Integrating the Healthcare Enterprise

IHE Cardiology
Technical Framework Supplement

Electrophysiology Implant/Explant Report Content
(EPRC-IE)

Trial Implementation

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Please verify you have the most recent version of this document. See here for Trial Implementation and Final Text versions and here for Public Comment versions.

Foreword

This is a supplement to the IHE Cardiology Technical Framework 5.0. Each supplement undergoes a process of public comment and trial implementation before being incorporated into the volumes of the Technical Frameworks.

This supplement is published on April 30, 2014 for Trial Implementation and may be available for testing at subsequent IHE Connectathons. The supplement may be amended based on the results of testing. Following successful testing it will be incorporated into the IHE Cardiology Technical Framework. Comments are invited and can be submitted at http://www.ihe.net/Cardiology_Public_Comments.

This supplement describes changes to the existing technical framework documents.

"Boxed" instructions like the sample below indicate to the Volume Editor how to integrate the relevant section(s) into the relevant Technical Framework volume.

Amend section X.X by the following:

Where the amendment adds text, make the added text **bold underline**. Where the amendment removes text, make the removed text ~~**bold strikethrough**~~. When entire new sections are added, introduce with editor's instructions to "add new text" or similar, which for readability are not bolded or underlined.

General information about IHE can be found at: www.ihe.net.

Information about the IHE Cardiology domain can be found at: ihe.net/IHE_Domains.

Information about the organization of IHE Technical Frameworks and Supplements and the process used to create them can be found at: http://ihe.net/IHE_Process and http://ihe.net/Profiles.

The current version of the IHE Cardiology Technical Framework can be found at: http://ihe.net/Technical_Frameworks.

CONTENTS

Introduction to this Supplement

This supplement introduces a new profile to the IHE Cardiology Technical Framework, with the overall design in Volume 1 and specific content in Volume 3. This profile relies heavily on content profile concepts specified in the IHE Patient Care Coordination Technical Framework and CDA templates specified in the HL7 Implementation Guide for CDA Release 2: IHE Health Story Consolidation, Release 1.1 DSTU (July 2012) (C-CDA).

This content profile is motivated by implanting physicians, who face an increasing demand from patient-care, data-quality and legislative perspectives to increase the usefulness of (discrete) clinical data across the various care-settings and stakeholders.

A solution for such interoperability is, however, not a simple undertaking. Unstructured textual data forms remains the predominate mechanism for information exchange among health care providers, and a good majority of data needed by physicians and other health care providers to make good clinical decisions is embedded in this free text. Efficient and effective interoperability therefore begins by identifying the most relevant clinical data.

Clinically-relevant Electrophysiology data is the key value proposition of this profile. The approach is to:

1. Reuse the distribution and structuring work from the XDS profiles (ITI domain), Medical summaries content profiles (PCC domain), Cath Report Content content profile (Card Domain) and the HL7 Implementation Guide for CDA Release 2: IHE Health Story Consolidation, Release 1.1 DSTU (C-CDA) for procedure note document type and related templates.
2. Extend it through adding and codifying the ACC-NCDR ICD dataset and the ACC NCDR ICD version 1.2 and leveraging clinical data standards like ICD9/10, SNOMED, LOINC and IEEE 11073-10103 nomenclature.
3. Evaluate it as it applies to industry publications, like:
    1. Standardized Cardiovascular Data for Clinical Research, Registries, and Patient Care. A Report From the Data Standards Workgroup of the National Cardiovascular Research Infrastructure Project

The aim is to enable collection and distribution of the most clinically-relevant discrete data on the EP Implant/Explant procedures common in cardiology. The usage of the discrete data is three-fold:

1. To enable individual Implant/Explant procedure related information to be more easily shared and used between care givers and systems
2. To enable population-based outcomes-based research on procedure effectiveness
3. To provide the ability to interact with data registries for data exchange.

These Implant/Explant procedures are used as key constituents of the patient's treatment during electrophysiology encounters and disease management. Allowing a means to extract and exchange key cardiac measures across providers and their systems will be a huge advantage to providing a complete, accessible and actionable cardiac data set in front of cardiologists.

There are very successful quality-improvement programs in place by the professional bodies such as the ACC, AHA, and state registries concentrating on the most invasive, and expensive cardiac procedures. However, the effort in translating and extracting the discrete data required by these registries still involves significant manual work and inefficiencies due to the absence of a standardized structuring of information at the point of clinical reporting.

This supplement provides a framework to make progress in these areas. This profile codifies representative areas of procedure indications, procedures, medications, observations, complications and findings for electrophysiology procedures and specifies how this discrete data can be organized to be used by both care-providers and automated data processing systems.

Relationship to Workflow Profiles

Electrophysiology Implant/Explant Report Content (EPRC-IE) is a *content* profile – it is agnostic with respect to the workflow or data exchange mechanism in which the data is produced and handled.

Content profiles define how the content used in a transaction is structured. The binding of the content to an IHE transaction that is part of an IHE workflow profile specifies how this payload may influence the metadata or the behavior of the transaction. Content modules within the content profile then define the payloads. Content modules are transaction neutral, in that what they describe is independent of the transaction in which they are used, whereas content bindings explain how the payload influences the transaction metadata and/ or behavior.

The EPRC-IE content is intended to be deployed, for example in the Displayable Reports (DRPT) workflow profile for in-patient environments, or the Cross-Enterprise Document Sharing (XDS) profile to propagate the content across organizational boundaries.

It is important to note that that key report-generation/distribution workflow aspects such as physician identification, insurance preauthorization, report routing and acknowledgement, and patient consent, are **out of scope** for this content profile.

Cardiac Electrophysiology Implant/Explant Report Content (EPRC-IE) Profile

The Electrophysiology Implant/Explant Report Content (EPRC-IE) Profile specifies the content structure for a clinical report of an electrophysiology procedure recorded in an EP Lab. Such procedures include:

- Implantable Cardioverter Defibrillator (ICD) Implant
- Permanent Pacemaker (PPM)/Implantable Pulse Generator (IPG) Implant
- Implantable Cardiac Monitor Implant
- Lead Implant
- ICD Explant
- Generator Change
- Lead Explant
- Lead Abandonment
- Imaging associated with Implant/Explant, e.g., Venogram

The EPRC-IE Profile specifies the use of an HL7 Clinical Document Architecture (CDA) format for the report. This format supports both the human readable narrative historically used for clinical reports, as well as a substantial set of discrete data elements that may be used for longitudinal or population analysis or other computer processing.

Note: It is expected that future evolution of cardiology reporting will incorporate more robust and extensive sets of data elements. This Profile is a first step beyond simple narrative to interoperable discrete data elements.

Not included in the scope of this profile are other EP procedures (e.g., EP Studies, Ablation, Cardioversion) and temporary pacemakers. Such use cases may be supported by other similar content profiles.

This profile also does not provide all of the details necessary to construct a CDA compliant document. Please refer to the HL7 CDA Release 2 Standard.

Open Issues and Questions

#	Open Issue Description
1	Depth vs. breadth presentation of sections and entries – the sections and entries are presented in Volume 3 per the order they are included in a clinical EPRC-IE report (as an instance of a EPRC-IE CDA document) (depth view) rather than organizing the sections by listing them ordered alphabetically and having the complete set of entries used within this document organized in a separate list ordered alphabetically (breadth view). Is this approach useful or preferred vs. the breadth approach?
3	Need to assign EPRC specific conformance IDs, like "CONF:EPRC-xxx".

#	Open Issue Description
4	For HL7 roleCode, 2.16.840.1.113883.5.111, in the header, encompassingEncounter, location/healthCareFacilty, need a specific code for EP Lab. We are using CVDX as the general code.
5	Is there a need to document in this EP procedure report that the administration of a medication has been held prior to the current procedure?
6	This profile should utilize UDI for representing devices. The goal is to harmonize representation of device serial numbers utilizing UDI. The committee will perform the update as soon as UDI become available for these devices.
7	Need additional codes for various value sets, including • EP Result Observations value set for specific observations/findings. (1.3.6.1.4.1.19376.1.4.1.5.51) • EP Problems/Concerns (1.3.6.1.4.1.19376.1.4.1.5.49) • Cardiac EP Activity Procedures (1.3.6.1.4.1.19376.1.4.1.5.52) • Cardiac EP Complications (1.3.6.1.4.1.19376.1.4.1.5.54) • Cardiac Drug Classes and Specific Cardiac Drugs (1.3.6.1.4.1.19376.1.4.1.5.55) • EP Postprocedure Diagnoses (1.3.6.1.4.1.19376.1.4.1.5.56) • Cardiovascular Family History (1.3.6.1.4.1.19376.1.4.1.5.58) • Cardiac Lab Results (1.3.6.1.4.1.19376.1.4.1.5.59) • Procedure Indications (1.3.6.1.4.1.19376.1.4.1.5.61) • Rx Recommendations (1.3.6.1.4.1.19376.1.4.1.5.62) The committee seeks input on missing items in these Value Sets (specific concepts with missing codes are highlighted in yellow).

Closed Issues

#	Closed Issue Description/ Resolution
2	Q: Existing Value Sets from CRC have been extended to include the values specifically used for EP. Should we create separate Value Sets for the same concept specifically for EP? A: We created new value sets with new OIDs for the EPRC-IE profile. These may be reused by other cardiac profiles.
8	Need SNOMED code for Electrophysiologist for service event/performer/assignedEntity Note, use cardiologist for this.

#	Closed Issue Description/ Resolution
9	Q - Is there a need for the Procedure Implants section? A:EPRC-IE., the C-CDA Procedure Implant Section does not contain any information other than narrative, which does not meet the need of our reporting. We are looking to associate devices used to a particular procedure as procedures are being performed. Information about implanted and explanted devices occurs in the Procedure Description-Cardiac Section.
10	Q - Should re-used CRC templates be referenced or included in this content profile A - We have chosen to include any templates created for CRC that are required for this profile.

Volume 1 – Profiles

13 Electrophysiology Implant/Explant Report Content Profile (EPRC-IE)

The Electrophysiology Implant/Explant Report Content (EPRC-IE) Profile specifies the content structure for a clinical report of an electrophysiology procedure recorded in an EP Lab. Such procedures include:

- Implantable Cardioverter Defibrillator (ICD) Implant
- Permanent Pacemaker (PPM)/Implantable Pulse Generator (IPG) Implant
- Implantable Cardiac Monitor Implant
- Lead Implant
- ICD Explant
- Generator Change
- Lead Explant
- Lead Abandonment
- Imaging associated with Implant/Explant (e.g., Venogram)

The EPRC-IE Profile specifies the use of an HL7 Clinical Document Architecture (CDA) format for the report.

Not included in the scope of this profile are other EP procedures (e.g., EP Studies, Ablation, Cardioversion, temporary pacemakers.) Such use cases may be supported by other similar content profiles.

This profile also does not provide all of the details necessary to construct a CDA compliant document. Please refer to the HL7 CDA Release 2 Standard.

13.1 EPRC-IE Actors, Transactions, and Content Modules

Figure 13.1-1 shows the actors directly involved in the EPRC-IE Profile and the relevant transactions between them. There are two actors in this profile, the Content Creator and the Content Consumer. Content is created by a Content Creator and is to be consumed by a Content Consumer. The sharing or transmission of content from one actor to the other is addressed by the appropriate use of other IHE profiles, and is out of scope of this profile; hence there is no transaction per se defined for this profile.

Figure 13.1-1: EPRC-IE Report Template Actor Diagram

Note: The primary intended transmission mechanism in the intra-institutional context is the IHE Displayable Reports Profile (DRPT), and in the inter-institutional context the IHE Portable Data for Imaging (PDI) or IHE Cross Enterprise Document Sharing Profiles (XDS, XDM, and XDR). A Report Creator, Document Source or a Portable Media Creator of those profiles may embody the Content Creator Actor. A Document Consumer, a Document Recipient or a Portable Media Importer may embody the Content Consumer Actor.

13.1.1 Actor Descriptions and Actor Profile Requirements

13.1.1.1 Content Creator

A Content Creator shall be able to create an Electrophysiology Implant/Explant Report Document according to the specifications for that content profile found in CARD TF-3.

13.1.1.2 Content Consumer

A Content Consumer shall be able to consume (receive and process) an EPRC-IE document.

13.2 EPRC-IE Actor Options

Options that may be selected for this content profile are listed in table 13.2-1 along with the actors to which they apply. Dependencies between options when applicable are specified in notes.

Table 13.2-1: EPRC-IE Profile Options

Actor	Option Name	Optionality	Section
Content Consumer	View Option	O (see 13.2.1)	PCC TF-2 :3.1.1
	Document Import Option	O (see 13.2.1)	PCC TF-2 :3.1.2
	Section Import Option	O (see 13.2.1)	PCC TF-2 :3.1.3
	Discrete Data Import Option	O (see 13.2.1)	PCC TF-2 :3.1.4
Content Creator	*No options defined*		

13.2.1 Content Consumer Options

The Content Consumer actor is required to support at least one of the View or Discrete Data Import options. The Document Import and Section Import options, if implemented, also require the View option. These options as specified in the PCC Technical Framework assume use of XDS or related profiles for transport; this Profile specifies bindings to other workflow profiles

(see section 13.5), and these options should be interpreted as applicable with any binding. See also section 13.6.2.

1. A Content Consumer that implements the View option shall be able to:
    a. Demonstrate rendering of the document for display.
    b. Print the document.
    c. Display the document with its original style sheet.
    d. Support traversal of any links contained within the document.
2. A Content Consumer that implements the Document Import option shall:
    a. Store the document.
    b. Demonstrate the ability to access the document again from that storage.
3. A Content Consumer that implements the Section Import option shall offer a means to import one or more document sections into the patient record as free text.
4. A Content Consumer that implements the Discrete Data Import option shall offer a means to import structured data from one or more sections of the document.

13.3 EPRC-IE Actor Required Groupings

Content modules describe the content of a payload found in an IHE transaction. Content profiles are transaction neutral. They do not have dependencies upon the transaction that they appear in.

The Content Creator shall be grouped with Time Client actor of the IHE IT Infrastructure Consistent Time Profile, as specified in ITI TF-1:7. This allows the Legal Authentication timestamp to be accurate.

13.4 EPRC-IE Document Content Module

There is often a very clear distinction between the transactions in a messaging framework used to package and transmit information, and the information content actually transmitted in those messages. This is especially true when the messaging framework begins to move towards mainstream computing infrastructures being adopted by the healthcare industry.

In these cases, the same transactions may be used to support a wide variety of use cases in healthcare, and so more and more the content and use of the message also needs to be profiled, sometimes separately from the transaction itself. Towards this end IHE has developed the concept of a content profile.

Content profiles specify how the payload of a transaction fits into a specific use of that transaction. A content profile has three main parts. The first part describes the use case (this is found in Volume 1 in the definition of each profile). The second part is a content module (found in this Volume 3), which describes the payload of the transaction; a content module is specified so as to be independent of the transaction in which it appears. The third part is binding to a specific IHE transaction, which describes how the content affects the transaction. The binding of

CDA-based medical documents to workflow transactions is described in the profile definition in Volume 1 (e.g., see IHE CARD TF-1:13.7).

13.5 EPRC-IE Overview

The Electrophysiology Implant/Explant Report Content (EPRC-IE) Profile specifies the content structure for a clinical report of a cardiology EP Lab Visit. Such procedures include:

- Implantable Cardioverter Defibrillator (ICD) Implant
- Permanent Pacemaker (PPM)/Implantable Pulse Generator (IPG) Implant
- Implantable Cardiac Monitor Implant
- Lead Implant
- ICD Explant
- Generator Change
- Lead Explant
- Lead Abandonment
- Imaging associated with Implant/Explant, e.g., Venogram

The EPRC-IE Profile specifies the use of an HL7 Clinical Document Architecture (CDA) format for the EP physician clinical report. This format supports both the human readable narrative historically used for clinical reports, as well as a substantial set of discrete data elements that may be used for longitudinal or population analysis or other computer processing.

Note: It is expected that future evolution of cardiology reporting will incorporate more robust and extensive sets of data elements. This Profile is a first step beyond simple narrative to interoperable discrete data elements.

Not included in the scope of this profile are other EP procedures (e.g., EP Studies, Ablation, Cardioversion, temporary pacemakers. Such use cases may be supported by other similar content profiles.

This profile does not address how discrete data is collected and transmitted for registry data collection and other secondary usages.

There may be a DICOM Study associated with the exam. In addition to reference images, the DICOM Study data may include discrete data elements encoded in DICOM Structured Report information objects that may be transcoded into the discrete data elements specified in this Profile. (See the Evidence Documents Profile and its cardiology options in Section 7.)

The EPRC-IE Profile does not presume to describe the complete content of an imaging study report. It does provide the framework of high level section titles and a set of discrete data elements. Within that framework reports can be created with the clinical content desired by their authors, including additional discrete data elements. In general, there are no constraints on the narrative text and figures that the cardiologist could include in the report document, although

there are requirements on minimum data elements reflecting expert consensus (ACC-NCDR ICD data elements)

This profile also does not provide all of the details necessary to construct a CDA compliant document. Please refer to the HL7 CDA Release 2 Standard.

13.5.1 Concepts

Not Applicable

13.5.2 Use Case #1: Report generated by Implant/Explant in the EP lab.

13.5.2.1 Use Case Description

This use case addresses the generation and transfer of a comprehensive set of data acquired during an EP lab procedure for an ICD and/or lead implant/explant. The initial content, structure and coding of the report to support this use case are detailed as part of this profile (see IHE CARD TF-3.6 Content Modules). However various reporting system implementations, institute reporting guidelines and individual Reporting Physician usage may result in some variability in the specific report content provided.

13.5.2.2 Process Flow

Pre conditions

The systems underlying the data collection and management for the various elements of the procedure report have all the *mandatory* data elements identified using codes, and are expected to be the source for the information used in creating the *majority* of the structured report document.

1. Data related to the condition of the patient when admitted to the EP Lab (i.e., medical history and risk factors, laboratory values, etc.) is stored in an external system.
2. The EP Lab systems record data related to the EP procedure.
3. Capture of data in the prescribed nomenclature is facilitated by devices compliant with the IEEE 11073-10103 nomenclature.

Main Flow

- Electrophysiologist reviews and/or records the codified
  - Procedures and protocols used in the procedure
  - Data generated from the various modalities and monitoring equipment used during the procedure so that they key physiological measures, acquired and derived (pre, during and post, procedure) are present in line with the ACC-NCDR ICD specifications.

- Other relevant patient characteristics
- Medications documented for the patient both pre and during procedure.
- Devices used during the procedure
- Indications and observations/complications noticed during the procedure.
- Findings, assessment and plan

- Electrophysiologist approves the procedure report and this marks it ready for distribution
- The content creator system will format the report appropriately (this profile) and send it via one of the IHE mechanisms to a content consumer system (an appropriate workflow profile).

Post conditions

The subsequent clinical stakeholder (system) receives the Procedure Report for import, processing and optionally viewing of the data.

13.5.3 Use Case #2: Review Procedure Report

13.5.3.1 Use case Description

A secondary use-case addressed by this profile involves the direct human use of the procedure report. In most practical cases consumers include:

- The referring physician who instigated/ordered the procedure, and other healthcare providers who manage subsequent patient care activities
- Another person involved in downstream clinical or administrative data processing e.g., someone validating/source-checking for QA the original report as part of JCAHO audits
- Pre-submission checking on the original reporting data against the case-data imported in the ACC-NCDR ICD registry-submission application.
- Device Manufacturer who will receive registration of device information.

13.5.3.2 Process Flow

Pre conditions

- The consumer has a system (EMR or other) capable of importing and displaying the received report in a clinically useful format
- The EP Lab Report has been received at this system

Note: This profile does not assume any explicitly specified relationship between the creator and consumer.

Main Flow

- The consumer selects the report of his patient and opens it for review

- The system displays the human readable content for the consumer to review

Post conditions

The consumer has accessed the necessary information from the report.

13.6 EPRC-IE Security Considerations

Security considerations are dealt with by the transport mechanism (e.g., XDS, DRPT) and are outside the scope of this content profile. See PCC TF-1: 3.8

13.7 EPRC-IE Cross Profile Considerations

A Content Creator or Content Consumer should be grouped with appropriate actors from workflow profiles that manage interchange of clinical data. Such groupings are described in this section.

Content profiles may impose additional requirements on the transactions used when grouped with actors from other IHE Profiles. The metadata sent in the document sharing or interchange messages has specific relationships to the content of the clinical document described in the content profile. These mappings between the workflow metadata and the content attributes are described in IHE PCC TF-2:4.

13.7.1 Content Bindings for Displayable Reports (DRPT) Profiles

CDA documents using the EPRC-IE content may be exchanged between a Report Creator and a Report Manager, as defined in the Displayable Reports (DRPT) Profile using the Encapsulated Report Submission [CARD-7] transaction. In this case, the EPRC-IE Content Creator actor is grouped with the DRPT Report Creator actor, and the EPRC-IE Content Consumer actor is grouped with the DRPT Report Manager actor.

