ACC, HIMSS, and RSNA Integrating the Healthcare Enterprise



# IHE Patient Care Device Technical Framework Year 1: 2005-2006

# Volume 2 Transactions

Revision 1.1

# **Trial Implementation Version**

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# Foreword

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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 20 (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
- 30 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

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period of public review, and maintained regularly through the identification and 40

correction of errors. The current version for these Technical Frameworks may be found at <u>www.ihe.net</u>.

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.

The present volume, PCD TF-2, provides detailed technical descriptions of IHE Patient Care Device transactions that support the IHE Patient Care Device Integration Profiles defined in the IHE Patient Care Device Technical Framework Volume 1 (PCD TF-1).

- 10 The other domains within the IHE initiative also produce Technical Frameworks within their respective areas that together form the IHE Technical Framework. Currently, the following IHE Technical Framework(s) are available:
  - IHE Cardiology Technical Framework
  - IHE IT Infrastructure Technical Framework
  - IHE Laboratory Technical Framework
  - IHE Radiology Technical Framework

Where applicable, references are made to these other Technical Frameworks. For the conventions on referencing these other Frameworks, see Section 1.6.4 within PCD TF-1.

This IHE Patient Care Device Technical Framework Year 1 is a working draft for public comment.

Comments on this document can be submitted to the online discussion forums at <u>http://forums.rsna.org</u>.

# 1 Introduction

# **1.1 Overview of the Technical Framework**

This document, the IHE Patient Care Device Technical Framework Volume 2 (IHE PCD TF-2), 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.

The present volume (PCD TF-2) provides detailed technical descriptions of IHE Patient Care Device transactions that support the IHE Patient Care Device Integration Profiles defined in the IHE Patient Care Device Technical Framework Volume 1.

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

- IHE Cardiology Technical Framework
- IHE IT Infrastructure Technical Framework
- IHE Laboratory Technical Framework
  - IHE Patient Care Device Technical Framework
  - IHE Radiology 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 these other Frameworks, see Section 1.6.4 within PCD TF-1 of the IHE Patient Care Device Technical Framework.

# 1.2 Overview of Volume 2

The remainder of Section 1 further describes the general nature, purpose and function of the Technical Framework. Section 2 presents the conventions used in this volume to define IHE transactions.

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Sections 3- 3.2 define the transactions in detail, specifying the roles for each Actor, the standards employed, the information exchanged, and in some cases, implementation

options for the transaction.

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The appendices following the main body of this volume provide technical details associated with the transactions.

# 1.3 Audience

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The intended audience of this document is:

- IT departments of healthcare institutions
- Technical staff of vendors planning to participate in the IHE initiative
- Experts involved in standards development
- Those interested in integrating healthcare information systems and workflows

# 1.4 Relationship to Standards

10 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 ASTM, DICOM, HL7, IEEE, IETF, ISO, OASIS and W3C standards. As the scope of the IHE initiative expands, transactions based on other standards may 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. Conformance claims for products must still be made in direct reference to specific standards. In addition, vendors who have implemented IHE integration capabilities in their products may publish IHE Integration Statements to communicate their products' capabilities. Vendors publishing IHE Integration Statements accept full responsibility for their content. By comparing the IHE Integration Statements from different products, a user familiar with the IHE concepts of actors and integration profiles can determine the level of integration between them. See Appendix H for the format of IHE PCD Integration Statements. IHE encourages implementers to ensure that products implemented in accordance with the IHE Technical

30 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 the real-world healthcare information system environment. While some of the transactions are traditionally performed by specific product categories (e.g. HIS, Clinical Data Repository, Radiology Information Systems, Clinical Information Systems or Cardiology Information Systems), 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

10 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

20 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 Comments

HIMSS and RSNA welcome comments on this document and the IHE initiative. They should be directed to the discussion server at http://ihe.rsna.org/ihetf/ or to:

Chris Carr Director of Informatics 820 Jorie Boulevard Oak Brook, IL 60523 Email: <u>ihe@rsna.org</u> Joyce Sensmeier Director of Professional Services 230 East Ohio St., Suite 500 Chicago, IL 60611 Email: <u>ihe@himss.org</u>

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## 1.7 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.

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.

# 2 Conventions

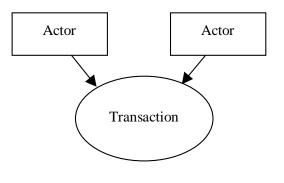
This document has adopted the following conventions for representing the framework concepts and specifying how the standards upon which the IHE PCD Technical Framework is based should be applied.

# 2.1 The Generic IHE Transaction Model

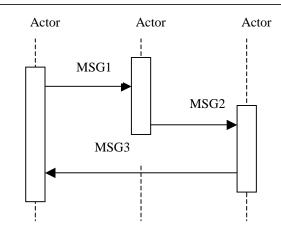
Transaction descriptions are provided in Section 3. In each transaction description, the actors, the roles they play, and the transactions between them are presented as use cases.

The generic IHE transaction description includes the following components:

- Scope: a brief description of the transaction.
- 10
- Use case roles: textual definitions of the actors and their roles, with a simple diagram relating them, e.g.:



- Referenced Standards: the standards (stating the specific parts, chapters or sections thereof) to be used for the transaction.
- Interaction Diagram: a graphical depiction of the actors and messages that support the transaction, with related processing within an Actor shown as a rectangle and time progressing downward, similar to:



The interaction diagrams used in the IHE-PCD Technical Framework are modeled after those described in Grady Booch, James Rumbaugh, and Ivar Jacobson, *The Unified Modeling Language User Guide*, ISBN 0-201-57168-4. Simple acknowledgment messages are often omitted from the diagrams for brevity. One or more messages may be required to satisfy a transaction. Each message is represented as an arrow starting from the Actor initiating the message.

• Message definitions: descriptions of each message involved in the transaction, the events that trigger the message, its semantics, and the actions that the message triggers in the receiver.

# 2.2 HL7 Profiling Conventions

HL7 messages are described in this document using message level and segment level tables according to static definitions of "HL7 constrainable message profiles" (see HL7 v2.5 section 2.12.6). For details of the HL7 message profiling conventions, the reader is referred to Appendix F.

A message level table represents one IHE-constrained message structure with its list of usable segments. A segment level table represents the IHE-constrained content of one segment with its usable fields:

- Message level tables are included in message subsections within each transaction section, and represent the static definition of the specified messages. A message table is followed by comments highlighting the segment usage. The subsection describing a message also provides the descriptions of any segments that are specific to this message.
- Only the segments that have a usage code R, RE, C or CE in at least one message are described. In other words, segments, which are always optional (O) or not supported (X), are not described in the IHE PCD TF.

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- The common static definition of the HL7 acknowledgement (ACK) message is described in Appendix G, "HL7 Implementation Notes".
- A number of detailed message examples are provided in Appendix E Examples of messages.

# 2.3 Use of Coded Entities and Coding Schemes

IHE does not produce, maintain or otherwise specify a coding scheme or other resource for controlled terminology (coded entities). For the IHE PCD implementations shall use the IEEE terms defined in Appendix D Device Content where defined. If an IEEE term is not defined in Appendix D, then an alternative LOINC term from Appendix D shall be used if defined, if neither an IEEE nor a LOINC term is defined in Appendix D, then a term mapped from the ISO/IEEE 11073 Nomenclature shall be used if defined. IF the term is not defined in the ISO/IEEE 11073 Nomenclature then a LOINC term should be used if defined. If neither IEEE nor LOINC supports a term then coding schemes required by the HL7 standard take precedence. In the cases where such resources are not explicitly identified by standards, implementations may utilize any resource (including proprietary or local) provided any licensing/copyright requirements are satisfied.)

# 2.4 Open Issues

- 1. The current balloted version of HL7 is 2.5. HL7 2.6 is currently in Committee Ballot 3. There are specific instances where changes have been made to HL7 V2.6 to support Patient Care Device communications. The PCD TF is based on HL7 2.5. Where specific elements of V2.6 are required they have been included and the have been flagged as being dependent on V2.6 and may change in the ballot process. One example is Observation Site (OBX-20), which supports specification of the body site(s) involved in a measurement.
- 2. HL7 requires that OBR field OBR-2 Placer Order Number be valued if the ORC segment is not present. The PCD TF does not use the ORC segment and, based on the HL7 rules, the OBR-2 field must be valued. For the PCD TF the usual case is that PCD data is the result of a "standing order" and there is not a unique order associated with each instance of communication of PCD data. In general, there is not a Placer (ordering application). For this document the recommendation is to treat the Device Observation Reporter as the placer as well as the filler. Need HL7 guideline for how to deal with case of standing orders.
- 3. The ISO/IEEE 11073 uses the EUI-64 as a Universal Identifier. The EUI-64 needs to be added to HL7 Table 0396. as a coding system.
- 4. OBX-20 Observation Site. For the PCD TF this field, which has been defined for HL7 V2.6, is required and has been added to the OBX segment. Since V2.6

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has not been through a final ballot there is a risk that changes could occur due to the balloting. The PCD believes that this is preferable to specification of a Z segment.

- 5. Need to define the process for assigning the Z trigger for the conformance statement for the PCD-02 transaction.
- 6. Need to clarify the method for defining the interval for which a subscription applies.
- 7. There is an issue of "best effort" where the Device Observation Filter actor is able to provide more data than requested but not the minimum requested. One problem with this approach is that the Device Observation Filter could claim conformance and just act as a direct pass through from the Device Observation Reporter. There is a need to clarify the notion of "best effort"
- 8. For the QPD Input Parameter Field Description and Commentary the MessageQueryName refers to HL7 Table 0396. Do we need to add the IHE to the recognized coding systems?
- 9. More examples are needed to illustrate specific points regarding the TF-2 use cases.
- 10. Value, Units, and Observation Status will be mapped to the OBX-17 or OBX-8. This is an **Open Issue related to events**.

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## 20 2.5 Closed Issues

- 1. XDS will be considered in years 2-3.
- 2. Version 2.X will be used for year 1. Unanimous decision of PCD.

# 3 Transactions

# 3.1 PCD-01 Communicate PCD Data

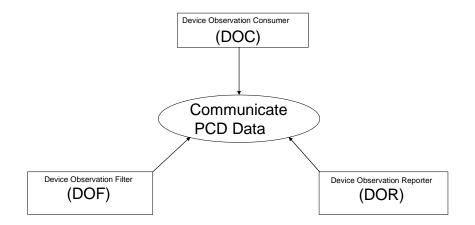
This section corresponds to Transaction PCD-01 of the IHE Patient Care Device Technical Framework. Transaction PCD-01 is used by the Device Observation Reporter, Device Observation Filter, and Device Observation Consumer actors.

## 3.1.1 Scope

This transaction is used to communicate PCD Data from:

- A Device Observation Reporter (DOR) to either a Device Observation Filter (DOF) or a Device Observation Consumer (DOC).
- 10 A Device Observation Filter (DOF) to a Device Observation Consumer (DOC).

## 3.1.2 Use Case Roles



### Figure 1 Communicate PCD Data Use Case

Actor: Device Observation Reporter (DOR)

**Role:** Sends PCD Data to DOF or to DOC

Actor: Device Observation Filter (DOF)

**Role:** Receives PCD Data from DOR and sends PCD Data to DOC based on defined filter predicates.

Actor: Device Observation Consumer (DOC)

**Role:** Receives PCD Data from DOR and/or DOF.

## 3.1.3 Referenced Standards

- HL7 Health Level 7 Version 2.5 Ch7 Observation Reporting
- ISO/IEEE 11073-10201 Domain Information Model
- ISO/IEEE 11073-10101 Nomenclature

## 3.1.4 Interaction Diagrams

The following interaction diagrams illustrate potential implementations.

## 3.1.5 DOR communicates with DOC

The PCD-01 is used to communicate PCD data from: Device Observation Reporter (DOR) to a Device Observation Consumer (DOC).

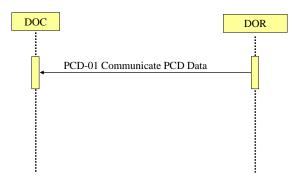


Figure 2 Communicate PCD Data Interaction Diagram

## 3.1.6 Communicate Filtered PCD Data

In the communication of filtered PCD Data the DOF receives PCD data from the DOR and communicates a selected set of the messages based upon a subscription which has been set up as a result of a PCD-02: Subscribe to PCD Data transaction. The PCD-02 transaction is shown for information in Figure 3 Communicate Filtered PCD Data and is defined in section 3.2 Transaction PCD-02 Subscribe to PCD Data.

IHE Patient Care Device Technical Framework, Vol. 2: Transactions

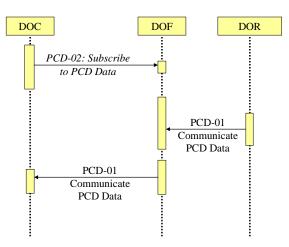


Figure 3 Communicate Filtered PCD Data

# 3.1.7 PCD-01 Communicate PCD Data (ORU^R01^ORU\_R01) static definition

The PCD-01 Communicate PCD Data message is used to communicate PCD data

- From a Device Observation Reporter (DOR) to a Device Observation Consumer (DOC).
- From a Device Observation Reporter (DOR) to a Device Observation Filter (DOC).
- From a Device Observation Filter (DOF) to a Device Observation Consumer (DOC).

Common HL7 segments (MSH, MSA, ERR, NTE, PID, PV1, OBR, OBX, QPD, RCP, TQ1) and data types (CE, CQ,CX, EI, HD, PL, TS, XPN, XTN) used in IHE PCD transactions are defined in Appendix B Common Message Segments for the Patient Care Device Technical Framework and Appendix C Common Data Types.

Segment	Meaning	Usage	Card.	HL7 chapter
MSH	Message Header	R	[11]	2
[{SFT}]	Software Segment	Х	[00]	2
{	PATIENT_RESULT begin			
]	PATIENT begin			
PID	Patient Identification	R	[11]	3
[PD1]	Additional Demographics	Х	[00]	3
[{NTE}]	Notes and Comments	Х	[0 0]	2

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Table 1 ORU^R01^ORU	R01 static definition
---------------------	-----------------------

[{NK1}]	Next of Kin/Associated Parties	Х	[00]	3
]	VISIT begin			
PV1	Patient Visit	0	[01]	3
[ PV2 ]	Patient Visit – Additional Info	Х	[00]	3
]	VISIT end			
]	PATIENT end			
{	ORDER_OBSERVATION begin			
[ORC]	Order Common	Х	[00]	4
OBR	Observation Request	R	[11]	7
[{NTE}]	Notes and Comments	0	[01]	2
[ {	TIMING_QTY begin			
TQ1	Timing/Quantity	0	[01]	4
[{TQ2}]	Timing/Quantity Order Sequence	Х		4
{]	{ ] TIMING_QTY end			
[CTD]	Contact Data	Х	[00]	11
[ {	OBSERVATION begin			
OBX	Observation Result	R	[11]	7
[{NTE}]	Notes and comments			2
}]	OBSERVATION end			
[{FT1}]	Financial Transaction	Х	[00]	6
[{CTI}]	Clinical Trial Identification	Х	[00]	7
] ]	SPECIMEN begin			
SPM	Specimen	Х	[00]	7
[{OBX}]	Observation related to Specimen	Х	[00]	7
}]	SPECIMEN end			
}	ORDER_OBSERVATION end			
}	PATIENT_RESULT end			
[DSC]	Continuation Pointer	Х	[00]	2

#### IHE Patient Care Device Technical Framework, Vol. 2: Transactions

### 3.1.7.1 Trigger events

The ORU^R01\_ORU\_R01 message is an unsolicited update. An application which implements the DOR receives data from one or more PCDs using either standards based or proprietary protocols which are outside the current scope of the IHE PCD TF.

In general, the DOR sends periodic reports at a minimum interval of 10 seconds (high acuity) and a maximum interval of 24 hours (chronic, home health) with a typical interval of 1 minute. The minimum and maximum intervals are configured at implementation.

The DOR may also send aperiodic reports for "event type" information. The DOR does not do interpolation of data received from the PCD source.

The DOF receives messages from the DOR and provides the same capabilities as the DOR regarding sending of reports. The DOR adds the service of filtering the message stream based on a predicate negotiated at run-time.

## 3.1.7.2 Message Semantics

Refer to the HL7 standard for the ORU message of HL7 2.5 Chapter 7 and the general message semantics.

The ORU^OR1^ORU\_R01 message structure provides the mechanisms for mapping the hierarchical structure of an IEEE 11073 containment tree to a series of OBX messages each of which is optionally qualified by an a note which immediately follows the respective OBX.

See Appendix A ISO/IEEE Nomenclature mapping to HL7 OBX-3 for further information on the mapping rules.

Examples of ORU^R01^ORU\_R01 messages implemented in both HL7 ER and XML are provided in Appendix E Examples of messages.

## 3.1.7.3 Expected Action

The ORU^R01^ORU\_R01 message is sent from the DOR to the DOC, DOF, or both. Upon receipt the DOC and DOF validate the message and respond with an acknowledgement as defined in Appendix G.2 Acknowledgment Modes.

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# 3.2 Transaction PCD-02 Subscribe to PCD Data

This section corresponds to Transaction PCD-02 of the IHE Patient Care Device Technical Framework. Transaction PCD-02 is used by the Device Observation Filter, and Device Observation Consumer actors.

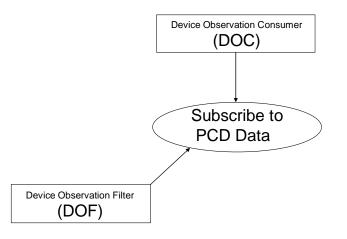
Common HL7 segments (MSH, MSA, ERR, NTE, PID, PV1, OBR, OBX, QPD, RCP) and data types (CE, CX, EI, HD, PL, TS, XPN, XTN) used in IHE PCD transactions are defined in Appendix B Common Message Segments for the Patient Care Device Technical Framework and Appendix C Common Data Types.

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## 3.2.1 Scope

This transaction is used by a Device Observation Consumer (DOC) to subscribe for PCD Data from a Device Observation Filter (DOF).

### 3.2.2 Use Case Roles



## Figure 4 Subscribe to PCD Data Use Case

Actor: Device Observation Filter

**Role:** Receives subscription request from the DOC and sets up filtering such that only those PCD-01 messages which satisfy the filter predicates are communicated to the DOC. In the absence of any explicit predicates regarding starting and stopping, the DOF will start as soon as the configuration of the predicate filters is completed and will continue until an explicit stop transaction is received. Each DOF is capable of supporting one or more subscriptions from a DOC.

# 10 more subscriptions from a DOC.

Actor: Device Observation Consumer

Role: Subscribes to PCD data.

## 3.2.3 Referenced Standards

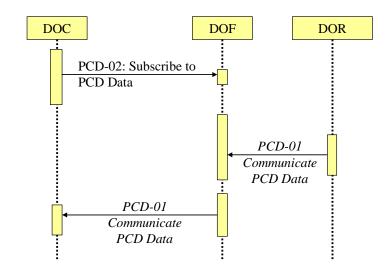
- HL7 Health Level 7 Version 2.5 Ch5 Query and CH7 Observation Reporting
- ISO/IEEE 11073-10201 Domain Information Model
- ISO/IEEE 11073-10101 Nomenclature

## 3.2.4 Interaction Diagram

The PCD-02 is used by a Device Observation Consumer (DOC) to subscribe for PCD Data from a Device Observation Filter (DOF). The transaction is based on the HL7 Publish and Subscribe Query model where the Device Observation Filter (DOF) plays the role of Publisher and the Device Observation Consumer (DOC) plays the role of Subscriber. The DOF defines a stream of data, but also agrees to selectively subset the

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message stream based on query-like data constraints. In the normal case, the right of the DOC to subscribe is decided at interface setup time. At runtime, the DOR controls the data rules, based on the subscription, under which it sends messages. Prospective data may be sent for a specified period of time, or for an open-ended period of time until further notice. Specific messages have been defined for subscription and the canceling of a subscription. See HL7 V2.5 Ch 5.7 for details of the Publish/Subscribe model.



### Figure 5 Subscribe to PCD Data Interaction Diagram

#### 10 **3.2.5 Message Static Definitions**

#### **3.2.5.1 Conformance Statement**

The HL7 Query model requires the definition of a Conformance Statement. The conformance statement for the PCD-02 Subscribe to PCD Data transaction described below is adapted from HL7 V2.5.

