ACC, HIMSS and RSNA

Integrating the Healthcare Enterprise

IHE Cardiology Technical Framework Supplement 2006-2007

Implantable Device Cardiac Observation Profile (IDCO)

Public Comment Version

Comments due May 19, 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 Public Comment between April 17, 2006 and May 19, 2006.

Comments shall be submitted before May 19, 2006 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 publish the Trial Implementation version in June 2006.

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 device parameters and measurements. 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.

2.2 Open Issues and Questions

1. IEEE 1073.1.1.3 ICD Terms is currently being prepared for ballot. Final specifications are not currently available for inclusion in the profile. Specifications going to ballot should be available for inclusion by late May. Example messages will need to be updated with new terms.
2. IEEE 1073.1.1.3 ICD Terms needs to go through the HL7 harmonization process. This will happen after the IEEE 1073.1.1.3 ICD Terms are normative.
3. Because IEEE 1073.1.1.3 Terms will be finalized several months later than public release of the IHE IDCO profile there is a risk that device and systems vendors will not have enough time to incorporate final nomenclature for Connectathon. This may limit the vendors that can participate.
4. This profile mandates the use of PIX for cross-referencing device identifiers to patients (See section 9.5). 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)?
5. 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-14 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 Processor / Repository?

6. 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?
7. This profile specifies an HL7 Router actor to distribute observations to multiple recipients in an institution. Is the HL7 Router actor needed? What value does the HL7 Router actor add to the integration profile? Should the HL7 Router provide the PIX consumer actor to match incoming observations with local patient identifiers? Discussion to date is the HL7 Router provides an approach for getting the integration engine vendors directly involved in the IHE process.
8. 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? Some discussion to date says ATNA should be required for remote follow-ups. Referencing ATNA makes defining security for the profile easy.

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.

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 Observation Processor and Observation Repository are required to be grouped with the Patient Identity 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

HL7 Message Router – A system that receives HL7 messages, routes them to one or more configured actors, and handles transport level acknowledgements.

Integration Profile / Actor	CATH	ECHO	ECG	DRPT	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	X	
Report Manager				X		
Report Reader				X		
Report Repository				X		
Enterprise Report Repository				X		
Time Client	(note 1)					
Display			X			
Information Source			X	(note 2)		
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-14]

Integration Profile / Transaction	CATH	ECHO	ECG	DRPT	ED	IDCO
Patient Registration [RAD-1]	X	X				
Placer Order Management [RAD-2]	X	X				
Filler Order Management [RAD-3]	X	X				

Integration Profile / Transaction	CATH	ECHO	ECG	DRPT	ED	IDCO
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	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	(note 2)		
Retrieve ECG List [CARD-5]			X			
Retrieve ECG Document for Display [CARD-6]			X			
Encapsulated Report Submission [CARD-7]				X		
Report Reference Submission [CARD-8]				X		
Encapsulated Report Storage [CARD-9]				X		
Encapsulated Report Query [CARD-10]				X		
Encapsulated Report Retrieve [CARD-11]				X		
Retrieve Document for Display [ITI-12]				(note 2)		
Send Observations [CARD-14]						**X**

Add to Section 2.5

- 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).
- 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

Figure 9.1-1 shows 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.

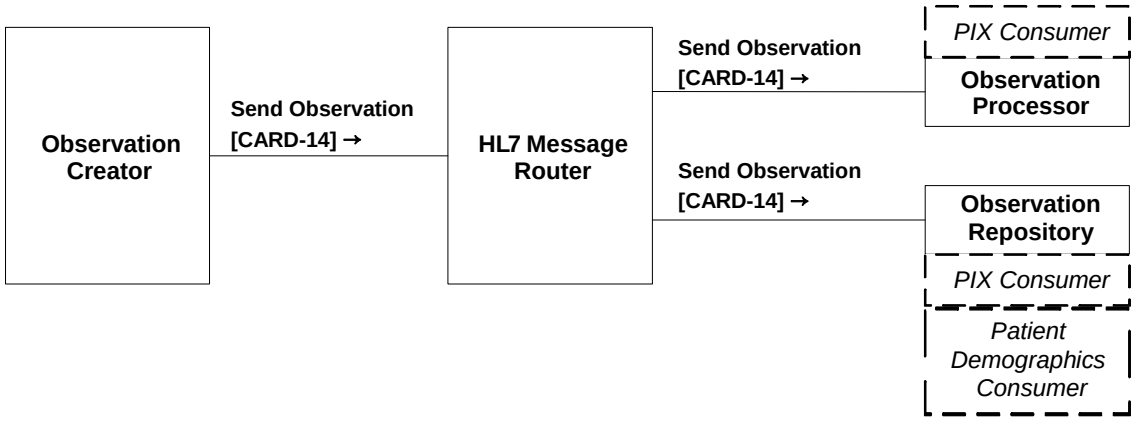


Figure 9.1-1. IDCO Actor Diagram

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-14]	R	CARD-TF 2: 4.14
HL7 Message Router	Send Observations [CARD-14]	R	CARD-TF 2: 4.14
Observation Repository	Send Observations [CARD-14]	R	CARD-TF 2: 4.14
Observation Processor	Send Observations [CARD-14]	R	CARD-TF 2: 4.14

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.

HL7 v3 messages are not widely supported by HL7 Routers, Observation Processors and Observation Repositories at this time. The defined Options accommodate the sending of observations as a standard HL7 v2.5 ORU message. Systems can be compliant with this profile through the use of these defined Options.

Table 9.2-1: IDCO - Actors and Options

Actor	Option Name	Vol & Section
Observation Creator	V2.5 Payload Option	CARD-TF 2: 4.14
Observation Repository	V2.5 Payload Option	CARD-TF 2: 4.14
Observation Processor	V2.5 Payload Option	CARD-TF 2: 4.14

9.3 IDCO Process Flow

The IDCO Profile defines a transaction to support the exchange of unsolicited observations created during an Implantable Device Cardiac Observation. The basic process flow for the IDCO profile is shown in Figure 9.3-1, and is described below.

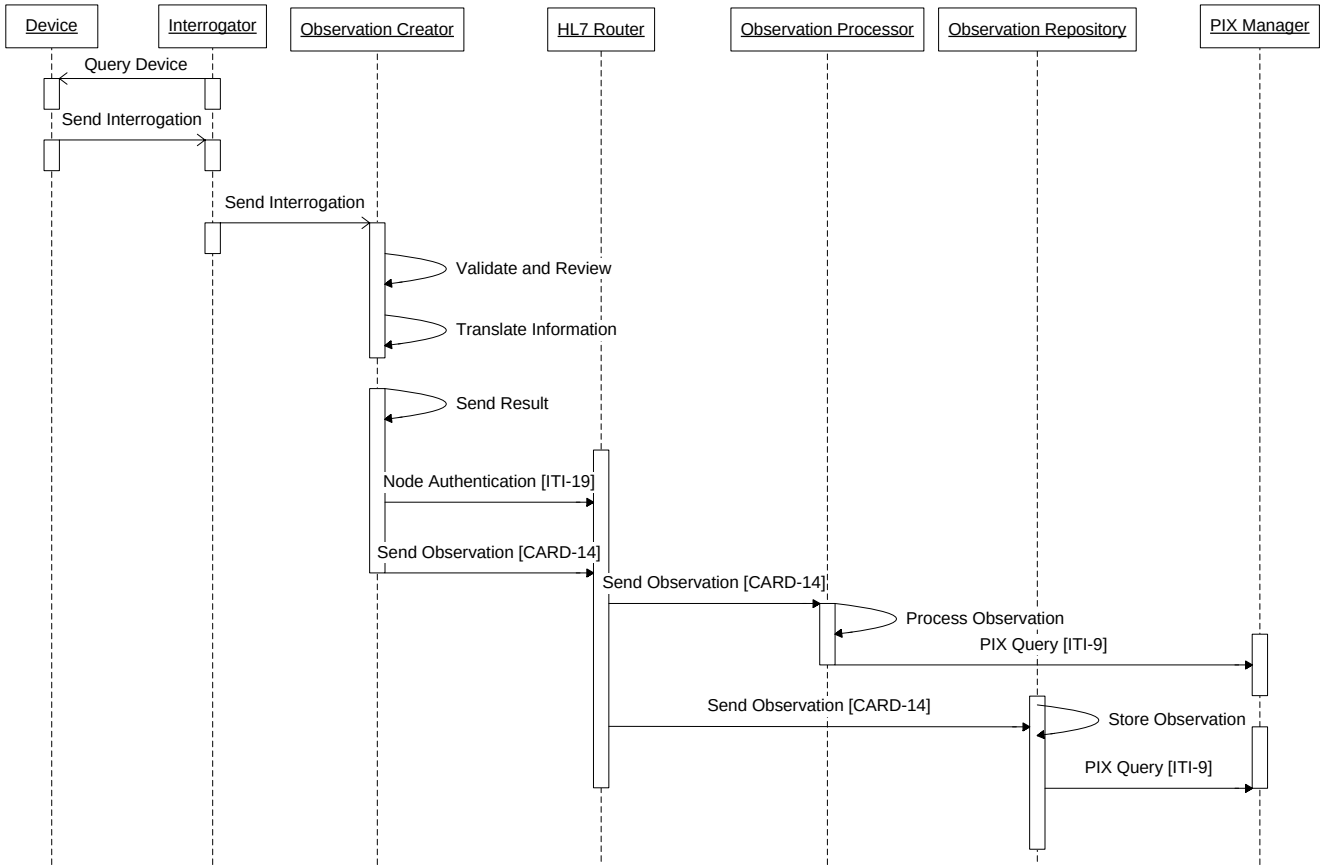


Figure 9.3-1. Basic Process Flow in IDCO Profile

1) Device interrogation

   a) The implanted cardiac device is interrogated in a manufacturer-proprietary manner. The Observation Creator is responsible for collecting the interrogation information, validating the information, converting it into the proper HL7 format.

      Note that the patient identifier used in the HL7 observation message is not necessarily the ID used by the receiving system. The interrogation system may 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 kind of patient ID. In this case, the "assigning authority" for the ID is the device manufacturer.

   b) Interrogations could be in-clinic or remote.

   c) The Observation Creator may attach a PDF file to the message that contains a displayable report.

      Note that the PDF may be a rendering of an electrocardiogram, or of trending data or other analytical data.

   d) Clinician review and approval of the information may take place within the Observation Creator before sending the information to the HL7 Router.

2) Send interrogation information

   a) The Observation Creator is configured to send the transaction to the HL7 Router. The profile employs a push model.

   b) Any necessary security on the link is managed, e.g., through the ATNA profile. Such security would be required for a remote interrogation that traverses the Internet. The ATNA Secure Node actor may be grouped with the Observation Creator and HL7 Router actors for secure transfer, and an ITI-19 Authenticate Node transaction would be used. The Secure Nodes would implement the ATNA Encryption Option for remote interrogations transported over unsecure networks.

   c) The HL7 Router forwards the message to its configured destinations (one or more).

      Note: If an HL7 Router is not part of the installed systems in the enterprise, the Observation Creator can send the CARD-14 message directly to an Observation Processor or Observation Repository. This is a system configuration outside the definition of this profile.

3) Store or Process interrogation information

   a) The Observation Processor and Observation Repository must reconcile patient identification as passed in identifiers within the observation message to the ID used in the local environment. It uses the PIX profile to interact with the Patient Identifier Cross-reference Manager to perform this function.

b) The Observation Processor further processes the observation message for inclusion within derivative products, such as clinical reports, databases, or transcoded/reformatted results.

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

d) 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.

9.4 Observation Processors and Repositories Extended Workflow Actor Groupings

This 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.

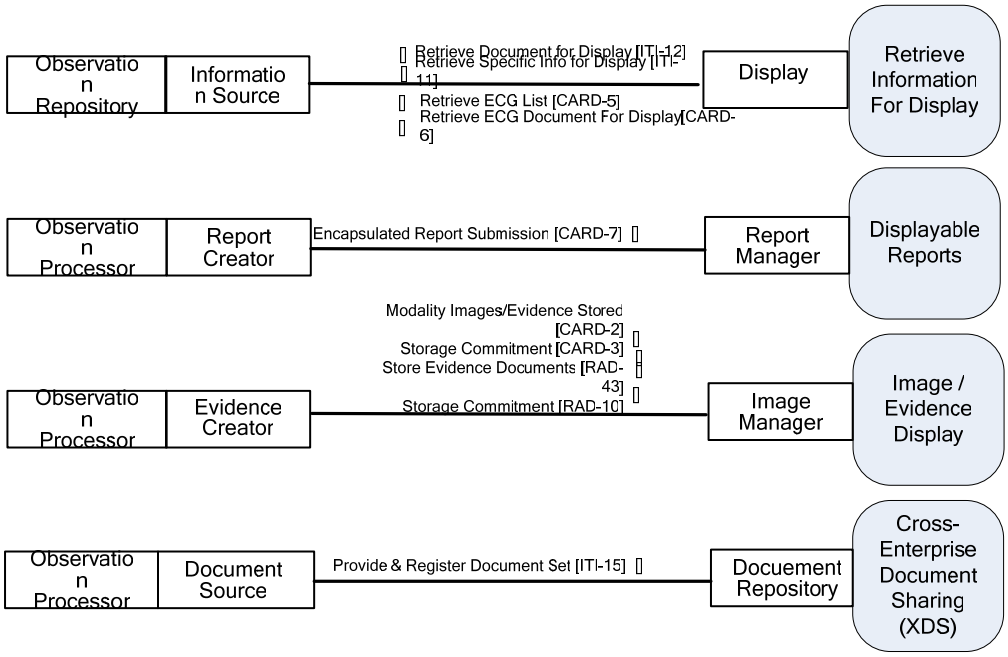


Figure 9.4-1 Extended Actor Groupings

9.4.1 Observation Repository with RID Information Source

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.