13.7.2 Content Bindings for XDS, XDM, XDR, XDS-I, and XDR-I

It is expected that the transfers of care will occur in an environment where the physician offices and hospitals have a coordinated infrastructure that serves the information sharing needs of this community of care. Several mechanisms are supported by IHE profiles:

- A registry/repository-based infrastructure is defined by the IHE Cross Enterprise Document Sharing (XDS) and other IHE Integration Profiles such as patient identification (PIX & PDQ) and notification of availability of documents (NAV). An extension for imaging study exchange is Cross Enterprise Document Sharing for Imaging (XDS-I).
- A media-based infrastructure is defined by the IHE Cross Enterprise Document Media Interchange (XDM) profile.

- A reliable messaging-based infrastructure is defined by the IHE Cross Enterprise Document Reliable Interchange (XDR) profile. An extension for imaging study exchange is Cross Enterprise Document Reliable Interchange for Imaging (XDR-I).
- All of these infrastructures support Security and privacy through the use of the Consistent Time (CT) and Audit Trail and Node Authentication (ATNA) profiles.

For more details on these profiles, see the IHE IT Infrastructure Technical Framework, and the IHE Radiology Technical Framework for XDS-I and XDR-I.

Document Source and Document Consumer Actors from the ITI XDS, XDM and XDR profiles are logically grouped with the EPRC-IE Content Creator and Content Consumer actors, respectively.

13.7.3 Binding for Portable Data for Imaging (PDI)

CDA documents using the EPRC-IE content may be exchanged on interchange media in accordance with the Portable Data for Imaging (PDI) profile. Such documents may be encapsulated within DICOM SOP Instances, or may be native CDA documents, as described in the IHE Radiology Technical Framework. In this case, the EPRC-IE Content Creator actor is grouped with the PDI Portable Media Creator actor, and the EPRC-IE Content Consumer actor is grouped with the PDI Display or Portable Media Importer actors.

13.7.4 Content Binding for Retrieve Form for Data Capture (RFD)

A CDA document may be used for pre-population of a data entry form managed by actors of the Retrieve Form for Data Capture (RFD) Profile. In particular, the EPRC-IE content, as a carrier of discrete encoded data, may be used to pre-populate data entry forms for cardiovascular data registries. The EPRC-IE profile has been developed with key data elements that support common research related data fields. This profile, however, does not provide mapping between EPRC-IE field content and any specific registry field content. In this case, the EPRC-IE Content Consumer actor is grouped with the RFD Form Manager actor for the purpose of extracting discrete data from the report to pre-populate the data capture form.

13.7.5 Relationship to Document Digital Signature (DSG)

When a Content Creator Actor needs to digitally sign a document in a submission set, it may support the Digital Signature (DSG) Content Profile as a Document Source. When a Content Consumer Actor needs to verify a Digital Signature, it may retrieve the digital signature document and may perform the verification against the signed document content.

Appendices

Actor Summary Definitions

Add the following terms to the IHE TF General Introduction Namespace list of Actors:

None

Transaction Summary Definitions

Add the following terms to the IHE TF General Introduction Namespace list of Transactions:

None

Glossary

None

Volume 3 – Content Modules

Add section 6.4

6 Content Modules

6.4 Electrophysiology Implant/Explant Report Content Modules

6.4.1 Electrophysiology Implant/Explant Report Content Specification 1.3.6.1.4.1.19376.1.4.1.1.3

This is the template for EP Implant/Explant Reports with discrete data elements as described in the NCDR ICD Registry version 1.2 Coder's Data Dictionary. The Template ID for conformance to this template is OID = 1.3.6.1.4.1.19376.1.4.1.1.3.

This CDA document is not a direct specialization of any existing CDA document template ID. However, some parts were based on the IHE Card CIRC and CRC profile supplements and the HL7 Implementation Guide for CDA Release 2: IHE Health Story Consolidation, Release 1.1 DSTU -July 2012 (C-CDA) Procedure Note document specification.

6.4.1.1 Format Code

The XDSDocumentEntry format code for this content is **urn:ihe:card:EPRC-IE:2014**

The mapping of CDA header attributes to XDS metadata shall be identical to the XDS-MS mapping specified in PCC TF-2: 4.1.1.

6.4.1.2 Relationship to the IHE Cardiology CRC Profile

This EPRC-IE document is consistent with the existing Cath Report Content (CRC) content profile that was published for Trial Implementation in 2013

These consistencies include:

- Overall document structure
- Adherence to header, sections, and entry definitions whenever possible with most deviations kept to Value Sets.

6.4.1.3 Relationship to C-CDA

Some CDA section and entries used within this EPRC-IE document were based on the HL7 Implementation Guide for CDA Release 2: IHE Health Story Consolidation, Release 1.1 DSTU (C-CDA) section and entry definitions.

a. Where constraints defined in C-CDA were not modified, the constraint remains as the C-CDA constraint identifier (e.g., CONF:5361). If only the value set was modified, then the constraint is considered unchanged.

b. Where constraints defined in C-CDA were modified, the original constraint ID is also modified by appending "-EPRC" (e.g., CONF:5253-EPRC). Modifications could include changes in the cardinality.

c. Where new constraints were introduced, a new constraint identifier was defined (e.g., CONF:EPRC-xxx)

If there are no new or modified constraints for a section or entry or if only the value sets are constrained, then the definition of the section or entry is considered unchanged from the C-CDA definition and the C-CDA template Id will be used. These unchanged sections/entries are referenced directly from the C-CDA specification and are not included in this specification.

If there are new or modified constraints for a section or entry, then that section or entry is assigned a new IHE Card specific template Id.

The description of the type of modification to affected section or entry content modules are outlined with boxes.

This profile uses HL7 V3 data types R1.

6.4.1.4 Conventions

6.4.1.4.1 Conformance Terms

The definitions of the conformance verbs, the terms *optional* and *required* and the cardinality indicator are as defined in C-CDA Section 1.8 – Conformance Conventions.

6.4.1.4.2 Narrative requirements

There is no general requirement for the section text narrative to completely contain the full coded content of all the elements of the section and its contained entries. However for this profile, it is recommended that all coded content in the section and its contained entries SHOULD be included in the narrative for each section. In any case, there SHALL be no conflicts between the narrative and the coded content.

In the case where the section ACT relationship is specified to be “DRIV” (derived), then the section narrative SHALL be based solely on the coded content. This narrative content SHOULD include as much of the coded content as possible.

The coded content may not be an equivalent of the narrative.

6.4.1.5 Standards

The following table identifies the standards upon which this specification is based.

Table 6.4.1.5-1: Reference Standards

Standard Name (short)	Standard Name (full)	Reference to Published Standard
ICD Registry	NCDR ICD Registry v1.2 Coder's Data Dictionary	https://www.ncdr.com/WebNCDR/docs/default-source/icd-registry-v2-data-collection-documents/icd_v2_datadictionary_codersdictionary_2-1.pdf?sfvrsn=3
CDAR2	HL7 CDA Release 2.0	http://www.hl7.org/documentcenter/private/standards/cda/r2/cda_r2_normativewebedition2010.zip
C-CDA	HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, Release 1.1 - US Realm	http://www.hl7.org/implement/standards/product_brief.cfm?product_id=258
DICOM	NEMA PS3.16 – DICOM Part 16: Content Mapping Resource	ftp://medical.nema.org/medical/dicom/2009/09_16pu.pdf
SNOMED CT	Systematized Nomenclature of Medicine – Clinical Terms	http://www.ihtsdo.org/snomed-ct/
LOINC	Logical Observation Identifiers Names and Codes	http://loinc.org/
IEEE 11073 10103	IEEE 11073_10103 MDC_IDC Nomenclature	http://standards.ieee.org/downloads/11073/
RxNorm	RxNorm - normalized naming system for generic and branded drugs	http://www.nlm.nih.gov/research/umls/rxnorm/
UCUM	Unified Code for Units of Measure	http://uinitsofmeasure.org/

6.4.2 Electrophysiology Implant/Explant Report Content Header Element Constraints

The header for the EPRC-IE document shall support the following header constraints as noted in this section. Note that this content profile is realm agnostic. These header constraints are based on the C-CDA header constraints but all references to US Realm specific types have been removed.

1. **SHALL** contain exactly one [1..1] **typeId** (CONF:5361).
   a. This typeId **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.1.3" (CONF:5250).
   b. This typeId **SHALL** contain exactly one [1..1] **@extension**="POCD_HD000040" (CONF:5251).
2. **SHALL** contain exactly one [1..1] **templateId** (CONF:5252) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.4.1.1.3" for the Electrophysiology Implant/Explant Report Content document template (CONF:EPRC-xxx).

3. **SHALL** contain exactly one [1..1] **id** (CONF:5363).
    a. This id **SHALL** be a globally unique identifier for the document (CONF:9991).
4. **SHALL** contain exactly one [1..1] **code** (CONF:5253).
    a. This code **SHALL** contain exactly one [1..1] **@code**, which **SHALL** be selected from ValueSet `ProcedureNoteDocumentTypeCodes 2.16.840.1.113883.11.20.6.1` **DYNAMIC** (CONF:17183).

Value Set: ProcedureNoteDocumentTypeCodes 2.16.840.1.113883.11.20.6.1 DYNAMIC Code System: LOINC 2.16.840.1.113883.6.1			
LOINC Code	**Type of Service 'Component'**	**Setting 'System'**	**Specialty/Training/Professional Level 'Method_Type'**
18750-0	Study report	Heart	Electrophysiology

5. **SHALL** contain exactly one [1..1] **title** (CONF:5254).
    a. Can either be a locally defined name or the display name corresponding to clinicalDocument/code (CONF:5255).
6. **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:5256).
    a. Signifies the document creation time, when the document first came into being. Where the CDA document is a transform from an original document in some other format, the ClinicalDocument.effectiveTime is the time the original document was created. The time when the transform occurred is not currently represented in CDA (CONF:9995).
7. **SHALL** contain exactly one [1..1] **confidentialityCode**, which **SHOULD** be selected from ValueSet `HL7 BasicConfidentialityKind 2.16.840.1.113883.1.11.16926` **STATIC** 2010-04-21 (CONF:5259).

```
<typeId root="2.16.840.1.113883.1.3" extension="POCD_HD000040"/>
<!—EPRC Template -->
<templateId root="1.3.6.1.4.1.19376.1.4.1.1.3"/>
<id extension="999021" root="2.16.840.1.113883.19"/>
<code codeSystem="2.16.840.1.113883.6.1"
      codeSystemName="LOINC" code="18750-0"
      displayName="Interventional Procedure Note - Electrophysiology"/>
<title>Electrophysiology report</title>
<effectiveTime value="20050329171504+0500"/>
<confidentialityCode code="N" codeSystem="2.16.840.1.113883.5.25"/>
```

Figure 6.4.2-1: header example

8. **SHALL** contain exactly one [1..1] **recordTarget** (CONF:5266-CRC). The recordTarget records the patient whose health information is described by the clinical document.

a. This recordTarget **SHALL** contain exactly one [1..1] **patientRole** (CONF:5267).
    i. This patientRole **SHALL** contain at least one [1..*] **id** (CONF:5268)
    ii. This patientRole **SHALL** contain at least one [1..*] **addr** (CONF:5271).
        1. This addr **SHALL** contain at least one [1..*] **postalCode** (CONF:CRC-xxx).
    iii. This patientRole **SHALL** contain at least one [1..*] **telecom** (CONF:5280).
    iv. This patientRole **SHALL** contain exactly one [1..1] **patient** (CONF:5283).
        1. This patient **SHALL** contain exactly one [1..1] **name** (CONF:5284).
            a. This name **SHALL** contain exactly one [1..1] **family** (CONF:7159).
            b. This name **SHALL** contain at least one [1..*] **given** (CONF:7157).
                i. The second occurrence of given (given[2]) if provided, **SHALL** include middle name or middle initial (CONF:7163).
        2. This patient **SHALL** contain exactly one [1..1] **administrativeGenderCode**, which **SHALL** be selected from ValueSet `Administrative Gender (HL7 V3) 2.16.840.1.113883.1.11.1` **DYNAMIC** (CONF:6394).
        3. This patient **SHALL** contain exactly one [1..1] **birthTime** (CONF:5298).
            a. **SHALL** be precise to year (CONF:5299).
            b. **SHOULD** be precise to day (CONF:5300).

```
<recordTarget>
  <patientRole>
    <id extension="12345" root="2.16.840.1.113883.19"/>
    <addr use="HP">
       <streetAddressLine>17 Daws Rd.</streetAddressLine>
       <city>Blue Bell</city>
       <state>MA</state>
       <postalCode>02368</postalCode>
       <country>US</country>
    </addr>
    <telecom value="tel:(781)555-1212" use="HP"/>
    <patient>
       <name>
          <prefix>Mr.</prefix>
          <given>Adam</given>
          <given>Frankie</given>
          <family>Everyman</family>
       </name>
```



```
        <administrativeGenderCode code="M"
              codeSystem="2.16.840.1.113883.5.1" displayName="Male"/>
        <birthTime value="19541125"/>
    </patient>
  </patientRole>
</recordTarget>
```

Figure 6.4.2-2: recordTarget example

9. **SHALL** contain at least one [1..*] **author** (CONF:5444). The author element represents the person who created the clinical document. If there are multiple procedures performed, there may be multiple authors for the content of this document.
    a. Such authors **SHALL** contain exactly one [1..1] **time** (CONF:5445). This is the time the author started to contribute to this document.
    b. Such authors **SHALL** contain exactly one [1..1] **assignedAuthor** (CONF:5448).
        i. This assignedAuthor **SHALL** contain exactly one [1..1] **id** (CONF:5449).
        i. This assignedAuthor **SHALL** contain at least one [1..*] **addr** (CONF:5452).
        ii. This assignedAuthor **SHALL** contain at least one [1..*] **telecom** (CONF:5428).
        iii. This assignedAuthor **SHALL** contain exactly one [1..1] **assignedPerson** (CONF:5430-CRC).
            1. This assignedPerson **SHALL** contain at least one [1..*] **name** (CONF:16789).


```
<author>
  <time value="20120329224411+0500"/>
  <assignedAuthor>
     <id extension="KP00017" root="2.16.840.1.113883.19.5"/>
     <addr>
        <streetAddressLine>21 North Ave.</streetAddressLine>
        <city>Burlington</city>
        <state>MA</state>
        <postalCode>02368</postalCode>
        <country>US</country>
     </addr>
     <telecom use="WP" value="tel:(555)555-1003"/>
     <assignedPerson>
        <name>
           <given>Henry</given>
           <family>Seven</family>
        </name>
     </assignedPerson>
  </assignedAuthor>
</author>
```

Figure 6.4.2-3: Person author example

10. **SHALL** contain exactly one [1..1] **custodian** (CONF:5519).
    a. This custodian **SHALL** contain exactly one [1..1] **assignedCustodian** (CONF:5520).
        i. This assignedCustodian **SHALL** contain exactly one [1..1] **representedCustodianOrganization** (CONF:5521).
            1. This representedCustodianOrganization **SHALL** contain at least one [1..*] **id** (CONF:5522).
            2. This representedCustodianOrganization **SHALL** contain exactly one [1..1] **name** (CONF:5524).
            3. This representedCustodianOrganization **SHALL** contain exactly one [1..1] **telecom** (CONF:5525).
            4. This representedCustodianOrganization **SHALL** contain at least one [1..*] **addr** (CONF:5559).


```
<custodian>
  <assignedCustodian>
     <representedCustodianOrganization>
        <id root="2.16.840.1.113883.19.5"/>
        <name>Good Health Clinic</name>
        <telecom value="tel:(555)555-1212" use="WP"/>
        <addr use="WP">
           <streetAddressLine>17 Daws Rd.</streetAddressLine>
           <city>Blue Bell</city>
           <state>MA</state>
           <postalCode>02368</postalCode>
           <country>US</country>
        </addr>
     </representedCustodianOrganization>
  </assignedCustodian>
</custodian>
```

Figure 6.4.2-4: custodian example

11. **SHALL** contain exactly one [1..1] **legalAuthenticator** (CONF:5579-CRC).
    a. This legalAuthenticator **SHALL** contain exactly one [1..1] **time** (CONF:5580).
    b. This legalAuthenticator **SHALL** contain exactly one [1..1] **signatureCode** (CONF:5583).
        i. This signatureCode **SHALL** contain exactly one [1..1] **@code**="S" (CodeSystem: `Participationsignature 2.16.840.1.113883.5.89`) (CONF:5584).
    c. This legalAuthenticator **SHALL** contain exactly one [1..1] **assignedEntity** (CONF:5585).
        i. This **assignedEntity** **SHALL** contain at least one [1..*] **id** (CONF:5586).
        ii. This assignedEntity **MAY** contain zero or one [0..1] **code** (CONF:17000-CRC).
        ii. This assignedEntity **SHALL** contain at least one [1..*] **addr** (CONF:5589).
        iii. This assignedEntity **SHALL** contain at least one [1..*] **telecom** (CONF:5595).
            1. Such telecoms **SHOULD** contain **@use** (CONF:7999-CRC).
        iv. This assignedEntity **SHALL** contain exactly one [1..1] **assignedPerson** (CONF:5597).
            1. This assignedPerson **SHALL** contain at least one [1..*] **name** (CONF:5598).

The **legalAuthenticator** identifies the single person legally responsible for the document and must be present if the document has been legally authenticated.


```
<legalAuthenticator>
  <time value="20050329224411+0500"/>
  <signatureCode code="S"/>
  <assignedEntity>
     <id extension="KP00017" root="2.16.840.1.113883.19"/>
     <addr>
        <streetAddressLine>21 North Ave.</streetAddressLine>
        <city>Burlington</city>
        <state>MA</state>
        <postalCode>02368</postalCode>
        <country>US</country>
     </addr>
     <telecom use="WP" value="tel:(555)555-1003"/>
     <assignedPerson>
        <name>
           <given>Henry</given>
           <family>Seven</family>
        </name>
     </assignedPerson>
  </assignedEntity>
</legalAuthenticator>
```

Figure 6.4.2-5: legalAuthenticator example

12. **MAY** contain zero or more [0..*] **authenticator** (CONF:5607).
    a. Such authenticators, if present, **SHALL** contain exactly one [1..1] **time** (CONF:5608).
    b. Such authenticators, if present, **SHALL** contain exactly one [1..1] **signatureCode** (CONF:5610).
        i. This signatureCode **SHALL** contain exactly one [1..1] **@code**="S" (CodeSystem: `Participationsignature 2.16.840.1.113883.5.89`) (CONF:5611).
    c. Such authenticators, if present, **SHALL** contain exactly one [1..1] **assignedEntity** (CONF:5612).
        i. This assignedEntity **SHALL** contain at least one [1..*] **id** (CONF:5613).
        iii. This assignedEntity **SHALL** contain at least one [1..*] **addr** (CONF:5616).
        ii. This assignedEntity **SHALL** contain at least one [1..*] **telecom** (CONF:5622).
        iii. This assignedEntity **SHALL** contain exactly one [1..1] **assignedPerson** (CONF:5624).
            1. This assignedPerson **SHALL** contain at least one [1..*] **name** (CONF:5625).

The **authenticator** identifies a participant or participants who attested to the accuracy of the information in the document.


```
<authenticator>
  <time value="20050329224411+0500"/>
  <signatureCode code="S"/>
  <assignedEntity>
     <id extension="KP00017" root="2.16.840.1.113883.19"/>
     <addr>
        <streetAddressLine>21 North Ave.</streetAddressLine>
        <city>Burlington</city>
        <state>MA</state>
        <postalCode>02368</postalCode>
        <country>US</country>
     </addr>
     <telecom use="WP" value="tel:(555)555-1003"/>
     <assignedPerson>
        <name>
           <given>Henry</given>
           <family>Seven</family>
        </name>
     </assignedPerson>
  </assignedEntity>
</authenticator>
```

Figure 6.4.2-6: Authenticator example

13. **MAY** contain zero or one [0..1] **inFulfillmentOf** (CONF:9952-CRC).
    a. Such inFulfillmentOf elements, if present, **SHALL** contain exactly one [1..1] **order** (CONF:9953-CRC).
        i. This order **SHALL** contain at least one [1..*] **id** (CONF:9954-EPRC).
            1. One id **SHALL** be the Accession Number for the EP procedure, with the root representing the Assigning Authority (Issuer of Accession Number) (CONF:EPRC-xxx).
        ii. This order **SHALL** contain at least one [1..*] **priorityCode** which **SHALL** be selected from ValueSet `ActPriority Value Set 2.16.840.1.113883.1.11.16866` **DYNAMIC** (CONF:8300-CRC).

```
<inFulfillmentOf>
  <order>
    <id root="1.2.3.4.5.6" extension="accession#1" />
    <priorityCode code="R" codeSystem=" 2.16.840.1.113883.5.7"
     codeSystemName="ActPriority" displayName="Routine">
  </order>
</inFulfillmentOf>
```

Figure 6.4.2-7: inFulfillmentOf example

14. **MAY** contain zero or more [0..*] **authorization** (CONF:16792).
    a. **SHALL** contain exactly one [1..1] **consent**. (CONF:16793).

i. This consent **MAY** contain zero or more [0..*] **id** (CONF:16794).
ii. This consent **MAY** contain zero or one [0..1] **code** (CONF:16795).
    1. The type of consent (e.g., a consent to perform the related serviceEvent) is conveyed in consent/code (CONF:16796).
    2. The following LOINC codes **SHOULD** be used (CONF:CRC-xxx):
        a. 64293-4 – procedure consent
        b. 61359-6 – anesthesia consent
iii. This consent **SHALL** contain exactly one [1..1] **statusCode** (CONF:16797).
    1. This statusCode **SHALL** contain exactly one [1..1] **@code**="completed" Completed (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC)** (CONF:16798)

An authorization consent **MAY** be provided for the procedure and an authorization consent **MAY** be provided for the anesthesia.

```
<authorization typeCode="AUTH">
    <consent classCode="CONS" moodCode="EVN">
       <id root="629deb70-5306-11df-9879-0800200c9a66" />
       <code codeSystem=" 2.16.840.1.113883.6.1" codeSystemName="LOINC"
             code="64293-4" displayName="Procedure Consent"/>
       <statusCode code="completed"/>
    </consent>
</authorization>
<authorization typeCode="AUTH">
    <consent classCode="CONS" moodCode="EVN">
       <id root="629deb70-5306-11df-9879-0800200c9a66" />
       <code codeSystem=" 2.16.840.1.113883.6.1" codeSystemName="LOINC"
             code="61359-6" displayName="Anesthesia Consent"/>
       <statusCode code="completed"/>
    </consent>
</authorization>
```

Figure 6.4.2-8: consent example

15. **SHALL** contain exactly one [1..1] **componentOf** (CONF:9955-CRC).
    a. This componentOf element **SHALL** contain exactly one [1..1] **encompassingEncounter** (CONF:9956).
        i. This encompassingEncounter **SHALL** contain at least one [1..*] **id** (CONF:9959).
        ii. This encompassingEncounter **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:9958).

