ACC, HIMSS and RSNA

Integrating the Healthcare Enterprise

IHE Cardiology Technical Framework Supplement 2006-2007

Implantable Device Cardiac Observation Profile (IDCO)

Published for Trial Implementation

June 8, 2006

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1 Foreword

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

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

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) and the Radiological Society of North America (RSNA). IHE Canada has also been formed. IHE Europe (IHE-EUR) is supported by a large coalition of organizations including the European Association of Radiology (EAR) and European Congress of Radiologists (ECR), the Coordination Committee of the Radiological and Electromedical Industries (COCIR), Deutsche Röntgengesellschaft (DRG), the EuroPACS Association, Groupement pour la Modernisation du Système d'Information Hospitalier (GMSIH), Société Francaise de Radiologie (SFR), Società Italiana di Radiologia Medica (SIRM), the European Institute for health Records (EuroRec), and the European Society of Cardiology (ESC). In Japan IHE-J is sponsored by the Ministry of Economy, Trade, and Industry (METI); the Ministry of Health, Labor, and Welfare; and MEDIS-DC; cooperating organizations include the Japan Industries Association of Radiological Systems (JIRA), the Japan Association of Healthcare Information Systems Industry (JAHIS), Japan 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, Laboratory, Radiology, etc.) defines specific implementations of established standards to achieve integration goals that promote appropriate sharing of medical information to support optimal patient care. It is expanded annually, after a period of public review, and maintained regularly through the identification and correction of errata. The current version for these Technical Frameworks may be found at www.ihe.net/Technical_Framework.

The IHE Technical Framework identifies a subset of the functional components of the healthcare enterprise, called IHE Actors, and specifies their interactions in terms of a set of coordinated, standards-based transactions. It describes this body of transactions in progressively greater depth. The volume I provides a high-level view of IHE functionality, showing the transactions organized into functional units called Integration Profiles that highlight their capacity to address specific clinical needs. The subsequent volumes provide detailed technical descriptions of each IHE transaction.

This supplement to the IHE Cardiology Technical Framework v2 is submitted for Trial Implementation through March 2007.

Comments arising from Trial Implementation should be submitted to:

http://forums.rsna.org

Under the "*IHE*" forum, select the "*IHE Cardiology Technical Framework Supplements 2006*" sub-forum.

The IHE Cardiology Technical Committee will address these comments and expects to publish the Final Text version in June 2007.

2 Introduction

This Supplement adds a new profile to the IHE Cardiology Technical Framework describing a means to transfer information from an interrogated implantable cardiac device to information management systems.

Cardiac electrophysiologists follow patients with implantable cardiac devices from multiple vendors. These devices are categorized as pacemakers, implantable cardioverter defibrillators, and cardiac resynchronization therapy devices. As part of patient follow-up an interrogation of a cardiac device is performed (either in-clinic or remotely from a patient's residence). Information is collected about the device such as device identification, therapy settings, device diagnostics, and device testing. These interrogations are performed by vendor proprietary equipment.

To improve workflow efficiencies Cardiology and Electro Physiology practices require the management of "key" summary implantable rhythm control device interrogation information in a central system such as an EHR or a device clinic management system.

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

2.1 Choice of Standards

The content of Implantable Device Cardiac Observation information has been standardized in HL7 v3 Therapeutic Devices Domain / Implantable Cardiac Device Topic / Implantable Cardiac Device Summary message. That message uses a highly structured XML-based format based on the HL7 Reference Information Model (RIM), and specifies use of the IEEE 1073 Nomenclature for Point-of-care Medical Device Communication – Implantable Device, Cardiac. That message provides the defined content structure for the observation message of this profile.

However, the HL7 v3 message transport infrastructure is not broadly implemented, and is unlikely to be broadly implemented in the next few years. Because HL7 v2.x is the widely supported version, this profile specifies conveying the v3 content as Encapsulated Data in a v2.x ORU (unsolicited observation) message. When v3 message transport infrastructures become available, it will be a relatively simple matter to replace the v2 message transport with a v3 transport; since the content is already in the v3 format, minimal changes to the application processing of the message would be needed.

Also, the IEEE 1073 Nomenclature for Point-of-care Medical Device Communication – Implantable Device, Cardiac is currently in the process of being balloted. The schema and structure of the version of the nomenclature for use with this profile is available on the IHE website at http://www.ihe.net/Technical_Framework/index.cfm#cardiology.

2.2 Open Issues and Questions

None

2.3 Closed Issues

1. Scheduling is not within scope of this profile for year 1.
2. How do we integrate the IDCO actors into the EP Workflow? This is a future issue.
3. IEEE 1073.1.1.3 ICD Terms is currently being prepared for ballot. Final specifications are not currently available for inclusion in the profile but will be referenced from the IHE site. Specifications going to ballot should be available for reference by early July.
4. This profile mandates the use of PIX for cross-referencing device identifiers to patients. Should PDQ also be referenced as another option for resolving patient IDs or should the methods of resolution be open to implementations (i.e. not specify PIX or PDQ)? No. PDQ is not appropriate for this profile. PDQ would require a query for every message received.
5. This profile mandates the use of PAM to update patient demographics in the observations stored in the Observation Repository. Is this necessary and appropriate for this profile? Yes.

6. This profile does not require the use of ATNA. There are several implementation models for this profile that do not require transmission of data over public networks including intra-institutional, VPN, etc. However, when public networks are used, ATNA is one option for secure transport over those networks. Should ATNA be required? ATNA should be required for remote follow-ups. Referencing ATNA makes defining security for the profile easy.
7. This profile specifies an HL7 Message Router actor to distribute observations to multiple recipients in an institution. Is the HL7 Message Router actor needed? What value does the HL7 Message Router actor add to the integration profile? Should the HL7 Message Router provide the PIX consumer actor to match incoming observations with local patient identifiers? The HL7 Message Router provides an approach for getting the integration engine vendors directly involved in the IHE process. The HL7 Message Router will continue to be used. The HL7 Message Router will be grouped with PIX consumer as to provide patient identification reconciliation. With this grouping the HL7 Message Router provides a service beyond pass-through routing.
8. Patient Identity Feeds are assumed to be part of the patient / device registration process, which will be required before an Observation Repository / Processor can receive CARD-12 transactions. This profile does not specify the Patient Identity Feed transaction. If PIX is used, should the PIX Identity Source actor be specified for registration of the device with the patient? Should it be grouped with the Observation Creator / Processor / Repository? No. The Observation Creator is not positioned to participate in PIX at this time. This is a possibility for future versions of the profile.

Changes to Volume I – Integration Profiles

Add to Section 1.7

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

Add to Section 2.1

Table 2-1 Integration Profile Dependencies

Integration Profile	Depends On	Dependency Type	Comments
IDCO	ITI-TF PIX Profile	The HL7 Message Router, Observation Processor, and Observation Repository are required to be grouped with the Patient Identifier Cross-Reference Consumer actor.	
	ITI-TF PAM Profile	The Observation Repository is required to be grouped with the Patient Demographic Consumer Actor.	

Add to Section 2.2

2.2.x Implantable Device Cardiac Observation Profile

The Implantable Device Cardiac Observation Integration Profile defines a mechanism for the creation, transmission, and processing of discrete data elements and report attachments associated with cardiac device interrogations (observations). It supports the uses cases for in-clinic and remote implanted cardiac device follow-ups.

Add to Section 2.3

Observation Creator - A system that creates and transmits diagnostic or therapeutic observational data.

Observation Processor - A system that receives clinical observations and further processes them for inclusion within derivative products, such as clinical reports, databases, or transcoded/reformatted results.

Observation Repository - A system that receives clinical observations and stores them for subsequent retrieval and display. The Observation Repository updates stored data with updated demographics through out the lifecycle of the data.

HL7 Message Router – A system that receives HL7 messages, routes them to one or more configured actors, and handles transport level acknowledgements. The HL7 Message Router may also provide modification of the messages in accordance with specific profiles.

Integration Profile / Actor	CATH	ECHO	ECG	ED	IDCO
Acquisition Modality	X	X		X	
ADT Patient Registration	X	X			
Department System Scheduler/Order Filler	X	X			
Evidence Creator	X	X		X	
Image Archive	X	X		X	
Image Display	X	X		X	
Image Manager	X	X		X	
Order Placer	X	X			
Performed Procedure Step Manager	X	X			
Report Creator				X	
Time Client	(note 1)				
Display			X		
Information Source			X		
Observation Creator					**X**
Observation Repository					**X**
Observation Processor					**X**
HL7 Message Router					**X**

Add to Section 2.4

Send Observations – Observations, measurements, or reports, are sent using an HL7 Observations message. [CARD-12]

Integration Profile / Transaction	CATH	ECHO	ECG	ED	IDCO
Patient Registration [RAD-1]	X	X			
Placer Order Management [RAD-2]	X	X			

Integration Profile / Transaction	CATH	ECHO	ECG	ED	IDCO
Filler Order Management [RAD-3]	X	X			
Procedure Scheduled [RAD-4]	X	X			
Query Modality Worklist [RAD-5]	X	X			
Modality Procedure Step In Progress [CARD-1]	X	X			
Modality Procedure Step Completed [RAD-7]	X	X			
Modality Images/Evidence Stored [CARD-2]	X	X		X	
Storage Commitment [CARD-3]	X	X		X	
Patient Update [RAD-12]	X	X			
Procedure Update [RAD-13]	X	X			
Query Images [RAD-14]	X	X			
Query Evidence Documents [RAD-44]				X	
Retrieve Images/Evidence [CARD-4]	X	X			
Instance Availability Notification [RAD-49]	X	X			
Maintain Time [ITI-1]	(note 1)				
Retrieve Specific Info for Display [ITI-11]			X		
Retrieve ECG List [CARD-5]			X		
Retrieve ECG Document for Display [CARD-6]			X		
Send Observations [CARD-12]					**X**
Patient Identity Query [ITI-9]					**(note 2)**
Patient Identity Feed [ITI-30]					**(note 2)**

Notes: 1. The Maintain Time transaction is not formally part of the Cath Workflow Profile, but it is required for the Time Client actor grouped with certain actors in that Profile.

2. The Patient Identity Query and Patient Identity Feed transactions are not formally part of the Implantable Device Cardiac Observations Profile, but are required for the PIX Consumer and Patient Demographics Consumer actors grouped with certain actors in that Profile.

Add to Section 2.5

- The HL7 Message Router actor participating in the IDCO Profile shall be grouped with the Patient Identity Cross-Reference Consumer actor of the PIX Profile (ITI-TF).
- The Observation Processor actor participating in the IDCO Profile shall be grouped with the Patient Identity Cross-Reference Consumer actor of the PIX Profile (ITI-TF) when the PIX-based Reconciliation Option is supported.
- The Observation Repository actor participating in the IDCO Profile shall be grouped with the Patient Identity Cross-Reference Consumer actor of the PIX Profile (ITI-TF), and with the Patient Demographics Consumer actor of the PAM Profile (ITI-TF).

Add the following new profile section

9 Implantable Device Cardiac Observation Profile (IDCO)

Cardiac electrophysiologists follow patients with implantable cardiac devices from multiple vendors. These devices are categorized as pacemakers, implantable cardioverter defibrillators, and cardiac resynchronization therapy devices. As part of patient follow-up an interrogation of a cardiac device is performed (either in-clinic or remotely from a patient's residence). Information is collected about the device such as device identification, therapy settings, device diagnostics, and device testing. These interrogations are performed by vendor proprietary equipment.

To improve workflow efficiencies Cardiology and Electro Physiology practices require the management of "key" summary implantable rhythm control device interrogation information in a central system such as an EHR or a device clinic management system.

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

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

9.1 Actors/ Transactions

Figures 9.1-1 and 9.1-2 show the actors and transactions directly involved in the IDCO Integration Profile with bold and with solid lines. Grouped actors are shown italicized and with dotted lines. Other actors and transactions that may be indirectly involved because of their participation in associated IHE Integration Profiles are not shown.

Note: See Appendix I for examples of grouping IDCO actors with actors of other Profiles.

Figure 9.1-1 shows a full configuration where the Observation Creator sends a CARD-12 transaction via an HL7 Message Router to an Observation Processor or Observation Repository. Figure 9.1-2 shows an alternate configuration where the Observation Creator sends the CARD-12 transaction directly to the Observation Processor and Observation Repository actors.

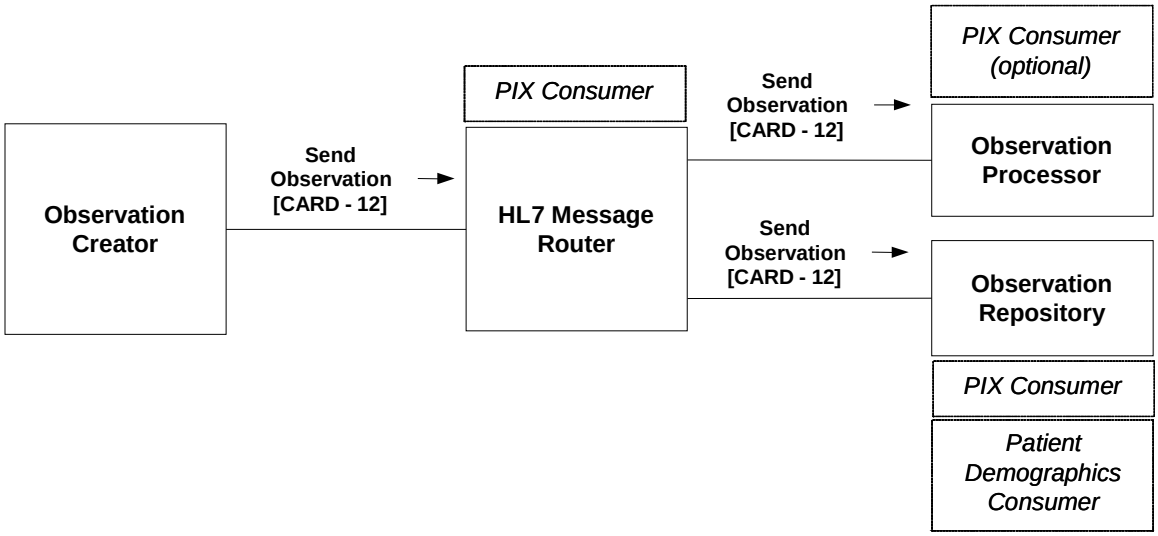


Figure 9.1-1. IDCO Actor Diagram

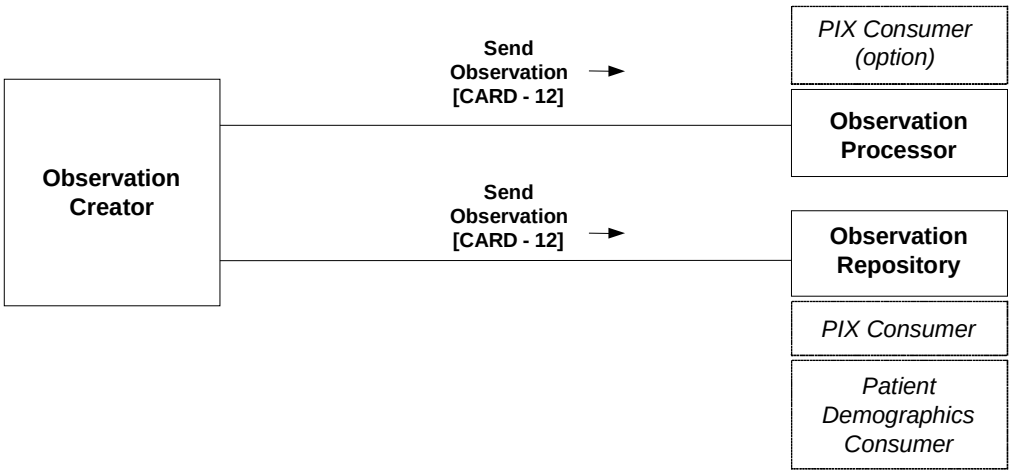


Figure 9.1-2. IDCO Actor Diagram (Alternate Configuration)

See section 9.5 Patient Identification for details concerning the grouped PIX Consumer and Patient Demographics Consumer actors.