Table 2	Conformance	Statement
---------	-------------	-----------

Publication ID (Query ID=Z02):	Z02
Туре:	Publish
Publication Name:	IHEPCD-02SubscribeToPCDData
Query Trigger (= MSH-9):	QSB^Z02^QSB_Q16
Query Mode:	Immediate
Response Trigger (= MSH-9):	ORU^R01^ORU_R01 (PCD-01)
Query Characteristics:	Returns PCD data as defined by the query characteristics
Purpose:	Communicate PCD data using the PCD-01 transaction, either

Publication ID (Query ID=Z02):	Z02					
	filtered or unfiltered, as specified in the input parameters.					
Response Characteristics:	PCD-01 ORU messages are returned corresponding to the constraints expressed in the input parameters.					
	The input parameters are ANDed when selecting data to be returned. That is, all input parameters that are specified must be satisfied in order for a result report to be sent.					
	Parameters that are left empty are ignored in defining the filter criteria					
Based on Segment Pattern:	R01					

## 3.2.6 PCD-02 – QSB^Z02^QSB\_Q16 static definition

Common HL7 segments (MSH, MSA, ERR, NTE, PID, PV1, OBR, OBX, QPD, RCP, TQ1) and data types (CE, CQ,CX, EI, HD, PL, TS, XPN, XTN) used in IHE PCD transactions are defined in Appendix B Common Message Segments for the Patient Care Device Technical Framework and Appendix C Common Data Types.

#### Table 3 PCD-02 - QSB^Z02^QSB\_Q16 static definition

QSB^Z02^QSB_Q16	Query Grammar: QSB Message	Usage	Card.	Section Ref.
MSH	Message Header Segment	R	[11]	2.15.9
[{SFT}]	Software Segment	Х	[00]	2.15.12
QPD	Query Parameter Definition	R	[11]	5.5.4
RCP	Response Control Parameter	R	[11]	Error!
				Reference
				source not found.
[ DSC ]	Continuation Pointer	CE	[01]	2.15.4

10 The IHE PCD TF supports filtering based on the parameters defined in Table 4 QPD Input Parameter Specification and described in Table 5 QPD Input Parameter Field Description and Commentary.

Table 4 (	QPD Input	Parameter	Specification
-----------	-----------	-----------	---------------

Field Seq (Query ID=Z02)	ColName	Кеу/ Search	S o r t	LEN	DT	O p t	RP/#	M a t c h O p	TBL #	Segment Field Name	Service Identifier Code	Element Name
1	MessageQueryName			60	CE	R	[11]					Message Query Name

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Field Seq (Query ID=Z02)	ColName	Key/Search	S o r t	LEN	DT	O p t	RP/#	M a t c h O p	TBL #	Segment Field Name	Service Identifier Code	Element Name
2	QueryTag			32	ST	R	[11]					Query Tag
3	MRN				СХ	0	[020]			PID.3		
4	ActionCode				ID	0	[01]		0323			
5	PatientLocation				PL	0	[020]			PV1.3		
6	DeviceClass				CE	0	[06]			OBX.3		
7	ParameterClass				CE	0	[06]			OBX.3		
8	StartDateTime				TS	0	[01]			TQ1-7		
9	EndDateTime				TS	0	[01]			TQ1-8		
10	Interval				CQ	0	[01]			TQ1-5		

#### Table 5 QPD Input Parameter Field Descripion and Commentary

Input Parameter (Query ID=ZXX)	Comp. Name	DT	Description
MessageQueryName		CE	Must be valued Z02^PCD-02-Subscription.
QueryTag		ST	Unique to each query message instance.
MRN		СХ	One or more patient identifiers may be sent. When a list is provided, results will be sent if any parameter matches any ID known for a patient. Sending no value matches all patients
ActionCode		ID	If the subscription is being modified, the desired action e.g., Add or Delete is carried in this field. Must be 'A', 'D', or null.
PatientLocation		PL	When a list is provided, results will be sent if any parameter matches PV1.3 for any result. Sending no value matches all results.
DeviceClass		IS	When a list is provided, results will be sent if any parameter matches OBX.3 for any result. Sending no value matches all results.
ParameterClass		CE	When a list is provided, results will be sent if any parameter matches OBX.3 for any result Sending no value matches all results.
StartDateTime		TS	The date/time at which the subscription is to start. If null subscription starts immediately
EndDateTime		TS	The date/time at which the subscription is to end. If null subscription starts immediately
Interval		CQ	The interval between observation reports.

The IHE PCD TF supports the RCP response control parameters described in Table 6 RCP Response Control Parameter Field Description and Commentary.

Field Seq (Query ID=Z99)	Name	Compo- nent Name	LEN	DT	Description
1	Query Priority		1	ID	I
3	Response Modality		60	C E	R

#### Table 6 RCP Response Control Parameter Field Description and Commentary

## 3.2.6.1 Trigger events

The QSB^Z02^QSB\_Q16 message is defined by the IHE PCD based on the rules defined in HL7 v2.5 Chapter 5.7 for Publish and Subscribe messages. The QSB^Z02^QSB\_Q16 is sent from a DOC to a DOF for the purpose of creating a new subscription or modifying an existing subscription. Permission for a DOC to send the QSB^Z02^QSB\_Q16 to a DOF is defined at implementation time.

## 3.2.6.2 Message Semantics

10 Refer to HL7 2.5 Chapter 5.4.4 for the general message semantics of the QSB message and Chapter 5.7 for the details of Publish and Subscribe.

The IHE PCD QSB^Z02^QSB\_Q16 message defines the parameters which define the filter to be applied to a stream of device observation messages. The current version of the IHE PCD TF provides facilities for selecting messages based on:

- A list of one or more patients identified by a patient identifier
- A list of one or more patient locations
- A list of one or more device classes
- A list of one of more specific device parameter classes

The IHE PCD QSB^Z02^QSB\_Q16 also provides parameters which define the:

- Date and time at which the subscription is to begin, the default is immediately.
- Date and time at which the subscription is to end, the default is never.
- The interval between periodic reports.

The parameters of the QSB^Z02^QSB\_Q16 are combined based on a logical AND to define the overall query. For those parameters which define a list of one or more entries the elements of the list are combined based on a logical OR and satisfaction of any member of the list satisfies the condition for the respective parameter.

If the Action Code is set to A, the parameters are added to an existing subscription.

If the Action Code is set to D, the parameters are deleted from an existing subscription.

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## 3.2.6.3 Expected Action

Upon receipt of a QSB^Z02^QSB\_Q16 the DOF establishes a subscription based on the parameters defined and communicates those messages satisfying the subscription predicate using the PCD-01 transaction to the subscriber.

# Appendix A ISO/IEEE 11073 Mapping to HL7

IEEE 11073 defines PCD semantics in terms of an information model and a nomenclature. The information model is defined in ISO/IEEE 11073-10201 Health Informatics – Point-of-care medical device communication – Part 10201 : Domain

10 Information Model. The nomenclature is defined in ISO/IEEE 11073-10101 Health Informatics – Point -of-care medical device communication – Part 10101: Nomenclature. Familiarity with these standards is necessary for implementers of the Device Observation Reporter and Device Observation Filter actors.

HL7 V2.5 Chapter 7 Observation Reporting defines the syntax and coding requirements used for PCD data communications in the PCD TF. Familiarity with HL7 Chapter 7 is necessary for implementers of the PCD TF transactions.

One of the key contributions of the PCD TF is the definition of common semantics for PCD data communication in the enterprise environment. This is accomplished by the Device Observation Reporter and Device Observation Filter actors through mapping of the IEEE 11073 semantics to equivalent elements of HL7.

The purpose of this appendix is to describe the model which is used to map from IEEE 11073 semantics to HL7.

# A.1 Mapping ISO/IEEE 11073 Domain Information Model to HL7

Figure 6 System Package Model represents the system level containment of the 11073 DIM.

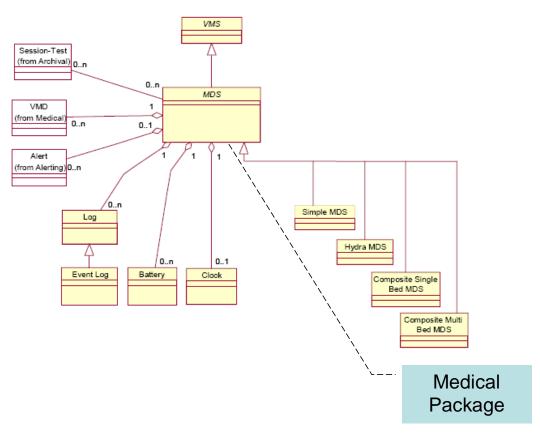
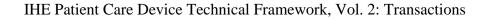


Figure 6 System Package Model

The mapping from 11073 to HL7 will be described by focusing on the Medical Package defined by the Medical Device System shown in Figure 6 System Package Model and elaborated in Figure 7 Medical Package Model.



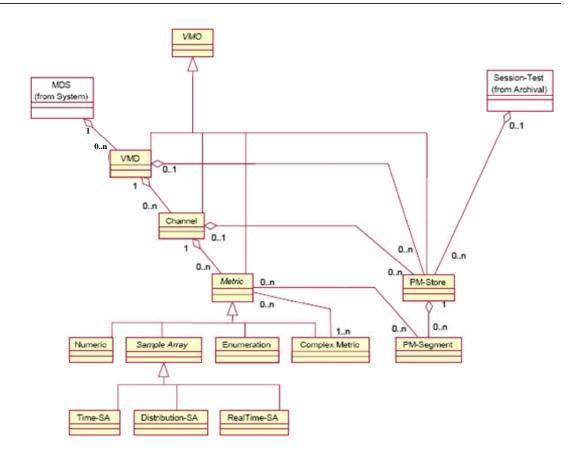


Figure 7 Medical Package Model

The HL7 OBX segment provides two fields which are used in mapping Figure 7 Medical Package Model, these are OBX-3 Observation Identifier and OBX-4 Observation Sub-Id.

OBX-3 is expressed as an HL7 Coded Element (CE) datatype and the details of mapping the 11073 MDC to the HL7 CE datatype are described in Appendix A.2 ISO/IEEE Nomenclature mapping to HL7 OBX-3.

10 OBX-4 is used to express the containment level of a particular item expressed in OBX-3. This is done by defining the nodes of the <MDS> <VMD> <CHAN> <METRIC> hierarchy of the containment tree as a set of ordinal numbers expressed in a dotted notation such that each OBX-3 is expressed unambiguously in terms of its containment as defined by OBX-4.

Subject	Containment Tree Hierarchical Level					
Medical:	<mds></mds>	<vmd></vmd>	<chan></chan>	<parametric instance&gt;</parametric 		

<u>Exar</u>	nples							
1	Virtual (Medical)	<vs mon=""></vs>	<pulsoxim></pulsoxim>	<oxim></oxim>	<spo2></spo2>			
	Ordinal	1	1	1	1			
2	Virtual (Medical)	<vs mon=""></vs>	<pulsoxim></pulsoxim>	<ptach></ptach>	<pr></pr>			
	Ordinal	1	1	2	2			
3	Virtual (Medical)	<vs mon=""></vs>	<ecg></ecg>	<ctach></ctach>	<hr/>			
	Ordinal	1	2	1	3			
					-7			

Recommend that Ordinal value is unique among entire set

#### Figure 8 Example of Mapping Containment to OBX-4

For example the OBX-4 for the <VS Mon> <ECG> <Ctach> <HR> would be expressed as 1.2.1.3.

OBX-2 the valid HL7 types for the mapping are NM, ST, SN, CE, CF (String may have some implied structure)

The specification of the containment tree provides a mechanism to address dynamic configuration of a PCD. For example, a patient monitor may have one or more "plug-ins" which may be added to and removed from the patient monitor as the patient's clinical condition changes. When a plug-in is removed the ordinal numbers previously assigned to that plug-in shall be reserved. Replacement of the plug-in shall result in the reassignment of the reserved ordinal numbers to the plug-in which has been replaced. Addition of a new plug-in shall result in the assignment of ordinal numbers which have not been reserved.

# A.2 ISO/IEEE Nomenclature mapping to HL7 OBX-3

The ISO/IEEE Nomenclature provides an unambiguous coding which is mapped to HL7 OBX-3 as follows:

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20 HL7 OBX-3 is of type CE consisting of:

	Table 7 HL7 Component Table - CE - Coded Element							
SEQ	LEN	DT	Usage	Card.	TBL#	Component Name	Comments	Sec Ref
1	20	ST	R	[11]		Identifier	Nomenclature Code	2.A.74
2	199	ST	R	[11]		Text	Reference ID	2.A.74
3	20	ID	R	[11]	0396	Name of Coding System	"MDC"	2.A.35
4	20	ST	0	[01]		Alternate Identifier		2.A.74
5	199	ST	0	[01]		Alternate Text		2.A.74
6	20	ID	0	[01]	0396	Name of Alternate Coding System		2.A.35

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Definition: This data type transmits codes and the text associated with the code.

#### Maximum Length: 483

Where:

10

Nomenclature Code is the string representation of the decimal value corresponding to the context free 32 bit representation of the Nomenclature Code

[context-free] Nomenclature Code == (Code Block number  $*2^{**}16$ ) + [context-sensitive], where [context-sensitive] is an offset, reflecting a particular variant of an associated "discriminator". The Reference ID is also modified to reflect the variant.

For example, for the "Device Type" Nomenclature, the Device Type discriminator is as follows:

Ref ID variant	Description	Term Code Offset
DEV	Not-otherwise specified	0
MDS	Medical Device System	1
VMD	Virtual Medical Device	2
CHAN	Channel	3

The *context-free* nomenclature code for a term in code block number 1 whose term code=4104 is equal to  $((1 * 2^{**}16) + 4104) = 1*65536 + 4104 = 69640$  (which uniquely identifies the SpO<sub>2</sub> monitor term) with a Reference ID of MDC\_DEV\_ANALY\_SAT\_O2. The *context-sensitive* form for the variant "MDS" is

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"MDC\_DEV\_ANALY\_SAT\_O2\_**MDS** (appending, of suffixing "MDS"), and the Term Code is 69640+1 = 69641 (adding the Term Code Offset to the base Term Code).

The OBX-3 representation is "69641^MDC\_DEV\_ANALY\_SAT\_O2\_MDS^MDC "

The Virtual Medical Device variants are: MDC\_DEV\_ANALY\_SAT\_O2\_VMD 69640, and "69642^ MDC\_DEV\_ANALY\_SAT\_O2\_VMD^MDC" in OBX-3 representation.

To distinguish between periodic and aperiodic data map from the IEEE 11073 Metric Access to HL7 and code in OBX-17. This is used where you want to distinguish periodic, aperiodic etc. Metric Category also provides distinction between manual and automatic.

MDS Status describes states - disconnected, configuring, operating, terminating,

10 disassociated, reconfiguring. Relates to general question of alerts and events. Value, Units, and Observation Status will be mapped to the OBX-17 or OBX-8.

MDS MODEL is used to provide device vendor/model and shall be mapped at the MDS level in the OBX with the value described by OBX-3.

MDS DEVICE TYPE is used to describe the type of the PCD such as monitor, ventilator, infusion pump...and shall be mapped at the MDS level in the OBX with the value described by OBX-3.

For PCDs with complex operation states such as an infusion pump with a set of states like "Stopped", "Infusing Primary", "Infusing Secondary", "Bolus", etc.. or a ventilator with states "Standby", "Ventilating", etc. the Device Operational Status Enumeration Object is mapped to OBX-3.

20

# A.3 Mapping 11073 Value Types to HL7 OBX-2.

There is an additional consideration when mapping 11073 units to HL7.

HL7 OBX-2 defines the Value Type that is used to express the value in OBX-5 based on HL7 Table 0125.

The PCD TF constrains the allowable value type to those shown in Table 8 PCD Constrained HL7 Table 0125

Value	Description	Comment
CD	Coded Entry	
CF	Coded Element with Formatted Values	
DT	Date	
ED	Encapsulated Data	
FT	Formatted Text	
NM	Numeric	
PN	Person Name	

Table 8 PCD	<b>Constrained HL7</b>	Table 0125
-------------	------------------------	------------

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Description	Comment
Structured Numeric	
String Data	
Time	
Time Stamp (Date and Time)	
Extended Composite Name and Number for	
	Structured Numeric String Data Time Time Stamp (Date and Time)

# Appendix B Common Message Segments for the Patient Care Device Technical Framework

## B.1 MSH - Message Header Segment

See HL7 v2.5: chapter 2 (2.15 Message control)

This segment defines the intent, source, destination, and some specifics of the syntax of a message.

SEQ	LEN	DT	Usage	Card.	TBL#	ITEM#	Element name
1	1	ST	R	[11]		00001	Field Separator
2	4	ST	R	[11]		00002	Encoding Characters
3	227	HD	R	[11]	0361	00003	Sending Application
4	227	HD	ORE	[01]	0362	00004	Sending Facility
5	227	HD	ORE	[01]	0361	00005	Receiving Application
6	227	HD	ORE	[01]	0362	00006	Receiving Facility
7	26	TS	R	[11]		00007	Date/Time of Message
8	40	ST	Х	[00]		00008	Security
9	15	MSG	R	[11]		00009	Message Type
10	20	ST	R	[11]		00010	Message Control Id
11	3	РТ	R	[11]		00011	Processing Id
12	60	VID	R	[11]		00012	Version ID
13	15	NM	RE	[101]		00013	Sequence Number
14	180	ST	Х	[00]		00014	Continuation Pointer
15	2	ID	R	[11]	0155	00015	Accept Acknowledgement Type
16	2	ID	R	[11]	0155	00016	Application Acknowledgement Type
17	3	ID	RE	[01]	0399	00017	Country Code
18	16	ID	RE	[01]	0211	00692	Character Set
19	250	CE	RE	[01]		00693	Principal Language of Message
20	20	ID	Х	[00]	0356	01317	Alternate Character Set Handling Scheme
21	427	EI	R	[11]		01598	Message Profile Identifier

 Table 9 MSH - Message Header

#### MSH-1 Field Separator, required:

The IHE PCD Technical Framework requires that applications support HL7-recommended value that is | (ASCII 124).

#### MSH-2 Encoding Characters, required:

This field contains the four characters in the following order: the component separator, repetition separator, escape character, and subcomponent separator. The IHE PCD Technical Framework requires that applications support HL7-recommended values ^~\& (ASCII 94, 126, 92, and 38, respectively).

#### 10 MSH-3 Sending Application (HD), required:

Components: <Namespace ID (IS)> ^ <Universal ID (ST)> ^ <Universal ID Type (ID)>

First component (optional): Namespace ID. Locally unique name for application implementing PCD actor(s).

Second component (required): Universal ID expressed as string of hexadecimal digits. Implementations of PCD actors shall use an EUI 64 identifier. The IEEE defined 64-bit extended unique identifier (EUI-64) is a concatenation of the 24-bit company\_id value by the IEEE Registration Authority and a 40-bit extension identifier assigned by the organization with that company\_id assignment.

20 Third component (required): EUI-64.

#### MSH-4 Sending Facility (HD), required but may be empty:

Components: <Namespace ID (IS)> ^ <Universal ID (ST)> ^ <Universal ID Type (ID)>

For the IHE PCD Technical Framework, when populated, this field shall be implemented as:

First component (required): Namespace ID. The name of the organizational entity responsible for the sending application.

Second component (optional): The URI (OID) of the organizational entity responsible for the sending application.

30 Third component (optional): The type of identification URI provided in the second component of this field. The codification of these three components is entirely site-defined. It may be detailed in the national extensions of this framework.

#### MSH-5 Receiving Application (HD), required but may be empty:

Components: <Namespace ID (IS)> ^ <Universal ID (ST)> ^ <Universal ID Type (ID)>

For the IHE PCD Technical Framework, when populated, this field shall be implemented as:

First component (required): Namespace ID. The name of the organizational entity responsible for the receiving application.

Second component (optional): The URI (OID) of the organizational entity responsible for the receiving application.

Third component (optional): The type of identification URI provided in the second component of this field. The codification of these three components is entirely site-defined. It may be detailed in the national extensions of this framework.

#### 10 MSH-6 Receiving Facility (HD), required but may be empty:

Components: <Namespace ID (IS)> ^ <Universal ID (ST)> ^ <Universal ID Type (ID)>

For the IHE PCD Technical Framework, when populated, this field shall be implemented as:

First component (required): Namespace ID. The name of the organizational entity responsible for the receiving application.

Second component (optional): The URI (e.g. OID) of the organizational entity responsible for the receiving application.

Third component (optional): The type of identification URI provided in the second component of this field. The codification of these three components is entirely site-defined. It may be detailed in the national extensions of this framework.

#### MSH-7 Date/Time of Message (TS), required:

The IHE PCD TF requires this field be populated with:

For the IHE PCD Technical Framework, when populated, this field shall be implemented as:

Format: YYYY[MM[DD[HH[MM[SS]]]]][+/-ZZZZ]

Time zone qualification of the date/time is required.

MSH-7 shall be used only to provide message created time

#### MSH-9 Message Type (MSG), required:

Components: <Message Code (ID)> ^ <Trigger Event (ID)> ^ <Message Structure (ID)>

Definition: This field contains the message type, trigger event, and the message structure ID for the message. All three components are required.

Its content is defined within each transaction-specific section of this document.

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#### MSH-10 Message Control Id (ST), required:

Definition: This field contains a number or other identifier that uniquely identifies the message. Each message should be given a unique identifier by the sending system. The receiving system shall echo this ID back to the sending system in the Message Acknowledgment segment (MSA). The combination of this identifier and the name of the sending application (MSH-3) shall be unique across the Healthcare Enterprise.