1. This effectiveTime **SHALL** be accurate to the day and **MAY** be accurate to the second (CONF:CRC-xxx).

iii. This encompassingEncounter **SHALL** contain exactly one [1..1] **code** (CONF:8501).

iv. This encompassingEncounter **SHALL** contain at least one [1..*] **location/healthCareFacility** (CONF:8500).

1. This healthCareFacility **SHALL** contain at least one [1..*] **code** representing the type of location (CONF:CRC).
2. This healthCareFacility **SHALL** contain at least one [1..*] **id** (CONF:8500).
3. This healthCareFacility **SHOULD** contain at least one [1..*] **serviceProviderOrganization** (CONF:CRC-xxx).
    a. This serviceProviderOrganization **SHALL** contain at least one [1..*]**name** (CONF:CRC-xxx).
    b. This serviceProviderOrganization **SHALL** contain at least one [1..*]**addr** (CONF:CRC-xxx).
    c. This serviceProviderOrganization **SHALL** contain at least one [1..*] **telecom** (CONF:CRC-xxx).
4. This healthCareFacility **MAY** contain zero or more [0..*] **location** (CONF:CRC-xxx).
    a. If present, this location **SHALL** contain at least one [1..*]**name** and/or **addr** to identify the place of the encounter (CONF:CRC-xxx).

v. This componentOf/encompassingEncounter **MAY** contain zero to four [0..4] **encounterParticipant** (CONF:8502-CRC) such that it

1. **MAY** contain at most two [0..2] **@typeCode**="REF" Referrer (CodeSystem: `HL7ParticipationType 2.16.840.1.113883.5.90`) for the referring cardiologist and referring physician (CONF:8503-CRC).
2. **MAY** contain zero or one [0..1] **@typeCode**="ATND" Physician of Record (CodeSystem: `HL7ParticipationType 2.16.840.1.113883.5.90`) (CONF:8503-CRC).
3. **MAY** contain zero or one [0..1] **@typeCode**="RESP" Responsible Party (CodeSystem: `HL7ParticipationType 2.16.840.1.113883.5.90`) (CONF:8503-CRC).


```
<componentOf>
  <encompassingEncounter>
     <id extension="KP00017" root="2.16.840.1.113883.19"/>
     <effectiveTime value=”20110407”/>
     <code code="233170003" codeSystem="2.16.840.1.113883.6.96"
           codeSystemName="SNOMED CT"
           displayName="ICD Implant "/>
     <location>
      <healthCareFacility>
        <id root=”1.2.3.4.5.6.7” extension=”facility ID”/>
        <code code=”CVDX” codeSystem=”2.16.840.1.113883.5.111”
          codeSystemName=”roleCode” displayName=”EP LAB”/>
        <serviceProviderOrganization>
           <name>My Favorite Cardiac Care Organization</name>
           <addr>
               <streetAddressLine>Healthcare Lane</streetAddressLine>
               <city>East Town</city>
               <state>OH</state>
               <country>US</country>
           </addr>
           <telecom value=”1-800-555-1212” use=”WP”/>
        </serviceProviderOrganization>
        <location>
           <name>My Cardiac Hospital</name>
           <addr>
               <streetAddressLine>Healthcare Lane</streetAddressLine>
               <city>East Town</city>
               <state>OH</state>
               <country>US</country>
           </addr>
        </location>
      </healthCareFacility>
    </location>
    <encounterParticipant typeCode=”REF”>
      <assignedEntity>
        <id root=”2.16.840.1.113883.4.6” extension=”12345”/>
        <code code=”xyz” codeSystem=”2.16.840.1.113883.6.101”
              codeSystemName=”nuccProviderCodes”
              displayName=”Referring cardiologist”/>
        <addr>Referring Physician Lane, USA</addr>
        <telecom value=”1-800-555-1212” use=”WP”/>
        <assignedPerson>
          <name>Dr. Referring Physician</name>
        </assignedPerson>
      </assignedEntity>
    </encounterParticipant>
  </encompassingEncounter >
</componentOf>
```

Figure 6.4.2-9: componentOf/encompassingEncounter example

16. **SHALL** contain at least one [1..*] **documentationOf** (CONF:8510).

a. This documentationOf **SHALL** contain exactly one [1..1] **serviceEvent** (CONF:10061).
    i. The value of serviceEvent/code **SHOULD** be selected from SNOMED CT (codeSystem 2.16.840.1.113883.6.96) and **MAY** be selected from a localized procedure coding system for a given country such as ICD9 CM Procedures (codeSystem 2.16.840.1.113883.6.104) or CPT-4 (codeSystem 2.16.840.1.113883.6.12) in the U.S (CONF:CRC-xxx).
    ii. This serviceEvent **MAY** contain zero or more [0..*] **id** values including the Study Instance UID used in the DICOM imaging data, with the UID value in the root attribute (CONF:CRC-xxx).
    iii. This serviceEvent **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:10062).
        1. This effectiveTime **SHALL** contain exactly one [1..1] **low** (CONF:26449).
        2. If a width is not present, the serviceEvent/effectiveTime **SHALL** include effectiveTime/high. (CONF:8514)
        3. When only the date and the length of the procedure are known a width element **SHALL** be present and the effectiveTime/high **SHALL** not be present. (CONF:8515).
        4. The effectiveTime **SHALL** be accurate to the day and **MAY** be accurate to the second (CONF:CRC-xxx).
    iv. This serviceEvent **SHALL** contain exactly one [1..1] **performer** (CONF:8520) such that it
        1. **SHALL** contain exactly one [1..1] **@typeCode**="PPRF" Primary Performer (CodeSystem: `HL7ParticipationType 2.16.840.1.113883.5.90`). (CONF:8521).
        2. **SHALL** contain exactly one [1..1] **assignedEntity** (CONF:14911).
            a. This assignedEntity **SHOULD** contain zero or one [0..1] **code** (CONF:14912).
                i. The code, if present, **SHOULD** contain zero or one [0..1] **@code**. (CONF:14913-CRC).
        3. Any assistants **SHALL** be identified and **SHALL** be identified as secondary performers (SPRF). (CONF:8524).


```
<documentationOf>
  <serviceEvent classCode="PROC">
    <code code="252425004" codeSystem="2.16.840.1.113883.6.96"
         codeSystemName="SNOMED CT"
         displayName="Cardiac Electrophysiology"/>
    <id root="DICOM study instance UID" extension="acc1"/>
    <effectiveTime>
      <low value="201003292240" />
      <width value="15" unit="m"/>
    </effectiveTime>
    <performer typeCode="PPRF">
      <assignedEntity>
        <id extension="IO00017" root="2.16.840.1.113883.19.5" />
        <code code="17561000"
            codeSystem="2.16.840.1.113883.6.96"
            codeSystemName="SNOMED CT"
            displayName="Cardiologist" />
        <addr>
          <streetAddressLine>1001 Hospital Lane</streetAddressLine>
          <city>Ann Arbor</city>
          <state>MI</state>
          <postalCode>99999</postalCode>
          <country>US</country>
        </addr>
        <telecom value="tel:(999)555-1212" />
        <assignedPerson>
          <name>
            <prefix>Dr.</prefix>
            <given>Tony</given>
            <family>Tum</family>
          </name>
        </assignedPerson>
       </assignedEntity>
     </performer>
  </serviceEvent>
</documentationOf>
```

Figure 6.4.2-10: documentationOf/serviceEvent example

6.4.3 Electrophysiology Implant/Explant Report Content Body Containment

The body for the Electrophysiology Implant/Explant Report Content document shall include section content modules. The section content modules will be specified by a set of constraints.

1. **SHALL** contain exactly one [1..1] **component** (CONF:9588).
    a. An Electrophysiology Implant/Explant Report Content **SHALL** have a **structuredBody** (CONF:9589-CRC).
        i. An Electrophysiology Implant/Explant Report Content document **SHALL** conform to CDA Level 3 (structuredBody containing sections that contain a narrative block and coded entries). In this template

(templateId 1.3.6.1.4.1.19376.1.4.1.1.3), some coded entries are used. (CONF:9590-CRC).

b. The component/structuredBody **SHALL** conform to the section constraints below (CONF:9595-CRC).

i. Each section **SHALL** have a **`title`** and the **`title`** **SHALL NOT** be empty (CONF:9937).

Table 6.4.3-1 identifies the set of specific *section content modules* that may be required, recommended, or allowed to be included in the EPRC-IE document. This table also identifies the most important *entry content modules* contained within those section content modules. The containment relationship among the section and entry content modules in the body of an Electrophysiology Implant/Explant Report Content document is represented in the "Template Title" column as noted by the indentation relative to the other content modules.

1. Section content modules
    a. Any section content module that is used exactly as specified in C-CDA does not have the C-CDA constraints replicated in this specification.
    b. If the section content module is used in this profile but with different vocabulary constraints, then the vocabulary constraints are listed in the "Constraints" columns of the table and shall be included in this specification.
    c. Sample XML is included for each section content module and does include XML for each entry contained within the section.
2. Entry content modules
    a. Any entry content module that is used exactly as specified in C-CDA does not have the specific constraints replicated in this specification.
    b. If the entry content module is relevant to this EPRC-IE profile, it is included in table 6.4.3-1 following the section content module it is contained within.
    c. If the entry content module has EPRC-IE specific vocabulary constraints, the constraints are identified in the "Constraints" columns of the table and are documented in this specification.
    d. Sample XML is included for the entries within the section content module where it is used.

Table 6.4.3-1: Template Containment for an Electrophysiology Implant/Explant Report Content document

Template Title	Cardinality	Template Type	templateId	Specification Document	Constraints
Electrophysiology Implant/Explant Report Content	R[1..1]	document	1.3.6.1.4.1.19376.1.4.1.1.3	CARD TF-3 6.4	
Document Summary Section	R[1..1]	section	1.3.6.1.4.1.19376.1.4.1.2.26	CARD TF-3 6.4.4.1	CARD TF-3 6.4.4.1
Medical History - Cardiac Section	R[1..1]	section	1.3.6.1.4.1.19376.1.4.1.2.17	CARD TF-3 6.4.4.2 (C-CDA 4.31 - parent)	CARD TF-3 6.4.4.2
Procedure Activity Observation	O[0..*]	entry	2.16.840.1.113883.10.20.22.4.13	C-CDA 5.62	CARD TF-3 6.4.4.2.2
Procedure Activity Procedure	O[0..*]	entry	2.16.840.1.113883.10.20.22.4.14	C-CDA 5.63	CARD TF-3 6.4.4.2.3
Problem Observation - Cardiac	O[0..*]	entry	1.3.6.1.4.1.19376.1.4.1.4.9	CARD TF-3 6.4.5.1 (C-CDA 5.59 – parent)	CARD TF-3 6.4.4.2.1
Age Observation	O[0..1]	entry	2.16.840.1.113883.10.20.22.4.31	C-CDA 5.3	
Health Status Observation	O[0..1]	entry	2.16.840.1.113883.10.20.22.4.5	C-CDA 5.30	
Problem Status	O[0..1]	entry	2.16.840.1.113883.10.20.22.4.6	C-CDA 5.60	
Severity Observation	O[0..1]	entry	2.16.840.1.113883.10.20.22.4.8	C-CDA 5.74	
Allergies Section	R[1..1]	section	2.16.840.1.113883.10.20.22.2.6	C-CDA 4.2	CARD TF-3 6.4.4.3
Allergy Problem Act	O[0..*]	entry	2.16.840.1.113883.10.20.22.4.30	C-CDA 5.5	
Allergy – Intolerance Observation	R[1..*]	entry	2.16.840.1.113883.10.20.22.4.7	C-CDA 5.4	CARD TF-3 6.4.4.3.1
Allergy Status Observation	O[0..1]	entry	2.16.840.1.113883.10.20.22.4.28	C-CDA 5.6	
Reaction Observation	O[0..1]	entry	2.16.840.1.113883.10.20.22.4.9	C-CDA 5.68	
Severity Observation	O[0..1]	entry	2.16.840.1.113883.10.20.22.4.8	C-CDA 5.74	
Family History Section	O[0..1]	section	2.16.840.1.113883.10.20.22.2.15	C-CDA 4.12	CARD TF-3 6.4.4.4
Family History Organizer	O[0..*]	entry	2.16.840.1.113883.10.20.22.4.45	C-CDA 5.26	
Family History Observation	O[0..*]	entry	2.16.840.1.113883.10.20.22.4.46	C-CDA 5.25	CARD TF-3 6.4.4.4.1
Social History Section	O[0..1]	section	2.16.840.1.113883.10.20.22.2.17	C-CDA 4.57	CARD TF-3 6.4.4.5

Template Title	Cardinality	Template Type	templateId	Specification Document	Constraints
Social History Observation	O[0..*]	entry	2.16.840.1.113883.10.20.22.4.38	C-CDA 5.76	CARD TF-3 6.4.4.5.1
Smoking Status Observation	O[0..*]	entry	2.16.840.1.113883.10.20.22.4.78	C-CDA 5.75	
Physical Exam Section	R[1..1]	section	2.16.840.1.113883.10.20.2.10	C-CDA 4.38	CARD TF-3 6.4.4.6
Vital Signs Section	R[1..1]	section	2.16.840.1.113883.10.20.22.2.4	C-CDA 4.60	CARD TF-3 6.4.4.7
Vital Signs Organizer	R[1..*]	entry	2.16.840.1.113883.10.20.22.4.26	C-CDA 5.82	
Vital Sign Observation	R[2..*]	entry	2.16.840.1.113883.10.20.22.4.27	C-CDA 5.81	CARD TF-3 6.4.4.7.1
Pre-Procedure Results – Cardiac Section	R[1..1]	section	1.3.6.1.4.1.19376.1.4.1.2.23	CARD TF-3 6.4.4.8 (C-CDA 4.55 – parent)	CARD TF-3 6.4.4.8
Result Organizer - Cardiac	R[1..*]	entry	1.3.6.1.4.1.19376.1.4.1.4.11	CARD TF-3 6.4.4.8.1 (C-CDA 5.71 – parent)	CARD TF-3 6.4.4.8.1
Result Observation	R[1..*]	entry	2.16.840.1.113883.10.20.22.4.2	C-CDA 5.70	CARD TF-3 6.4.4.8.2
Planned Procedure Section	R[1..1]	section	2.16.840.1.113883.10.20.22.2.30	C-CDA 4.40	CARD TF-3 6.4.4.9
Plan of Care Activity Procedure	O[0..*]	entry	2.16.840.1.113883.10.20.22.4.41	C-CDA 5.49	
Procedure Indications Section	R[1..1]	section	2.16.840.1.113883.10.20.22.2.29	C-CDA 4.50	CARD TF-3 6.4.4.10
Indication	O[0..*]	entry	2.16.840.1.113883.10.20.22.4.19	C-CDA 5.37	CARD TF-3 6.4.4.10.1
Anesthesia Section	O[0..1]	section	2.16.840.1.113883.10.20.22.2.25	C-CDA 4.3	CARD TF-3 6.4.4.11
Medication Activity	O[0..*]	entry	2.16.840.1.113883.10.20.22.4.16	C-CDA 5.39	

Template Title	Cardinality	Template Type	templateId	Specification Document	Constraints
Medications Administered Section	R[1..1]	section	2.16.840.1.113883.10.20.22.2.38	C-CDA 4.32	CARD TF-3 6.4.4.12
Medication Activity	R[1..*]	entry	2.16.840.1.113883.10.20.22.4.16	C-CDA 5.39	
Medication Information	R[1..*]	entry	2.16.840.1.113883.10.20.22.4.23	C-CDA 5.41	CARD TF-3 6.4.4.12.1
Procedure Description - Cardiac EPIE Section	R[1..1]	section	1.3.6.1.4.1.19376.1.4.1.2.24	CARD TF-3 6.4.4.13 (C-CDA 4.45 – parent)	CARD TF-3 6.4.4.13
Procedure Device Organizer – Cardiac EPIE	O[0..*]	entry	1.3.6.1.4.1.19376.1.4.1.4.20	CARD TF-3 6.4.4.13.2	CARD TF-3 6.4.4.13.2
Device Observation EPIE	R[1..*]	entry	1.3.6.1.4.1.19376.1.4.1.4.18	CARD TF-3 6.4.4.13.3	CARD TF-3 6.4.4.13.3
Procedure Activity Procedure - Cardiac EPIE	R[1..*]	entry	1.3.6.1.4.1.19376.1.4.1.4.19	CARD TF-3 6.4.4.13.1 (C-CDA 5.63 – parent)	CARD TF-3 6.4.4.13.1
Product Instance	O[1..*]	entry	2.16.840.1.113883.10.20.22.4.37	C-CDA 5.65	
Procedure Device Organizer – Cardiac EPIE	O[0..*]	entry	1.3.6.1.4.1.19376.1.4.1.4.20	CARD TF-3 6.4.4.13.2	CARD TF-3 6.4.4.13.2
Device Observation - EPIE	R[1..*]	entry	1.3.6.1.4.1.19376.1.4.1.4.18	CARD TF-3 6.4.4.13.3	CARD TF-3 6.4.4.13.3
Procedure Disposition Section	R[1..1]	section	2.16.840.1.113883.10.20.18.2.12	C-CDA 4.46	CARD TF-3 6.4.4.14
Procedure Results - Cardiac EPIE Section	R[1..1]	section	1.3.6.1.4.1.19376.1.4.1.2.25	CARD TF-3 6.4.4.15 (C-CDA 4.48 – parent)	CARD TF-3 6.4.4.15
Procedure Results Organizer – Cardiac EPIE	R[1..*]	entry	1.3.6.1.4.1.19376.1.4.1.4.23	CARD TF-3 6.4.4.15.1 (C-CDA 5.71 – parent)	
Result Observation – Cardiac EPIE	R[1..*]	entry	1.3.6.1.4.1.19376.1.4.1.4.22	CARD TF-3 6.4.4.15.2 (C-CDA 5.70 – parent)	
Severity Observation	O[0..1]	entry	2.16.840.1.113883.10.20.22.4.8	C-CDA 5.74	
Complications Section	R[1..1]	section	2.16.840.1.113883.10.20.22.2.37	C-CDA 4.8	CARD TF-3 6.4.4.16
Problem Observation	O[0..*]	entry	2.16.840.1.113883.10.20.22.4.4	C-CDA 5.59	CARD TF-3 6.4.4.16.1
Postprocedure Diagnosis Section	R[1..1]	section	2.16.840.1.113883.10.20.22.2.36	C-CDA 4.42	CARD TF-3 6.4.4.17

Template Title	Cardinality	Template Type	templateId	Specification Document	Constraints
Postprocedure Diagnosis	R[1..1]	entry	2.16.840.1.113883.10.20.22.4.51	C-CDA 5.53	
Problem Observation	R[1..*]	entry	2.16.840.1.113883.10.20.22.4.4	C-CDA 5.59	CARD TF-3 6.4.4.17.1
Plan of Care – Cardiac Section	O[0..1]	section	1.3.6.1.4.1.19376.1.4.1.2.22	CARD TF-3 6.4.4.18 (C-CDA 4.39 - parent)	CARD TF-3 6.4.4.18
Plan of Care Activity Act - Cardiac	R[1..1]	entry	1.3.6.1.4.1.19376.1.4.1.4.17	CARD TF-3 6.4.4.18.1 (C-CDA 5.46 – parent)	CARD TF-3 6.4.4.18.1
Key Images – Cardiac Section	O[0..1]	section	1.3.6.1.4.1.19376.1.4.1.2.21	CARD TF-3 6.4.4.19	CARD TF-3 6.4.4.19
Sop Instance Observation	R[1..*]	entry	2.16.840.1.113883.10.20.6.2.8	C-CDA 5.77	
DICOM Object Catalog Section	O[0..1]	section	2.16.840.1.113883.10.20.6.1.1	C-CDA 4.9	
Study Act	R[1..*]	entry	2.16.840.1.113883.10.20.6.2.6	C-CDA 5.78	
Series Act	R[1..*]	entry	2.16.840.1.113883.10.20.6.4.63	C-CDA 5.72	
Sop Instance Observation	R[1..*]	entry	2.16.840.1.113883.10.20.6.2.8	C-CDA 5.77	

6.4.4 Electrophysiology Implant/Explant Report Content Document Section/Entry Constraints

6.4.4.1 Document Summary - EPRC Section 55112-7

[section: templateId 1.3.6.1.4.1.19376.1.4.1.2.26 (open)]

The Document Summary - EPRC section content module includes a summary of most significant aspects of the procedures in a narrative form. It is a condensed form of the full narrative report whose structure has no constraint. This is where the actual narrative report should be placed. If images are included, they must be referenced using the technique described below in Constraint 5 of this section.