9.4.2 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.

9.4.3 Observation Processor with DRPT Report Creator

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.

9.4.4 Observation Processor with ED Evidence Creator

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.

9.4.5 Observation Processor with Document Source

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 to 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.

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 require cross-referencing of patient identifiers across the two Patient Identifier Domains: the device vendor systems providing the observations and the clinics receiving the observations.

The profile uses the PIX Query (ITI-9) transaction for those actors to obtain cross-referencing information. The PIX Consumer actor is grouped with the Observation Repository and Observation Processor actors. The PIX Manager actor is not specified within this profile but is assumed to exist.

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 unique identifier as specified in the Send Observation (CARD-14) 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.

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 Intrastructure Technical Framework for more information.

9.6 IDCO Use Cases

9.6.1 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.

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 Router / Observation Processor / Observation Repository actors. The HL7 formatted implanted cardiac device interrogation message is the CARD-14 transaction.

9.6.2 Use Case I2: 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.

9.6.3 Use Case I3: 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 anaysis, 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 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 essential.

Add to Appendix D Glossary

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

Changes to Volume II – Transactions

Add New Transaction

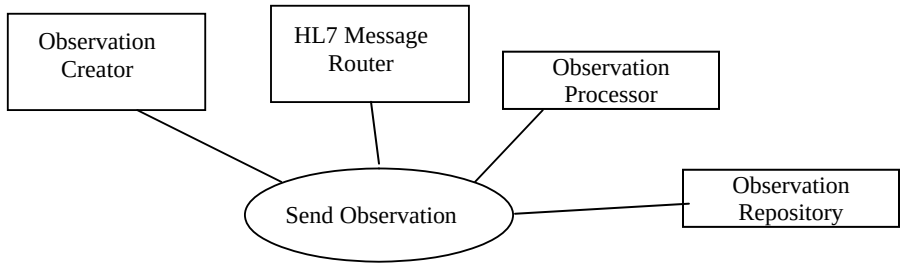
4.14 Send Observation (CARD-14)

This section corresponds to transaction CARD-14 of the IHE Technical Framework. Transaction CARD-14 is used by the Observation Creator, HL7 Message Router, Observation Repository and Observation Processor actors.

4.14.1 Scope

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

4.14.2 Use Case Roles



Actor: Observation Creator

Role: Outputs the Observation as an HL7 ORU message upon completion of the observation. This message contains all of the discrete data for the observation plus optional encapsulated XML and PDF documents containing discrete and graphical data relating to the observation.

Actor: HL7 Message Router

Role: Receives the HL7 ORU message from the Observation Creator, and outputs the message unchanged to each actor that has subscribed (has been configured) to the HL7 Message router.

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, reformated data, population statistics, etc.).

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. It maintains demographic information consistency with the enterprise based on patient update transactions of the PAM profile.

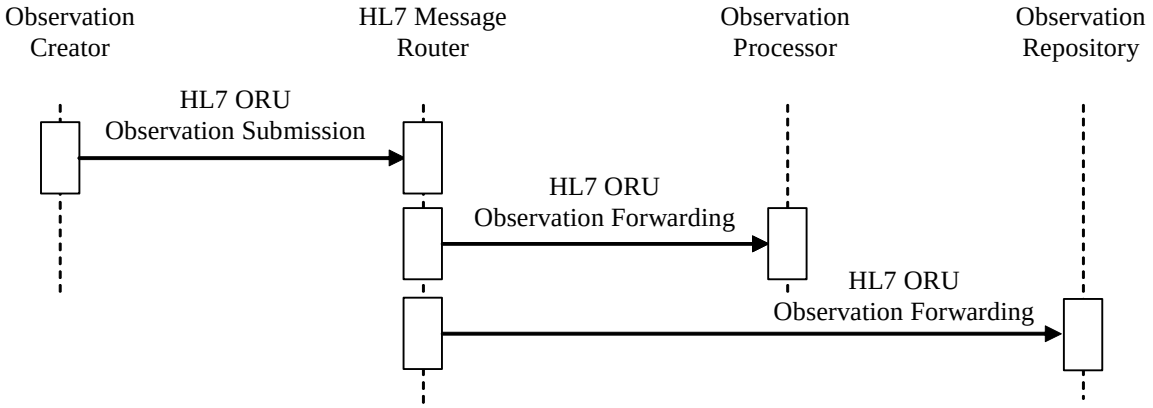
4.14.3 Referenced Standards

HL7 Messaging Standard v.2.5

HL7 Messaging Standard v.3

IEEE 1073.1.1.3 Implantable Cardiac Device Nomenclature

4.14.4 Interaction Diagram



4.14.5 Observation Submission

4.14.5.1 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.

4.14.5.2 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 HL7 v3 Implantable Cardiac Device Follow-up message, an optional encapsulated PDF document, and an optional set of individual observations or measurements transcoded from the encapsulated v3 message into separate 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.

4.14.5.2.1 ORU - Unsolicited Observation Message

The constrained message structure is given in Table 4.14-1, with additional details provided in sections below.

Table 4.14-1 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 XML payload	7
[OBX]	Observation result	PDF document payload	7
[	--- optional v2.5 payload BEGIN	If V2.5 Payload Option is claimed	
OBR	Observations Request for Pulse Generator	Pulse Generator Device context of v2.5 payload OBX's	2
{OBX}	Observation results	v2.5 payload items related to the pulse generator	7
[{	--- Lead grouping BEGIN		
OBR	Observations Request for Lead	Lead Device context of v2.5 payload OBX's	2
{OBX}	Observation results	v2.5 payload items related to the lead	
}]	--- Lead grouping END		
]	--- optional v2.5 END		
[DSC]	Continuation Pointer		2

4.14.5.2.2 MSH Segment – Message Header

Table 4.14-2 – MSH Segment

ELEMENT NAME	SEQ	DT SEQ	DT	LEN	OPT	RP/#	MIN / MAX	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		IS	20	R		1/1		00003		Device Vendor App
Sending Facility	4		CWE	40	R		1/1		00004		GDT
Receiving Application	5		IS	40	R		0/1		00005		*Clinic Application*
Receiving Facility	6		IS	40	R		0/1		00006		Clinic ID

ELEMENT NAME	SEQ	DT SEQ	DT	LE N	OPT	RP/ #	MIN / MAX	TBL #	ITEM #	Fixed	Ex. Values
Message Type	9		CM	7	R		1/1	0076	00009		
Message Code		*1*	*ID*	*3*	*R*		*1/1*	0076	00009	*Y*	*ORU*
Trigger Event		*2*	*ID*	*3*	*R*		*1/1*			*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	Y	1/1	0211	00692		8859/1

4.14.5.2.2 PID Segment – Patient Identification

Table 4.14-3 – PID Segment

ELEMENT NAME	SEQ	DT SEQ	DT	LEN	OPT	RP/#	MIN / MAX	TBL#	ITEM #	Fixed	Ex. Values
Patient Identifier List	3		CX	20	R	Y	1/*		00106		
ID Number		*1*	*ST*	*50*	*R*		*1/1*				*123456-1234567890*
Assigning Authority		*3*	*HD*	*20*	*R*		*1/1*				*Device Vendor*
Identifier Type Code		*4*	*ID*		*R*			*0203*			*MS*
Patient Name	5		XPN	140	RE	Y	1/*		00108		Smith^John
Date/Time Of Birth	7		TS	8	RE		0/1		001100		19590602
Sex	8		IS	1	RE		0/1		00111		M
Patient Address	11		XAD	106	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 User Defined Table 0203 list below (others can be included as defined in the 2.5 standard). 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 4.14-4 User Defined Table 0203

Code	Description	Notes	OPT
MS	Model and Serial Number of Device IEEE E1073.1.3 MDC_IDC_DEVICE_MODEL_NUMBER and MDC_IDC_DEVICE_SERIAL_NUMBER	Model and Serial number should 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 should be included if known.	RE

4.14.5.2.3 PV1 Segment – Patient Visit (Optional)

Table 4.14-5 – PV1 Segment

ELEMENT NAME	SEQ	DT SEQ	DT	LEN	OPT	RP/#	MIN / MAX	TBL#	ITEM #	Fixed	Ex. Values
Set ID - PV1	1		SI	1	R		1/1			Y	1
Patient Class	2		IS	1	R		1/1		0004	Y	R
Location	3		ST	40	O		0/1				Clinic Location
Attending Doctor	7		XCN	60	O		0/1		0010		
Visit Number	19		NM	10	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.

4.14.5.2.4 OBR Segment – Observation Request

Table 4.14-6 – OBR Segment

ELEMENT NAME	SEQ	COMP	DT	LEN	OPT	RP/#	MIN / MAX	TBL#	ITEM #	Fixed	Ex. Values
Set ID – OBR	1		SI	1	R		1/1		00237	Y	1
Placer Order Number	2		ST	10	RE		1/1		00216		1234567890
Filler Order Number	3		ST	10	RE		1/1		00217		1234567891
Universal Service ID	4		CE	200	R		1/1		00238		
Identifier		*1*	*ST*	*25*	*R*		*1/1*			*Y*	*Follow-up*

ELEMENT NAME	SEQ	COMP	DT	LEN	OPT	RP/#	MIN / MAX	TBL#	ITEM #	Fixed	Ex. Values
Text		*2*	*ST*	*25*	*R*		*1/1*			*Y*	*HL7 v2.5 device observations for a Follow-up*
Observation Date/Time #	7		TS	24	R		1/1		00241		20060317160000+0006
Observation End Date/Time #	8		TS	24	RE		0/1		00242		20060317170000+0006
Ordering Provider	16		ST	10	RE		0/1		00226		janderson
Filler Field 1	20		ST	50	RC		0/1				Model:12345678/serial:123234345
Results Rpt/Status Chng - Date/Time +	22		TS	24	RE		0/1				20060317170000+0006
Result Status +	25		ID	1	R		1/1	0123			F
Principal Result Interpreter	32		NDL	835	O		0/1				
Assistant Result Interpreter	33		NDL	835	O	Y	0/1				
Technician	34		NDL	835	O	Y	0/1				

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 generated by the interrogator system. The assigning authority is the interrogator system.

OBR-4.1-2 Universal Service ID, Identifier and Text can identify unique OBR segments that partition observations. There may be multiple OBR segments for a message. A separate OBR should be created for each Lead being reported on. The following table lists of values for these fields.

Table 4.14-7 User Defined Table

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

OBR-16.1 Ordering Provider, ID Number is the name of the user account performing the interrogation (on the interrogating system).

OBR-20 Filler Field 1 is conditional and is required if the v2.5 payload option is supported and the OBR is meant for device context. It will contain the concatenated model-serial number of the

Implanted Cardiac Device or Lead (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_NUMBER, MDC_IDC_DEVICE_SERIAL_NUMBER, MDC_IDC_LEAD_MODEL terms.

OBR-25 Result Status values shall be one of the following table.

Table 4.14-8 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 should at a minimum define components Name and Facility.

4.14.5.2.5 OBX Segment with Encapsulated v3 Message

An attached XML document containing the HL7 v3 Therapeutic Device Domain / Implantable Device – Cardiac / Implantable Cardiac Device Results Notification message must be included as part of the observation. The XML document must be encapsulated within an OBX-5 Observation Value field of the OBX segment.

Table 4.14-9 – OBX Segment

ELEMENT NAME	SEQ	COMP	DT	LEN	OPT	RP/#	MIN / MAX	TBL#	ITEM #	Fixed	Ex. Values
Set ID - OBX	1		SI	3	R		1/1				1
Value Type	2		ID	2	R		1/1	0125		Y	ED
Observation Identifier	3		CE	80	R		1/1				
Identifier		*1*	*ST*	*40*	*R*		*1/1*			*Y*	*POTD_RM000001*
Text		*2*	*ST*	*80*	*R*		*1/1*			*Y*	*Embedded HL7 v3 ICD Message*
Observation Value	5		ED	*	R		1/1				
Type of Data		*2*	*ST*	*10*	*R*		*1/1*			*Y*	*Application*
Data Subtype		*3*	*ST*	*10*	*R*		*1/1*			*Y*	*XML*
Encoding		*4*	*ST*	*10*	*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		Y	F

ELEMENT NAME	SEQ	COMP	DT	LEN	OPT	RP/#	MIN / MAX	TBL#	ITEM #	Fixed	Ex. Values
Date/Time of the Observation	14		DTM	8	RE		0/1				20060317170000+0006
Observation Method	17		CE								
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	O	Y	0/1				Programmer XXXX

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 instance only, message wrappers (transmission and control act) should not be included. The RMIM POTD_RM000001 is shown in Figure 4.14-3 - POTD_RM000001, and the Hierarchical Message Description (HMD) POTD_HD000001 for the message is defined in Table 4.14-10 following. Refer to the HL7 Therapeutic Devices Implantable Cardiac Device Topic ballot at http://www.hl7.org/v3ballot/html/domains/td/hmpotd.htm for detailed message implementation specifications.

