

Medical Device – Enterprise System Communication Use Case Test Methods

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Medical Device – Enterprise System Communication

Test Methods

Release 1

Version 1.0

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Revision History

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1 Introduction

The Office of the National Coordinator for Health Information Technology (ONC) is at the forefront of HHS's health IT efforts and is a resource to the entire health system to support the adoption of health information technology and the promotion of nationwide health information exchange to improve health care.

The ConCert by HIMSS™ program is intended to compliment the ONC's efforts in this regard via the validation of HIT products against a set of standards, services and policies, aligned with the ONC CEHRT requirements whenever applicable, that helps enable secure health information exchange over the Internet. ConCert will provide a foundation for the exchange of health information across diverse entities, within communities and across the country, helping to achieve the goals of the HITECH Act. This critical part of the national health IT agenda will enable health information to follow the consumer, be available for clinical decision making, and support appropriate use of healthcare information beyond direct patient care so as to improve population health.

1.1 Purpose of this document

The purpose of this document is to provide specific guidance and clarifications to the conformity assessment testing procedures of the ConCert by HIMSS™ program. It must be used in conjuncture with the ConCert by HIMSS™ program document which provides the overall requirements schemes for the program and sets the context and applicability of these testing methods.

1.2 Definitions¹

- **Document types** are any clinical record(s) clinicians may choose to submit or retrieve for a specific patient such as: Continuity of Care Documents, Immunizations, Labs, Discharge Summary, etc.
- **Dual Factor Authentication** is a security constraint that requires two independent pieces of evidence to assert an entity's identification, easily summarized by "something one knows", "something one has", or "something one is". Examples of the three independent factors would be a password, an identification card, a fingerprint.
- **Statewide Master Patient Index (SMPI)** is master patient index stored at the state level.
- **Health Information Exchange (HIE)** is defined as the transfer of healthcare information electronically and securely across Health Information Organizations within a region such as a state, community, hospital system or a physician network.

¹ Individual actors are defined within each test procedure.

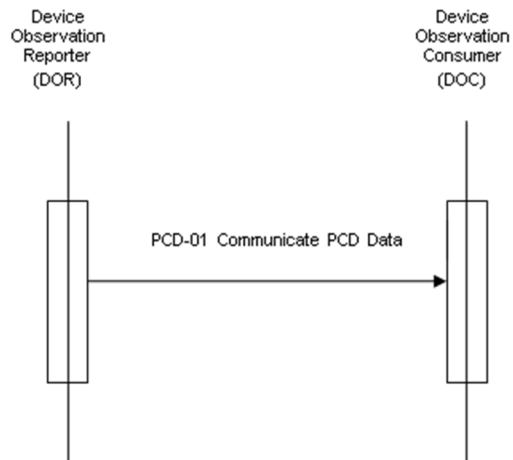
- **Health Information Organization (HIO)** is an organization that oversees and governs the exchange of health-related information among organizations according to nationally recognized standards. As defined by the National Alliance for Health Information Technology Report.
- **HIE Portal** is a Health Information Exchange Portal offered by an HIE vendor for their stakeholders to access health information.
- **IHE Cross Community Access (XCA)** is a profile that supports the means to query and retrieve patient relevant medical data held by other communities.
- **IHE Cross-Community Patient Discovery (XCPD)** is a profile that supports the means to locate communities that hold patient relevant health data and the translation of patient identifiers across communities holding the same patient's data.
- **Local Clinical Application** refers to a clinician's local clinical application such as an Electronic Health Record application, Hospital Information systems, Lab Information Systems, etc.
- **Patient Demographics Query (PDQ)** is a method that provides ways for multiple distributed applications to query a patient information server for a list of patients, based on user-defined search criteria, and retrieve a patient's demographic (and, optionally, visit or visit-related) information directly into the application.
- **Patient Identifier Cross-Reference (PIX)** is a method that provides cross-referencing of patient identifiers from multiple Patient Identifier Domains. These patient identifiers can then be used by identity consumer systems to correlate information about a single patient from sources that know the patient by different identifiers.
- **Patient Data Inquiry Service (PLS)** is a statewide patient record look-up service which consists of a SMPI and a statewide RLS to identify patients and their records across disparate health systems.
- **Record Locator Service (RLS)** is a registry of documents available at various HIOs. Allows end users to identify the documents available at various HIOs once a patient has been identified.

2 System Functions

2.1 System Functions

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

The following interaction diagram illustrates the implementation being tested.



3 Test Methods

The test methods specified in this section are based on the IHE Profile as specified in IHE PCD TF-1:3, section from Rev. 5.0 Final Text of this Technical Framework, issued October 14th 2015, without any additional Final Text Change Proposals.

The test methods are described in relation to the specific Test Actor designations called out in the above mentioned Technical Framework.

3.1 Device Observation Consumer Actor

3.1.1 List of test cases

Test Case ID	Test Case Name	Test Case Description	Test Case and Test Data with Version and Reference	Supporting Test Tool ID
DEC DOC POI SUT	DEC_DOR_D OC_POI_(DO C_SUT)	Evaluates the capability of a DEC DOC which supports POI to consume valid PCD-01 messages from a DOR and transmit the Accept ACKs.	Version : CATS2016 Last modified : 4/7/16 12:16:36 PM Permanent number : 12660	PCD Tool
DEC DOC SUT	DEC_DOR_D OC_(DOC_S UT)	Evaluates the capability of a DEC DOC to consume valid PCD-01 messages from a DOR and transmit the Accept ACKs.	Version : CATS2016 Last modified : 4/7/16 12:16:45 PM Permanent number : 12658	PCD Tool

3.1.2 List of related test tools

Test Tool ID	Test Tool Name	Test Tool Version	Developed by	Test Tool Info Page	Tool Category
PCD Tool	PCD HL7	1.6.2	NIST	http://ihe-pcd-precon.nist.gov/PCD-HL7WebPreCon/	Simulator & Validator

3.2 Device Observation Reporter Actor

3.2.1 List of test cases

Test Case ID	Test Case Name	Test Case Description	Test Case and Test Data with Version and Reference	Supporting Test Tool ID
DEC DOR POI SUT	DEC_DOR_DOC_POI(DOR_SUT)	Evaluates the capability of a DEC DOR which supports POI to transmit valid PCD-01 messages to a DOC and consume the Accept ACKs.	Version : CATS2016 Last modified : 4/7/16 12:16:53 PM Permanent number : 12659	PCD Tool
DEC DOR SUT	DEC_DOR_DOC_(DOR_SUT)	Evaluates the capability of a DEC DOR to transmit valid PCD-01 messages to a DOC and consume the Accept ACKs.	Version : CATS2016 Last modified : 4/7/16 12:17:01 PM Permanent number : 12657	PCD Tool

3.2.2 List of related test tools

Test Tool ID	Test Tool Name	Test Tool Version	Developed by	Test Tool Info Page	Tool Category
PCD Tool	PCD HL7	1.6.2	NIST	http://ihe-pcd-precon.nist.gov/PCD-HL7WebPreCon/	Simulator & Validator