#### MSH-11 Processing ID (PT), required:

Components: <Processing ID (ID)> ^ <Processing Mode (ID)>

10

Definition: This data type indicates whether to process a message as defined in HL7 Application (level 7) processing rules.

The IHE PCD-TF requires the first component Processing ID be valued based on HL7 Table 0103. Use of the second component Processing Mode is optional but if used is based on HL7 Table 0207.

### MSH-12 Version ID (VID), required:

Components: <Version ID (ID)> ^ <Internationalisation Code (CE)> ^ <International Version ID (CE)>

Definition: This field is matched by the receiving system to its own version to be sure the message will be interpreted correctly.

20 The PCD TF is based on HL7 V2.5. Where specific elements of V2.6 are required they have been used and their usage flagged.

Although HL7 allows international affiliate versions to be specified the IHE PCD-TF uses only the core version.

### MSH-13 Sequence Number (ID), required but may be empty:

Definition: A non-null value in this field implies that the sequence number protocol is in use. This numeric field is incremented by one for each subsequent value.

### MSH-15 Accept Acknowledgement Type (ID), required:

Definition: This field identifies the conditions under which accept acknowledgments are required to be returned in response to this message. Required for enhanced acknowledgment mode. Refer to HL7 Table 0155 - Accept/application acknowledgment conditions for valid values. The PCD TF requires that this field be

valued as NE.

### MSH-16 Application Acknowledgement Type (ID), required:

Definition: This field identifies the conditions under which application acknowledgments are required to be returned in response to this message. Required

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for enhanced acknowledgment mode. Refer to HL7 Table 0155 - Accept/application acknowledgment conditions for valid values. The PCD TF requires that this field be valued as AL.

Note that the combination of MSH-16 valued as AL and MSH-15 valued as NE is consistent with the original acknowledgement rules used in other IHE TFs.

#### MSH-17 Country Code (ID), required but may be empty:

Definition: This field contains the country of origin for the message. It will be used primarily to specify default elements, such as currency denominations. The values to be used are those of ISO 3166,.5. The ISO 3166 table has three separate forms of the country code: HL7 specifies that the 3-character (alphabetic) form be used for the country code.

Note that the combination of MSH-16 valued as AL and MSH-15 valued as NE is consistent with the original acknowledgement rules used in other IHE TFs.

#### MSH-18 Character Set (ID), required but may be empty:

Definition: This field contains the character set for the entire message. Refer to HL7 Table 0211 - Alternate character sets for valid values.

An HL7 message uses field MSH-18-character set to specify the character set(s) in use. Valid values for this field are specified in HL7 Table 0211, "Alternate Character Sets". MSH-18-character set may be left blank, or may contain a single value. If the field is left blank, the character set in use is understood to be the 7-bit ASCII set, decimal 0 through decimal 127 (hex 00 through hex 7F). This default value may also be explicitly specified as ASCII.

Any encoding system, single-byte or multi-byte, may be specified as the default character encoding in MSH-18-character set. If the default encoding is other than 7bit ASCII, sites shall document this usage in the dynamic conformance profile or other implementation agreement. This is particularly effective in promoting interoperability between nations belonging to different HL7 Affiliates, while limiting the amount of testing required to determine the encoding of a message.

By using built-in language functions for string and character manipulation, parsers and applications need not be concerned whether a single or double byte character set is in use, provided it is applied to the entire message. Using a built in function to extract the fourth CHARACTER will always yield the field separator character, regardless of coding set. On the other hand, if the parser looks at the fourth BYTE, it is then limited to single byte character sets, since the fourth byte would contain the low order 8 bits of the character S in a double-byte system.

See HL7 V2.5 for the semantics for alphabetic languages other than English (2.15.9.18.1) and for non-alphabetic languages (2.15.9.18.2)

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The PCD TF requires this field to be valued if the character set is other than ASCII. If the character set is ASCII the field may be null or have the value of ASCII. A single character set is required for a given message.

#### MSH-19 Principal Language of Message (RE), required but may be empty:

Components: <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^<Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate Coding System (ID)>

Definition: This field contains the principal language of the message. Codes come from ISO 639.

10 The PCD uses a default of EN^English^ISO659 if the field is empty.

#### MSH-21 Message Profile Identifier (EI), required:

Components: <Entity Identifier (ST)> ^ <Namespace ID (IS)> ^ <Universal ID (ST)> ^<Universal ID Type (ID)>

For PCD TF, this field is required. It is proposed that PCD message profiles be registered with HL7 and that the appropriate ID be used here in conformant messages When multiple message profiles are listed in this field they should be (vendor specific, country specific) constraints of the PCD Profile. Note that the overriding of PCD Profile constraints is only allowed in national extensions to this framework.

The details for profile identification for Publish/Subscribe profiles are provided in Section 3.2 Transaction PCD-02 Subscribe to PCD Data

## B.2 MSA - Message Acknowledgement segment

HL7 v2.5: chapter 2 (2.15 Message control)

This segment contains information sent while acknowledging another message.

SEQ	LEN	DT	Usage	Card.	TBL#	ITEM#	Element name
1	2	ID	R	[11]	0008	00018	Acknowledgement code
2	20	ST	R	[11]		00010	Message Control Id
3	80	ST	Х	[00]		00020	Text Message
5	1	ID	Х	[00]		00022	Delayed Acknowledgment Type
6	250	CE	Х	[00]	0357	00023	Error Condition

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Table 10 MSA - Message Acknowledgement

MSA-1 Acknowledgment Code (ID), required:

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The IHE PCD Technical Framework authorizes only one of the three values below, taken from HL7 table 0008 - Acknowledgement code:

		-
Value	Description	Comment
AA	Original mode: Application Accept	The message has been accepted and integrated by the receiving application
AE	Original mode: Application Error	The sender should try again to send the message later
AR	Original mode: Application Reject	The message has been rejected by the receiving application

Table 11: HL7 table 0008 - Acknowledgement code

## MSA-2 Message Control ID (ST), required:

Definition: This field contains the message control ID from the MSH-10 - Message Control ID of the incoming message for which the acknowledgement is sent.

## MSA-3 Text Message (ST), not supported:

See the ERR segment.

## 10 B.3 ERR - Error segment

HL7 v2.5 : chapter 2 (2.15 Message control)

This segment is used to add error comments to acknowledgment messages.

						-	
SEQ	LEN	DT	Usage	Card.	TBL#	ITEM#	Element name
1	493	ELD	RE	[01]		00024	Error Code and Location
3	705	CWE	R	[11]	0357	01813	HL7 Error Code
4	2	ID	R	[11]	0516	01814	Severity

Table 12 ERR - Error segment

Notes: ERR-1 is included in HL7 v2.5 for backward compatibility only. Within the context of IHE PCD, this field shall not be used.

ERR-3 and ERR-4 are required by HL7 v2.5

## B.4 NTE - Notes and Comment segment

HL7 v2.5 : chapter 2 (2.15 Message control)

20 This segment is used for sending notes and comments.

The IHE PCD Technical Framework limits the use of this segment to only one purpose: To comment the observations and the orders. Therefore, in the messages of this Integration Profile, NTE segments appear only following either OBR or OBX segments.

Information that can be coded in OBX segments or OBR segments shall not be sent in a NTE segment.

Detail of the fields used by the NTE segment in the PCD Observation Message is given in **Error! Reference source not found.** 

SEQ	LEN	DT	Usage	Card.	TBL#	ITEM#	Element name
1	4	SI	R	[11]		00096	Set ID – NTE
2	8	ID	Х	[00]		00097	Source of Comment
3	65536	FT	RE	[01]		00098	Comment
4	250	CE	Х	[00]		01318	Comment Type

 Table 13 NTE - Notes and Comment segment

## NTE-1 Set ID - NTE (SI), required:

## NTE-3 Comment (FT), required but may be empty:

This field contains the text of the comment. This text may be formatted. In order to delete an existing comment, the field shall contain empty quotation marks: "".

Comment text of identical type and source shall be included in the same occurrence of an NTE segment, and not be split over multiple segments.

## B.5 PID - Patient Identification segment

HL7 v2.5 : chapter 3 (3.4.2)

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The PID segment is used by all applications as the primary means of communicating patient identification information. This segment contains permanent patient identifying and demographic information that, for the most part, is not likely to change frequently.

SEQ	LEN	DT	Usage	Card.	TBL#	ITEM#	Element name
1	4	SI	Х	[00]		00104	Set ID - PID
2	20	CX	Х	[00]		00105	Patient ID
3	250	CX	R	[16]		00106	Patient Identifier List
4	20	CX	Х	[00]		00107	Alternate Patient ID - PID
5	250	XPN	R	[16]		00108	Patient Name
6	250	XPN	RE	[01]		00109	Mother's Maiden Name
7	26	TS	RE	[01]		00110	Date/Time of Birth
8	1	IS	RE	[01]	0001	00111	Administrative Sex
9	250	XPN	Х	[00]		00112	Patient Alias
10	250	CE	RE	[01]	0005	00113	Race
11	250	XAD	RE	[01]		00114	Patient Address

Table 14 PID - Patient Identification segment

SEQ	LEN	DT	Usage	Card.	TBL#	ITEM#	Element name
12	4	IS	RE	[01]	0289	00115	County Code
13	250	XTN	RE	[02]		00116	Phone Number - Home
14	250	XTN	Х	[01]		00117	Phone Number - Business
15	250	CE	RE	[01]	0296	00118	Primary Language
16	250	CE	RE	[01]	0002	00119	Marital Status
17	250	CE	RE	[00]	0006	00120	Religion
18	250	CX	RE	[01]		00121	Patient Account Number
19	16	ST	Х	[01]		00122	SSN Number - Patient
20	25	DLN	RE	[01]		00123	Driver's License Number - Patient
21	250	CX	RE	[01]		00124	Mother's Identifier
22	250	CE	RE	[01]	0189	00125	Ethnic Group
23	250	ST	RE	[01]		00126	Birth Place
24	1	ID	RE	[01]	0136	00127	Multiple Birth Indicator
25	2	NM	RE	[01]		00128	Birth Order
26	250	CE	RE	[01]	0171	00129	Citizenship
27	250	CE	RE	[01]	0172	00130	Veterans Military Status
28	250	CE	RE	[01]	0212	00739	Nationality
29	26	TS	RE	[01]		00740	Patient Death Date and Time
30	1	ID	RE	[01]	0136	00741	Patient Death Indicator
31	1	ID	RE	[01]	0136	01535	Identity Unknown Indicator
32	20	IS	RE	[01]	0445	01536	Identity Reliability Code
33	26	TS	RE	[01]		01537	Last Update Date/Time
34	241	HD	RE	[01]		01538	Last Update Facility
35	250	CE	RE	[01]	0446	01539	Species Code
36	250	CE	С	[00]	0447	01540	Breed Code
37	80	ST	С	[01]		01541	Strain
38	250	CE	RE	[02]	0429	01542	Production Class Code
39	250	CWE	RE	[01]	0171	01840	Tribal Citizenship

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The following describes the IHE PCD usage of those fields which have a usage other than X in the above table.

## PID-3 Patient Identifier List (CX), required:

Definition: This field contains the list of identifiers (one or more) used by the healthcare facility to uniquely identify a patient (e.g., medical record number, billing number, birth registry, national unique individual identifier, etc.). In Canada, the Canadian Provincial Healthcare Number shall be sent in this field.

Subfields CX-1 "ID number", CX-4 "Assigning authority", and CX-5 "Identifier Type Code" are required for each identifier. See Appendix C.2 CX Data Type for further details.

The workflow and mechanism by which patient identification is bound to the data from a particular PCD device is outside of the scope of this version of the IHE PCD Framework. Common implementations employ either automated or manual entry based on information provided by an authoritative source of patient identity. The workflow and transactions to bind patient identity are included on the IHE PCD Roadmap for consideration in future versions of the IHE PCD Framework.

10 The IHE PCD recognizes that for some use cases, such as medication administration, additional identification information or other patient demographic information is required in addition to an organizationally assigned unique identifier. Patient name, date of birth, gender, and other information are commonly used to provide the additional patient identification context for these use cases. Additional patient demographic information is provided by the fields of the PID segment and the patient location, which is often a key element in PCD communications, is provided in the PV1-3 element.

## PID-5 Patient Name (XPN), required:

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Definition: This field contains the names of the patient, the primary or legal name of the patient is reported first. Therefore, the name type code in this field should be "L - Legal". Refer to **Error! Reference source not found.** for valid values. Note that "last name prefix" is synonymous to "own family name prefix" of previous versions of HL7, as is "second and further given names or initials thereof" to "middle initial or name". Multiple given names and/or initials are separated by spaces.

For animals, if a Name Type of "R" is used, use "Name Context" to identify the authority with which the animal's name is registered.

The workflow and mechanism by which patient name is bound to the data from a particular PCD device is outside of the scope of this version of the IHE PCD Framework. Common implementations employ either automated or manual entry based on information provided by an authoritative source of patient identity. The workflow and transactions to bind patient name are included on the IHE PCD Roadmap for consideration in future versions of the IHE PCD Framework.

Value	Description	Comment
А	Alias Name	
В	Name at Birth	
С	Adopted Name	

See Appendix C.7 Type for further information.

## Table 15 HL7 Table 0200 - Name Type

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D	Display Name	
Ι	Licensing Name	
L	Legal Name	
М	Maiden Name	
Ν	Nickname /"Call me" Name/Street Name	
Р	Name of Partner/Spouse - obsolete	Deprecated in V2.4
R	Registered Name (animals only)	
S	Coded Pseudo-Name to ensure anonymity	
Т	Indigenous/Tribal/Community Name	
U	Unspecified	

## PID-6 Mother's Maiden Name (XPN), required but may be empty:

Definition: This field contains the family name under which the mother was born (i.e., before marriage). It is used to distinguish between patients with the same last name.

See Appendix C.7 Type for further information.

## PID-7 Date/Time of Birth (TS), required but may be empty:

For the IHE PCD Technical Framework, when populated, this field shall be implemented as:

## Format: YYYY[MM[DD[HH[MM[SS]]]]][+/-ZZZZ]

10 See Appendix C.6 TS Data Type for further information.

## PID-8: Administrative Sex (IS), required but may be empty:

Definition: This field contains the patient's sex. Refer to HL7 User-defined Table 0001 - Administrative Sex for suggested values.

## Table 16 HL7 User Defined Table 0001 - Administrative Sex

Value	Description	Comment
F	Female	
М	Male	
0	Other	
А	Ambiguous	
Ν	Not applicable	

## **PID-10:** Race (CE), required but may be empty:

Definition: This field refers to the patient's race. Refer to User-defined Table 0005 - Race for suggested values. The second triplet of the CE data type for race (alternate identifier, alternate text, and name of alternate coding system) is reserved for governmentally assigned codes.

Value	Description	Comment								
1002-5	American Indian of Alaska Native									
2028-9	Asian									
2054-5	Black or African American									
2076-8	Native Hawaiian of Other Pacific Islander									
2106-3	White									
2131-1	Other Race									

## Table 17 HL7 User Defined Table 0005 - Race

## **PID-11:** Patient Address (XAD), required but may be empty:

Components: <Street Address (SAD)> ^ <Other Designation (ST)> ^ <City (ST)> ^ <State or Province (ST)> ^ <Zip or Postal Code (ST)> ^ <Country (ID)> ^ <Address Type (ID)> ^ <Other Geographic Designation (ST)> ^ <County/Parish Code (IS)> ^ <Census Tract (IS)> ^ <Address Representation Code (ID)> ^ <Address Validity Range (DR)> ^ <Effective Date (TS)> ^ <Expiration Date (TS)>

Subcomponents for Street Address (SAD): <Street or Mailing Address (ST)> & <Street Name (ST)> & <Dwelling Number (ST)>

10 Subcomponents for Address Validity Range (DR): <Range Start Date/Time (TS)> & <Range End Date/Time (TS)>

Subcomponents for Range Start Date/Time (TS): <Time (DTM)> & <Degree of Precision (ID)>

Subcomponents for Range End Date/Time (TS): <Time (DTM)> & <Degree of Precision (ID)>

Subcomponents for Effective Date (TS): <Time (DTM)> & <Degree of Precision (ID)>

Subcomponents for Expiration Date (TS): <Time (DTM)> & <Degree of Precision (ID)>

20 Definition: This field contains the mailing address of the patient. Address type codes are defined by HL7 Table 0190 - Address Type. The PCD only requires the first, third, fourth, and fifth components to be valued with the mailing address and the Address Type to be valued as M.

## **PID-13:** Phone Number – Home, required but may be empty:

Definition: This field contains the patient's personal phone numbers. This data type is usually in a repeatable field, to allow a list of numbers. The PCD requires the sequence to be the primary number (for backward compatibility). The PCD constrains this field to 2 repetitions to allow for a phone number and an email address.

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See Appendix C.8 XTN Data Type for further information.

### **PID-15:** Primary Language required but may be empty:

See HL7 V2.5 Section 3.4.2.15 for details. The PCD TF requires the use of ISO639 for the codes.

### **PID-16:** Marital Status

See HL7 V2.5 Section 3.4.2.16 for details. The PCD TF does not further constrain this field.

### PID-17: Religion

See HL7 V2.5 Section 3.4.2.17 for details. The PCD TF does not further constrain this field.

## 10 **PID-18:** Patient Account Number (CX), required but may be empty:

See HL7 V2.5 Section 3.4.2.18 for details. The PCD TF does not further constrain this field. Additional requirements may be documented in Regional or National appendices to the IHE PCD Technical Framework.

## PID-20: Driver's License Number – Patient (CX), required but may be empty:

See HL7 V2.5 Section 3.4.2.20 for details. The PCD TF does not further constrain this field.

## **PID-21:** Mother's Identifier (CX), required but may be empty:

See HL7 V2.5 Section 3.4.2.21 for details. The PCD TF does not further constrain this field.

## 20 **PID-22:** Ethnic Group (CE), required but may be empty:

See HL7 V2.5 Section 3.4.2.22 for details. The PCD TF does not further constrain this field.

## **PID-23:** Birth Place (ST), required but may be empty:

See HL7 V2.5 Section 3.4.2.23 for details. The PCD TF does not further constrain this field.

## PID-24: Multiple Birth Indicator (ID), required but may be empty:

See HL7 V2.5 Section 3.4.2.24 for details. The PCD TF does not further constrain this field.

## **PID-25:** Birth Order (NM), required but may be empty:

30 See HL7 V2.5 Section 3.4.2.25 for details. The PCD TF does not further constrain this field.

## **PID-26:** Citizenship (CE), required but may be empty:

See HL7 V2.5 Section 3.4.2.26 for details. The PCD TF does not further constrain this field.

### **PID-27:** Veterans Military Status (CE), required but may be empty:

See HL7 V2.5 Section 3.4.2.27 for details. The PCD TF does not further constrain this field.

### **PID-28:** Nationality (CE), required but may be empty:

See HL7 V2.5 Section 3.4.2.28 for details. The PCD TF does not further constrain this field.

### PID-29: Patient Death Date and Time (TS), required but may be empty:

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Definition: This field contains the date and time at which the patient death occurred. See Appendix C.6 TS Data Type for PCD constraints.

### PID-30: Patient Death Indicator (ID), required but may be empty:

See HL7 V2.5 Section 3.4.2.30 for details. The PCD TF does not further constrain this field.

### PID-31: Identity Unknown Indicator (ID), required but may be empty:

See HL7 V2.5 Section 3.4.2.31 for details. The PCD TF does not further constrain this field.

### PID-32: Identity Reliability Code (IS), required but may be empty:

See HL7 V2.5 Section 3.4.2.32 for details. The PCD TF does not further constrain this field.

## PID-33: Last Update Date/Time (TS), required but may be empty:

Definition: This field contains the last update date and time for the patient's/person's identifying and demographic data, as defined in the PID segment. Receiving systems will use this field to determine how to apply the transaction to their systems. If the receiving system (such as an enterprise master patient index) already has a record for the person with a later last update date/time, then the EMPI receiving system could decide not to apply the patient's/person's demographic and identifying data from this transaction.

See Appendix C.6 TS Data Type for PCD constraints.

## 30 **PID-34:** Last Update Facility (HD), required but may be empty:

See HL7 V2.5 Section 3.4.2.34 for details. The PCD TF does not further constrain this field.

## **PID-35:** Species Code (CE), required but may be empty:

See HL7 V2.5 Section 3.4.2.35 for details. The PCD TF does not further constrain this field.

## PID-36: Breed Code (CE), conditional.

See HL7 V2.5 Section 3.4.2.36 for details. The PCD TF does not further constrain this field.

## PID-37: Strain (ST), conditional.

See HL7 V2.5 Section 3.4.2.37 for details. The PCD TF does not further constrain this field.

## **PID-38:** Production Class Code (CE), required but may be empty:

See HL7 V2.5 Section 3.4.2.38 for details. The PCD TF does not further constrain this field.

