

**Integrating the Healthcare Enterprise**



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

**Volume 1**

**PCD TF-1**

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**Integration Profiles**

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**Revision 3.0 - Final Text**

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## 115 **1 Introduction**

Integrating the Healthcare Enterprise (IHE) is an initiative designed to stimulate the integration of the information systems that support modern healthcare institutions. Its fundamental objective is to ensure that in the care of patients all required information for medical decisions is both correct and available to healthcare professionals. The IHE initiative is both a process and a forum for encouraging integration efforts. It defines a technical framework for the implementation of established messaging standards to achieve specific clinical goals. It includes a rigorous testing process for the implementation of this framework. And it organizes educational sessions and exhibits at major meetings of medical professionals to demonstrate the benefits of this framework and encourage its adoption by industry and users.

120 The approach employed in the IHE initiative is not to define new integration standards, but rather to support the use of existing standards, HL7, DICOM, IETF, and others, as appropriate in their respective domains in an integrated manner, defining configuration choices when necessary. When clarifications or extensions to existing standards are necessary, IHE refers recommendations to the relevant standards bodies.

125 This initiative has numerous sponsors and supporting organizations in different medical specialty domains and geographical regions. In North America the primary sponsors are the Healthcare Information and Management Systems Society ([HIMSS](#)) and the Radiological Society of North America ([RSNA](#)). [IHE Canada](#) has also been formed. IHE Europe ([IHE-EUR](#)) is supported by a large coalition of organizations including the European Association of Radiology ([EAR](#)) and European Congress of Radiologists ([ECR](#)), the Coordination Committee of the Radiological and Electromedical Industries ([COCIR](#)), Deutsche Röntgengesellschaft ([DRG](#)), the [EuroPACS Association](#), Groupement pour la Modernisation du Système d'Information Hospitalier ([GMSIH](#)), Société Française de Radiologie ([[www.sfr-radiologie.asso.fr](http://www.sfr-radiologie.asso.fr) SFR]), and Società Italiana di Radiologia Medica ([SIRM](#)). In Japan [IHE-J](#) is sponsored by the Ministry of Economy, Trade, and Industry ([METI](#)); the [Ministry of Health, Labor, and Welfare](#); and [[www.medis.or.jp](http://www.medis.or.jp) MEDIS-DC]; cooperating organizations include the Japan Industries Association of Radiological Systems ([JIRA](#)), the Japan Association of Healthcare Information Systems Industry ([JAHIS](#)), Japan Radiological Society ([JRS](#)), Japan Society of Radiological Technology ([JSRT](#)), and the Japan Association of Medical Informatics ([JAMI](#)). Other organizations representing healthcare professionals are actively involved and others are invited to join in the expansion of the IHE process across disciplinary and geographic boundaries.

130 The IHE Technical Frameworks for the various domains (Patient Care Coordination, IT Infrastructure, Cardiology, Laboratory, Radiology, etc.) define specific implementations of established standards to achieve integration goals that promote appropriate sharing of medical information to support optimal patient care. These are expanded annually, after a period of public review, and maintained regularly through the identification and correction of errata. The current version for these Technical Frameworks may be found at [www.ihe.net](http://www.ihe.net).

145 The IHE Technical Framework identifies a subset of the functional components of the healthcare enterprise, called IHE Actors, and specifies their interactions in terms of a set of coordinated,

155 standards-based transactions. It describes this body of transactions in progressively greater depth. Volume 1 provides a high-level view of IHE functionality, showing the transactions organized into functional units called Integration Profiles that highlight their capacity to address specific clinical needs. Subsequent volumes provide detailed technical descriptions of each IHE transaction.

## 160 **1.1 Overview of Technical Framework**

This document, the IHE Patient Care Device Technical Framework Volume 1 (IHE PCD TF-1), defines specific implementations of established standards to achieve integration goals for the Patient Care Device domain. Such integration promotes appropriate sharing of medical information to support optimal patient care.

165 The IHE PCD TF will be expanded annually, after a period of public review, and maintained regularly through the identification and correction of errors.

The IHE PCD TF identifies a subset of the functional components of the healthcare enterprise, called IHE actors, and specifies their interactions in terms of a set of coordinated, standards-based transactions. It describes this body of transactions in progressively greater depth. Volume 170 1 of the Patient Care Device Technical Framework (IHE PCD TF-1) provides a high-level view of IHE functionality, showing the transactions organized into functional units called Integration Profiles that highlight their capacity to address specific clinical needs. IHE PCD TF-2 provides detailed technical descriptions of each PCD-specific IHE transaction. IHE PCD TF-3 provides detailed specifications for content oriented profiles and includes content from specific device 175 classes.

The IHE PCD TF is part of a related set of IHE Technical Frameworks, including the following domain-specific documents:

- IHE Cardiology Technical Framework
- IHE IT Infrastructure Technical Framework
- 180 • IHE Radiology Technical Framework
- IHE Laboratory Technical Framework
- IHE Patient Care Coordination Technical Framework

The IHE Patient Care Device Integration Profiles rely on, and reference, the transactions defined in those other IHE Technical Framework documents. For the conventions on referencing other 185 frameworks, see [Section 1.6.4](#) within this volume.

## **1.2 Overview of Volume 1**

The remainder of Section 1 further describes the general nature, purpose and function of the Technical Framework. Section 2 introduces the concept of IHE Integration Profiles that make up the Technical Framework.

190 Section 3 and the subsequent Sections of this volume provide detailed documentation on each Integration Profile, including the clinical problem it is intended to address and the IHE actors and transactions it comprises.

The appendices following the main body of the document provide detailed discussion of specific issues related to the Integration Profiles and a glossary of terms and acronyms used.

### 195 **1.3 Audience**

The intended audience of this document is:

- Clinicians interested in the technical aspects of integrating healthcare information systems
- Technical staff of vendors participating in the IHE initiative
- 200 • IT, Clinical Engineering and Medical Informatics departments of healthcare institutions
- Experts involved in standards development

### **1.4 Relationship to Standards**

205 The IHE Technical Framework identifies functional components of a distributed healthcare environment (referred to as IHE actors), solely from the point of view of their interactions in the healthcare enterprise. At its current level of development, it defines a coordinated set of transactions based on the HL7, IEEE, DICOM, W3C and other industry standards. As the scope of the IHE initiative expands, transactions based on other standards will be included as required.

In some cases, IHE recommends selection of specific options supported by these standards; however, IHE does not introduce technical choices that contradict conformance to these  
210 standards. If errors in or extensions to existing standards are identified, IHE's policy is to report them to the appropriate standards bodies for resolution within their conformance and standards evolution strategy.

IHE is therefore an implementation framework, not a standard. Referencing IHE as a standard is inappropriate. Conformance claims by product must still be made in direct reference to specific  
215 standards. In addition, vendors who have implemented IHE integration capabilities shall use an IHE Integration Statement to describe the conformance of their product to the specifications in the IHE Technical Framework. The purpose of an IHE Integration Statement is to communicate in a uniform manner to the users of the corresponding product the IHE capabilities it has been designed to support. Vendors publishing IHE Integration Statements accept full responsibility for  
220 their content. By comparing the IHE Integration Statements from different implementations, a user familiar with the IHE concepts of actors and Integration Profiles should be able to determine whether and to what extent communications might be supported between products. See IHE PCD TF-2: Appendix I for the format of such IHE Integration Statements.

225 IHE encourages implementers to ensure that products implemented in accordance with the IHE Technical Framework also meet the full requirements of the standards underlying IHE, allowing the products to interact, although possibly at a lower level of integration, with products that have

been implemented in conformance with those standards, but not in full accordance with the IHE Technical Framework.

## 1.5 Relationship to Real-world Architectures

- 230 The IHE actors and transactions described in the IHE Technical Framework are abstractions of  
real-world healthcare information system environments. While some of the transactions are  
traditionally performed by specific product categories (e.g., HIS, Electronic Patient Record, RIS,  
PACS, Clinical Information Systems, patient care devices or imaging modalities), the IHE  
Technical Framework intentionally avoids associating functions or actors with such product  
235 categories. For each actor, the IHE Technical Framework defines only those functions associated  
with integrating information systems. The IHE definition of an actor should therefore not be  
taken as the complete definition of any product that might implement it, nor should the  
framework itself be taken to comprehensively describe the architecture of a healthcare  
information system.
- 240 The reason for defining actors and transactions is to provide a basis for defining the interactions  
among functional components of the healthcare information system environment. In situations  
where a single physical product implements multiple functions, only the interfaces between the  
product and external functions in the environment are considered to be significant by the IHE  
initiative. Therefore, the IHE initiative takes no position as to the relative merits of an integrated  
245 environment based on a single, all-encompassing information system versus one based on  
multiple systems that together achieve the same end. To illustrate most dramatically the  
possibilities of the IHE Technical Framework, however, the IHE demonstrations emphasize the  
integration of multiple vendors' systems based on the IHE Technical Framework.

## 1.6 Conventions

- 250 This document has adopted the following conventions for representing the framework concepts  
and specifying how the standards upon which the IHE Technical Framework is based should be  
applied.

### 1.6.1 Actor and Transaction Diagrams and Tables

- 255 Each integration profile is a representation of a real-world capability that is supported by a set of  
actors that interact through transactions. Actors are information systems or components of  
information systems that produce, manage, or act on categories of information required by  
operational activities in the enterprise. Transactions are interactions between actors that transfer  
the required information through standards-based messages.

- 260 The tables of actors and transactions given in subsequent sections indicate which transactions  
each actor must support.

The transactions shown on the diagrams are identified both by their name and the transaction  
number as defined in PCD TF-1. The transaction numbers are shown on the diagrams as  
bracketed number prefixed with the specific Technical Framework domain.

265 In some cases in IHE, a profile is dependent on a pre-requisite profile in order to function properly and be useful. For example, many PCD profiles depend on Consistent Time. These dependencies are discussed in Section 2.1. An actor must implement all required transactions in the prerequisite profiles in addition to those in the desired profile.

### 1.6.2 Process Flow Diagrams

270 The descriptions of Integration Profiles that follow include Process Flow Diagrams that illustrate how the profile functions as a sequence of transactions between relevant actors.

These diagrams are intended to provide a “big picture” so the transactions can be seen in the context of the overall workflow. Certain transactions and activities not defined in detail by IHE are shown in these diagrams in *italics* to provide additional context on where the relevant IHE transactions fit into the broader scheme of healthcare information systems.

275 These diagrams are not intended to present the only possible scenario. Often other actor groupings are possible, and complementary transactions from other profiles may be interspersed.

In some cases the sequence of transactions may be flexible. Where this is the case there will generally be a note pointing out the possibility of variations.

280 Transactions are shown as arrows oriented according to the flow of the primary information handled by the transaction and not necessarily the initiator.

### 1.6.3 Normative versus informative contents of the Technical Framework

285 Most parts of the Technical Framework describe required or optional characteristics of Integration Profiles, actors and transactions: these are normative. For a better understanding of the text, there also exist illustrations (or examples) in the Technical Framework that are informative and non-normative.

According to IETF RFC 2119, certain words indicate whether a specific content of the Technical Framework is normative: either required (e.g., “must”, “required”, “shall”) or optional (e.g., “may”, “recommended”). Informative content does not contain these key words.

### 1.6.4 Technical Framework Cross-references

290 When references are made to a Section within the same Technical Framework volume, a section number is used by itself. When references are made to other volumes or to a Technical Framework in another domain, the following format is used:

IHE <domain designator> TF-<volume number>: <section number>, where:

295 <domain designator> is a short designator for the IHE domain (e.g., ITI = IT Infrastructure, RAD = Radiology, CARD = Cardiology, LAB = Laboratory, PCD = Patient Care Device)

<volume number> is the applicable volume within the given Technical Framework (e.g., 1, 2, 3), and <section number> is the applicable section number.

For example: IHE ITI TF-1: 3.1 refers to Section 3.1 in volume 1 of the IHE IT Infrastructure Technical Framework, IHE RAD TF-3: 4.33 refers to Section 4.33 in volume 3 of the IHE Radiology Technical Framework.

### 1.6.5 Transaction Referencing

When references are made to a transaction, the following format is used:

<domain designator>-<transaction number>, where:

<domain designator> is a short designator for the IHE domain (e.g., ITI = IT Infrastructure, RAD = Radiology, CARD = Cardiology, LAB = Laboratory, PCD = Patient Care Device)

<transaction number> is the applicable transaction number as specified in the Technical Framework for that domain.

Transactions may also be referenced by name, but only after that transaction name has been identified with its domain and transaction number within that Section of the document.

## 1.7 IHE Patient Care Device Current Year Scope

IHE PCD is involved in developing various types of Integration Profiles as well as other documents such as supporting Test Environments, White Papers and User Guides. Currently not all profile types have been addressed; however we envision the provision of:

- Transaction Integration Profiles (focused on Messages)
- Content Integration Profiles (focused on Syntax and Semantics)
- Device Integration Profiles (focused on specific device types)
- Clinical Integration Profiles (focused on specific clinical workflows)
- And potentially other profile types as required

This version of the IHE PCD Technical Framework Final Text includes the following profiles and work products:

- **[DEC] Device Enterprise Communication** is a Transaction Profile which describes mechanisms to communicate PCD data to enterprise information systems. The typical PCD data includes: periodic physiologic data (heart rate, invasive blood pressure, respiration rate, etc.), aperiodic physiologic data (non-invasive blood pressure, patient weight, cardiac output, etc.), and CLIA waived (or equivalent international waiver) point-of-care laboratory tests (i.e., home blood glucose, etc.). The data may also include contextual information such as the patient ID, caregiver identification, and patient care device configuration information.
- **[PIV] Point-of-care Infusion Verification** is a Transaction Profile which supports communication of a 5-Rights validated medication delivery / infusion order from a BCMA system to an infusion pump or pump management system, thus "closing the loop."

