Patient Care Device (PCD) Domain

Formed in 2005 to address Point-of-Care Medical Device integration issues
To enable “Out of the Box”, Reliable, “Functionally Interoperable” solutions
Utilizing IHE and PCD open Processes and open Standards
Technical Underpinnings
HL7 version 2.6 baseline, with profile specific drawing upon 2.7, 2.8, and 2.8.2
IEEE 11073 Standards
  10101 – Standardized Nomenclature
  10201 – Standardized Information Model
Wireless Communication Transfer Protocol (WCTP) version 1.3
IHE ITI domain Consistent Time (CT) profile – Network Time Protocol (NTP)

IHE PCD Co-sponsors
Patient Care Device (PCD) Domain

Focuses on devices associated with patients, including...
Patient monitors, vital signs monitors, pulse oximetry, ventilators, Infusion pumps, syringe pumps, PCA pumps, etc.

Collecting and reporting data from devices for immediate access and for retrospective storage and retrieval (EMR)

Harmonizing terminology – nomenclature, enumerations, units of measure

Getting alerts (alarms & advisories) to staff (clinicians, physicians, clinical engineers, IT, etc.) on local wireless, mobile, and desktop devices

Improving infusion order safety
Patient Care Device (PCD) Domain

Implantable Cardiac Device Observations

Waveform support in observations and alerts

Medical Equipment Management (MEM)

Medical Device Management Communication (DMC)

Point of Care Identity Management (PCIM)

Location Services (LS, RTLS)

System, Device, and Usage Cyber Security

For more information  http://www.ihe.net/Patient_Care_Devices
Patient Care Device (PCD) Domain

- Device to Enterprise Communication (DEC) profile
- Alert Communication Management (ACM) profile
- Point of care Infusion Verification (PIV) profile
- Infusion Pump Event Communications (IPEC) profile
- Implantable Device – Cardiac Observation (IDCO) profile
- Retrospective Data Query (RDQ) profile
- Medical Equipment Management (MEM)
  - Device Management Communication (MEMDMC) profile
  - Location Services (MEMLS) profile
- Rosetta Terminology Management (RTM)
- Waveform Content Module (WCM)
- Optimized Message Syntax (OMS)
- NIST Testing Tools
The DEC profile allows a consuming system (DOC) to receive patient clinical information including vitals, demographics, settings, and location from a reporting device/system (DOR).

The Subscribe to Patient Data (SPD) option allows the consumer to filter the data by:
- Medical Record #
- Device Class
- Update Interval
- Start & End Times
- Parameter Class
- Patient Location
Alert Communication Management (ACM)

HL7 Messages per ACM and WCM profiles

Parameters, waveforms, etc. as evidentiary data items

Device Specific graphics

Alert Reporter

Alert Manager

Disseminate Alert

Alert Communicator

Report Alert

Disseminate Alert Status

Report Alert Status

Disseminate Alert Status

Alert Information
Source, Phase, State, Priority
Patient Location Instance Alert text Callback Timestamp Evidentiary data

Dissemination Status
Instance Accepted by AC Undeliverable Delivered Read Accepted Rejected Cancelled Callback start/stop
Point of care Infusion Verification (PIV)

Physician’s Order

Medication

Physician’s
Order

Nurse
Review

Medication Administered

Pharmacist
Review

• Right Patient
• Right Medication
• Right Dose
• Right Time
• Right Route
• Right Device

BCMA to Pump (PCD-03)
Pump may provide data to EMR (PCD-01)
Infusion Pump Event Communication (IPEC)

Infusion Pump Event Communication enables reporting of clinical and operational events from an infusion pump to a Bedside Computer-assisted Medication Administration (BCMA) system or EMR. Clinicians can then view and validate this information for infusion documentation.

**BCMA/EMR**

Prior to medication administration, nurse confirms the 6 Rights of administration using BCMA/EMR:
- Right Patient
- Right Medication
- Right Dose
- Right Time
- Right Route
- Right Device

Infusion-related events are displayed, validated, and/or recorded by the clinician using the BCMA/EMR.