## **PID-39:** Tribal Citizenship (CWE), required but may be empty:

See HL7 V2.5 Section 3.4.2.39 for details. The PCD TF does not further constrain this field.

## B.6 PV1 - Patient Visit Segment

See HL7 V2.5 Section 3.4.3 for details.

The PV1 segment is used by Registration/Patient Administration applications to communicate information on an account or visit-specific basis. The default is to send account level data. To use this segment for visit level data PV1-51 - Visit Indicator must

20 be valued to 'V'. The value of PV-51 affects the level of data being sent on the PV1, PV2, and any other segments that are part of the associated PV1 hierarchy (e.g. ROL, DG1, or OBX).

The facility ID, the optional fourth component of each patient location field, is a HD data type that is uniquely associated with the healthcare facility containing the location. A given institution, or group of intercommunicating institutions, should establish a list of facilities that may be potential assignors of patient locations. The list will be one of the institution's master dictionary lists. Since third parties other than the assignors of patient locations may send or receive HL7 messages containing patient locations, the facility ID in the patient location may not be the same as that implied by the sending and receiving

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systems identified in the MSH. The facility ID must be unique across facilities at a given site. This field is required for HL7 implementations that have more than a single healthcare facility with bed locations, since the same <point of care> ^ <room> ^ <bed> combination may exist at more than one facility.

Details of the PV1 segment as used in the IHE PCD Technical Framework are given in **Error! Reference source not found.** 

		Table	18 HL7	Attribute T	able - P	V1 - Patie	ent Visit
SEQ	LEN	DT	Usage	Card.	TBL#	ITEM#	Element name
1	4	SI	Х	[00]		00131	Set ID - PV1
2	1	IS	R	[11]	0004	00132	Patient Class
3	80	PL	RE	[01]		00133	Assigned Patient Location
4	2	IS	Х	[00]	0007	00134	Admission Type
5	250	CX	Х	[00]		00135	Preadmit Number
6	80	PL	Х	[00]		00136	Prior Patient Location
7	250	XCN	Х	[00]	0010	00137	Attending Doctor
8	250	XCN	Х	[00]	0010	00138	Referring Doctor
9	250	XCN	Х	[00]	0010	00139	Consulting Doctor
10	3	IS	Х	[00]	0069	00140	Hospital Service
11	80	PL	Х	[00]		00141	Temporary Location
12	2	IS	Х	[00]	0087	00142	Preadmit Test Indicator
13	2	IS	Х	[00]	0092	00143	Re-admission Indicator
14	6	IS	Х	[00]	0023	00144	Admit Source
15	2	IS	Х	[00]	0009	00145	Ambulatory Status
16	2	IS	Х	[00]	0099	00146	VIP Indicator
17	250	XCN	Х	[00]	0010	00147	Admitting Doctor
18	2	IS	Х	[00]	0018	00148	Patient Type
19	250	CX	RE	[01]		00149	Visit Number
20	50	FC	Х	[00]	0064	00150	Financial Class
21	2	IS	Х	[00]	0032	00151	Charge Price Indicator
22	2	IS	Х	[00]	0045	00152	Courtesy Code
23	2	IS	Х	[00]	0046	00153	Credit Rating
24	2	IS	Х	[00]	0044	00154	Contract Code
25	8	DT	Х	[00]		00155	Contract Effective Date
26	12	NM	Х	[00]		00156	Contract Amount
27	3	NM	Х	[00]		00157	Contract Period
28	2	IS	Х	[00]	0073	00158	Interest Code
29	4	IS	Х	[00]	0110	00159	Transfer to Bad Debt Code
30	8	DT	Х	[00]		00160	Transfer to Bad Debt Date
31	10	IS	Х	[00]	0021	00161	Bad Debt Agency Code
32	12	NM	Х	[00]		00162	Bad Debt Transfer Amount
33	12	NM	Х	[00]		00163	Bad Debt Recovery Amount
34	1	IS	Х	[00]	0111	00164	Delete Account Indicator
35	8	DT	Х	[00]		00165	Delete Account Date
36	3	IS	Х	[00]	0112	00166	Discharge Disposition
37	47	DLD	Х	[00]	0113	00167	Discharged to Location

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SEQ	LEN	DT	Usage	Card.	TBL#	ITEM#	Element name
38	250	CE	Х	[00]	0114	00168	Diet Type
39	2	IS	Х	[00]	0115	00169	Servicing Facility
40	1	IS	Х	[00]	0116	00170	Bed Status
41	2	IS	Х	[00]	0117	00171	Account Status
42	80	PL	Х	[00]		00172	Pending Location
43	80	PL	Х	[00]		00173	Prior Temporary Location
44	26	TS	Х	[00]		00174	Admit Date/Time
45	26	TS	Х	[00]		00175	Discharge Date/Time
46	12	NM	Х	[00]		00176	Current Patient Balance
47	12	NM	Х	[00]		00177	Total Charges
48	12	NM	Х	[00]		00178	Total Adjustments
49	12	NM	Х	[00]		00179	Total Payments
50	250	CX	Х	[01]	0203	00180	Alternate Visit ID
51	1	IS	RE	[01]	0326	01226	Visit Indicator

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### PV1-2: Patient Class (IS), required

Definition: This field is used by systems to categorize patients by site. It does not have a consistent industry-wide definition. It is subject to site-specific variations. Refer to *HL7User-defined Table 0004 - Patient Class* for IHE PCD suggested values.

Value	Description	Comment
E	Emergency	
I	Inpatient	
0	Outpatient	
Р	Preadmit	
R	Recurring patient	
В	Obstetrics	
U	Unknown	

### PV1-3: Assigned Location (PL), required but may be empty:

IHE PCD definition: This field contains the patient's initial assigned location or the location to which the patient is being moved. The first component may be the nursing station for inpatient locations, or clinic or department, for locations other than inpatient.

## 10 inj

For IHE PCD usage see Appendix C.5 PL Data Type.

### **PV1-19: Visit Number (CX), required but may be empty:**

IHE PCD definition: This field contains the unique number assigned to each patient visit.

For IHE PCD usage see Appendix C.2 CX Data Type

## PV1-51: Visit Indicator (IS), required but may be empty:

HL7 definition: This field specifies the level on which data are being sent. It is the indicator used to send data at two levels, visit and account. IHE PCD implementations shall send an 'A' or no value when the data in the message are at the account level, or 'V' to indicate that the data sent in the message are at the visit level.

The value of this element affects the context of data sent in PV1, PV2 and any associated hierarchical segments (e.g. DB1, AL1, DG1, etc.).

## B.7 OBR – Observation Request segment

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In the reporting of clinical data, the Observation Request Segment (OBR) serves as the report header. It identifies the observation set represented by the following atomic observations. It includes the relevant ordering information when that applies and many of the attributes that apply to all of the following observations.

Use as specified in HL7 – place here all header information for report content – as distinct from MSH above which covers both patient and report info. Details of the OBR fields used in the IHE PCD Technical Framework are given in **Error! Reference source not found.** 

Details of the fields used in the Patient Care Device Observation Message are given in **Error! Reference source not found.** 

SEQ	LEN	DT	Usage	Card.	TBL#	ITEM#	Element name
1	4	SI	R	[11]		00237	Set ID OBR
2	427	EI	R	[11]		00216	Placer Order Number
3	427	EI	R	[11]		00217	Filler Order Number
4	250	CE	R	[11]		00238	Universal Service Identifier
5	2	ID	Х	[00]		00239	Priority - OBR
6	26	TS	Х	[00]		00240	Requested Date/Time
7	26	TS	RE	[01]		00241	Observation Date/Time

Table 20 OBR segment

## 20 OBR-1: Set ID OBR (SI), required:

Definition: For the first order transmitted, the sequence number shall be 1; for the second order, it shall be 2; and so on.

## **OBR-2:** Placer Order Number (EI), required:

Definition: This field is a case of the Entity Identifier data type. The first component is a string that identifies an individual order (e.g., OBR). It is assigned by the place (ordering application). It identifies an order uniquely among all orders from a particular ordering application. The second through fourth components contain the application ID of the placing application in the same form as the HD data type. The second component, namespace ID, is a user-defined coded value that will be uniquely associated with an application. A given institution or group of intercommunicating institutions should establish a unique list of applications that may be potential placers and fillers and assign unique application IDs. The components are separated by component delimiters.

The PCD TF does not use the ORC segment and, based on the HL7 rules, the OBR-2 field must be valued. For the PCD TF the usual case is that PCD data is the result of a "standing order" and there is not a unique order associated with each instance of communication of PCD data. In general, there is not a Placer (ordering application).

10 The PCD TF requires the first and second components be valued, and recommends that the second component shall refer to the locally unique application identifier assigned to the Device Observation Reporter or Device Observation Filter applications implementing IHE PCD actors which fill the role of an ordering application such as the DOR and DOF. The PCD TF requires that the third component be valued with the EUI-64 code for the respective Device Observation Reporter or Device Observation Filter application implementing the respective IHE PCD actors which fill the role of an ordering application and the coding scheme be identified as EUI-64. The PCD specifies the length of the OBR-2 as 427 which is consistent with the defined length of the EI data type and with the OBR-2 length 20 recommended in HL7 V2.6.

See Appendix C.3 EI Data Type for further information.

## **OBR-3:** Filler Order Number (EI), required:

Definition: This field is the order number associated with the filling application. This is a permanent identifier for an order and its associated observations. It is a special case of the Entity Identifier data type. The first component is a string that identifies an order detail segment (e.g., OBR). It is assigned by the order filler (receiving) application. This string must uniquely identify the order (as specified in the order detail segment) from other orders in a particular filling application (e.g., clinical laboratory). This uniqueness must persist over time. The second through fourth components contain the filler application ID, in the form of the HD data type. The second component is a user-defined coded value that uniquely defines the application from other applications on the network. The second component of the filler order number always identifies the actual filler of an order.

The PCD TF requires the first and second components be valued and recommends that the second component refer to the locally unique application identifier assigned to the application implementing IHE actors supporting the role of an order filler such as the DOR and DOF. Device Observation Reporter or Device Observation Filter. The PCD TF requires that the third component be valued with the EUI-64 code for the respective Device Observation Reporter or Device Observation Filter and the coding scheme be identified as EUI-64. The PCD specifies the length of the OBR-2

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as 427 which is consistent with the defined length of the EI data type and with the OBR-2 length recommended in HL7 V2.6.

See Appendix C.3 EI Data Type for further information.

## **OBR-4:** Universal Service ID (CE), required:

Definition: This field contains the identifier code for the requested observation/test/battery. This can be based on local and/or "universal" codes. We recommend the "universal" procedure identifier.

In general PCD communications occur as a result of "standing orders" and the specific clinical reason for a particular PCD measurement is not known to the Device

Observation Reporter or Device Observation Filter actor. In this case the PCD 10 Framework recommends this field to be mapped at the highest level of containment without additional specification for the system which is the source of the related OBXs.

See Appendix A ISO/IEEE 11073 Mapping to HL7 for further details.

See HL7 V2.5 Section 7.4.1.4 for details related to OBR-4.

## **OBR-7:** Observation Date/Time (TS), required:

Time zone qualification of the date/time is optional. If the time zone is omitted from the message, 'local time' (time zone where the Device is located) is assumed.

Local time is assumed to be valid.

20 Resolution to seconds allows neonatal and OR messages at 10 second frequency, most other uses are not more than 60 second frequency.

> Format: YYYY[MM[DD[HH[MM[SS]]]]][+/-ZZZZ] where the time zone is optional.

For the DEC Profile PCD messages should be sent at a frequency of not more than on every 10 seconds.

See Appendix C.6 TS Data Type for further details.

#### **B.8 OBX - Observation/Result segment**

Refer to HL7 v2.5: Section 7.4.2

The HL7 OBX segment is used to transmit a single observation or observation fragment. Details of the fields used by the OBX segment in the PCD Observation/Result Message 30 are given in Error! Reference source not found..

It is important to note that the values used for the OBX fields depend upon if the OBX is being used to provide information about the device(s) from which measurements are derived or to provide information related to the measurement metrics and related

information. Where this is the case the IHE PCD TF defines the appropriate coding for usage in a device related or metric related context. Each OBX shall be coded for a specific context – device related or metric related.

SEQ	LEN	DT	Usage	Card.	TBL#	ITEM#	Element name
1	4	SI	R	[11]		00569	Set ID – OBX
2	2	ID	С	[01]	0125	00570	Value Type
3	250	CE	R	[11]		00571	Observation Identifier
4	20	ST	R	[11]		00572	Observation Sub-ID
5	99999	Varies	С	[01]		00573	Observation Value
6	250	CE	С	[01]		00574	Units
7	60	ST	CE	[01]		00575	References Range
8	5	IS	CE	[01]	0078	00576	Abnormal Flags
9	5	NM	Х	[00]		00577	Probability
10	2	ID	CE	[01]	0080	00578	Nature of Abnormal Test
11	1	ID	R	[11]	0085	00579	Observation Result Status
12	26	TS	Х	[00]		00580	Effective Date of Reference Range
13	20	ST	Х	[00]		00581	User Defined Access Checks
14	26	TS	RE	[01]		00582	Date/Time of the Observation
15	250	CE	RE	[01]		00583	Producer's ID
16	250	XCN	RE	[01]		00584	Responsible Observer
17	250	CE	RE	[01]		00936	Observation Method
18	22	EI	RE	[01]		01479	Equipment Instance Identifier
19	26	TS	CE	[01]		01480	Date/Time of the Analysis
20	705	CWE	RE	[0*]	0163	02179	Observation Site

Table 21 OBX segment

## **OBX-1 Set ID - OBX (SI), required:**

This field contains the sequence number of the OBX in this message; i.e.  $1^{st}$  OBX Set ID = 1,  $2^{nd}$  OBX set\_ID = 2, etc., regardless of whether the OBX refers to a device or a metric value.

## **OBX-2** Value Type (ID), required:

10 Condition Predicate: must be valued if the value of OBX-11 is not X.

The Value Type field shall be filled according to HL7 Version 2.5 standard (table 0125). For example, if the result is ">300" the Value Type "SN" (Structured Numeric) SHALL be used instead of the "ST" (String) value type that was used in previous versions of HL7. See the details and the examples in the HL7 V2.5 (7.4.2). For an observation that consists of a time measurement (e.g. bleeding time) the TM Value Type is preferred to NM but this is not made mandatory.

Refer to TF-3 for details of the data types used in the mappings.

## **OBX-3** Observation Identifier (CE), required:

Identifies the type of device providing the related values. This is required if structured device (and if relevant, subdevice) identification is provided in the message. For the PDC TF This shall be used for all devices capable of providing structured device information. The preferred format is an MDC value, secondly a LOINC value.

See Appendix A ISO/IEEE 11073 Mapping to HL7 for further details.

### **OBX-4** Observation Sub-ID (ST), required:

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Condition predicate: This field shall be used to distinguish between multiple OBX segments by providing an unambiguous mapping from the IEEE 11073 containment tree. For device related data this field is used to group devices hierarchically. For metric related data this field is used to associate metrics to devices hierarchically, and to each other. The dotted notation provided for in HL7 Ch7, 7.4.2.4, Fig 4 shall be used as follows: <MDS>.<VMD>.<Channel>.<Metric> .

See Appendix A ISO/IEEE 11073 Mapping to HL7 for further details.

## **OBX-5** Observation Value (varies), conditional.

Definition: This field contains the value observed by the observation producer. OBX-2-value type contains the data type for this field according to which observation value is formatted. It is not a required field because some systems will report only the normalcy/abnormalcy (OBX-8), especially in product experience reporting. The length of the observation field is variable, depending upon OBX-3-value type. This field may repeat for multipart, single answer results with appropriate data types, e.g., CE, TX, and FT data types.

For the PCD TF this field is required for metric related segments and is null for device related segments. The preferred format, if valued, is an MDC value, secondly a LOINC value.

## **OBX-6** Units (CE), conditional

See HL7 2.5 Section 7.4.2.6 for further information.

For the PCD TF:

30 Condition predicate: If OBS-5 is populated then populate. For Device Related if OBX-7 is being used for operating range then populate.

The preferred format is an MDC value, secondly a LOINC value. however, other coding systems or local names may be used.

## **OBX-7 References Range** (**ST**), required if available.

For the PCD TF the preferred format is an MDC value, secondly a LOINC value. For device related segments although not strictly a reference range this may be used to

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provide the device measurement range capability – NOT the metric value 'alarm' ranges which shall be in the appropriate observed value metric OBX. For metric related segments although not strictly a reference range in the sense of the examples given in HL7 this should be used to provide the value 'alarm' ranges set with respect to the observed value metric in this OBX.

### **OBX-8** Abnormal Flags (IS), required but may be empty:

For the PCD TF the preferred format is an MDC value, secondly a LOINC value. This represents a PCD TF recommendation for HL7 User Table 0078. For device related segments use for device status alerts – not the value "alert" flags which should be in the appropriate observed metric value OBX. For Metric related segments use for observed value metric status alerts with respect to the observed value metric in this OBX.

### **OBX-11** Observation Result Status (ID), required:

This field should be filled according to HL7 Table 0085 described in Chapter 7 of HL7. For the IHE PCD TF, the possible values for this field for this profile are shown in **Error! Reference source not found.**. The value of X is used for device related segments where OBX-7 is not used to express the device measurement range capability.

Value	Description	Comment
С	Record coming over is a correction and thus replaces a final result	
D	Deletes the OBX record	
F	Final results; Can only be changed with a corrected result.	
Р	Preliminary results	
R	Results entered not verified	
S	Partial results	
U	Results status change to final without retransmitting results already sent as 'preliminary.'	
W	Post original as wrong, e.g., transmitted for wrong patient	
Х	Results cannot be obtained for this observation	

### Table 22 HL7 Table 0085 selected values

## 20 **OBX-14 Date/Time of the Observation (TS), required but may be empty:**

For the PCD TF the value is the same as OBX19, but should be used in preference to OBX19 if time is relevant. Information may be duplicated in OBX19 if local needs dictate

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## **OBX-16 Responsible Observer (XCN), required but may be empty:**

### For the PCD TF:

The identifier values for the Operator ID field may null, if unknown or unspecified at the sending device.

This field should be sent at the highest level of device related OBX possible: i.e. MDS, then VMD, and then Channel. Inheritance should be assumed; i.e. for multivalued results from the same Device, this field is required only in the first OBX segment.

For device related segments this should only be sent if no device related OBXs precede this metric OBX.

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### Table 23 extended composite ID number and name for persons

SEQ	LEN	DT	Usage	Card.	TBL#	Component name
1	15	ST	R	[1.1]		
2	194	FN	RE	[01]		
3	30	ST	RE	[01]		

### **OBX-17** Observation Method (CE), conditional:

For the PCD TF:

For device related segments observation methods are explicit in MDC Ref\_ID/codes; use of OBX17 is superfluous in device related OBX. Although not strictly a reference range in the sense of the examples given in HL7 this should be used to provide the value 'alarm' ranges set with respect to the observed value metric in this OBX.

For metric related segments observation methods are explicit in device related MDC Ref\_ID/codes; use of OBX17 is superfluous if given there. However, <u>if</u> observation method is needed <u>and</u> no device detail is shown <u>then</u> the method <u>shall</u> be given here.

The preferred format is an MDC value, secondly a LOINC value.

## **OBX-18** Equipment Instance Identifier (EI), required but may be empty:

For the PCD TF:

The preferred format is an EUI64 Device ID. The Device Identifier should be globally unique.

Every device be should identified by a universally unique identifier in the format specified by IEEE for the EUI64 identifier (e.g., "1234567890ABCDEF"). To allow the Observation Reporting interface to be employed with 'legacy' Devices, this field may also be populated by a combination of Device name and serial number. If the EUI64 identifier is available, it should be recorded in the 'universal ID' component of this field. If it is not available, the manufacturer's Device

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identifier (e.g., serial number) should be recorded in 'universal ID' component, with the Device or manufacturer name in 'universal ID type' component.

Should be sent at the highest level of device related OBX possible: i.e. MDS, then VMD, and then Channel. Inheritance should be assumed; i.e. for multivalued results from the same Device, this field is required only in the first OBX segment.

For metric related data this field is not required – unless no device hierarchy, and therefore related OBXs, is being declared; in which case the device ID should be provided here if available. Inheritance should be assumed; i.e. for multivalued results from the same Device, this field is required only in the first OBX segment

## 10 **OBX-19 Date/Time of the Analysis (TS), conditional may be empty:**

Conditional Predicate : May be used if duplicate of OBX-14

For the PCD TF use OBX-14 preferentially if device time is relevant. Information in OBX-14 may be duplicated here if local needs dictate.

## **OBX-20** Observation Site (CWE), required may be empty:

Components: <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^ <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding System Version ID (ST)> ^ <Original Text (ST)>

For the PCD TF this field, which has been defined for HL7 V2.6, is required and has been added to the OBX segment. Since V2.6 has not been through a final ballot there is a risk that changes could occur due to the balloting. The PCD believes that this is preferable to specification of a Z segment. Comment is invited.