- 335 • **[IDCO] Implantable Device Cardiac Observation** is a Transaction Profile which specifies a mechanism for the translation, transmission, and processing of discrete data elements and report attachments associated with cardiac device interrogations (observations).
- 340 • **[ACM] Alert Communication Management** integration profile defines the communication of alerts from alert (alerts = alarms physiological + technical + advisories) source systems to alert manager systems and from alert manager systems to alert communicator systems.
- 345 • **[RTM] Rosetta Terminology Mapping** is a managed value set which establishes a nomenclature expressed in a set of tools (Excel spreadsheets & XML files) that map the proprietary semantics communicated by medical devices today to a standard representation using ISO/IEEE 11073 semantics and UCUM units of measurement.
- 350 • **[EC] Event Communication** is a collection of profiles that define event exchanges (such as infusion events or device association events) between 2 participating systems. (Alarms and alert events are defined in the ACM profile which handles events ultimately intended for clinical personnel.)
- 355 • **PCD User Handbook** - A tool to help implementers understand specific topics in the PCD domain. This first effort is targeted for administrators to show how to specify IHE PCD Profiles in an RFP or RFI. The document will discuss the various profiles and the benefits of specifying and implementing them.
- 360 • Additional profiles and workitems have been or are being developed but have not yet met the requirements necessary to progress to Final Text. These include:
  - **[WCM] Waveform Content Module** is an object description which will extend existing IHE PCD profiles to provide a method for passing near real-time waveform data using HL7 v2 observation message syntax.
  - **[RDQ] Retrospective Data Query** is a transaction profile which will support a solicited mode of obtaining data from patient care devices or patient care data stored in devices or IT systems

In addition, technical reports and enhancements to existing documents are being developed as part of current year efforts. These include:

- 365 • **[DPI] Device Point-of-care Integration** is a Transaction Profile which brings focus on device connectivity around a patient-centric point-of-care, including "first link" interfaces between devices or a device manager / supervisor system. This activity includes initial development of a white paper, followed by a number of proposed profiles such as: discovery and association, data reporting, symmetric (bi-directional) communication, and external control.
- 370 • **[SA] Semantic Architecture White Paper** will provide an overview of the sometimes bewildering subject of nomenclature, terminology and information models that are used to enable true semantic interoperability of patient care device information. It will also lay

the groundwork for the new terminology development that is required to fill gaps that have been identified, especially during [RTM] "Rosetta" profile development.

- 375 • **[MEM] Medical Equipment Management** is a White Paper that investigates the question of how health I.T. might support the activities of clinical engineering / biomedical engineering staff, improving quality and workflow efficiency. Key topics include unique device identification, real-time location tracking, hardware/software configuration and patch management, battery management, and more. PCD anticipates this will develop into a Transaction Profile.
- 380 • **Profile Conformance Testing** - IHE and NIST are collaborating to test vendor implementations as defined across the IHE-PCD profiles. This cycle year includes IHE-PCD V2 message verification, both syntactically and semantically. Terminology is constrained to "Harmonized Rosetta" terminology from the ISO/IEEE 11073 standard.

## 1.8 Comments

- 385 IHE International welcomes comments on this document and the IHE initiative. They can be submitted using the Web-based comment form at [http://ihe.net/PCD\\_Public\\_Comments](http://ihe.net/PCD_Public_Comments) or by sending an email to the co-chairs and secretary of the Patient Care Device domain committees at [pcd@ihe.net](mailto:pcd@ihe.net).

## 1.9 Copyright Permission

- 390 Health Level Seven, Inc., has granted permission to the IHE to reproduce tables from the HL7 standard. The HL7 tables in this document are copyrighted by Health Level Seven, Inc. All rights reserved.

The National Electrical Manufacturers Association (NEMA) has granted permission to the IHE to incorporate portions of the DICOM standard.

- 395 The Institute of Electrical and Electronics Engineers has granted permission to the IHE to reproduce limited sections of relevant IEEE standards. Use of copyrighted IEEE material in this technical framework from the ISO/IEEE 11073 standards is covered by the IEEE-SA Royalty-free permission guidelines.

Material drawn from these documents is credited where used.

## 400 1.10 IHE Technical Framework Development and Maintenance Process

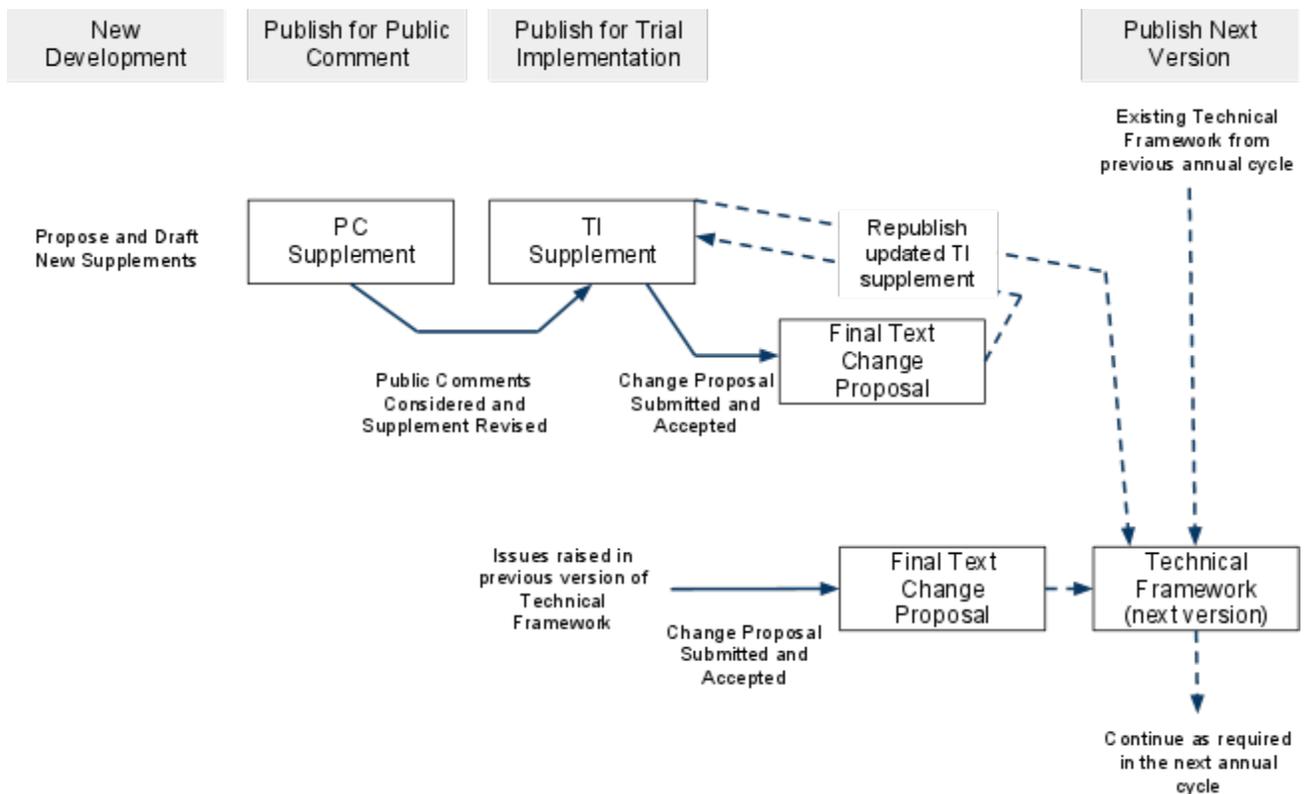
- 405 The IHE PCD Technical Frameworks is continuously maintained and expanded on an annual basis by the PCD Technical Committee in cooperation with the other domain-specific Technical Committees. The development and maintenance process of the Framework follows a number of principles to ensure stability of the specification so that both vendors and users may use it reliably in specifying, developing and acquiring systems with IHE integration capabilities.

A simplified document publication portion of the broader IHE process includes an annual three-step process:

410 The PCD Technical Committee develops Supplements to the current Final Text version of the Technical Framework to support new functionality identified by the IHE PCD Strategic and Planning Committees and issues the Supplement(s) for Public Comment.

415 The PCD Technical Committee addresses all comments received during the public comment period and publishes an updated version of the Supplements for Trial Implementation. This version of the specification is used by vendors in developing trial implementation software for annual IHE Connectathons testing events.

420 The PCD Technical Committee considers Change Proposals to the Trial Implementation version of the Supplements, including those from implementers who participate in the Connectathon. After resolution of all change proposals and sufficient implementations, the Supplement is incorporated into the Technical Framework Volumes and published as Final Text. Change Proposals may also be submitted to Final Text for future incorporation into the Technical Framework volumes.



425

**Figure 1.10-1: The process of developing and maintaining the Technical Framework during an annual cycle**

430 **1.10.1 Use of Technical Framework**

The current version of the Technical Framework is considered the primary reference document. Final Text Change Proposals from the current annual cycle complement this document. Past Final Text documents are retained to provide convenient summaries of differences to prior versions of the Technical Framework or Trial Implementation versions of Supplements.

435 During the annual development and maintenance cycle, it is recommended to use Technical Framework documents for implementations as follows:

- Product Implementations

440 Products implemented based on Trial Implementation text are expected to review the subsequent Final Text and update their products as necessary. Further, it is expected that vendors will monitor Final Text Change Proposals and make any corrections relevant to their product in a timely fashion.

- Connectathon Implementations

445 Testing at the Connectathon will be based on the current version of the Technical Framework for the appropriate IHE Domain, plus any relevant Supplements for Trial Implementation and Final Text Change Proposals.

**1.10.2 Product Verification and Validation Implications**

450 The IHE process is geared around additional activities designed to assist in assuring interoperability of implementations, and correctness of the specification. Each year Connectathons are held where solution suppliers test their implementation of IHE profiles with other suppliers, typically as pairs of information suppliers and consumers. These activities not only test the implementations of the profiles, but also serve to test the completeness and quality of the Supplements which will find their way into the Final Text documents. In fact, a Supplement cannot become Final Text until the Profile has been vetted during a Connectathon.

455 The IHE testing activities can have some relationship to the product verification and validation activities that product vendors must engage in, in order to release their products. Indeed, involvement in the IHE process ideally would be complementary to the product development process with the goal of reducing the overall development effort.

460 The testing activities during the Connectathon can be referred to as Product Verification activities by the solution suppliers and the results can be included as part of a regulatory submission package. However it is up to each organization to decide whether this is appropriate according to their internal development policies.

While the IHE process is also built around Use Cases, it may also be tempting to consider that the IHE testing is also a form of product validation. This is probably not appropriate since the Intended Use of specific devices is not considered during the IHE testing activities.

## 465 2 PCD Integration Profiles

IHE Patient Care Device Integration Profiles, offer a common language that healthcare professionals and vendors may use in communicating requirements for the integration of products. Integration Profiles describe real-world scenarios or specific sets of capabilities of integrated systems. An Integration Profile applies to a specified set of actors, and for each actor specifies the transactions necessary to support those capabilities.

Integration Profiles provide a convenient way for both users and vendors to reference a subset of the functionality detailed in the IHE Technical Framework. They enable users and vendors to be more specific than simply requesting or promising overall IHE support, without laborious restatement of the details regarding IHE actors and transactions defined by the IHE Technical Framework.

### 2.1 Dependencies between Integration Profiles

Dependencies among IHE Integration Profiles exist when implementation of one integration profile is a prerequisite for achieving the functionality defined in another integration profile. Table 2.1-1 Patient Care Device Integration Profile Dependencies defines the required dependencies. Some dependencies require that an actor supporting one profile be grouped with one or more actors supporting other integration profiles.

There are of course other useful synergies that occur when different combinations of profiles are implemented, but those are not described in the table below. For instance, actors of the various PCD profiles may implement profiles of the IT Infrastructure domain for user or node authentication, audit trails, patient identifier cross-referencing, etc.

**Table 2.1-1: Patient Care Device Integration Profile Dependencies**

Integration Profile	Depends on	Dependency Type	Purpose
Device Enterprise Communication (DEC)	Consistent Time	Each actor implementing DEC shall be grouped with the Time Client Actor	Required for consistent time-stamping of messages and data
Point-of-Care Infusion Verification (PIV)	Consistent Time	Each actor implementing PIV shall be grouped with the Time Client Actor	Required for consistent time-stamping of messages and data
Alert Communication Management (ACM)	Consistent Time	Each actor implementing ACM shall be grouped with the Time Client Actor	Required for consistent time-stamping of messages and data
Implantable Device - Cardiac - Observation (IDCO)	None	N/A	N/A

490 Vendor products support an Integration Profile by implementing the appropriate actor-transactions as outlined in the Integration Profile in Section 4. A product may implement more than one actor and more than one Integration Profile.

To support a dependent profile, an actor must implement all required transactions in the prerequisite profiles in addition to those in the dependent profile. In some cases, the prerequisite is that the actor selects any one of a given set of profiles.

495 Actors (see Section 3.1) are information systems or components of information systems that produce, manage, or act on information associated with operational activities in the enterprise.

Transactions (see Section 3.2) are interactions between actors that transfer the required information through standards-based messages.