This Document Summary - EPRC section content module is a new content module that has no equivalent in C-CDA. The complete set of constraints for the Document Summary - EPRC section content module is listed below.

1. **SHALL** contain exactly one [1..1] **templateId** (CONF:CRC-xxx) such that it

a. **SHALL** contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.4.1.2.26" (CONF:EPRC-xxx).

2. **SHALL** contain exactly one [1..1] **code** (CONF:EPRC-xxx).
   a. This code **SHALL** contain exactly one **@code**="55112-7" Document Summary - EPRC (CodeSystem: LOINC 2.16.840.1.113883.6.1) (CONF:EPRC-xxx).
3. **SHALL** contain exactly one [1..1] **title** (CONF:EPRC-xxx).
4. **SHALL** contain exactly one [1..1] **text** (CONF:EPRC-xxx).
   a. The text element **MAY** contain one or more **renderMultiMedia** element representing an in-line graphic. The related observationMedia entry may be within the summary section structured entries or may be referenced from another section.
5. **MAY** contain zero or more [0..*] **entry** (CONF:EPRC-xxx) such that it
   a. **SHALL** contain exactly one [1..1] **ObservationMedia** element (CONF:EPRC-xxx) such that it
      i. **SHALL** contain exactly one [1..1] **@classCode**="OBS" (CONF:EPRC-xxx).
      ii. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001) (CONF:EPRC-xxx).
      iii. **SHALL** contain at least one [1..*] **id** (CONF:EPRC-xxx).
      iv. **SHALL** contain at least one [1..*] **value** with @xsi:type=”ED” (CONF:EPRC-xxx)
         1. This value **SHALL** contain exactly one [1..1] **@mediaType** drawn from the ValueSet SupportedFileFormats 1.3.6.1.4.1.19376.1.4.1.5.45 **STATIC** (CONF:EPRC-xxx).
         2. This value **MAY** contain zero or one [0..1] **reference** (CONF:EPRC-xxx).
            a. The URL of a referenced graphic element **MAY** be present (CONF:EPRC-xxx).
         3. The encapsulated data value SHALL have inline data. (CONF:EPRC-xxx).


```
<!-- example with external content referenced by file name -->
<section>
    <templateId root="1.3.6.1.4.1.19376.1.4.1.2.26"/>
    <code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
        code="55112-7" displayName="DOCUMENT SUMMARY"/>
    <title> Dual Chamber ICD Implant Procedure Summary</title>
    <text>
      <paragraph>A ICD Implant was performed. The following image shows the
region of interest.</paragraph>
       <renderMultiMedia referencedObject="EPRC-image1"/>
      <paragraph>The patient needed no further interventions.</paragraph>
    </text>
    <entry>
      <observationMedia classCode="OBS" moodCode="EVN" ID="EPRC-image1">
         <id root="2.16.840.1.113883.19.2.1"/>
         <value xsi:type="ED" mediaType="image/jpeg">
            <reference value="sample image.jpeg"/>
         </value>
      </observationMedia>
    </entry>
</section>

<!-- alternative example - embed the content within the reference element value
attribute -->
<section>
    …
    <text mediaType="image/jpeg" representation="B64">e1xydGY...</text>
    <entry>
      <observationMedia classCode="OBS" moodCode="EVN" ID="EPRC-embedded">
         <id root="2.16.840.1.113883.19.2.1"/>
         <value xsi:type="ED" mediaType="image/jpeg" reference=”B64”>
            <reference value="e1xydGY..."/>
         </value>
      </observationMedia>
    </entry>
</section>
```

Figure 6.4.4.1-1: Document Summary - EPRC section example

6.4.4.2 Medical History - Cardiac Section 11329-0

[section: templateId 1.3.6.1.4.1.19376.1.4.1.2.17(open)]

([section: templateId 2.16.840.1.113883.10.20.22.2.39(open)] - parent)

The Medical History – Cardiac section content module describes all aspects of the medical history of the patient even if not pertinent to the current procedure, and may include chief complaint, past medical history, social history, family history, surgical or procedure history, medication history, and other history information. The history may be limited to information pertinent to the current procedure or may be more comprehensive. The history may be reported as a collection of random clinical statements or it may be reported categorically. Entries for

History of Past Illness and History of Present Illness have been consolidated into this section. Social and Family History are discussed in their own sections. Each document type(top level document template) that invokes this Medical History – Cardiac section content module may specify vocabulary bindings(Value Sets) for specific relevant problems as problem observations for that document type uses.

In the event that the patient was transferred from another facility where there was a problem indication that the patient was determined to need a cardiac procedure, this will be noted as a problem observation in this medical history section as text in the narrative for now until there is a code representing this.

This Medical History – Cardiac section content module extends the Medical (General History Section (C-CDA 4.31). The additional constraints are listed below.

1. **SHALL** contain exactly one [1..1] **templateId** (CONF:8160) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.4.1.2.17" (CONF:10403-CRC).
2. **MAY** contain zero or more [0..*] **entry** (CONF:CRC-xxx) such that it
   a. **SHALL** contain exactly one [1..1] **Problem Observation - Cardiac** (templateId:1.3.6.1.4.1.19376.1.4.1.4.9) (CONF:CRC-xxx).

   MAY contain zero or more [0..*] **entry** (CONF:CRC-xxx) such that it
   b. **SHALL** contain exactly one [1..1] **Procedure Activity Observation** (templateId:2.16.840.1.113883.10.20.22.4.13) (CONF:CRC-xxx).
3. **MAY** contain zero or more [0..*] **entry** (CONF:CRC-xxx) such that it
   a. **SHALL** contain exactly one [1..1] **Procedure Activity Procedure** (templateId:2.16.840.1.113883.10.20.22.4.14) (CONF:CRC-xxx).


```
<section>
  <templateId root="1.3.6.1.4.1.19376.1.4.1.2.17"/>
  <templateId root="2.16.840.1.113883.10.20.22.2.39"/>
  <code code="11329-0" codeSystem="2.16.840.1.113883.6.1"
        codeSystemName="LOINC"
        displayName="MEDICAL (GENERAL) HISTORY"/>
  <title>MEDICAL (GENERAL) HISTORY</title>
  <text>
    <list listType="ordered">
      <item>Patient has had a recent issue with chest pain that does
           not seem to be related to any particular cause.</item>
      <item>Previous concerns of heart disease were actually
related to other causes.</item>
      <item>Patient had recent weight gain due to sedentary lifestyle and
           new job.</item>
    </list>
  </text>
  <entry>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="1.3.6.1.4.1.19376.1.4.1.4.9"/>
      <!-- Problem Observation - Cardiac template -->
      <id root="d11275e7-67ae-11db-bd13-0800200c9a66"/>
      <code code="55607006" codeSystem="2.16.840.1.113883.6.96"
            codeSystemName="SNOMED CT"
            displayName="Problem"/>
      <text>There was history of hypertension.</text>
      <statusCode code="completed"/>
      <effectiveTime>
      </effectiveTime>
      <value xsi:type="CD" code="38341003"
            codeSystem="1.2.840.10008.6.1.253" codeSystemName="SNOMED CT"
            displayName="Hypertension"/>
      <entryRelationship typeCode="SUBJ" inversionInd="true">
        <observation classCode="OBS" moodCode="EVN">
         <templateId root="2.16.840.1.113883.10.20.22.4.31"/>
         <!-- Age observation template -->
         <code code="445518008" codeSystem="2.16.840.1.113883.6.96"
               displayName="Age At Onset"/>
         <statusCode code="completed"/>
         <value xsi:type="PQ" value="57" unit="a"/>
        </observation>
      </entryRelationship>
      <entryRelationship typeCode="SUBJ" inversionInd="true">
        <observation classCode="OBS" moodCode="EVN">
         <templateId root="2.16.840.1.113883.10.20.22.4.6"/>
         <!—Problem status template -->
         <code code="33999-4" codeSystem="2.16.840.1.113883.6.1"
               displayName="Status"/>
         <statusCode code="completed"/>
         <value xsi:type="CD" code="55561003"
                     codeSystem="2.16.840.1.113883.6.96"
                     codeSystemName="SNOMED CT" displayName="Active"/>
        </observation>
      </entryRelationship>
      <entryRelationship typeCode="REFR" inversionInd="true">
```



```
        <observation classCode="OBS" moodCode="EVN">
         <templateId root="2.16.840.1.113883.10.20.22.4.5"/>
         <!-- Health status observation template -->
         <code code="11323-3"
               codeSystem="2.16.840.1.113883.6.1"
               codeSystemName="LOINC"
               displayName="Health status"/>
         <statusCode code="completed"/>
         <value xsi:type="CE" code="413322009"
               codeSystem="2.16.840.1.113883.6.96"
               codeSystemName="SNOMED CT"
               displayName="Resolved"/>
        </observation>
      </entryRelationship>
      <entryRelationship typeCode="REFR" inversionInd="true">
        <observation classCode="OBS" moodCode="EVN">
         <templateId root="2.16.840.1.113883.10.20.22.4.8"/>
         <!-- Severity observation template -->
         <code code="SEV" displayName="Severity Observation"
               codeSystem="2.16.840.1.113883.5.4"
               codeSystemName="ActCode"/>
         <text>
            <reference value="#severity"/>
         </text>
         <statusCode code="completed"/>
         <value xsi:type="CD" code="371924009" displayName="Moderate to severe"
                codeSystem="2.16.840.1.113883.6.96"
                codeSystemName="SNOMED CT"/>
        </observation>
      </entryRelationship>
    </observation>
  </entry>
  </entry>
    <procedure classCode="PROC" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.22.4.14"/>
      <!-- Procedure Activity Procedure template -->
      <id root="e401f340-7be2-11db-9fe1-0800200c9a66"/>
      <code code="500786010" codeSystem="1.3.6.1.4.1.19376.1.4.1.5.40"
            displayName="Left Heart Cath Procedure">
        <originalText>Left Heart Cath Procedure
            <reference value="procedure1"/></originalText>
      </code>
      <text>
        <reference value="procedure1"/>
      </text>
      <statusCode code="completed"/>
      <effectiveTime value="1998"/>
      <targetSiteCode code="41879009" codeSystem="2.16.840.1.113883.6.96"
             displayName="Distal RCA"/>
```



```
    </procedure>
  </entry>
  </entry>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.22.4.13"/>
      <!-- Procedure Activity Observation template -->
      <id extension="proc1" root="2.16.840.1.113883.19"/>
      <code code="500786010" codeSystem="2.16.840.1.113883.6.96"
            displayName="Left Heart Cath Procedure" codeSystemName="SNOMED CT">
        <originalText>
           <reference value="#procedure1"/>
        </originalText>
      </code>
      <statusCode code="aborted"
                  codeSystem="2.16.840.1.113883.5.14"
                  codeSystemName="ActStatus"/>
      <effectiveTime value="20110203"/>
      <priorityCode code="CR" codeSystem="2.16.840.1.113883.5.7"
                    codeSystemName="ActPriority"
                    displayName="Callback results"/>
      <value xsi:type="CD" code="" codeSystem="2.16.840.1.113883.6.96"/>
      <methodCode nullFlavor="UNK"/>
      <targetSiteCode code="91083009" codeSystem="2.16.840.1.113883.6.96"
                  codeSystemName="SNOMED CT"
                  displayName=" Proximal Right Coronary Artery" />
      <performer>
        <assignedEntity>
          <id root="1.2.3.4" extension="1234"/>
          <addr>
            <streetAddressLine>17 Daws Rd.</streetAddressLine>
            <city>Blue Bell</city>
            <state>MA</state>
            <postalCode>02368</postalCode>
            <country>US</country>
          </addr>
          <telecom use="WP" value="1(555)555-1234"/>
          <representedOrganization>
            <id root="2.16.840.1.113883.19.5"/>
            <name>Good Health Clinic</name>
            <telecom nullFlavor="UNK"/>
            <addr nullFlavor="UNK"/>
          </representedOrganization>
        </assignedEntity>
      </performer>
    </observation>
  </entry>
</section>
```

Figure 6.4.4.2-1: Medical History – Cardiac section example

6.4.4.2.1 Problem Observation – Cardiac Constraints

`[Observation: templateId 1.3.6.1.4.1.19376.1.4.1.9(open)]`

This Problem Observation – Cardiac entry is used exactly as specified in the CRC Common Entry Content Modules - section 6.4.5.1, except for vocabulary constraints.

A Content Creator SHALL be able to include a Problem Observation – Cardiac Entry for each of the conditions identified in Value Set `1.3.6.1.4.1.19376.1.4.1.5.49` Cardiac EP Problems/Concerns. The value set for CONF:9058 (**`value`**) **SHOULD** be selected from ValueSet Cardiac EP Problems/Concerns Value Set `1.3.6.1.4.1.19376.1.4.1.5.49` **STATIC**.

A Content Creator SHALL be able to indicate the NYHA Class using the Value Set `1.3.6.1.4.1.19376.1.4.1.5.48` New York Heart Class.

A Content Creator SHALL be able to indicate the absence of the condition for the patient using the negation indicator.

A Content Creator SHALL be able to include a Problem Observation – Cardiac Entry with code {160245001, SNOMED CT, "No current problems or disability"}.

Additional entryRelationships to observation acts can be used to provide further supporting observations (SPRT typeCode) or reasons for the observation (RSON typeCode) for this problem/concern observation. An example includes specifying that there are syndromes for risk of sudden death with an additional entryRelationship to another observation to identify the specific sudden death type (e.g., Brugada syndrome).

6.4.4.2.2 Procedure Activity Observation - Constraints

[`observation`: `templateId` `2.16.840.1.113883.10.20.22.4.13(open)`]

This entry is used exactly as specified in C-CDA - section 5.62, except for vocabulary constraints for targetSiteCode.

This entry is used to document the prior observations for this patient that may be relevant to this EP or implant procedure.

If recording observations made during prior Cath/PCI procedures, the value set for CONF:10121 (**`targetSiteCode`**) **SHOULD** be selected from ValueSet Coronary Anatomy Value Set `1.3.6.1.4.1.19376.1.4.1.5.32` **STATIC**.

6.4.4.2.3 Procedure Activity Procedure - Constraints

[`procedure`: `templateId` `2.16.840.1.113883.10.20.22.4.14(open)`]

This entry is used exactly as specified in C-CDA - section 5.63, except for vocabulary constraints for code and targetSiteCode.

This entry is used to document the prior procedures for this patient that may be relevant to this EP /Implant procedure. Prior procedures can include but are not limited to Invasive/Non-Invasive cardiac/electrophysiology procedures. Examples include Echocardiography or left

ventricular angiography (EF documentation), Electrophysiology study, 12- lead EKG. The value set for CONF:7657 (**code**) **SHOULD** be selected from ValueSet Cardiac Procedures Value Set `1.3.6.1.4.1.19376.1.4.1.5.63` **STATIC**.

6.4.4.3 Allergies Section 48765-2

[`section`: `templateId` `2.16.840.1.113883.10.20.22.2.6(open)`]

This Allergies section content module lists and describes any medication allergies, adverse reactions, idiosyncratic reactions, anaphylaxis/anaphylactoid reactions to food items, and metabolic variations or adverse reactions/allergies to other substances (such as latex, iodine, tape adhesives) used to assure the safety of health care delivery. At a minimum, it should list currently active and any relevant historical allergies and adverse reactions. This Allergies section content module is used exactly as specified in C-CDA - section 4.2.

Within this Allergies section content module the Content Creator SHALL be able to create an Allergy – Intolerance Observation entry for each of the cardiac imaging agent classes identified in ValueSet Contrast Agents Classes for Adverse Reactions Value Set `1.3.6.1.4.1.19376.1.4.1.5.34`.

```
<section>
    <templateId root="2.16.840.1.113883.10.20.22.2.6"/>
    <code code="48765-2"
          displayName="Allergies, adverse reactions, alerts"
          codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
    <title>Allergies</title>
    <text>
      The patient has allergies to penicillin based products
    </text>
    <entry typeCode="DRIV">
      <act classCode="ACT" moodCode="EVN">
        <templateId root="2.16.840.1.113883.10.20.22.4.30"/>
        <!--   Allergy Problem Act template   -->
        ...
      </act>
    </entry>
</section>
```

Figure 6.4.4.3-1: Allergies section example

6.4.4.3.1 Allergy – Intolerance Observation - Constraints

[`observation`: `templateId` `2.16.840.1.113883.10.20.22.4.7(open)`]

This Allergy – Intolerance Observation entry content module is used exactly as specified in C-CDA - section 5.4, except for vocabulary constraints on CONF:10083.

If the allergy is to Contrast Agents, the value set for CONF:10083 (**code**) **SHALL** be selected from ValueSet Contrast Agents Classes for Adverse Reactions Value Set `1.3.6.1.4.1.19376.1.4.1.5.34` **STATIC**.

6.4.4.4 Family History Section 10157-6

[section: templateId 2.16.840.1.113883.10.20.22.2.15 (open)]

This Family History section content module contains data defining the patient's genetic relatives in terms of possible or relevant health risk factors that have a potential impact on the patient's healthcare risk profile.

This Family History section content module is used exactly as specified in C-CDA - section 4.12.

If the relatedSubject of the Family History Organizer is a family member but the specific family member role is not known, the value "FAMMEMB" can be used to represent that the relatedSubject is a family member.

```
<section>
  <templateId root="2.16.840.1.113883.10.20.22.2.15"/>
  <!--  Family history section template  -->
  <code code="10157-6" codeSystem="2.16.840.1.113883.6.1"/>
  <title>Family history</title>
  <text> No Family History of Cardiovascular Disease</text>
  <entry typeCode=”DRIV”>
    <organizer classCode=”CLUSTER” moodCode=”EVN”>
      <templateId root=”2.16.840.1.113883.10.20.22.4.45”/>
      <statusCode code=”completed”/>
      <subject>
        <relatedSubject classCode=”PRS”>
          <code code=”FAMMEMB” codeSystem=”2.16.840.1.113883.5.111”>
            <translation code=”303071001” codeSystem=”2.16.840.1.113883.6.96”/>
          </code>
        </relatedSubject>
      </subject>
      <component>
        <observation classCode=”OBS” moodCode=”EVN”>
          <templateId root=”2.16.840.1.113883.10.20.22.4.46”/>
          <id root=”d11275e7-67ae-11db-bd13-0800200c9a66”/>
          <code code=”404684003” codeSystem=”2.16.840.1.113883.6.96”
                codeSystemName=”SNOMED CT” displayName=”Finding”/>
          <text>There was no family history of cardiovascular disease.</text>
          <statusCode code=”completed”/>
          <effectiveTime>
          </effectiveTime>
          <value xsi:type=”CD” code=”160270001”
              codeSystem=”2.16.840.1.113883.6.96” codeSystemName=”SNOMED CT”
              displayName=” No family history of cardiovascular disease”/>
        </observation>
      </component>
    </organizer>
  </entry>
</section>
```

Figure 6.4.4.4-1: Family History section example

6.4.4.4.1 Family History Observation - Constraints

[Observation: templateId 2.16.840.1.113883.10.20.22.4.46(open)]

The Family History Observation entry content module is used exactly as specified in C-CDA - section 5.25, except for vocabulary constraints on CONF:8591.

The value set for CONF:8591 (**code**) **SHOULD** be selected from ValueSet Cardiovascular Family History Value Set 1.3.6.1.4.1.19376.1.4.1.5.58 **STATIC**.

6.4.4.5 Social History Section 29762-2

[section: templateId 2.16.840.1.113883.10.20.22.2.17(open)]

The Social History section content module is used exactly as specified in C-CDA - section 4.57.