Table 9.1-1 lists the transactions for each actor directly involved in the IDCO Profile. In order to claim support of this Integration Profile, an implementation must perform the required transactions (labeled "R"). Transactions labeled "O" are optional. A complete list of options defined by this Integration Profile that implementations may choose to support are listed in the appropriate actor profile; as specified in the Section column in the table defined below.

Table 9.1-1. Implantable Device Cardiac Observation Integration Profile - Actors and Transactions

Actors	Transactions	Optionality	Section in Vol. 2
Observation Creator	Send Observations [CARD-12]	R	CARD-TF 2: 4.12
HL7 Message Router	Send Observations [CARD-12]	R	CARD-TF 2: 4.12
Observation Repository	Send Observations [CARD-12]	R	CARD-TF 2: 4.12
Observation Processor	Send Observations [CARD-12]	R	CARD-TF 2: 4.12

9.2 IDCO Integration Profile Options

Many Actors have Options defined in order to accommodate variations in use across domains or implementations. Options that may be selected for this Integration Profile are listed in the table 9.2-1 along with the Actors to which they apply.

Table 9.2-1: IDCO - Actors and Options

Actor	Option Name	Vol & Section
Observation Creator	*None*	
Observation Repository	*None*	
Observation Processor	PIX-based Reconciliation	CARD-TF 2: 4.12.5.2.7
HL7 Message Router	*None*	

9.2.1 PIX-based Reconciliation Option

The Observation Processor is required to reconcile the Patient ID from the Observation Creator with the Patient ID used in the local domain (see Section 9.5). Observation Processor claiming this PIX-based Reconciliation Option shall be grouped with the Patient Identifier Cross-Reference Consumer actor of the IHE Patient Identifier Cross-Referencing Profile (PIX) to perform the ID mapping.

9.3 IDCO Use Cases

9.3.1 Use Case I1: Implantable Cardiac Device In-Clinic Followup

Note: This use case is identical to HL7 v3 Implantable Cardiac Device Follow-Up Storyboard (POTD_ST000001).

Clinical Context:

Adam Everyman presents at the electrophysiology (EP) follow-up clinic for his appointment. Adam will present for follow-up 7-10 days after implant and every 3-6 months thereafter, depending on the therapy protocol.

Dr. Ed Electrode, an Electrophysiologist - also referred to as a following physician, and Nancy Nightingale, an R.N., work in the electrophysiology (EP) follow-up clinic.

Note: In the area of Electrophysiology, a "programmer" is a commonly used term to describe a specialized computer that is capable of communicating with an implanted device. Programmers are used to interrogate implanted devices and "program", or make changes to, implanted cardiac device settings.

Nancy interrogates the device using the programmer and extracts the data (e.g., settings, status, events) from the device. Nancy reviews the device data and captures the "current state" device data from the programmer screen and/or prints out the settings and/or uses an information transfer mechanism (e.g., floppy disk, analog cable, etc.) to transmit device data, which is in a proprietary format, to a translator system.

If the device data has been sent to the translator system, the clinician may desire to transmit data to an electronic health record system (EHR) or device clinic management system. In this case, a necessary subset (pre-determined by the clinic and the entity responsible for the translator system) of the data that represents the device's 'summary data' is converted from the proprietary format and transmitted using HL7 messaging to the EP office EHR or device clinic management system.

Dr. Ed Electrode reviews the device data and identifies appropriate changes to device settings. Nancy Nightingale makes these changes via the programmer. Nancy then captures the "final state" device data. Nancy then uses the information transfer mechanism to transmit device data, which is in a proprietary format, to a translator system, which again converts the data into an HL7 message and communicates the 'summary data' to the clinic's EHR or device clinic management system. This second message will utilize the same HL7 message format as the first.

These summary reports are sent as unsolicited observation events.

For example a device summary could contain the following items:

Device Diagnostics

Events Counters

Device Observations

Programmed Therapy Settings

Clinician Comments

Note: Electrocardiograms are not currently addressed in the HL7 standards. They can be sent as a PDF attachment to the HL7 message.

IHE Context:

In the use case the translator system equates to the Observation Creator actor and the EHR or device clinic management system equates to the HL7 Message Router / Observation Processor / Observation Repository actors. The HL7 formatted implanted cardiac device interrogation message is the CARD-12 transaction.

9.3.2 Use Case I2: Implantable Cardiac Device In-Clinic Followup with Networked Programmer that Translates Information

Clinical Context:

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

IHE Context:

Same as in-clinic use case above with the following change. The programmer assumes the role the actor Observation Creator.

9.3.3 Use Case I3: Implantable Cardiac Device Remote Followup

Clinical Context:

Portions of the previous use case also apply to Adam Everyman having his device followed remotely. Adam will present to an interrogation device located outside of the clinic (e.g., in Adam's residence) which will capture the state of his implanted device and will transmit the information to a translator system. The translator system converts the data into an HL7 message and communicates the 'summary data' to the clinic's EHR.

IHE Context:

Same as in-clinic use case above. The Observation Creator, Processor, and Repository actors should be grouped with the Secure Node actor of the ATNA Profile to secure communications for remote follow-ups if data is sent across an un-trusted network.

9.3.4 Use Case I4: Third Party Value-Added Services

Clinical Context:

The translator system described in use cases I1 and I2 may be implemented as a service of a third party, e.g., the device manufacturer or a monitoring service. This system may provide various types of value-added services, such as data aggregation and analysis, trending, and statistical reports. Such additional data may be appended to the standard device observation 'summary data' message sent to the recipient system.

IHE Context:

Same as in-clinic use case above. The additional data aggregation or rendering can be sent as a PDF attachment to the HL7 message.

These types of value-added services are likely to be provided by a party that will send the results over the Internet. In this case, use of the ATNA profile on the link between the Observation Creator and the HL7 Message Router is recommended.

9.4 IDCO Process Flow

The IDCO Profile defines a transaction to support the exchange of unsolicited observations created during an Implantable Device Cardiac Observation. The two basic process flows for the IDCO profile is shown in Figures 9.4-1 and 9.4-2, and are described below.

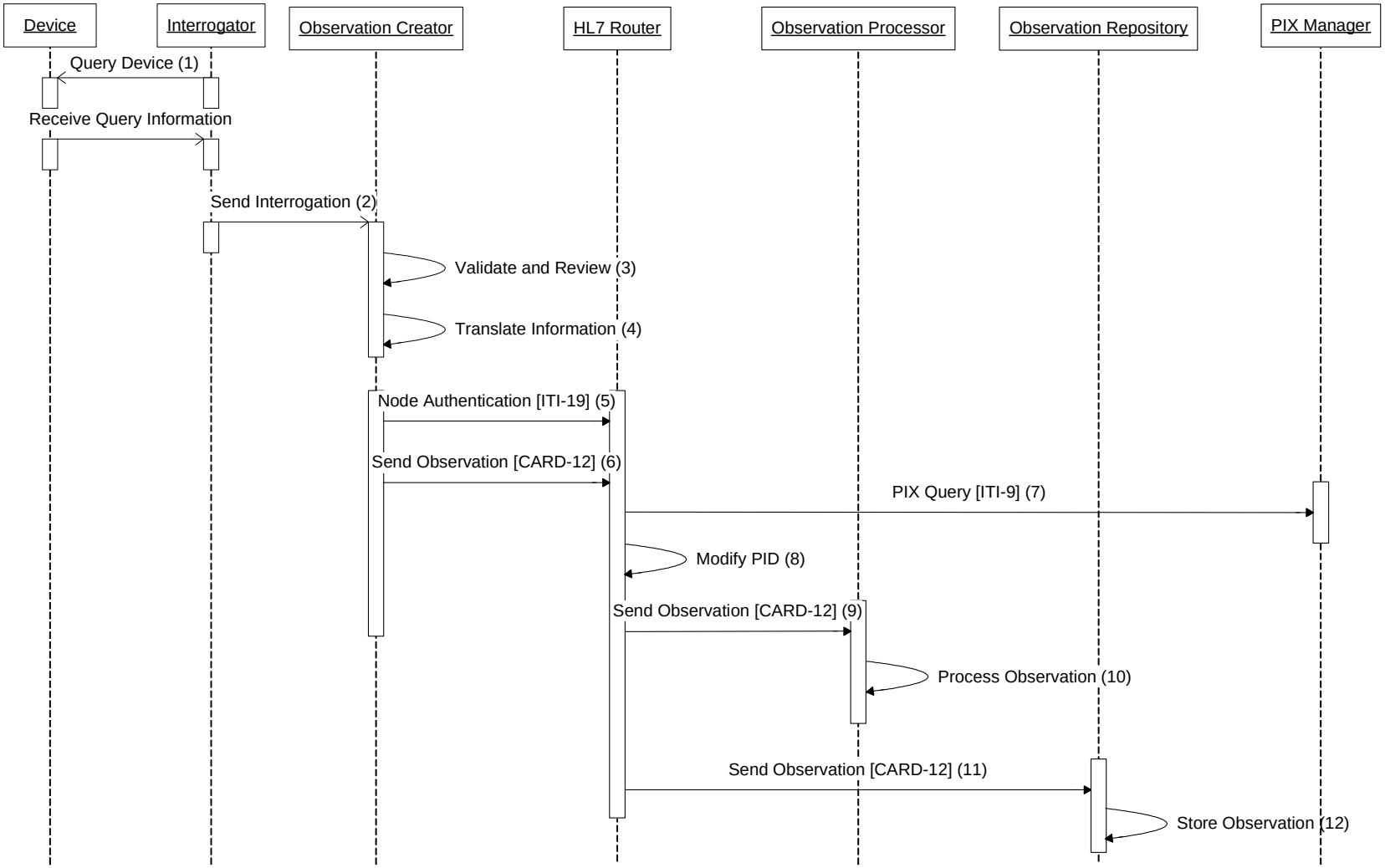


Figure 9.4-1. Basic Process Flow in IDCO Profile with HL7 Message Router and Secured Connection

Note: Device and Interrogator actors and associated transactions are outside the scope of this profile.

Process Flow Steps for Figure 9.4-1

1) Query Device - The implanted cardiac Device is interrogated in a manufacturer-proprietary manner by the Interrogator
2) Send Interrogation – The Interrogator sends information in a manufacturer-proprietary manner to the Observation Creator.
3) Validate and Review – The Observation Creator validates the information. This may include the clinician reviewing and approving the information.
4) Translate Information – The Observation Creator translates the information into the proper HL7 format.
5) Node Authentication – Security is required for transactions that traverse un-trusted networks. The ATNA Secure Node actor should be grouped with the Observation Creator and HL7 Message Router actors in these situations. The Observation Creator is authenticated by the HL7 Message Router using the ATNA Node Authentication [ITI-9] transaction. A secured network connection must be established between the secured nodes as defined by the ATNA Encryption Option.
6) Send Observation – The Observation Creator sends the device information to the HL7 Message Router using the CARD-12 transaction.
7) PIX Query – The HL7 Message Router matches the Patient ID provided by the Observation Creator to the internal Patient ID within the clinic domain using the PIX Query ITI-9 transaction.

   Note that the patient identifier used in the HL7 observation message is not the ID used by the receiving system. The interrogation system will have no knowledge of patient ID other than the serial number of the device; since the device is implanted into only one patient, it can serve as a type of patient ID. In this case, the "assigning authority" for the ID is the device manufacturer. The ID will be a combination of the manufacturer, model number, and serial number of the device. See section 9.5 for details concerning Patient ID reconciliation.
8) Modify PID – The HL7 Message Router modifies the PID segment of the CARD-12 transaction supplying the appropriate Patient ID.
9) Send Transaction – The HL7 Message Router sends the device information to the Observation Processor using the CARD-12 transaction.
10) Process Observation – The Observation Processor further processes the observation message for inclusion within derivative products, such as clinical reports, databases, or trans-coded / reformatted results.

11) Send Transaction – The HL7 Message Router sends the device information to the Observation Repository using the CARD-12 transaction.

12) Store Observation – The Observation Repository provides long-term storage of the observation, and makes it available through mechanisms beyond the scope of this profile.

    The Observation Repository must manage patient demographic updates for the life of the data. It uses the PAM Profile to interact with the Patient Demographics Source to perform this function (actors not shown on model).