The deviceObservation, patientObservation, deviceTherapy, and deviceTherapySettings classes of observations should 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 & Name of Coding system – values will 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.

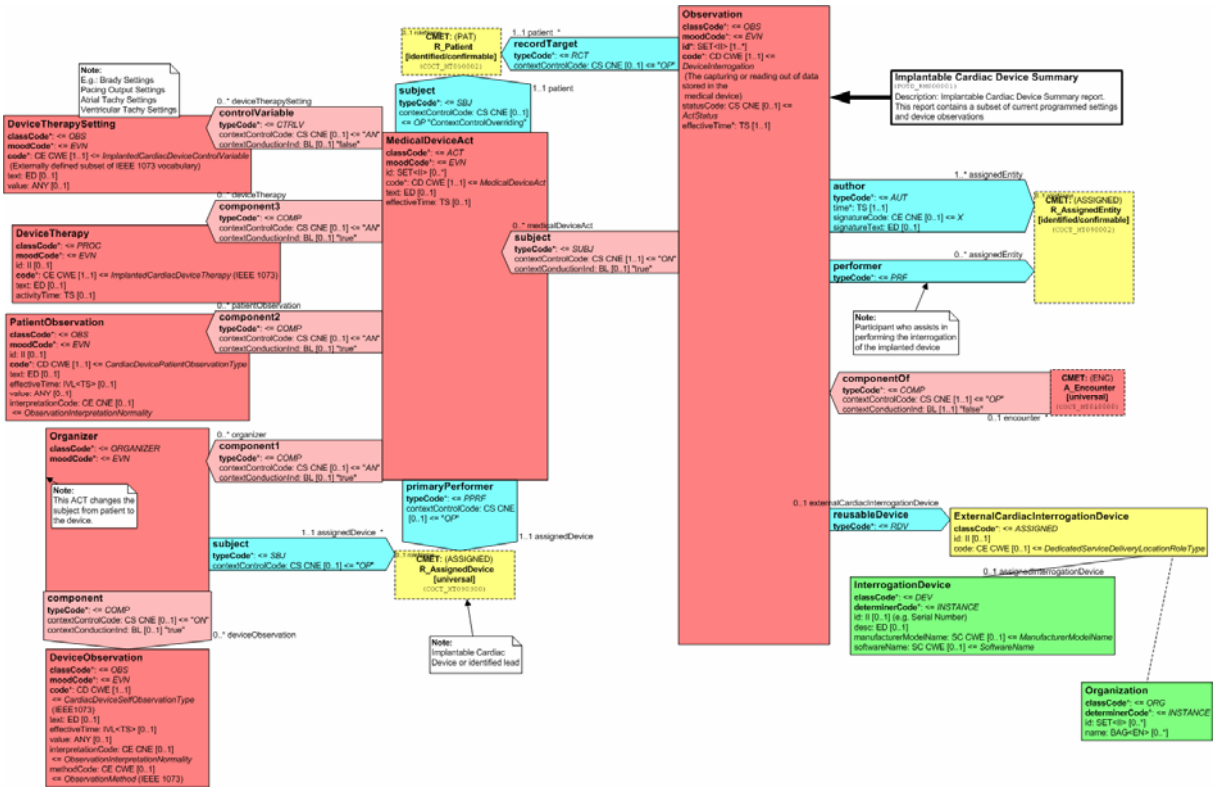


Figure 4.14-3 - POTD_RM000001

Table 4.14-10 - HMD

No	Element Name	Card	Mand	Conf	Rim Source	of Message Element Type	CS
	Implanted Cardiac Device Follow-Up	Common message for POTD_HD000001					
1	**Observation**	0..1			Observation	Observation	
2	classCode	1..1	M	R	Act	CS	CNE
3	moodCode	1..1	M	R	Act	CS	CNE
4	id	1..*	M	R	Act	SET<II>	
5	code	1..1	M	R	Act	CD	CWE
6	statusCode	0..1			Act	CS	CNE
7	effectiveTime	1..1		R	Act	TS	
8	**reusableDevice**	0..1			Act	ReusableDevice	
9	typeCode	1..1	M	R	Participation	CS	CNE
10	**externalCardiacInterrogationDevice**	1..1			Participation	ExternalCardiacInterrogationDevice	
11	classCode	1..1	M	R	Role	CS	CNE
12	id	0..1			Role	II	
13	code	0..1			Role	CE	CWE
14	**assignedInterrogationDevice**	0..1			Role	InterrogationDevice	
15	classCode	1..1	M	R	Entity	CS	CNE
16	determinerCode	1..1	M	R	Entity	CS	CNE
17	id	0..1			Entity	II	
18	desc	0..1			Entity	ED	
19	manufacturerModelName	0..1			Device	SC	
20	softwareName	0..1			Device	SC	
21	**recordTarget**	1..1		R	Act	RecordTarget	
22	typeCode	1..1	M	R	Participation	CS	CNE
23	contextControlCode	0..1			Participation	CS	CNE
24	***patient***	1..1		R	Participation	COCT_MT050002UV04	
25	**performer**	0..*			Act	SET<Performer>	
26	typeCode	1..1	M	R	Participation	CS	CNE
27	***assignedEntity***	1..1			Participation	COCT_MT090002UV01	
28	**author**	1..*			Act	SET<Author2>	
29	typeCode	1..1	M	R	Participation	CS	CNE
30	time	1..1		R	Participation	TS	
31	signatureCode	0..1			Participation	CE	CNE
32	signatureText	0..1			Participation	ED	
33	***assignedEntity***	1..1			Participation	COCT_MT090002UV01	
34	**subject**	0..*			Act	SET<Subject1>	
35	typeCode	1..1	M	R	ActRelationship	CS	CNE
36	contextControlCode	1..1			ActRelationship	CS	CNE
37	contextConductionInd	0..1			ActRelationship	BL	
38	**medicalDeviceAct**	1..1			ActRelationship	MedicalDeviceAct	
39	classCode	1..1	M	R	Act	CS	CNE
40	moodCode	1..1	M	R	Act	CS	CNE
41	id	0..*			Act	SET<II>	
42	code	1..1		R	Act	CD	CWE
43	text	0..1			Act	ED	
44	effectiveTime	0..1			Act	TS	
45	**subject**	1..1			Act	Subject3	
46	typeCode	1..1	M	R	Participation	CS	CNE
47	contextControlCode	0..1			Participation	CS	CNE

Table 4.14-10 - HMD (cont.)

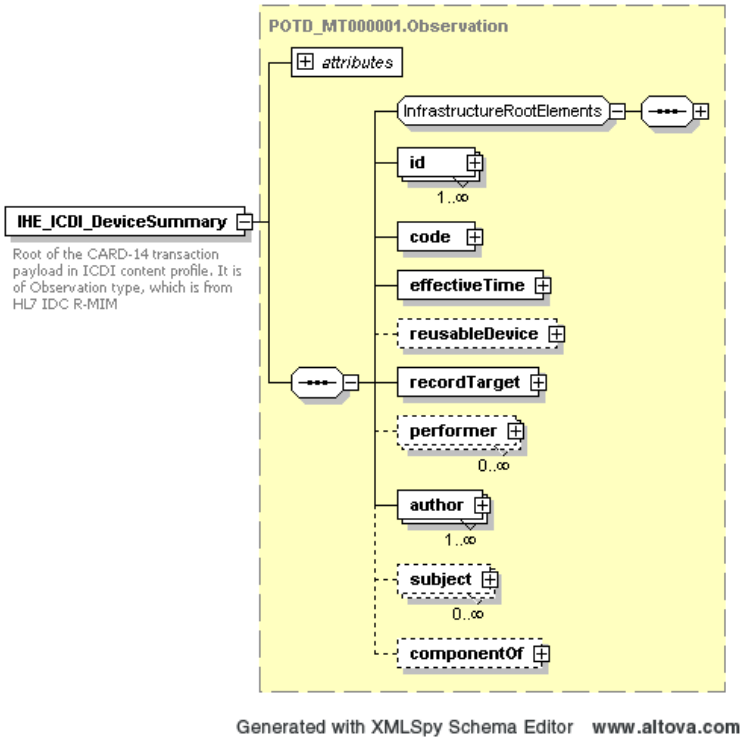
No	Element Name	Card	Mand	Conf	Rim Source	of Message Element Type	CS
48	***patient***	1..1			Participation	COCT_MT050002UV04	
49	**primaryPerformer**	1..1			Act	PrimaryPerformer	
50	typeCode	1..1	M	R	Participation	CS	CNE
51	contextControlCode	0..1			Participation	CS	CNE
52	***assignedDevice***	1..1			Participation	COCT_MT090300UV01	
53	**component1**	0..*			Act	SET<Component1>	
54	typeCode	1..1	M	R	ActRelationship	CS	CNE
55	contextControlCode	0..1			ActRelationship	CS	CNE
56	contextConductionInd	0..1			ActRelationship	BL	
57	**organizer**	1..1			ActRelationship	Organizer	
58	classCode	1..1	M	R	Act	CS	CNE
59	moodCode	1..1	M	R	Act	CS	CNE
60	**subject**	1..1		R	Act	Subject2	
61	typeCode	1..1	M	R	Participation	CS	CNE
62	contextControlCode	0..1			Participation	CS	CNE
63	***assignedDevice***	1..1		R	Participation	COCT_MT090300UV01	
64	**component**	0..*			Act	SET<Component2>	
65	typeCode	1..1	M	R	ActRelationship	CS	CNE
66	contextControlCode	0..1			ActRelationship	CS	CNE
67	contextConductionInd	0..1			ActRelationship	BL	
68	**deviceObservation**	1..1			ActRelationship	DeviceObservation	
69	classCode	1..1	M	R	Act	CS	CNE
70	moodCode	1..1	M	R	Act	CS	CNE
71	code	1..1	M	R	Act	CD	CWE
72	text	0..1			Act	ED	
73	effectiveTime	0..1			Act	IVL<TS>	
74	value	0..1			Observation	ANY	
75	interpretationCode	0..1			Observation	CE	CNE
76	methodCode	0..1			Observation	CE	CWE
77	**component2**	0..*			Act	SET<Component3>	
78	typeCode	1..1	M	R	ActRelationship	CS	CNE
79	contextControlCode	0..1			ActRelationship	CS	CNE
80	contextConductionInd	0..1			ActRelationship	BL	
81	**patientObservation**	1..1			ActRelationship	PatientObservation	
82	classCode	1..1	M	R	Act	CS	CNE
83	moodCode	1..1	M	R	Act	CS	CNE
84	id	0..1			Act	II	
85	code	1..1	M	R	Act	CD	CWE
86	text	0..1			Act	ED	
87	effectiveTime	0..1			Act	IVL<TS>	
88	value	0..1			Observation	ANY	
89	interpretationCode	0..1			Observation	CE	CNE
90	**component3**	0..*			Act	SET<Component4>	
91	typeCode	1..1	M	R	ActRelationship	CS	CNE
92	contextControlCode	0..1			ActRelationship	CS	CNE
93	contextConductionInd	0..1			ActRelationship	BL	
94	**deviceTherapy**	1..1			ActRelationship	DeviceTherapy	
95	classCode	1..1	M	R	Act	CS	CNE
96	moodCode	1..1	M	R	Act	CS	CNE
97	id	0..1			Act	II	
98	code	1..1	M	R	Act	CE	CWE
99	text	0..1			Act	ED	
100	activityTime	0..1			Act	TS	
101	**controlVariable**	0..*			Act	SET<ControlVariable>	
102	typeCode	1..1	M	R	ActRelationship	CS	CNE
103	contextControlCode	0..1			ActRelationship	CS	CNE
104	contextConductionInd	0..1			ActRelationship	BL	
105	**deviceTherapySetting**	1..1			ActRelationship	DeviceTherapySetting	
106	classCode	1..1	M	R	Act	CS	CNE
107	moodCode	1..1	M	R	Act	CS	CNE
108	code	1..1	M	R	Act	CE	CWE
109	text	0..1			Act	ED	
110	value	0..1			Observation	ANY	
111	**componentOf**	0..1		R	Act	Component5	
112	typeCode	1..1	M	R	ActRelationship	CS	CNE
113	contextControlCode	1..1			ActRelationship	CS	CNE
114	contextConductionInd	1..1			ActRelationship	BL	
115	***encounter***	1..1		R	ActRelationship	COCT_MT010000UV01	

4.14.5.2.5.1 XML scheme

The IDCO profile defines constraints for the IDC R-MIM usage in CARD-14 transaction at the XML scheme level.