## 2.2 Integration Profiles Overview

500 In PCD-TF-1, each Integration Profile may be defined by:

- The IHE actors involved
- The specific set of IHE transactions required for each IHE actor

505 These requirements are presented in the form of a table of transactions required for each actor supporting the Integration Profile. Actors supporting multiple Integration Profiles are required to support all the required transactions of each Integration Profile supported. When an Integration Profile depends upon another Integration Profile, all transactions required for the dependent Integration Profile have been included in the table.

510 Note that IHE Integration Profiles are not statements of conformance to standards, and IHE is not a certifying body. Users should continue to request that vendors provide statements of their conformance to relevant standards, such as IEEE, DICOM and HL7. Standards conformance is a prerequisite for vendors adopting IHE Integration Profiles.

515 Also note that there are critical needs for any successful integration project that IHE cannot address. Successfully integrating systems still requires a project plan that minimizes disruptions and describes fail-safe strategies, specific and mutually understood performance expectations, well-defined user interface requirements, clearly identified systems limitations, detailed cost objectives, plans for maintenance and support, etc.

520 In a recent HIMSS survey of requirements for Patient Care Device (PCD) the respondents identified Enterprise Sharing of PCD data as their highest priority. Goals include shortening decision time, increasing productivity, minimizing transcription errors, and obtaining increased contextual information regarding the data.

PCD data includes:

- periodic physiologic data (heart rate, invasive blood pressure, respiration rate, etc.)
- aperiodic physiologic data (non-invasive blood pressure, patient weight, cardiac output, etc.)

- 525
- alarm and alert information
  - device settings and the ability to manipulate those settings
  - CLIA waived (or equivalent international waiver) point-of-care laboratory tests (i.e., home blood glucose, etc.)

530 PCD data may also include contextual data such as the patient ID, caregiver identification, and physical location of the device.

### **2.2.1 Device Enterprise Communication (DEC)**

The Device Enterprise Communication (DEC) profile addresses the need for consistent communication of PCD data to the enterprise. Enterprise recipients of PCD data include, but are not limited to, Clinical Decision Support applications, Clinical Data Repositories (CDRs),  
535 Electronic Medical Record applications (EMRs), and Electronic Health Records (EHRs).

The current profile does not address issues of privacy, security, and confidentiality associated with cross-enterprise communication of PCD data. The assumption is made that the DEC profile is implemented in a single enterprise on a secure network. These aspects are on the IHE PCD roadmap for subsequent years.

540 The current profile does not address use cases and transactions associated with either open loop or closed loop control of patient care devices. Real-time data such as alarms and alerts, waveforms (ECG, EEG, etc.) is currently not addressed.

#### **2.2.1.1 Note on Patient Identification**

545 Patient Identification is perhaps the most essential infrastructural component of any interoperability and communication process, particularly when PCD data is exported to the enterprise. It is the key element in medical device, communication, data analysis, reporting and record keeping. Automation of the entry of patient identification to patient care device has the potential for improving throughput, reducing errors, increasing safety and device and drug effectiveness, and efficiency. It is strongly recommended that implementations use IHE  
550 compliant transactions for acquisition of Patient Identification credentials. These transactions include: ITI-21, ITI-30 and ITI-31. Other mechanisms such as bar code or RFID are also perfectly valid alternatives or complements.

#### **2.2.2 Point-of-Care Infusion Verification (PIV)**

555 The goal of the proposed integration is to bring infusion systems into the electronic medication administration process. The following primary steps comprise this process:

- Order medication
- Verify order for inclusion in the eMAR
- Prepare and dispense medication
- Administer medication

560 While medication errors can occur at each point in this process, this proposal is concerned with the “Administer medication” step, where half of the errors made by clinicians involve infusions. These errors usually involve a breach of one of the 5 Rights of Medication Administration:

- Right Patient
- Right Drug
- 565 • Right Dose
- Right Route
- Right Time

It is the caregiver’s responsibility to ensure that these rights are reviewed prior to administering each drug or starting each infusion.

570 Because manual programming of the pump may still result in administration errors, this profile was developed to support automated programming of the pump, thereby closing the loop between the clinician who uses a BCMA system to verify the 5 Rights and the actual programming of the pump.

575 The Point-of-Care Infusion Verification profile supports the electronic transfer of infusion parameters from a Bedside Computer assisted Medication Administration (BCMA) system to an infusion pump. This capability will reduce errors by eliminating keystroke errors and by increasing the use of automatic dosage checking facilitated by the onboard drug libraries in “smart pump” systems. In addition to the reduction of medication administration errors, this integration may also increase caregiver productivity and provide more contextual information  
580 regarding infusion data.

Electronic transfer of infusion status information from an infusion pump to a clinical information system can be accomplished using the PCD-01 (Communicate PCD Data) or PCD-02 (Subscribe to PCD Data) transactions of the IHE-PCD Device Enterprise Communication profile.

585 The use case addressed in this profile includes the following steps (note that the workflow supported by the BCMA application may not necessarily occur in the order specified):

- Clinician uses BCMA to administer an IV
- Clinician identifies self, medication, patient, pump
- Clinician confirms or edits infusion parameters for an IV medication order using the BCMA
- 590 • Infusion parameters are transmitted to pump
- Clinician confirms settings directly on pump and starts infusion

### **2.2.3 Implantable Device – Cardiac - Observation (IDCO)**

The Implantable Device – Cardiac – Observation Integration Profile defines a mechanism for the translation, transmission, and processing of discrete data elements and report attachments

595 associated with cardiac device interrogations (observations). It supports the uses cases for in-clinic and remote implanted cardiac device follow-ups by standardizing the messages from clinical reviewer to the medical record system.

#### **2.2.4 ACM Integration Profile**

This is an alert (alarms and advisories) distribution solution providing the following:

- 600 • Communication of alerts from reporting devices to concentrating gateways
- Communication from the gateway to an alert manager or distributor
- Communication to an alert communicator for dissemination to people using both wired and wireless communication devices, typically clinicians, physicians, or other healthcare staff, for responding to patient needs or related workflows
- 605 • Communication of status updates and responses from people back to the alert manager for delivery confirmation

#### **2.2.5 Rosetta Terminology Mapping (RTM)**

610 The primary purpose of the Rosetta Terminology Mapping (RTM) managed value set is to *harmonize the use of existing ISO/IEEE 11073-10101 nomenclature terms* by systems compliant with IHE PCD profiles. The RTM profile also specifies the *units-of-measure* and *enumerated values* permitted for each numeric parameter to facilitate safe and interoperable communication between devices and systems. Use of RTM is required in IHE-PCD profiles.

615 The Rosetta Table also is designed to serve as a temporary repository that can be used to define *new nomenclature terms* that are currently not present in the ISO/IEEE 11073-10101 nomenclature. Based on our experience to date, well over 100 new terms will be required, principally in the area of ventilator and ventilator settings. The RTM will also serve as a framework for capturing new terms to support the IEEE 11073 ‘Personal Health Devices’ (PHD) initiative. Additional information on RTM can be found in the Appendix.

### 3 Overview of Actors and Transactions

#### 620 3.1 Actor Descriptions

Actors are information systems or components of information systems that produce, manage, or act on information associated with operational activities in the enterprise. The following are the actors defined by IHE and referenced throughout the rest of this document, as well as in other domain Technical Framework documents.

#### 625 New actors

**Alert Reporter** – The Alert Reporter (AR) actor sources the alert to Alert Manager (AM).

**Alert Manager** – The Alert Manager (AM) actor receives the alert from the Alert Reporter (AR), potentially analyzes the alert, and dispatches the alert to the Alert Communicator (AC).

630 **Alert Communicator** – The Alert Communicator (AC) actor receives the alert from the Alert Manager (AM) and sends the alert to the client application in the endpoint device.

#### Existing actors

635 **Device Observation Reporter** – The Device Observation Reporter (DOR) actor receives data from PCDs, including those based on proprietary formats, and maps the received data to transactions providing consistent syntax and semantics.

**Device Observation Consumer** – The actor responsible for receiving PCD data from the Device Observation Reporter, the Device Observation Filter, or both.

640 **Infusion Order Programmer** – The Infusion Order Programmer (IOP) actor sends the information comprising an order to the Infusion Order Consumer (IOC). The mechanism by which the IOP obtains the order information is outside the scope of this profile.

**Infusion Order Consumer** – The Infusion Order Consumer (IOC) actor receives the order information from the IOP actor and in turn programs the pump. The mechanism by which the IOC programs the pump with the received information is outside the scope of this profile.

645 **Implantable Device Cardiac Reporter** – This actor reports data from systems which communicate with Cardiac Implantable Devices.

**Implantable Device Cardiac Consumer** – This actor receives data from Implantable Device Cardiac Reporters.

Table 3.1-1 shows which actors are used in which Integration Profiles.

650

**Table 3.1-1: Integration Profile Actors**

Integration Profile \ Actor	DEC	PIV	IDCO	ACM
Device Observation Reporter	X			
Device Observation Consumer	X			
Infusion Order Consumer		X		
Infusion Order Programmer		X		
Implantable Device – Cardiac – Reporter			X	
Implantable Device – Cardiac – Consumer			X	
Alert Reporter				X
Alert Manager				X
Alert Communication				X

### 3.2 Transaction Descriptions

655 Transactions are interactions between actors that transfer the required information through standards-based messages. The following are the transactions defined by IHE and referenced throughout the rest of this document. Those transactions specified in other domain Technical Framework documents are identified with the domain identifier and transaction number.

**Communicate PCD Data** – Transmit PCD data to enterprise clients from a Device Observation Reporter and Receive PCD data by a Device Observation Consumer.

660 **Communicate Infusion Order** – This transaction contains the information from the Infusion Order Programmer, such as caregiver, patient, and pump identification, medication, volume, and rate for the infusion being programmed.

**Communicate IDC Observations** – This transaction contains the observations, measurements or reports from the IDCO Reporter.

665 The following table shows which transactions are used in which Integration Profiles.

**Table 3.2-1: Integration Profile Transactions**

Integration Profile \ Transaction	DEC	PIV	IDCO	ACM
Communicate PCD Data [PCD-01]	X			
Communicate Infusion Order [PCD-03]		X		
Communicate IDC Observations [PCD-09]			X	
Report Alert [PCD-04]				X
Disseminate Alert [PCD-06]				X
Report Dissemination Alert Status [PCD-07]				X

### 3.3 Product Implementations

Notes: Developers have a number of options in implementing IHE actors and transactions in product implementations. The decisions cover four levels of optionality:

- 670     • For a system, select which actors it will incorporate. (Multiple actors per system are acceptable).
- For each actor, select which Integration Profiles it will participate in.
- For each actor-profile, select which optional transactions will be implemented. All required transactions must be implemented for the profile to be supported. (Refer to the  
675     Integration Profile Tables in the Integration Profile sections).
- Finally, for each transaction, select which optional features will be supported. (Refer to the transaction descriptions in the appropriate domain TF).

Implementers should provide a statement describing which IHE actors, IHE Integration Profiles, optional transactions and optional features are incorporated in a given product. The  
680     recommended form for such a statement is defined in IHE PCD-TF2 Appendix H.

In general, a product implementation may incorporate any single actor or combination of actors. However, in the cases specified below, the implementation of one actor requires the implementation of one or more additional actors:

- None at this time

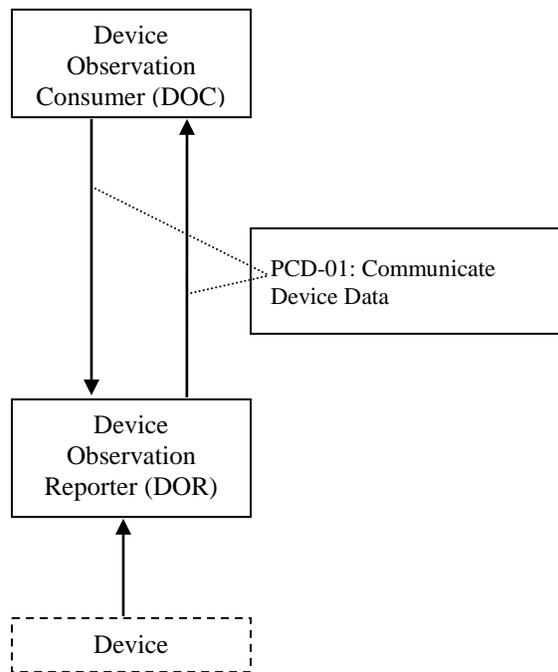
685     When multiple actors are grouped in a single product implementation, all transactions originating or terminating with each of the supported actors shall be supported (i.e., the IHE transactions shall be offered on an external product interface). The exceptions to this rule are any transactions defined between actors in the required groupings defined above.

## 4 Device Enterprise Communication (DEC)

690 The Device Enterprise Communication Integration Profile supports communication of vendor  
 independent, multi-modality Patient Care Devices data to Enterprise Applications using  
 consistent semantics. It accomplishes this by mapping PCD data from proprietary syntax and  
 semantics into a single syntactic and semantic representation for communication to the  
 enterprise. The PCD data is time stamped with a consistent enterprise time. Options are provided  
 695 to allow applications to filter particular PCD data of interest.

### 4.1 Actors/Transactions

The following figure diagrams the actors involved with this profile and the transactions between actors.



700

**Figure 4.1-1: DEC Integration Profile with Actors and Transactions**

705 Table 4.1-1 DEC - Actors and Transactions lists the transactions for each actor directly involved  
 in the DEC Integration Profile. In order to claim support of this Integration Profile, an  
 implementation must perform the required transactions (labeled “R”). Transactions labeled “O”  
 are optional. A complete list of options defined by this Integration Profile that implementations  
 may choose to support is listed in Section 4.2.