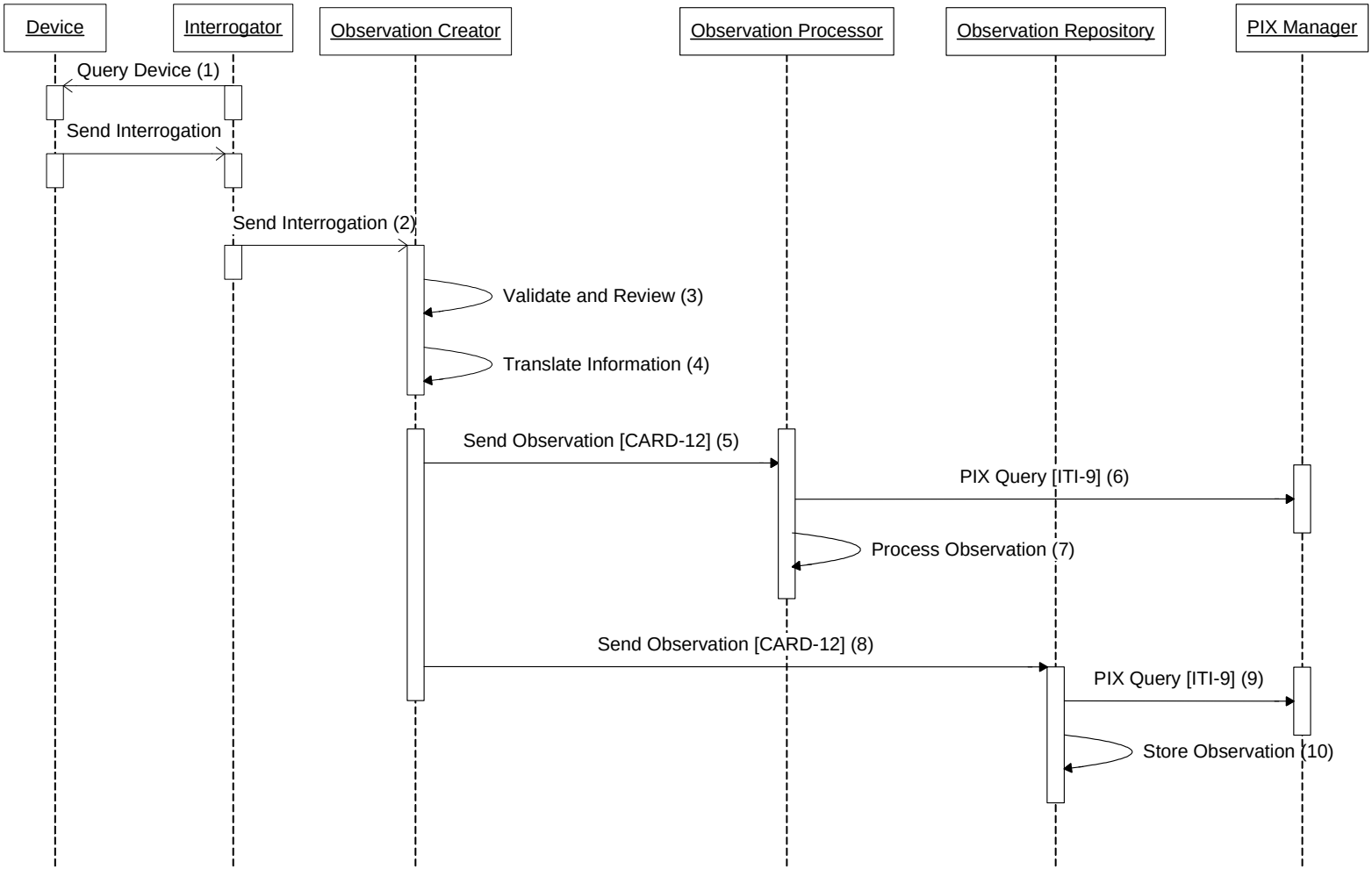


Figure 9.4-2. Basic Process Flow in IDCO Profile with No HL7 Message Router

Process Flow Steps for Figure 9.4-2

1) Query Device - The implanted cardiac Device is interrogated in a manufacturer-proprietary manner by the Interrogator
2) Send Interrogation – The Interrogator sends information in a manufacturer-proprietary manner to the Observation Creator.
3) Validate and Review – The Observation Creator validates the information. This may include the clinician reviewing and approving the information.
4) Translate Information – The Observation Creator translates the information into the proper HL7 format.
5) Send Observation – The Observation Creator sends the device information to the Observation Processor using the CARD-12 transaction.
6) PIX Query – The Observation Processor matches the Patient ID provided by the Observation Creator to the internal Patient ID within the clinic domain. It may do this using an implementation-specific ID mapping mechanism, or if it claims the PIX-based Reconciliation Option it will use the PIX Query ITI-9 transaction.
7) Process Observation – The Observation Processor further processes the observation message for inclusion within derivative products, such as clinical reports, databases, or trans-coded / reformatted results.
8) Send Transaction – The Observation Creator sends the device information to the Observation Repository using the CARD-12 transaction.
9) PIX Query – The Observation Repository matches the Patient ID provided by the Observation Creator to the internal Patient ID within the clinic domain using the PIX Query ITI-9 transaction.
10) Store Observation – The Observation Repository provides long-term storage of the observation, and makes it available through mechanisms beyond the scope of this profile.

    The Observation Repository must manage patient demographic updates for the life of the data. It uses the PAM Profile to interact with the Patient Demographics Source to perform this function (actors not shown on model).

9.5 Patient Identification

This profile specifies two actors, the Observation Repository and the Observation Processor, that are the endpoints for observation messages. These actors must cross-reference patient identifiers across the two Patient Identifier Domains: the device vendor systems providing the observations and the clinics receiving the observations.

IHE specifies the Patient Identifier Cross-Referencing Profile (PIX) as the mechanism to obtain such cross-references from a central server (the PIX Manager). The IDCO profile uses the PIX Query (ITI-9) transaction for its actors to obtain cross-referencing information. The PIX Consumer actor is grouped with the HL7 Message Router, the Observation Repository, and optionally the Observation Processor. The PIX Manager actor is not specified within this profile but is assumed to exist.

The Observation Processor may use an implementation-specific ID mapping mechanism, rather than the PIX transaction. However, the HL7 Message Router and the Observation Repository must use the PIX mechanism.

It is assumed that a Patient Identity Feed (ITI-8) transaction, or the equivalent, will occur to register the cross-referencing of the device identity with the identity of the patient having the device. The identity feed can be manual or automatic per existing patient registration policies and procedures. Configuration of the PIX Manager for matching the device identifier with the patient record is considered out-of-scope for this profile.

The PIX Consumer actor will pass to the PIX Manager the patient identifier as specified in the Send Observation (CARD-12) specification. The identifier is the concatenation of the device model number and device serial number. The identifier assigning authority is the device manufacturer. The PIX Manager returns the local patient identifier.

An alternate configuration has the HL7 Message Router actor grouped with the PIX Consumer actor. In this case the HL7 Message Router will be responsible for obtaining patient identification cross-referencing information and modifying the CARD-12 transaction appropriately. In this configuration, the Observation Repository and Observation Processor will recognize that the assigning authority for the Patient ID in the received observation matches the local domain, and will therefore not need to perform reconciliation.

The PAM Patient Demographics Consumer actor is grouped with the Observation Repository to provide support for the Patient Identity Feed (ITI-30) transaction to keep the patient demographics data up to date.

Refer to the PIX and PAM profiles within the IHE IT Infrastructure Technical Framework for more information.

Add to Appendix D Glossary

Implantable Device Cardiac (IDC): Implantable medical devices that treat heart rhythm problems. These devices are categorized as pacemakers, implantable cardioverter defibrillators, cardiac resynchronization therapy devices, and implantable monitors.

Add new Sections to Appendix H

H.5 Patient Identifier Cross-referencing Integration Profile (PIX)

The full specification of the Patient Identifier Cross-referencing Integration Profile (PIX) Integration Profile is found in **ITI-TF 1:5**.

The ***Patient Identifier Cross-referencing Integration Profile (PIX)*** is targeted at healthcare enterprises of a broad range of sizes (hospital, a clinic, a physician office, etc.). It supports the cross-referencing of patient identifiers from multiple Patient Identifier Domains via the following interactions:

- The transmission of patient identity information from an identity source to the Patient Identifier Cross-reference Manager.
- The ability to access the list(s) of cross-referenced patient identifiers either via a query/ response or via update notification.

Figure H.5-1 shows the actors and involved in this Profile and the transactions between actors.

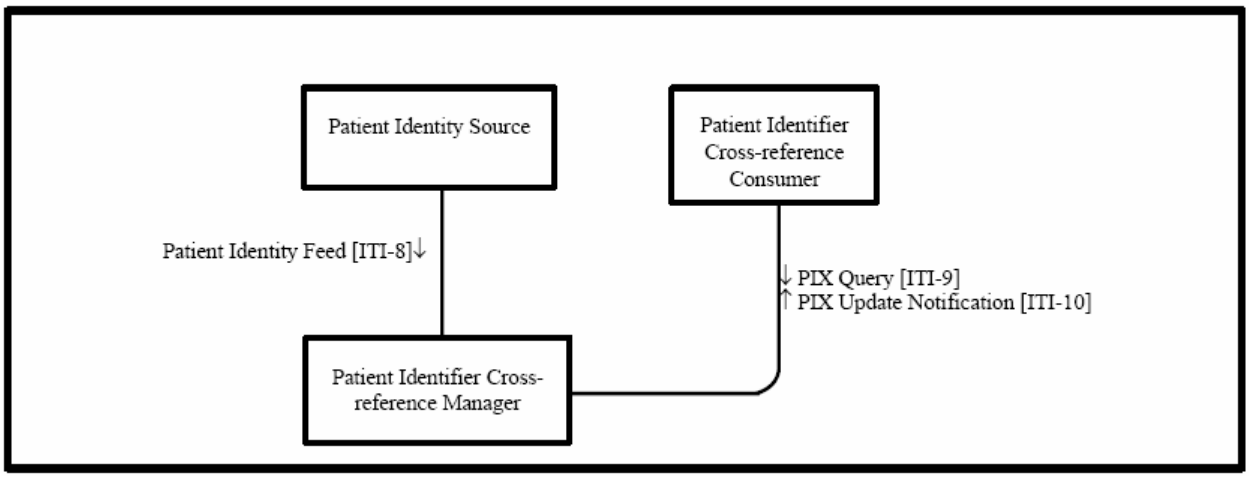


Figure H.5-1 PIX Actors and Transactions

H.5.1 Cardiology Use Case

Cardiology patients are typically seen and treated in a variety of institutional contexts, each of which may have its own Patient Identifier Domain. For effective patient care, it is required that patient identifiers across Patient Identifier Domains be cross-referenced so that patient records containing clinical observations from one context can be matched to medical records in another context.

One specific use case is the mapping of the patient identifier from an implanted cardiac device observation to the identifier used in an electronic medical record system. Certain actors within the IDCO Profile (see section 9) are required to participate in the PIX profile to support this mapping.

H.6 Audit Trail and Node Authentication (ATNA)

The full specification of the Audit Trail and Node Authentication (ATNA) Integration Profile is found in **ITI-TF 1:9**.

The Audit Trail and Node Authentication (ATNA) Integration Profile establishes security measures which, together with the Security Policy and Procedures of the enterprise, provide patient information confidentiality, data integrity and user accountability. The goals of the Audit Trail and Node Authentication Integration Profile are:

- Access and authentication controls that prevent unauthorized access to information
- Integrity controls that safeguard the integrity and reliability of protected health information
- Accountability controls that provide user accountability through audit record generation and a centralized audit repository

Figure H.6-1 shows the actors and involved in this Profile and the transactions between actors.

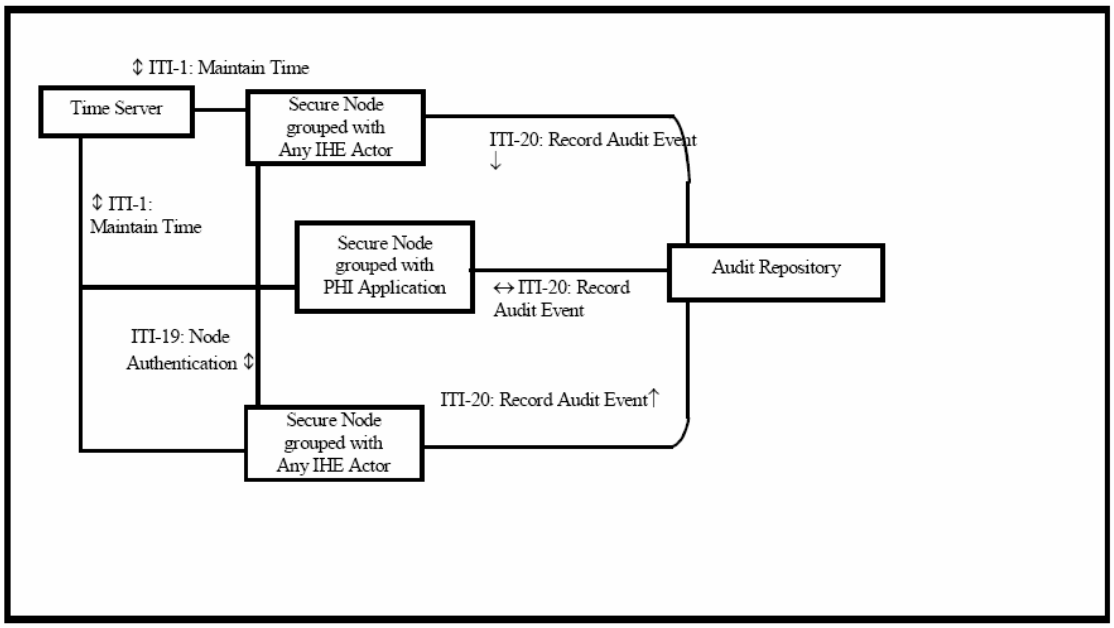


Figure H.6-1 ATNA Actors and Transactions

H.6.1 Cardiology Use Case

Cardiology patients are typically seen and treated in a variety of institutional contexts, whose information systems are often in different security domains connected by public data communications networks (the Internet). For effective patient care, data must be transported across those networks, and it is required that network transmissions of protected health information across un-trusted networks be appropriately secured. Certain actors of the XDS profile are required to participate in the ATNA profile, and actors of the IDCO profile may also use ATNA when such transport across public networks is required.

Add New Appendix

Appendix I: Observation Processors and Repositories - Extended Workflow Actor Groupings

The IDCO profile specifies two actors, the Observation Repository and the Observation Processor, that are endpoints for observation messages within the defined workflow, but which are actually transition points to other use of the observation data in other workflows. This section describes some of the use cases for these actors.

I.1 Basic IDCO Report Display using Retrieve Information for Display Profile (RID)

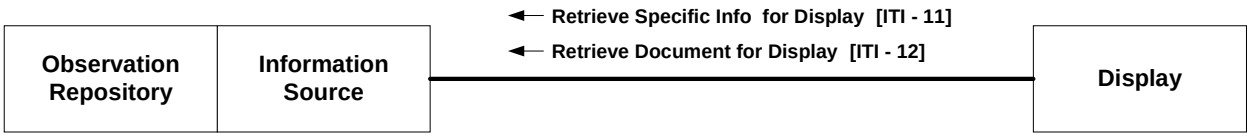


Figure I.1-1 Extended Actor Groupings - RID

The Observation Repository actor may be grouped with the Information Source actor of the Retrieve Information for Display (RID) Profile. The full specification of the Retrieve Information for Display Profile is found in **ITI-TF 1:3**; a summary is included in Appendix H.3 of this document (CARD-TF 1:H.3).

With this grouping, the system would store received observations, perhaps providing some aggregating function (e.g., managing replacement of individual observations with later results), and serving the data in a ready-for-display format in response to a RID query transaction.

As an Observation Repository, the system is also required to be grouped with the Patient Demographics Consumer actor, and thus to support update of patient demographic data in the stored observations.

I.2 IDCO Data Incorporation into a Report using Displayable Reports Profile (DRPT)

Figure I.2-1 Extended Actor Groupings - DRPT

The Observation Processor actor may be grouped with the Report Creator actor of the Displayable Reports (DRPT) Profile.

With this grouping, the system would receive observations and provide a mechanism to create a report, perhaps combining the observations from several devices (e.g., implanted device observations with electrophysiology lab evidence).

As a Report Creator, the created report would be forwarded to a Report Manager for signature and distribution.

I.3 IDCO Discrete Data Storage using Evidence Documents Profile (ED)

Figure I.3-1 Extended Actor Groupings - ED

The Observation Processor actor may be grouped with the Evidence Creator actor of the Evidence Documents (ED) Profile.

Such a system would be able to generate Evidence Documents (DICOM Structured Reports) based on content in the Observation message. If the Observation comes from within the context of an implant procedure, e.g., the record of the initial device settings, the derived evidence document would be linked to the other images and evidence of the implant procedure via the Study Instance UID.

I.4 IDCO Submission to an EHR using Cross Domain Document Sharing Profile (XDS)

Figure I.4-1 Extended Actor Groupings - XDS

The Observation Processor actor may be grouped with the Document Source actor of the Cross-Enterprise Document Sharing (XDS) Profile.

With this grouping, the system would create a medical summary report, perhaps combining the observations from several devices (e.g., implanted device observations with electrophysiology lab evidence), to be shared cross encounters, with referral doctors, etc. As a Document Source, the created report would be forwarded to a Document Repository and, in turn, would be registered at Document Registry and made available in community of care. Another possibility is to share and publish the attached PDF report as is, if it was provided by Observation Creator.

I.5 Observation Repository with a Database

The Observation Repository actor may store received observations in a database suitable for longitudinal patient studies, outcomes research, clinical trials, or data mining. While IHE does not currently define any Profiles or Transactions for such a database actor, there are several such types of systems which could participate in the IDCO Profile as an Observation Repository.

Such a system would be required to be grouped with the Patient Demographics Consumer actor, and thus to support update of patient demographic data in the stored observations.

