ACC, HIMSS, and RSNA

Integrating the Healthcare Enterprise

IHE Patient Care Device Technical Framework

Year 1: 2006-2007

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Volume 1

Integration Profiles

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Contents

Foreword

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.

The approach employed in the IHE initiative is not to define new integration standards, but rather to support the use of existing standards, HL7, IEEE, 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.

This initiative has numerous sponsors and supporting organizations in different medical specialty domains and geographical regions. In North America the primary sponsors are the American College of Cardiology (ACC), the Healthcare Information and Management Systems Society (HIMSS) the Radiological Society of North America (RSNA), and the American College of Clinical Engineers (ACCE). IHE Canada has also been formed. IHE Europe (IHE-EUR) is supported by a large coalition of organizations including the European Society of Cardiology (ESC), 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 (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 MEDIS-DC; cooperating organizations include the Japan Industries Association of Radiological Systems (JIRA), the Japan Association of Healthcare Information Systems Industry (JAHIS), Radiological Society (JRS), Japan Society of Radiological Technology (JSRT), and the Japan Association of Medical Informatics (JAMI). Other organizations representing healthcare professionals are invited to join in the expansion of the IHE process across disciplinary and geographic boundaries.

The IHE Technical Frameworks for the various domains (IT Infrastructure, Cardiology, Patient Care Device, 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. They are expanded annually, after a period of public review, and maintained regularly through the identification and correction of errors. The current version for these Technical Frameworks may be found at www.ihe.net .

The IHE Technical Frameworks identify a subset of the functional components of the healthcare enterprise, called IHE actors, and specify their interactions in terms of a set of coordinated, standards-based transactions. They describe 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. The subsequent volumes provide detailed technical descriptions of each IHE transaction.

This IHE Patient Care Device Technical Framework Year 1 is a working draft issued for Public Comment.

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Comments on this supplement can be submitted to the online discussion forums at http://forums.rsna.org.

1 Introduction

1.1 Overview of Technical Framework

This document, the IHE Patient Care Device Technical Framework (IHE PCD TF), 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.

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 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 1 of the Patient Care Devices Technical Framework (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. PCD TF-2 provides detailed technical descriptions of each PCD-specific IHE transaction. PCD TF-3 provides detailed specifications for content oriented profiles and includes content from specific device classes.

The 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
- IHE Radiology Technical Framework
- IHE Laboratory Technical Framework
- IHE Patient Care Device 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 frameworks, see Section 1.6.4 within this volume.

1.2 Overview of Volume I

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.

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.

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
- IT departments of healthcare institutions
- Experts involved in standards development

1.4 Relationship to Standards

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 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 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 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 PCD TF-2:Appendix E for the format of such IHE Integration Statements. 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

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 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.

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 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

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

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.

The tables of actors and transactions given in Section 3 indicate which transactions each actor must support.

In some cases in IHE, a profile is dependent on a pre-requisite profile in order to function properly and be useful. For Year 1 a single profile Device Enterprise Communication (DEC) is defined so this is not an issue.

1.6.2 Interaction Diagrams

The descriptions of Integration Profiles that follow include Interaction 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.

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.

The convention used in these diagrams is the arrow on the line for the transaction points from the initiator of the transaction to the destination.

1.6.3 Normative versus informative contents of the Technical Framework

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 illustrating parts 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 Referencing

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:

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

<domain designator> is a short designator for the IHE domain (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: ITI TF-1: 3.1 refers to Section 3.1 in volume 1 of the IHE IT Infrastructure Technical Framework, 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 (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

This document refers to Year 1 of the IHE Patient Care Device initiative. It will be the basis for the testing and exhibition process associated with the HIMSS 2007 annual meetings. The current IHE Patient Care Device Technical Framework addresses the following primary features:

- The Device Enterprise Communication Integration Profile describes mechanisms to communicate PCD data to enterprise information systems. The scope of Year 1 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.), CLIA waived (or equivalent international waiver) point-of-care laboratory tests (i.e. home blood glucose, etc.) and may include contextual data such as the patient ID, caregiver identification, and patient care device configuration information.
- The scope of Year 1 does not include real time alarms and alerts, waveforms (ECG, EEG, etc.), or control operations. These are areas for consideration in Year 2 and subsequent Years.

1.8 Comments

The ACCE welcomes comments on this document and the IHE initiative. They should be directed to iheinfo@accenet.org

1.9 Copyright Permission

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.

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.