**Table 4.1-1: DEC - Actors and Transactions**

Actors	Transactions	Optionalit y	Section in Volume 2
Device Observation Consumer	Communicate PCD Data [PCD-01]	R	Section 3.1
Device Observation Reporter	Communicate PCD Data [PCD-01]	R	Section 3.1

710

Refer to Table 2.1-1 Patient Care Device Integration Profile Dependencies for other profiles that may be pre-requisites for this profile.

#### 4.1.1 Patient Demographics – Recommended Transactions

715 While not required, it is recommended that IHE transactions be employed for acquisition of Patient Demographics from other systems. The recommended transactions include:

**Patient Demographics Query** – This transaction contains the Patient Demographics information in response to a specific query on a specific patient. [ITI-21]

**Patient Identity Feed** - This transaction is broadcast from the Patient Demographics supplier when changes to the patient demographics occur. [ITI-30]

720

**Patient Encounter Management** - The Patient Encounter Source registers or updates an encounter (inpatient, outpatient, pre-admit, etc.) and forwards the information to other systems implementing the Patient Encounter Consumer Actor. This information will include the patient’s location and care providers for a particular (usually current) encounter. [ITI-31]

#### 725 4.2 Integration Profile Options

Many actors have Options defined in order to accommodate variations in use across domains or implementations. Options that may be selected for this Integration Profile are listed in Table 4.2-1 DEC - Actors and Options along with the actors to which they apply. A subset of these Options is required for implementation by actors in this Profile (although they may be truly optional in other Profiles).

730

**Table 4.2-1: DEC - Actors and Options**

Actor	Option Name	Section in Volume 2
Device Observation Reporter	<i>None (assumes MLLP Transport)</i>	Appendix I
Device Observation Consumer	<i>None (assumes MLLP Transport)</i>	Appendix I

#### 4.3 Process Flow Diagram

This Section describes the specific use cases and interactions defined for the DEC Workflow Profile. There are both standard Use Cases as well as optional Use Cases.

735 **4.3.1 Standard Use Cases**

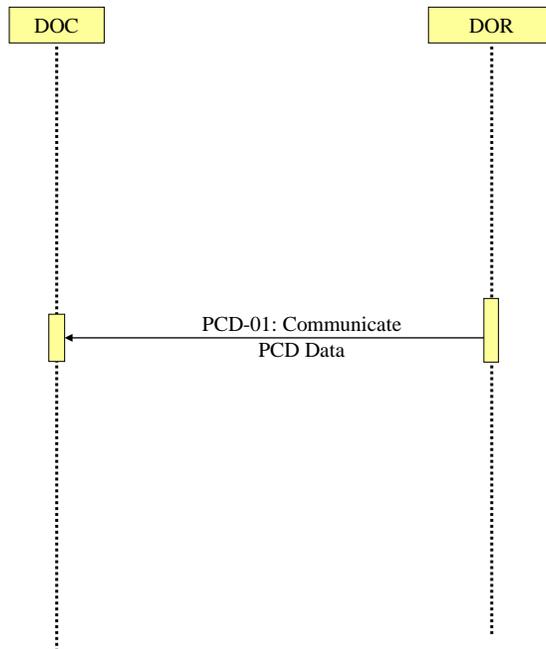
**4.3.1.1 Case DEC-1: Communicate patient identified DEC data to EMR/EHR**

740 Data from all of the patient care devices associated with a particular patient is communicated by a Gateway, Device or Clinical Information System (CIS) implementing the DOR actor to an EMR/EHR, implementing the DOC actor. Examples include data from bedside monitors, ventilators, and infusion pumps. Discrete parameters representing both periodic and aperiodic data are typically communicated at an interval of no less than once per minute. The data is time stamped with a consistent time across the data from the respective patient care devices.

745 The primary intent is communication of structured data, however provisions are made for inclusion of unstructured data. The application provides facilities to bind an authoritative enterprise patient identifier required for inclusion of the PCD data in the patient record. The workflow for associating the authoritative enterprise patient identifier to the PCD data is outside the scope of the current PCD TF.

**4.3.1.2 Case DEC-2: Communicate validated periodic DEC data to EMR/EHR**

750 This Use Case builds on Case C1 by communicating only data which has been validated by a caregiver by identifying the caregiver in the PCD data. The workflow implementing validation is outside the scope of the current PCD TF.



**Figure 4.3.1.2-1: DEC Process Flow (No filtering)**

755

### 4.3.2 Optional Use Cases for Automatic Patient Demographics Acquisition

The following examples describe which actors typical systems might be expected to support. This is not intended to define requirements, but rather to provide illustrative examples.

- 760 • A general purpose observation reporting gateway which combines the Device Observation Reporter and patient demographics.
- A patient care device which bundles the Device Observation Reporter and patient demographics.
- Patient Demographic Data that can be used in identifying the patient includes the following:
  - 765 • Partial or complete patient name (printed on the patient record or wrist band, or related by the patient)
  - Patient ID (from printed barcode, bedside chart, RFID, scan, etc.)
  - Date of Birth / age range

Note: Bed ID is not accepted by the Joint Commission as a means of patient identity verification.

770 Patient Identification Binding Use Cases: The caregiver connects the patient to a patient care device. The patient is physically identified by the caregiver, using some institutionally unique protocol for identification such as verification of information contained on a wristband. The caregiver uses the information from the physical patient identification to authorize an electronic identification, made by the device or an independent device or system, binding the patient's  
775 electronic identity to all data communicated from the patient care device. The verification may involve direct entry of data to the device being bound, a gateway, or an actor residing in a separate system. It may be based on direct physical identification of the patient by the caregiver, or on confirmation by the caregiver of an electronic identification made by the device in concert  
780 with other devices or systems. The verification may also include fully automated binding when a unique logical authentication can be made. The end result is that data communicated from the patient care device contains an authoritative institutionally unique electronic identifier.

#### 4.3.2.1 Case DEC-ID-1: Patient ID known in ADT, locally available

Note: The following are Use Cases in support of automatic acquisition of patient demographics. They do not map into any specific PCD profiles or transactions.

785 A patient is connected to a bedside monitor of a cardiac monitoring system (e.g., central station with continuous ADT feed via PAM broadcasts that includes a number of bedside monitors. The patient may or may not be able to provide positive ID information. Demographic information used to identify a patient includes: partial or complete patient name (printed on the patient record or told by the patient); Patient MRN (this may be obtained from printed barcode, a bed-side  
790 chart, etc.); Partial ID entry or scan; Date of birth / age range. *Note: Bed ID is not permitted as an identifier in accord with Joint Commission standards.*) Caregiver selects the patient from a

pick list on the system console, in response to prompts by caregiver. System information includes showing the Medical Record Number (MRN), full name, age, sex, room/bed, and admit date. The central station binds the patient identity information with the device data.

795 **4.3.2.2 Case DEC-ID-2: Patient ID known in ADT, not locally available**

In the event that the patient above is not registered in the cardiac monitoring system, due to ADT lag or other situations, caregiver can execute a PDQ query of the patient registry to receive a pick list of patients and enter the patient ID into the system

**4.3.2.3 Case DEC-ID-3 Patient ID not known in ADT, locally available**

800 This is the John/Jane Doe patient, for whom the system has set up a Proxy Identification. The Proxy Identification is determined by either method, in accord with institutional policy and later linked with the true patient ID via ITI-PAM.

**4.3.2.4 Case DEC-ID-4: Patient ID not known in ADT, not locally available.**

805 This is the case of a patient presenting in the ER who is not registered in the system, where care must continue and identification may follow. When the patient demographics are unknown, time and device MAC address can be sent automatically, providing unique identification to the data. This last approach can also be used to create an audit trail as a complement to the other binding mechanisms.

**4.3.2.5 Other Clinical Examples**

810 **DEC-ID-A:** A patient is connected to an infusion device. The infusion device is connected to the network but is not managed by an infusion or drug administration management application. Caregiver scans barcode of the patient and the device. Caregiver is presented with a display of patient IDs from ADT and device ID from an authoritative database. Caregiver confirms.

815 **DEC-ID-B:** A patient is connected to an infusion device. The infusion device is connected to the network but is not managed by an infusion or drug administration management application. No ADT feed is available to confirm the ID. Caregiver confirms patient's wristband identity through interactive communication with patient. The Patient ID wristband is scanned (barcode, RFID, etc.) and bound to the PCD.

820 **DEC-ID-C:** A patient is connected to a ventilator. The ventilator is connected to the network but is not managed by a system. Ventilator and patient have RFID tags. Proximity of the tags implies binding of patient's ADT identification and device's ID from an authoritative database. Verification of an existing Order for a Ventilator for the identified patient is required. If verified, Patient Id is bound to PCD.

825

## 5 Point-of-Care Infusion Verification (PIV)

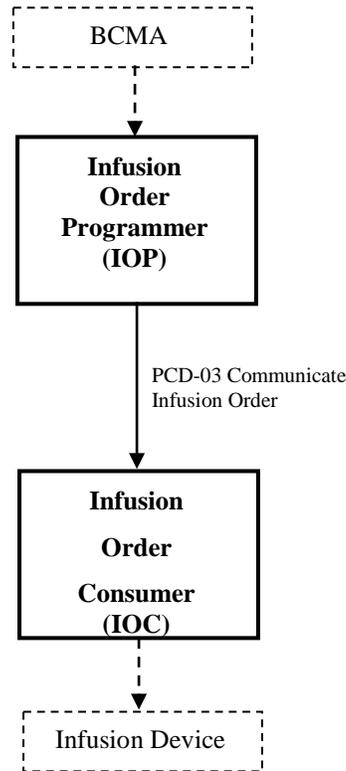
830 The Point-of-Care Infusion Verification profile supports the electronic transfer of infusion parameters from a Bedside Computer assisted Medication Administration (BCMA) system to a general-purpose infusion pump. This capability will reduce errors by eliminating keystroke errors and by increasing the use of automatic dosage checking facilitated by the onboard drug libraries in “smart pump” systems. In addition to the reduction of medication administration errors, this integration may also increase caregiver productivity and provide more contextual information regarding infusion data.

835 Electronic transfer of infusion status information from a pump to a clinical information system can be accomplished using the PCD-01 (Communicate PCD Data), possibly with PCD-02 (Subscribe to PCD Data) transactions of the IHE-PCD Device Enterprise Communication profile.

The goal of the proposed integration is to bring infusion systems into the electronic medication delivery process.

### 840 5.1 Actors/Transactions

Figure 5.1-1 shows the actors involved in the Point-of-Care Infusion Verification Integration Profile and the relevant transactions between them.



845

**Figure 5.1-1: Point-of-Care Infusion Verification Actor Diagram**

Table 5.1-1 lists the transactions for each actor directly involved in the Point-of-Care Infusion Verification Profile. In order to claim support of this Integration Profile, an implementation must perform the required transactions (labeled “R”). Transactions labeled “O” involve optional actors. A complete list of options defined by this Integration Profile and that implementations may choose to support is listed in Volume 1, Section 3.3.

850

**Table 5.1-1: Point-of-Care Infusion Verification Integration Profile - Actors and Transactions**

Actors	Transactions	Optionality	Section in Vol. 2
Infusion Order Programmer	Communicate Infusion Order [PCD-03]	R	3.3
Infusion Order Consumer	Communicate Infusion Order [PCD-03]	R	3.3

855 **5.2 Integration Profile Options**

Options that may be selected for this Integration Profile are listed in the table 5.2-1 along with the Actors to which they apply. Dependencies between options when applicable are specified in notes.

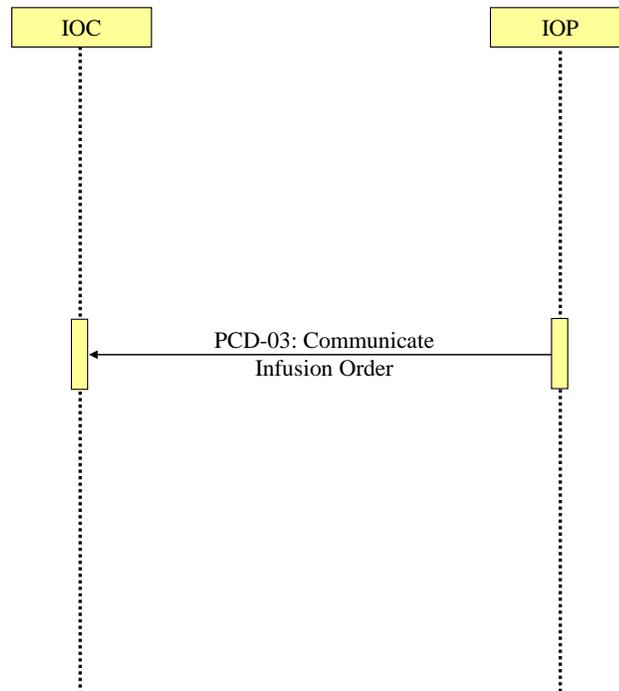
**Table 5.2-1: Evidence Documents - Actors and Options**

Actor	Options	Section in Volume 2
Infusion Order Programmer	<i>No options defined</i>	--
Infusion Order Consumer	<i>No options defined</i>	--

860

### 5.3 Integration Profile Process Flow

Figure 5.3-1 shows the sequence diagram for this profile. The use case is described in section 2.2.2 above.