Definition: This field typically contains the body site(s) where the measurement being reported was obtained. This field should not be used for a specimen source or specimen collection site.

This information is of particular importance if the clinical meaning of a value is modified either directly by the site (for example, is the temperature central or peripheral?) or if the site of one measurement impacts the value of another measurement (for example, is the finger SpO2 probe on the same arm as the NIBP cuff?). In most cases these observations are performed directly upon the patient and

do not involve a specimen.

Any nationally recognized coding system might be used for this field including SNOMED or MDC; alternatively the HL7 Table 0163 may be used. Veterinary medicine may choose the tables supported for the components of this field as decided by their industry.

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## B.9 QPD – Query Parameter Definition segment

The QPD segment defines the parameters of the query.

Table 24 HL7 Attribute Table - QPD - Query Parameter Definition

SEQ	LEN	DT	Usage	Card	TBL#	ITEM#	ELEMENT Value for PCD-02
1	250	CE	R	[11]	0471	01375	ZXX^PCD-02 Subscription^
2	32	ST	С	[01]		00696	Query Tag
3	256	varies	R	[1*]		01435	User Parameters (in successive fields)

### QPD-1 Message Query Name (CE) 01375

Components: <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^ <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate Coding System (ID)>

Definition: This field contains the name of the query. These names are assigned by the function-specific chapters of the HL7 V2.5 specification. It is one to one with the conformance statement for this query name, and it is in fact an identifier for that conformance statement. Site-specific query names begin with the letter "Z." Refer to HL7 User defined table 0471 - Query name for suggested values.

Table 25 HL7 User-defined Table 0471 - Query name

Value	Description	Comment
ZXX	PCD-02 Subscription	Used for IHE PCD-02
		transaction

## QPD-2 Query Tag (ST) 00696

Definition: This field may be valued by the initiating system to identify the query, and may be used to match response messages to the originating query. If this field is valued, the responding system is required to echo it back as the first field in the query acknowledgement segment (QAK).

This field differs from MSA-2-Message control ID in that its value remains constant for each message (i.e. all continuation messages) associated with the query, whereas MSA-2-Message control ID may vary with each continuation message, since it is associated with each individual message, not the query as a whole.

Implementation considerations: It is not necessary to value this field in implementations where the only return message on the socket will be the response to the query that was just sent. Conversely, in an "asynchronous" implementation where many queries, responses, and other messages may be communicated bidirectionally over the same socket, it is essential that this field be valued so that the Client knows to which query the Server is responding.

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## **QPD-3** User Parameters (Varies) 01435

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Definition: These successive parameter fields hold the values that the Client passes to the Server.

The client data is presented as a sequence of HL7 fields. Beginning at *QPD-3-User parameters*, the remaining fields of the QPD segment carry user parameter data. Each QPD user parameter field corresponds to one parameter defined in the Conformance Statement, where each name, type, optionality, and repetition of each parameter has been specified. While these parameters are understood to be usually "and ed" together, the user must inspect the required Conformance Statement to properly understand each.

10 For the PCD-TF each parameter field is specified in the Conformance Statement to be a segment group (ID) field

Parameter fields in the QPD segment appear in the same order as in the Conformance Statement.

## B.10 RCP – Response Control Parameter segment

The RCP segment is used to restrict the amount of data that should be returned in response to query.

Table 26 HL7 Attribute Table – RCP – Response Control Parameter

SEQ	LEN	DT	Usage	Card	TBL#	ITEM#	ELEMENT NAME
1	1	ID	R		0091	00027	Query Priority
2	10	CQ	х		0126	00031	Quantity Limited Request
3	250	CE	R		0394	01440	Response Modality
4	26	TS	х			01441	Execution and Delivery Time
5	1	ID	х		0395	01443	Modify Indicator
6	512	SRT	х	Y		01624	Sort-by Field
7	256	ID	Х	Y		01594	Segment group inclusion

## RCP-1 Query Priority (ID) 00027

Definition: This field contains the time frame in which the response is expected.

Refer to HL7 Table 0091 - Query priority for valid values. Table values and subsequent fields specify time frames for response.

Table 27 HL7 Table 0091 - Query Priority

Value	Description	Comment
D	Deferred	Not used for PCD-TF
I	Immediate	Required for PCD-TF

## RCP-3 Response Modality (CE) 01440

Components: <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^ <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate Coding System (ID)>

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Definition: This field specifies the timing and grouping of the response message(s). Refer to HL7 Table 0394 – Response modality for valid values.

· · · · ·									
Value	Description	Comment							
R	Real Time	Required for PCD TF							
т	Bolus (a series of responses sent at the same time without use of batch formatting)	Not Used for PCD TF							
В	Batch	Not Used for PCD TF							

HL7 Table 0394 – Response modality

## Appendix C Common Data Types

This section describes PCD constraints of commonly used HL7 data types.

## C.1 CE Data Type

### 10

SEQ	LEN	DT	Usage	Card.	TBL#	Component name			
1	20	ST	R	[11]		Identifier			
2	199	ST	R	[11]		Text			
3	20	ID	RE	[01]	0396	Name of Coding System			
4	20	ST	RE	[01]		Alternate Identifier			
5	199	ST	RE	[01]	0396	Alternate Text			
6	20	ID	RE	[01]		Name of Alternate Coding System			

Table 28 CE: Coded Element

Definition: This data type transmits codes and the text associated with the code.

## C.2 CX Data Type

## Table 29 CX: Extended Composite ID with check digit

SEQ	LEN	DT	Usage	Card.	TBL#	Component name
1	15	ST	R	[11]		ID Number
2	1	ST	RE	[01]		Check Digit
3	3	ID	RE	[01]	0061	Check Digit Scheme
4	227	HD	R	[11]	0363	Assigning Authority
5	5	ID	RE	[01]	0203	Identifier Type Code

SEQ	LEN	DT	Usage	Card.	TBL#	Component name
6	227	HD	RE	[01]		Assigning Facility
7	8	DT	RE	[01]		Effective Date
8	8	DT	RE	[01]		Expiration Date
9	705	CWE	RE	[01]		Assigning Jurisdiction
10	705	CWE	RE	[01]		Assigning Agency or Department

The constraints above particularly apply to the Patient Identifiers carried in the PID segment.

The data type has been constrained because the PCD Framework regards the Assigning Authority and the Identifier Type Code as essential components.

A common value of the Identifier Type Code for a Patient Identifier assigned by the healthcare organization (PID-5) is "PI". Other values are defined in Table 0203 of HL7 2.5 section 2.A.14.5

Example: 12345 ^ ^ Saint-John Hospital PI

## C.3 El Data Type

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## Table 30 EI: Entity Identifier

SEQ	LEN	DT	Usage	Card.	TBL#	Component name
1	16	ST	R	[11]		Entity Identifier
2	20	IS	RE	[01]	0363	Namespace ID
3	199	ST	RE	[01]		Universal ID
4	6	ID	RE	[01]	0301	Universal ID Type

Component 1 is required. Either component 2 or both components 3 and 4 are required. Components 2, 3 and 4 may be all present.

The EI is appropriate for machine or software generated identifiers. The generated identifier goes in the first component. The remaining components, 2 through 4, are known as the assigning authority; they can also identify the machine/system responsible for generating the identifier in component 1.

Example 1: AB12345^RiversideHospital

Example 2: AB12345<sup>1</sup>.2.840.45.67<sup>1</sup>SO

20 Example 3: AB12345^RiversideHospital^1.2.840.45.67^ISO

IHE constrains the length of the first component to 16 characters. National extensions can extend this length up to a maximum of 199.

IHE recommends that Component 2, "Namespace ID," always be populated. Particularly when there are several concurrent assigning authorities within the healthcare enterprise,

this Namespace ID will indicate which assigning authority provided the identifier in Component 1.

## C.4 HD Data Type

SEQ	LEN	DT	Usage	Card.	TBL#	Component name
1	20	IS	R	[11]	0300	Namespace ID
2	199	ST	RE	[01]		Universal ID
3	6	ID	RE	[01]	0301	Universal ID Type

The PCD TF requires that a field of Data Type HD be populated with:

- Either the first component "Namespace ID" alone, which in this case contains a local identifier of the object.
- Or with all three components, "Namespace ID" containing the name of the object, "Universal ID" containing its universal OID, and "Universal ID Type" containing the value **ISO**.

This data type is particularly used in this profile to identify facilities, applications and assigning authorities: sending and receiving applications, sending and receiving facilities, last update facility, assigning authority of an identifier, etc.

## C.5 PL Data Type

10

SEQ	LEN	DT	Usage	Card.	TBL#	Component name
1	20	IS	RE	[01]	0302	Point of Care
2	20	IS	RE	[01]	0303	Room
3	20	IS	RE	[01]	0304	Bed
4	227	HD	RE	[01]		Facility
5	20	IS	RE	[01]	0306	Location Status
6	20	IS	CE	[01]	0305	Person Location Type
7	20	IS	RE	[01]	0307	Building
8	20	IS	RE	[01]	0308	Floor
9	199	ST	RE	[01]		Location Description
10	427	EI	RE	[01]		Comprehensive Location Identifier
11	227	HD	RE	[01]		Assigning Authority for Location

Table 32 PL: Person Location

IHE PCD Definition: This data type is used to specify a patient location within a healthcare institution. Which components are valued depends on the needs of the site. For example for a patient treated at home, only the person location type is valued.

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Component 1: Point of Care (IS), required but may be empty:

20 HL7 definition: This component specifies the code for the point where patient care is administered. It is related to PL.6 Person Location Type (e.g., nursing unit or department or clinic). After floor, it is the most general patient location designation.

HL7 user-defined table 0302 does not suggest any values. The codification of points of care will be defined at the site level in acute care settings.

Component 2: Room (IS), required but may be empty:

HL7 definition: This component specifies the code for the patient's room. After point of care, it is the most general person location designation.

HL7 user-defined table 0303 does not suggest any values. The codification of rooms shall be defined at the site level in acute care settings.

Component 3: Bed (IS), required but may be empty:

HL7 definition: This component specifies the code for the patient's bed. After room, it is the most general person location designation.

HL7 user-defined table 0304 does not suggest any values. The codification of beds shall be defined at the site level in acute care settings.

Component 4: Facility (HD), required but may be empty:

HL7 definition: This component is subject to site interpretation but generally describes the highest level physical designation of an institution, medical center or enterprise. It is the most general person location designation.

The codification of facilities shall be defined at the highest level, according to the context of use of the PCD profile (acute care setting, ambulatory domain, etc.).

Component 6: Person Location Type (IS), conditional but may be empty:

20 IHE PCD condition: PL.6 is only populated if none of the other components of the PL data type are populated.

HL7 definition: Person location type is the categorization of the person's location defined by facility, building, floor, point of care, room or bed. Although not a required field, when used, it may be the only populated field. It usually includes values such as nursing unit, department, clinic, SNF, physician's office. Refer to HL7 User-defined Table 0305 - Person location type for suggested values.

Table 33 HL7 User Defined Table 0305 - Person Location Type

		71
Value	Description	Comment
С	Clinic	
D	Department	
Н	Home	
N	Nursing Unit	
0	Provider's Office	
Р	Phone	
S	SNF	

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National extensions of this profile may further constrain on extend this table.

Component 7: Building (IS), required but may be empty:

HL7 definition: This component specifies the code for the building where the person is located. After facility, it is the most general person location designation.

HL7 user-defined table 0307 does not suggest any values. The codification of buildings shall be defined at the site level in acute care settings.

Component 8: Floor (IS), required but may be empty:

HL7 definition: This component specifies the code for the floor where the person is located. After building, it is the most general person location designation.

HL7 user-defined table 308 does not suggest any values. The codification of floors shall be defined at the site level in acute care settings.

10 Component 9: Location description (ST), required but may be empty:

HL7 definition: This component describes the location in free text.

Component 10: Comprehensive Location Identifier (EI), required but may be empty:

HL7 definition: The unique identifier that represents the physical location as a whole without regard for the individual components. This accommodates sites that may have a different method of defining physical units or who may code at a less granular level. For example, point of care, room, and bed may be 1 indivisible code.

Component 11: Assigning Authority for Location (HD), required but may be empty:

HL7 definition: The entity that creates the data for the individual physical location components. If populated, it should be the authority for all components populated.
Refer to HL7 User-defined Table 0363 - Assigning authority for suggested values for the first sub-component of the HD component, <namespace ID>.

By site agreement, implementers may continue to use HL7 User-defined Table 0300 - Namespace ID for the first sub-component.

## C.6 TS Data Type

## Table 34 TS: Time Stamp

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SEQ	LEN	DT	Usage	Card.	TBL#	Component name
1	24	DTM	R	[11]		Time
2	1	ID	Х	[00]	0529	Degree of Precision

The first subfield is required. It specifies a point in time.

Maximum length: 24.

30 HL7 Format: YYYY[MM[DD[HH[MM[SS[.S[S[S]]]]]]]][+/-ZZZZ] Constrained format in this PCD profile: YYYY[MM[DD[HH[MM[SS]]]]][+/-ZZZZ]

The least precise date possible is YYYY (only the year).

The most precise date possible is YYYYMMDDHHMMSS (up to the second).

The time zone (+/-ZZZZ) is represented as +/-HHMM offset from Coordinated Universal Time (UTC), (formerly Greenwich Mean Time (GMT)), where +0000 or -0000 both represent UTC (without offset).

Note that if the time zone is not included, the time zone defaults to the local time zone of the sender.

The second subfield is deprecated in HL7 v2.5, therefore not supported by this PCD profile.

## 10 C.7 XPN Data Type

SEQ	LEN	DT	Usage	Card.	TBL#	Component name
1	194	FN	RE	[01]		Family Name
2	30	ST	RE	[01]		Given Name
3	30	ST	RE	[01]		Second and Further Given Names or Initials Thereof
4	20	ST	RE	[01]		Suffix (e.g., JR or III)
5	20	ST	RE	[01]		Prefix (e.g., DR)
6	6	IS	Х	[00]	0360	Degree (e.g., MD)
7	1	ID	R	[11]	0200	Name Type Code
8	1	ID	RE	[01]	0465	Name Representation Code
9	483	CE	RE	[01]	0448	Name Context
10	53	DR	Х	[00]		Name Validity Range
11	1	ID	RE	[01]	0444	Name Assembly Order
12	26	TS	RE	[01]		Effective Date
13	26	TS	RE	[01]		Expiration Date
14	199	ST	RE	[01]		Professional Suffix

Table 35 XPN: Extended Person Name

This data type is usually in a repeatable field, to allow a list of names. Examples: Legal name, display name.

Subfield 1 "Family Name" is required if known to the sender.

Subfield 7 "Name Type Code" is required. The PAM profile allows these values from HL7 Table 0200 – Name type:

		71
Value	Description	Comment
A	Alias Name	
В	Name at Birth	
С	Adopted Name	
D	Display Name	
I	Licensing Name	

Table 36 HL7 Table 0200 - Name Type

Value	Description	Comment
L	Legal Name	
М	Maiden Name	
N	Nickname /"Call me" Name/Street Name	
R	Registered Name (animals only)	
S	Coded Pseudo-Name to ensure anonymity	
Т	Indigenous/Tribal/Community Name	
U	Unspecified	

This table may be further defined and restrained in national extensions of this profile.

Subfields 6 (Degree) and 10 (Name Validity Range) are deprecated in HL7 v2.5, therefore not supported by the PCD profile.

## C.8 XTN Data Type

SEQ	LEN	DT	Usage	Card.	TBL#	Component name
1	199	ST	Х			Telephone Number
2	3	ID	R	[01]	0201	Telecommunication Use Code
3	8	ID	R	[01]	0202	Telecommunication Equipment Type
4	199	ST	RE	[01]		Email Address
5	3	NM	RE	[01]		Country Code
6	5	NM	RE	[01]		Area/City Code
7	9	NM	RE	[01]		Local Number
8	5	NM	RE	[01]		Extension
9	199	ST	RE	[01]		Any Text
10	4	ST	RE	[01]		Extension Prefix
11	6	ST	Х	[01]		Speed Dial Code
12	199	ST	Х	[01]		Unformatted Telephone number

Table 37 XTN: Extended Telecommunication Number

Subfield 2 "Telecommunication Use Code" is required and is valued as either PRN "Primary Residence Number" or NET "Network (email) address. See HL7 Table 201.

Subfield 3 "Telecommunication Equipment Type" is required and is valued as PH "Telephone", Internet "Internet Address: Use Only If Telecommunication Use Code Is NET", or X.400 "X.400 email address: Use Only If Telecommunication Use Code Is NET". See HL7 Table 202.

## Appendix D Device Content

Though the transactions and messages defined in this TF-2 provide for syntactic interoperability, in order to achieve semantic interoperability, each class of device must use the same terminology and data organization or modeling for common information. This appendix defines common abstract semantics or content profiles for patient care devices that fall within this domain. The semantics are based on the ISO/IEEE 11073-

10101 nomenclature/terminology and the ISO/IEEE 11073-10201 domain information model, with additional semantics systems specified as appropriate (e.g., LOINC or SNOMED-CT), either as mappings to ISO/IEEE concepts or independently for non-mappable concepts. Other sections of the PCD Technical Framework define the mapping of these semantics to the information technologies defined for each transaction (for example, section on *ISO/IEEE 11073 Mapping to HL7*).

Note that this content specification is not intended to be exhaustive – the referenced standards should be consulted for more complete information.

In general, if a concept is not specified in this content profile nor in the base standards,
 the standards develop pent organizations ("SDOs") responsible for the appropriate
 controlled content should be contacted regarding addition of the additional concepts.
 Typically, this may be accomplished without significant delays, and if necessary,
 temporary term codes provided. See discussions below for additional information.

## D.1 General device content considerations

This section addresses those issues that are transitive across all device types. Subsequent sections integrate these considerations as applicable to specific device specializations.

## D.1.1 Hierarchical containment tree information

Each data item associated with a device specialization is specified within the context of its "containment tree" – all parameters are formalized either as attributes of a given
object, or as instances of data objects that are contained within other objects in accordance to the following basic hierarchy<sup>1</sup>:

<sup>&</sup>lt;sup>1</sup> See ISO/IEEE 11073-10201 Domain Information Model for complete details on these and other objects.

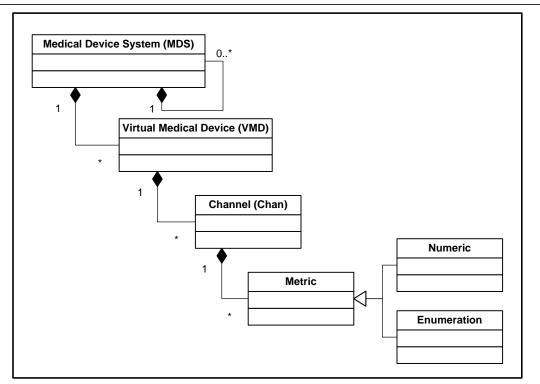


Figure 9 Basic ISO/IEEE 11073 Containment Tree

There are many additional objects defined in the ISO/IEEE 11073 information model (e.g., waveform and alarm / alert monitoring objects); however, for the purposes of this technical framework, only the above objects are utilized. Each object provides the following:

## **Medical Device System**

Top level object that establishes the overall context for all device data. In addition to a basic device name (e.g., Ventilator), this object includes attributes for a unique identifier (e.g., ,EUI-64), manufacturer and model, subcomponent serial numbers, device date and time, A/C power status, battery charge level, locale, etc. Note that an MDS may contain additional MDS objects. This would be the case when, for example, a physiological monitor integrates additional devices such as external infusion pumps and ventilators.<sup>2</sup>

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<sup>&</sup>lt;sup>2</sup> Note that not show here are the 4 MDS specializations: Simple MDS (contains a single VMD instance), Hydra MDS (contains multiple VMD instances); Composite Single Bed MDS (contains embedded MDSs for a single patient); and Composite Multi Bed MDS (multiple MDSs for multiple patients). None of these

There are many additional objects defined in the ISO/IEEE 11073 information model (e.g., waveform and alarm / alert monitoring objects); however, for the purposes of this technical framework, only the above objects are utilized. Each object provides the following:

10	Medical Device System	Top level object that establishes the overall context for all device data. In addition to a basic device name (e.g., Ventilator), this object includes attributes for a unique identifier (e.g., ,EUI-64), manufacturer and model, subcomponent serial numbers, device date and time, A/C power status, battery charge level, locale, etc. Note that an MDS may contain additional MDS objects. This would be the case when, for example, a physiological monitor integrates additional devices such as external infusion pumps and ventilators. <sup>3</sup>
20	Virtual Medical Device	Supports a particular device specialization that may contain multiple channels and reflects a basic device building block. For example, an airway VMD may contain channels for pressure, flow, volume, and breath metrics. For devices with plug- in modules, each component is typically formalized by a VMD instance.
	Channel	Provides for the aggregation of closely related data objects. For example, an infusion pump VMD may contain multiple fluid source channels, each with its own parameters for delivery rate, volume to be infused ("VTBI"), volume infused, drug label, etc.
30	Metric	This abstract class (it is only inherited by the specialization objects and may not be instantiated alone) provides a basic set of attributes for all the specialization objects. For example, status (e.g., available, disabled, etc.), body site list, measurement start/stop time, label, etc.
	Numeric	Supports values that are represented as a numeric quantity (e.g., a set breath rate). Attributes include value, units, time stamp, ranges, resolution, etc.

specialization objects add any attribution – they only reflect the relationships between the MDS and other objects (namely, other MDSs, VMDs, and Patient Demographics).