1.10 IHE Technical Framework Development and Maintenance Process

Since this is the first year for the IHE PCD there is no previous version. For subsequent years the process which will be followed is illustrated in Figure 1 IHE Development Process.

The Technical Framework is continuously extended and maintained by the IHE Patient Care Device 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 both vendors and users may rely upon in specifying, developing and acquiring IHE compatible products.

The process is intended to address the need for extensions, clarifications and corrections while maintaining backward compatibility of framework definitions to support implementations claiming conformance to any previously defined Integration Profile and its actors.

To maintain stability of the IHE Technical Framework, modifications occur in a regular annual cycle (Figure 1) according to one of two controlled paths: new development, and maintenance.

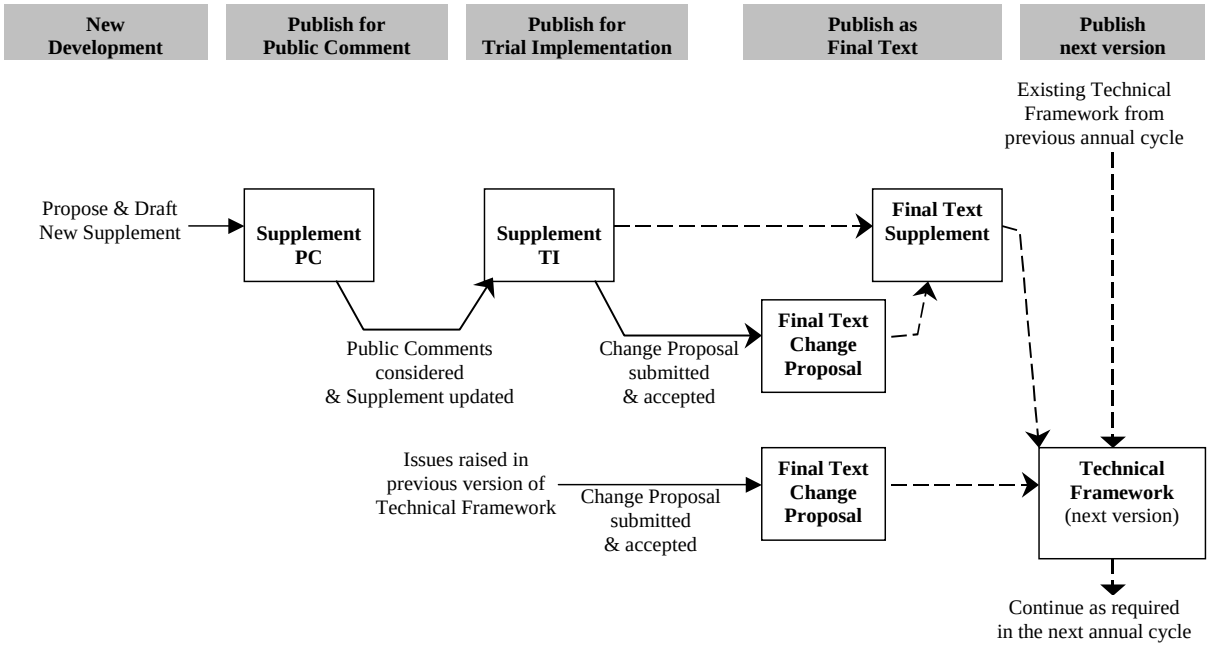


Figure 1 IHE Development Process

Figure 1 IHE Development Process shows the process of developing and maintaining the Technical Framework during an annual cycle. Dashed arrows indicate the assembly (merging) of text.

1.10.1 New Development – Extending the Existing Technical Framework

Each year, new functionality to be developed is identified by the IHE Patient Care Device Planning Committee. Individuals or organizations wishing to submit recommendations for new development are encouraged to join and participate in the PCD Planning Committee. The Technical Committee performs the necessary analysis and design work and generates new text for the Technical Framework. Generally, new functionality is published in the form of a Supplement. The scope of a Supplement is to make one of the following additions to the Technical Framework:

- A new Integration Profile, usually including the introduction of new actors and transactions.
- New actors in an existing Integration Profile: These may be either actors previously defined elsewhere in the Technical Framework, or new ones not yet defined. Transactions identifying the new actors responsibilities in this profile are identified or defined and may be designated as required or optional. To avoid causing compatibility problems for systems that have already implemented that profile, no new required transactions are added for existing actors in the profile.
- New Options in an existing Integration Profile: These usually add optional transactions for existing actors in the profiles, or add optional features within existing transactions.
- Major conceptual changes: They do not change the behavior of existing Integration Profiles but may imply changes or additions to actors, transactions, or content in the future.