The xml document that is encoded in OBX.5 segment shall be constructed based on the xml scheme 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 IDCO 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_MT000001.xsd"/>
	<xs:complexType name="IEEE1073_Enumerated">
		<xs:complexContent>
			<xs:extension base="CD"/>
		</xs:complexContent>
```

```
        </xs:complexType>
        <xs:complexType name="IEEE1073_NumberwithUnit">
                <xs:complexContent>
                        <xs:extension base="PQ"/>
                </xs:complexContent>
        </xs:complexType>
        <xs:complexType name="IEEE1073_Type_String">
                <xs:complexContent>
                        <xs:extension base="ST"/>
                </xs:complexContent>
        </xs:complexType>
        <xs:element name="IHE_IDCO_DeviceSummary" type="POTD_MT000001.Observation">
                <xs:annotation>
                        <xs:documentation>Root of the CARD-14 transaction payload in IDCO content profile.
It is of Observation type, which is from HL7 IDC R-MIM </xs:documentation>
                </xs:annotation>
        </xs:element>
        <xs:complexType name="IEEE1073_DateTime">
                <xs:complexContent>
                        <xs:extension base="TS"/>
                </xs:complexContent>
        </xs:complexType>
        <xs:complexType name="IEEE1073_Type_Number_Integer">
                <xs:complexContent>
                        <xs:extension base="INT"/>
                </xs:complexContent>
        </xs:complexType>
        <xs:complexType name="IEEE1073_Type_Number_Real">
                <xs:complexContent>
                        <xs:extension base="REAL"/>
                </xs:complexContent>
        </xs:complexType>
        <xs:complexType name="IEEE1073_Type_CompositeValue">
                <xs:complexContent>
                        <xs:extension base="CD">
                                <xs:sequence>
                                        <xs:element name="value" type="ANY" minOccurs="2"
maxOccurs="unbounded"/>
                                </xs:sequence>
                        </xs:extension>
                </xs:complexContent>
        </xs:complexType>
</xs:schema>
```

4.14.5.2.5.2 IHE_IDCO_DeviceSummary->effectiveTime element constraints

IHE_IDCO_DeviceSummary ->effectiveTime element is set to the timestamp of the session where this device summary data was captured. It shall have a meaning of the

MDC_IDC_PREVIOUS_SESSION_DATE_TIME item defined in IEEE 1073.1.1.3 nomenclature. If OBX-14 is set in the HL7 2.5 message wrapper, these values should match.

4.14.5.2.5.3 ReusableDevice - Interrogation device – programmer

This is optional but recommended.

reusableDevice->externalCardiacInterrogationDevice->assignedInterrogationDevice element 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 manufacturer has own code tables defined, but the values shall be also stored as *st* element values. If OBX-18 Equipment Instance Identifier is set in the HL7 v2.5 wrapper, these values should match.

4.14.5.2.5.4 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
- The demographics data in other elements - *name, administrativeGenderCode, birthTime* are strongly recommended to be populated as much as available to Observation Creator. It will be necessary to for Observation Processor for patient identity mapping.

4.14.5.2.5.5 Interrogation device – Author

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

- *assignedEntity->id* element shall contain the clinical ID of the clinician
- assignedEntity->assignedPerson->*name* element should contain at least *family* and *given* elements
- *Author*->assignedEntity->*representedOrganization* 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 33 Assistant Result Interpreter are set in the HL7 2.5 message wrapper, these values should match.

4.14.5.2.5.6 Performer

This element is optional. According to R-MIM, 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 message wrapper, these values should match.

4.14.5.2.5.7 Encounter

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

4.14.5.2.5.8 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 R-MIM model and generated XML scheme 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 constraint 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 equals with *IHE_IDCO_DeviceSummary ->effectiveTime*.

4.14.5.2.5.9 Implantable Cardiac Device – pulse generator

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

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

- assignedDevice shall have 1 instance of child *id* element, no other elements nor attributes are required
    - *id.extension* is set to combination of MDC_IDC_DEVICE_MODEL_NUMBER in nomenclature and MDC_IDC_DEVICE_SERIAL_NUMBER, formatted by same rules that apply to PID-3.1 in HL7 2.5 wrapper (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 should 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*.

The nomenclature item MDC_IDC_DEVICE_LEADS_NUMBER_ACTIVE is added to Organizer that represents Implantable Cardiac Device.

4.14.5.2.5.10 Leads

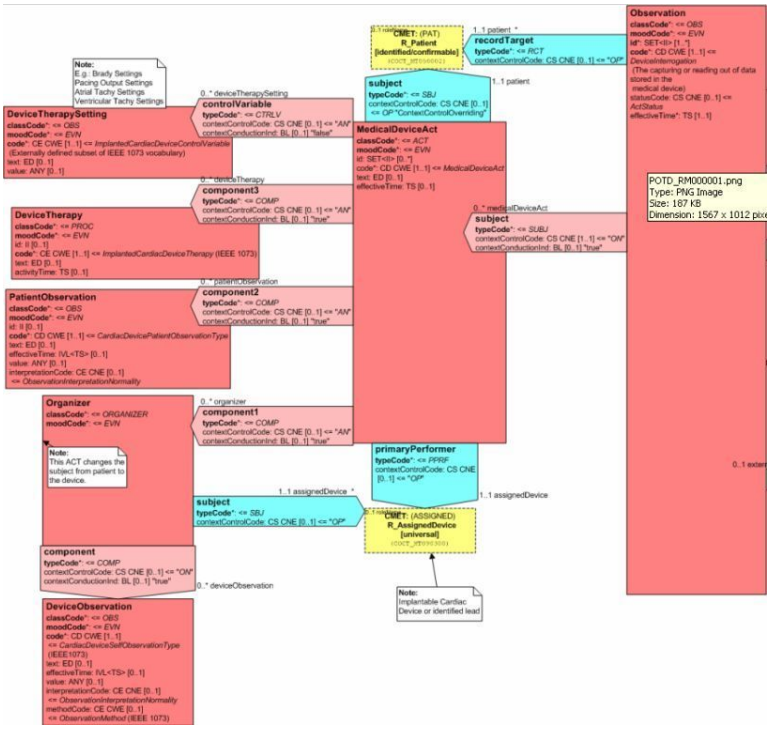
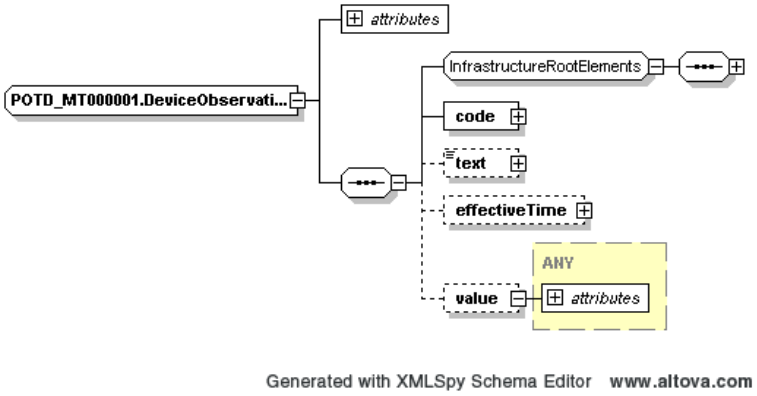
Each lead is represented with one instance of *medicalDeviceAct ->component1->Organizer* element. The cardinality of *medicalDeviceAct ->component1* shall be number of leads +1. The number of leads shall be equal to the value of DeviceObservation with Reference ID == MDC_IDC_DEVICE_LEADS_NUMBER_ACTIVE in the nomenclature.

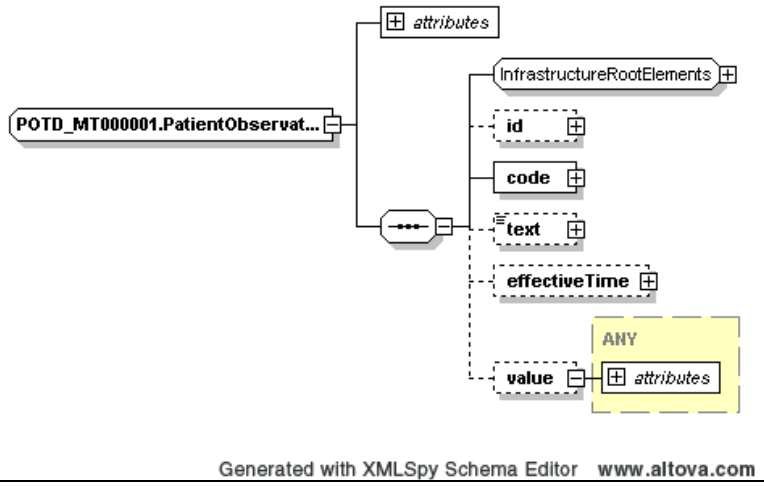
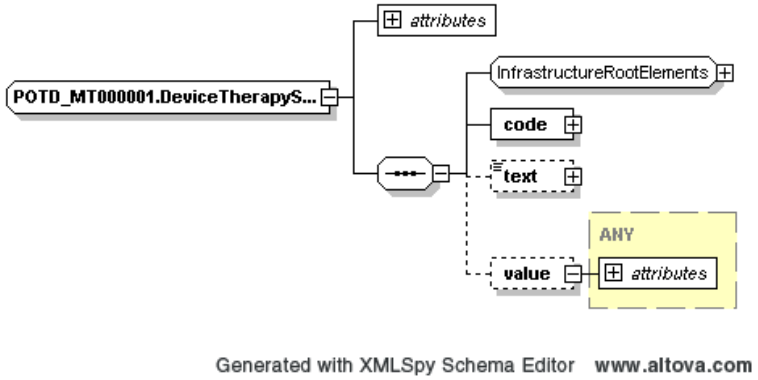
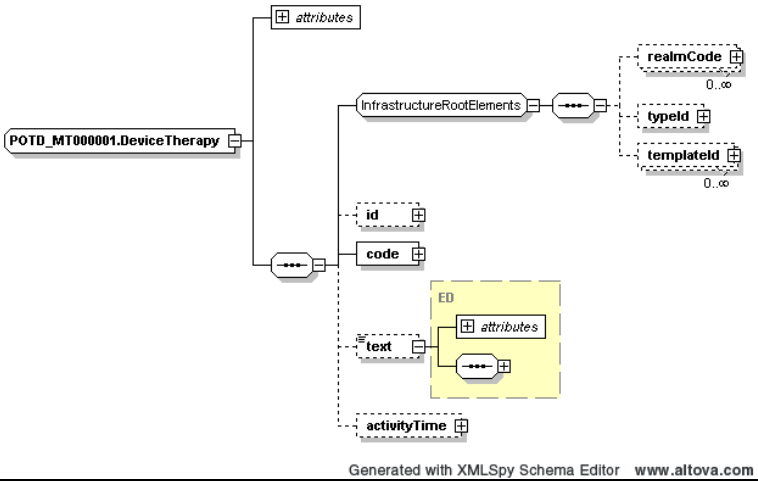
The *Organizer->subject->assignedDevice* element shall be created

- assignedDevice shall have 1 instance of child *id* element, no other elements nor attributes are required
    - *id.extension* is set to combination of MDC_IDC_LEAD_MODEL in nomenclature and MDC_IDC_LEAD_SERIAL_NUMBER, formatted by same rules that apply to PID-3.1 in HL7 2.5 wrapper (model:xxx/serial:yyy)
    - *id.root* is optional and shall be set to UID of the manufacturer, if available

4.14.5.2.5.11 IEEE 1073.1.1.3 item mapping

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

IEEE 1073.1.1.3	HL7 POTD_MT000001	Mapping details
All groups	 Click on picture to open Browser	*code* element stores the identity of this observation item. See section 0 for details. *id* element should not be created, *code* is used for identity *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)
Device Observation	 Generated with XMLSpy Schema Editor www.altova.com	The value is stored in *value* element of corresponding type (see section 0) and is required. The *text* element is optional and if present then it holds a free text comment about this observation. Note! *text* can be used instead of value in case where value does not exist, but

		there is a need to communicate the reason of absence!
Patient Observation		The value is stored in *value* element of corresponding type (see section 0) and is required. The *text* element is optional and if present then it holds a free text comment about this observation.
Device Therapy Setting		The value is stored in *value* element of corresponding type (see section 0) and is required. The *text* element is optional and if present then it holds a free text comment about this observation.
Device Therapy		The value of String type is stored in *text* element The *activityTime* element should be created if it is different from *effectiveTime* of this Observation.

4.14.5.2.5.12 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)
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

code	name	definition
		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, whether or not they would normally use the IEEE nomenclature.

Example: MDC_IDC_PACING_VENTRICULAR_OFFSET has numeric values with exceptional value “Off”. Because *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 “OTH” – meaning Other. The description of the reason i.e. “Off” shall be stored in *text* element.

Example:

```
<deviceTherapySetting classCode="OBS" moodCode="EVN">
  <code code="MDC_IDC_PACING_SENSED_AV_OFFSET" codeSystemName="IEEE P1073.1.1.3"
      codeSystemVersion="1.0" codeSystem=”HL7 MDC OID” displayName="Sensed AV Offset" />
  <text>Off</text>
  <value nullFlavor="OTH" xsi:type="IEEE1073_NumberwithUnit" />
</deviceTherapySetting>
```

4.14.5.2.5.13 *code* mapping

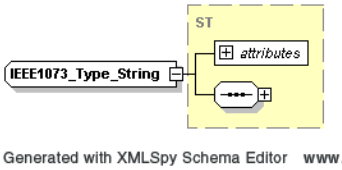
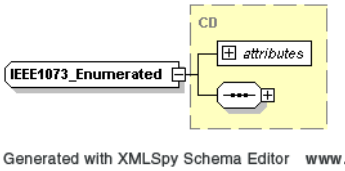
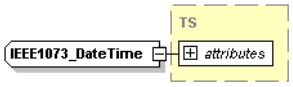
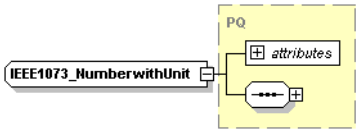
Each observation item is defined by its *code* element.

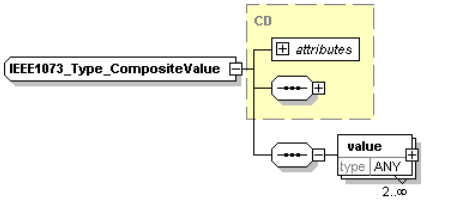
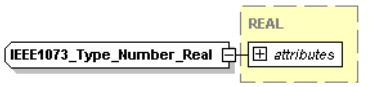
***code* element attribute**	**IEEE 1073.1.1.3 field**	**Example**
code	Reference ID	“MDC_IDC_BATTERY_LIFE”
codeSystem	uid of IEEE 1073.1.1.3	**TBD**
codeSystemName	IEEE 1073.1.1.3 ICD terms	“IEEE 1073.1.1.3 ICD terms”
codeSystemVersion	Used version	“1.0”
displayName	IEEE Common Name	“Battery Life”

```
<code code="MDC_IDC_BATTERY_LIFE" codeSystem="TBD" codeSystemName="IEEE 1073.1.1.3 ICD
      terms" displayName="BatteryLife" />
```

4.14.5.2.5.14 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 R-MIM 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
	string, not enumerated	The value is stored in element. None of the attributes is used.	<value xsi:type= "IEEE1073_Type_String">this is string value</value>
	string, enumerated values	As minimum *displayName* attribute is required. If the code is defined by any code table, then the *code and codeSystemName* should also be present. If the Table is normative then *codeSystem* attribute should be set	<value code="BOL" codeSystemName= "IEEE 1073.1.1.3 ICD terms" displayName="Beginning of Life" xsi:type="IEEE 1073_Enumerated" />
	Date	The value is stored in *value* attribute, which is simple xml **ts** type	<value value="20060117" xsi:type="IEEE1073_DateTime"/>
	Number(x,y) Number(x) with Units specified	The value is stored *value* attribute with is of XML type *real*. The unit is stored in *unit* attribute,	<value unit="1/min" value="100.0" xsi:type= "IEEE1073_NumberwithUnit"/>

		which is XML simple type *cs*, is coded with UCUM unit code as string specified in UCUM c/s column if nomenclature	
	Complex types which consist of two or more sub-values	The complex type is separated to more than one sub-element. Consist of 2 or more *value* elements; each is of any types described in this table and in IHE_IDCO.xsd	<value xsi:type= "**IEEE1073_Type_CompositeValue** "> <value unit="**mV**" value="**900.0**" xsi:type= "**IEEE1073_NumberwithUnit** " /> <value unit="**ms**" value="**0.5**" xsi:type= "**IEEE1073_NumberwithUnit** " /> </value>
	Number(x) Number(x,0) With no units specified	The value is stored *value* attribute which is of XML type **int**.	<value value="**5**" xsi:type="**IEEE1073_Type_Number_Integer**" />
	Number(x,y) Where y!=0 With no units specified	The value is stored *value* attribute which is of XML type **real**.	There is no items of such type in current nomenclature

4.14.5.2.5.15 IEEE 1073.1.1.3 nomenclature Automatic/Manual mapping

The 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

4.14.5.2.6 OBX Segment with Encapsulated PDF [Optional]

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

Table 4.14-13 – OBX Segment

ELEMENT NAME	SEQ	COMP	DT	LEN	OPT	RP/#	MIN / MAX	TBL#	ITEM #	Fixed	Ex. Values
Set ID - OBX	1		SI	3	R		1/1				1
Value Type	2		ID	2	R		1/1	0125		Y	ED
Observation Identifier	3		CE	80	R		1/1				
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				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		Y	
Date/Time of the Observation	14		DTM	8	RE		0/1				20060317170000+0006
Observation Method	17		CE								
Identifier		*1*	*ST*	*20*	*R*		*1/1*				*MDC_IDC_SESSION_TYPE*

ELEMENT NAME	SEQ	COMP	DT	LEN	OPT	RP/#	MIN / MAX	TBL#	ITEM #	Fixed	Ex. Values
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	Y	1/1				Programmer XXXX

OBX-3 is report ID from LOINC coding system, and should 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.

4.14.5.2.7 OBX Segment – Observation Results with v2.5 Observations

If the Observation Creator claims the V2.5 Payload Option, it shall encode into separate OBX segments significant individual observations or measurements transcoded from the encapsulated v3 message. These OBX segments shall be preceded by an appropriate OBR segment (see 4.14.5.2.4) to set the context for observations dealing with the pulse generator or with the leads.

Table 4.14-14 – OBX Segment

ELEMENT NAME	SEQ	COMP	DT	LEN	OPT	RP/#	MIN / MAX	TBL#	ITEM #	Fixed	Ex. Values
Set ID - OBX	1		SI	3	R		1/1				1
Value Type	2		ID	2	R		1/1	0125			NM
Observation Identifier	3		CE	80	R		1/1				
Identifier		*1*	*ST*	*40*	*R*		*1/1*				*MDC_IDC_PACED_PERCENT_RECENT_LV*
Text		*2*	*ST*	*80*	*R*		*1/1*				*Recent Left Ventricular Pacing Percent: The percent of all left ventricular events since the last counter reset that were paced*
Name of Coding System		*3*	*ST*	*12*	*R*		*1/1*				*IEEE P10731.1.3*
Observation Value	5		varies	*	RE		0/1				50
Units	6		ST	20	RE		0/1				%
Observation Result Status	11		ID	1	R		1/1	0085		Y	
Date/Time of the Observation	14		TS	8	RE		0/1				20060317170000+0006
Observation Method	17		CE								
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	O	Y	0/1				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 4.14-15.

Table 4.14-15 – 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 should be ST.

OBX-2 3.1 Observation Identifier, Identifier – IEEE P10731.1.3 IDC Nomenclature Reference ID field for associated observation

OBX-2 3.2 Observation Identifier, Text - IEEE P10731.1.3 IDC Nomenclature Common Name field for associated observation

OBX-2 6 Unit – IEEE P10731.1.3 IDC Nomenclature Unit field for associated observation

OBX-2 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-2 18 Equipment Instance Identifier – A unique identifier for the equipment or software that was responsible for the production of the observation.

4.14.5.2.8 NTE Segment – Notes and Comments [Optional]

Table 4.14-16 – NTE Segment – Notes and Comments

ELEMENT NAME	SEQ	COMP	DT	LEN	OPT	RP/#	MIN/MAX	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	Y	1/*		01318		

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

4.14.5.3 Expected Actions – 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 route the message to all configured recipients. The HL7 Message Router shall not modify the content of the observation report it receives. Recipients include Observation Processor and/or Observation Repository actors.

4.14.6 Observation Forwarding

4.14.6.1 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.

4.14.6.2 Message Semantics

The message semantics are identical to the HL7 ORU message used in Observation Submission (see 4.14.5.2).

4.14.6.3 Expected Actions

4.14.6.3.1 Observation Processor

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

Upon receipt of this message, the Observation Processor shall reconcile the Patient ID in the message with the Patient ID of the assigning authority domain of the Observation Processor, using the PIX Profile transactions.

The Observation Processor will perform additional actions that are specific to that application. Reference section 4.14.2 for a description of the types of actions this actor may support.

If the Observation Processor claims the V2.5 Payload Option, it shall perform its application specific actions on the separate OBX segments of significant individual observations or measurements transcoded from the encapsulated v3 message.

4.14.6.3.2 Observation Repository

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

Upon receipt of this message, 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.

The Observation Repository shall store the received data and make it available through means that are specific to that application. Reference section 4.14.2 for a description of the types of actions this actor may support.

If the Observation Repository claims the V2.5 Payload Option, it shall perform its application specific actions on the separate OBX segments of significant individual observations or measurements transcoded from the encapsulated v3 message.

4.14.6.3.3 HL7 Message Router

The HL7 Message Router shall maintain a copy of the HL7 ORU message until all configured recipients have returned an acknowledgement, or until an implementation-specific timeout is reached.

Appendix Z – IDCO Observation Message Examples

HL7 v2.5 message example

This is an example of the message where all different payload options are used.

```
MSH|^~\&|Device Vendor App|GDT|Clinical App|Some Clinic|||ORU^R01|123450|P|2.5||||||8859/1|
PID|1|250004836|model:IMD_XZY/seraial:nr_123^^MS^GDT|| Anderson^John^A^JR||19310203000000|F|||Pinetree
3^^Valencia^CA^123456^US|||||||123-12-1234|
PV1|1|R|^^^Clinic Facility||||1234567890^John^Baker^^|||||||||||1234567890|||||||||||||||||||||||||||||V|

OBR|1||1234567890|Follow-Up^ HL7 v2.5 device observations for a Follow-up
|||20060317160000.0000+0006|20060317170000.0000+0006|||||||jbaker||||||20060317170000.0000+0006|||F|
OBX|1|ED|POTD_RM000001^Embedded HL7 v3 ICD Message^IEEE P10731.1.3||^Application^XML^Base64^Encoded XML File
Goes Here||||T|F|||20060317170000+0006|||MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer XXXX
OBX|2|ED|18750-0^Cardiac Electrophysiology Report^LN||^Application^PDF^Base64^Encoded PDF File Goes
Here||||||F|||20060317170000+0006|||MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer XXXX

OBR|2||1234567890| Follow-Up^ HL7 v2.5 device observations for a Follow-up
|||20060317160000.0000+0006|20060317170000.0000+0006|||||||jbaker||||model:IMD_XZY/seraial:nr_123
||20060317170000.0000+0006|||F|
OBX|1|ST|MDC_IDC_SESSION_TYPE^Session Type^IEEE P10731.1.3||Remote
Interrogation|||T||F|||||T|MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|2|ST|MDC_IDC_DEVICE_MANUFACTURER^Device Manufacturer^IEEE
P10731.1.3||GDT|T|||||F|T|||||MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|3|ST|MDC_IDC_DEVICE_TYPE^Device Type^IEEE P10731.1.3||CRT-D||||||F||||||MDC_IDC_SESSION_TYPE^In Clinic^IEEE
P10731.1.3|Programmer XXXX|
OBX|4|ST|MDC_IDC_DEVICE_NAME^Device Name^IEEE P10731.1.3||DeviceName||||||F||||||MDC_IDC_SESSION_TYPE^In
Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|5|ST|MDC_IDC_DEVICE_MODEL^Device Model^IEEE P10731.1.3||DeviceModel||||||F||||||MDC_IDC_SESSION_TYPE^In
Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|6|ST|MDC_IDC_DEVICE_MODEL_NUMBER^Device Model Number^IEEE
P10731.1.3||N123|||||||F|||||||MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|7|ST|MDC_IDC_DEVICE_SERIAL_NUMBER^Device Serial Number^IEEE
P10731.1.3||1234567890|T|||||F|T|||||MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|8|DT|MDC_IDC_SESSION_DATE_TIME^Date/Time of Communication Session^IEEE
P10731.1.3||20060317170000.0000+0006||||||F||||||MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer
XXXX|
OBX|9|ST|MDC_IDC_BATTERY_LIFE^Battery Life^IEEE P10731.1.3||BOL||||||F||||||MDC_IDC_SESSION_TYPE^In Clinic^IEEE
P10731.1.3|Programmer XXXX|
OBX|10|ST|MDC_IDC_BATTERY_STATUS_REMAINING^Battery Status^IEEE
P10731.1.3||Normal||||||F||||||MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|11|NM|MDC_IDC_BATTERY_MONITORING_VOLTAGE^Monitoring Voltage^IEEE
P10731.1.3||3.09|V|||||F|T|||||MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|12|NM|MDC_IDC_CAPACITOR_LAST_CHARGE_TIME^Charge Time^IEEE
P10731.1.3||0.3|s|||||F|T|||||MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|13|DTM|MDC_IDC_CAPACITOR_LAST_REFORM_CHARGE_DATE^Last Reform Charge Date^IEEE
P10731.1.3||20060317170000.0000+0006|||||T|F|||||T|MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer
XXXX|
OBX|14|DTM|MDC_IDC_COUNTERS_CLEARED_DATE^Last Counters Cleared Date^IEEE
P10731.1.3||20060101120000.0000+0006||||||F||||||MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer
XXXX|
OBX|15|NM|MDC_IDC_CTR_FIB_EPISODES_RECENT_RV^Ventricular Fibrillation Episodes^IEEE
P10731.1.3||1|||||T|F|T|||||MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|16|NM|MDC_IDC_CTR_TACHY_EPISODES_RECENT_RV^Ventricular Tachy Episodes^IEEE
P10731.1.3||0|||||T|F|T|||||MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|17|NM|MDC_IDC_CTR_TACHY_EPISODES_RECENT_RA^Atrial Tachy Episodes^IEEE
P10731.1.3||0|||||T|F|T|||||MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|18|NM|MDC_IDC_CTR_TACHY_NONSUSTAINED_VT_EPISODES_RV^Non-Sustained Ventricular Episodes^IEEE
P10731.1.3||0|||||T|F|T|||||MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|19|NM|MDC_IDC_CTR_MODESWITCH_EPISODES_RECENT_RA^Mode Switch Episodes^IEEE
P10731.1.3||2|||||T|F|T|||||MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|20|NM|MDC_IDC_PACED_PERCENT_RECENT_RA^Atrial Percent Paced^IEEE
P10731.1.3||0|%|||||F|||T|||MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|21|NM|MDC_IDC_PACED_PERCENT_RECENT_RV^Recent Right Ventricular Percent Paced^IEEE
P10731.1.3||4|%|||||F|||T|||MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|22|NM|MDC_IDC_PACED_PERCENT_RECENT_LV^LV Percent Paced^IEEE
P10731.1.3||4|%|||||F|||T|||MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer XXXX|