	Compound values are supported where multiple values are realized in a single numeric (e.g., diastolic and systolic blood pressure is typically represented as a compound numeric value).
Enumeration	Supports parameters that are typically represented by a set of specified values. For example, a device's operational mode may be represented by one of a finite set (e.g., for a ventilator the mode may be CPAP, SIMV, assist, etc.).

10 Though the sequential ordering of objects and attributes are typically not important (e.g., information from multiple VMDs in an MDS may be communicated in any order), the containment associations must be maintained. For example, multiple channels may have the same "infusion rate" parameter – if they are not properly associated to the right channel, then the information will not be correctly interpreted. Additionally, containment is strictly enforced (e.g., an Enumeration instance may not be contained directly under a VMD or MDS without a Channel).

For each of the device specializations specified below, the containment tree associated with each device and parameter is specified sufficiently to ensure proper communication when the information is exchanged in a transaction. It should be noted that for some devices, though the containment relationships are specified, they may not be necessary

20 devices, though the containment relationships are specified, they may not be necessary (save the top level MDS that identifies the device source). In these cases, the actual information communicated by a given transaction may be limited to the individual parameters grouped together in a single medical device system containment.

## D.1.2 Device semantics / controlled terminologies

Specific device semantics are formalized as a combination of terminology / vocabulary codes organized according to a common information model. The containment tree discussion above presented the basic ISO/IEEE 11073 information model used to organize and associate various device parameters. Terminologies are required, through, to represent each concept that is communicated. For example, an infusion rate may be communicated as "100 mL/Hr". At least two terms are required, one for the parameter name ("infusion rate") and one for the units of measurement ("mL/Hr"). In the device specialization sections below, all of the required semantics are specified, so as to ensure that the same term set is used for a given class of device.

# D.1.3 Overview of the ISO/IEEE 11073 nomenclature/terminology

The ISO/IEEE 11073-10101 (and related) nomenclature is optimized for medical device (esp. acute care) semantics, containing an extensive set of term codes supporting the

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information model, device parameters, units of measurement, body sites, alert events, etc.. Each term in this system is formalized as a text-based Reference Identifier and a 16bit or 32-bit numeric code. The 16-bit code is "context sensitive" in that it may be used when you know the class of information that it represents. For example, if in a message a field is being processed that represents Units of Measurement, then the 16-bit numeric code may be used, given that the semantic context has been established. The 32-bit code is "context free" in that it is guaranteed to be unique across the entire terminology.

All text-based Reference ID's are formalized as a continugous string of either capitalized letters or underscores ("\_"). For example, MDC\_RESP\_RATE or MDC\_PULS\_RATE. Note that the prefix "MDC" stands for medical device communication, and is often used to identify this nomenclature (e.g., "MDC" is used in HL7 to identify terms from this standard).

By convention, this Technical Framework will specify 11073 terms using the following format:

<Ref ID> (<partition<sup>4</sup> or code block>::<16-bit term code>)

For example, the two terms above would be specified as follows:

MDC\_RESP\_RATE (2::20490) MDC\_PULS\_RATE (2::18442)

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To determine the 32-bit value:  $< partition > * 2^{16} + < 16$ -bit term code>. So the pulse rate code above would have a 32-bit representation of 18444 (or hex 0x0002480A). The mapping rules for a given transaction technology shall indicate whether the textual Reference ID, 32-bit, or 16-bit codes may be used and how to properly encoded the terms (e.g., whether the numeric codes are formatted as text or binary values).

If additional or alternative terms are needed from other systems, such as LOINC or SNOMED-CT, they will be specified as well.

## D.1.4 Private terms & scope

Some devices communicate concepts that are either not standardized (in any terminology system) or are private and should only be recognized by applications that are aware of this device's specific semantics. In this case, the 11073 terminology provides for

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"private" sections of the terminology where manufacturers may define these semantics without worry of overlapping other terms already assigned. The 16-bit range from 0xF000 to 0xFFFF (hex) for each code block is reserved for private terms. If an entire private block of terms (65536 items) is required, the partition 1024 may be used.

<sup>&</sup>lt;sup>4</sup> Note: Partition numbers are defined in ISO/IEEE 11073-10101, section B.1.2, or in ISO/IEEE 11073-10201, type *NomPartition* definition.

In complex environments, though, where multiple devices are connected to a single patient and where two or more vendors may define terms with the same private codes (i.e., even the 32-bit identifier may not be unique), it is necessary to ensure proper scoping of these terms to ensure there are no collisions. To accomplish this, the scope associated with any private codes is defined by the containing VMD. This allows for modular systems where different plug-in components may be from different manufacturers.

#### D.1.5 New or non-specified terms

Additional terminology not contained in the device specializations below may:

- $\checkmark$  Exist in a terminology and simply hasn't been included in this version of the Framework, or
- $\checkmark$  Be a new concept that should be standardized (e.g., resulting from a new device modality), or
- $\checkmark$  Is a private or custom term that is particular to a single manufacturer's device and should not necessarily be standardized

In the first case, change requests may be submitted to this Technical Framework to have the needed semantics added. In general, if the semantics exist (either as terms and/or attributes in the Domain Information Model, they may be used in transactions without being added to this content specification; however, in order to achieve semantic

interoperability and heterogeneity with a class of device, there must be agreement 20 regarding the way a given concept is represented.

In the second case, new terms may be submitted to the relevant standard group for consideration. For these, either a pre-assigned term may be used or a private term until standardization is complete.<sup>5</sup>

In the third case, a private code should be used and is out-of-scope for inclusion in this content specification.

#### Episodic vs. periodic data updates D.1.6

Device information is typically reported in a manner appropriate for the given parameter and consuming application. Data reporting modes include:

30  $\checkmark$  Periodically – for parameters that change or are updated regularly. For example, the volume delivered on an infusion pump changes regularly based on the fluid delivery rate.

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<sup>&</sup>lt;sup>5</sup> Note: The ISO/IEEE 11073 group has indicated that it will make a best effort to address all new term requests as quickly as possible and where appropriate to provide rapid assignment of Reference IDs and term codes.

- ✓ Periodically High-Frequency for data that is reported periodically but at high data rates. For example, physiological waveforms.<sup>6</sup>
- ✓ Episodically for parameters that change infrequently or based on an external event. For example, an operational setting is modified by the clinician or a breath or heart beat has been detected.
- ✓ Snap-shot for those applications that only request the current value of a device's information at infrequent intervals. For example, once every 10 minutes or an hour.

Where appropriate, the device parameter specifications below shall indicate whether a

10 particular item is updated periodically or episodically. In the ISO/IEEE 11073 information model, the Metric::MetricRelevance and Metric::MetricAccess provide this information.

In the ISO/IEEE 11073 information model, provision for creating data updates or "event reports" for these various methods fall to a number of "extended services" objects such as an episodic scanner, periodic scanner, or fast periodic scanner. Each instance of these objects "scans" a configured list of data items and when changes are detected, generates an update including those parameters. For example, a "breath" episodic scanner instance would report all breath-to-breath related parameters (e.g., I:E ratio, inspiratory time, peak inspiratory pressure, etc.) whenever a breath completion has been detected.

20 Depending on the transaction profile conveying the device data, identification of these update classes may be supported. If so, the following terms should be used to differentiate the update type being reported:

Update Report Type Identification					
Update Type	Term Code				
Episodic Update	MDC_NOTI_UNBUF_SCAN_RPT (1:: 3350)				
Periodic Update	MDC_NOTI_BUF_SCAN_RPT (1:: 3331)				

<sup>&</sup>lt;sup>6</sup> For the IHE PCD TF Year 1, real-time waveform communication is out-of-scope.

## D.1.7 Alternative Units of Measurement Mapping

Though the basic units of measurement specified in this technical framework are from the ISO/IEEE 11073-10101 Units of Measurement partition, mappings to alternative terminology systems may be required for some implementations of this technical framework. For each parameter in the device specializations that includes a unit of measurement specification, the ISO/IEEE term is called out. The following table provides a summary of all the units of measurement terms utilized by this framework and provides for their mapping to alternative systems

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ISO/IEEE 11073 Alternative Units Mapping							
ISO/IEEE 11073	UCUM	LOINC	SNOMED-CT	Discussion			
MDC_DIM_CM_H2O (4::3904)				cmH <sub>2</sub> O			
MDC_DIM_MICRO_G_PER_HR (3379)				µG/hr			
MDC_DIM_MICRO_G_PER_MIN (3347)				µG/min			
MDC_DIM_MILLI_G_PER_HR (3378)				mG/hr			
MDC_DIM_MILLI_G_PER_MIN (3346)				mG/min			
MDC_DIM_MILLI_L (4::1618)				mL			
MDC_DIM_MIN (4:2208)				minutes			
MDC_DIM_PERCENT (4::544)				%			
MDC_DIM_RESP_PER_MIN (4::2784)				rpm			
MDC_DIM_SEC (4::2176)				seconds			
MDC_DIM_X_INTL_UNIT_PER_HR (5696)				i.u./hr			
MDC_DIM_X_L_PER_MIN (4::3072)				L/min			

## D.2 Alert and event semantics

Most medical devices provide indications of event or alert conditions. These are typically technical (e.g., a sensor needs to be calibrated or has been detached from the device), or physiological (e.g., a patient's spontaneous breath rate is too high). There is also a prioritization associated with alert conditions (low, medium and high), and each

device specifies the prioritization within a given class (e.g., if a device has 10 high priority alerts, and three are active, which is the highest priority of the three?).<sup>7</sup>

Additionally, an alert condition may be associated with the entire device (e.g., low battery), a particular channel (e.g., occlusion on infusion channel #2), or a specific parameter (e.g., heart rate too high). When communicated, the alert conditions should be associated with the appropriate device scope or entity within the device's information containment tree or hierarchy. When associated with a given parameter (e.g., a monitored temperature or pressure reading), generic event codes are preferred over more specific terms. For example, "low" or "high" or "irregular" as associated with a monitored heart rate parameter vs." high beat rate" and "low beat rate", etc. In most cases, though, specific codes must be used, such as "gas contaminated" or "asystole".

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Though some of these semantics are particular to a specific device, most are general and may be applied to multiple devices. The following table provides examples of common alert semantics that may be used in this  $TF^8$ :

<b>Device Alert Event Semantics</b>			
Description	Term Code		
General Events			
Alarm	MDC_EVT_ALARM (3::8)		
Disconnected	MDC_EVT_DISCONN (3:22)		
Empty	MDC_EVT_EMPTY (3::26)		
Error	MDC_EVT_ERR (3::30)		
Failure	MDC_EVT_FAIL (3::38)		
High	MDC_EVT_HI (3::40)		
High – Greater than set limit	MDC_EVT_HI_GT_LIM (3::42)		
INOP (device is inoperable)	MDC_EVT_INOP (3::52)		
Low	MDC_EVT_LO (3::62)		
Low – Less than set limit	MDC_EVT_LO_LT_LIM (3::64)		
Occlusion	MDC_EVT_OCCL (3::80)		
Range Error	MDC_EVT_RANGE_ERR (3::164)		
Door / Handle Position Problem	MDC_EVT_DOOR_OR_HANDLE_POSN_PROB (3::234)		
Fluid Line Problem	MDC_EVT_FLUID_LINE_PROB (3::252)		
Gas is contaminated	MDC_EVT_GAS_CONTAM (3::256)		
Lead is off / disconnected	MDC_EVT_LEAD_OFF (3::272)		
Sensor problem	MDC_EVT_SENSOR_PROB (3::312)		
Low signal level	MDC_EVT_SIG_LO (3::380)		
Timeout	MDC_EVT_TIMEOUT (3::584)		
Physiological/Medical Events			
Apnea	MDC_EVT_APNEA (3::3072)		

<sup>&</sup>lt;sup>7</sup> Note: For IHE PCD TF Year 1, real-time alert communication and monitoring is out of scope.

<sup>&</sup>lt;sup>8</sup> For a more complete listing of device alert semantics, see ISO/IEEE 11073-10101 section A.9 *Nomenclature, data dictionary, and codes for alerts (Block E)*, or Annex B.4 in the same standard.

Device Alert Event Semantics			
Description	Term Code		
Asystole	MDC_EVT_ECG_ASYSTOLE (3::3076)		
Sustained Bradycardia	MDC_EVT_ECG_BRADY_SUST (3::3088)		
Tachycardia	MDC_EVT_ECG_TACHY (3::3120)		
Arrhythmia	MDC_EVT_ECG_ARRHY (3::3266)		
Technical Events			
Battery failed	MDC_EVT_BATT_FAIL (3::192)		
Low Battery	MDC_EVT_BATT_LO (3::194)		
Battery Malfunction	MDC_EVT_BATT_MALF (3::196)		
Pressure cuff leak	MDC_EVT_CUFF_LEAK (3::228)		
Pressure cuff position error	MDC_EVT_CUFF_POSN_ERR (3::430)		
Pump in Free Flow	MDC_EVT_PUMP_FLOW_FREE (3::598)		
General Status Events			
Alarming Turned Off	MDC_EVT_STAT_AL_OFF (3::6144)		
Alarming Turned On	MDC_EVT_STAT_AL_ON (3::6146)		
Battery Charging	MDC_EVT_STAT_BATT_CHARGING (3::6150)		
Standby Mode	MDC_EVT_STAT_STANDBY_MODE (3::6166)		
Alarm Silence	MDC_EVT_STAT_AL_SILENCE (3::6214)		
Door Open	MDC_EVT_STAT_DOOR_OPEN (3::6220)		
Door Closed	DC_EVT_STAT_DOOR_CLOS (3::6244)		
Advisory Events			
Check Device	MDC_EVT_ADVIS_CHK (3::6658)		
Check Settings	MDC_EVT_ADVIS_SETTINGS_CHK (3::6668)		
Replace Battery	MDC_EVT_ADVIS_BATT_REPLACE (3::6678)		
Replace Syringe Warning	MDC_EVT_ADVIS_PUMP_SYRINGE_REPLACE_WARN (3::6712)		
Check Ventilator Air Supply	MDC_EVT_ADVIS_VENT_AIR_SUPP_CHK (3::6728)		

Note: Private event codes may be used to define non-standardized events that are not contained in the table above or in the base ISO/IEEE 11073-10101 standard. Any use of private event codes should be clearly described in the device's documentation.

#### **Body site semantics D.3**

One or more body sites may be associated with a given device parameter. For example, a temperature may have the same term codes, but are differentiated by the location of the where the temperature is taken. Other parameters (especially EEG and BIS measurements) are derived from signals from multiple sites. The ISO/IEEE 11073

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Metric object includes an attribute listing body sites, either from the base 11073-10101 terminology or from other vocabularies. The following table provides some examples of body sites that may be associated with a device parameter:

Body Site Terms				
Description <sup>9</sup>	Term Code			
Left ear (theta 120, phi 180)	MDC_HEAD_EAR_L (7::1289)			
Right ear (theta 120, phi 0)	MDC_HEAD_EAR_R (7::1290)			
Electrode 1 cm above the right eye on the eyebrow, in the middle between the center point of the eye and the lateral canthus.	MDC_EYE_CANTH_LAT_ABOVE_R (7::1362)			
Subarachnoid, Left [T-X1502-LFT] (for neurological measurements and drainage)	MDC_BRAIN_SUBARACHNOIDAL (7::1412)			
Left Atrium [T-32300]	MDC_HEART_ATR_L (7::1429)			
Right Ventricle [T-32500]	MDC_HEART_VENT_R (7::1442)			
Umbilical Artery [T-88810]	MDC_ART_UMBILICAL (7::1480)			
Lower extremity, Great toe [T-Y9810]	MDC_LOEXT_TOE_GREAT (7::1620)			
Upper extremity, Ring finger, NOS [T-Y8840]	MDC_UPEXT_FINGER_RING (7::1764)			
Vena umbilicalis [T-49062] (child) (e.g., for fluid therapy)	MDC_VEIN_UMBILICAL_CHILD (7::1808)			

#### D.4 Basic data type specifications

All communicated information must conform to common abstract data type specifications. The ISO/IEEE 11073-10201 standard defines data types for each object attribute using ASN.1 specification. The following listing identifies the data types used in this Technical Framework. When appropriate, the definition includes the analogous C/C++ constructs:

AbsoluteTime Date / Time specification as follows (BCD digits): struct AbsoluteTime { UInt8 century; UInt8 year; UInt8 month; UInt8 day; UInt8 hour; UInt8 minute; UInt8 second; UInt8 sec-fractions; }

BatMeasure

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Battery-related measurement:

<sup>&</sup>lt;sup>9</sup> Bracketed identifiers in Descriptions indicate the analogous SNOMED code.

struct BatMeasure { FLOAT-Type value; OID-Type units; } Basic numerical representation floating point **FLOAT-Type** representation, made up of a 24-bit signed magnitude and an 8-bit signed exponent, where: value = (magnitude) \* (10<sup>^</sup>exponent) Special values are provided as follows: 10 Not a Number (NaN)  $+(2^{2}-1)$ Not at this Resolution (NRes)  $-(2^{23})$ +INFINITY  $+(2^{23-2})$ -INFINITY -(2^23-2) Int<sub>16</sub> 16-bit signed integer (*short int*) Specification of localization information for the device, Locale including language and max string lengths<sup>10</sup>: struct Locale { UInt32 language; // From ISO 639-1 / 629-2 20 UInt32 country; // From ISO 3166-1, -2, -3 UInt16 char-set; // IANA MIBenum values StringSpec str-spec;// Max length + null term. } **OID-Type** 16-bit term code (context-sensitive portion) **ProdSpecEntry** A specification of a production serial number or other configuration identifier: 30 struct ProdSpecEntry { TEXT<sup>11</sup> spec\_type; UInt16 component id; // Mfgr's ID TEXT prod-spec; } TEXT A printable text string (*char* []); either counted or null terminated. TYPE 32-bit context-free term code:

<sup>10</sup> For more complete details on the Locale data type, see the specification in ISO/IEEE 11073-10201.

<sup>&</sup>lt;sup>11</sup> In the 11073-10201 standard, this is defined as a enumeration of UInt16 values, but for this framework it is specified as an identifying text string.

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	struct TYPE { UInt16 Partition; UInt16 Code; }		
UInt8	8-bit unsigned integer (unsigned char)		
UInt16	16-bit unsigned integer (unsigned short int)		
UInt32	32-bit unsigned integer (unsigned long int)		

#### **D.5** MDS semantics

Parameters for each device specialization are contained within an MDS containment hierarchy. The following table describes some of those attributes defined by an MDS which may be applicable for any of the devices specified below:

	Medical Device System (MDS) Attributes				
Attribute	Description	Term Code	Data Type <sup>12</sup>	Values	
System- Type	General category of the device (e.g., infusion pump)	MDC_ATTR_SYS_TYPE (1::2438)	TYPE	For example, MDC_DEV_PUMP_INFUS_MDS (1::4449)	
Mds-Status	Device's connection state (based on FSM)	MDC_ATTR_VMS_MDS_STAT (1::2471)	TEXT <sup>13</sup>	"disconnected", "associated", "configuring", "configured", "operating", "re-configuring", "disassociating", "terminating"	
System- Model	Manufacturer & Model label strings	MDC_ATTR_ID_MODEL (1::2344)	SystemModel	manufacturer="Philips" model="IntelliVue MP70"	
System-Id	Device unique identifier – typically EUI- 64; top 24 bits = unique company ID; lower 40 bits = serialization code; related to MAC addresses.	MDC_ATTR_SYS_ID (1::2436)	TEXT	For example, "00-00-00-00-00-00-00-00-00", where each "00" represents a hexadecimal representation of a byte.	
Soft-Id	Locally (non- manufacturer) ID (e.g., hospital inventory number)	MDC_ATTR_ID_SOFT (1::2350)	TEXT	"TMC Vent 42"	
Production- Specification	List of serial numbers and other items such as GMDN code	MDC_ATTR_ID_PROD_SPECN (1::2349)	List of ProdSpecEntry	serial-number="XYZ12345" sw-revision="03.02.01"	

<sup>&</sup>lt;sup>12</sup> Data types are further defined in section 3.2.6.3D.4 Basic data type specifications.