The publication process consists of certain phases and is clearly indicated on each document.

First, the text is published for **Public Comment** (with a "PC" designation). During the Public Comment period (typically 30 days), the text and a comment submission facility are available on the IHE Website. Following this period, the Technical Committee will review the comments.

Updated text of Supplements is then published for **Trial Implementation** (with a "TI" designation), based on the modifications resulting from the comments received.

IHE provides a process for vendors to test their implementation of the Trial Implementation specifications of IHE actors and Integration Profiles. The IHE testing process, culminating in a multi-party interactive testing event called the Connectathon, provides vendors with valuable feedback and provides a baseline indication of the conformance of their implementations. It also serves as a validation of the technical approach of the Trial Implementation specifications.

After trial implementations have been judged to have sufficiently exercised the new functionality (e.g., due to experience from the Connectathon), and the text is considered sufficiently stable, the new text will be published as **Final Text** (with a "FT" designation).

Final Text Supplements will be merged at the end of the annual development cycle with the current version of the Technical Framework resulting in a new version of the Technical Framework with an increased version number.

1.10.2 Maintenance of existing Technical Framework content

Despite the best efforts of the Technical Committee, a published current version of the Technical Framework or Trial Implementation documents may contain text that is incorrect, incomplete or unclear. Such issues are handled as Change Proposals and cover:

- Corrections: technical issues causing non-interoperability of implementations are fixed without introducing changes in functionality of a stable Integration Profile.
- Clarifications: text that can be misunderstood or is ambiguous is made easier to understand or disambiguated, without introducing any technical changes.

The publication process is the same for both Corrections and Clarifications, and addresses both changes to Trial Implementations and changes to a current version of the Technical Framework.

A **Submitted Change Proposal** results from issues raised by users, vendors or Technical Committee members, e.g. from experiences with Trial Implementation or Final Text Integration Profiles or at a Connectathon. The resulting Change Proposal document should explicitly state:

- the parts of the Technical Framework requested to be changed,
- a problem description,
- a rationale why the change is considered necessary,
- and a solution or approach to the problem.

The Technical Committee regularly considers Change Proposals which are then either accepted or rejected.

A **Rejected Change Proposal** is published with a rationale from the Technical Committee explaining why the change is not appropriate.

An **Accepted Change Proposal** is assigned to a member of the Technical Committee as a work item for further investigation with the goal to produce adequate clarifications or corrections. The resulting text will again be reviewed by the Technical Committee before being approved.

Once approved, a **Final Text Change Proposal** is published by the Technical Committee, and then is to be considered as effective. It will be merged into the next version of the Technical Framework at the end of the annual development cycle. Submitting a Change Proposal to a Final Text Change Proposal or a Final Text Supplement is not possible.

1.10.3 Use of Technical Framework

The current version of the Technical Framework is considered the primary reference document. Final Text Supplements and 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.

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

- Product Implementations
  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
  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.

2 Integration Profiles

IHE Patient Care Device Integration Profiles, depicted in Figure 2 IHE PCD 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

In general, IHE Integration Profiles do not operate independently. Objects that serve as useful input to one profile may have been produced as a result of implementing another profile.

Figure 2 IHE PCD Integration Profiles provides a graphical view of the dependencies of IHE PCD Integration Profiles. The arrows in the diagram point from the dependent profile to the profile(s) on which it relies.

The profiles shown with a thick border are PCD profiles, the profiles shown with a thin border are defined by other IHE domains.

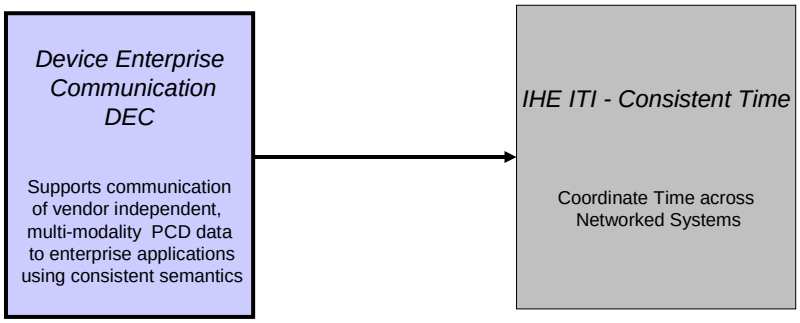


Figure 2 IHE PCD Integration Profiles

Table 1 Patient Care Device Integration Profiles and Dependencies defines the required dependencies between the Integration Profiles in a tabular form.