OBR|3||1234567890| Follow-Up^ HL7 v2.5 device observations for a Follow-up
|||20060317160000.0000+0006|20060317170000.0000+0006|||||||jbaker||||model:leadXZY1/seraial:nr_123
||20060317170000.0000+0006|||F|
OBX|23|ST|MDC_IDC_LEAD_STATUS_RA^Right Atrial Lead Status^IEEE
P10731.1.3||OK|||||F|T|||||MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer XXXX|
```



```
OBX|24|NM|MDC_IDC_LEAD_INTRINSIC_AMPLITUDE_RA^RA Intrinsic Amplitude^IEEE
P10731.1.3||2.9|mV||||F||||||MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|25|NM|MDC_IDC_LEAD_PACE_IMPEDANCE_RA^Right Atrial Pace Impedance^IEEE
P10731.1.3||311|Ohms||||F|||||MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|26|ST|MDC_IDC_LEAD_STATUS_RV^Right Ventricular Lead Status^IEEE
P10731.1.3||OK|||||F|||||MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|27|NM|MDC_IDC_LEAD_INTRINSIC_AMPLITUDE_RV^Right Ventricular Intrinsic Amplitude^IEEE
P10731.1.3||4.1|mV||||F||||||MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|28|NM|MDC_IDC_LEAD_PACE_IMPEDANCE_RV^RV Pace Impedance^IEEE
P10731.1.3||462|Ohms||||F|||||MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|29|ST|MDC_IDC_LEAD_STATUS_LV^Left Ventricular Lead Status^IEEE P10731.1.3||Check
Impedance ||||||F|||||MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|30|NM|MDC_IDC_LEAD_INSTRINSIC_AMPLITUDE_LV^LV Intrinsic Amplitude^IEEE
P10731.1.3||4.6|mV||||F||||||MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|31|NM|MDC_IDC_LEAD_PACE_IMPEDANCE_LV^Left Ventricular Pace Impedance ^IEEE
P10731.1.3||1766|Ohms||||F||||||MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|32|ST|MDC_IDC_LEAD_SHOCKVECTOR_STATUS^Shock Lead Status^IEEE
P10731.1.3||OK|||||F|||||MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|33|NM|MDC_IDC_LEAD_SHOCK_IMPEDANCE^Defibrillation Impedance Test^IEEE
P10731.1.3||111|Ohms||||F||||||MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|34|ST|MDC_IDC_VTACHY_MODE^V-Tachy Mode^IEEE P10731.1.3||Monitor +
Therapy|||||F||||||MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|35|ST|MDC_IDC_BRADY_MODE^Brady Mode^IEEE P10731.1.3||DDD||||||F||||||MDC_IDC_SESSION_TYPE^In Clinic^IEEE
P10731.1.3|Programmer XXXX|
OBX|36|NM|MDC_IDC_PACING_LRL^Lower Rate Limit^IEEE P10731.1.3||40|bpm|||||F||||||MDC_IDC_SESSION_TYPE^In
Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|37|NM|MDC_IDC_PACING_MTR^Maximum Tracking Rate^IEEE P10731.1.3||120|bpm|||||F||||||MDC_IDC_SESSION_TYPE^In
Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|38|NM|MDC_IDC_PACING_MSR^Maximum Sensor Rate^IEEE P10731.1.3||--|bpm|||||F||||||MDC_IDC_SESSION_TYPE^In
Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|39|ST|MDC_IDC_PACING_SENSITIVITY_RA^Right Atrial Sensitivity^IEEE
P10731.1.3||Nominal|||||F||||||MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|40|ST|MDC_IDC_PACING_SENSITIVITY_RV^Sensitivity RV^IEEE
P10731.1.3||Nominal|||||F||||||MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|41|ST|MDC_IDC_PACING_SENSITIVITY_LV^Sensitivity LV^IEEE
P10731.1.3||Nominal|||||F||||||MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|42|NM|MDC_IDC_PACING_AVDELAY_FIXED^Paced AV Delay^IEEE
P10731.1.3||120|ms|||||F||||||MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|43|NM|MDC_IDC_PACING_SENSED_AV_OFFSET^Sensed AV Offset^IEEE
P10731.1.3||Off|ms|||||F||||||MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|44|NM|MDC_IDC_PACING_PVARP_FIXED^A-Refractory (PVARP) (Fixed)^IEEE P10731.1.3||240 -
250|ms|||||F|||||MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|45|NM|MDC_IDC_PACING_RVRP_FIXED^RV-Refractory (RVRP)^IEEE P10731.1.3||240 -
250|ms|||||F|||||MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|46|NM|MDC_IDC_PACING_LVRP^LV-Refractory (LVRP)^IEEE P10731.1.3||250|ms|||||F||||||MDC_IDC_SESSION_TYPE^In
Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|47|NM|MDC_IDC_PACING_LV_PROTECTION_PERIOD^LV Blanking Period^IEEE
P10731.1.3||400|ms|||||F|||||MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|48|ST|MDC_IDC_PACING_VENTRICULAR_CHAMBER^Ventricular Pacing Chamber^IEEE
P10731.1.3||BiV||||||F||||||MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|49|NM|MDC_IDC_PACING_VENTRICULAR_OFFSET^V-V Delay^IEEE P10731.1.3||50|ms|||||F||||||MDC_IDC_SESSION_TYPE^In
Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|50|ST|MDC_IDC_LEAD_PACE_THRESHOLD_RA^Right Atrial Pace Threshold  Amplitude @ Pulse Width^IEEE
P10731.1.3||5.0 V @  1.0 ms|||||F|||||MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|51|NM|MDC_IDC_LEAD_PACE_THRESHOLD_AMPLITUDE_RA^Right Atrial Pace Threshold [Amplitude]^IEEE
P10731.1.3||5.0|V|||||F|||||MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|52|NM|MDC_IDC_LEAD_PACE_THRESHOLD_PULSE_WIDTH_RA^Right Atrial Pace Threshold [Pulse Width]^IEEE
P10731.1.3||1.0|ms||||F|||||MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|53|ST|MDC_IDC_LEAD_PACE_THRESHOLD_RV^Right Ventricular Pace Threshold Amplitude @ Pulse Width^IEEE
P10731.1.3||7.5 V @  1.0 ms|||||F|||||MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|54|NM|MDC_IDC_LEAD_PACE_THRESHOLD_AMPLITUDE_RV^Right Ventricular Pace Threshold [Amplitude]^IEEE
P10731.1.3||7.5|V|||||F|||||MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|55|NM|MDC_IDC_LEAD_PACE_THRESHOLD_PULSE_WIDTH_RV^Right Ventricular Pace Threshold [Pulse Width]^IEEE
P10731.1.3||1.0|ms||||F|||||MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|56|ST|MDC_IDC_LEAD_PACE_THRESHOLD_LV^Left Ventricular Pace Threshold Amplitude @ Pulse Width^IEEE
P10731.1.3||7.5 V @  0.4 ms|||||F|||||MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|57|NM|MDC_IDC_LEAD_PACE_THRESHOLD_AMPLITUDE_LV^Left Ventricular Pace Threshold [Amplitude]^IEEE
P10731.1.3||7.5|V|||||F|||||MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|58|NM|MDC_IDC_LEAD_PACE_THRESHOLD_PULSE_WIDTH_LV^Pacing Output - LV^IEEE
P10731.1.3||0.4|ms||||F|||||MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|59|ST|MDC_IDC_TACHY_ATR_MODE_SWITCH^Mode Switch Mode^IEEE
P10731.1.3||VDI|||||F|||||MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|60|ST|MDC_IDC_TACHY_ATR_MODE_SWITCH_RATE^Mode Switch Rate^IEEE
P10731.1.3||150|bpm||||F|||||MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|61|NM|MDC_IDC_TACHY_DETECTRATE_VFZONE^VF Zone^IEEE P10731.1.3||165|bpm|||||F||||||MDC_IDC_SESSION_TYPE^In
Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|62|NM|MDC_IDC_TACHY_SHOCK_ENERGY_1_VFZONE^VF Shock 1 Energy^IEEE
P10731.1.3||0.9|J|||||F||||||MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|63|NM|MDC_IDC_TACHY_SHOCK_ENERGY_2_VFZONE^VF Shock 2 Energy^IEEE
P10731.1.3||31|J|||||F|||||MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|64|NM|MDC_IDC_TACHY_SHOCK_ENERGY_MAX_VFZONE^VF Max Shock Energy^IEEE
P10731.1.3||31|J|||||F|||||MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|65|NM|MDC_IDC_TACHY_ADDITIONALSHOCKS_VFZONE^VF Number Of Additional Shocks^IEEE
P10731.1.3||3|||||F|||||MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer XXXX|
```



```
OBR|4||1234567890|Implant^HL7 v2.5 device observations at
Implant|||20060317160000.0000+0006|20060317170000.0000+0006|||||||jbaker||||||20060317170000.0000+0006|||F||||
|^^||
OBX|1|ST|MDC_IDC_SESSION_TYPE^Session Type^IEEE P10731.1.3||Remote
Interrogation|||T||F|||||T|MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|2|ST|MDC_IDC_DEVICE_MANUFACTURER^Device Manufacturer^IEEE
P10731.1.3||GDT|T|||||F|T|||||MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|3|ST|MDC_IDC_DEVICE_TYPE^Device Type^IEEE P10731.1.3||CRT-D||||||F||||||MDC_IDC_SESSION_TYPE^In Clinic^IEEE
P10731.1.3|Programmer XXXX|
OBX|4|ST|MDC_IDC_DEVICE_NAME^Device Name^IEEE P10731.1.3||DeviceName||||||F||||||MDC_IDC_SESSION_TYPE^In
Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|5|ST|MDC_IDC_DEVICE_MODEL^Device Model^IEEE P10731.1.3||DeviceModel||||||F||||||MDC_IDC_SESSION_TYPE^In
Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|6|ST|MDC_IDC_DEVICE_MODEL_NUMBER^Device Model Number^IEEE
P10731.1.3||N123|T|||||F|T|||||MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|7|ST|MDC_IDC_DEVICE_SERIAL_NUMBER^Device Serial Number^IEEE
P10731.1.3||1234567890|T|||||F|T|||||MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|8|DT|MDC_IDC_DEVICE_IMPLANT_DATE^Device Implant Date^IEEE
P10731.1.3||20040209|||T||F|||||T|MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|9|NM|MDC_IDC_LEAD_INTRINSIC_AMPLITUDE_IMPLANT^Lead Intrinsic Amplitude at Implant^IEEE
P10731.1.3||3.5|mV|||||F|||||||MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|10|NM|MDC_IDC_LEAD_PACE_IMPEDANCE_RA^RA Pace Impedance^IEEE
P10731.1.3||500|Ohms|||T||F|T|||||MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|11|ST|MDC_IDC_LEAD_PACE_THRESHOLD_RA^Right Atrial Pace Threshold Amplitude @ Pulse Width^IEEE
P10731.1.3||8V @ 0.5 ms|||||T|F||||||MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|12|NM|MDC_IDC_LEAD_INTRINSIC_AMPLITUDE_RV^Right Ventricular Intrinsic Amplitude^IEEE
P10731.1.3||10|mV|||||F|||||||MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|13|NM|MDC_IDC_LEAD_PACE_IMPEDANCE_RV^Right Ventricular Pace Impedance^IEEE
P10731.1.3||600|Ohms|||T||F|T|||||MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|14|ST|MDC_IDC_LEAD_PACE_THRESHOLD_RV^Right Ventricular Pace Threshold Amplitude @ Pulse Width^IEEE
P10731.1.3||4.0 V @ 0.5 ms|T|||||F|||||T|MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|15|NM|MDC_IDC_LEAD_INSTRINSIC_AMPLITUDE_LV^Left Ventricular Intrinsic Amplitude^IEEE
P10731.1.3||11.1|mV|||||F|||||||MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|16|NM|MDC_IDC_LEAD_PACE_IMPEDANCE_LV^LV Pace Impedance^IEEE
P10731.1.3||900|Ohms|||T||F|T|||||MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|17|NM|MDC_IDC_LEAD_PACE_THRESHOLD_LV^Left Ventricular Pace Threshold Amplitude @ Pulse Width^IEEE
P10731.1.3||2.4 V @ 0.5 ms|T|||||F|||||T|MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer XXXX|
OBX|18|NM|MDC_IDC_LEAD_SHOCK_IMPEDANCE^Shock Impedance^IEEE
P10731.1.3||46|Ohms|||T||F|||T||MDC_IDC_SESSION_TYPE^In Clinic^IEEE P10731.1.3|Programmer XXXX|
```

Embedded XML Data Payload Example

The following XML document will be base64 encoded. When the XML document is being encoded, special consideration must be made for escape characters. Escape characters are whatever display ASCII character is specified in the <escape character> component of MSH-2-encoding characters. See section 2.7 of the HL7 v2.5 specification for more details.