Infusion order sent from BCMA/EMR to Pump (PCD-03)

Pump provides information on infusion-related events to BCMA/EMR (PCD-10) such as:
- Delivery Start
- Delivery Stop
- Delivery Complete
Retrospective Data Query (RDQ)

Supports retrospective query of PCD data from databases. Supports Use Cases such as Clinical Decision Support, back-filling of EMR databases, etc.
Device Management (MEMDMC) & Location Services (MEMLS)

Profile based messages relay IV pump status including:
- Infusing
- Stopped

RTLS uses location to interpret asset status:
- Biomed (PM / Repair)
- CS (Cleaning)
- Clean Utility
- Patient Room (In Use)
- Dirty Utility

Combined data generates asset state:
- Available
- In Active Use
- Unavailable but Idle
- Unavailable (PM / Technical Assessment): Future based on CMMS Data

Drives workflow and analytics:
- Where can I find idle pumps to return to circulation and meet requests?
- How often are pumps sitting idle in patient rooms?
- What is my true utilization?
- Is the pump leaving the building running (with a patient) or idle (possible theft)?
- Do I have more inventory than I need? (And what is related maintenance cost? Replacement cost?)
Optimized Message Syntax (OMS)

Optimized Message Syntax is an effort to adapt IHE PCD profiles for devices that have slow legacy RS-232 serial ports. OMS will optimize the PCD messages to reduce their size but still maintain consistency with mainstream PCD messages.

OMS Messages

Bedside Computer

Data Collection System

EMR, CDSS, CIS, Etc.
NIST Testing Tools

Validation
- Test Management
- Test Services
- Test System Development Components

Test Harness
- Test Resources
- Test System Instance

Specification Constraints
- Standards Profile
- Domain Framework
- Terminology/Nomenclature
- Test Case/Value(s)

Based on Use Case(s)

Testable Assertions:
IHE-PCD Validation Requirements Used by NIST Test Tools

Report

Message E.g., HL7 V2

User / Device

Etc.
NIST Testing Tools

Services
- HL7 V2 Message Validation
- Report

Test Artifacts
- Conformance Profile
- HL7 Tables
- Device Test Agents
- ISO/IEEE 11073/Rosetta Terminology

Registry/Repository

Instance Test Environment
E.g., IHE-PCD Conformance Testing of an HL7 V2 IHE-PCD Message using a NIST Web Application Client

Isolated System Test Environment
E.g., IHE-PCD Functional Behavior Conformance Testing using a NIST Web Application Client and Test Agents

Test Management
- HL7 V2 Message Validation Test Case
- Results HL7 V2 Message Validation Report

Test Execution
- Test Harness (Java Code)
- Web Application Client

Services
- HL7 V2 Message Validation
- HL7 V2 Message Generation
- IHE-PCD DOC Test Agent
- IHE-PCD IOR Test Agent
- IHE-PCD DOC/DOR Test Agent
- IHE-PCD IOR Test Agent
- IHE-PCD AM Test Agent
- IHE-PCD AR Test Agent
- IHE-PCD IDCC Test Agent
- IHE-PCD AR Test Agent

Vendor

Test Management
- IHE-PCD Client Test Scenario
- Results HL7 V2 Message Validation Reports

Test Execution
- Test Harness (Java Code)
- Web Application Client

Router/Logger/Proxy

System Under Test
2017 Update

Document housekeeping and Change Proposals (CP) for several profiles
Update of PCD Technical Framework (PCDTF) for profiles at Final Text status
Publish of updated versions of some profiles at Trial Implementation status
Work with IEEE P1847 Working Group – Location Services for Healthcare
Point of Care Identity Management (PCIM) Whitepaper & Trial Implementation
Medical Equipment Management Remote Device Control (MEMRDC) Whitepaper
IEEE 11073 new version -10101(b) to include nomenclature for MEMDMC, MEMLS, alarms/alerts/events
Medical Equipment Management Remote Device Control (MEMRDC)

