, for example that a device has been prepared to collect data about a patient. |
| Binding | A process of associating two related elements of information. |
| Biometrics | A measurable physical characteristic or personal behavioral trait used to recognize the identity, or verify the claimed identity of a person. |
| Direct Association | A patient association established by the observation and recording of a physical connection of a device to the patient. |
| Direct Device-Patient Association Assertion | A claim of direct device-patient association based on evidence. |
| Duplicate Patient Identification Record | Two records representing the same patient, with differing identifiers of the same type with the same assigning authority. For example, two different medical record numbers issued by the same hospital to the same patient. In the context of device-patient association, an unintentional duplicate patient record may result if device data is recorded without a permanent unique patient identifier being recorded, as in an emergency. A human-validated merge operation is necessary to associate the device data with the patient after the fact. |
| Entity | In the context of this Profile, an organizational unit within a healthcare enterprise, typically, but not necessarily, associated with a free-standing building, office, or sub-unit within a common hospital corporation. For example, a patient visit would occur within a specific entity. |
| False Negative | Patient algorithm matching error occurring when two different records for the same person are thought to represent different people (for example name, gender, date of birth, MRN…). |
| False Positive | Patient algorithm matching error occurring when information for two different people appears to be a match representing the same individual (for example name, gender, date of birth, MRN…). |
| Identity Assertion | A claim attributing a particular identity to a person or device. |
| Identity Management | Identity management (IdM) is composed of the set of business processes, and a supporting infrastructure, for the creation, maintenance, and use of digital identities within a legal and policy context. |
| Indirect Device-Patient Association | A patient association asserted on the basis of a common attribute shared by a device and patient, such as a location. |
| Location-based Assertion | An assertion of an association between two objects (e.g. a patient and a device, device-to-device, patient-to-caregiver), based solely upon the co-location (e.g. same room and bed) of these two objects. |
| Minimal Guarantee | The fewest promises the system makes to its stakeholders, particularly when the primary actor's goal cannot be delivered. |
| Multi-Entity | A healthcare enterprise consisting of two or more entities. For example, a hospital corporation which owns three hospitals. |
| Observation-Patient Association | The assignment of a device measurement/parameter to a specific patient. Observation - patient associations are established through the connection relationship of a unique patient to a unique device at the point in time that the measurement was recorded by the device. |
| Overlap Record | One person with two or more unique enterprise identifiers. Without the two records being linked, information not available for point of care and clinical decisions are made in the absence of data. There is an increase in costs associated with repeat test, clinical procedures, etc., as well as rework in clinical and business processes. |
| Overlay Record | Records of two different people are “combined” into one record in error. Person A is treated with Person B’s clinical information. This has huge implications for quality of care and patient safety. |
| Device-Patient Association Conflict Notification | A message from a particular clinical IT system that it detects an inconsistency between different identity assertions. For example, a device and an intermediary system may be simultaneously asserting that a single data stream represents two different patients. |
| Device-Patient Record Linkage | The process of binding and/or associating a discrete patient record to a discrete device record. |
| Patient Identity Management | Patient identity management (PIM) has been defined as the “ability to ascertain a distinct, unique identity for an individual (a patient), as expressed by an identifier that is unique within the scope of the exchange network, given characteristics about that individual such as his or her name, date of birth, gender [etc.].” The scope of this definition can be expanded to refer to PIM as the process of accurately and appropriately identifying, tracking, managing, and linking individual patients and their digitized health care information, often within and across multiple electronic systems. |
| Patient Index (Master Patient Index) | A system, typically centralized for a provider institution or organization, which is authoritative for patient demographic information including identity data, for patients under care. Typically can respond to queries and give a unique identity or a set of candidate identities that are consistent with a set of identity factors. |
| Patient Linkage | The general problem of determining whether two existing records pertain to the same patient. This is distinct from device-patient association and uses different methods. |
| Patient Matching | Record linkage is the task of identifying pieces of scattered information that refer to the same thing. Patient matching is a specific application, in which we try to identify records that belong to the same patient among different data sources. |
| Precondition | "What the system under analysis will ensure is true before letting the use case start." |
| Proofing (Identity Proofing) | The process of collecting and verifying sufficient information (e.g. identity history, credentials, documents) from an applicant to a service provider for the purpose of proving that a person or object is the same person or object it claims to be. |
| Receiving System | In the context of PCIM, any system which is a consumer of device-patient association or observation messages, such as an electronic medical record system, device gateway, or a device at the point of care. |
| Record | The discrete representation of a specific and unique patient or the device in either the reporting or consuming system's database. |
| Strong Identity Assertion | A presumption of patient or device unique recognition using multiple factors that provides a high degree of accuracy and certainty (e.g., barcode, biometric). |
| Strong Identity Factors | An identifier designed to be unique (applies to only one person) and consistent over the appropriate domain for at least throughout the visit or encounter, for example, Medical Record Number or National ID number. |
| Success Guarantee | A success guarantee is a statement of what interests of the stakeholders are satisfied after a successful conclusion of the use case. |
| Unique Device Identifier | In the US, a unique identifier for a medical device that is recognized by the US FDA and which has a part that identifies the maker and model of the device (DI) and a part that identifies the particular instance of the device. More generally, any identifier which allows a particular device to be uniquely identified. |
| Weak Identity Assertion | A presumption of patient or device unique recognition using factors that provides a low degree of accuracy and certainty (e.g., name, location). |
| Weak Identity Factors | Factors which can contribute to identification, but typically are not unique to patient; for example, name, sex, date of birth. |