This Social History section content module contains data defining the patient's occupational, personal (e.g., lifestyle), social, and environmental history and health risk factors, as well as administrative data such as marital status, race, ethnicity and religious affiliation. Social history can have significant influence on a patient's physical, psychological and emotional health and wellbeing so should be considered in the development of a complete record.

Smoking status shall be documented using the Smoking Status Observation entry content module as specified in C-CDA section 5.75.


```
<section>
   <templateId root="2.16.840.1.113883.10.20.22.2.17"/>
   <!--  **  Social history section template   ** -->
   <code code="29762-2" codeSystem="2.16.840.1.113883.6.1"
      displayName="Social History"/>
   <title>Social History</title>
   <text>
      The patient was a former smoker.
   </text>
   <entry typeCode="DRIV">
      <observation classCode="OBS" moodCode="EVN">
         <templateId root="2.16.840.1.113883.10.20.22.4.78"/>
         <!--  **  Smoking status observation template   ** -->
         <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"/>
         <statusCode code="completed"/>
         <effectiveTime>
            <low value="1973"/>
            <high value="2001"/>
         </effectiveTime>
         <value xsi:type="CD" code=”8517006”
                codeSystem=”2.16.840.1.113883.6.96”
                displayName=”Former Smoker”/>
      </observation>
   </entry>
</section>
```

Figure 6.4.4.5-1: Social History section example

6.4.4.5.1 Social History Observation - Constraints

`[observation: templateId 2.16.840.1.113883.10.20.22.4.38(open)]`

The Social History Observation entry content module is used exactly as specified in C-CDA - section 5.76.

6.4.4.6 Physical Exam Section 29545-1

[`section`: `templateId` `2.16.840.1.113883.10.20.2.10(open)`]

The Physical Exam section content module is used exactly as specified in C-CDA - section 4.38.

The Physical Exam section content module includes direct observations made by the clinician. The examination may include the use of simple instruments and may also describe simple maneuvers performed directly on the patient’s body. This Physical Exam section includes only observations made by the examining clinician using inspection, palpation, auscultation, and percussion; it does not include laboratory or imaging findings. The exam may be limited to pertinent body systems based on the patient’s chief complaint or it may include a comprehensive examination. The examination may be reported as a collection of random clinical statements or it may be reported categorically.


```
<section>
    <templateId root="2.16.840.1.113883.10.20.2.10"/>
    <code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
        code="29545-1" displayName="PHYSICAL FINDINGS"/>
    <title>PHYSICAL EXAMINATION</title>
    <text>
      <paragraph>All normal to examination.</paragraph>
    </text>
</section>
```

Figure 6.4.4.6-1: Physical Exam section example

6.4.4.7 Vital Signs Section 8716-3

[section: templateId 2.16.840.1.113883.10.20.22.2.4(open)]

The Vital Signs Section content module is used exactly as specified in C-CDA - section 4.60.

The Vital Signs section content module is intended to include vital sign measurements taken at admission and at the time of procedure.


```
<section>
  <templateId root="2.16.840.1.113883.10.20.22.2.4"/>
  <code code="8716-3"
        codeSystem="2.16.840.1.113883.6.1"
        codeSystemName="LOINC"
        displayName="VITAL SIGNS" />
  <title>Vital Signs</title>
  <text>These are the vital signs related to the procedure </text>
  <entry typeCode="DRIV">
    <organizer classCode="CLUSTER" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.22.4.26"/>
      <!-- Vital signs organizer template -->
      <id root="c6f88320-67ad-11db-bd13-0800200c9a66"/>
      <code code="46680005" codeSystem="2.16.840.1.113883.6.96"
            codeSystemName="SNOMED CT" displayName="Vital signs"/>
      <statusCode code="completed"/>
      <effectiveTime value="19991114"/>
      <component>
        <observation classCode="OBS" moodCode="EVN">
          <templateId root="2.16.840.1.113883.10.20.22.4.27"/>
          <!-- Vital sign observation for BP Mean -->
          <id root="c6f88321-67ad-11db-bd13-0800200c9a66"/>
          <code code="8478-0"
                codeSystem="2.16.840.1.113883.6.1"
                codeSystemName="LOINC"
                displayName="BP Mean"/>
          <text><reference value="#BPMEAN1"/></text>
          <statusCode code="completed"/>
          <effectiveTime value="19991114"/>
          <value xsi:type="PQ" value="84" unit="mmHg"/>
          <interpretationCode code="N" codeSystem="2.16.840.1.113883.5.83"/>
        </observation>
      </component>
    </organizer>
  </entry>
</section>
```

Figure 6.4.4.7-1: Vital Signs section example

6.4.4.7.1 Vital Sign Observation - Constraints

[observation: templateId 2.16.840.1.113883.10.20.22.4.27(open)]

The Vital Sign Observation entry content module is used exactly as specified in C-CDA - section 5.81, except for vocabulary constraints.

The value set for CONF:7301 (**code**) **SHOULD** be selected from ValueSet Vital Signs Results Value Set 1.3.6.1.4.1.19376.1.4.1.5.60 **STATIC**.

For Oxygen measure or cerebral oximetry, the specific location where the measurement was obtained may be specified using the Observation.targetSiteCode and/or Observation.methodCode attributes.

6.4.4.8 Pre-Procedure Results – Cardiac Section 30954-2

[section: templateId 1.3.6.1.4.1.19376.1.4.1.2.23 (open)]

([section: templateId 2.16.840.1.113883.10.20.22.2.3(open)] – parent)

This Pre-Procedure Results – Cardiac Section content module is based on the C-CDA Results Section content module as specified in C-CDA - section 4.55.

Note: This section is intended to capture results of tests pre-requisite for the planned procedure or providing indication for the planned procedure.

This Pre-Procedure Results – Cardiac section content module contains the results of observations generated by laboratories, imaging procedures, and other procedures. The scope includes observations such as electrophysiology study, hematology, chemistry, serology, virology, toxicology, microbiology, plain x-ray, ultrasound, CT, MRI, angiography, echocardiography, nuclear medicine, pathology, and procedure observations. Lab and imaging values affecting ACC-NCDR ICD submission include BUN, Hemoglobin, Sodium, Creatinine, Potassium, BNP, NT-proBNP, 12 lead EKG with associated automated measurements and angiography/echocardiography for associated ejection fraction documentation.

Imaging results are typically generated by a clinician reviewing the output of an imaging procedure, such as where a cardiologist reports the left ventricular ejection fraction based on the review of a cardiac echocardiogram.

This Pre-Procedure Results – Cardiac section content module modifies the Results Section (C-CDA 4.55). The complete set of constraints for the Pre-Procedure Results – Cardiac section content module are defined below. The substitutions are highlighted in yellow. This Pre-Procedure Results – Cardiac section content module is also conformant to the C-CDA Results Section content module.

1. **SHALL** contain two or more [2..*] **templateId** (CONF:7116-CRC) such that it
    a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.2.3" (CONF:9136).
    b. **SHALL** contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.4.1.2.23" (CONF:CRC-xxx).
2. **SHALL** contain exactly one [1..1] **code** (CONF:15431).
    a. This code **SHALL** contain exactly one [1..1] **@code**="30954-2" Relevant diagnostic tests and/or laboratory data (CodeSystem: LOINC 2.16.840.1.113883.6.1) (CONF:15432).
3. **SHALL** contain exactly one [1..1] **title** (CONF:8891).
4. **SHALL** contain exactly one [1..1] **text** (CONF:7118).
5. **SHALL** contain at least one [1..*] **entry** (CONF:7119) such that it
    a. **SHALL** contain exactly one [1..1] **Result Organizer - Cardiac** (templateId:1.3.6.1.4.1.19376.1.4.1.4.11) (CONF:15515-CRC).


```
<section>
    <templateId root="1.3.6.1.4.1.19376.1.4.1.2.23"/>
    <templateId root="2.16.840.1.113883.10.20.22.2.3"/>
    <code code="30954-2"
          codeSystem="2.16.840.1.113883.6.1"
          codeSystemName="LOINC"
          displayName="RESULTS" />
    <title>Results</title>
    <text>
       ...
    </text>
    <entry typeCode="DRIV">
      <organizer classCode="CLUSTER" moodCode="EVN">
        <templateId root="1.3.6.1.4.1.19376.1.4.1.4.11"/>
        <id root="7d5a02b0-67a4-11db-bd13-0800200c9a66"/>
        <code code="57021-8" displayName="CBC W Auto Differential panel"
              codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
        <statusCode code="completed"/>
        <component>
          <observation classCode="OBS" moodCode="EVN">
            <!-- Result observation template -->
            <templateId root="2.16.840.1.113883.10.20.22.4.2"/>
            <id root="107c2dc0-67a5-11db-bd13-0800200c9a66"/>
            <code code="30313-1" displayName="HGB"
                  codeSystem="2.16.840.1.113883.6.1"
                  codeSystemName="LOINC"/>
            <statusCode code="completed"/>
            <effectiveTime value="200003231430"/>
            <value xsi:type="PQ" value="13.2" unit="g/dl"/>
            <interpretationCode code="N" codeSystem="2.16.840.1.113883.5.83"/>
            <methodCode/>
            <targetSiteCode/>
            <referenceRange>
              <observationRange>
                <text>M 13-18 g/dl; F 12-16 g/dl</text>
              </observationRange>
            </referenceRange>
          </observation>
        </component>
        <reference typeCode="REFR">
          <externalDocument>
             <id root="b50b7910-7ffb-4f4c-bbe4-177ed68cbbf3"/>
             <text mediaType="application/pdf">
                <reference
                    value="PreProcedureResults.pdf"/>
             </text>
          </externalDocument>
        </reference>
      </organizer>
    </entry>
</section>
```

Figure 6.4.4.8-1: Pre-Procedure Results - Cardiac section example

6.4.4.8.1 Result Organizer - Cardiac

[organizer: templateId 1.3.6.1.4.1.19376.1.4.1.4.11 (open)]

([organizer: templateId 2.16.840.1.113883.10.20.22.4.1(open)] – parent)

This clinical statement identifies a set of result observations. It contains information applicable to all of the contained result observations. Result type codes categorize a result into one of several commonly accepted values (e.g., "ICD Implant", "Lead Placement", “ICD Implant and Lead Placement"). These values are often implicit in the Result Organizer code (e.g., an Organizer/code of “complete blood count” implies a Result Observation code of “Hematology”).

An appropriate nullFlavor can be used when a single result observation is contained in the organizer, and organizer/code or organizer/id is unknown.

There may also be a reference to an optional external document in the result organizer.

This Result Organizer – Cardiac entry content module extends the C-CDA Result Organizer entry definition (C-CDA 5.71) by adding the constraints listed below.

1. **SHALL** contain exactly one [1..1] **templateId** (CONF:CRC-xxx) such that it
    a. **SHALL** contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.4.1.4.11" (CONF:CRC-xxx).
2. **MAY** contain zero or more [0..*] **reference** (CONF:CRC-xxx) such that it
    a. **SHALL** contain exactly one [1..1] **@typeCode**="REFR" Refers to (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:CRC-xxx).
    b. **SHALL** contain exactly one [1..1] **externalDocument** (CONF:CRC-xxx).
        i. This externalDocument **SHALL** contain at least one [1..*] **id** (CONF:CRC-xxx).
        ii. This externalDocument **MAY** contain zero or one [0..1] **text** (CONF:CRC-xxx).
            1. The text, if present, **MAY** contain zero or one [0..1] **@mediaType** (CONF:CRC-xxx).
            2. The text, if present, **MAY** contain zero or one [0..1] **reference** (CONF:CRC-xxx).
                a. The URL of a referenced pre-procedure results document **MAY** be present, and **SHALL** be represented in organizer/reference/ExternalDocument/text/reference (CONF:CRC-xxx).
                b. If a URL is referenced, then it **SHOULD** have a corresponding linkHTML element in narrative block (CONF:CRC-xxx).

6.4.4.8.2 Result Observation - Constraints

[observation: templateId 2.16.840.1.113883.10.20.22.4.2(open)]

This clinical statement represents details of a lab, radiology, or other study performed on a patient. A clinical statement for documentation of associated lab values, radiology values, and other observations that may have occurred prior to the implant procedure.

This Result Observation entry is used exactly as specified in C-CDA - section 5.70 except for vocabulary constraints for the code and value elements.

For prior cardiac specific results, the constraints on the code and value elements should be selected from the EP Result Observations Constraints Set 1.3.6.1.4.1.19376.1.4.1.5.51 **STATIC.**

For prior lab results, the value set for CONF:9109 (**code**) **SHOULD** be selected from ValueSet Cardiac Lab Results Value Set 1.3.6.1.4.1.19376.1.4.1.5.59 **STATIC**.

6.4.4.9 Planned Procedure Section 59772-4

[section: templateId 2.16.840.1.113883.10.20.22.2.30(open)]

The Planned Procedure section content module is used exactly as specified in C-CDA - section 4.40.

The Planned Procedure section content module records the procedure(s) that a physician or clinician thought would need to be done based on the preoperative assessment. Procedures include but are not limited to ICD Implant, Venogram, Lead Placement, Lead Extraction, ICD Explant, Generator Change, Lead Reuse, and Lead Abandon. It may be important to record the procedure(s) that were originally planned for, consented to, and perhaps pre-approved by the payor, particularly if different from the actual procedure(s) and procedure details, to provide evidence to various stakeholders that the providers are aware of the discrepancy and the justification can be found in the procedure details.

To represent specific planned EP procedures in the Plan of Care Activity Procedure entry content module, a code element may be included and the code attribute **SHOULD** be selected from ValueSet Cardiac EP Activity Procedures Value Set 1.3.6.1.4.1.19376.1.4.1.5.52 **STATIC.**


```
<section>
   <templateId root="2.16.840.1.113883.10.20.22.2.30"/>
   <!--  ******** Planned Procedure Section template  ******** -->
   <code code="59772-4" codeSystem="2.16.840.1.113883.6.1"
      codeSystemName="LOINC" displayName="Planned Procedure"/>
   <title>Planned Procedure</title>
   <text>
      An ICD Implant is planned.
   </text>
   <entry>
      <procedure moodCode="RQO" classCode="PROC">
         <templateId root="2.16.840.1.113883.10.20.22.4.41"/>
         <!-- ** Plan of Care Activity Procedure Template ** -->
         <id root="9a6d1bac-17d3-4195-89c4-1121bc809b5a"/>
         <code code="233170003" codeSystem="2.16.840.1.113883.6.96"
               displayName="ICD Implant"/>
         <statusCode code="new"/>
         <effectiveTime>
             <center value="20000421"/>
         </effectiveTime>
      </procedure>
   </entry>
</section>
```

Figure 6.4.4.9-1: Planned Procedure section example

6.4.4.10 Procedure Indications Section 59768-2

[section: templateId 2.16.840.1.113883.10.20.22.2.29(open)]

The Procedure Indications section content module is used exactly as specified in C-CDA - section 4.50.

The Procedure Indications section content module records details about the reason for this Implant/Explant procedure. This Procedure Indications section content module may include the pre-procedure diagnosis or diagnoses as well as one or more symptoms that contribute to the reason the procedure is being performed. As an example-allowing for documentation of primary prevention or secondary prevention for the associated ICD implant.


```
<section>
   <templateId root="2.16.840.1.113883.10.20.22.2.29"/>
   <code code="59768-2" codeSystem="2.16.840.1.113883.6.1"
      codeSystemName="LOINC" displayName="PROCEDURE INDICATIONS"/>
   <title>Procedure Indications</title>
   <text>The procedure is performed for screening in a low risk individual.
   </text>
   <entry>
      <observation classCode="OBS" moodCode="EVN">
         <!-- Indication Entry -->
         <templateId root="2.16.840.1.113883.10.20.22.4.19"/>
         <code code="409586006"
               codeSystem="2.16.840.1.113883.6.96"
               codeSystemName="SNOMED CT" displayName="Complaint"/>
         <statusCode code="completed"/>
         <value xsi:type="CD"
                code="29857009" codeSystem="2.16.840.1.113883.6.96"
                codeSystemName="SNOMED CT" displayName="Chest pain"/>
      </observation>
   </entry>
</section>
```

Figure 6.4.4.10-1: Procedure Indications section example

6.4.4.10.1 Indication - Constraints

[observation: templateId 2.16.840.1.113883.10.20.22.4.19(open)]

This Indication entry content module is used exactly as specified in C-CDA - section 5.37 except for vocabulary constraints.

The Indication entry content module documents the rationale for an activity. It can do this with the id element to reference a problem recorded elsewhere in the document or with a code and value to record the problem type and problem within the Indication. For example, the indication associated for implant may be relative to an inducible ventricular arrhythmia, abnormal cardiac rhythm or abnormal intraventricular conduction.

The value set for CONF:15985 (**value**) **SHOULD** be selected from ValueSet Procedure Indications Value Set 1.3.6.1.4.1.19376.1.4.1.5.61 **STATIC**.

6.4.4.11 Anesthesia Section 59774-0

[section: templateId 2.16.840.1.113883.10.20.22.2.25(open)]

The Anesthesia section content module is used exactly as specified in C-CDA - section 4.3.

The Anesthesia section content module briefly describes the general anesthesia used and may state the actual agent used. The Procedure Activity Procedure entry content module describes the anesthesia procedure. The Medication Activity entry content module may describe the general anesthesia medication used during this EP/Implant procedure.


```
<section>
    <templateId root="2.16.840.1.113883.10.20.22.2.25"/>
    <code code="59774-0"
          codeSystem="2.16.840.1.113883.6.1"
          codeSystemName="LOINC"
          displayName="PROCEDURE ANESTHESIA"/>
    <title>Procedure Anesthesia</title>
    <text> Conscious sedation with propofol 200 mg IV </text>
    <entry>
      <substanceAdministration classCode="SBADM" moodCode="EVN">
        <!-- Medication activity template -->
        <templateId root="2.16.840.1.113883.10.20.22.4.16"/>
        ...
      </subtanceAdministration>
    </entry>
</section>
```

Figure 6.4.4.11-1: Anesthesia section example

6.4.4.12 Medications Administered Section 29549-3

[section: templateId 2.16.840.1.113883.10.20.22.2.38(open)]

This Medications Administered section content module is used exactly as specified in C-CDA - section 4.32 except for vocabulary constraints.

The Medications Administered section content module defines medications and fluids administered during the procedure, encounter, or other activity excluding general anesthetic medications.

A Content Creator **SHALL** be able to create a Medications Activity entry with a Medication Information Entry for each of the cardiac medication classes identified in Value Set Cardiac Drug Classes and Specific Cardiac Drugs Value Set 1.3.6.1.4.1.19376.1.4.1.5.55 **STATIC**.

A Content Creator **SHALL** be able to create a Medications Activity entry with a Medication Information entry for the relevant cardiac contrast agents identified in ValueSet Contrast Agents Value Set 1.3.6.1.4.1.19376.1.4.1.5.39 **STATIC**.

The set of contrast agents implemented may be limited to a subset of the Value Set, based on the types of procedures for which the Content Creator creates reports, hence the term "*relevant* cardiac contrast agents".


```
<section>
    <templateId root="2.16.840.1.113883.10.20.22.2.38" />
    <code code="29549-3"
          codeSystem="2.16.840.1.113883.6.1"
          codeSystemName="LOINC"
          displayName="MEDICATIONS ADMINISTERED" />
    <title>Medications Administered</title>
    <text>Aspirin, other antiplatelet agents</text>
    <entry>
      <substanceAdministration classCode="SBADM" moodCode="EVN">
        <templateId root="2.16.840.1.113883.10.20.22.4.16"/>
        <!-- Medication Activity template -->
        <id root="cdbd33f0-6cde-11db-9fe1-0800200c9a66"/>
        <text>
          <reference value="#med1”/>
          Aspirin, other antiplatelet agents
        </text>
        <statusCode code="completed"/>
        <effectiveTime xsi:type="IVL_TS">
          <low value="20110926"/>
          <high value="20111014"/>
        </effectiveTime>
        <effectiveTime xsi:type="PIVL_TS" institutionSpecified="true"
            operator="A">
          <period value="6" unit="h"/>
        </effectiveTime>
        <doseQuantity value="1"/>
        <consumable>
          <manufacturedProduct classCode="MANU">>
            <templateId root="2.16.840.1.113883.10.20.22.4.23"/>
            <!-- Medication Information template -->
            <id/>
            <manufacturedMaterial>
              <code code="7947003"
                    codeSystem="2.16.840.1.113883.6.96"
                    displayName="Aspirin"/>
            </manufacturedMaterial>
            <manufacturerOrganization>...</manufacturerOrganization>
          </manufacturedProduct>
        </consumable>
        <performer>
        </performer>
      </substanceAdministration>
    </entry>
</section>
```

Figure 6.4.4.12-1: Medications administered section example

6.4.4.12.1 Medication Information - Constraints

[`manufacturedProduct`: `templateId` `2.16.840.1.113883.10.20.22.4.23(open)`]

This Medication Information entry is used exactly as specified in C-CDA - section 5.41 except for vocabulary constraints.