Changes to Volume II – Transactions

Add New Transaction

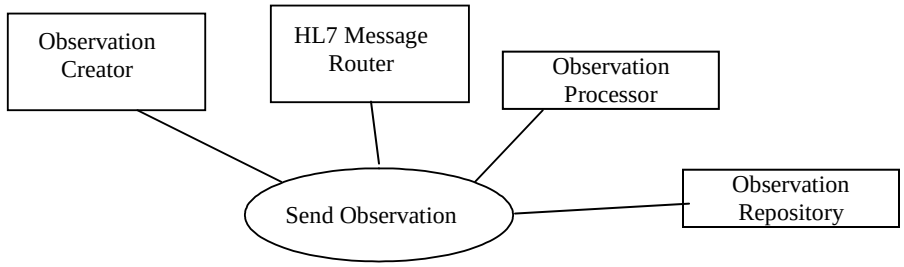
4.12 Send Observation (CARD-12)

This section corresponds to transaction CARD-12 of the IHE Technical Framework. Transaction CARD-12 is used by the Observation Creator, HL7 Message Router, Observation Repository and Observation Processor actors.

4.12.1 Scope

In the Send Observation transaction, the Observation Creator sends the observation as an unsolicited HL7 ORU message to the HL7 Message Router, and the HL7 Message Router sends the observation as an unsolicited HL7 ORU message to the Observation Repository and Observation Processor actors. Optionally, the Observation Creator can send an unsolicited HL7 ORU message directly to the Observation Processor and Observation Repository.

4.12.2 Use Case Roles



Actor: Observation Creator

Role: Outputs the Observation as an HL7 ORU message upon completion of the observation. This message contains the encapsulated XML data, and optionally discrete data for the observation and/or a PDF document containing displayable data relating to the observation.

Actor: HL7 Message Router

Role: Receives the HL7 ORU message from the Observation Creator, reconciles patient identification using transactions from the PIX profile, and outputs the message to each configured destination actor.

Actor: Observation Processor

Role: Receives the HL7 ORU message and provides some implementation-specific processing. This may include creation of reports, integration of information into electronic health records, or creation of derived data (trends, analyses, reformatted data, population statistics, etc.). If needed,

it will reconcile patient identification using an implementation-specific mapping function or using transactions from the PIX profile.

Actor: Observation Repository

Role: Receives the HL7 ORU message and provides long-tem storage of information contained within the message. It makes this data available in some implementation-specific manner. If needed, it will reconcile patient identification using transactions from the PIX profile. It maintains demographic information consistency with the enterprise based on patient update transactions of the PAM profile.

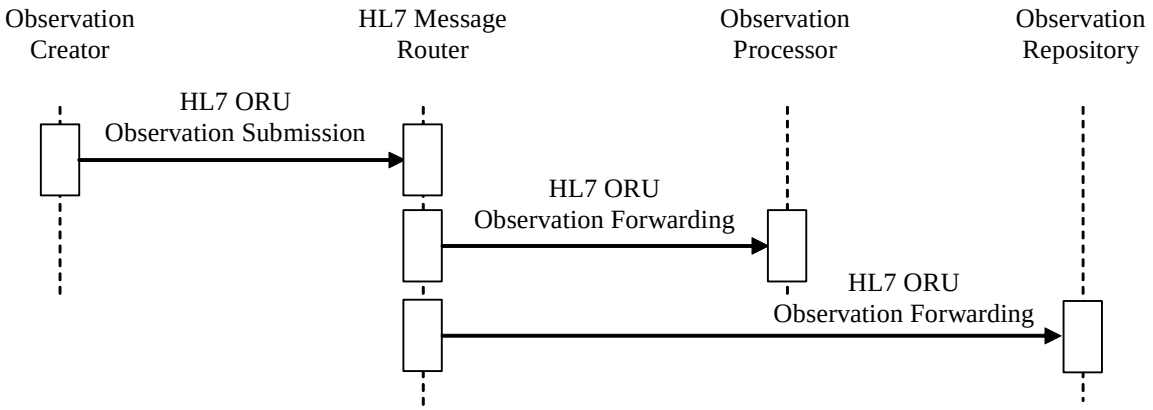
4.12.3 Referenced Standards

HL7 Messaging Standard v2.5

HL7 Messaging Standard v3

IEEE 1073.1.1.3 Implantable Cardiac Device Nomenclature

4.12.4 Interaction Diagram



4.12.5 Observation Submission

4.12.5.1 Trigger Events

The Observation Creator initiates the HL7 ORU message to the HL7 Message Router following an implanted cardiac device interrogation, when it has assembled all the data desired to be reported.

4.12.5.2 Message Semantics

The message is an unsolicited v2.5 ORU message from the Observation Creator to the HL7 Message Router with a corresponding ACK message back to the Observation Creator. The

contents of the message (in OBX segments) are a required encapsulated Implantable Cardiac Device Follow-up observation, an optional encapsulated PDF document, and an optional set of individual observations or measurements trans-coded into separate v2.5 OBX segments.

Refer to the HL7 2.5 Standard, Chapter 7 ORU Message for general message semantics.

Refer to the HL7 v3 Standard, Therapeutic Device Domain – Implantable Cardiac Device Topic, and the subsections below for the content of the required OBX.

The constrained message structure is given in Table 4.12-1, with additional details provided in sections below.

Table 4.12-1 ORU Message Structure

ORU	Observation Results Message	Usage	Chapter in HL7
MSH	Message Header		2
[{ SFT }]	Software Segment		2
PID	Patient Identification		3
[PV1]	Patient Visit		3
OBR	Observations Request	Main OBR - clinical context	7
[{ NTE }]	Notes and comments	Implementation specific	2
OBX	Observation result	HL7 v3-derived XML payload	7
[{OBX}]	Observation result	PDF document payload	7
[	--- optional Pulse Generator BEGIN		
OBR	Observations Request for Pulse Generator		2
{OBX}	Observation results	items related to the pulse generator	7
]	--- optional Pulse Generator END		
[{	--- optional Lead grouping BEGIN	May repeat for each lead reported	
OBR	Observations Request for Lead		2
{OBX}	Observation results	items related to the lead	
}]	--- optional Lead grouping END		
[DSC]	Continuation Pointer		2

4.12.5.2.1 MSH Segment – Message Header

Table 4.12-2 – MSH Segment

ELEMENT NAME	SEQ	DT SEQ	DT	LEN	USAGE	CARD	TBL#	ITEM #	Fixed	Ex. Values
Field Separator	1		ST	1	R	[1..1]		00001		|
Encoding Characters	2		ST	4	R	[1..1]		00002		^~\&
Sending Application	3		HD	227	RE	[0..1]	0361	00003		Device Vendor App
Sending Facility	4		HD	227	RE	[0..1]		00004		Vendor
Receiving Application	5		HD	227	RE	[0..1]		00005		*Clinic Application*
Receiving Facility	6		HD	227	RE	[0..1]		00006		Clinic ID
Date/Time Of Message	7		TS	26	R	[1..1]		00007		20070117130129

ELEMENT NAME	SEQ	DT SEQ	DT	LEN	USAGE	CARD	TBL#	ITEM #	Fixed	Ex. Values
Message Type	9		MSG	15	R	[1..1]		00009		
Message Code		*1*	*ID*	*3*	*R*	*[1..1]*	*0076*		*Y*	*ORU*
Trigger Event		*2*	*ID*	*3*	*R*	*[1..1]*	*0003*		*Y*	*R01*
Message Control ID	10		ST	20	R	[1..1]		00010		123450
Processing ID	11		ID	1	R	[1..1]	0103	00011		P
Version ID	12		ID	5	R	[1..1]	0104	00012	Y	2.5
Character Set	18		ID	6	C	[1..*]	0211	00692		8859/1

4.12.5.2.2 PID Segment – Patient Identification

Table 4.12-3 – PID Segment

ELEMENT NAME	SEQ	DT SEQ	DT	LEN	USAGE	CARD	TBL#	ITEM #	Fixed	Ex. Values
Patient Identifier List	3		CX	20	R	[1..*]		00106		
ID Number		*1*	*ST*	*199*	*R*	*[1..1]*				*model:xxx/serial:yyy*
Assigning Authority		*4*	*HD*	*227*	*R*	*[1..1]*				*GDT*
Identifier Type Code		*5*	*ID*	*50*	*R*		*0203*			*MS*
Patient Name	5		XPN	250	R	[1..*]		00108		Smith^John
Date/Time Of Birth	7		TS	26	RE	[0..1]		001100		19590602
Sex	8		IS	1	RE	[0..1]		00111		M
Patient Address	11		XAD	250	RE	[0..1]		00114		

PID-3.1 Patient Identifier List - ID Number contain a unique identifier for the patient assigned by the Observation Creator. Identifier Type Code is constrained by Table 0203 listed below (others can be included as defined in the 2.5 standard). An identifier of type MS is required. This will be used by the Observation Processor / Repository actor to match the device interrogations with the patient accounts. Assigning Authority is a unique name of the Observation Creator system or owning organization that creates the observation and will be coded using the IEEE P10731.1.3 IDC Nomenclature, MDC_IDC_DEVICE_MANUFACTURER term.

Table 4.12-4 Table 0203

Code	Description	Notes	Usage
MS	Model and Serial Number of Device IEEE E1073.1.1.3 MDC_IDC_DEVICE_MODEL and MDC_IDC_DEVICE_SERIAL_NUMBER	Model and Serial number shall be concatenated together and must be unique within an Assigning Authority. The format of the ID shall be following: "model:xxx/serial:yyy"	R

		Example: model:XZY987/serial:abc123	
SS	Patient Social Security Number	Social Security number shall be included if known.	RE

4.12.5.2.3 PV1 Segment – Patient Visit (Optional)

Table 4.12-5 – PV1 Segment

ELEMENT NAME	SEQ	DT SEQ	DT	LEN	USAGE	CARD	TBL#	ITEM #	Fixed	Ex. Values
Set ID - PV1	1		SI	4	R	[1..1]		00131	Y	1
Patient Class	2		IS	1	R	[1..1]		00132	Y	R
Location	3		PL	80	O	[0..1]		00133		Clinic Location
Attending Doctor	7		XCN	250	O	[0..1]		00137		
Visit Number	19		CX	250	RE	[0..1]		00149		1234567890

Because this is an unsolicited observation and the Observation Creator will not be aware of an associated order, this segment is optional. The Observation Creator may want to track the interrogation as a visit using this segment. If information is provided here it must match corresponding information provided in the OBX segments.

PV1-7 Attending Doctor will be captured by the Interrogator / Observation Creator actor. If present, PV1-7.1 Attending Doctor ID Number will be a unique identifier for each doctor in the context of the Interrogator / Observation Creator actor, not the Observation Processor / Repository actor.

PV1-19 Visit Number, ID Number will be a unique identifier generated by the Observation Creator for each visit.

4.12.5.2.4 OBR Segment – Observation Request

Table 4.12-6 – OBR Segment

ELEMENT NAME	SEQ	COMP	DT	LEN	USAGE	CARD	TBL#	ITEM #	Fixed	Ex. Values
Set ID – OBR	1		SI	4	R	[1..1]		00237	Y	1
Placer Order Number	2		EI	427	RE	[1..1]		00216		1234567890
Filler Order Number	3		EI	427	R	[1..1]		00217		1234567891
Universal Service ID	4		CE	250	R	[1..1]	4.12-7 (below)	00238		
Identifier		*1*	*ST*	*256*	*R*	*[1..1]*				*Follow-up*

ELEMENT NAME	SEQ	COMP	DT	LEN	USAGE	CARD	TBL#	ITEM #	Fixed	Ex. Values
Text		*2*	*ST*	*256*	*R*	*[1..1]*				*HL7 v2.5 device observations for a Follow-up*
Observation Date/Time #	7		TS	26	R	[1..1]		00241		20060317160000+0006
Observation End Date/Time #	8		TS	26	RE	[0..1]		00242		20060317170000+0006
Filler Field 1	20		ST	256	C	[0..1]		00253		Model:12345678/serial:123234345
Results Rpt/Status Chng - Date/Time +	22		TS	24	RE	[0..1]		00255		20060317170000+0006
Result Status +	25		ID	1	R	[1..1]	0123	00258		F
Principal Result Interpreter	32		NDL	200	O	[0..1]		00264		
Assistant Result Interpreter	33		NDL	200	O	[0..*]		00265		
Technician	34		NDL	200	O	[0..*]		00266		

OBR-2 Placer Order Number will usually be empty given that this is an unsolicited order.

OBR-3 Filler Order Number will contain a unique identifier for the observation / interrogation session generated by the Observation Creator actor.

OBR-4.1-2 Universal Service ID, Identifier and Text can identify unique OBR segments that partition observations. The following table lists of values for these fields.

Table 4.12-7 OBR-4 Table

ID	Text
Implant	HL7 v2.5 device observations at Implant
Follow-up	HL7 v2.5 device observations for a Follow-up

OBR-25 Result Status values shall be one of the values in Table 4.12-8.

Table 4.12-8 Result Status

Value	Description
R	Results stored; not yet verified
P	Preliminary: A verified early result is available, final results not yet obtained
F	Final results; results stored and verified. Can only be changed with a corrected result.
C	Correction to results

OBR-32 Principal Result Interpreter, OBR-33 Assistant Result Interpreter, and OBR-34 Technician if present shall at a minimum define components Name and Facility.

4.12.5.2.5 OBX Segment with Encapsulated v3 Message

An encapsulated XML document containing the Implantable Cardiac Device Follow-up observation shall be included in the Observation message. The XML document must be encapsulated within an OBX-5 Observation Value field of the OBX segment.

Table 4.12-9 – OBX Segment

ELEMENT NAME	SEQ	COMP	DT	LEN	USAGE	CARD	TBL#	ITEM #	Fixed	Ex. Values
Set ID - OBX	1		SI	4	R	[1..1]		00569		1
Value Type	2		ID	2	R	[1..1]	0125	00570	Y	ED
Observation Identifier	3		CE	250	R	[1..1]		00571		
Identifier		*1*	*ST*	*20*	*R*	*[1..1]*			*Y*	*IDC*
Text		*2*	*ST*	*80*	*R*	*[1..1]*			*Y*	*Implantable Cardiac Device Follow-up Observation*
Name of Coding System		*3*	*ST*	*20*	*R*	*[1..1]*			*Y*	*99IHE*
Observation Value	5		ED	*	R	[1..1]		00573		
Type of Data		*2*	*ST*	*20*	*R*	*[1..1]*			*Y*	*Application*
Data Subtype		*3*	*ST*	*20*	*R*	*[1..1]*			*Y*	*XML*
Encoding		*4*	*ST*	*20*	*R*	*[1..1]*			*Y*	*Base64*
Data		*5*	*TX*	*	*R*	*[1..1]*				*Encapsulated and Base64 binary encoded XML File*
Observation Result Status	11		ID	1	R	[1..1]	0085	00579	Y	F
Date/Time of the Observation	14		TS	26	RE	[0..1]		00582		20060317170000+0006
Observation Method	17		CE	250				00936		
Identifier		*1*	*ST*	*20*	*R*	*[1..1]*				*MDC_IDC_SESSION_TYPE*
Text		*2*	*ST*	*40*	*R*	*[1..1]*				*In Clinic*
Name of Coding System		*3*	*ST*	*12*	*R*	*[1..1]*				*IEEE P10731.1.3*
Equipment Instance Identifier	18		EI	128	O	[0..*]		01479		Programmer XXXX

OBX-3 Observation Identifier shall have the coded value identifier “IDC” from Coding System “99IHE”, with Text meaning “Implantable Cardiac Device Follow-up Observation”.

OBX-5.2 Type of Data component shall have the value “Application”

OBX-5.3 Data Subtype component shall have the value “XML”.

OBX-5.4 Encoding component shall have the value “Base64”.