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 1 Patient Care Device Integration Profiles and 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 PCD data.

Vendor products support an Integration Profile by implementing the appropriate actor-transactions as outlined in the Integration Profile in Section 3. A product may implement more than one actor and more than one Integration Profile.

An actor must implement all required transactions in the pre-requisite profiles in addition to those in the desired profile.

Actors (see Section 2.2) 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 2.4) are interactions between actors that transfer the required information through standards-based messages.

2.2 Integration Profiles Overview

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.

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.

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.

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.

2.2.1 Device Enterprise Communication (DEC)

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.), CLIA waived (or equivalent international waiver) point-of-care laboratory tests (i.e. home blood glucose, etc.) and may include contextual data such as the patient ID, caregiver identification, and patient care device configuration information.

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), 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. For year 1 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.

The current profile does not address use cases and transactions associated with either open loop or closed loop control of PCDs. Real-time PCD data such as alarms and alerts, waveforms (ECG, EEG, etc.) is outside the scope of the current profile. Applications such as these are also on the IHE PCD roadmap for subsequent years.

Consuming all of the data from a collection of PCDs at the rates at which meaningful parametric PCD data can be produced has been described as “drinking from a fire hose”. The Device Enterprise Communication profile provides an optional publish/subscribe mechanism for applications to negotiate which PCD messages are communicated to a given application based on negotiated predicates.

“Publish and subscribe” refers to the ability of one system, the “Publisher”, to offer a data stream that can be sent to recipient systems upon subscription. In one sense, the entire HL7 unsolicited update paradigm, in which the sender sends out a stream of messages to recipients, is a kind of publish and subscribe mechanism. Subscriptions to unsolicited updates are established at interface set-up time when analysts on both sides agree to start sending a stream of data.

DEC describes a mechanism by which an optional DOF actor defined in Section **Error! Reference source not found.** agrees to selectively subset the message stream based on query-like data constraints. In the normal case, the right of the Subscriber to subscribe is decided at interface setup time. At runtime, the Subscriber controls the data rules under which it receives messages.

2.3 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.

New actors

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. The mechanism by which the DOR actor receives the PCD data is out of scope for year 1.

Device Observation Filter – The Device Observation Filter (DOF) actor is responsible for providing PCD data filtering services based on publish/subscribe predicates negotiated with client applications implementing the Device Observation Consumer.

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

Existing actors

Time Client – A system unit that synchronizes its time of day clock to the correct time provided by a time server

The following table shows which actors are used in which Integration Profiles.

Table 2 Integration Profile Actors

Integration Profile / Actor	DEC
Device Observation Reporter	X
Device Observation Filter	X
Device Observation Consumer	X
Time Client	X

2.4 Transaction Descriptions

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 or Observation Filter and Receive PCD data by a Device Observation Consumer.

Subscribe To PCD Data – Defines predicate for communication of PCD data from DOF to a Device Observation Consumer.

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

Table 3 Integration Profile Transactions

Transaction \ Integration Profile	DEC
Communicate PCD Data	X
Subscribe To PCD Data	X
Maintain Time	X

2.5 Product Implementations

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

- For a system, select which actors it will incorporate. (Multiple actors per system is 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 Integration Profile Tables in Sections 3-5)
- 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 recommended form for such a statement is defined in IHE PCD-TF2 Appendix E.

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:

- Device Observation Filter

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.

~~For example,~~

When two or more actors are grouped together, internal communication between actors is assumed to be sufficient to allow the necessary information flow to support their functionality; for example, the Device Observation Reporter provides necessary information updates to the

Observation Filter to support its Communicate PCD Data functionality. The Communicate PCD Data transaction does not need to be supported between the Device Observation Reporter actor and the Device Observation Filter actor when these are grouped together in a single system. The exact mechanisms of such internal communication are outside the scope of the IHE PCD Technical Framework.

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.

- A general purpose observation reporting gateway which combines the Device Observation Reporter and the Device Observation Filter.
- A clinical decision support application which combines the Device Observation Consumer and Device Observation Filter.
- A patient care device which bundles the Device Observation Reporter and the Device Observation Filter.