The value set for CONF:7412 (**manufacturedMaterial/code@code**) SHOULD be selected from ValueSet Cardiac Drug Classes and Specific Cardiac Drugs Value Set 1.3.6.1.4.1.19376.1.4.1.5.55 **STATIC** or SHOULD be selected from ValueSet Contrast Agents Value Set 1.3.6.1.4.1.19376.1.4.1.5.39 **STATIC**.

6.4.4.13 Procedure Description – Cardiac EPIE Section 29554-3

[section: templateId 1.3.6.1.4.1.19376.1.4.1.2.24(open)]

([section: templateId 2.16.840.1.113883.10.20.22.2.27(open)] – parent)

The Procedure Description – Cardiac EPIE section content module records the details of the cardiac procedures and may include procedure site preparation, surgical site preparation, pertinent details related to sedation/anesthesia, pertinent details related to measurements and markings, procedure times, medications administered, estimated blood loss, specimens removed, instrumentation, sponge counts, tissue manipulation, wound closure, sutures used, vital signs and other monitoring data. Local practice often identifies the level and type of detail required based on the procedure or specialty.

This Procedure Description – Cardiac EPIE section content module may include a device organizer to record information about each device used during the procedures. Each device should be defined at this section level within a Procedure Device Organizer – Cardiac EPIE entry. Additional characteristics inherent to each device should be defined using an additional Procedure Device Organizer – Cardiac EPIE entry within this section.

The devices and leads are represented as participants in the procedure using enumeration values of IEEE 11073_10103 MDC_IDC Nomenclature (MDC). Parent values of the enumerations can be determined from the MDC standard. Examples of this are shown below.

Code	Mnemonic	Parent Code	Parent Code Mnemonic
753666	MDC_IDC_ENUM_DEV_TYPE_ICD	720897	MDC_IDC_DEV_TYPE
753751	MDC_IDC_ENUM_MFG_STJ	720900	MDC_IDC_DEV_MFG
753796	MDC_IDC_ENUM_LEAD_POLARITY_TYPE_QUAD	720965	MDC_IDC_LEAD_POLARITY_TYPE

In addition, dynamic attributes of these devices, like device interrogation, should be recorded in the Procedure Activity Procedure – Cardiac EPIE entry within this section content module.

The various phases in this EP procedure being documented can be represented using the Procedure Activity Procedure - Cardiac EPIE entry content module. For each of these phases, devices can be referenced back to the original device inventory. Device measurements and settings may be recorded here.

For Lead placements and extractions, individual leads will be defined in this section as separate devices which are identified by a unique id. Procedure findings and results can be recorded in Procedure Results - Cardiac Section.

Include procedures that were attempted but not successful. For example, due to anatomical constraints that were discovered during the implant procedure, the LV lead of the planned biventricular implant did not occur.

Note: Lesion Observations are not used for EP Implant/Explant procedures.

This Procedure Description – Cardiac EPIE section content module extends the C-CDA Procedure Description section (C-CDA 4.45) by adding the constraints listed below.

1. **SHALL** contain exactly one [1..1] **templateId** (CONF:EPRC-xxx) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.4.1.2.24" (CONF:EPRC-xxx).
2. **MAY** contain zero or more [0..*] **entry** (CONF:EPRC-xxx) such that it
   a. **SHALL** contain exactly one [1..1] **Procedure Device Organizer – Cardiac EPIE**(templateId:1.3.6.1.4.1.19376.1.4.1.4.20) (CONF:EPRC-xxx).
3. **SHALL** contain at least one [1..*] **entry** (CONF:EPRC-xxx) such that it
   a. **SHALL** contain exactly one [1..1] **Procedure Activity Procedure – Cardiac EPIE**(templateId:1.3.6.1.4.1.19376.1.4.1.4.19) (CONF:EPRC-xxx).

```
<section>
      <templateId root="1.3.6.1.4.1.19376.1.4.1.2.24"/>
      <templateId root="2.16.840.1.113883.10.20.22.2.27"/>
      <!-- Procedure Description – Cardiac EPIE section template -->
      <code code="29554-3"
                  codeSystem="2.16.840.1.113883.6.1"
                  codeSystemName="LOINC"
                  displayName="PROCEDURE DESCRIPTION"/>
      <title>Procedure Description - 1 lead ICD implant</title>
      <text>
      </text>
      <entry>
      <!-- Procedure Device Organizer – Cardiac EPIE for device inventory  -->
      <!-- closure devices can be included under this section     -->

            <organizer classCode="CLUSTER" moodCode="EVN">
                  <templateId root="1.3.6.1.4.1.19376.1.4.1.4.20"/>
                        …
            </organizer>
      </entry>
        …
</section>
```

Figure 6.4.4.13-1: Procedure Description - Cardiac section example (see the EPRC-IE XML sample for a complete ICD implant procedure example)

6.4.4.13.1 Procedure Activity Procedure - Cardiac EPIE

[procedure: templateId 1.3.6.1.4.1.19376.1.4.1.4.19 (open)]

([procedure: templateId 2.16.840.1.113883.10.20.22.4.14(open)] – parent)

This clinical statement represents procedures whose immediate and primary outcome (post-condition) is the alteration of the physical condition of the patient. Examples of these procedures are ICD Implant/Explant, pacemaker implant/explant, generator change, Lead Implant, Lead Extraction.

This Procedure Activity Procedure – Cardiac EPIE entry content module may also include a device organizer to record specific properties of the devices as observed during the procedure. Dynamic attributes of these devices, like device interrogation, should be recorded in this Procedure Activity Procedure – Cardiac EPIE entry.

Within this Procedure Activity Procedure – Cardiac EPIE entry content module, Product Instances are used to document the devices used. Record as many devices as needed unless the EP Implant/Explant procedure is aborted. In this case, there may be no devices used.

Developers using this EPRC-IE content profile will map specific equipment using appropriate inventory numbering and product descriptions provided by the EP recording system or equivalents. If this EPRC-IE content profile is to be consumed and used in a CVIS, it is up to the developer to map the actual device codes to the appropriate registry required codes.

For EPIE procedures, targetSiteCode is not relevant.

This Procedure Activity Procedure – Cardiac EPIE entry content module is used exactly as specified in C-CDA - section 5.63 except for the modifications to the constraints highlighted in yellow below. This Procedure Activity Procedure – Cardiac EPIE entry content module is also conformant to the C-CDA Procedure Activity Procedure entry content module.

1. **SHALL** contain exactly one [1..1] **@classCode**="PROC" Procedure (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:7652).
2. **SHALL** contain exactly one [1..1] **@moodCode**, which **SHALL** be selected from ValueSet MoodCodeEvnInt 2.16.840.1.113883.11.20.9.18 **STATIC** 2011-04-03 (CONF:7653).
3. **SHALL** contain two or more [2..*] **templateId** (CONF:7654-EPRC) such that
    a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.4.19" (CONF:10521).
    b. **SHALL** contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.4.1.4.19" (CONF:EPRC-xxx).
4. **SHALL** contain at least one [1..*] **id** (CONF:7655).
5. **SHALL** contain exactly one [1..1] **code** (CONF:7656).
    a. This code **SHOULD** be selected from ValueSet Cardiac EP Activity Procedures Value Set 1.3.6.1.4.1.19376.1.4.1.5.52. (CONF:19207-EPRC)
    b. This code **SHOULD** contain zero or one [0..1] **originalText** (CONF:19203).

i. The originalText, if present, **SHOULD** contain zero or one [0..1] **reference** (CONF:7659).
1. The originalText, if present, **SHOULD** contain zero or one [0..1] **@value** (CONF:19205).
a. This reference/@value **SHALL** begin with a '#' and **SHALL** point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:19206).

6. **SHALL** contain exactly one [1..1] **statusCode**, where the @code **SHALL** be selected from ValueSet `ProcedureAct statusCode 2.16.840.1.113883.11.20.9.22` **DYNAMIC** (CONF:7661).
7. **SHOULD** contain zero or one [0..1] **effectiveTime** (CONF:7662).
8. **MAY** contain zero or one [0..1] **priorityCode**, where the @code **SHALL** be selected from ValueSet `ActPriority 2.16.840.1.113883.1.11.16866` **DYNAMIC** (CONF:7668).
9. **MAY** contain zero or one [0..1] **methodCode** (CONF:7670).
a. methodCode **SHALL NOT** conflict with the method inherent in Procedure / code (CONF:7890).
10. **MAY** contain zero or one [0..1] **targetSiteCode** (CONF:7683-EPRC).
a. The targetSiteCode **SHALL** contain exactly one [1..1] **@code**, which **SHALL** be SNOMED-CT code 51185008, Chest (CONF:16082-EPRC).
11. **MAY** contain zero or more [0..*] **specimen** (CONF:7697).
a. This specimen is for representing specimens obtained from a procedure (CONF:16842).
b. The specimen, if present, **SHALL** contain exactly one [1..1] **specimenRole** (CONF:7704).
i. This specimenRole **SHOULD** contain zero or more [0..*] **id** (CONF:7716).
1. If you want to indicate that the Procedure and the Results are referring to the same specimen, the Procedure/specimen/specimenRole/id **SHOULD** be set to equal an Organizer/specimen/ specimenRole/id (CONF:7717).
12. **SHOULD** contain zero or more [0..*] **performer** (CONF:7718) such that it
a. **SHALL** contain exactly one [1..1] **assignedEntity** (CONF:7720).
i. This assignedEntity **SHALL** contain at least one [1..*] **id** (CONF:7722).
ii. This assignedEntity **SHALL** contain exactly one [1..1] **addr** (CONF:7731).
iii. This assignedEntity **SHALL** contain exactly one [1..1] **telecom** (CONF:7732).
iv. This assignedEntity **SHOULD** contain zero or one [0..1] **representedOrganization** (CONF:7733).
1. The representedOrganization, if present, **SHOULD** contain zero or more [0..*] **id** (CONF:7734).

2. The representedOrganization, if present, **MAY** contain zero or more [0..*] **name** (CONF:7735).
3. The representedOrganization, if present, **SHALL** contain exactly one [1..1] **addr** (CONF:7736).
4. The representedOrganization, if present, **SHALL** contain exactly one [1..1] **telecom** (CONF:7737).

13. **MAY** contain zero or more [0..*] **participant** (CONF:7751) such that it
    a. **SHALL** contain exactly one [1..1] **@typeCode**="DEV" Device (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:7752).
    b. **SHALL** contain exactly one [1..1] **Product Instance** (templateId:2.16.840.1.113883.10.20.22.4.37) (CONF:15911).
14. **MAY** contain zero or more [0..*] **entryRelationship** (CONF:7886) such that it
    a. **SHALL** contain exactly one [1..1] **@typeCode**="COMP" Has Component (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:7887).
    b. **SHALL** contain exactly one [1..1] **Medication Activity** (templateId:2.16.840.1.113883.10.20.22.4.16) (CONF:15915).
15. **MAY** contain zero or more [0..*] **entryRelationship** (CONF:EPRC-xxx) such that it
    a. **SHALL** contain exactly one [1..1] **@typeCode**="REFR" References (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:EPRC-xxx).
    b. **SHALL** contain exactly one [1..1] **Procedure Device Organizer – Cardiac EPIE** (templateId:1.3.6.1.4.1.19376.1.4.1.4.20) (CONF:EPRC-xxx).

6.4.4.13.2 Procedure Device Organizer – Cardiac EPIE

[organizer: templateId 1.3.6.1.4.1.19376.1.4.1.4.20 (open)]

This Procedure Device Organizer – Cardiac EPIE entry content module identifies a set of observations related to a device used during EP procedures. It is intended to be used to further describe the devices used during these procedures.

1. **SHALL** contain exactly one [1..1] **@classCode**="CLUSTER" Cluster (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF:EPRC-xxx).
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001) (CONF:EPRC-xxx).
3. **SHALL** contain exactly one [1..1] **templateId** (CONF:EPCRC-xxx) such that it
    a. **SHALL** contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.4.1.4.20" (CONF:EPRC-xxx).
4. **SHALL** contain at least one [1..*] **id** (CONF:EPRC-xxx).
5. **SHALL** contain exactly one [1..1] **statusCode** (CONF:EPRC-xxx)..

a. This statusCode **SHALL** contain exactly one [1..1] **@code** which **SHALL** be selected from CodeSystem: `ActStatus 2.16.840.1.113883.5.14` (CONF:EPRC-xxx).

6. **SHOULD** contain zero or one [0..1] **participant** (CONF:EPRC-xxx) such that it
   a. **SHALL** contain exactly one [1..1] **@typeCode**="SBJ" (CodeSystem: `HL7ParticipationType 2.16.840.1.113883.5.90`) (CONF:EPRC-xxx).
   b. **SHALL** contain exactly one [1..1] **participantRole** (CONF:EPRC-xxx).
      i. This participantRole **SHALL** contain exactly one [1..1] **@classCode**="MANU" Manufactured Product (CodeSystem: `RoleClass 2.16.840.1.113883.5.110`) (CONF:EPRC-xxx).
      ii. This participantRole **SHALL** contain exactly one [1..1] **playingDevice** (CONF:EPRC-xxx).
         1. This playingDevice **SHALL** contain exactly one [1..1] **@classCode**="MMAT" Manufactured Material (CodeSystem: `EntityClass 2.16.840.1.113883.5.41`) (CONF:EPRC-xxx).
         2. This playingDevice **SHALL** contain exactly one [1..1] **code** (CONF:EPRC-xxx).
      iii. This participantRole **SHALL** contain at least one [1..*] **id** (CONF:EPRC-xxx).
7. **MAY** contain zero or more [0..*] **component** (CONF:EPRC-xxx) such that it
   a. **SHALL** contain exactly one [1..1] **Device Observation - EPIE** (`templateId:1.3.6.1.4.1.19376.1.4.1.4.18`) (CONF:EPRC-xxx).

6.4.4.13.3 Device Observation - EPIE

[`observation: templateId 1.3.6.1.4.1.19376.1.4.1.4.18(open)`]

This Device Observation - EPIE entry represents observations made of devices used during a procedure, such as an EP/Implant procedure. An example of a device observation would be shock impedance, induction method, cycle length, rhythm, sensing threshold.

IEEE 11073-10103 MDC IDC is the recommended nomenclature for EP Device Observations.

1. **SHALL** contain exactly one [1..1] **@classCode**="OBS" Observation (CodeSystem: `HL7ActClass 2.16.840.1.113883.5.6`) (CONF:EPRC-xxx).
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" Event (CodeSystem: `ActMood 2.16.840.1.113883.5.1001`) (CONF:EPRC-xxx).
3. **SHALL** contain exactly one [1..1] **templateId** (CONF:EPRC-xxx) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.4.1.4.18" (CONF:EPRC-xxx).
4. **SHALL** contain at least one [1..*] **id** (CONF:EPRC-xxx).
5. **SHALL** contain exactly one [1..1] **code** (CONF:EPRC-xxx).

a. **SHOULD** be from IEEE 11073-10103 MDC IDC (CodeSystem: 2.16.840.1.113883.6.24) or may be from LOINC (CodeSystem: 2.16.840.1.113883.6.1) or may be from SNOMED CT (CodeSystem: 2.16.840.1.113883.6.96) (CONF:EPRC-xxx) .

6. **SHOULD** contain zero or one [0..1] **text** (CONF:EPRC-xxx).
   a. The text, if present, **SHOULD** contain zero or one [0..1] **reference/@value** (CONF:EPRC-xxx).
      i. This reference/@value **SHALL** begin with a '#' and **SHALL** point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:EPRC-xxx).
7. **SHALL** contain exactly one [1..1] **statusCode**="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14) (CONF:EPRC-xxx).
8. **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:EPRC-xxx).
9. **SHALL** contain exactly one [1..1] **value** (CONF:EPRC-xxx).

6.4.4.14 Procedure Disposition Section 59775-7

[section: templateId 2.16.840.1.113883.10.20.18.2.12(open)]

This Procedure Disposition section is used exactly as specified in C-CDA - section 4.46.

```
<section>
  <templateId root="2.16.840.1.113883.10.20.18.2.12"/>
  <code code="59775-7" codeSystem="2.16.840.1.113883.6.1"
        codeSystemName="LOINC"
        displayName="PROCEDURE DISPOSITION"/>
  <title>PROCEDURE DISPOSITION</title>
  <text>The patient was taken to the ICU Recovery Unit in stable
        condition.</text>
</section>
```

Figure 6.4.4.14-1: Procedure disposition section example

6.4.4.15 Procedure Results - Cardiac EPIE Section 30954-2

[section: templateId 1.3.6.1.4.1.19376.1.4.1.2.25 (open)]

([section: templateId 2.16.840.1.113883.10.20.22.2.3.1(open)] – parent)

This Procedure Results – Cardiac EPIE section content module records clinically significant results confirmed or discovered during the procedure. Results include findings, measurements, calculations, and observations.

For this EPRC-IE profile, this Procedure Results – Cardiac EPIE section content module should be organized using Procedure Results Organizer – Cardiac EPIE entry content modules for

specific categories (e.g., ICD Implant findings, generator change findings, ICD extraction findings, Lead implant findings, and Lead extraction findings, Lead Abandon findings, Lead Reuse findings, DFT Results, Zone VT final device programming, Zone VF final device programming, Monitor Zone Settings, and Bradycardia parameters). There shall be a Procedure Result Organizer – Cardiac EPIE entry content module for one or more of these categories of findings. The allowed categories are defined in ValueSet Cardiac EP Activity ProceduresValue Set `1.3.6.1.4.1.19376.1.4.1.5.52` which can be expanded to include other procedures.

Result Observation -Cardiac EPIE entries are used to record specific findings(e.g., induction method, shock impedance, sensing sensitivity, detection interval, ATP) in each category. The specific findings should be selected from the EP Result Observations Constraints Set 1.3.6.1.4.1.19376.1.4.1.5.51.

The result observation statement would include associated details related to the specific implantation procedure that occurred on a patient at that time, including final documentation of success or unsuccessful results, any associated secondary testing on the implanted device and details of the type of device and associated leads that were implanted.

This Procedure Results – Cardiac EPIE section content module is a modification of the C-CDA Results Section with Coded Entries Required (C-CDA 4.55). The modifications are highlighted in yellow below. This Procedure Results – Cardiac EPIE section content module is also conformant to the C-CDA Results Section content module.

1. **SHALL** contain three or more [3..*] **templateId** (CONF:7108-EPRC) such that it
    a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.2.3" (CONF:9136).
    b. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.2.3.1" (CONF:9137).
    c. **SHALL** contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.4.1.2.25" (CONF:EPRC-xxx).
2. **SHALL** contain exactly one [1..1] **code** (CONF:15433).
    a. This code **SHALL** contain exactly one [1..1] **@code**="30954-2" Relevant diagnostic tests and/or laboratory data (CodeSystem: LOINC 2.16.840.1.113883.6.1) (CONF:15434).
3. **SHALL** contain exactly one [1..1] **title** (CONF:8892).
4. **SHALL** contain exactly one [1..1] **text** (CONF:7111).
5. **SHALL** contain at least one [1..*] **entry** (CONF:7112-EPRC) such that it
    a. **SHALL** contain exactly one [1..1] **Procedure Results Organizer – Cardiac EPIE** (templateId:1.3.6.1.4.1.19376.1.4.1.4.23) (CONF:7113-EPRC).


```
<section>
    <templateId root="1.3.6.1.4.1.19376.1.4.1.2.25" />
    <templateId root="2.16.840.1.113883.10.20.22.2.3.1" />
    <templateId root="2.16.840.1.113883.10.20.22.2.3" />
    <code code="30954-2"
          codeSystem="2.16.840.1.113883.6.1"
          codeSystemName="LOINC"
          displayName="RESULTS" />
    <title>Procedure results</title>
    <text>
    </text>
    <entry>
      <organizer classCode="CLUSTER" moodCode="EVN">
        <templateId root="2.16.840.1.113883.10.20.22.4.1"/>
        <!-- Procedure Results Organizer - Cardiac EPIE -->
        <templateId root="1.3.6.1.4.1.19376.1.4.1.4.23"/>
        <id root="7d5a02b0-67a4-11db-bd13-0800200c9a66"/>
       <code nullFlavor="OTH" displayName="Zone VT"/>
        <component>
          <observation classCode="OBS" moodCode="EVN">
            <!-- Result observation – cardiac EPIE template -->
            <templateId root="1.3.6.1.4.1.19376.1.4.1.4.22"/>
            <templateId root="2.16.840.1.113883.10.20.22.4.2"/>
            …
          </observation>
        </component>
        <component>
          <observation classCode="OBS" moodCode="EVN">
            <!-- Result observation – cardiac EPIE template -->
            <templateId root="1.3.6.1.4.1.19376.1.4.1.4.22"/>
            ...
          </observation>
        </component>
      </organizer>
    </entry>
</section>
```

Figure 6.4.4.15-1: Results section example (see the EPRC-IE XML sample for a complete ICD implant procedure example)

6.4.4.15.1 Procedure Results Organizer - Cardiac EPIE

[organizer: templateId 1.3.6.1.4.1.19376.1.4.1.4.23 (open)]

([observation: templateId 2.16.840.1.113883.10.20.22.4.1(open)] – parent)

This Procedure Results Organizer – Cardiac EPIE entry content module identifies a set of related procedure results, findings and observations. It contains information applicable to all of the contained procedure findings including the type of implant that occurred and final site location of lead placement. Related procedure finding type codes categorize a finding into one of several

commonly accepted values (e.g., : Permanent Pacemakers, Implantable Cardioverter Defibrillators, Biventricular Implantable Cardioverter Defibrillator/Pacemaker.)