865

**Figure 5.3-1: Basic Process Flow in Point-of-Care Infusion Verification Profile**

### 5.4 Integration Profile Safety and Security Considerations

This profile relies on the BCMA system to verify the clinician and patient, as well as the correct medication and infusion parameters, prior to initiating the Communicate Infusion Order transaction.

870

Although the profile provides infusion settings for an infusion pump, the infusion is not started automatically. The clinician must always verify all settings and start the infusion directly on the pump.

## 6 Implantable Device – Cardiac – Observation (IDCO)

875 Cardiac physicians follow patients with implantable cardiac devices from multiple  
 manufacturers. These devices are categorized as implantable pacemakers, cardioverter  
 defibrillators, cardiac resynchronization therapy devices, and implantable cardiac monitor  
 devices. As part of patient follow-up an interrogation of an implanted cardiac device is  
 performed (either in-clinic or remotely from a patient’s residence). These initial device  
 interrogations (solicited or unsolicited) are typically performed by manufacturer provided  
 880 interrogation equipment using manufacturer specific protocols.. Information is collected  
 regarding the implanted device (attributes, settings and status), the patient (demographics and  
 observations) and therapy (delivery and results).

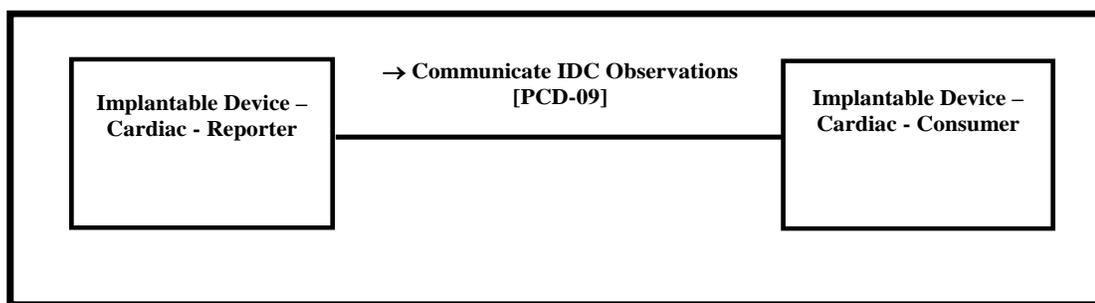
885 To improve workflow efficiencies cardiology and electrophysiology practices require the  
 management of “key” information in a central system such as an EHR or a device clinic  
 management system.

To address this requirement, the Implantable Device – Cardiac – Observation (IDCO) Profile  
 defines a standards based translation and transfer of summary device interrogation information  
 from the manufacturer provided interrogation equipment to the information management system.

890 The IDCO profile specifies a mechanism for the translation, transmission, processing, and  
 storage of discrete data elements and report attachments associated with cardiac device  
 interrogations (observations).

### 6.1 Actors/ Transactions

895 Figure 6.1-1 shows the actors directly involved in the IDCO Integration Profile and the relevant  
 transactions between them. Other actors that may be indirectly involved due to their participation  
 in other related profiles are not necessarily shown.



**Figure 6.1-1: IDCO Actor Diagram**

See section 6.5 Patient Identification for details concerning how patient identity is managed.

900 Table 6.1-1 lists the transactions for each actor directly involved in the IDCO Profile. In order to  
 claim support of this Integration Profile, an implementation must perform the required  
 transactions (labeled “R”). Transactions labeled “O” are optional. A complete list of options

defined by this Integration Profile and that implementations may choose to support is listed in Volume 1, Section 6.2.

905

**Table 6.1-1: IDCO Integration Profile - Actors and Transactions**

Actors	Transactions	Optionalit y	Section in Volume 2
Implantable Device – Cardiac – Reporter	Communicate IDC Observation [PCD-09]	R	3.9
Implantable Device – Cardiac – Consumer	Communicate IDC Observation [PCD-09]	R	3.9

## 6.2 IDCO Integration Profile Options

Options that may be selected for this Integration Profile are listed in the table 6.2-1 along with the Actors to which they apply. Dependencies between options when applicable are specified in notes.

910

**Table 6.2-1: IDCO - Actors and Options**

Actor	Options	Section in Volume 2
Implantable Device – Cardiac – Reporter	PV1 – Patient Visit	3.9.4.1.2.3
	OBX – Encapsulated PDF or Reference Pointer	3.9.4.1.2.7
Implantable Device – Cardiac – Consumer	PV1 – Patient Visit	3.9.4.1.2.3
	OBX – Encapsulated PDF or Reference Pointer	3.9.4.1.2.7

Patient Visit Option – Because this is an unsolicited observation and the Implantable Device – Cardiac – Reporter will not be aware of an associated order, this segment is optional. The Implantable Device – Cardiac – Reporter may want to track the interrogation as a visit using this segment.

915

Encapsulated PDF or Reference Pointer Option - observations or additional analyses may be provided in an encapsulated PDF containing displayable information or as a reference pointer to an external report.

## 6.3 IDCO Use Cases

920

### 6.3.1 Use Case IDCO-1: Implantable Cardiac Device In-Clinic Follow-up

#### Clinical Context:

Alex Everyman presents at the implantable cardiac device follow-up clinic for his appointment. Alex will present for follow-up 7-10 days after implant and every 3-6 months thereafter, depending on the therapy protocol.

925

Dr. Tom Electrode, a cardiac physician, and Nicci Nightingale, a registered nurse (R.N.), work in the implantable cardiac device follow-up clinic.

930 Nicci interrogates the device using a cardiac device programmer. The programmer extracts the device data (e.g., settings, status, events) from the device. Nicci reviews and verifies the device data and initiates a transfer of the data from the programmer to a translator system. A necessary subset of the data that represents a summary is converted by the translator system from a proprietary data format to a standard HL7 format. The data is then transmitted using HL7 messaging to the EHR or device clinic management system.

This summary data is sent as an unsolicited observation message.

935 Notes:

1. In the area of Electrophysiology, a "programmer" is a commonly used term to describe a specialized computer that is capable of communicating with an implanted device. Programmers are used to interrogate implanted devices (as are "interrogators") and "program", or make changes to the cardiac device settings.
- 940 2. In this use case the translator system is a clinical information computer system that can receive proprietary structured data from the programmer and perform the necessary transformation and communication protocols to communicate effectively with the EMR.
3. Electrocardiograms are not currently addressed in the HL7 standards. They can be sent as a PDF attachment to the HL7 message.

**IHE Context:**

945 In the use case the translator system equates to the Implantable Device – Cardiac – Reporter actor and the EHR or device clinic management system equates to the Implantable Device – Cardiac – Consumer actor. The HL7 formatted cardiac device message is the [PCD-09] transaction.

950 **6.3.2 Use Case IDCO2: Implantable Cardiac Device In-Clinic Followup with Networked Programmer that Translates Information**

**Clinical Context:**

Same as in-clinic use case above with the following change. The programmer communicates directly with an EHR or device clinic management system, acting as a translator system.

**IHE Context:**

955 Same as in-clinic use case above with the following change. The programmer assumes the role the actor Implantable Device – Cardiac – Reporter.

**6.3.3 Use Case IDCO-3: Implantable Cardiac Device Remote Followup**

**Clinical Context:**

960 Portions of the previous use case also apply to Alex Everyman having his device followed remotely. Alex will present to an interrogation device located outside of the clinic (e.g., in Alex's residence) which will capture the state of his implanted device and will transmit the information

to a translator system. The translator system converts the data into an HL7 message and communicates the summary data to the clinic's EHR.

**IHE Context:**

- 965 Same as in-clinic use case 6.3.1 above. It is recommended that the Implantable Device – Cardiac – Reporter actor be grouped with the Secure Node actor of the ATNA Profile to secure communications for remote follow-ups if data is sent across an un-trusted network.

**6.3.4 Use Case IDCO-4: Remote Monitoring of Implanted Cardiac Devices**

**Clinical Context:**

- 970 The translator system described in use case IDCO-3 may be implemented as a service, e.g., the device manufacturer or a monitoring service. This system may collect data provided on a periodic basis to enable early detection of trends and problems, or provide other event information. This system may also provide various types of value-added services, such as data aggregation and analysis, trending, statistical reports, and the ability to review and verify data
- 975 before sending to the EMR. Depending on user selectable settings in the translator system, detailed information concerning the current status of the patient and reports may be sent to the recipient system.

**IHE Context:**

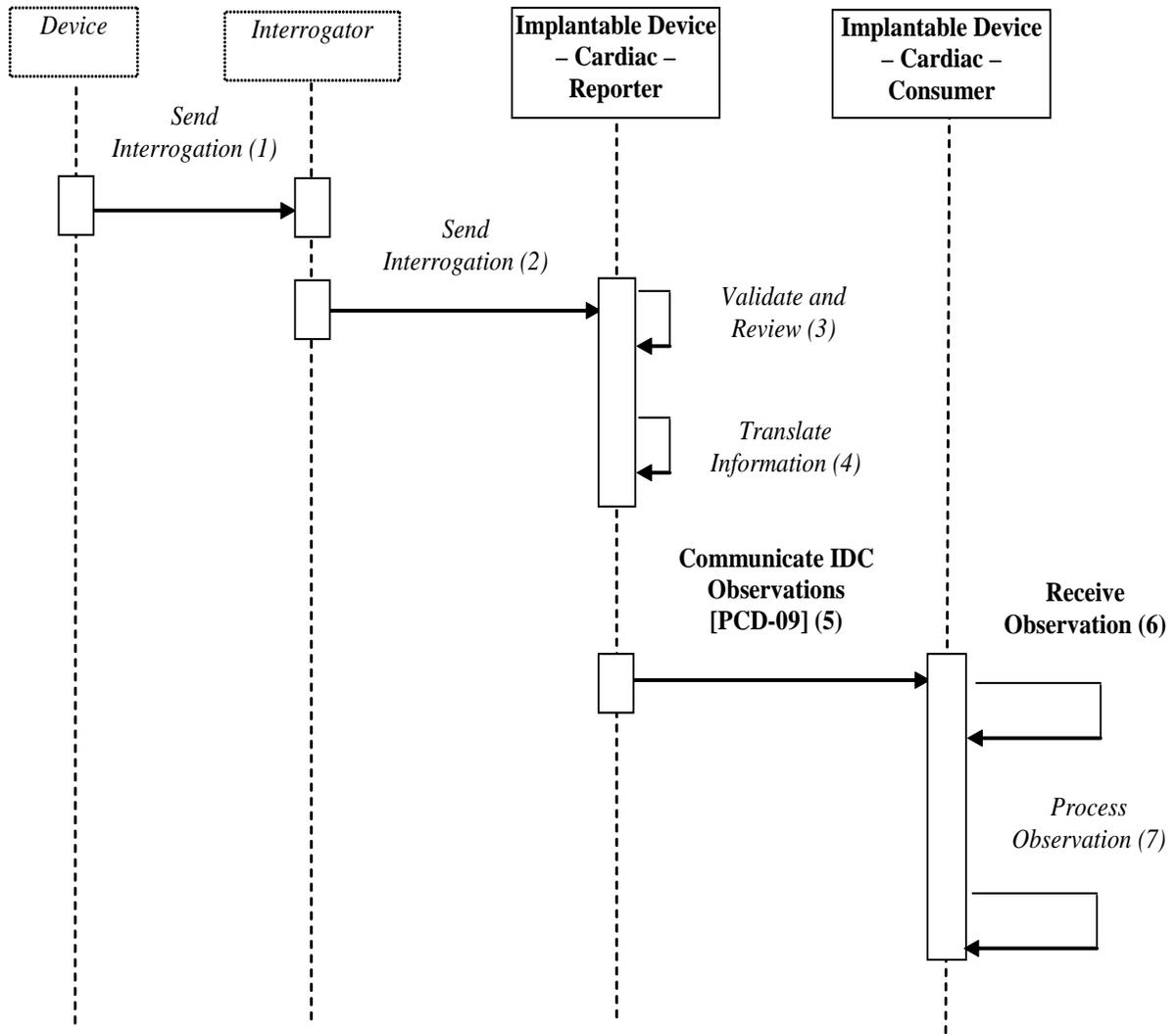
- 980 The same as the Remote Follow-up use case above. The additional data aggregation or rendering can be sent as a PDF attachment to the HL7 message.

These types of value-added services are likely to be provided by a party that will send the results over the Internet. It is recommended that the Implantable Device – Cardiac – Reporter actor be grouped with the Secure Node actor of the ATNA Profile to secure communications for remote follow-ups if data is sent across an un-trusted network.

985

990

995 **6.4 IDCO Process Flow**



**Figure 6.4-1: Basic Process Flow in IDCO Profile**

1000

Note: Device, Interrogator, and steps 1 thru 4, 6 and 7 are informative and are not formal actors or transactions of the IDCO profile.

1005

1. Send Interrogation – The Device sends information in a manufacturer-proprietary manner to the Interrogator.

2. Send Interrogation – The Interrogator sends information in a manufacturer-proprietary manner to the Implantable Device – Cardiac – Reporter.
3. Validate and Review – The Implantable Device – Cardiac – Reporter validates the information. This may include the clinician reviewing and approving the information.
- 1010 4. Translate Information – The Implantable Device – Cardiac – Reporter translates/maps/transforms the information into the proper HL7 format.
5. Send Observation – The Implantable Device – Cardiac – Reporter sends the device information to the Observation Consumer using the [PCD-09] transaction.
- 1015 6. Receive Observation – The Implantable Device – Cardiac – Consumer receives the observation message.
7. Process Observation – The Implantable Device – Cardiac – Consumer further processes the observation message for inclusion within derivative products, such as clinical reports, databases, or trans-coded / reformatted results.