OBX-5.5 Data component contains the encapsulated Base64-encoded XML document.

*Note! The base64 encoded XML document **must not include** CR/LF characters, which are forbidden within HL7 field text streams. Breaking a base64 encoded stream into lines of 76 characters or less is used for email in accordance with RFC 822, but is not applicable to encapsulated data in HL7.*

The encapsulated XML document will consist of the message content specified by the HL7 v3 Therapeutic Device Domain / Implantable Device – Cardiac / Implantable Cardiac Device Results Notification message, message wrappers (transmission and control act) shall not be included. The Refined Message Implementation Model (RMIM) POTD_RM000001 is shown in Figure 4.12-3, and the Hierarchical Message Description (HMD) POTD_HD000001 for the message is defined in Table 4.12-10 following. Refer to the HL7 Therapeutic Devices Implantable Cardiac Device Topic RMIM at http://www.ihe.net/Technical_Framework/index.cfm#cardiology for more details.

The deviceObservation, patientObservation, deviceTherapy, and deviceTherapySettings classes of observations shall be coded using “IEEE 1073.1.1.3 Health Informatics - Point-of-Care Medical Device Communication - Nomenclature - Implantable Cardiac Device” terms. (IEEE 1073.1.1.3 specification forthcoming pending final balloting of the standard.)

OBX-17.1-3 Observation Method Identifier, Text, and Name of Coding system values shall be coded using the IEEE P10731.1.3 IDC Nomenclature, MDC_IDC_SESSION_TYPE term.

OBX-18.1 Equipment Instance Identifier, Entity Identifier – A unique identifier for the equipment or software that was responsible for the production of the observation.

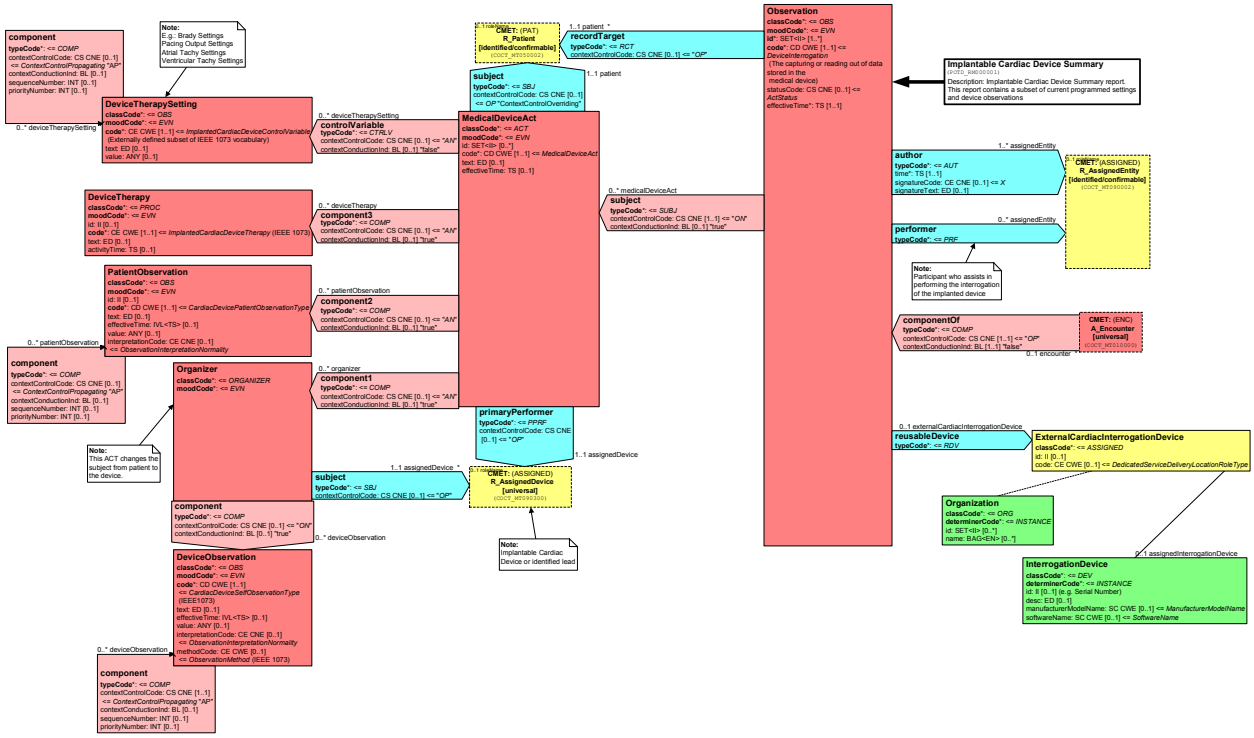


Figure 4.12-3 - POTD_RM000001

Table 4.12-10 - HMD

No	Element Name	Card	Mand	Conf	Rim Source	of Message Element Type	Src
1	**Observation**	0..1			Observation	Observation	N
2	classCode	1..1	M	R	Act	CS	D
3	moodCode	1..1	M	R	Act	CS	D
4	id	1..*	M	R	Act	SET<II>	D
5	code	1..1	M	R	Act	CD	D
6	statusCode	0..1			Act	CS	D
7	effectiveTime	1..1		R	Act	TS	D
8	**reusableDevice**	0..1			Act	ReusableDevice	N
9	typeCode	1..1	M	R	Participation	CS	D
10	**externalCardiacInterrogationDevice**	1..1			Participation	ExternalCardiacInterrogationDevice	N
11	classCode	1..1	M	R	Role	CS	D
12	id	0..1			Role	II	D
13	code	0..1			Role	CE	D
14	**assignedInterrogationDevice**	0..1			Role	InterrogationDevice	N
15	classCode	1..1	M	R	Entity	CS	D
16	determinerCode	1..1	M	R	Entity	CS	D
17	id	0..1			Entity	II	D
18	desc	0..1			Entity	ED	D
19	manufacturerModelName	0..1			Device	SC	D
20	softwareName	0..1			Device	SC	D
21	**recordTarget**	1..1		R	Act	RecordTarget	N
22	typeCode	1..1	M	R	Participation	CS	D
23	contextControlCode	0..1			Participation	CS	D
24	***patient***	1..1		R	Participation	COCT_MT050002UV0	C
25	**performer**	0..*			Act	SET<Performer>	N
26	typeCode	1..1	M	R	Participation	CS	D
27	***assignedEntity***	1..1			Participation	COCT_MT090002	C
28	**author**	1..*			Act	SET<Author2>	N
29	typeCode	1..1	M	R	Participation	CS	D
30	time	1..1		R	Participation	TS	D
31	signatureCode	0..1			Participation	CE	D
32	signatureText	0..1			Participation	ED	D
33	***assignedEntity***	1..1			Participation	COCT_MT090002	U
34	**subject**	0..*			Act	SET<Subject1>	N
35	typeCode	1..1	M	R	ActRelationship	CS	D
36	contextControlCode	1..1			ActRelationship	CS	D
37	contextConductionInd	0..1			ActRelationship	BL	D

No	Element Name	Card	Mand	Conf	Rim Source	of Message Element Type	Src
38	**medicalDeviceAct**	1..1			ActRelationship	MedicalDeviceAct	N
39	classCode	1..1	M	R	Act	CS	D
40	moodCode	1..1	M	R	Act	CS	D
41	id	0..*			Act	SET<II>	D
42	code	1..1		R	Act	CD	D
43	text	0..1			Act	ED	D
44	effectiveTime	0..1			Act	TS	D
45	**subject**	1..1			Act	Subject3	N
46	typeCode	1..1	M	R	Participation	CS	D
47	contextControlCode	0..1			Participation	CS	D
48	***patient***	1..1			Participation	COCT_MT050002UV0	U
49	**primaryPerformer**	1..1			Act	PrimaryPerformer	N
50	typeCode	1..1	M	R	Participation	CS	D
51	contextControlCode	0..1			Participation	CS	D
52	***assignedDevice***	1..1			Participation	COCT_MT090300UV0	C
53	**controlVariable**	0..*			Act	SET<ControlVariable>	N
54	typeCode	1..1	M	R	ActRelationship	CS	D
55	contextControlCode	0..1			ActRelationship	CS	D
56	contextConductionInd	0..1			ActRelationship	BL	D
57	**deviceTherapySetting**	1..1			ActRelationship	DeviceTherapySetting	N
58	classCode	1..1	M	R	Act	CS	D
59	moodCode	1..1	M	R	Act	CS	D
60	code	1..1	M	R	Act	CE	D
61	text	0..1			Act	ED	D
62	value	0..1			Observation	ANY	D
63	**component**	0..*			Act	SET<Component7>	N
64	typeCode	1..1	M	R	ActRelationship	CS	D
65	contextControlCode	0..1			ActRelationship	CS	D
66	contextConductionInd	0..1			ActRelationship	BL	D
67	sequenceNumber	0..1			ActRelationship	INT	D
68	priorityNumber	0..1			ActRelationship	INT	D
69	***deviceTherapySetting***	1..1			ActRelationship	DeviceTherapySetting	R
70	**component1**	0..*			Act	SET<Component1>	N
71	typeCode	1..1	M	R	ActRelationship	CS	D
72	contextControlCode	0..1			ActRelationship	CS	D
73	contextConductionInd	0..1			ActRelationship	BL	D
74	**organizer**	1..1			ActRelationship	Organizer	N
75	classCode	1..1	M	R	Act	CS	D

No	Element Name	Card	Mand	Conf	Rim Source	of Message Element Type	Src
76	moodCode	1..1	M	R	Act	CS	D
77	**subject**	1..1		R	Act	Subject2	N
78	typeCode	1..1	M	R	Participation	CS	D
79	contextControlCode	0..1			Participation	CS	D
80	***assignedDevice***	1..1		R	Participation	COCT_MT090300UV0	U
81	**component**	0..*			Act	SET<Component2>	N
82	typeCode	1..1	M	R	ActRelationship	CS	D
83	contextControlCode	0..1			ActRelationship	CS	D
84	contextConductionInd	0..1			ActRelationship	BL	D
85	**deviceObservation**	1..1			ActRelationship	DeviceObservation	N
86	classCode	1..1	M	R	Act	CS	D
87	moodCode	1..1	M	R	Act	CS	D
88	code	1..1	M	R	Act	CD	D
89	text	0..1			Act	ED	D
90	effectiveTime	0..1			Act	IVL<TS>	D
91	value	0..1			Observation	ANY	D
92	interpretationCode	0..1			Observation	CE	D
93	methodCode	0..1			Observation	CE	D
94	**component**	0..*			Act	SET<Component8>	N
95	typeCode	1..1	M	R	ActRelationship	CS	D
96	contextControlCode	1..1			ActRelationship	CS	D
97	contextConductionInd	0..1			ActRelationship	BL	D
98	sequenceNumber	0..1			ActRelationship	INT	D
99	priorityNumber	0..1			ActRelationship	INT	D
100	***deviceObservation***	1..1			ActRelationship	DeviceObservation	R
101	**component2**	0..*			Act	SET<Component3>	N
102	typeCode	1..1	M	R	ActRelationship	CS	D
103	contextControlCode	0..1			ActRelationship	CS	D
104	contextConductionInd	0..1			ActRelationship	BL	D
105	**patientObservation**	1..1			ActRelationship	PatientObservation	N
106	classCode	1..1	M	R	Act	CS	D
107	moodCode	1..1	M	R	Act	CS	D
108	id	0..1			Act	II	D
109	code	1..1	M	R	Act	CD	D
110	text	0..1			Act	ED	D
111	effectiveTime	0..1			Act	IVL<TS>	D
112	value	0..1			Observation	ANY	D
113	interpretationCode	0..1			Observation	CE	D

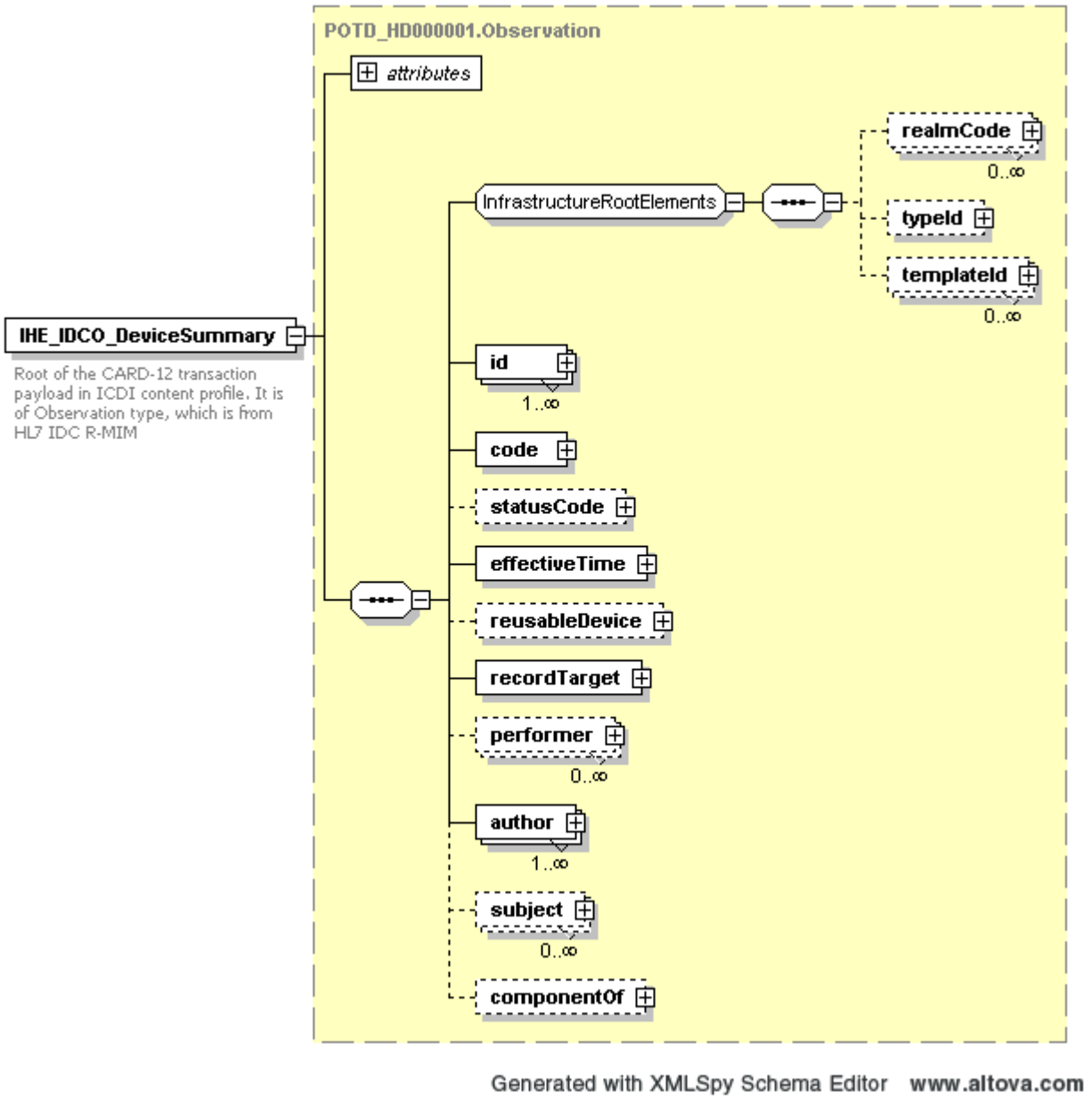
No	Element Name	Card	Mand	Conf	Rim Source	of Message Element Type	Src
114	**component**	0..*			Act	SET<Component6>	N
115	typeCode	1..1	M	R	ActRelationship	CS	D
116	contextControlCode	0..1			ActRelationship	CS	D
117	contextConductionInd	0..1			ActRelationship	BL	D
118	sequenceNumber	0..1			ActRelationship	INT	D
119	priorityNumber	0..1			ActRelationship	INT	D
120	***patientObservation***	1..1			ActRelationship	PatientObservation	R
121	**component3**	0..*			Act	SET<Component4>	N
122	typeCode	1..1	M	R	ActRelationship	CS	D
123	contextControlCode	0..1			ActRelationship	CS	D
124	contextConductionInd	0..1			ActRelationship	BL	D
125	**deviceTherapy**	1..1			ActRelationship	DeviceTherapy	N
126	classCode	1..1	M	R	Act	CS	D
127	moodCode	1..1	M	R	Act	CS	D
128	id	0..1			Act	II	D
129	code	1..1	M	R	Act	CE	D
130	text	0..1			Act	ED	D
131	activityTime	0..1			Act	TS	D
132	**componentOf**	0..1		R	Act	Component5	N
133	typeCode	1..1	M	R	ActRelationship	CS	D
134	contextControlCode	1..1			ActRelationship	CS	D
135	contextConductionInd	1..1			ActRelationship	BL	D
136	***encounter***	1..1		R	ActRelationship	COCT_MT010000UV0	C

4.12.5.2.5.1 XML schema

The IDCO profile defines constraints for the IDC RMIM usage in CARD-12 transaction at the XML schema level.