This Procedure Results Organizer – Cardiac EPIE entry content module is a modification of the C-CDA Result Organizer Section (C-CDA 5.71). The modifications are highlighted in yellow below. This Procedure Results Organizer – Cardiac EPIE entry content module is also conformant to the C-CDA Results Organizer entry content module.

1. **SHALL** contain exactly one [1..1] **@classCode** (CONF:7121).
    a. **SHALL** contain exactly one [1..1] @classCode="CLUSTER" Cluster (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) (CONF: 7165-EPRC).
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001) (CONF:7122).
3. **SHALL** contain two or more [2..*] **templateId** (CONF:7126-EPRC) such that it
    a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.4.1" (CONF:9134).
    b. **SHALL** contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.4.1.4.23" (CONF:EPRC-xxx).
4. **SHALL** contain at least one [1..*] **id** (CONF:7127).
5. **SHALL** contain exactly one [1..1] **code** (CONF:7128).
    a. **SHOULD** be selected from ValueSet Cardiac EP Activity Procedures Value Set 1.3.6.1.4.1.19376.1.4.1.5.52 or **MAY** be selected from LOINC (codeSystem 2.16.840.1.113883.6.1) or SNOMED CT (codeSystem 2.16.840.1.113883.6.96), or CPT-4 (codeSystem 2.16.840.1.113883.6.12) (CONF:19219-EPRC).
6. **SHALL** contain exactly one [1..1] **statusCode** (CONF:7123).
    a. This statusCode **SHALL** contain exactly one [1..1] **@code** which **SHALL** be selected from ValueSet ResultStatus 2.16.840.1.113883.11.20.9.39 **STATIC** (CONF:14848).
7. **SHALL** contain at least one [1..*] **component** (CONF:7124) such that it
    a. **SHALL** contain exactly one [1..1] **Result Observation – Cardiac EPIE** (templateId:1.3.6.1.4.1.19376.1.4.1.4.22) (CONF:14850-EPRC).

6.4.4.15.2 Result Observation – Cardiac EPIE

[observation: templateId 1.3.6.1.4.1.19376.1.4.1.4.22 (open)]

([observation: templateId 2.16.840.1.113883.10.20.22.4.2(open)] – parent)

A result observation is a clinical statement that a clinician has noted during the EP Lab Implant/Explant procedure. This Result Observation – Cardiac EPIE entry content module is used to describe the specific procedure findings that were observed during the specific Implant/Explant procedure.

The specific result observations are defined in the EP Result Observations Constraints Set `1.3.6.1.4.1.19376.1.4.1.5.51`.

This Result Observation – Cardiac EPIE entry content module is a modification of the C-CDA Result Observation (C-CDA 5.70). The modifications are highlighted in yellow below. This Result Observation – Cardiac EPIE entry content module is also conformant to the C-CDA Result Observation entry content module.

1. **SHALL** contain exactly one [1..1] **@classCode**="OBS" Observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:7130).
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001) (CONF:7131).
3. **SHALL** contain two or more [2..*] **templateId** (CONF:7136-EPRC) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.4.2" (CONF:9138).
   b. **SHALL** contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.4.1.4.22" (CONF:EPRC-xxx).
4. **SHALL** contain at least one [1..*] **id** (CONF:7137).
5. **SHALL** contain exactly one [1..1] **code** (CONF:7133).
   a. **SHOULD** be from EP Result Observations Constraints Set (1.3.6.1.4.1.19376.1.4.1.5.51) or **MAY** be from LOINC (CodeSystem: 2.16.840.1.113883.6.1) or **MAY** be from SNOMED CT (CodeSystem: 2.16.840.1.113883.6.96) (CONF:19211-EPRC).
6. **SHOULD** contain zero or one [0..1] **text** (CONF:7138).
   a. The text, if present, **SHOULD** contain zero or one [0..1] **reference** (CONF:15924).
      i. The reference, if present, **SHOULD** contain zero or one [0..1] **@value** (CONF:15925).
         1. This reference/@value **SHALL** begin with a '#' and **SHALL** point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:15926).
7. **SHALL** contain exactly one [1..1] **statusCode** (CONF:7134).
   a. This statusCode **SHALL** contain exactly one [1..1] **@code** which **SHALL** be selected from ValueSet Result Status 2.16.840.1.113883.11.9.39) **STATIC** (CONF:14849).
8. **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:7140).
   a. Represents clinically effective time of the measurement, which may be when the measurement was performed (e.g., a BP measurement), or may be when sample was taken (and measured some time afterwards) (CONF:16838).
9. **SHALL** contain exactly one [1..1] **value** (CONF:7143).
10. **SHOULD** contain zero or more [0..*] **interpretationCode** (CONF:7147).
11. **MAY** contain zero or one [0..1] **methodCode** (CONF:7148).
12. **MAY** contain zero or one [0..1] **targetSiteCode** (CONF:7153).

13. **MAY** contain zero or one [0..1] **author** (CONF:7149).
14. **SHOULD** contain zero or more [0..*] **referenceRange** (CONF:7150).
    a. The referenceRange, if present, **SHALL** contain exactly one [1..1] **observationRange** (CONF:7151).
        i. This observationRange **SHALL NOT** contain [0..0] **code** (CONF:7152).
15. **SHOULD** contain zero or one [0..1] **entryRelationship** (CONF:EPRC-xxx) such that it
    a. **SHALL** contain exactly one [1..1] **@typeCode**="SUBJ" Has subject (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:EPRC-xxx).
    b. **SHALL** contain exactly one [1..1] **@inversionInd**="true" TRUE (CONF:EPRC-xxx).
    c. **SHALL** contain exactly one [1..1] **Severity Observation** (templateId:2.16.840.1.113883.10.20.22.4.8) (CONF:EPRC-xxx).

6.4.4.16 Complications Section 55109-3

[section: templateId 2.16.840.1.113883.10.20.22.2.37(open)]

This Complications section content module records problems that occurred during the EPRC-IE lab procedure. The complications may have been known risks or unanticipated problems.

This Complications section content module is used exactly as specified in C-CDA - section 4.8, except for vocabulary constraints for Problem Observation entries.

There is a EPRC-IE specific value set defined for complications recorded as Problem Observation entries in this Complications section content module based on the ACC NCDR ICD complication specification, **examples include** Cardiac Arrest , Drug Reaction, Cardiac Perforation , Cardiac Valve Injury , Conduction Block, Coronary Venous Dissection, Hematoma (Req re-op, evacuation or transfusion) , Hemothorax, Lead Dislodgement, Pneumothorax, Peripheral Nerve Injury, Peripheral Embolus, TIA or Stroke (CVA), Myocardial Infarction, Pericardial Tamponade, Infection Requiring Antibiotics, Venous Obstruction , Set Screw Problem , and Urgent Cardiac Surgery.

```
<section>
```



```
  <templateId root="2.16.840.1.113883.10.20.22.2.37"/>
  <code code="55109-3" codeSystem="2.16.840.1.113883.6.1"
        codeSystemName="LOINC"
        displayName="Complications"/>
  <title>Complications</title>
  <text>Complications for the Implant/Explant procedure for patient included:
        x, y, z…
  </text>
  <entry>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.22.4.4"/>
      <id root="d11275e7-67ae-11db-bd13-0800200c9a66"/>
      <code code="404684003" codeSystem="2.16.840.1.113883.6.96"
            displayName="Finding"/>
      <text>The patient has had a myocardial infarction..</text>
      <statusCode code="completed"/>
      <effectiveTime>
         <low value="201201251000"/>
      </effectiveTime>
      <value xsi:type="CD" code="410429000"
            codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT"
            displayName="Cardiac Arrest"/>
      <entryRelationship typeCode="REFR">
         <observation classCode="OBS" moodCode="EVN">
           <templateId root="2.16.840.1.113883.10.20.22.4.6"/>
           <!-- Problem Status template -->
           <code code="33999-4" codeSystem="2.16.840.1.113883.6.1"
                 codeSystemName="LOINC" displayName="Status"/>
           <statusCode code="completed"/>
           <value xsi:type="CD" code="55561003"
                  codeSystem="2.16.840.1.113883.6.96"
                  codeSystemName="SNOMED CT" displayName="Active"/>
         </observation>
      </entryRelationship>
    </observation>
  </entry>
  <entry>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="1.3.6.1.4.1.19376.1.4.1.4.9"/>
      <id root="xyz"/>
      …
    </observation>
  </entry>
</section>
```

Figure 6.4.4.16-1: Complications section example

6.4.4.16.1 Problem Observation – Constraints

```
[observation: templateId 2.16.840.1.113883.10.20.22.4.4 (open)]
```

A problem is a clinical statement that a clinician has noted during the Implant/Explant procedure. This entry is used to describe the presence or absence of specific "complications" as defined by ACC.

This Problem Observation entry content module is used exactly as specified in C-CDA - section 5.59, except for vocabulary constraints.

The value set for CONF:9058 (**`value@code`**) **SHOULD** be selected from ValueSet Cardiac EP Complications Value Set `1.3.6.1.4.1.19376.1.4.1.5.54` **STATIC.**

6.4.4.17 Postprocedure Diagnosis Section 59769-0

[`section`: `templateId` `2.16.840.1.113883.10.20.22.2.36(open)`]

The Postprocedure Diagnosis section content module records the diagnosis or diagnoses discovered or confirmed during the procedure. Often it is the same as the pre-procedure diagnosis or indication.

This Postprocedure Diagnosis section content module is used exactly as specified in C-CDA - section 4.42, except for vocabulary constraints.

There is an EPRC-IE specific value set defined for problem observations recorded as part of postprocedure diagnosis which is included in the Problem Observation entry.


```
<section>
   <templateId root="2.16.840.1.113883.10.20.22.2.36"/>
   <code code="59769-0" codeSystem="2.16.840.1.113883.6.1"
      codeSystemName="LOINC" displayName="POSTPROCEDURE DIAGNOSIS"/>
   <title>Postprocedure Diagnosis</title>
   <text> It was observed that post procedurally the patient has
        <contentID="PostDiag1">Brugada Syndrome</content>
   </text>
   <entry>
      <act moodCode="EVN" classCode="ACT">
       <templateId root="2.16.840.1.113883.10.20.22.4.51"/>
       <!-- ** Postprocedure Diagnosis Entry ** -->
       <code code="59769-0" codeSystem="2.16.840.1.113883.6.1"
             codeSystemName="LOINC"
             displayName="Postprocedure Diagnosis"/>
       <entryRelationship typeCode="SUBJ">
        <observation classCode="OBS" moodCode="EVN">
         <templateId root="2.16.840.1.113883.10.20.22.4.4"/>
         <!-- Problem Observation template -->
          <id root="d11275e7-67ae-11db-bd13-0800200c9a66"/>
         <code code="404684003" codeSystem="2.16.840.1.113883.6.96"
               codeSystemName="SNOMED CT"
               displayName="Finding"/>
         <text>
              <reference value="#PostDiag1"/>
         </text>
         <statusCode code="completed"/>
         <effectiveTime>
          <low value="201309261400"/>
         </effectiveTime>
         <value xsi:type="CD" code="418818005"
                      codeSystem="2.16.840.1.113883.6.96"
                      codeSystemName="SNOMED CT"
                      displayName="Brugada Syndrome"/>
         <entryRelationship typeCode="REFR">
           <observation classCode="OBS" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.22.4.6"/>
              <!-- Problem Status template -->
              <code code="33999-4" codeSystem="2.16.840.1.113883.6.1"
                    codeSystemName="LOINC" displayName="Status"/>
              <statusCode code="completed"/>
              <value xsi:type="CD" code="55561003"
                       codeSystem="2.16.840.1.113883.6.96"
                       codeSystemName="SNOMED CT" displayName="Active"/>
           </observation>
          </entryRelationship>
         </observation>
        </entryRelationship>
      </act>
   </entry>
</section>
```

Figure 6.4.4.17-1: Postprocedure diagnosis section example

6.4.4.17.1 Problem Observation – Constraints

`[observation: templateId 2.16.840.1.113883.10.20.22.4.4 (open)]`

The Problem Observation entry is used to describe a final diagnosis.

This Problem Observation entry is used exactly as specified in C-CDA - section 5.59, except for vocabulary constraints.

The value set for CONF:9058 (**`value`**) **SHOULD** be selected from ValueSet EPRC Postprocedure Diagnoses Value Set `1.3.6.1.4.1.19376.1.4.1.5.56` **STATIC**.

6.4.4.18 Plan of Care - Cardiac Section 18776-5

[`section: templateId 1.3.6.1.4.1.19376.1.4.1.2.22 (open)`]

([`section: templateId 2.16.840.1.113883.10.20.22.2.10(open)`] – `parent`)

This Plan of Care - Cardiac section content module is intended to be used to describe the post-procedure plan.

The Plan of Care - Cardiac section content module contains data that defines pending orders, interventions, encounters, services, and procedures for the patient. It is limited to prospective, unfulfilled, or incomplete orders and requests only, which are indicated by the @moodCode of the entries within this section. All active, incomplete, or pending orders, appointments, referrals, procedures, services, or any other pending event of clinical significance to the current care of the patient should be listed unless constrained due to privacy issues. The plan may also contain information about ongoing care of the patient and information regarding goals and clinical reminders. Clinical reminders are placed here to provide prompts for disease prevention and management, patient safety, and health-care quality improvements, including widely accepted performance measures. The plan may also indicate that patient education was given or will be provided and should include associated medications required at discharge to alert those individuals that discharge the patient will meet the documentation requirements for discharge medications.

This Plan of Care – Cardiac section content module is a modification of the C-CDA Plan of Care section (C-CDA 4.39). The modifications are highlighted in yellow below. This Plan of Care – Cardiac section content module is also conformant to the C-CDA Plan of Care section content module.

1. **SHALL** contain two or more [2..*] **`templateId`** (CONF:7723-CRC) such that it
   a. **SHALL** contain exactly one [1..1] **`@root`**`="2.16.840.1.113883.10.20.22.2.10"` (CONF:10435).
   b. **SHALL** contain exactly one [1..1] **`@root`**`="1.3.6.1.4.1.19376.1.4.1.2.22"` (CONF:CRC-xxx).
2. **SHALL** contain exactly one [1..1] **`code`** (CONF:14749).
   a. This code **SHALL** contain exactly one [1..1] **`/@code`**`="18776-5"` Plan of Care (CodeSystem: `LOINC 2.16.840.1.113883.6.1`) (CONF:14750).

3. **SHALL** contain exactly one [1..1] **title** (CONF:16986).
4. **SHALL** contain exactly one [1..1] **text** (CONF:7725).
5. **MAY** contain zero or more [0..*] **entry** (CONF:7726) such that it
    a. **SHALL** contain exactly one [1..1] **Plan of Care Activity Act - Cardiac** (templateId:1.3.6.1.4.1.19376.1.4.1.4.17) (CONF:14751-CRC).
6. **MAY** contain zero or more [0..*] **entry** (CONF:8805) such that it
    a. **SHALL** contain exactly one [1..1] **Plan of Care Activity Encounter** (templateId:2.16.840.1.113883.10.20.22.4.40) (CONF:14752).
7. **MAY** contain zero or more [0..*] **entry** (CONF:8807) such that it
    a. **SHALL** contain exactly one [1..1] **Plan of Care Activity Observation** (templateId:2.16.840.1.113883.10.20.22.4.44) (CONF:14753).
8. **MAY** contain zero or more [0..*] **entry** (CONF:8809) such that it
    a. **SHALL** contain exactly one [1..1] **Plan of Care Activity Procedure** (templateId:2.16.840.1.113883.10.20.22.4.41) (CONF:14754).
9. **MAY** contain zero or more [0..*] **entry** (CONF:8811) such that it
    a. **SHALL** contain exactly one [1..1] **Plan of Care Activity Substance Administration** (templateId:2.16.840.1.113883.10.20.22.4.42) (CONF:14755).
10. **MAY** contain zero or more [0..*] **entry** (CONF:8813) such that it
    a. **SHALL** contain exactly one [1..1] **Plan of Care Activity Supply** (templateId:2.16.840.1.113883.10.20.22.4.43) (CONF:14756).
11. **MAY** contain zero or more [0..*] **entry** (CONF:14695) such that it
    a. **SHALL** contain exactly one [1..1] **Instructions** (templateId:2.16.840.1.113883.10.20.22.4.20) (CONF:16751).


```
<section>
   <templateId root="1.3.6.1.4.1.19376.1.4.1.2.22" />
   <templateId root="2.16.840.1.113883.10.20.22.2.10" />
   <!--  **** Plan of Care – Cardiac section template  **** -->
   <code code="18776-5" codeSystem="2.16.840.1.113883.6.1"
      codeSystemName="LOINC" displayName="Treatment plan"/>
   <title>Plan of Care</title>
   <text>
      ...
   </text>
   <entry>
      <act moodCode="RQO" classCode="ACT">
         <!--  ****  Plan of Care Activity Act - Cardiac template   **** -->
         <templateId root="1.3.6.1.4.1.19376.1.4.1.4.17"/>
         <templateId root="2.16.840.1.113883.10.20.22.4.39"/>
         <id root="9a6d1bac-17d3-4195-89a4-1121bc809a5c"/>
         <code code="304508008" codeSystem="2.16.840.1.113883.6.96"
               displayName="Recommendation to avoid functional activity:
                            Avoid lifting elbow above shoulder"/>
         <statusCode code="new"/>
         <effectiveTime>
            <center value="201309261430"/>
         </effectiveTime>
      </act>
   </entry>
</section>
```

Figure 6.4.4.18-1: Plan of care section example

6.4.4.18.1 Plan of Care Activity Act - Cardiac

[act: templateId 1.3.6.1.4.1.19376.1.4.1.4.17 (open)]

([act: templateId 2.16.840.1.113883.10.20.22.4.39(open)] – parent)

This Plan of Care Activity Act – Cardiac entry content module is a modification of the C-CDA Plan of Care Activity Act (C-CDA 5.46). The modifications are highlighted in yellow below. This Plan of Care Activity Act – Cardiac entry content module is also conformant to the C-CDA Plan of Care Activity Act entry content module.

1. **SHALL** contain exactly one [1..1] **@classCode**="ACT" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:8538).
2. **SHALL** contain exactly one [1..1] **@moodCode**, which **SHALL** be selected from ValueSet Plan of Care moodCode (Act/Encounter/Procedure) 2.16.840.1.113883.11.20.9.23 **STATIC** 2011-09-30 (CONF:8539).
3. **SHALL** contain two or more [2..*] **templateId** (CONF:8544-CRC) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.4.39" (CONF:10510).

b. **SHALL** contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.4.1.4.17" (CONF:CRC-xxx).

4. **SHALL** contain at least one [1..*] **id** (CONF:8546).
5. **SHALL** contain exactly one [1..1] **code** (CONF:CRC-xxx)
   a. This code **SHALL** contain exactly one [1..1] **/@code** which **SHOULD** be selected from ValueSet Rx Recommendations 1.3.6.1.4.1.19376.1.4.1.5.62 **STATIC** (CONF:EPRC-XXX).
6. **SHOULD** contain zero or one [0..1] **effectiveTime** (CONF:CRC-xxx).

6.4.4.19 Key Images – Cardiac Section – DCM 121180

[section: templateId 1.3.6.1.4.1.19376.1.4.1.2.21(open)]

The Key Images section content module contains narrative description of and references to DICOM Image Information Objects that illustrate the findings of the procedure reported.

1. **SHALL** contain exactly one [1..1] **templateId** (CONF:CRC-xxx) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.4.1.2.21" (CONF:CRC-xxx).
2. **SHALL** contain exactly one [1..1] **code** (CONF:CRC-xxx).
   a. This code **SHALL** contain exactly one [1..1] **@code**="121180" Key Images (CodeSystem: 1.2.840.10008.2.16.4 DCM) (CONF:CRC-xxx).
3. **SHALL** contain exactly one [1..1] **text** (CONF:CRC-xxx).
4. **SHALL** contain at least one [1..*] **entry** (CONF:CRC-xxx)
   a. **SHALL** contain exactly one [1..1] **Sop Instance Observation** (templateId:2.16.840.1.113883.10.20.6.2.8) (CONF:CRC-xxx).

6.4.5 Common Entry Content Modules

6.4.5.1 Problem Observation – Cardiac

[Observation: templateId 1.3.6.1.4.1.19376.1.4.1.9(open)]

([Observation: templateId 2.16.840.1.113883.10.20.22.4.4(open)] – parent)

A problem is a clinical statement that a clinician has noted. In health care it is a condition that requires monitoring Frequency for device interrogation to be completed in the outpatient clinic setting, or diagnostic, therapeutic, or educational action. It also refers to any unmet or partially met basic human need. In cardiology, problems include hypertension, diabetes, and dyslipidemia.