## 6.5 IDCO Patient Identification Considerations

1020 This profile assumes a pre-coordinated association of identifiers across the two Patient Identifier Domains: the device manufacturer systems providing the observations and the clinics receiving the observations.

1025 Depending on local regulations each implantable cardiac device manufacturer may be obligated to maintain a registry that maps a unique device identifier with the patient in which it is implanted. In some locales this mapping is the strict responsibility of the implanting or other organization. Specific patient identification information is typically not stored in the device but is made available in the registry or by other means. Consequently the Implantable Device – Cardiac – Reporter is only required to send this identifier which represents the patient to device relationship for an implanted device as part of the [PCD-09] transaction. This identifier by  
1030 normative convention is the concatenation of a unique industry wide manufacturer id, unique manufacturer model number, and unique manufacturer serial number.

This profile specifies one actor, the Implantable Device – Cardiac – Consumer, as the endpoint for observation messages. The Implantable Device – Cardiac – Consumer will have pre-coordinated a cross-reference of patient identifiers across the two Patient Identifier Domains.  
1035 This will be done by storing the unique device identifier within the patient’s record. This will typically be the patient’s unique identity but could be the patient’s location in emergency situations.

In some cases the Implantable Device – Cardiac – Reporter will have detailed patient identification information like name, address, etc. In these cases the Implantable Device –  
1040 Cardiac – Reporter can send this information as part of the [PCD-09] transaction.

## 6.6 IDCO Security Considerations

1045 This profile does not require the use of ATNA. There are several implementation models for this profile that do not require transmission of data over public networks including intra-institutional, VPN, etc. However, when public networks are used, ATNA is one option for secure transport over those networks. It is recommended that the Implantable Device – Cardiac – Reporter actor be grouped with the Secure Node actor of the ATNA Profile to secure communications for remote follow-ups if data is sent across an un-trusted network.

## 7 Alert Communication Management (ACM) Integration Profile

1050 Alert Communication Management defines the communication of alerts (alarms and advisories) from alert source systems to alert manager systems and from alert manager systems to alert communicator systems.

This is an alert (alarms and advisories) distribution solution providing the following:

- Communication from the gateway to an alert manager or distributor
- 1055
- Communication to an alert communicator for dissemination to people using both wired and wireless communication devices, typically clinicians, physicians, or other healthcare staff, for responding to patient needs or related workflows

The intended use of the IHE PCD Alert Communications Management Profile is to serve in communication of alert information from patient care devices to an alert manager system communicating with additional means of notification to caregivers. Notification devices would include those capable of supporting this profile, in particular PCD-06 and PCD-07.

1060

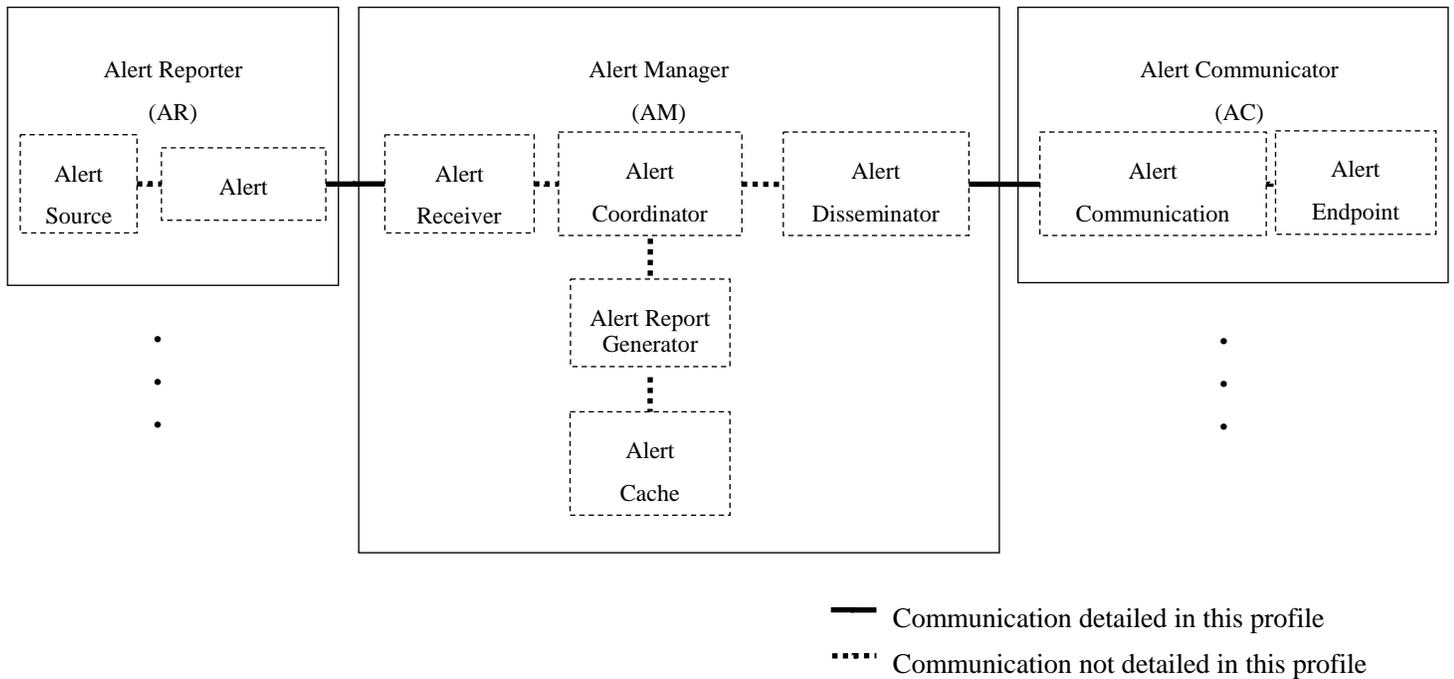


Figure 7-1: ACM Profile Actor Diagram

1065

**Out of Scope**

Grouping or consolidation of alerts is out of scope for this profile.

The definition of escalation actions in response to a notification not being responded to are outside the scope of this profile.

1070 **7.1 Actors/ Transactions**

Figure 7.1-1 shows the actors directly involved in the ACM Integration Profile and the relevant transactions between them. Other actors that may be indirectly involved due to their participation in other related profiles, etc. are not necessarily shown.



1075

Figure 7.1-1 ACM Profile Actor Diagram

1080 Table 7.1-1 lists the transactions for each actor directly involved in the ACM Profile. In order to claim support of this Integration Profile, an implementation must perform the required transactions (labeled “R”). Transactions labeled “O” are optional. A complete list of options defined by this Integration Profile and that implementations may choose to support is listed in Volume 1, Section 7.2.

**Table 7.1-1: ACM Integration Profile – Actors and Transactions**

Actors	Transactions	Direction	Optionality	Section in Vol. 2
Alert Reporter (AR)	Report Alert [PCD-04]	Outbound	R	<a href="#">3.4</a>
Alert Manager (AM)	Report Alert [PCD-04]	Inbound	R	<a href="#">3.4</a>
	Disseminate Alert [PCD-06]	Outbound	R	3.6
	Report Dissemination Alert Status [PCD-07]	Inbound	R	<a href="#">3.7</a>
Alert Communicator (AC)	Disseminate Alert [PCD-06]	Inbound	R	<a href="#">3.6</a>
	Report Dissemination Alert Status [PCD-07]	Outbound	R	<a href="#">3.7</a>

1085

## 7.2 ACM Integration Profile Options

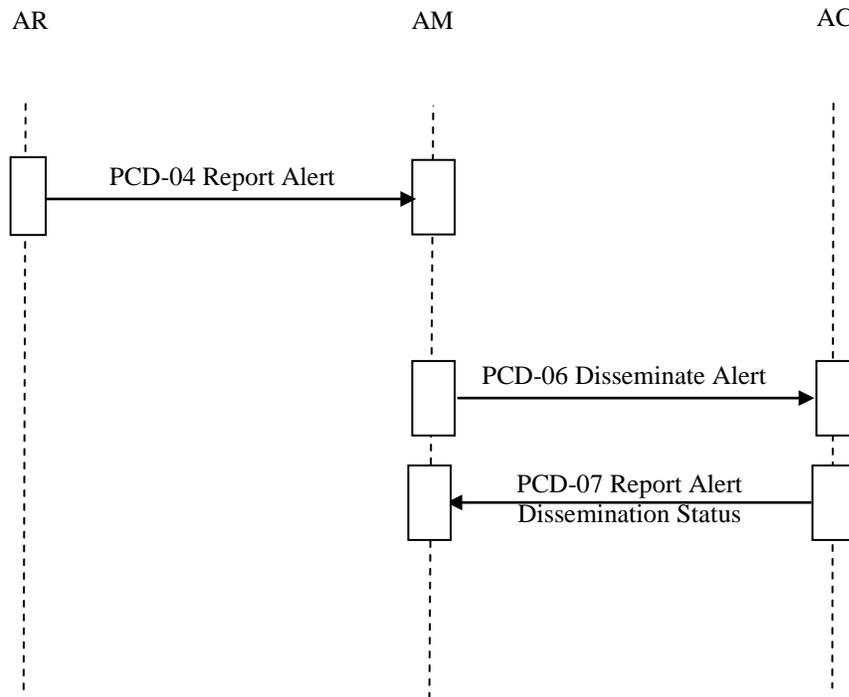
There are no options for this integration profile.

## 7.3 ACM Process Flow and Use Cases and Interaction Diagrams

1090 Alert Communication Management is meant to improve clinical efficiency by using technology to deliver the right alerts, with the right priority, to the right individuals via devices with the right content, and through configuration escalating communication of alerts to devices associated with other individuals.

1095 The following are the use cases. The use cases are noticeably generic and not so much focused on the alert clinical purpose as they are focused on the system interactions. The use cases may be directly applicable to other IHE domains, and may be supplemented with additional use cases to serve specific needs in other domains.

### 7.3.1 ACM Process Flow



**Figure 7.3.1-1: Basic Process Flow in ACM Profile**

1100

Each actor is identified below. Actor identity is implicitly identified in the alert (for example, through MSH-21 Message Profile, identifying the message as PCD-04 by OID, which is sent by an ACM AR actor, which is identified in MSH-3 Sending Application).

1105

The functional units comprising an actor may be provided by one or more vendors in one or more systems. Reducing the total number of systems is preferred, but is not required.

Data flow of individual use model messaging communication indicates the command response sequences and directions.

#### 7.3.1.1 Alert Reporter (AR) Actor

This actor originates the alert (an alarm, either physiological or technical, or an advisory).

1110

The semantics and data types used to represent alert type, alert priority, alert inactivation state and escalation and de-escalation of priority in the messages of this actor are based on IEC 60601-1-8 definitions.

A single source can produce multiple, possibly concurrent, alerts.

A single Report Alert transaction can contain at most a single alert.

1115

This profile specifies the required data and data types produced by this actor.

This profile specifies communication of the data produced by this actor.

This actor may optionally cancel an outstanding alert condition.

This may optionally indicate cancellation of any related escalation.

An outstanding alert condition may be optionally escalated via follow-on alert.

1120 This actor may aggregate and adapt alerts from multiple sources as needed to make them interoperable with the AM actor. It does not need to be the original source of the alert data.

In large alert source populations, an aggregation system may be useful for concentration and possible alert coordination (smart alerting).

### 7.3.1.2 Alert Manager (AM) Actor

1125 This actor receives alerts from the AR, manages them, and dispatches them to the AC actor.

The semantics and data types used to represent alert type, alert priority, alert inactivation state and escalation and de-escalation of priority in the messages of this actor are based on IEC 60601-1-8 definitions.

1130 This profile specifies the required data and data types produced by this actor in communication with the AC and AR actors.

If the following is performed, it is likely performed within the AM.

- Alert formatting for dissemination
- Alert harmonization across multiple similar and dissimilar AR
- Any additional alert priority actions following any performed by the AR
- 1135 • Alert mapping to AC actor endpoints,
- Additional recipients are optionally indicated in the Report Alert [PCD-04] transaction
- Alert dissemination escalation
- Alert dissemination sequencing to AC actor endpoints
- Alert dissemination escalation to AC actor endpoints
- 1140 • Location to staff assignments
- Patient identification to staff assignments
- Equipment to patient to staff assignments
- Staff to AC actor endpoint assignments
- Alert reporting
- 1145 • Alert caching

To accomplish assignments the AM may receive HL7 ADT or SCH message feeds from one or more sourcing systems for the following purposes:

- Identify patients
- Assign resources to patients (staff, equipment, rooms)

1150 This profile specifies the required data and data types produced by this actor.

The protocol used in the communication of the data to/from the Alert Manager (AM) actor and the Alert Communicator (AC) actor is the Wireless Communication Transfer Protocol (WCTP).

### 7.3.1.3 Alert Communicator (AC) Actor

1155 The Alert Communicator (AC) actor is not responsible for taking action in the event that the endpoint operator has received but not responded to the notification. Actions for non-response by the Alert Communicator (AC) endpoint operator (clinical user) are within the scope of the Alert Manager (AM) actor. These actions are commonly referred to as escalation whether it is repeatedly sending the same message to the same recipient or to alternate recipients. The definition of such actions has been identified as out-of-scope for the ACM profile.

1160 The Alert Communicator (AC) actor receives alerts from the Alert Manager (AM) actor. Endpoint devices are connected either directly or indirectly to the Alert Communicator (AC) actor. The Alert Communicator (AC) may utilize a locally controlled or public infrastructure.