<sup>&</sup>lt;sup>13</sup> For the summary of this technical framework, this data targe which is MDSS takes an enumerated act of

Attribute	Description	Term Code	Data Type <sup>12</sup>	Values
Bed-Label	String identifying the bed to which the device has been assigned	MDC_ATTR_ID_BED_LABEL (1::2334)	TEXT	For example, "PICU 13"
Date-and- Time	Device's current date / time setting	MDC_ATTR_TIME_ABS (1::2439)	AbsoluteTime	20, 06, 08, 14, 23, 43, 12, 34
Power- Status <sup>14</sup>	A/C or D/C	MDC_ATTR_POWER_STAT (1::2389)	TEXT <sup>15</sup>	"onMains", "onBattery", "chargingFull", "chargingTrickle", "chargingOff"
Battery- Level	<i>Percentage</i> of battery capacity remaining	MDC_ATTR_VAL_BATT_CHARGE (1::2460)	UInt16	50 %
Remaining- Battery- Time	Estimated battery run- time remaining (typically in minutes)	MDC_ATTR_VAL_BATT_REMAIN (1::2440)	BatMeasure	120.5 MDC_DIM_MIN (4:2208)
Altitude	In meters above / below sea level	MDC_ATTR_ALTITUDE (1::2316)	Int16	120
Locale	Structure defining the device's country, language and character setting.	MDC_ATTR_LOCALE (1::2600)	Locale	language = 0x656E0000 ("en"), country = 0x55530000 ("US"), charset = charset-iso-10646-ucs- 2(1000), str-spec { str-max-len = 0x0040, str-flags = str-flag-nt(0) [0x8000] }

#### **D.6 VMD semantics**

Each MDS contains one or more Virtual Medical Devices (VMD). As stated above, a VMD may be used to represent either a major functional unit within a device (e.g., a ventilator may have one VMD to contain settings and general operational parameters and another as an Airway monitor or Airway Gas Analyzer). Additionally, VMDs typically represent units that may be plugged into other devices such as physiological monitors.

<sup>&</sup>lt;sup>14</sup> A separate battery object is defined in the 11073-10201 standard for systems that report more advanced battery information.

<sup>&</sup>lt;sup>15</sup> This attribute is defined as a PowerStatus enumeration; however, for this Technical Framework, the value strings are defined.

specializations defined below:

	Virtual Medical Device (VMD) Attributes				
Attribute	Description	Term Code	Data Type <sup>16</sup>	Values	
Туре	General category of the VMD (e.g., infusion pump)	MDC_ATTR_ID_TYPE (1::2351)	TYPE	For example, MDC_DEV_SYS_PT_VENT_VMD (1::4466)	
VMD-Status	VMD's basic operational status	MDC_ATTR_VMD_STAT (1::2466)	TEXT <sup>17</sup>	"vmd-off", "vmd-not-ready", "vmd- standby", "vmd-transduc-discon", "vmd-hw-discon"	
VMD-Model	Manufacturer & Model label strings	MDC_ATTR_ID_MODEL (1::2344)	SystemModel	manufacturer="Philips" model="IntelliVue MP70"	
Production- Specification	List of serial numbers and other items such as GMDN code	MDC_ATTR_ID_PROD_SPECN (1::2349)	List of ProdSpecEntry	serial-number="XYZ12345" sw-revision="03.02.01"	
Position	Physical "slot" that the VMD is plugged into	MDC_ATTR_ID_POSN (1::2348)	UInt16	3	
Locale	Structure defining the device's country, language and character setting.	MDC_ATTR_LOCALE (1::2600)	Locale	Same as MDS above.	

#### **D.7 Channel semantics**

Channels provide aggregation for closely related parameters. For devices that contain "channels" (e.g., ECG channels or infusion pump fluid channels), these definitions provide a means for differentiating parameters with identical term codes (e.g., fluid source channel rate or volume infused) but contained in different channels. The attributes

<sup>&</sup>lt;sup>16</sup> Data types are further defined in section 3.2.6.3D.4 Basic data type specifications.

<sup>&</sup>lt;sup>17</sup> For the purposes of this technical framework, this data type which is VMDStatus, an enumerated set of bit flags, is defined as a set of string values; multiple of these may be active at the same time.

below

	Channel Attributes				
Attribute	Description	Term Code	Data Type <sup>18</sup>	Values	
Type <sup>19</sup>	General category of the device (e.g., infusion pump)	MDC_ATTR_ID_TYPE (1::2351)	TYPE	For example, MDC_DEV_SYS_PT_VENT_CHAN (4467)	
Channel- Status	Channel's operational status	MDC_ATTR_CHAN_STAT (1::2320)	TEXT <sup>20</sup>	"chan-off", "chan-not-ready", "chan- standby", "chan-transduc-discon", "chan-hw-discon"	
Physical- Channel- No	Numeric ID of a hardware channel	MDC_ATTR_CHAN_NUM_PHYS (1::2319)	UInt16	12	
Logical- Channel- No	Dynamically assigned channel number; for channels that may have an assignment that changes due to reconfiguration.	MDC_ATTR_CHAN_NUM_LOGICAL (1::2606)	UInt16	3	

<sup>&</sup>lt;sup>18</sup> Data types are further defined in section 3.2.6.3D.4 Basic data type specifications.

<sup>&</sup>lt;sup>19</sup> Note: A Channel-Type attribute has been proposed, which would allow for parameters such as "secondary infusion channel".

 $<sup>^{20}</sup>$  For the summary of this tash is all formula this 80 tasks which is Channel Status or summarial at a f

## D.8 Device: Infusion Pump

#### D.8.1 Containment tree

Infusion pumps organize their information as follows:

Infusion Pump Containment Tree			
MDS: Infusion	MDS: Infusion Pump		MDC_DEV_PUMP_INFUS_MDS (1::4449)
	VMD: Infusio	on Pump	MDC_DEV_PUMP_INFUS_VMD (1::4450)
		Channel: Source	MDC_DEV_PUMP_INFUS_CHAN_SOURCE (1::61441)
		Channel: Delivery	MDC_DEV_PUMP_INFUS_CHAN_DELIVERY (1::61442)

For devices that support a secondary or "piggy-back" channel, two Source channels should be defined, one as the primary channel, and one as the secondary. In other words, source channels are defined for each fluid that is routed to a given delivery or distal path. An infusor VMD shall have one and only one delivery channel. Devices that contain multiple delivery channels shall define multiple infusor VMD instances.

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## D.8.2 Channel: Source

Fluid source infusion channels may contain the following parameters:

	Infusor Source Channel Parameters						
Name	Term Code	Data Type	Units	Values			
Set Fluid Delivery Rate	MDC_FLOW_FLUID_PUMP (2::26712)	Numeric::FLOAT-Type	MDC_DIM_MILLI_L_PER_HR (4::3122)				
Remaining VTBI	MDC_VOL_FLUID_TBI_REMAIN (2::26800)	Numeric::FLOAT-Type	MDC_DIM_MILLI_L (4::1618)				
Duration	MDC_TIME_PD_REMAIN (2::26844)	Numeric::FLOAT-Type	MDC_DIM_MIN (4::2208)				
Drug Dose Rate	MDC_FLOW_DRUG_DELIV (2::26732)	Numeric::FLOAT-Type	MDC_DIM_MILLI_G_PER_HR 4:: (3378) / MDC_DIM_MILLI_G_PER_MI N (4::3346) / MDC_DIM_MICRO_G_PER_H R (4::3379) / MDC_DIM_MICRO_G_PER_MI N (4::347) / MDC_DIM_X_INTL_UNIT_PE R_HR (4::5696)				
Volume Infused	MDC_VOL_FLUID_DELIV (2::26792)	Numeric::FLOAT-Type	MDC_DIM_MILLI_L (4::1618)				
Drug Label	MDC_DRUG_NAME_TYPE (2::53258)	Enumeration::TEXT	N/A				

	Infusor Source Channel Parameters					
Name	Term Code	Data Type	Units	Values		
Total Current Rate	MDC_FLOW_FLUID_PUMP (2::26712)	Numeric::FLOAT-Type	MDC_DIM_MILLI_L_PER_HR (4::3122)			
Total Volume Infused	MDC_VOL_INFUS_ACTUAL_TOTAL (2::26876)	Numeric::FLOAT-Type	MDC_DIM_MILLI_L (4::1618)			
Operationa 1 Status	MDC_PUMP_STAT (2::53436)	Enumeration::TEXT <sup>21</sup>	N/A	"pump-status- infusing" + "pump-status- kvo" + "pump- status-ready" +" pump-status- standby" + "pump-status- paused"		
Operationa 1 Mode	MDC_PUMP_MODE (2::53432)	Enumeration::TEXT <sup>21</sup>	N/A	"pump-mode- nominal" + "pump-mode- secondary" + "pump-mode- drug-dosing"		

#### D.8.3 Channel: Delivery

<sup>&</sup>lt;sup>21</sup> This parameter is specified as a set of bit flags, but for this technical framework, the enumerated text strings shall be used.

## D.9 Device: Ventilator

#### D.9.1 Containment tree

Ventilators organization their information according to the following containment tree:

	Ventilator Containment Tree			
MDS: Ventilat	tor		MDC_DEV_SYS_PT_VENT_MDS (1::4465)	
	VMD: Ventila	tor	MDC_DEV_SYS_PT_VENT_VMD (1::4466)	
		Channel: Ventilator	MDC_DEV_SYS_PT_VENT_CHAN (4467)	
		Channel: Nebulizer <sup>22</sup>		
	VMD: Airway	Multi-Parameter	MDC_DEV_ANALY_AWAY_MULTI_PARAM_VMD (1::4146)	
		Channel: Pressure	MDC_DEV_ANALY_PRESS_AWAY_CHAN (1::4171)	
		Channel: Flow <sup>23</sup>	MDC_DEV_ANALY_FLOW_AWAY_CHAN (1::4131)	
		Channel: Volume	MDC_DEV_ANALY_VOL_AWAY_CHAN (1::61452)	
		Channel: Breath Pattern	MDC_DEV_ANALY_BREATH_PATTERN_CHAN (61456)	
	VMD: Pulse-C	Dximeter <sup>22</sup>		
		Channel: Pulse-Ox		
		Channel: Pulse Rate		
	VMD: Airway	Gas Analyzer <sup>22</sup>		
		Channel: Oxygenation		
		Channel: NO/NO <sub>2</sub>		
		Channel: CO <sub>2</sub>		
		Channel: Resp CO <sub>2</sub>		
		Channel: Anesthesia Agent		

## D.9.2 Channel: Ventilator

<sup>&</sup>lt;sup>22</sup> This item is beyond the scope of the Year 1 technical framework.

<sup>&</sup>lt;sup>23</sup> This Channel is also out-of-scope for Year 1 since it only contains the flow waveform object.

	Ventilator Channel Parameters					
Name	Term Code	Data Type	Units	Values		
Operationa 1 Mode	MDC_VENT_MODE (2::53280)	Enumeration::TEXT <sup>21</sup>	N/A	"vent-mode- cpap" + "vent-mode- simv" + "vent-mode- insp-assist"		
Set Breath Rate	MDC_RESP_RATE (2::20490)	Numeric::FLOAT-Type	MDC_DIM_RESP_PER_MIN (4::2784)			
Set Tidal Volume	MDC_VOL_AWAY_TIDAL_EXP (2::61454)	Numeric::FLOAT-Type	MDC_DIM_MILLI_L (4::1618)			
Set Peak Inspiratory Flow	MDC_VENT_FLOW_INSP (2::61440)	Numeric::FLOAT-Type	MDC_DIM_X_L_PER_MIN (4::3072)			
Set PEEP	MDC_PRESS_AWAY_END_EXP_POS (2::20732)	Numeric::FLOAT-Type	MDC_DIM_CM_H2O (4::3904)			
Set Inspiratory Time	MDC_TIME_PD_INSP (2::61458)	Numeric::FLOAT-Type	MDC_DIM_SEC (4::2176)			
Set Inspiratory Pause	MDC_VENT_TIME_PD_PAUSE_INSP (2::61443)	Numeric::FLOAT-Type	MDC_DIM_SEC (4::2176)			
Set Flow Shape	MDC_VENT_FLOW_SHAPE (2::61449)	Enumeration::TEXT	N/A	"waveform- shape-square"; "waveform- shape- decelerating"		
Set FiO2	MDC_VENT_CONC_AWAY_O2 (2::20648)	Numeric::FLOAT-Type	MDC_DIM_PERCENT (4::544)			

The ventilator channel contains the following semantics:

# D.9.3 Channel: Airway Pressure

The airway pressure channel includes the following parameters:

	Airway Pressure Channel Parameters					
Name	Term Code	Data Type	Units	Values		
Peak Inspiratory Pressure (PIP)	MDC_PRESS_AWAY_INSP_PEAK (2::20745)	Numeric::FLOAT-Type	MDC_DIM_CM_H2O (4::3904)			
Mean Airway Pressure (MAP)	MDC_PRESS_AWAY_MEAN (2::61451)	Numeric::FLOAT-Type	MDC_DIM_CM_H2O (4::3904)			
PEEP	MDC_PRESS_AWAY_END_EXP_P OS (2::20732)	Numeric::FLOAT-Type	MDC_DIM_CM_H2O (4::3904)			

## D.9.4 Channel: Airway Volume

	Airway Volume Channel Parameters				
Name	Term Code	Data Type	Units	Values	
Exhaled Tidal Volume	MDC_VOL_AWAY_TIDAL_EXP (2::61454))	Numeric::FLOAT-Type	MDC_DIM_MILLI_L (4::1618)		
Exhaled Minute Volume	MDC_VOL_AWAY_MINUTE_EXP (2::61455)	Numeric::FLOAT-Type	MDC_DIM_X_L (4::1600)		

The airway volume channel includes the following parameters:

## D.9.5 Channel: Airway Breath Pattern

The airway breath pattern channel includes the following parameters:

	Airway Breath Pattern Channel Parameters				
Name	Term Code	Data Type	Units	Values	
I:E Ratio	MDC_RATIO_IE (2::20760) MDC_RATIO_INSP (2::61461) MDC RATIO EXP (2::61462)	Numeric::Compound::F LOAT-Type	MDC_DIM_DIMLESS (4::512)		
Breath Rate	MDC_RESP_RATE (2::20490)	Numeric::FLOAT-Type	MDC_DIM_RESP_PER_MIN (4::2784)		
Inspiratory Time	MDC_TIME_PD_INSP (2::61458)	Numeric::FLOAT-Type	MDC_DIM_SEC (4::2176)		

## **D.10** Physiological Monitor

## D.10.1 Containment tree

Physiological monitors are comprised of a number of different VMDs as indicated in the following containment tree:

	Physiological Monitor Containment Tree				
MDS: Physiological Monitor		MDC_DEV_METER_PHYSIO_MULTI_PARAM_M DS (1::4301)			
	VMD: Blood I	Pressure	MDC_DEV_METER_PRESS_BLD_VMD (1::4318)		
		Channel: Invasive BP	MDC_DEV_METER_PRESS_BLD_CHAN (1::4319)		
		Channel: Non-Invasive BP	MDC_DEV_PRESS_BLD_NONINV_CHAN (1::5151)		
		Channel: Pulse Rate BP			
	VMD: Temper	ature	MDC_DEV_METER_TEMP_VMD (1::4366)		
		Channel: Temperature	MDC_DEV_METER_TEMP_CHAN (1::4367)		
	VMD: Pulse O	Dximeter	MDC_DEV_ANALY_SAT_O2_VMD (1::4106)		
		Channel: Pulse Ox	MDC_DEV_ANALY_SAT_O2_CHAN (1::4107)		

 Physiological Monitor Containment Tree				
	Channel: Pulse Rate Ox			
VMD: ECG M	onitor	MDC_DEV_ECG_VMD (1::4262)		
	Channel: ECG	MDC_DEV_ECG_CHAN (1::4263)		
	Channel: ECG Resp	MDC_DEV_ECG_RESP_CHAN (1::5131)		
	Channel: Heart Rate	MDC_DEV_GEN_RATE_HEART_CHAN (1::4251)		
	Channel: Arrhythmia	MDC_DEV_ARRHY_CHAN (1::5135)		
	Channel: Ischemia			
	Channel: ECG Measurements			
VMD: Cardiac	Output	MDC_DEV_ANALY_CARD_OUTPUT_VMD (1::4134)		
I	Channel: Continuous CO			
	Channel: Intermittent CO			
VMD: Hemod	ynamics Calculator	MDC_DEV_CALC_HEMO_VMD (1::4210)		
	Channel: Hemodynamics Calc.	MDC_DEV_CALC_HEMO_CHAN (1::4211)		

## D.10.2 Channel: Invasive Blood Pressure

Invasive blood pressure channels may contain the following parameters:

	Invasive Blood Pressure Channel Parameters				
Name	Term Code	Data Type	Units	Values	
Arterial Blood Pressure	MDC_PRESS_BLD_ART_ABP (2::18964) MDC_PRESS_BLD_ART_ABP_SYS (2::18965) MDC_PRESS_BLD_ART_ABP_DIA (2::18966) MDC_PRESS_BLD_ART_ABP_MEAN (2::18967)	Numeric::Compound::F LOAT-Type	MDC_DIM_CM_H2O (4::3904)		
Wedge Pressure	MDC_PRESS_BLD_ART_PULM_WED GE (2::18980)	Numeric::FLOAT-Type	MDC_DIM_CM_H2O (4::3904)		

## D.10.3 Channel: Blood Pressure – Non-Invasive

Non-invasive blood pressure channels may contain the following parameters:

	Non-Invasive Blood Pressure Channel Parameters				
Name	Term Code	Data Type	Units	Values	
Non- Invasive Blood Pressure	MDC_PRESS_BLD_NONINV (2::18948) MDC_PRESS_BLD_NONINV_SYS (2::18949) MDC_PRESS_BLD_NONINV_DIA (2::18950) MDC_PRESS_BLD_NONINV_MEAN	Numeric::Compound::F LOAT-Type	MDC_DIM_CM_H2O (4::3904)		
Cuff Pressure	(2::18951) MDC_PRESS_CUFF (2::19228) MDC_PRESS_CUFF_SYS (2::19229) MDC_PRESS_CUFF_DIA (2::19230)	Numeric::FLOAT-Type	MDC_DIM_CM_H2O (4::3904)		

Non-Invasive Blood Pressure Channel Parameters				
Name	Term Code	Data Type	Units	Values
	MDC_PRESS_CUFF_MEAN (2::19231)			

#### D.10.4 Channel: Blood Pressure – Pulse Rate

Pulse rate blood pressure channels may contain the following parameters:

Pulse Rate (Blood Pressure) Channel Parameters				
NameTerm CodeData TypeUnitsValues				Values
Pulse Rate	MDC_PRESS_RATE (2:: 18442)	Numeric::Compound::F LOAT-Type	MDC_DIM_CM_H2O (4::3904)	

#### D.10.5 Channel: Temperature

Temperature channels may contain the following parameters:

	Temperature Channel Parameters				
Name	Term Code	Data Type	Units	Values	
Body Temp	MDC_TEMP_BODY (2::19292)	Numeric::FLOAT-Type	NOM_DIM_DEGC (4:: 6048)		
Skin Temp	MDC_TEMP_SKIN (2::19316)	Numeric::FLOAT-Type	NOM_DIM_DEGC (4:: 6048)		
Core Temp	MDC_TEMP_CORE (2::19296)	Numeric::FLOAT-Type	NOM_DIM_DEGC (4:: 6048)		

## D.10.6 Channel: Pulse Ox

Pulse oximeter channels may contain the following parameters:

	Pulse Ox Channel Parameters				
Name	Term Code	Data Type	Units	Values	

#### 10 D.10.7 Channel: Pulse Rate Ox

Pulse rate oximeter channels may contain the following parameters:

	Pulse Rate Ox Channel Parameters				
Name	Term Code	Data Type	Units	Values	

## D.10.8 Channel: ECG Monitoring

ECG monitoring channels may contain the following parameters:

	ECG Monitoring Channel Parameters				
Name	Term Code	Data Type	Units	Values	

## D.10.9 Channel: ECG Resp

ECG respiration channels may contain the following parameters:

ECG Respiration Channel Parameters				
Term Code	Data Type	Units	Values	
	<b>A</b>	<b>k</b>	▲ I I I I I I I I I I I I I I I I I I I	

#### D.10.10 Channel: Heart Rate

ECG heart rate channels may contain the following parameters:

10

	Heart Rate Channel Parameters				
Name	Term Code	Data Type	Units	Values	

## D.10.11 Channel: Arrhythmia

ECG arrhythmia channels may contain the following parameters:

	Arrhythmia Channel Parameters			
Name	Term Code	Data Type	Units	Values

## D.10.12 Channel: Ischemia

ECG ischemia channels may contain the following parameters:

	Ischemia Channel Parameters			
Name	Term Code	Data Type	Units	Values

#### D.10.13 Channel: ECG Measurements

ECG measurement channels may contain the following parameters:

	ECG Measurements Channel Parameters				
Name	Term Code	Data Type	Units	Values	

#### D.10.14 Channel: Cardiac Output – Continuous

10 Continuous cardiac output channels may contain the following parameters:

	<b>Continuous Card</b>	iac Output Chan	nel Parameters	
Name	Term Code	Data Type	Units	Values

## D.10.15 Channel: Cardiac Output – Intermittent

Intermittent cardiac output channels may contain the following parameters:

	<b>Intermittent Car</b>	diac Output Channel	l Parameters	
Name	<b>Term Code</b>	Data Type	Units	Values

#### D.10.16 Channel: Hemodynamics Calculator

Hemodynamics calculator channels may contain the following parameters:

	Hemodynamics Calculator Channel Parameters				
Name	Term Code	Data Type	Units	Values	

#### Appendix E Examples of messages

These message examples illustrate the uses cases defined in PCD TF-1. They are not intended to be the final version to be used in implementation but as examples to reinforce the use cases and the mapping of ISO/IEEE 11073 to HL7.