```
<?xml version="1.0" encoding="UTF-8" ?>
- <IHE_IDCO_DeviceSummary xmlns="urn:hl7-org:v3" xmlns:mif="urn:hl7-org:v3/mif"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" classCode="OBS" moodCode="EVN"
xsi:schemaLocation="urn:hl7-org:v3 IHE_IDCO.xsd">
  <id />
  <code code="DeviceInterrogation" />
  <effectiveTime />
 <reusableDevice typeCode="RDV">
 <externalCardiacInterrogationDevice classCode="ASSIGNED">
 <assignedInterrogationDevice classCode="DEV" determinerCode="INSTANCE">
  <manufacturerModelName>APS III</manufacturerModelName>
  <softwareName>#832763 pv8.9</softwareName>
  </assignedInterrogationDevice>
  </externalCardiacInterrogationDevice>
```

```
 </reusableDevice>
<recordTarget contextControlCode="OP" typeCode="RCT">
<patient>
 <id assigningAuthorityName="STJ" extension="model:IMD_XZY/serial:nr_123" />
 <id assigningAuthorityName="US Social Security Number" extension="1930070598765" />
<addr>
 <streetAddressLine>Pinetree 3</streetAddressLine>
 <postalCode>123456</postalCode>
 <city>Valencia</city>
 <county>Orange</county>
 <state>CA</state>
 <country>US</country>
 </addr>
<patientPerson>
<name>
 <family>Willis</family>
 <given>Jane</given>
 </name>
 <administrativeGenderCode code="F" />
 <birthTime value="19310203000000" />
 </patientPerson>
 </patient>
 </recordTarget>
<author typeCode="AUT">
 <time />
<assignedEntity>
 <id extension="19650712-7654" />
<assignedPerson>
<name>
 <family>Smith</family>
 <given>David</given>
 </name>
 </assignedPerson>
<representedOrganization>
 <id extension="123bnm567" />
 <name>St.Patrick Hospital</name>
 </representedOrganization>
 </assignedEntity>
 </author>
<subject contextControlCode="ON" typeCode="SUBJ">
<medicalDeviceAct classCode="ACT" moodCode="EVN">
 <code code="MedicalDeviceAct" />
```

```
<subject contextControlCode="OP" typeCode="SBJ">
<patient>
<id />
</patient>
</subject>
<primaryPerformer contextControlCode="OP" typeCode="PPRF">
<assignedDevice>
<id assigningAuthorityName="STJ" extension="model:IMD_XZY/serial:nr_123" />
</assignedDevice>
</primaryPerformer>
<component1 contextControlCode="AN" typeCode="COMP">
<organizer classCode="ORGANIZER" moodCode="EVN">
<subject contextControlCode="OP" typeCode="SBJ">
<assignedDevice>
<id assigningAuthorityName="STJ" extension="model:IMD_XZY/serial:nr_123" />
</assignedDevice>
</subject>
<component contextControlCode="ON" typeCode="COMP">
<deviceObservation classCode="OBS" moodCode="EVN">
<code code="MDC_IDC_DEVICE_MANUFACTURER" codeSystemName="IEEE P1073.1.1.3"
codeSystemVersion="1.0" displayName="Device Manufacturer" />
<value code="STJ" codeSystemName="IEEE1073.1.1.3" displayName="St.Jude Medical"
xsi:type="IEEE1073_Enumerated" />
</deviceObservation>
</component>
<component contextControlCode="ON" typeCode="COMP">
<deviceObservation classCode="OBS" moodCode="EVN">
<code code="MDC_IDC_DEVICE_TYPE" codeSystemName="IEEE P1073.1.1.3" codeSystemVersion="1.0"
displayName="Device Type" />
<value code="ICD" codeSystemName="IEEE1073.1.1.3" displayName="Defibrilator"
xsi:type="IEEE1073_Enumerated" />
</deviceObservation>
</component>
<component contextControlCode="ON" typeCode="COMP">
<deviceObservation classCode="OBS" moodCode="EVN">
<code code="MDC_IDC_DEVICE_NAME" codeSystemName="IEEE P1073.1.1.3" codeSystemVersion="1.0"
displayName="Device Name" />
<value xsi:type="IEEE1073_Type_String">Epic II</value>
</deviceObservation>
</component>
<component contextControlCode="ON" typeCode="COMP">
<deviceObservation classCode="OBS" moodCode="EVN">
<code code="MDC_IDC_CAPACITOR_CHARGE_ENERGY" codeSystemName="IEEE P1073.1.1.3"
codeSystemVersion="1.0" displayName="Delivered Charge Energy" />
<effectiveTime value="20060311133759" />
```

```
  <value unit="J" value="31.0" xsi:type="IEEE1073_NumberwithUnit" />
  </deviceObservation>
  </component>
  <component contextControlCode="ON" typeCode="COMP">
  <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" />
  <value xsi:type="IEEE1073_Type_CompositeValue">
  <value unit="V" value="0.7" xsi:type="IEEE1073_NumberwithUnit" />
  <value unit="ms" value="0.4" xsi:type="IEEE1073_NumberwithUnit" />
  </value>
  </deviceObservation>
  </component>
  <component contextControlCode="ON" typeCode="COMP">
  <deviceObservation classCode="OBS" moodCode="EVN">
  <code code="MDC_IDC_DEVICE_LEADS_NUMBER_ACTIVE" codeSystemName="IEEE P1073.1.1.3"
codeSystemVersion="1.0" displayName="Number of Active Leads" />
  <value value="3" xsi:type="IEEE1073_Type_Number_Integer" />
  </deviceObservation>
  </component>
  </organizer>
  </component1>
T  <component1 contextControlCode="AN" typeCode="COMP">
  <organizer classCode="ORGANIZER" moodCode="EVN">
  <subject contextControlCode="OP" typeCode="SBJ">
  <assignedDevice>
  <id assigningAuthorityName="STJ" extension="model:Lead_XZY/serial:Lead_121" />
  </assignedDevice>
  </subject>
  <component contextControlCode="ON" typeCode="COMP">
  <deviceObservation classCode="OBS" moodCode="EVN">
  <code code="MDC_IDC_LEAD_MANUFACTURER" codeSystemName="IEEE P1073.1.1.3"
codeSystemVersion="1.0" displayName="Lead Manufacturer" />
  <value code="STJ" codeSystemName="IEEE1073.1.1.3" displayName="St.Jude Medical"
xsi:type="IEEE1073_Enumerated" />
  </deviceObservation>
  </component>
  </organizer>
  </component1>
  <component1 contextControlCode="AN" typeCode="COMP">
  <organizer classCode="ORGANIZER" moodCode="EVN">
  <subject contextControlCode="OP" typeCode="SBJ">
  <assignedDevice>
  <id assigningAuthorityName="STJ" extension="model:Lead_XZY/serial:Lead_122" />
```

```
  </assignedDevice>
  </subject>
 <component contextControlCode="ON" typeCode="COMP">
 <deviceObservation classCode="OBS" moodCode="EVN">
  <code code="MDC_IDC_LEAD_MANUFACTURER" codeSystemName="IEEE P1073.1.1.3"
codeSystemVersion="1.0" displayName="Lead Manufacturer" />
  <value code="STJ" codeSystemName="IEEE1073.1.1.3" displayName="St.Jude Medical"
xsi:type="IEEE1073_Enumerated" />
  </deviceObservation>
  </component>
  </organizer>
  </component1>
 <component1 contextControlCode="AN" typeCode="COMP">
 <organizer classCode="ORGANIZER" moodCode="EVN">
 <subject contextControlCode="OP" typeCode="SBJ">
 <assignedDevice>
  <id assigningAuthorityName="STJ" extension="model:Lead_XZY/serial:Lead_123" />
  </assignedDevice>
  </subject>
 <component contextControlCode="ON" typeCode="COMP">
 <deviceObservation classCode="OBS" moodCode="EVN">
  <code code="MDC_IDC_LEAD_MANUFACTURER" codeSystemName="IEEE P1073.1.1.3"
codeSystemVersion="1.0" displayName="Lead Manufacturer" />
  <value code="STJ" codeSystemName="IEEE1073.1.1.3" displayName="St.Jude Medical"
xsi:type="IEEE1073_Enumerated" />
  </deviceObservation>
  </component>
  </organizer>
  </component1>
 <component2 contextControlCode="AN" typeCode="COMP">
 <patientObservation classCode="OBS" moodCode="EVN">
  <code code="MDC_IDC_COUNTERS_CLEARED_DATE" codeSystemName="IEEE P1073.1.1.3"
codeSystemVersion="1.0" displayName="Last Counters Cleared Date" />
  <effectiveTime value="20060411115613" />
  <value value="20060411115613" xsi:type="IEEE1073_DateTime" />
  </patientObservation>
  </component2>
 <component2 contextControlCode="AN" typeCode="COMP">
 <patientObservation classCode="OBS" moodCode="EVN">
  <code code="MDC_IDC_LEAD_INTRINSIC_AMPLITUDE" codeSystemName="IEEE P1073.1.1.3"
codeSystemVersion="1.0" displayName="Intrinsic Amplitude" />
  <value unit="mV" value="3.0" xsi:type="IEEE1073_NumberwithUnit" />
  </patientObservation>
  </component2>
 <component2 contextControlCode="AN" typeCode="COMP">
```



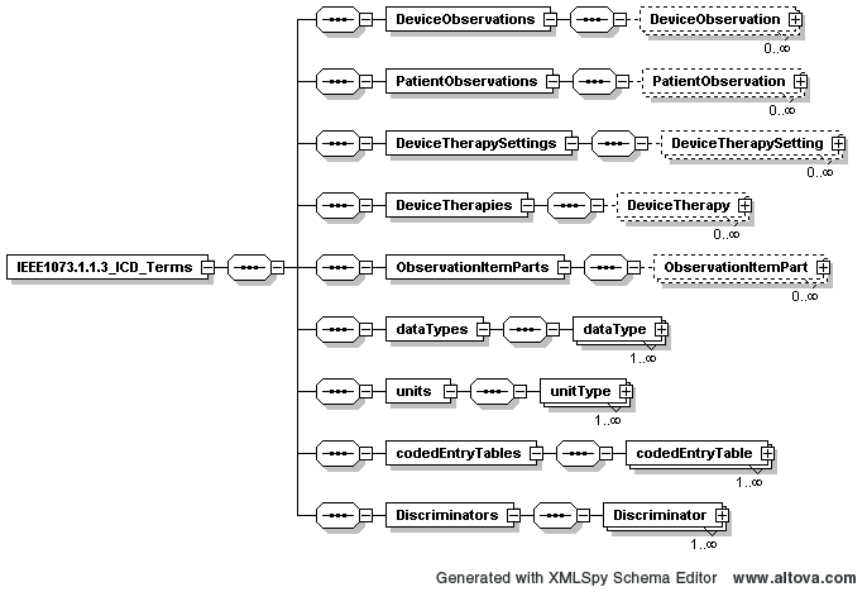
```
  <patientObservation classCode="OBS" moodCode="EVN">
  <code code="MDC_IDC_LEAD_PACE_THRESHOLD_RA" codeSystemName="IEEE P1073.1.1.3"
codeSystemVersion="1.0" displayName="Lead Pace Threshold “Amplitude” @ “Pulse Width" />
  <value xsi:type="IEEE1073_Type_CompositeValue">
  <value unit="V" value="0.8" xsi:type="IEEE1073_NumberwithUnit" />
  <value unit="ms" value="0.5" xsi:type="IEEE1073_NumberwithUnit" />
  </value>
  <interpretationCode code="A" displayName="Automatic" />
  </patientObservation>
  </component2>
  <component2 contextControlCode="AN" typeCode="COMP">
  <patientObservation classCode="OBS" moodCode="EVN">
  <code code="MDC_IDC_CTR_TACHY_EPISODES_RECENT_RA" codeSystemName="IEEE P1073.1.1.3"
codeSystemVersion="1.0" displayName="Tachy Episodes" />
  <text>Atrial episodes</text>
  <value value="5" xsi:type="IEEE1073_Type_Number_Integer" />
  </patientObservation>
  </component2>
  <component2 contextControlCode="AN" typeCode="COMP">
  <patientObservation classCode="OBS" moodCode="EVN">
  <code code="MDC_IDC_CTR_TACHY_EPISODES_RECENT_RV" codeSystemName="IEEE P1073.1.1.3"
codeSystemVersion="1.0" displayName="Tachy Episodes" />
  <text>Ventricular episodes</text>
  <value value="6" xsi:type="IEEE1073_Type_Number_Integer" />
  </patientObservation>
  </component2>
  <component3 contextControlCode="AN" typeCode="COMP">
  <deviceTherapy classCode="PROC" moodCode="EVN">
  <code code="MDC_IDC_THERAPY" codeSystemName="IEEE P1073.1.1.3" codeSystemVersion="1.0"
displayName="Therapy" />
  <text>Waran with substance x mg/tablet, 50mg, 2 times a day, together with food</text>
  </deviceTherapy>
  </component3>
  <controlVariable contextControlCode="AN" typeCode="CTRLV">
  <deviceTherapySetting classCode="OBS" moodCode="EVN">
  <code code="MDC_IDC_PACING_LRL" codeSystemName="IEEE P1073.1.1.3" codeSystemVersion="1.0"
displayName="Lower Rate Limit" />
  <value unit="1/min" value="40.0" xsi:type="IEEE1073_NumberwithUnit" />
  </deviceTherapySetting>
  </controlVariable>
  <controlVariable contextControlCode="AN" typeCode="CTRLV">
  <deviceTherapySetting classCode="OBS" moodCode="EVN">
  <code code="MDC_IDC_TACHY_AFIBZONE_ENERGY_SHOCK" codeSystemName="IEEE P1073.1.1.3"
codeSystemVersion="1.0" displayName="AFib Zone Shock Energy @ Number" />
  <value xsi:type="IEEE1073_Type_CompositeValue">
```