Volume 1 – Profiles

Add to Section …

# 7 Point-of-Care Identity Management (PCIM)> Profile

The Point-of-Care Identity Management (PCIM) Profile is a Transport Profile specifying HL7 v2 standard messaging for devices and IT systems at an acute-care point-of-care to exchange and synchronize information about the identity of specific devices collecting clinical information about a specific patient, to:

1. Assist in the reliable association of the collected data to the proper patient record, based on first-hand observation and data entry by a person at the point of care, specifically designed to avoid wrong attribution of data from before or after the period of actual measurement on the patient.
2. Assist in maintaining a correct “census” of devices that frequently move between patients such as infusion pumps, and mechanical ventilators.

The messaging defined provides for capable devices to originate messages asserting association and disassociation to a particular patient, for human interface software components to afford users the opportunity to originate or confirm association or disassociation assertions, for one or more systems to receive and persist device-patient association information, to distribute reporting messages or receive and respond to queries about such associations.

## 7.1 PCIM Actors, Transactions, and Content Modules

This section defines the actors, transactions, and/or content modules in this profile. General definitions of actors are given in the Technical Frameworks General Introduction Appendix A at [http://www.ihe.net/Technical Framework/index.cfm](http://www.ihe.net/Technical_Framework/index.cfm).

Figure 7.1-1 shows the actors directly involved in the Profile and the relevant transactions between them. If needed for context, other actors that may be indirectly involved due to their participation in other related profiles are shown in dotted lines.

Register Device [PCD-xx]

↑ Transaction 4 [4]

Assert Device-Patient Association [PCD-17] ↓

↓

Transaction 1 [1] ↓

↓  Assert Device-Patient Disassociation [PCD-18]

↓ Transaction 2 [2]

Device-Patient Association Reporter

Actor A

Device-Patient Association Consumer

Actor F

Device-Patient Association Manager

Actor D

Device Registrant

Actor B

Query / Subscribe to Device-Patient Associations [PCD-19] ↓

↑

Transaction 1 [1] ↑

↑ Device-Patient Association Query Response / Subscription

↑ Transaction 2 [2]

Figure X.1-1: Actor Diagram

Table 7.1-1 lists the transactions for each actor directly involved in the Profile. To claim compliance with this Profile, an actor shall support all required transactions (labeled “R”) and may support the optional transactions (labeled “O”).