The protocol for communication between the Alert Manager (AM) and the Alert Communicator (AC) is WCTP.

1165 This profile does not specify the protocol used in the communication of the data to the final destination as it is potentially not controllable by the Alert Communicator (AC).

This profile does not specify the presentation of the data at the endpoint as that is beyond its control.

This profile does not specify the human interface at the endpoint as that is beyond its control.

1170 This profile does make recommendations as to the significant data items to be included in alert notifications with consideration for ePHI (electronic Patient Healthcare Information). The correlation of what data items are to be sent for specific alerts is defined in IHE PCD Device Profiles in conjunction with alert inclusion in the IHE PCD Rosetta Terminology Mapping (RTM) activities.

1175 It is recognized that in healthcare communication there are certain data items which should not be transported over unsecured and unencrypted communication connections. A number of controls come into play including HIPAA requirements and ePHI guidelines. It is the responsibility of the deploying parties to insure that capabilities are put into place and monitored to assure that information protection requirements are met.

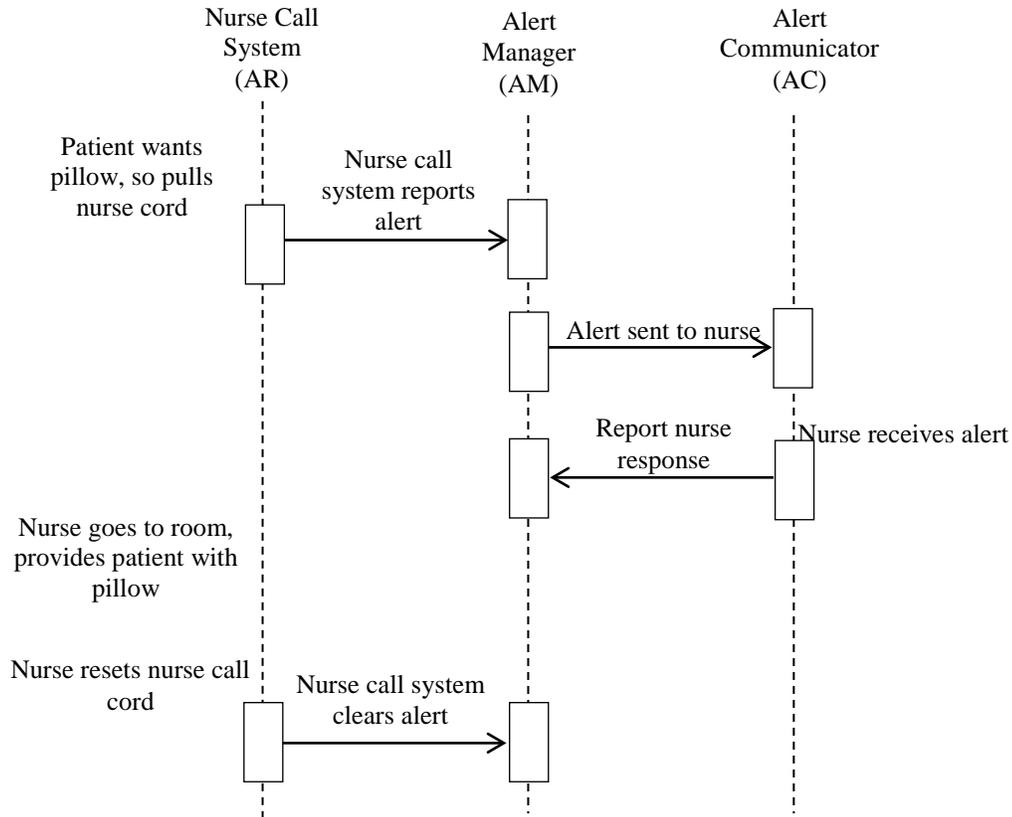
1180 WCTP was originally defined by the Personal Communications Industry Association (PCIA) consortium. The PCIA is not an SDO and is not at this time actively sustaining or enhancing WCTP. WCTP is in popular and stable use by a number of wide area communication service

1185 providers. The protocol provides the capabilities required by AM to AC communication,  
specifically Internet common practice recognized HTTP or HTTPS securable application to  
application communication, reliable TCP/IP transport, extensible XML data envelope,  
1190 transactions for application to individual person communication, and communication status  
responses for closed loop confirmations for delivery to Alert Communicator (AC), delivery to  
endpoint device, read by device operator, and operator responses. With permission from the  
PCIA, this IHE PCD ACM profile includes and adopts version 1.3 update 1 of the WCTP  
1195 protocol as defined by PCIA at [www.wctp.org](http://www.wctp.org) for use in Alert Manager (AM) to Alert  
Communicator (AC) communication. Corrections and extensions to this capture of the protocol  
are the responsibility of the Alert Communication Management (ACM) Working Group (WG)  
within the Patient Care Devices (PCD) domain of IHE. As the protocol has been in live operation  
with major communication carriers for some time the risk of changes required for corrective  
actions is perceived as low. The protocol includes defined areas for client-server agreed two-  
party extensions. The ACM profile will make use of that capability as needs arise.

Not all of the WCTP protocol possible request/response transactions are required for Alert  
Manager (AM) to Alert Communicator (AC) communication. Later sections of this document  
1200 identify the specifics.

### **7.3.2 ACM Use Cases**

### Case A1: Location Sourced



#### 7.3.2.1 Case A1: Location Sourced

1205 Use Case – Patient wants a pillow. Patient pulls nurse call. Nurse call system lights the room’s dome light and light at central station. Nurse call system, operating as an Alert Reporter (AR) actor sends Report Alert [PCD-04] to Alert Manager (AM) indicating nurse call alert. The Alert Manager (AM) logs receipt of the alert. The Alert Manager (AM) identifies the appropriate nurse based upon configured nurse to patient assignments, identifies the appropriate Alert

1210 Communicator (AC) actor and destination communication device based upon nurse to device configuration in Alert Manager (AM), sends Disseminate Alert [PCD-06] to nurse’s communication device. The Alert Manager (AM) logs the dissemination to the Alert Communicator (AC). The nurse receives the alert on their assigned device. The information minimally includes the patient location (room number). The nurse replies to the alert on the communication device, the Alert Communicator (AC) sends a Report Dissemination Alert Status [PCD-07] to the Alert Manager (AM). The nurse goes to the room, determines the needs of the

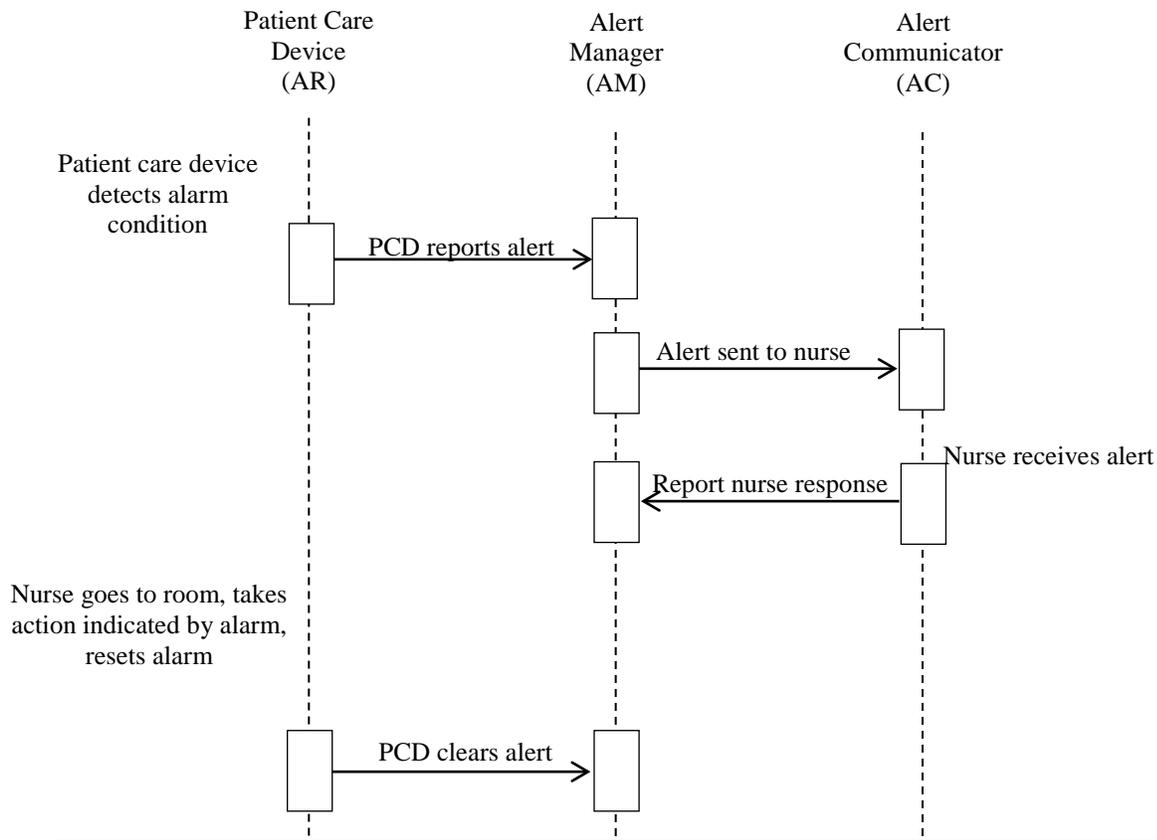
1215 patient, and provides the patient with a pillow. The nurse then resets the nurse call pull. The nurse call system turns off the room’s dome light and the light at the central station. The nurse

1220 call system, operating as an Alert Reporter (AR) actor sends Report Alert [PCD-04] to Alert Manager (AM) indicating reset of the nurse call alert. The Alert Manager (AM) receives the alert turns off any configured alert escalation and logs the alert.

**7.3.2.2 Case A2: Identified Patient Source**

1225 Use Case – Alert occurs on PCD assigned to patient. PCD or PCD gateway system, operating as an Alert Reporter (AR) actor sends Report Alert [PCD-04] to Alert Manager (AM) indicating PCD alert. The Alert Manager (AM) logs receipt of the alert. The Alert Manager (AM) identifies the appropriate nurse based upon configured nurse to patient assignments, identifies the appropriate Alert Communicator (AC) actor and destination communication device based upon nurse to device configuration in Alert Manager (AM), sends Disseminate Alert [PCD-06] to nurse’s communication device. The Alert Manager (AM) logs the dissemination to the Alert Communicator (AC). The nurse receives the alert on their assigned device. The information  
 1230 minimally includes the patient identification. The nurse replies to the alert on the communication device, the Alert Communicator (AC) sends a Report Dissemination Alert Status [PCD-07] to the Alert Manager (AM). The nurse goes to the room, determines the needs of the patient, and responds to the PCD alert. The nurse then clears the PCD alert. The PCD or PCD gateway system, operating as an Alert Reporter (AR) actor sends Report Alert [PCD-04] to Alert

**Case A2: Identified Patient Source**



1235 Manager (AM) indicating reset of the PCD alert. The Alert Manager (AM) receives the alert turns off any configured alert escalation and logs the alert.

### **7.3.2.3 Case A3: Same as A1/A2 with Escalation with Cancel at Alert Source**

1240 Use Case 3: (same as use case 1 or 2 with escalation with cancel at source) if the communication destination is inaccessible or the target individual is indicated as unavailable, then the alert is rerouted to one or more alternatives with escalation to higher levels of responsibility until the alert is canceled at its source and the alert system notified of the cancel.

### **7.3.2.4 Case A4: Same as A1/A2 with Escalation with Cancel at Communication Endpoint**

1245 Use Case 4: (same as use case 1 or 2 with escalation with cancel of any active Alert Manager (AM) escalation actions at communication endpoint) if the communication destination is inaccessible or the target individual is indicated as unavailable then the alert is rerouted to one or more alternatives with escalation to higher levels of responsibility until the alert is canceled by a recipient at a communication endpoint.

### **7.3.2.5 Case A5: Same as A1/A2 with Escalation with Cancel at AM**

1250 Use Case 5: (same as use case 1 or 2 with escalation with cancel of any active Alert Manager (AM) escalation actions at alert management system) if the communication destination is inaccessible or the target individual is indicated as unavailable then the alert is rerouted to one or more alternatives with escalation to higher levels of responsibility until the alert is canceled by a user on the Alert Manager (AM), however not automatically via algorithms in the Alert Manager (AM).

### **7.3.2.6 Case A6: Information with no destination other than logging by the Alert Manager (AM) actor**

1260 Use Case 6: The use case for this is to log information from the Alert Reporter (AR) with the Alert Manager (AM) and not to disseminate the information to the Alert Communicator (AC). The information can be information meant to be used in concert with alerts received from the Alert Reporter (AR), or for logs or information not meant for dissemination to users, but used in reporting alert environment after the fact.

### **7.3.2.7 Case A7: Equipment Sourced Alert**

1265 Use Case 7: The use case for this alert is to communicate medical equipment management events from devices when those events are not patient focused, such as battery low or failure to charge or malfunctioning of alerts. Such indications are device specific, patient independent, and potentially location independent.

## 7.4 ACM Security Considerations

1270 This profile itself does not impose specific requirements for authentication, encryption, or auditing, leaving these matters to site-specific policy or agreement. The IHE PCD Technical Framework identifies security requirements across all PCD profiles.