```
  <value unit="J" value="14.0" xsi:type="IEEE1073_NumberwithUnit" />
  <value value="1" xsi:type="IEEE1073_Type_Number_Integer" />
  </value>
  </deviceTherapySetting>
  </controlVariable>
 <controlVariable contextControlCode="AN" typeCode="CTRLV">
 <deviceTherapySetting classCode="OBS" moodCode="EVN">
  <code code="MDC_IDC_TACHY_ENERGY_VT1ZONE_SHOCK" codeSystemName="IEEE P1073.1.1.3"
codeSystemVersion="1.0" displayName="Slow VT Shock Energy @ Number" />
 <value xsi:type="IEEE1073_Type_CompositeValue">
  <value unit="J" value="14.0" xsi:type="IEEE1073_NumberwithUnit" />
  <value value="1" xsi:type="IEEE1073_Type_Number_Integer" />
  </value>
  </deviceTherapySetting>
  </controlVariable>
 <controlVariable contextControlCode="AN" typeCode="CTRLV">
 <deviceTherapySetting classCode="OBS" moodCode="EVN">
  <code code="MDC_IDC_TACHY_AFIBZONE_ENERGY_SHOCK" codeSystemName="IEEE P1073.1.1.3"
codeSystemVersion="1.0" displayName="AFib Zone Shock Energy @ Number" />
 <value xsi:type="IEEE1073_Type_CompositeValue">
  <value unit="J" value="15.0" xsi:type="IEEE1073_NumberwithUnit" />
  <value value="2" xsi:type="IEEE1073_Type_Number_Integer" />
  </value>
  </deviceTherapySetting>
  </controlVariable>
 <controlVariable contextControlCode="AN" typeCode="CTRLV">
 <deviceTherapySetting classCode="OBS" moodCode="EVN">
  <code code="MDC_IDC_TACHY_ENERGY_VT1ZONE_SHOCK" codeSystemName="IEEE P1073.1.1.3"
codeSystemVersion="1.0" displayName="Slow VT Shock Energy @ Number" />
 <value xsi:type="IEEE1073_Type_CompositeValue">
  <value unit="J" value="15.0" xsi:type="IEEE1073_NumberwithUnit" />
  <value value="2" xsi:type="IEEE1073_Type_Number_Integer" />
  </value>
  </deviceTherapySetting>
  </controlVariable>
 <controlVariable contextControlCode="AN" typeCode="CTRLV">
 <deviceTherapySetting classCode="OBS" moodCode="EVN">
  <code code="MDC_IDC_PACING_SENSED_AV_OFFSET" codeSystemName="IEEE P1073.1.1.3"
codeSystemVersion="1.0" displayName="Sensed AV Offset" />
  <text>Off</text>
  <value nullFlavor="OTH" xsi:type="IEEE1073_NumberwithUnit" />
  </deviceTherapySetting>
  </controlVariable>
 <controlVariable contextControlCode="AN" typeCode="CTRLV">
```

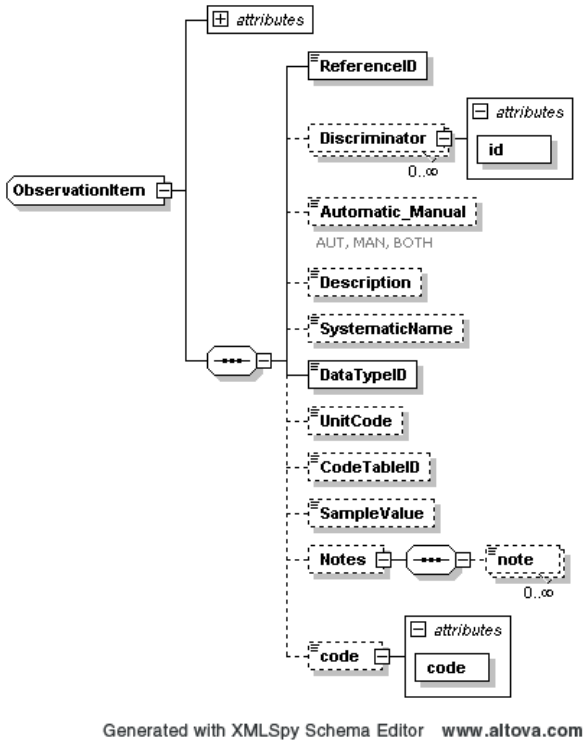
```
  <deviceTherapySetting classCode="OBS" moodCode="EVN">
  <code code="MDC_IDC_PACING_AUTOMATIC_CAPTURE_LA" codeSystemName="IEEE P1073.1.1.3"
codeSystemVersion="1.0" displayName="Automatic Pacing Output Enabled" />
  <value code="On" codeSystemName="IEEE1073.1.1.3" displayName="On"
xsi:type="IEEE1073_Enumerated" />
  </deviceTherapySetting>
  </controlVariable>
  <controlVariable contextControlCode="AN" typeCode="CTRLV">
  <deviceTherapySetting classCode="OBS" moodCode="EVN">
  <code code="MDC_IDC_PACING_AUTOMATIC_CAPTURE_RA" codeSystemName="IEEE P1073.1.1.3"
codeSystemVersion="1.0" displayName="Automatic Pacing Output Enabled" />
  <value code="Off" codeSystemName="IEEE1073.1.1.3" displayName="Off"
xsi:type="IEEE1073_Enumerated" />
  </deviceTherapySetting>
  </controlVariable>
  </medicalDeviceAct>
  </subject>
  </IHE_IDCO_DeviceSummary>
```


Appendix A – IEEE 1073.1.1.3 ICD Terms nomenclature

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

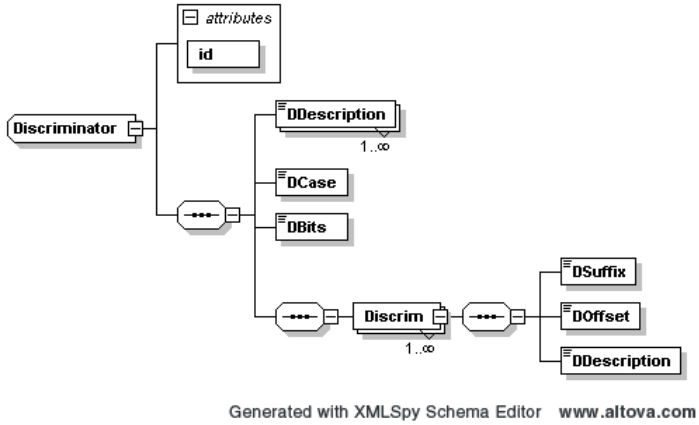


All four observation groups have base type ObservationItem



Usage of Discriminators

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



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 Scheme

The nomenclature schema and XML specification are available as a zipped file at www.ihe.net .

Add new Section 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.

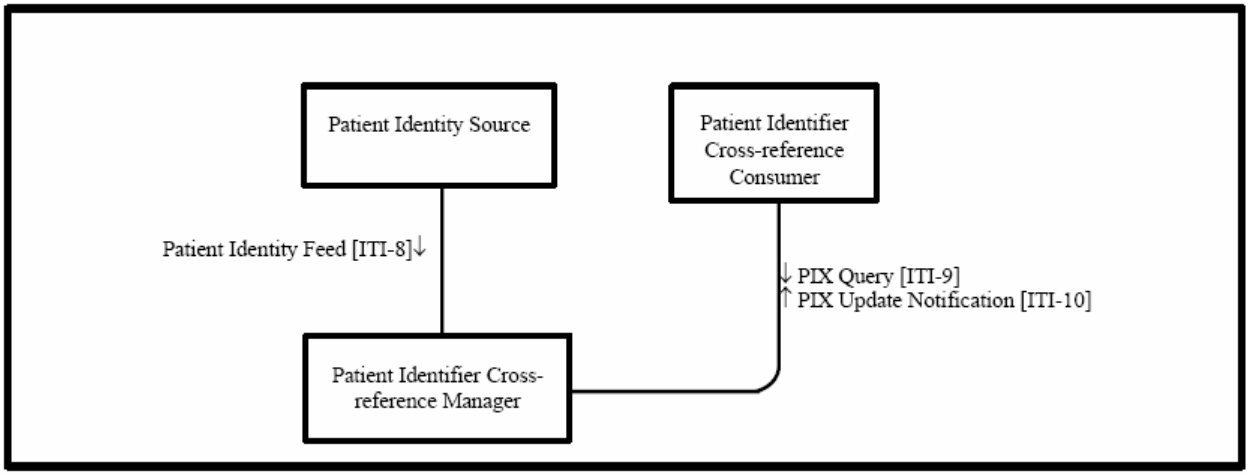


Figure H.5-1 PIX Actors and Transactions

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.

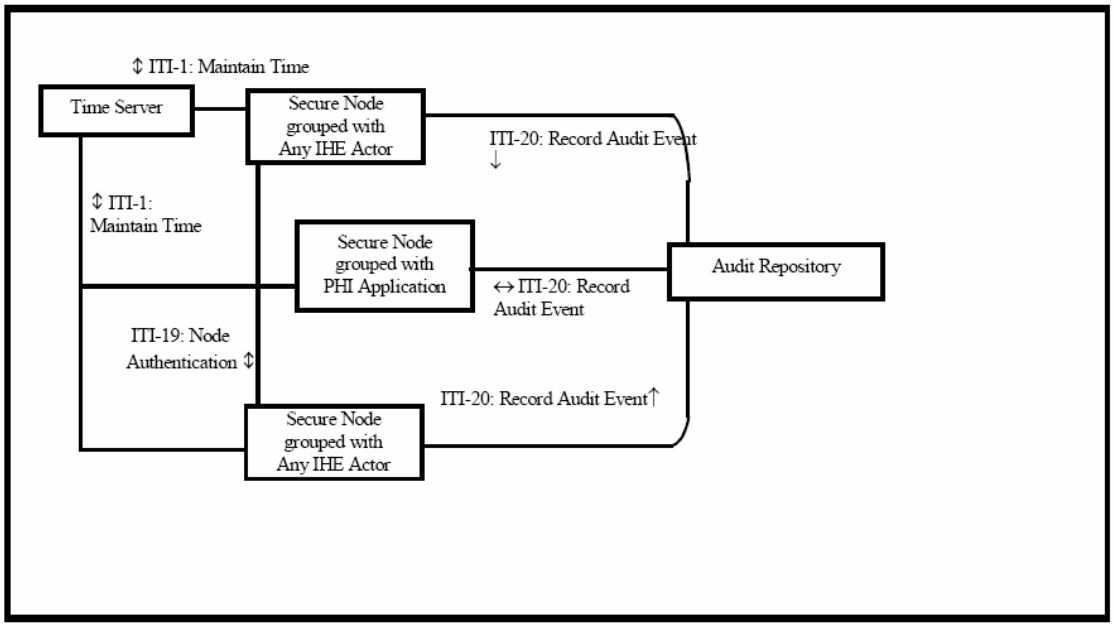


Figure H.6-1 ATNA Actors and Transactions

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 untrusted networks be appropriately secured. Certain actors of the XDS and PDQ-IDC profiles 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.