Focus
- Device Security, Patient Safety
- Data
  - Identification/Credentials (Requestor, Destination, Command)
  - Acknowledgements, Responses
  - Closed Loop (delivery confirmation, verification, completion)
- Integration
  - Identify contextual data to implement ease of use of human interfaces
- Initial Feasibility Demonstration
  - Focus on limited set of non-controversial use cases
  - Pause alert audio, Reset displayed infusion thus far, Unlock device panel

Requestor Initiates Request
- Communicate Identification, Credentials, Request

Remote Device Control Request (RDCRQ) PCD-17 → PCD-18 Remote Device Control Response (RDCRS)

Server Validates Request Performs Request
- Confirm Received, Validated, Performed
Point of Care Identity Management (PCIM)

Right Patient, Right Devices, Right Time
Every measurement to the right chart
Every measurement to a chart
Every patient affecting device command sent to the correct device

Purpose of PCIM Working Group is to discuss additional use cases, and means for recording events of devices becoming associated with patients, and means for systems to receive notifications of such events, as well as to query the state of patient-device associations.

Device-Patient Association Supplier

Device-Patient Association Query

Device-Patient Association Consumer

Device-Patient Associations have a beginning and an end
Discusses Device-Patient Association workflows
Discusses barcodes or RFID to assist in identifications of patients, devices, and staff
Supports fixed (ADT), mobile, and transient (spot-check) device associations
Utilizes HL7 v2.7 plus Participate (PRT) segment US FDA UDI extensions from v2.8.2
Utilizes ITI profiles Patient Administration Management (PAM) & Patient Encounter Management (PEM)
Single authoritative source for device-patient associations (Device-Patient Association Manager) recording associations from other systems (Device-Patient Association Reporters) and responding to association queries from other systems (Device-Patient Association Consumers)

Identifies the Device Registrant as system, device, or person identifying that a device may participate in an association
Identifies a Patient Registration System as a system that identifies patients that may participate in associations
Role of Device Vendors

Support the Mission of IHE PCD

Become an IHE member
Participate in PCD efforts
  Increased consistency and conformance – listen and be heard

Plant the Seed

Support IHE PCD Profile based Interoperability
Encourage active IHE participation by vendors

Request customers purchase IHE PCD compliant products
  Provide IHE Integration Statements
  Participate in Connectathons
  Promote browsing of Connectathon Results and Product Registry sites
  Participate in Interoperability Demonstrations (HIMSS and AAMI)
Role of Device Users

Support the Mission of IHE PCD

Become an IHE member
Participate in PCD efforts
  Increased consistency and conformance – listen and be heard

Plant the Seed
Encourage active IHE participation by users

Purchase IHE PCD compliant products
  Expect IHE Integration Statements from vendors
  Expect vendor participation in Connectathons as external verification
  Look for products in Connectathon Results and Product Registry sites
  Visit Live Interoperability Demonstrations (HIMSS and AAMI)
  Purchase commercially available PCD profile interoperable products
The IHE PCD domain maintains a listing of commercially available devices and systems which have passed IHE Connectathons for PCD profiles. The list is cooperatively maintained by IHE PCD, contributing vendors, and comments from end users. This is an ever changing list that is too long to be easily presented here in its entirety.

The most recent version can be found at

ftp://ftp.ihe.net/Patient_Care_Devices/Deployment/Commercially_Available_PCD_Systems/
Additional Resources

IHE PCD web site

www.ihe.net/pcd/index.cfm

IHE PCD Wiki

wiki.ihe.net/index.php?title=Patient_Care_Devices

Tool web sites

PCD Pre-Connectathon

http://ihe-pcd-precon.nist.gov/PCD-HL7WebPreCon/

PCD Connectathon

http://ihe-pcd-con.nist.gov/PCD-HL7WebCon/#home.htm

Rosetta Terminology

https://rtmms.nist.gov/rtmms/index.htm
Contacts

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- **IHE PCD** – [www.ihe.net/Patient_Care_Devices](http://www.ihe.net/Patient_Care_Devices)
- **Connectathon Results** – [http://connectathon-results.ihe.net](http://connectathon-results.ihe.net)
- **IHE PCD list of Commercially Available Devices and Systems**