The XML document that is encoded in the OBX.5 segment shall be constructed based on the XML schema defined by this profile – shown below.

Further descriptions of constraints follow in subsequent sections of this document.




```
<?xml version="1.0" encoding="UTF-8" standalone="no"?>
<!-- edited with XMLSpy v2006 U (http://www.altova.com) by Jürgen Kerstna (St. Jude Medical AB) -->
<xs:schema xmlns:xs="http://www.w3.org/2001/XMLSchema" xmlns="urn:hl7-org:v3" xmlns:mif="urn:hl7-org:v3/mif" targetNamespace="urn:hl7-org:v3" elementFormDefault="qualified">
	<xs:annotation>
```

```
                <xs:documentation>Manual creation IHE - Cardiology EP ICDI profile.xsl
version 2.0</xs:documentation>
        </xs:annotation>
        <xs:include schemaLocation="../coreschemas/infrastructureRoot.xsd"/>
        <xs:include schemaLocation="../coreschemas/NarrativeBlock.xsd"/>
        <xs:include schemaLocation="POTD_HD000001.xsd"/>
        <xs:element name="IHE_IDCO_DeviceSummary"
type="POTD_HD000001.Observation">
                <xs:annotation>
                        <xs:documentation>Root of the CARD-12 transaction payload in IDCO
integration profile. It is of Observation type, which is from HL7 IDC RMIM
</xs:documentation>
                </xs:annotation>
        </xs:element>
</xs:schema>
```

4.12.5.2.5.2 IHE_IDCO_DeviceSummary->effectiveTime element constraints

IHE_IDCO_DeviceSummary ->effectiveTime element is set to the timestamp of the session that captured the device summary data. It shall have a meaning of the MDC_IDC_PREVIOUS_SESSION_DATE_TIME item defined in the IEEE 1073.1.1.3 nomenclature. If OBX-14 is set in the HL7 2.5 OBX segment, these values shall match.

4.12.5.2.5.3 ReusableDevice - Interrogation device – programmer

This is optional but recommended.

The element *reusableDevice->externalCardiacInterrogationDevice->assignedInterrogationDevice* shall have two child elements created:

- *manufacturerModelName* – name of the programmer used to interrogate the data
- *softwareName* – name and version of the programmer application used to interrogate the data in this message.

Both elements are of SC type – Character String. The code is optional and can be present, if the manufacturer has its own code tables defined, but the values shall also be stored as *st* element values. If the OBX-18 Equipment Instance Identifier is set in the HL7 v2.5 OBX segment, these values shall match.

4.12.5.2.5.4 recordTarget – Patient

The element *recordTarget->patient->patientPerson* specifies the patient of this observation

- Sequence of *id* elements shall match the PID segment of HL 2.5 wrapper of this XML document

- It is strongly recommended that the demographics data in other elements – *name, administrativeGenderCode, birthTime* – be populated if available.

4.12.5.2.5.5 Interrogation device – Author

This element is required. *author*->assignedEntity->assignedPerson shall be the clinician who is responsible for the interrogation.

- *assignedEntity->id* element shall contain the clinical ID of the clinician
- assignedEntity->assignedPerson->*name* element shall contain at least *family* and *given* elements
- *Author*->assignedEntity->*representedOrganization* element shall contain the information of the clinic/hospital where interrogation took place and where the Author belongs to.

There may be several instances of *author* elements provided; each of them shall represent *assignedPerson*. If OBR-32 Principal Result Interpreter or OBR-33 Assistant Result Interpreter are set in the HL7 2.5 OBR segment, these values shall match.

4.12.5.2.5.6 Performer

This element is optional. According to RMIM, performer is "participant who assists in performing the interrogation of the device". There maybe none to several assistants specified in the message. This profile does not constrain this element. If OBR-34 Technician is set in the HL7 2.5 OBR Segment, these values shall match.

4.12.5.2.5.7 Encounter

This is optional and not constrained by this profile. However, if information about the interrogation/clinic/hospital is available, this can be provided in *medicalDeviceAct->componentOf->encounter* element.

4.12.5.2.5.8 IHE_IDCO_DeviceSummary –> subject element constraints and multiple device mappings

IDC Summary incorporates data and IEEE 1073 defines terms that may be related to different physical devices. For example there are terms for the pulse generator device itself or connected leads.

IDC RMIM model and generated XML schema is designed with this in mind, but it can be achieved in different ways. The following multiple device mapping constraints are required for unambiguous XML document content.

The cardinality of *medicalDeviceAct* is constrained to 1, i.e. the root element IHE_IDCO_DeviceSummary of Observation type shall have one and only one child *subject* element.

medicalDeviceAct ->effectiveTime element shall be omitted, as its timestamp is the same as *IHE_IDCO_DeviceSummary ->effectiveTime*.

4.12.5.2.5.9 Implantable Cardiac Device – pulse generator

The *medicalDeviceAct ->primaryPerformer->assignedDevice* element specifies the Implantable Cardiac Device.

It contains only minimal information required for its identification. All its other descriptive items defined in the IEEE1073.1.1.3 nomenclature are stored as DeviceObservation elements.

- assignedDevice shall have 1 instance of child *id* element, no other elements or attributes are required
    - *id.extension* is set to the combination of IEEE1073.1.1.3 nomenclature terms MDC_IDC_DEVICE_MODEL and MDC_IDC_DEVICE_SERIAL_NUMBER, formatted by same rules that apply to PID-3.1 in HL7 2.5 PID segment ("model:xxx/serial:yyy")
    - *id.root* is optional and shall be set to UID of the manufacturer, if available

This *Organizer* has to have a child *subject->assignedDevice* element, which is carbon copy of the *medicalDeviceAct ->primaryPerformer->assignedDevice*.

Note! *assignedDevice* is referred via two different paths with strong 1..1 cardinality:

1. medicalDeviceAct->primaryPerformer->assignedDevice
2. medicalDeviceAct->component1->organizer->subject->assignedDevice

We end up with 2 identical instances for assignedDevice that represents Pulse Generator.

These two elements shall refer to the same device by containing identical ID of the device for lookup.

There shall be one instance of *medicalDeviceAct ->component1->Organizer* element created for Implantable Cardiac Device.

All DeviceObservation that belong to the Implantable Cardiac Device shall be child elements of this *Organizer*.

4.12.5.2.5.10 Leads

Each lead is represented with one instance of *medicalDeviceAct ->component1->Organizer* element. The cardinality of *medicalDeviceAct ->component1* shall be number of leads +1.

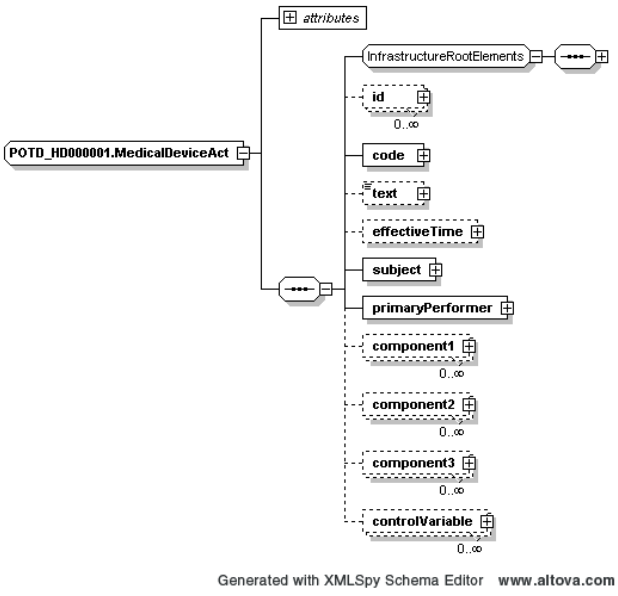
The *Organizer->subject->assignedDevice* element shall be created

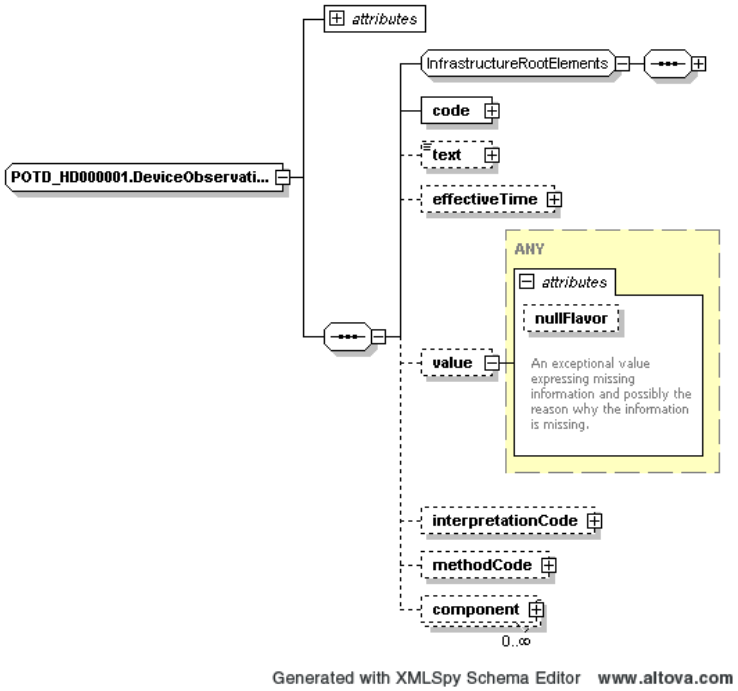
- assignedDevice shall have 1 instance of child *id* element, no other elements or attributes are required

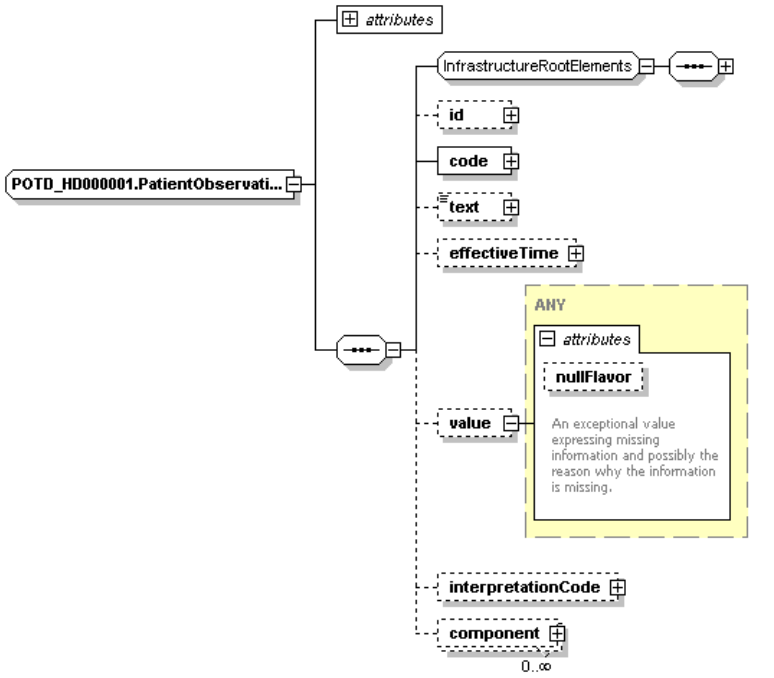
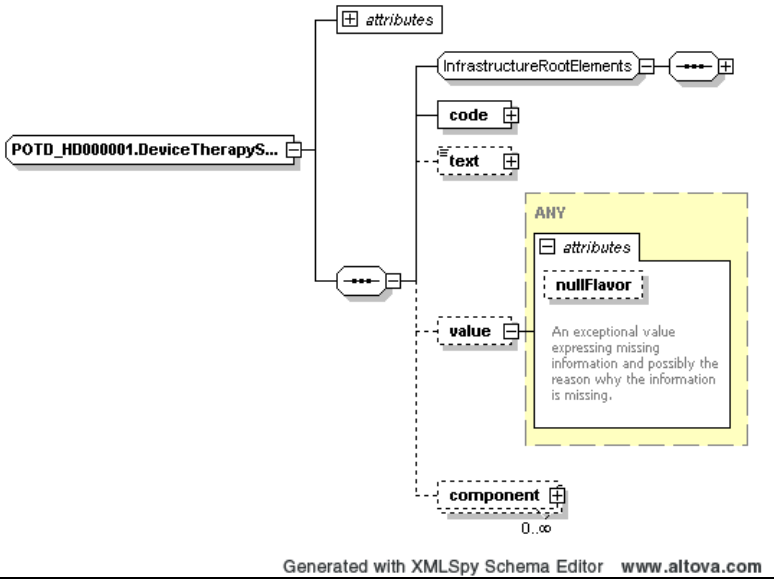
- *id.extension* is set to the combination of IEEE1073.1.1.3 nomenclature terms MDC_IDC_LEAD_MODEL and MDC_IDC_LEAD_SERIAL_NUMBER, formatted by same rules that apply to PID-3.1 in HL7 2.5 PID segement ("model:xxx/serial:yyy")
- *id.root* is optional and shall be set to UID of the manufacturer, if available

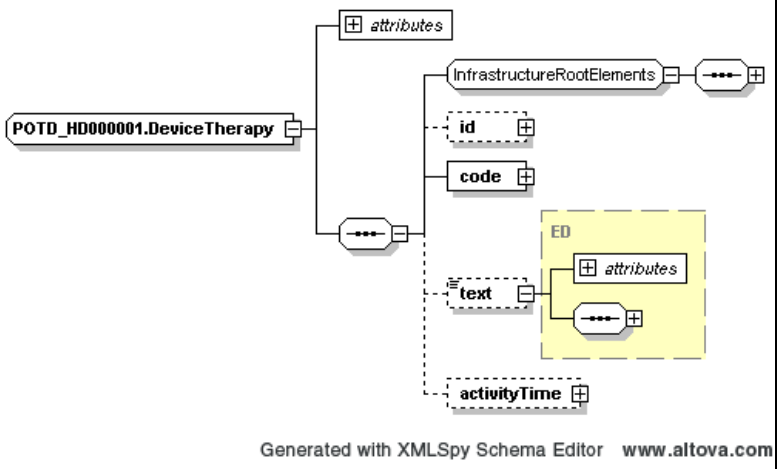
4.12.5.2.5.11 IEEE 1073.1.1.3 item mapping

The nomenclature defines items that are divided into Observation Groups. These groups correspond to four different HL7 IDC RMIM observation groups. This section defines the mapping between IEEE and RMIM/XML observation groups

IEEE 1073.1.1.3	POTD_HD000001.Observation	Mapping details
All groups		The *code* element stores the identity of this observation item. See section 14.5.2.5.13 for details. The *id* element shall not be created, *code* is used for identity The *effectiveTime* element might not be present, if the observation shares the *effectiveTime* of Observation element, but it might be set to distinguish several instances of occurrence of same type of observation. (Example: MDC_IDC_CAPACITOR_CHARGE_ENERGY requires timestamp of the delivered shock)

IEEE 1073.1.1.3	POTD_HD000001.Observation	Mapping details
Device Observation		The value is stored in the *value* element of corresponding type (see section 14.5.2.5.14) and is required. The *text* element is optional and if present then it holds a free text comment about this observation. Note! The *nullFlavor* attribute of the *value* element shall be used instead of the *value* attribute in case where value does not exist, but there is a need to communicate the reason of absence! The *nullFlavor* attribute and *value* elements are mutually exclusive.