## Appendix A - Rosetta Terminology Mapping (RTM)

### A.1 Problem Statement

1275 The majority of PCD devices use vendor-specific or proprietary nomenclatures and  
terminologies. As a result, even though information may be exchanged using standards-based  
transactions such as Device Enterprise Communication (DEC), semantic interoperability requires  
that the content be mapped to a standard nomenclature as well. This mapping is often  
1280 inconsistent and subject to loss of semantic precision when mapping from a specific term to a  
more generic term.

The RTM value set identifies the core set of semantics appropriate for medical devices typically  
used in acute care settings (e.g., physiological monitors, ventilators, infusion pumps, etc.) and  
mapping them to a standard terminology. The RTM mapping effort initially focused on numeric  
parameters and their associated units of measurement and enumerated values. The RTM  
1285 mapping effort currently is focused on numeric parameters and associated units of measure and  
enumerated values, and will likely be expanded to include aspects of the observation hierarchy  
expressed in OBR-4 and event content models in the future.

The RTM information is represented in a uniform manner e.g., in a machine readable form that is  
easily adaptable by industry, as a set of Excel worksheets and a set of XML files for publication  
and distribution. This will facilitate use by production systems, but more importantly, facilitate  
1290 comparison between vendors that have (or will) implement the nomenclature standards in their  
systems, with the following goals:

- identify terms that are missing from the standard nomenclature
- ensure correct and consistent use if multiple representations are possible
- 1295 • ensure correct and consistent use of units-of-measure
- ensure correct and consistent use of enumerated values
- ensure correct and consistent identification of 'containment hierarchy'

During the development of the RTM and later, gaps in the standardized medical device  
terminology will be identified. In these cases, proposals will be made for adding the semantics to  
1300 the appropriate terminologies. Although the immediate focus of the RTM will be to standardize  
the content in transaction profiles such as DEC, which are typically between a device data  
gateway and enterprise level applications, the standardized terms should also support direct  
device communication, enabling semantic interoperability literally from the sensor to the EHR.

The availability of the RTM information will also facilitate development of tools that can more  
1305 rigorously validate messages, such as enforcing the use of the correct units-of-measure and  
correct enumerated values associated with specific numeric values. For example, ST segment  
deviation will be expressed in "uV" or "mV", rather than the traditional "mm". This will promote  
greater interoperability, clarity and correctness which will in turn benefit patient safety.

1310 The consistent and correct use of standard nomenclatures such as ISO/IEEE 11073-10101 and UCUM for medical device and system data exchange will facilitate further development of real-time clinical decision support, smart alarms, safety interlocks, clinical algorithms, and data mining and other clinical research. This work can also be expanded at a future date to support events and alarms, waveforms, device settings and other critical monitoring information.

## **A.2 Actors/Transactions**

1315 Contents of the RTM tables will affect most, if not all, IHE PCD Transaction Profiles.

## **A.3 Integration Profile Options**

No options have been defined.

## **A.4 Integration Profile Process Flow**

There is no process flow.

## **A.5 Key Use Case**

1320 A patient is monitored at home. A potentially life-threatening cardiac event is detected and reported to a remote monitoring service that confirms and forwards the event to his caregiver. The patient is subsequently admitted to the ER complaining about chest pain. A diagnostic 12-lead is taken followed by continuous vital signs monitoring or telemetry for further observation.

1325 Following a series of premonitory episodes of ST segment deviation, the patient exhibits short runs of ventricular ectopy that rapidly devolve into ventricular tachycardia and then fibrillation, all along triggering alarms from the monitor. The patient is cardioverted in the ER and scheduled for CABG surgery. During surgery, the patient is connected to well over a dozen medical devices

1330 (e.g., multiparameter patient monitor, anesthesia machine, multiple infusion pumps, bypass machine, etc.) and the data from these devices and systems is displayed in a unified and comprehensible manner and automatically charted. After successful surgery, the patient is monitored in the ICU. The patient is discharged a week later to continue his recovery at home, where, among other things, he uses a spirometer with a low-cost wireless interface to facilitate recovery. He also exercises while walking around in and outside the house attached to a wireless

1335 sensor that records and transmits his ECG via his cell phone to a remote monitoring service. The patient also has follow-up visits to cardiac rehab, where his ECG and glucose measurements are taken before and after exercise, with all the data also electronically recorded. This information is ultimately stored in the patient's personal health record and made available for a follow-up clinical research study regarding the cardiac medications he was taking.

1340 The key point of this comprehensive but realistic use case is that the patient's data is "touched" by well over three dozen medical devices and systems designed and manufactured by nearly an equal number of different vendors. An essential first step towards achieving interoperability across all these devices and systems is that they use a shared and common semantic foundation.

1345 **Glossary**

**ACC:** American College of Cardiology. <http://www.acc.org/>

**ACCE:** American College of Clinical Engineering. <http://www.acenet.org/>

**Actor:** An entity within a use case diagram that can perform an action within a use case diagram. Possible actions are creation or consumption of a message.

1350 **ACM:** Alert Communication Management (formerly Alarm Communication Management) is an IHE PCD Profile for communication of clinical alarms and technical alerts from patient care devices to Alert Managers and from Alert Managers to Alert Communicators which announce the alert.

**ADT:** Admit, Discharge & Transfer.

1355 **Advisory:** An alert that is not an alarm, meaning it is not an immediate patient safety event

**Alarm:** A clinical alarm is an indication from a system or device, that when activated, indicates a condition requiring urgent clinical assessment and possible intervention.

**Alert:** Either an alarm or an advisory.

**Aperiodic:** PCD data which occurs at irregular intervals such as a Cardiac Output measurement.

1360 **Authoritative:** Acknowledged to be reliable.

**Bedside:** The point of care, typically in an acute care environment.

**BCMA:** Bedside Computer assisted Medication Administration system, aka Barcode Medication Administration system.

1365 **Binding:** Process of associating two related elements of information. In the PCD context this typically means the association of a Patient with a device or set of devices.

**Biometric:** Measurable, physical characteristic or personal behavioral trait used to recognize the identity, or verify the claimed identity.

1370 **Cardiac Device Programmer:** A device used to noninvasively interrogate, monitor, and alter the operating parameters of an implantable pacemaker, implantable defibrillator, implantable cardiac resynchronization device, or implantable cardiac monitor.

**CDR:** Clinical Data Repository.

**CIS:** Clinical Information System.

**CLIA:** Clinical Laboratory Improvement Amendments. <http://www.cms.hhs.gov/clia/>

1375 **Connectathon:** IHE testing process - a weeklong interoperability testing event where participating companies test their implementation of IHE capabilities with corresponding systems from industry peers.

**CT:** Consistent Time Integration Profile.

**DEC:** Device Enterprise Communication.

**DICOM:** Digital Imaging and Communications in Medicine. <http://medical.nema.org/>

1380 **DOB:** Date of Birth.

**DOC:** Device Observation Client: Actor responsible for receipt of PCD data.

- DOF:** Device Observation Filter: Actor responsible for filtering of PCD transactions based on negotiated predicate.
- 1385 **DOR:** Device Observation Reporter: Actor responsible for mapping legacy and standards based PCD data to the IHE PCD message profile(s). Based upon the ISO/IEEE 11073.
- ECG:** Electrocardiogram.
- EEG:** Electroencephalogram.
- EHR:** Electronic Health Record.
- eMAR:** Electronic Medication Administration Record.
- 1390 **eMPI:** Enterprise Master Patient Index.
- EMR:** Electronic Medical Record.
- Event:** A machine to machine communicated indication or a status or other technical change
- FDA:** The United States Food and Drug Administration.
- 1395 **General Purpose Infusion Pump:** a pump used to infuse fluids intravenously in a wide variety of clinical settings. Differentiated from specialty infusion pumps, which are used for a specific purpose or in a specific setting, such as PCA (patient-controlled analgesia) or syringe pumps.
- Grouping:** Associating Actors together in one system such that information transferred between the actors is accomplished through direct application program interfaces, being out of scope to the IHE.
- 1400 **HIMSS:** Healthcare Information and Management Systems Society.
- HIS:** Hospital Information System.
- HL7:** Health Level 7. <http://www.hl7.org/>
- IHE:** Integrating the Healthcare Enterprise. <http://www.ihe.net>
- 1405 **IEEE:** Institute of Electrical and Electronics Engineers. <http://www.ieee.org>
- IETF:** Internet Engineering Task Force. <http://www.ietf.org/>
- Implantable Cardiac Monitor:** An electronic device implanted beneath the skin used for monitoring/recording the electrical signals of the heart muscle.
- 1410 **Implantable Cardiac Resynchronization Therapy (CRT) Device:** An electronic device implanted beneath the skin used to reestablish ventricular synchrony in an effort to improve left ventricular efficiency.
- Implantable Defibrillator:** An electronic device implanted beneath the skin used to counteract fibrillation of the heart muscle and restore normal heartbeat by applying an electric shock.
- 1415 **Implantable Pacemaker:** An electronic device implanted beneath the skin for providing a normal heartbeat by electrical stimulation of the heart muscle, used in certain heart conditions.
- Interaction Diagram:** A diagram that depicts data flow and sequencing of events.
- IT:** Information Technology.

- 1420 **MAC:** Media Access Control – A unique identification/serial number associated with every device used in network communications.
- MLLP:** Minimal Lower Layer Protocol – is used for transferring HL7 messages over Ethernet. It defines delimiters which identify the beginning and ends of the HL7 message.
- MPI:** Master Patient Index.
- MRN:** Medicare Record Number (US) or Medical Record Number.
- 1425 **NEMA:** National Electrical Manufacturers Association.
- NTP:** Network Time Protocol. This is the standard Internet protocol for synchronizing computer clocks. The web site <http://www.ntp.org> provides extensive background documentation at the introductory and expert level on how to synchronize computers.
- PAM:** Patient Administration Management, an IHE-ITI implementation profile.
- 1430 **PDQ:** Patient Demographics Query, an IHE-ITI implementation profile.
- PES:** Patient Encounter Source, a system responsible for adding, updating and maintaining encounter information about a patient. It supplies new and updated information to the Patient Encounter Consumer.
- PEC:** Patient Encounter Consumer, a system that uses patient encounter information provided by
- 1435 the Patient Encounter Source about a patient.
- Physiological Alarm:** an alert reflecting the physiological state of the patient (such as a heart rate above or below a caregiver-specified safe range for the patient).
- Primary Alarm System:** the patient care device itself provides visual and aural indications of alarms that can be seen and heard in the immediate patient vicinity, and that are the
- 1440 authoritative primary indicators of alarms resulting from monitoring the patient. It is understood that caregivers shall be in a position to take immediate action based on these primary alarm indications and shall not rely exclusively on secondary alarm systems for alarm notifications.
- PCD:** Patient Care Device.
- 1445 **PIV:** Pump Infusion Verification profile for communicating orders from Medication Administration Systems to infusion devices.
- PnP:** Plug and Play.
- Point of Care:** Physical area in close proximity to the patient under clinical care. Usually the vicinity around the patient bedside and may include adjacent areas (glucose, blood gas).
- 1450 **Physiologic:** Mechanical, physical, and biochemical functions of living organisms.
- RFC:** Request for comment. <http://www.rfc-editor.org/>
- RFID:** Radio frequency identification.
- Role:** The actions of an actor in a use case.
- RSNA:** Radiological Society of North America. <http://www.rsna.org/>
- 1455 **RTM:** Rosetta Terminology Management Profile

**Safety Infusion System (Smart Pump System):** infusion devices designed to reduce the error rates associated with infusions through the use of one or more of the following “smart” features:

- 1460 • Ability to check programmed doses against pre-configured limits in an onboard drug library.
- Ability to read infusion parameters from RFID tags or bar codes.
- Ability to send and receive infusion parameters via a wired or wireless network.
- Ability to communicate through a server or gateway.

**Scope:** A brief description of the transaction.

1465 **Secondary alarm system:** A system intended to give "best effort" notification of alarms at additional locations, to additional persons, or for additional purposes such as archiving, but not intended to take the place of a primary alarm system as the authoritative primary indicator of alarms resulting from monitoring the patient.

1470 **SNTP:** Simple Network Time Protocol. This is a reduced accuracy version of NTP. The protocol fields are the same, but the data values and algorithms used have greatly reduced accuracy so that it can be implemented on limited capacity systems.

**Subscribe:** Make a request that only messages satisfying specific predicates be sent to the subscriber.

1475 **Technical alarm:** an alert that is an alarm reflecting the state of the patient care device itself that may require action from caregivers (such as ECG leads off the patient, an infusion pump door open, or a battery not maintaining a charge), or the alerts may be advisories representing indications other than alarms (such as clinical workflow notifications not involving medical devices, or patient physiological indications that could be precursors to an alarm not yet indicated).

1480 **The Joint Commission:** Formerly “The Joint Commission on Accreditation of Healthcare Organizations” (JCAHO).

**Trigger Event:** An event such as the reception of a message or completion of a process, which causes another action to occur.

**UID:** Unique Identifier.

1485 **Unbinding:** Disassociation of a patient from a device.

**Unsolicited:** Within the context of HL7 when the transfer of information is initiated by the application system that deals with the triggering event, the transaction is termed an unsolicited update.

1490 **Universal ID:** Unique identifier over time within the UID type. Each UID must belong to one of specifically enumerated species. Universal ID must follow syntactic rules of its scheme.

**Use Case:** A graphical depiction of the actors and operation of a system.

**UTC:** Universal Coordinated Time. This is the replacement for GMT. It defines a reference time base that is internationally recognized and supported.

**Validated:** PCD data which has been marked as correct by a caregiver.

1495 **W3C:** World Wide Web Consortium. <http://www.w3.org/>