#### 10 E.1 Case C1: Communicate periodic data to CIS

Periodic data from all of the patient care devices associated with a particular patient are communicated to a CIS. Examples include data from a bedside monitor, point of care lab devices, ventilators, and infusion pumps. Discrete and data are communicated to the CIS. The primary intent is communication of structured data however provisions are made for inclusion of unstructured data. The patient associated with the data is identified and the data is time stamped with a consistent time across the respective patient care devices.

## E.1.1 Simple device – minimal context

An observation result from a simple finger plethysmographic pulse monitor with no other VMDs or channels. Minimal information beyond required fields populated. Both the HL7 ER7 and the HL7 XML forms are given

```
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2006^HL7^2.16.840.1.113883.9.n.m^HL7
PID|||12345^^PI^Downtown Campus||Doe^John^Joseph^JR^^L^A|||M
OBR|1|AB12345^ORIGatewayInc ICU-04^ACDE48234567ABCD^EUI-64|CD12345^ORIGatewayInc ICU-
04^ACDE48234567ABCD^EUI-64|149538^MDC_PLETH_PULS_RATE^MDC|||20060713095715-0400
OBX|1|NM|149538^MDC_PLETH_PULS_RATE^MDC|1.1.1.1|83|264896^MDC_DIM_PULS_PER_MIN^MDC|||||R|||20060
713095715-0400|||264896^MDC_UPEXT_FINGER^MDC
```

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#### 30

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	<hd.2>ACDE48234567ABCD</hd.2> <hd.3>EUI-64</hd.3>
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1.0	
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30	<pid.8>M</pid.8> 
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	<ei.4>EUI-64</ei.4>
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	<ei.2>ORIGatewayInc ICU-04</ei.2> <ei.3>ACDE48234567ABCD</ei.3>
	<ei.4>EUI-64</ei.4>

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```
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                       <CE.2>MDC_PLETH_PULS_RATE</CE.2>
                       <CE.3>MDC</CE.3>
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               </OBX.14>
30
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                       <CE.2>MDC_UPEXT_FINGER</CE.2>
                       <CE.3>MDC</CE.3>
               </OBX.17>
               </OBX>
       </ >
```

## E.1.2 Simple device

An observation result from a simple finger plethysmographic pulse monitor with no other
 VMDs or channels. A number of RE fields have been populated in this example. Both the
 HL7 ER7 and the HL7 XML forms are given

```
MSHI^~\&|ORIGatewavInc^ACDE48234567ABCD^EUI-64||CU-
       04|EnterpriseEHRInc|DowntownCampus|20060713095730-
       0400||ORU^R01^ORU_R01|MSGID1233456789|P|2.5|2||NE|AL|USA|ASCII|EN^English^ISO639||IHE PCD ORU-R01
       2006<sup>°</sup>HL7<sup>2</sup>.16.840.1.1138<sup>8</sup>3.9.n.m<sup>HL7</sup>
       PIDIII12345^^^PI^Downtown
       Campus||Doe^John^Joseph^JR^/L^A//G|Jones^Mary/Roberta///G//G|19440712|M||2028-
       9^Asian^HL70005|10&Market Street^^San
50
       Fransisco^CA^94111^USA^M||^PRN^PH^^1^415^1234567||EN^English^ISO639|M^Married^HL70002
       OBR/1/AB12345^OR/GatewayInc ICU-04^ACDE48234567ABCD^EUI-64/CD12345^OR/GatewayInc ICU-
       04^ACDE48234567ABCD^EUI-64|149538^MDC_PLETH_PULS_RATE^MDC|||20060713095715-0400
       OBX|1|NM|149538^MDC_PLETH_PULS_RATE^MDC|1.1.1.183|264896^MDC_DIM_PULS_PER_MIN^MDC|||||R|||20060
       713095715-0400|||264896^MDC_UPEXT_FINGER^MDC
       <?xml version="1.0" encoding="UTF-8"?>
       <_>
                <MSH>
                <MSH.1>|</MSH.1>
```

	<msh.2>^~\&amp;</msh.2>
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	<hd.1>OKIGatewayint</hd.1> <hd.2>ACDE48234567ABCD</hd.2>
	<hd.3>EUI-64</hd.3>
	<msh.4> <hd.1>ICU-04</hd.1></msh.4>
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	<pre><hd.1>EnterpriseEHRInc</hd.1></pre>
	 <msh.6></msh.6>
	<hd.1>DowntownCampus</hd.1>
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20	<msh.9></msh.9>
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	<msd.z>k01</msd.z> <msg.3>ORU_R01</msg.3>
	<msh.10>MSGID1233456789</msh.10>
	<msh.11> <pt.1>P</pt.1></msh.11>
30	2.5 /UD.1 
	<msh.13>2</msh.13>
	<msh.15>NE</msh.15>
	<msh.16>AL</msh.16> <msh.17>USA</msh.17>
	<msh.18>ASCII/MSH.18&gt;</msh.18>
	<msh.19></msh.19>
	<ce.1>EN</ce.1> <ce.2>English</ce.2>
	<ce.3>ISO639</ce.3>
40	
	<msh.21> <ei.1>IHE PCD ORU-R01 2006</ei.1></msh.21>
	<ei.2>HL7</ei.2>
	<ei.3>2.16.840.1.113883.9.n.m</ei.3>
	<ei.4>HL7</ei.4> 
	<pid></pid>
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	<cx.6></cx.6>
	<hd.1>Downtown Campus</hd.1>
	<pid.5></pid.5>
	<xpn.1></xpn.1>
	<fn.1>Doe</fn.1> 
60	<xpn.2>John</xpn.2>
	<xpn.3>Joseph</xpn.3>
	<xpn.4>JR</xpn.4> <xpn.7>L</xpn.7>
	<xpn.7>L&lt;7XPN.7&gt; <xpn.8>A&lt;7XPN.8&gt;</xpn.8></xpn.7>

	<xpn.11>G</xpn.11> 
	<pid.6></pid.6>
	<xpn.1></xpn.1>
10	<fn.1>Jones</fn.1>  <xpn.2>Mary</xpn.2> <xpn.3>Roberta</xpn.3> <xpn.8>G</xpn.8>
10	<xpn.11>G</xpn.11> 
	<pid.7></pid.7>
	<ts.1>19440712</ts.1>
	 <pid.8>M</pid.8> <pid.10></pid.10>
	<ce.1>2028-9</ce.1>
	<ce.2>Asian</ce.2> <ce.3>HL70005</ce.3>
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	<pid.11></pid.11>
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	<sad.2>Market Street</sad.2>
	 <xad.3>San Fransisco</xad.3>
	<xad.4>CA</xad.4>
	<xad.5>94111</xad.5>
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	<pid.13> <xtn.2>PRN</xtn.2></pid.13>
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	<ce.3>ISO639</ce.3> 
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	<obr.2></obr.2>
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	<0BR.3>
60	<ei.1>CD12345</ei.1>
00	<ei.2>ORIGatewayInc ICU-04</ei.2> <ei.3>ACDE48234567ABCD</ei.3> <ei.4>EUI-64</ei.4>
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```
<CE.1>149538</CE.1>
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30
                       <CE.2>MDC UPEXT FINGER</CE.2>
                       <CE.3>MDC</CE.3>
               </OBX.17>
               </OBX>
       </_>
```

## Appendix F HL7 Message Profiling Convention

The messages used by each transaction are described in this document using static definitions as described for HL7 constrainable message profiles; refer to HL7 Version 2.5, Chapter 2, Section 2.12.6. The static definition of each message is represented within tables. The message level table represents the IHE-constrained message structure with its list of usable segments. The segment level table represents the IHE-constrained content of one segment with its usable fields.

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## F.1 Static definition - Message level

The message table representing the static definition contains 5 columns:

• Segment: gives the segment name, and places the segment within the hierarchy of the message structure designed by HL7, but hiding the traditional square brackets and braces that designate optionality and repeatability in HL7 standard message tables. The beginning and end lines of a segment group (see HL7 Version 2.5, Chapter 2, Section 2.5.2 for definition) are designated in this column by --- (3 dashes).

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• Meaning: Meaning of the segment as defined by HL7. The beginning of a segment group is designated by one line in this column giving the segment group name in all

caps, prefixed by --- (3 dashes), and followed by the keyword "begin". The end of a segment group is designated by one line in this column giving the segment group name in all caps, prefixed by --- (3 dashes), and followed by the keyword "end".

- Usage: Coded usage of the segment, in the context of this IHE Integration Profile. The coded values used in this column are:
  - **R**: Required: A compliant sending application shall populate all "R" elements with a non-empty value. A compliant receiving application may ignore the information conveyed by required elements. A compliant receiving application shall not raise an error due to the presence of a required element, but may raise an error due to the absence of a required element.
  - **RE**: Required but may be empty. The element may be missing from the message, but shall be sent by the sending application if there is relevant data. A conformant sending application shall be capable of providing all "RE" elements. If the conformant sending application knows a value for the element, then it shall send that value. If the conformant sending application does not know a value, then that element may be omitted. Receiving applications may ignore data contained in the element, but shall be able to successfully process the message if the element is omitted (no error message should be generated if the element is missing).
- O: Optional. The usage for this field within the message is not defined . The sending application may choose to populate the field; the receiving application may choose to ignore the field.
  - C: Conditional. This usage has an associated condition predicate. (See HL7 Version 2.5, Chapter 2, Section 2.12.6.6, "Condition Predicate".)
    If the predicate is satisfied: A compliant sending application shall populate the element. A compliant receiving application may ignore data in the element. It may raise an error if the element is not present.
    If the predicate is NOT satisfied: A compliant sending application shall NOT populate the element. A compliant receiving application shall NOT raise an error if the condition predicate is false and the element is not present, though it may raise an error if the element IS present.
  - CE: Conditional but may be empty. This usage has an associated condition predicate. (See HL7 Version 2.5, Chapter 2, Section 2.12.6.6, "Condition Predicate".)
    If the predicate is satisfied: If the conforming sending application knows the required values for the element, then the application must populate the element. If the conforming sending application does not know the values required for this element, then the element shall be omitted. The conforming sending application must be capable of populating the element (when the predicate is true) for all 'CE' elements. If the element is present, the

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conformant receiving application may ignore the values of that element. If the element is not present, the conformant receiving application shall not raise an error due to the presence or absence of the element. If the predicate is NOT satisfied: The conformant sending application shall not populate the element. The conformant receiving application may raise an application error if the element is present.

- X: Not supported. For conformant sending applications, the element will not be sent. Conformant receiving applications may ignore the element if it is sent, or may raise an application error.
- Cardinality: Within square brackets, minimum and maximum number of occurrences authorized for this segment in the context of this Integration Profile.
  - HL7 chapter: Reference of the HL7 v2.5 chapter that describes this segment.

Segment	Meaning	Usage	Card.	HL7 chapter
MSH	Message Header	R	[11]	2
[	PATIENT begin		[11]	
PID	Patient Identification	R	[11]	3
[	PATIENT VISIT begin		[11]	
PV1	Patient Visit	RE	[01]	3

Table 3.2-1: Example: Initial segments of a message description

#### F.2 Static definition – Segment level and Data Type level

The Segment table and the Data Type table each contain 8 columns:

- **SEQ**: Position (sequence) of the field within the segment.
- LEN: Maximum length of the field
- **DT**: Field Data Type
- Usage: Usage of the field within this IHE Integration Profile. Same coded values as in the message level: R, RE, C, CE, O, X.
- **Cardinality**: Minimum and maximum number of occurrences for the field in the context of this Integration Profile.
- **TBL**#: Table reference (for fields using a set of defined values)
- **ITEM#**: HL7 unique reference for this field
- Element Name: Name of the field in a Segment table. / Component Name: Name of a subfield in a Data Type table.

SEQ	LEN	DT	Usage	Card.	TBL#	ITEM#	Element name
1	1	ST	R	[11]		00001	Field Separator

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 Table 3.2-2: Example: The MSH segment description

2	4	ST	R	[11]		00002	Encoding characters
3	227	HD	R	[11]	0361	00003	Sending Application

## Appendix G HL7 Implementation Notes

## G.1 Network Guidelines

The HL7 2.5 standard does not define a network communications protocol. Beginning with HL7 2.2, the definitions of lower layer protocols were moved to the Implementation Guide, but are not HL7 requirements. The IHE Framework makes these recommendations:

- A Applications shall use the Minimal Lower Layer Protocol defined in Appendix C of the HL7 Implementation Guide.
- 3. An application that wants to send a message (initiate a transaction) will initiate a network connection to start the transaction. The receiver application will respond with an acknowledgement or response to query but will not initiate new transactions on this network connection.

## G.2 Acknowledgment Modes

#### 2.14 ACKNOWLEDGMENT MESSAGES

Acknowledgment messages may be defined on an application basis. However the simple general acknowledgment message (ACK) may be used where the application does not define a special message (application level acknowledgment) and in other cases as described in Section 2.9, "Message Processing Rules".

#### 20 2.14.1 ACK - general acknowledgment

The simple general acknowledgment (ACK) can be used where the application does not define a special application level acknowledgment message or where there has been an error that precludes application processing. It is also used for accept level acknowledgments. The details are described in Section 2.9, "Message Processing Rules".

#### ACK^varies^ACK General Acknowledgment Status Chapter

MSH Message Header 2

MSA Message Acknowledgment 2

[{ ERR }] Error 2

**Note**: For the general acknowledgment (ACK) message, the value of MSH-9-2-Trigger event is equal to the value of MSH-9-2-Trigger event in the message being

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acknowledged. The value of MSH-9-3-Message structure for the general acknowledgment message is always ACK.

Applications that receive HL7 messages shall send acknowledgments using the HL7 Original Mode (versus Enhanced Acknowledgment Mode).

# G.3 Message granularity

The sending application shall send as many messages as there are events recorded. For instance, if at the same time there is a change both to the patient's location (from emergency room to GI surgery ward) and to the patient's attending doctor (from Dr. Eric Emergency to Dr. John Appendectomy), the sending application will transmit two movements using HL7 messages ADT^A02 (transfer) and ADT^A54 (change attending doctor). Both events will have the same effective date/time (EVN-6 – Event Occurred). If the Historic Movement option is in use, each of these movements will have a unique identifier.

The exceptions to this fine granularity are:

- The Admit Inpatient (A01) and Register Outpatient (A04) events can also assign a location and an attending doctor to the patient, known when the event is recorded.
- A change of patient class (A06 or A07) also assigns at the same time a new location to the patient.
- The Cancel Discharge/End Visit event also includes at the same time the patient location after the cancellation has been processed.

## G.4 HL7 empty field convention

According to the HL7 standard, if the value of a field is not present, the receiver shall not change corresponding data in its database. However, if the sender defines the field value to be the explicit NULL value (*i.e.*, two double quotes ""), it shall cause removal of any values for that field in the receiver's database. This convention is fully applied by IHE profiles based on HL7 v2.x messages.

## Appendix H IHE Integration Statements

## H.1 IHE Integration Statements

IHE Integration Statements are documents prepared and published by vendors to describe
 the intended conformance of their products with the IHE Technical Framework. They
 identify the specific IHE capabilities a given product is designed to support in terms of
 the key concepts of IHE: Actors and Integration Profiles (described in Volume I, section
 2 of the IHE Technical Framework).

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Users familiar with these concepts can use Integration Statements as an aid to determine what level of integration a vendor asserts a product supports with complementary systems and what clinical and operational benefits such integration might provide. Integration Statements are intended to be used in conjunction with statements of conformance to specific standards (e.g. HL7, DICOM, W3C, etc.).

IHE provides a process for vendors to test their implementation of IHE Actors and Integration Profiles. The IHE testing process, culminating in a multi-party interactive testing event called the Connect-a-thon, provides vendors with valuable feedback and provides a baseline indication of the conformance of their implementations. The process

10 is not, however, intended to independently evaluate, or ensure, product compliance. In publishing the results of the Connect-a-thon, and facilitating access to vendors' IHE Integration Statements, IHE and its sponsoring organizations are in no way attesting to the accuracy or validity of any vendor's IHE Integration Statements or any other claims by vendors regarding their products.

IMPORTANT -- PLEASE NOTE: Vendors have sole responsibility for the accuracy and validity of their IHE Integration Statements. Vendors' Integration Statements are made available through IHE simply for consideration by parties seeking information about the integration capabilities of particular products. IHE and its sponsoring organizations have not evaluated or approved any IHE Integration Statement or any related product, and IHE and its sponsoring organizations shall have no liability or responsibility to any party for any claims or damages, whether direct, indirect, incidental or consequential, including but not limited to business interruption and loss of revenue, arising from any use of, or reliance upon, any IHE Integration Statement.

#### H.2 Structure and Content of an IHE Integration Statement

An IHE Integration Statement for a product shall include:

- 4. The Vendor Name
- 5. The Product Name (as used in the commercial context) to which the IHE Integration Statement applies.
- 6. The Product Version to which the IHE Integration Statement applies.
  - 7. A publication date and optionally a revision designation for the IHE Integration Statement.
  - 8. The following statement:
  - 9. "This product is intended to implement all transactions required in the IHE Technical Framework to support the IHE Integration Profiles, Actors and Options listed below:"

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10. A list of IHE Integration Profiles supported by the product and, for each Integration Profile, a list of IHE Actors supported. For each integration profile/actor combination one or more of the options defined in the IHE Technical Framework may also be stated. Profiles, Actors and Options shall use the names defined by the IHE Technical Framework Volume I. (Note: The vendor may also elect to indicate the version number of the Technical Framework referenced for each Integration Profile.)

Note that implementation of the integration profile presumes implementation of all required transactions for an actor; options include optional transactions or optional functions for required transactions.

- The statement shall also include references and/or internet links to the following information:
  - 1. The specific internet address (or universal resource locator [URL]) where the vendor's Integration Statements are posted
  - 2. The specific URL where the vendor's standards conformance statements (e.g., HL7, DICOM, etc.) relevant to the IHE transactions implemented by the product are posted.
  - 3. The URL of the IHE Initiative's web page for general information on IHE (www.rsna.org/IHE).
- 20 An IHE Integration Statement is not intended to promote or advertise aspects of a product not directly related to its implementation of IHE capabilities.

#### **1.2 Format of an IHE Integration Statement**

Each Integration Statement shall follow the format shown below. Vendors may add a cover page and any necessary additional information in accordance with their product documentation policies.

IHE Integration Statement								
Vendor	Version	Date						
Any Medical Systems Company	Enterprise Communicator	V3.5	12 Dec 2006					
This product implements all transactions in the IHE Technical Framework to support the IHE Integration Profiles, Actors, and Options listed below:								
Integration Profiles Implemented	Actors Implemented	Opt Impler						
Enterprise Communication of PCD Data	Device Observation Reporter	None						

#### IHE Patient Care Device Technical Framework, Vol. 2: Transactions

Filter PCD Data	Device Observa	ation Filter		None				
Patient Identification Association	NA	None						
Internet address for ve	Internet address for vendors IHE Information: http://www.anymedicalsystems.com/ihe							
Links to Standards Conformance Statements for the Implementation								
HL7	HL7 http://www.anymedicalsystems.com/hl7							
IEEE http://www.anymedicalsystems.com/hl7								
Links to general information on IHE								
In North America: http://www.rsna.org/IHE		In Europe: http://www.ihe-europe.org	In Japan: http://ww	w.ihe-j.org				

# **Appendix IDevice Content**

#### Glossary

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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.

20 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.

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

**DEC:** Device Enterprise Communication.

DOB: Date of Birth.

**DOC:** Device Observation Client.

**DOF:** Device Observation Filter.

30 **DOR:** Device Observation Reporter.

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/

10 **MDC:** Medical Device Communication

**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.
- 20

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

**Device Observation Reporter**: Actor responsible for mapping legacy and standards based PCD data to the IHE PCD message profile(s). Based upon ISO/IEEE 11073

PCD: Patient care device.

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

**RFC:** Request for comment. <u>http://www.rfc-editor.org/</u>

**RFID:** Radio frequency identification.

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

Scope: A brief description of the transaction.

- 30 **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.
- **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.
- 10 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/