IEEE 1073.1.1.3	POTD_HD000001.Observation	Mapping details
Patient Observation		The value is stored in *value* element of corresponding type (see section 14.5.2.5.14) and is required. All that applies for *text* element and *nullFlavor* attribute for DeviceObservation applies here as well.
Device Therapy Setting		The value is stored in *value* element of corresponding type (see section 14.5.2.5.14) and is required. All that applies for *text* element and *nullFlavor* attribute for DeviceObservation applies here as well.

IEEE 1073.1.1.3	POTD_HD000001.Observation	Mapping details
Device Therapy		The value of String type is stored in the *text* element The *activityTime* element shall be created if it is different from *effectiveTime* of this Observation. The *nullFlavor* attribute of *text* element is used if text is missing.

4.12.5.2.5.12 Missing and out-of-type values

Sometimes there is no value captured for a certain item, but the Observation Creator wants to denote the fact that the value is not available. In this case the HL7 v3 NullFlavor mechanism shall be used. The *value* element shall not contain the *value* attribute. Instead, the *nullFlavor* attribute shall be used to code the reason for the missing value as determined by the Observation Creator system. The codes are from the Table 3 in HL7 v3 ballot specification section Data Types - Abstract Specification.

code	name	definition
NI	NoInformation	No information whatsoever can be inferred from this exceptional value. This is the most general exceptional value. It is also the default exceptional value.
OTH	other	The actual value is not an element in the value domain of a variable. (e.g., concept not provided by required code system).
NINF	negative infinity	Negative infinity of numbers.
PINF	positive infinity	Positive infinity of numbers.
UNK	unknown	A proper value is applicable, but not known.
ASKU	asked but unknown	Information was sought but not found (e.g., patient was asked but didn't know)

code	name	definition
NAV	temporarily unavailable	Information is not available at this time but it is expected that it will be available later.
NASK	not asked	This information has not been sought (e.g., patient was not asked)
TRC	trace	The content is greater than zero, but too small to be quantified.
MSK	masked	There is information on this item available but it has not been provided by the sender due to security, privacy or other reasons. There may be an alternate mechanism for gaining access to this information. Note: using this null flavor does provide information that may be a breach of confidentiality, even though no detail data is provided. Its primary purpose is for those circumstances where it is necessary to inform the receiver that the information does exist without providing any detail.
NA	not applicable	No proper value is applicable in this context (e.g., last menstrual period for a male).
NP	not present	Value is not present in a message. This is only defined in messages, never in application data! All values not present in the message must be replaced by the applicable default, or no-information (NI) as the default of all defaults.

The same mechanism shall be used to encode missing or out-of-type values for observations. Example of denoting missing value:

```
<deviceTherapySetting classCode="OBS" moodCode="EVN">
  <code code="MDC_IDC_SENSED_AVDELAY" codeSystemName="IEEE P1073.1.1.3"
      codeSystemVersion="1.0" codeSystem="HL7 MDC OID" displayName=" Sensed AV Delay " />
  <value nullFlavor="OTH" xsi:type="PQ" />
</deviceTherapySetting>
```

Additional to null values defined in the table above, IEEE P1073.1.13 code tables can define possible out-of-type null values.

Example of denoting out-of-type value:

MDC_IDC_PACING_VENTRICULAR_OFFSET has numeric values with exceptional value “Off”. Because the *value* element is typed, only numeric values can be set. In this case *value* attribute shall not be created, and the *nullFlavor* attribute shall be set to “OFF”

Example:

```
<deviceTherapySetting classCode="OBS" moodCode="EVN">
```



```
  <code code="MDC_IDC_PACING_VENTRICULAR_OFFSET" codeSystemName="IEEE P1073.1.1.3"
      codeSystemVersion="1.0" codeSystem="HL7 MDC OID" displayName=" V-V Delay" />
  <value nullFlavor="OFF" xsi:type="PQ" />
</deviceTherapySetting>
```

"OFF" is defined in Table 20 of the IEEE1073.1.13 nomenclature. The ordinary type is PQ.

4.12.5.2.5.13 *code* mapping

Each observation item is defined by its *code* element.

***code* element attribute**	**IEEE 1073.1.1.3 field**	**Example**
Code	Reference ID	"MDC_IDC_BATTERY_LIFE"
codeSystem	uid of IEEE 1073.1.1.3	**TBD -**
codeSystemName	IEEE 1073.1.1.3 ICD terms	"IEEE P1073.1.1.3"
codeSystemVersion	Used version	"1.0"
displayName	IEEE Common Name	"Battery Life"

Example:

```
<code code="MDC_IDC_BATTERY_LIFE" codeSystemName="IEEE P1073.1.1.3"
      displayName="BatteryLife"/>
```

4.12.5.2.5.14 IEEE 1073.1.1.3 nomenclature Data Type mapping

The nomenclature defines several data types for values of its items. IHE_IDCO.xsd defines corresponding XML data types for each of these types. The *value* element type in RMIM is defined as ANY. That means the actual type definition is up to the profiles of this message. IHE IDCO is such profile and hereby defines actual data types.

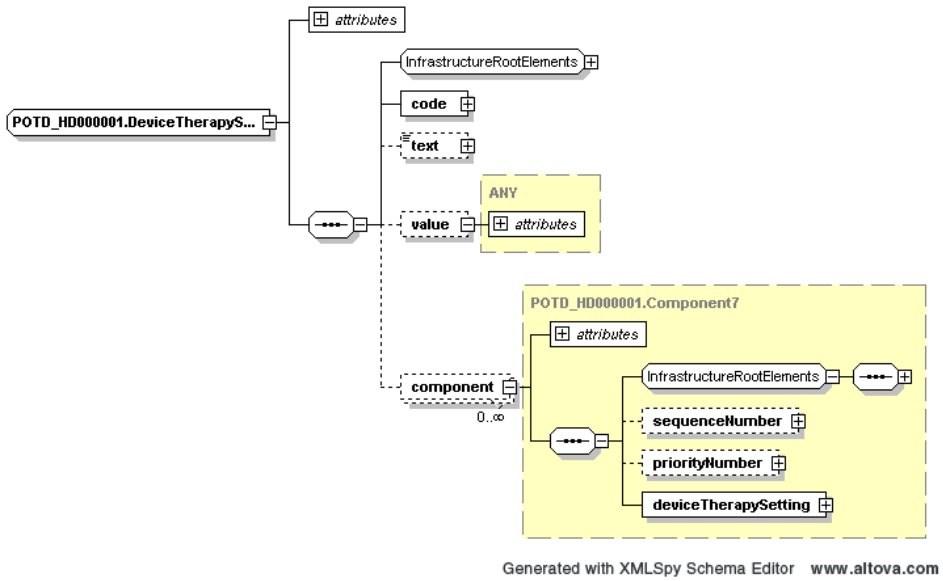
IHE_IDCO data type	**Applicable IEEE 1073 types**	**Mapping details**	**Example**
ST	String (not enumerated)	The value is stored in the element. None of the attributes are used.	`<value xsi:type= "ST">this is string value</value>`

IHE_IDCO data type	Applicable IEEE 1073 types	Mapping details	Example
CD	Enumerated	As minimum *displayName* attribute is required. If the code is defined by any code table, then the *code and codeSystemName* shall also be present. If the table is normative then *codeSystem* attribute shall be set	<value code="**BOL**" codeSystemName= "**IEEE P1073.1.1.3**" displayName="**Beginning of Life**" xsi:type="**CD**" />
TS	Timestamp	The value is stored in the *value* attribute, which is a simple XML **ts** type	<value value="**20060117**" xsi:type="**TS**"/>
PQ	Number(x,y)U Number(x)U with Units specified	The value is a stored *value* attribute which is of the XML type *real*. The unit is stored in the *unit* attribute, which is of the XML simple type *cs*, and is coded with a UCUM unit code as string specified in UCUM c/s column of the IEEE 1073.1.1.3 nomenclature	<value unit="**1/min**" value="**100.0**" xsi:type= "**PQ**"/>

IHE_IDCO data type	Applicable IEEE 1073 types	Mapping details	Example
ST	Complex types which consist of two or more sub-values	The complex type consists of more than one sub-observation item. The parent of the complex type will contain the concatenated values for report display purposes. Also see section 4.12.5.2.5.15 for more information about Hierarchy Mapping.	<value xsi:type= "ST"> **0.8 V @ 0.5 ms** </value> Also see section 4.12.5.2.5.15 for more information about Hierarchy Mapping.
INT	Number(x) Number(x,0) With no units specified	The value is stored in the *value* attribute which is of XML type **int**.	<value value="**5**" xsi:type="**INT**" />
REAL	Number(x,y) Where y!=0 With no units specified	The value is stored in the *value* attribute which is of XML type **real**.	There is no items of such type in current nomenclature

4.12.5.2.5.15 IEEE 1073.1.1.3 Hierarchy Mapping

The HL7 IDC RMIM specifies a possible hierarchy for each item in each observation group (excluding DeviceTherapy).



This means that an observation item may have sub-items, if the IEEE1073.1.1.3 nomenclature specifies so. There are 2 types of hierarchical items.

Sub-Items of Complex type

An example of such case is MDC_IDC_LEAD_PACE_THRESHOLD_CONFIGURATION_IMPLANT. In this case, this item in the IEEE1073.1.1.3 nomenclature is followed by two sub-elements, each of them of type PQ. The sub-items shall be in the sequence specified in the IEEE1073.1.1.3 nomenclature. The *sequenceNumber* attribute is required.

```
<deviceObservation classCode="OBS" moodCode="EVN">
        <code code="MDC_IDC_LEAD_PACE_THRESHOLD_IMPLANT" codeSystemName="IEEE
        P1073.1.1.3" codeSystemVersion="1.0" displayName="Lead Pace Threshold at Implant Amplitude
        @ Pulse Width" />
        <value xsi:type= "ST”> 0.8 V @ 0.5 ms </value>
        <component contextControlCode="AP" typeCode="COMP">
                <sequenceNumber value="1" />
                <deviceObservation classCode="OBS" moodCode="EVN">
                        <code code="MDC_IDC_LEAD_PACE_THRESHOLD_IMPLANT_AMPLITUDE"
                        codeSystemName="IEEE P1073.1.1.3" codeSystemVersion="1.0" displayName="Lead
                        Pace Threshold at Implant Amplitude" />
                        <value unit="V" value="0.8" xsi:type="PQ" />
                </deviceObservation>
        </component>
        <component contextControlCode="AP" typeCode="COMP">
                <sequenceNumber value="2" />
                <deviceObservation classCode="OBS" moodCode="EVN">
                        <code code="MDC_IDC_LEAD_PACE_THRESHOLD_IMPLANT_PULSE_WIDTH"
                        codeSystemName="IEEE P1073.1.1.3" codeSystemVersion="1.0" displayName="Lead
                        Pace Threshold at Implant Pulse Width" />
                         <value unit="ms" value="0.5" xsi:type="PQ" />
                </deviceObservation>
        </component>

</deviceObservation>
```


Generic hierarchies

Any item may have sub-items. Which ones have is specified in the IEEE1073.1.1.3 nomenclature, where sub-items have their parent's referenceID set, as well as their sequence number. The hierarchy can be more than one level. The sub-items shall be inserted in the order of their sequence number within their parent item. The *sequenceNumber* attribute is required and elements order in XML must follow the sequence numbering within their parent.

Example:

```
<deviceTherapySetting classCode="OBS" moodCode="EVN">
  <code code="MDC_IDC_TACHY_THERAPY_ZONE_PARAMETERS" codeSystemName="IEEE P1073.1.1.3"
codeSystemVersion="1.0" displayName="Therapy Zone Parameters" />
    <value code="Afib" codeSystemName="IEEE1073.1.1.3" displayName="Afib" xsi:type="CD" />
<component contextControlCode="AP" typeCode="COMP">
  <sequenceNumber value="1" />
<deviceTherapySetting classCode="OBS" moodCode="EVN">
  <code code="MDC_IDC_TACHY_THERAPY_STATUS" codeSystemName="IEEE P1073.1.1.3"
codeSystemVersion="1.0" displayName="Therapy Status" />
  <text>The status (i.e., On or Off) of the device therapy functions</text>
  <value code="On" codeSystemName="IEEE1073.1.1.3" displayName="On" xsi:type="CD" />
  </deviceTherapySetting>
  </component>
<component contextControlCode="AP" typeCode="COMP">
  <sequenceNumber value="2" />
<deviceTherapySetting classCode="OBS" moodCode="EVN">
  </component>
<component contextControlCode="AP" typeCode="COMP">
  <sequenceNumber value="3" />
<deviceTherapySetting classCode="OBS" moodCode="EVN">
  <code code="MDC_IDC_TACHY_ATP_THERAPY" codeSystemName="IEEE P1073.1.1.3"
codeSystemVersion="1.0" displayName="ATP Therapy" />
  <text>ATP therapy parent, its value is ATP number - i.e. 1 or 2 - which means ATP1 or ATP2
etc.</text>
  <value value="1" xsi:type="INT" />
<component contextControlCode="AP" typeCode="COMP">
<component contextControlCode="AP" typeCode="COMP">
  </deviceTherapySetting>
  </component>
<component contextControlCode="AP" typeCode="COMP">
<component contextControlCode="AP" typeCode="COMP">
<component contextControlCode="AP" typeCode="COMP">
  <sequenceNumber value="6" />
<deviceTherapySetting classCode="OBS" moodCode="EVN">
  <code code="MDC_IDC_TACHY_ADDITIONALSHOCKS" codeSystemName="IEEE P1073.1.1.3"
codeSystemVersion="1.0" displayName="Number Of Additional Shocks" />
  <text>Number Of Additional Shocks: The number of additional max energy shocks in the zone
programmed for delivery.</text>
  <value value="3" xsi:type="INT" />
  </deviceTherapySetting>
  </component>
  </deviceTherapySetting>
```

4.12.5.2.5.16 IEEE 1073.1.1.3 nomenclature Automatic/Manual mapping

The IEEE1073.1.1.3 nomenclature allows specifying for each DeviceObservation and PatientObservation whether it is automatically device-determined or manually clinician determined during the device session, if applicable (the value is not N/A). In nomenclature the column IEEE Automatic/Manual is used to specify this.

PatientObservation-> interpretationCode and *DeviceObservation-> interpretationCode* element shall be created to set the value.