3 Device Enterprise Communication (DEC)

The Device Enterprise Communication Integration Profile supports ~~consistent~~ communication of vendor independent, multi-modality Patient Care Device data to Enterprise Applications using consistent semantics. It accomplishes this by mapping ~~of~~ PCD data from proprietary ~~legacy~~ 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 to allow applications to filter particular PCD data of interest.

~~Depending on the use case the PCD data includes identification of the patient either by location or by means of one or more authoritative enterprise patient identifiers, and is time stamped with a consistent enterprise time.~~

3.1 Actors/Transactions

Figure 3 DEC Integration Profile : Actors and Transactions diagrams the actors involved with this profile and the transactions between actors.

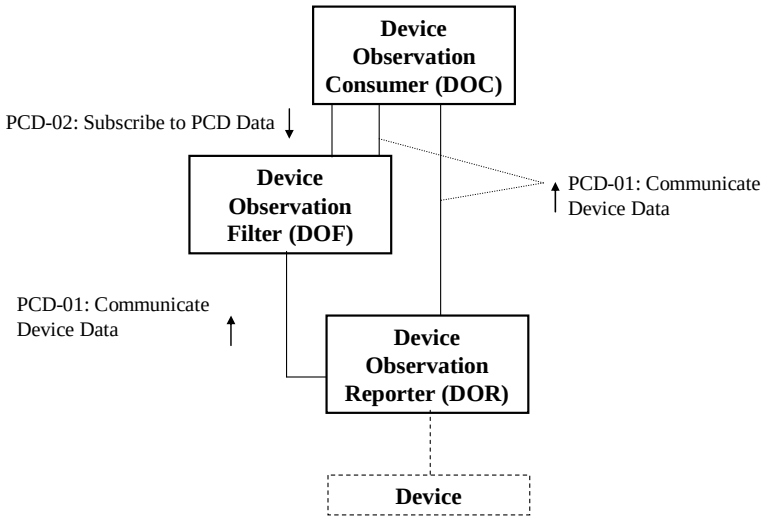


Figure 3 DEC Integration Profile : Actors and Transactions

Table 4 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 3.2.

Table 4 DEC - Actors and Transactions

Actors	Transactions	Optionality	Section
Device Observation Consumer	Communicate PCD Data [PCD-01]	R	Section 3
	Request PCD Data [PCD-02]	O	Section 3
Device Observation Filter	Communicate PCD Data [PCD-01]	R	Section 3
	Request PCD Data [PCD-02]	R	Section 3
Device Observation Reporter	Communicate PCD Data [PCD-01]	R	Section 3

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

3.2 DEC 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 5 DEC - Actors and Options along with the actors to which they apply. Certain of these Options are required for implementation by actors in this Profile (although they may be truly optional in other Profiles).

Table 5 DEC - Actors and Options

Actor	Option Name	Vol & Section
Device Observation Consumer	*Request PCD Data*	TF-1:3.1
Observation Filter	*No options defined*	
Device Observation Reporter	*No options defined*	

3.3 DEC Interaction Diagram

This Section describes the specific use cases and interactions defined for the DEC Workflow Profile.-The Use Cases fall into two distinct groups based upon the choice to implement the optional Request PCD Data [PCD-02] transaction. The two groups are described below.

3.3.1 Case C1: Communicate patient identified data to EMR/EHR

Data from all of the patient care devices associated with a particular patient is communicated by a Clinical Information System (CIS) implementing the DOR actor to a 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 communicated to the CIS at an interval no less than 1 minute. The data is time stamped with a consistent time across the data from the respective patient care devices.

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.

3.3.2 Case C2: Communicate validated periodic data to EMR/EHR

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.

3.3.3 Case F1: Subscribe To PCD Data at specific interval.

An EHR does not require data at the frequency that the Device Observation Reporter uses for default reporting. To receive data at an acceptable interval the EHR application makes a request of the Device Observation Filter for a subscription specifying the frequency at which PCD data should be sent to the EHR application.

3.3.4 Case F2: Subscribe To PCD Data for specfic patients.

A clinical research application is being evaluated for clinical decision support on a specific population of patients. The application requests a subscription for PCD data for a known group of patients appropriate to the study being conducted.

3.3.5 Case F3: Subscribe To PCD Data for patients from a specific location.

A clinical application only wants to be informed of PCD data for patients in a specific hospital unit. The application requests a subscription for PCD data for the hospital unit of interest.

3.3.6 Case F4: Subscribe To PCD Data for a specific device or class of devices.

A respiration clinical decision support application only requires data from ventilators. The application requests a subscription for PCD data for ventilators.