Table 7.1-1: Profile - Actors and Transactions

| Actors | Transactions  | Optionality | Reference |
| --- | --- | --- | --- |
| Device-Patient Association Reporter | Report Device-Patient Association | R | <Domain Acronym> TF-2: 3.Y1 |
| Report Device-Patient Disassociation | R | <Domain Acronym> TF-2: 3.Y2 |
| Device-Patient Association Manager | Report Current Device-Patient Association Status | R | <Domain Acronym> TF-2: 3.Y1 |
| Publish Device-Patient Association Event | R | <Domain Acronym> TF-2: 3.Y2 |
| Device-Patient Association Consumer | Query Device-Patient Associations | O | <Domain Acronym> TF-2: 3.Y1 |
| Subscribe to Device-Patient Association Events | O | <Domain Acronym> TF-2: 3.Y2 |
| Device Registrant  | Register Device | R |  |
| Report Registered Device Details | R |  |

### 7.1.1 Actor Descriptions and Actor Profile Requirements

Requirements are documented in Transactions (Volume 2) and Content Modules (Volume 3). This section documents any additional requirements on profile’s actors.

#### 7.1.1.1 Device-Patient Association Reporter

<If the summary description of the actor in Appendix A is insufficient to understand its role in this Profile, elaborate here.>

#### 7.1.1.2 Device-Patient Association Consumer

#### Device Registrant

## 7.2 Actor Options

There are no options specified in the Point-of-Care Identity Management (PCIM) profile.

## 7.3 Required Actor Groupings

There are no required actor groupings specified in the Point-of-Care Identity Management (PCIM) profile.

## 7.4 Overview

### 7.4.1 Concepts

[XXX discuss the importance and implications of validated associations are, the factors in a reliable unique identifier for a person and for a device, including UDI]

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

### 7.4.2 Use Cases

[XXX incorporate use case descriptions from the white paper and add any missing ones, including device registrati

#### 7.4.2.1 Use Case #1: Associating Device With Patient and Verifying

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

<Note that Section X.4.2.1 repeats in its entirety for additional Use Cases (replicate as section X.4.2.2, X.4.2.3, etc.).>

##### 7.4.2.1.1 Associating Device With Patient and Verifying Use Case Description

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

##### 7.4.2.1.2 Associating Device With Patient and Verifying Process Flow

<Diagram and describe the process flow(s) covered by this profile in order to satisfy the use cases. Demonstrate how the profile transactions are combined/sequenced. To provide context and demonstrate how the profile interacts with other profiles, feel free to include transactions and events that are “external” to this profile (using appropriate notation.)
The set of process flows will typically be exemplary, not exhaustive (i.e., it will address all the use cases, but will not show all possible combinations of actors, or all possible sequencing of transactions).
If there are detailed behavioral rules that apply to a specific process flow or multiple process flows, an appendix may be added as needed.>

<The roles at the top of the swimlane diagram should correspond to actor names, include the profile acronym:actor name if referencing an actor from a different profile.>

<Modify the following “Swimlane Diagram”.>

Transaction\_2 [2]

Transaction\_2 [2]

Transaction\_1 [1]

Transaction\_1 [1]

Actor D/

Actor E

Actor D/

Actor E

Actor A /

Actor B

Actor A /

Actor B

*Internal action 1*

*Internal action 1*

Transaction-D [D]

Transaction-D [D]

Transaction-C [C]

Transaction-C [C]

Actor B/ Actor C

Actor B/ Actor C

Transaction\_2 [2]

Transaction\_2 [2]

Transaction\_3 [3]

Transaction\_3 [3]

*Internal action 2*

*Internal action 2*

Transaction-A [A]

Transaction-A [A]

Transaction-B [B]

Transaction-B [B]

Figure 7.4.2.2-1: Basic Process Flow in Profile

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

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

Pre-conditions:

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

Main Flow:

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

Post-conditions:

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

## 7.5 Security Considerations

[XXX Include here security text from White Paper]

## 7.6 Cross Profile Considerations

ITI Patient Demographic Query - Patient Demographic Reporter

A Patient Demographic Consumer in IT Infrastructure might be grouped with a Device-Patient Association Reporter to allow presentation of a pick list of candidate patients to associate with one or more devices at the point-of-care.

Device Registrant

 A Device Registrant Actor in the present might be grouped with a Device-Patient Association Reporter to allow presentation of a pick list of candidate devices to be paired with a patient