The type of *interpretationCode* element is CE – coded entry.

It shall be populated as following:

XML attribute	Values	Optionality
Code	"A","M"	R
displayName	"Automatic", "Manual"	O
All other attributes		O

4.12.5.2.6 OBX Segment with Encapsulated PDF [Optional]

Optionally, observations or additional analyses can be provided in an encapsulated PDF containing displayable information.

Table 4.12-13 – OBX Segment

ELEMENT NAME	SEQ	COMP	DT	LEN	USAGE	CARD	TBL#	ITEM #	Fixed	Ex. Values
Set ID - OBX	1		SI	3	R	[1..1]		00569		1
Value Type	2		ID	2	R	[1..1]	0125	00570	Y	ED
Observation Identifier	3		CE	80	R	[1..1]		00571		
Identifier		*1*	*ST*	*40*	*R*	*[1..1]*			*Y*	*18750-0*
Text		*2*	*ST*	*80*	*R*	*[1..1]*			*Y*	*Cardiac Electrophysiology Report*
Name of Coding System		*3*	*ST*	*12*	*R*	*[1..1]*			*Y*	*LN*
Observation Value	5		ED	*	RE	[0..1]		00573		Encapsulated PDF
Type of Data		*2*	*ST*	*10*	*R*	*[1..1]*			*Y*	*Application*
Data Subtype		*3*	*ST*	*10*	*R*	*[1..1]*			*Y*	*PDF*
Encoding		*4*	*ST*	*10*	*R*	*[1..1]*			*Y*	*Base64*
Data		*5*	*TX*	*	*R*	*[1..1]*				*Encapsulated and Base64 binary encoded PDF File*
Observation Result Status	11		ID	1	R	[1..1]	0085	00579	Y	F
Date/Time of the Observation	14		DTM	8	RE	[0..1]		00582		20060317170000+0006

ELEMENT NAME	SEQ	COMP	DT	LEN	USAGE	CARD	TBL#	ITEM #	Fixed	Ex. Values
Observation Method	17		CE					00936		
Identifier		*1*	*ST*	*20*	*R*	*[1..1]*				*MDC_IDC_SESSION_TYPE*
Text		*2*	*ST*	*40*	*R*	*[1..1]*				*In Clinic*
Name of Coding System		*3*	*ST*	*12*	*R*	*[1..1]*				*IEEE P10731.1.3*
Equipment Instance Identifier	18		ST	50	RE	[1..*]		01479		Programmer XXXX

OBX-3 is report ID from LOINC coding system, and shall be set to `18750-0^Cardiac Electrophysiology Report^LN.`

OBX-5.2 Type of Data component shall have the value “Application”

OBX-5.3 Data Subtype component shall have the value “PDF”.

OBX-5.4 Encoding component shall have the value “Base64”.

OBX-5.5 Data component contains the encapsulated Base64-encoded PDF document.

*Note! The base64 encoded PDF stream **must not include** CR/LF characters, which are forbidden within HL7 field text streams. Breaking a base64 encoded stream into lines of 76 characters or less is used for email in accordance with RFC 822, but is not applicable to encapsulated data in HL7.*

OBX-17.1-3 Observation Method, Identifier, Text & Name of Coding system – values will be coded using the IEEE P10731.1.3 IDC Nomenclature, MDC_IDC_SESSION_TYPE term.

OBX-18 Equipment Instance Identifier – A unique identifier for the equipment or software that was responsible for the production of the observation.

The attached PDF shall contain in its content the device ID, patient ID and name if known, and the dates of the procedure and document.

Note: If the PDF content is electrocardiogram see the CARD-6 Retrieve ECG Document for Display for recommendations on the message semantics of an ECG document. The limitations of an ECG collected by an IDC may make some of those recommendations inappropriate.

4.12.5.2.7 OBR Segments – Pulse Generator and Lead Observation Results

The ORU message may include discrete OBX segments for individual observations also reported in the XML payload. An OBR Segment shall be used for each set of such OBX segments to establish the equipment context for the observations (i.e., whether they apply to the pulse generator, or to a specific lead).

The OBR segment shall be formatted in accordance with Section 4.12.5.2.4, with the additional constraints specified in this section.

OBR-20 Filler Field 1 shall be used for device context. This field must be present. It shall contain the concatenated model-serial number of the Implanted Cardiac Device, Lead, or other device component ("model:xyz/serial:123") that is being reported on and will be coded using the IEEE P10731.1.3 IDC Nomenclature, MDC_IDC_DEVICE_MODEL, MDC_IDC_DEVICE_SERIAL_NUMBER terms.

4.12.5.2.8 OBX Segments – Pulse Generator and Lead Observation Results

Discrete OBX segments for individual observations also reported in the XML payload may be encoded into separate OBX segments as individual observations or measurements. These OBX segments shall be preceded by an appropriate OBR segment (see 4.12.5.2.7) to set the context for observations dealing with the implantable devices or leads.

Table 4.12-14 – OBX Segment

ELEMENT NAME	SEQ	COMP	DT	LEN	USAGE	CARD	TBL#	ITEM #	Fixed	Ex. Values
Set ID - OBX	1		SI	4	R	[1..1]		00569		1
Value Type	2		ID	2	R	[1..1]	0125	00570		DTM
Observation Identifier	3		CE	250	R	[1..1]		00571		
Identifier		*1*	*ST*	*80*	*R*	*[1..1]*				*MDC_IDC_DEVICE_IMPLANT_DATE*
Text		*2*	*ST*	*256*	*R*	*[1..1]*				*The implant date of the device*
Name of Coding System		*3*	*ST*	*20*	*R*	*[1..1]*				*IEEE P10731.1.3*
Observation Sub-ID	4		ST	20	C	[1..1]		00572		3.1
Observation Value	5		varies	*	RE	[0..1]		00573		20060317
Units	6		CE	250	RE	[0..1]				
Observation Result Status	11		ID	1	R	[1..1]	0085	00579	Y	F
Date/Time of the Observation	14		TS	26	RE	[0..1]		00582		20060317170000+0006
Observation Method	17		CE	250				00936		
Identifier		*1*	*ST*	*80*	*R*	*[1..1]*				*MDC_IDC_SESSION_TYPE*
Text		*2*	*ST*	*256*	*R*	*[1..1]*				*In Clinic*
Name of Coding System		*3*	*ST*	*20*	*R*	*[1..1]*				*IEEE P10731.1.3*
Equipment Instance Identifier	18		EI	256	O	[0..*]		01479		Programmer XXXX

OBX-2 Value Type – The HL7 data type of the Observation Value will depend on the IEEE P10731.1.3 term data type, as shown in Table 4.12-15.

Table 4.12-15 – HL7 to IEEE Data Type Matching

HL7 v2 data type	Applicable IEEE 1073 types
ST	String, not enumerated
CWE	String, enumerated values
DTM	Date / Time
NM	Number(x,y), Number(x,0), Number(x)
ST	Complex – For complex data types multiple observation values may be provided. One for each discrete data element and one for the combined. For combined elements that HL7 type shall be ST.

OBX-3.1 Observation Identifier, Identifier – Must be coded with the IEEE P10731.1.3 IDC Nomenclature Reference ID field for associated observation.

OBX-3.2 Observation Identifier, Text – Must be coded with the IEEE P10731.1.3 IDC Nomenclature Common Name field for associated observation.

OBX-4 Observation Sub-ID – Used to organize hierarchical relationships within sets of observations or composite (complex data type) observations. Use a dot notation to represent hierarchical relationships.

OBX-5 Observation Value – This is the actual value of the observation.

OBX-6 Unit – Must be coded with the IEEE P10731.1.3 IDC Nomenclature Unit field for associated observation.

OBX-17.1-3 Observation Method, Identifier, Text & Name of Coding system – These values will be coded using the IEEE P10731.1.3 IDC Nomenclature, MDC_IDC_SESSION_TYPE term.

OBX-18 Equipment Instance Identifier – A unique identifier for the equipment or software that was responsible for the production of the observation

4.12.5.2.9 NTE Segment – Notes and Comments [Optional]

Table 4.12-16 – NTE Segment – Notes and Comments

ELEMENT NAME	SEQ	COMP	DT	LEN	USAGE	CARD	TBL#	ITEM #	Fixed	Ex. Values
Set ID - NTE	1		SI	4	O	[1..1]		00096		1
Source of comment	2		CX	20	O	[1..1]		00097	Y	L
Comment	3		FT	65536	O	[1..*]		01318		

NTE-3 Comments – Contains any notes, comments needed that are not included as part of an observation.

4.12.5.3 Expected Actions

4.12.5.3.1 HL7 Message Router

The HL7 Message Router shall return the standard HL7 acknowledgement message to the Observation Creator actor.

Upon receipt of this message, the HL7 Message Router shall reconcile the Patient ID in the message with the Patient ID of the assigning authority domain of the local institution, using the PIX Profile transactions. It shall update the PID-3 and PID-5 fields to reflect the local institution Patient ID and name. The HL7 Message Router shall not otherwise modify the content of the observation report it receives. After performing this update the HL7 Message Router shall route the message to all configured recipients. Recipients include Observation Processor and/or Observation Repository actors.

4.12.6 Observation Forwarding

4.12.6.1 Trigger Events

The HL7 Message Router initiates the HL7 ORU message to the configured Observation Processor and Observation Repository recipients when it has received the message from the Observation Creator.

4.12.6.2 Message Semantics

The message semantics are identical to the HL7 ORU message used in Observation Submission (see 4.12.5.2).

4.12.6.3 Expected Actions

4.12.6.3.1 Observation Processor

The Observation Processor actor shall return the standard HL7 acknowledgement message to the Observation Creator or the HL7 Message Router actor.

Upon receipt of this message, if the Patient ID has not been reconciled with the local assigning authority, the Observation Processor shall reconcile the Patient ID in the message with the Patient ID of the assigning authority domain of the local institution. If the Observation Processor supports the PIX-based Reconciliation Option, it shall use the PIX Profile transactions (PIX ITI-9) to perform the reconciliation.

The Observation Processor will perform additional actions that are specific to that application. Reference section 4.12.2 for a description of the types of actions this actor may support.

4.12.6.3.2 Observation Repository

The Observation Repository actor shall return the standard HL7 acknowledgement message to the Observation Creator or HL7 Message Router actors.

Upon receipt of this message, if the Patient ID has not been reconciled with the local assigning authority, the Observation Repository shall reconcile the Patient ID in the message with the Patient ID of the assigning authority domain of the Observation Repository using the PIX Profile transactions (PIX ITI-9).

The Observation Repository shall store the received data and make it available through means that are specific to that application. Reference section 4.12.2 for a description of the types of actions this actor may support.

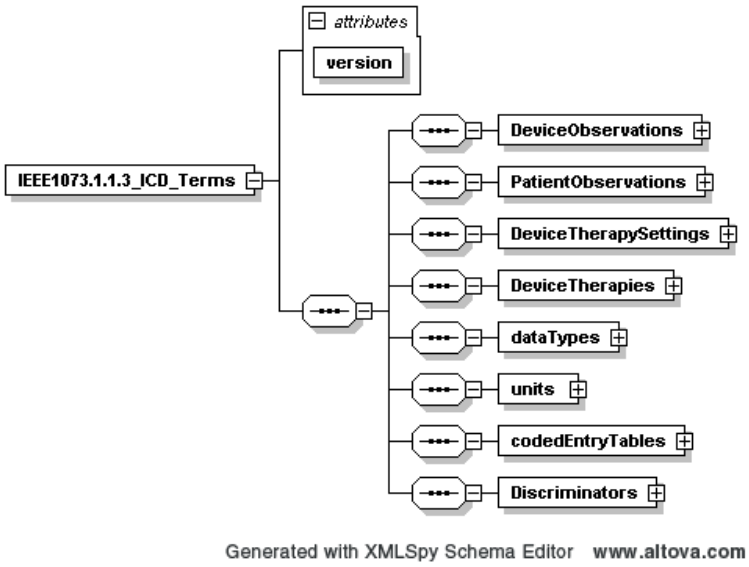
The demographic data in the stored data is updated by means of the Patient Demographics Consumer actor grouped with the Observation Repository actor (PAM Profile transaction ITI-30). Any such updates shall be applied to data made available by this application.

Appendix Z – IDCO Observation Message Examples

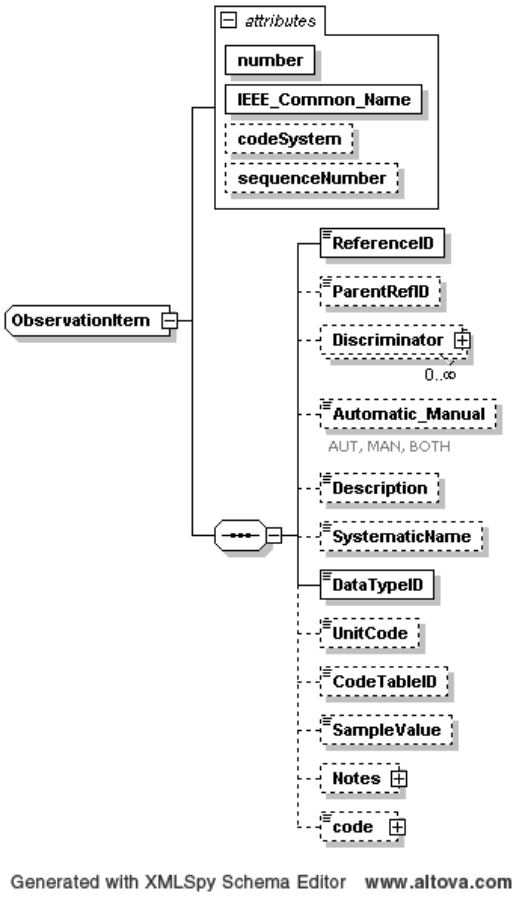
HL7 v2.5 message and v3 XML data payload examples are available in the IDCO SDK published at http://www.ihe.net/Technical_Framework/index.cfm#cardiology.

Appendix A – IEEE 1073.1.1.3 ICD Terms nomenclature

This nomenclature terms are provided in machine parse-able XML document. This appendix provides the XML schema of the nomenclature.

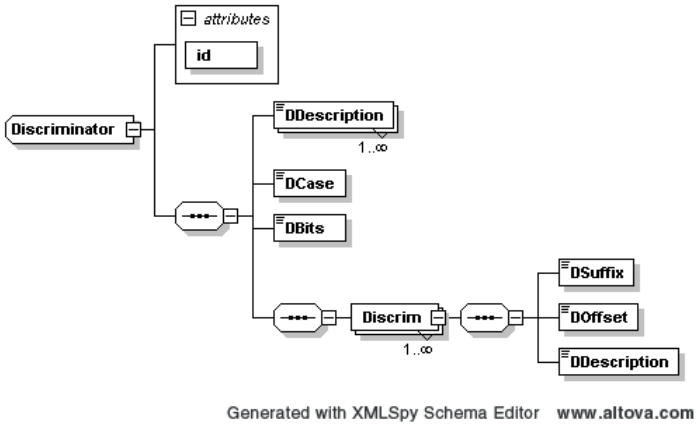


All four observation groups have base type ObservationItem



Usage of Discriminators

The nomenclature uses discriminators that provide suffixes to the base term. The discriminators are defined by following:



If the ObservationItem has discriminator specified, multiple terms are derived based on the discriminator table. The *DSuffix* is concatenated to the base reference ID for each *Discrim* element of the specified discriminator.

XML Schema

The nomenclature schema and XML specification are available as part of SDK at from http://www.ihe.net/Technical_Framework/index.cfm#cardiology.