3.3.7 Case F5: Subscribe To PCD Data for specific parameters or classes of parameters.

A clinical decision support application is based upon correlation of a selected set of monitored PCD data. The application requests a subscription for only the PCD data of interest.

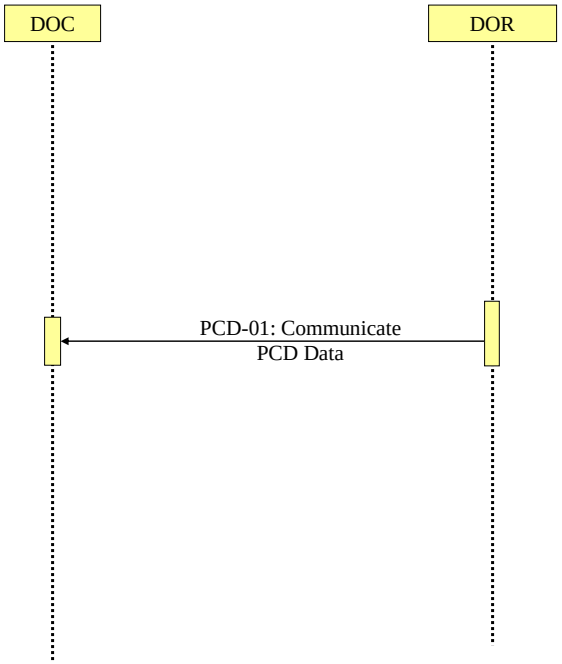
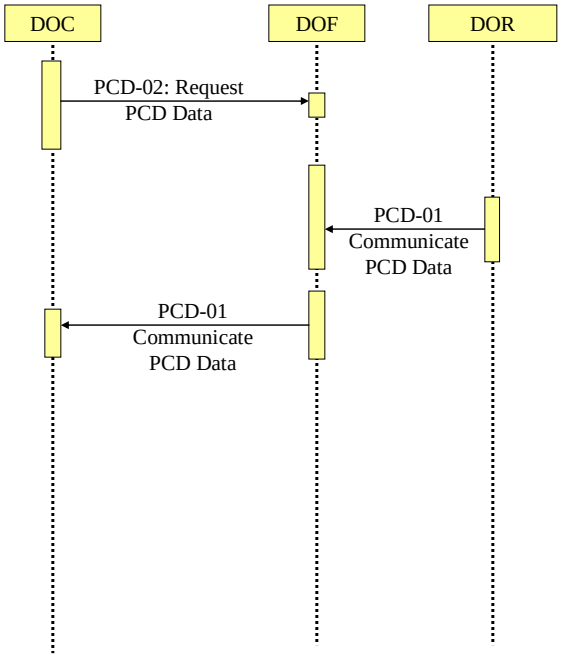


Figure 4 DEC Interactions (No filtering)



620 **Figure 5 DEC Interactions (With filtering)**

Glossary

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

ACCE: American College of Clinical Engineering http://www.accenet.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

ADT: Admit, Discharge & Transfer.

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

Alert: A clinical alert is an indication from a system or device that a condition exists which requires attention.

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

Authoritative: Acknowledged to be reliable.

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

Binding: Process of associating two related elements of information.

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

CDR: Clinical Data Repository.

CIS: Clinical Information System.

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

Connectathon: IHE testing process a weeklong interoperability testing event where participating companies to 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/

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.

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.

eMPI: Enterprise Master Patient Index.

EMR: Electronic Medical Record.

HIMSS: Healthcare Information and Management Systems Society.

HIS: Hospital Information System.

HL7: Health Level 7. http://www.hl7.org/

IHE: Integrating the Healthcare Enterprise.

IEEE: Institute of Electrical and Electronics Engineers. http://www.ieee.org

IETF: Internet Engineering Task Force. http://www.ietf.org/

MPI: Master Patient Index – see eMPI.

Interaction Diagram: A diagram that depicts data flow and sequencing of events.

IT: Information Technology.

MPI: Master Patient Index.

MRN: Medicare Record Number or Medical Record Number.

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.

Role: The actions of an actor in a use case.

PCD: Patient care device.

Physiologic: Mechanical, physical, and biochemical functions of living organisms.

RFC: Request for comment. http://www.rfc-editor.org/

RFID: Radio frequency identification.

RSNA: Radiological Society of North America. http://www.rsna.org/

Scope: A brief description of the transaction.

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 are 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.

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

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.

690 **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.

W3C: World Wide Web Consortium. http://www.w3.org/