Additional entryRelationships to observation acts can be used to provide further supporting observations (SPRT typeCode) or reasons for the observation (RSON typeCode) for this observation. An example includes specifying that there are syndromes for risk of sudden death and the entryRelationship to and observation to identify the specific sudden death type (e.g., Brugada syndrome).

This Problem Observation – Cardiac entry content module extends the C-CDA Problem Observation entry definition (C-CDA 5.59) by adding the following constraints:

1. **SHALL** contain exactly one [1..1] **templateId** (CONF:CRC-xxx) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.4.1.9" (CONF:CRC-xxx).
2. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:CRC-xxx) such that it
   a. **SHALL** contain exactly one [1..1] **@typeCode**="SUBJ" Has subject (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:CRC-xxx).
   b. **SHALL** contain exactly one [1..1] **@inversionInd**="true" TRUE (CONF:CRC-xxx).
   c. **SHALL** contain exactly one [1..1] **Severity Observation** (templateId:2.16.840.1.113883.10.20.22.4.8) (CONF:CRC-xxx).

6.4.6 Electrophysiology Implant/Explant Report Content Vocabulary Constraints

The following are the value sets that are referenced in the content templates for this EPRC-IE profile. Value sets include a name for the concept and one or more values from code systems.

In cases where no appropriate value from the specified code system has been identified for the concept, no value is listed and the table cell is hightlighted in yellow.

6.4.6.1 Coronary Anatomy Value Set - Vocabulary Constraint

The content creator shall be capable of specifying the coronary anatomy selected from Value Set 1.3.6.1.4.1.19376.1.4.1.5.32, listed below. This structure is used to represent the native coronary structure of the heart for prior cath/PCI procedures.

Table 6.4.6.1-1: Coronary Anatomy Value Set 1.3.6.1.4.1.19376.1.4.1.5.32 STATIC

Coding Scheme / Concept	SNOMED CT
Left Main Coronary Artery	3227004
Left Main Coronary Artery Ostium	76862008
Left Anterior Descending Coronary Artery	59438005
Proximal Left Anterior Descending Coronary Artery	68787002
Mid Left Anterior Descending Coronary Artery	91748002
Distal Left Anterior Descending Coronary Artery	36672000
Left Posterior Descending Artery	56322004
Left Posterior Descending Circumflex Coronary Artery	91760001
Left Posterolateral Circumflex Coronary Artery	57823005
Right Coronary Artery	13647002
Right Coronary Artery Ostium	56789007
Proximal Right Coronary Artery	91083009

Coding Scheme / Concept	SNOMED CT
Mid Portion of Right Coronary Artery	450960006
Distal Right Coronary Artery	41879009
Circumflex Coronary Artery	57396003
Proximal Circumflex Coronary Artery	52433000
Mid Circumflex Coronary Artery	91753007
Distal Circumflex Coronary Artery	6511003
Posterior Descending Right Coronary Artery	53655008
Intermediate Artery (Ramus)	244252004
Right posterior AV Coronary Artery	12800002
1st Diagonal Coronary Artery	91750005
1st Left Posterolateral Coronary Artery	91757008
1st Marginal Coronary Artery	91754001
1st Right posterolateral Coronary Artery	91761002
1st Septal Coronary Artery	244251006
2nd Diagonal Coronary Artery	91751009
2nd Left Posterolateral Coronary Artery	91758003
2nd Marginal Coronary Artery	91755000
2nd Right Posterolateral Coronary Artery	91762009
3rd Diagonal Coronary Artery	91752002
3rd Left Posterolateral Coronary Artery	91759006
3rd Marginal Coronary Artery	91756004
3rd Right posterolateral Coronary Artery	91763004
Marginal Right Coronary Artery	22765000
AV groove continuation of Circumflex Artery	75902001

6.4.6.2 Contrast Agents Classes for Adverse Reactions

The content creator shall be capable of creating a Contrast Agents Classes for Adverse Reactions selected from Value Set 1.3.6.1.4.1.19376.1.4.1.5.34, listed below.

2760

Table 6.4.6.2-1: Contrast Agents Classes for Adverse Reactions 1.3.6.1.4.1.19376.1.4.1.5.34 STATIC

Coding Scheme / Concept	SNOMED CT
Iodinated contrast agent	426722004
Gadolinium compound	105879004
Echocardiography agent	409290009

Concept \ Coding Scheme	SNOMED CT
Radiopharmaceutical	349358000

6.4.6.3 Contrast Agents - Vocabulary Constraints

2765 The content creator shall be capable of creating Contrast Agents selected from Value Set 1.3.6.1.4.1.19376.1.4.1.5.39, listed below.

Table 6.4.6.3-1: Contrast Agents 1.3.6.1.4.1.19376.1.4.1.5.39 STATIC

Concept \ Coding Scheme	SNOMED CT	NDC
Radionuclide: F-18 FDG for viability	422975006	
Radionuclide: Rubidium-82 perfusion	79197006	
Radionuclide: Nitrogen-13 ammonia perfusion	21576001	
Radionuclide: Tc-99m tetrofosmin (Myoview)	404707004	
Radionuclide: Tc-99m sestamibi (Cardiolite)	404706008	
Radionuclide: Tl-201	353842007	
Echo Contrast: Optison (Perflutren)	409291008	00019-2707-03
Echo Contrast: Definity (Perflutren Lipid Microsphere)		11994-*011-04
Echo Contrast: Agitated saline	373757009	
Echo Contrast: Iodinated contrast	426722004	
High Osmolar Ionic Contrast: Diatrizoate meglumine and diatrizoate sodium (Renografin, etc.)	416688007	
High Osmolar Ionic Contrast: Iothalamate dimeglumine (Conray)	109221002	
Low osmolar non-ionic contrast: Iopamidol (Isovue)	109219007	
Low osmolar non-ionic contrast: Iohexol (Omnipaque)	109218004	
Low osmolar non-ionic contrast: Ioversol (Optiray)	109222009	
Low osmolar non-ionic contrast: Ioxaglate (Hexabrix)	353924001	
Low osmolar non-ionic contrast: Iomeprol (Iomeron)	356671000	
Low osmolar non-ionic contrast: Iopromide (Ultravist)	353903006	
Iso-osmolar nonionic contrast: Iodixanol (VisiPaque)	353962003	
Paramagnetic agent: Gadopentetate dimeglumine (Magnevist)	404846007	
Paramagnetic agent: Gadodiamide (Omniscan)	354088005	
Paramagnetic agent: Gadoversetamide (Optimark)	409477004	
Paramagnetic agent: Gadobenate dimeglumine (MultiHance)	414307008	

6.4.6.4 Supported File Formats - Vocabulary Constraints

The content creator shall be capable of creating Supported File Formats selected from Value Set 1.3.6.1.4.1.19376.1.4.1.5.45, listed below.

Table 6.4.6.4-1: Supported File Formats 1.3.6.1.4.1.19376.1.4.1.5.45 STATIC

Value Set: SupportedFileFormats 1.3.6.1.4.1.19376.1.4.1.5.45 STATIC	
Graphic Formats	**Code**
GIF Image	image/gif
TIF Image	image/tiff
JPEG Image	image/jpeg
PNG Image	image/png

6.4.6.5 New York Heart Class - Vocabulary Constraints

The content creator shall be capable of including one New York Heart class selected from Value Set 1.3.6.1.4.1.19376.1.4.1.5.48, listed below.

Table 6.4.6.5-1: New York Heart Class 1.3.6.1.4.1.19376.1.4.1.5.48 STATIC

Coding Scheme / Concept	SNOMED CT
NYHA Class 1	420300004
NYHA Class 2	421704003
NYHA Class 3	420913000
NYHA Class 4	422293003

6.4.6.6 Cardiac EP Problems/Concerns - Vocabulary Constraints

The content creator shall be capable of including cardiac EP problems and concerns selected from Value Set 1.3.6.1.4.1.19376.1.4.1.5.49, listed below.

Table 6.4.6.6-1: Cardiac EP Problems/Concerns 1.3.6.1.4.1.19376.1.4.1.5.49 STATIC

Coding Scheme / Concept	SNOMED CT	ACC-NCDR ICD Seq#
Hypertension	38341003	4260
Dyslipidemia	370992007	NA
Diabetes	73211009	4245

Coding Scheme / Concept	SNOMED CT	ACC-NCDR ICD Seq#
Acute renal failure	42399005	
Cerebrovascular disease	62914000	4235
Irreversible Brain Damage from existing Cerebral Disease		
Cardiac arrhythmia	44808001	
Heart failure	84114007	4000
Myocardial infarction	22298006	
Angina	194828000	
Currently on Dialysis	108241001	4255
Chronic Lung Disease	413839001	4240
Anti-Anginal Medication: Beta Blockers	33252009	9110
Anti-Anginal Medication: Calcium Channel Blockers	48698004	9115,9120,9125
Left Ventricular Systolic Dysfunction	134401001	
Non-Ischemic Dilated Cardiomyopathy	111000119104	4025
Ischemic Heart Disease	414545008	4160
Cardiac Arrest	410429000	4080, 8005
Cardiac Arrest Vtach/Vfib	71908006	4090
Cardiac Arrest Brady	488867003	4095
History of MI	399211009	4170
Valve Surgery/Procedure	73544002	
PCI	415070008	4180
CABG	232717009	4190
Heart Transplant	161666008 (32413006 if tracking actual procedures)	4035
ICD	395218007	4110
Cardiomyopathy	194849004	
Amyloid myopathy (Amyloidosis)	193247000	4210
Common Ventricle	45503006	4213
Hypertropic Dysplasis (HCM)	233873004	4216
Right Ventricular Dysplasia (ARVD)	253528005	4219
Tetralogy of Fallot	86299006	4222
Atrial Septal Defect	70142008	4211
Ebsteins Anamoly	204357006	4214

Coding Scheme / Concept	SNOMED CT	ACC-NCDR ICD Seq#
Left Ventricular Aneurysm	297160003	4217
Cardiac Sarcoidosis	75403004	4220
Ventricular Septal Defect	30288003	4223
Chagas Disease	77506005	4212
Giant Cell Myocarditis	60812006	4215
LV Non-compaction Syndrome (LVNC or NCC)	447935001	4218
Transposition of Great Vessel	204296002	4221
Primary Valvular Heart Disease	368009	4200
Syncope	271594007	4045
Atrial Fibrillation	49436004	4055
Atrial Flutter	5370000	4055
Atrial fibrillation and flutter	195080001	4060
Chronic atrial fibrillation	426749004	4060
Controlled atrial fibrillation	300996004	4060
Lone atrial fibrillation	233910005	4060
Non-rheumatic atrial fibrillation	33911009	4060
Paroxysmal atrial fibrillation	282825002	4060
Permanent atrial fibrillation	440028005	4060
Persistent atrial fibrillation	440059007	4060
Rapid atrial fibrillation	314208002	4060
Chronic atrial flutter	425615007	4060
Paroxysmal atrial flutter	427665004	4060
Ventricular Tachycardia	25569003	4065
VT hemodynamic Instability	422773005	4070
VT Type	Pick one from Value Set - VT Types 1.3.6.1.4.1.19376.1.4.1.5.57	4075
Sinus Node Dysfunction	60423000	
AV Conduction (block)	233917008	
Intraventricular conduction	4554005	
ECG	164847006	
Hx of Therapeutic Strategies AF		

Coding Scheme / Concept	SNOMED CT	ACC-NCDR ICD Seq#
Long QT Syndrome	9651007	4105
Short QT Syndrome	77867006	4105
Brugada Syndrome	418818005	4105
Catechcholaminergic polymorphic VT	419671004	4105
Idiopathic Primary VT/VF		4105
Sleep Apnea	73430006	4250
Life Expectancy >= 1 year		4270
Dyspnea	267036007	
Fatigue	84229001	
Congenital Heart Disease	13213009	
Myocardial infiltrative or storage disease	34420000	
Inflammatory myocarditis	471841009	
Primary myocardial hypertrophic or other muscle disease (HCM)	233873004	
chronic liver disease	328383001	
Peripheral Vascular Disease	400047006	
Medication Allergies	416098002	
LVEF Assessed	250908004	5000
LVEF Assessment Method		

6.4.6.7 ICD Device Types - Vocabulary Constraints

The content creator shall be capable of including ICD device types selected from Value Set 1.3.6.1.4.1.19376.1.4.1.5.50, listed below.

Table 6.4.6.7-1: ICD Device Types 1.3.6.1.4.1.19376.1.4.1.5.50 STATIC

Coding Scheme / Concept	MDC_ICD
Pacemaker	753665
IPG Single Chamber	54866009(SNOMED)
IPG Dual Chamber	58863009(SNOMED)
ICD Implantable Cardioverter Defibrillator	753666
CRT-P Cardiac resynchronization therapy BiVentricular Pacing	753668
CRT-D (CRT-P w/defibrillator)	753667
Implantable Diagnostic Monitor	753669

6.4.6.8 EP Result Observations - Vocabulary Constraints

The content creator shall be capable of creating result observations selected from Value Set 1.3.6.1.4.1.19376.1.4.1.5.51 listed below.

- Cardinality - indicates the minimum and maximum number of these observations that are included for the procedure. If multiple procedure are listed in the Procedure Parameter Group column, the cardinality applies to each procedure type. Procedures are found in Value Set EP Activity Procedures 1.3.6.1.4.1.19376.1.4.1.5.52 If multiple zone therapies are listed in the Procedure Parameter Group column, the cardinality applies to each zone. Zones are grouped using an organizer for VF, VT, Monitor and Bradycardia.
- Procedure Parameter Group below indicates the procedure type for which this specific result observation should be included in the entry. For example, for VT Zone. IF R: is present, it means that it is required for that procedure type.
- Observation/code - this defines the code element of this observation. If a code exists, the following are defined: 1. numeric code. 2. code system name. 3. reference id. 4. display name. If only a string is listed, it means we did not find codes.
- Registry - The sequence number of the ACC-NCDR ICD Registry.
- HL7 V3 Data Type R1- the data type of the observation value.
- Unit of Measure - the unit of measure for the observation value using UCUM standard.
- Value Set - set of values that are allowed for the observation value. This is only used for coded values that need additional explanation.

Table 6.4.6.8-1: EP Result Observations 1.3.6.1.4.1.19376.1.4.1.5.51 STATIC

Cardinality	Procedure Parameter Group	observation/code	Registry	HL7 v3 Data Type	Unit of Measure	Value Set
[0..1]	R:ICD Lead	729537, MDC_IDC, MDC_IDC_SET_LEADCHNL_RV_SENSING_SENSITIVITY, “RV Sensing Amplitude”		PQ	mV	
[0..1]	R:ICD Lead	722433, MDC_IDC, MDC_IDC_MSMT_LEADCHNL_RV_IMPEDANCE_VALUE, “RV Impedance”		PQ	ohms	
[0..1]	R:ICD Lead	722177, MDC_IDC, MDC_IDC_MSMT_LEADCHNL_RV_PACING_THRESHOLD_AMPLITUDE,”RV pacing Threshold”		PQ	ohms	

Cardinality	Procedure Parameter Group	observation/code	Registry	HL7 v3 Data Type	Unit of Measure	Value Set
[0..1]	R:ICD Lead	722241, MDC_IDC, MDC_IDC_MSMT_LEADCHNL_RV_PACING_THRESHOLD_PULSEWIDTH, “RV pacing Threshold Pulsewidth”		PQ	ms	
[0..1]	R:ICD DFT Testing	Shock Configuration				Need to define with an explanation
[0..1]	R:ICD DFT Testing	Induction Method		Text		This is modeled using a nullFlavor of "OTH" using originalText of "Induction Method". Value has a nullFlavor of "OTH" with an originalText to describe Induction Method, like "T-Wave Shock"
[0..1]	R:ICD DFT Testing	731648, MDC_IDC, MDC_IDC_SET_ZONE_TYPE-Induced Rhythm, "Induced Rhythm"				MDC_IDC_ENUM_EPISODE_TYPE
[0..1]	R:ICD DFT Testing	722624, MDC_IDC, MDC_IDC_MSMT_LEADHVCHNL_IMPEDANCE-Shock,,”Shock Impedance”		PQ	ohms	
[0..1]	R:ICD DFT Testing	732225, MDC_IDC, MDC_IDC_SET_ZONE_SHOCK_ENERGY_1,”Shock Energy”		PQ	J	
[0..1]	R:ICD DFT Testing R:ICD Bradycardia Parameters	722051, MDC_IDC_MSMT_LEADCHNL_RV_SENSING_INTR_AMPL_MEAN “RV Sensing INTR Amplitude Mean”		PQ	mV	
[0..1]	R:ICD VT Zone R:ICD VF Zone R:ICD Monitor Zone	731840, MDC_IDC, MDC_IDC_SET_ZONE_DETECTION_INTERVAL, “Zone Detection Interval”		PQ	ms	
[0..1]	R:ICD VT Zone R:ICD VF Zone	732097, MDC_IDC_SET_ZONE_TYPE_ATP_1, Therapy				MDC_IDC_ENUM_ATP_TYPE_
[0..1]	R:ICD VT Zone R:ICD VF	732161, MDC_IDC, MDC_IDC_SET_ZONE_NUM_ATP_SEQS_1,		INT		

Cardinality	Procedure Parameter Group	observation/code	Registry	HL7 v3 Data Type	Unit of Measure	Value Set
	Zone	"ATP Seqs"				
[0..1]	R:ICD VT Zone R:ICD VF Zone	732225, MDC_IDC, MDC_IDC_SET_ZONE_SHOCK_ENERGY_1, "Shock Energy 1"		PQ	J	
[0..1]	R:ICD VT Zone R:ICD VF Zone	732289, MDC_IDC, MDC_IDC_SET_ZONE_NUM_SHOCKS_1, "Num of Shocks 1"		INT		
[0..1]	R:ICD VT Zone	732226, MDC_IDC, MDC_IDC_SET_ZONE_SHOCK_ENERGY_2, "Shock Energy 2"		PQ	J	
[0..1]	R:ICD VT Zone	732290, MDC_IDC, MDC_IDC_SET_ZONE_NUM_SHOCKS_2, "Num of Shocks 2"		INT		
[0..1]	R:ICD Bradycardia Parameters	730752, MDC_IDC, MDC_IDC_SET_BRADY_MODE, "Brady Mode"		CD		MDC_IDC_ENUM_BRADY_MODE_
[0..1]	R:ICD Bradycardia Parameters	730880, MDC_IDC, MDC_IDC_SET_BRADY_LOWRATE, "Low Rate"		PQ	bpm	
[0..1]	R:ICD Bradycardia Parameters	729985, MDC_IDC, MDC_IDC_SET_LEADCHNL_RV_PACING_AMPLITUDE, "RV Pacing Amplitude"		PQ	V	
[0..1]	R:ICD Bradycardia Parameters	730049, MDC_IDC, MDC_IDC_SET_LEADCHNL_RV_PACING_PULSEWIDTH, "RV Pacing Pulse Width"		PQ	ms	
[0..1]	R:ICD Implant	"Lowest Energy Tested that was Successful(joules)"	6180	PQ	J	
[0..1]	R:ICD Implant	"Upper limit of Vulnerability(joules)"	6180	PQ	J	
[0..1]	R:ICD Implant(CRT-D)	"CS/LV lead successful"	6145			Yes Not Implanted Previously Implanted
[0..1]	R:ICD Implant(CRT-D)	"Reason CS/LV not implanted"	6150			Vascular Access Coronary sinus access

Cardinality	Procedure Parameter Group	observation/code	Registry	HL7 v3 Data Type	Unit of Measure	Value Set
						Tributary vein access CS Dissection Unacceptable Threshold Diaphragmatic stimulation
[0..1]	R:ICD Implant Biventricular	"LV First"		PQ	ms	
[0..1]	R:ICD Implant Biventricular	"Simultaneous RV first"		PQ	ms	
[0..1]	R:ICD Implant Biventricular	" A-V Pace"		PQ	ms	
[0..1]	R:ICD Implant Biventricular	"A-V (sensed)"		PQ	ms	
[0..1]	R:ECG	"Simultaneous ECG leads"				
[0..1]	R:ECG	"P-Wave Duration"				
[0..1]	R:ECG	"PR Interval"	ICD: 5055			
[0..1]	R:ECG	"QRS Duration"	ICD: 5060			
[0..1]	R:ECG	"Epsilon Wave"				
[0..1]	R:ECG	"Hx of prolonged QT Interval"				
[0..1]	R:ECG	"Long QT"				
[0..1]	R:ICD Explant	"Returned to Manufacturer"	ICD: 6235	CD	NA	True or False
[0..1]	R:ICD Explant	"Battery Voltage"	ICD: 6240			
[0..1]	R:ICD Existing Lead	"Lead Function"	ICD: 7070			Need code (Normal) Need code (Abnormal) Need code (Not assessed)
[0..1]	R:ICD Existing Lead	"Lead Status"	ICD: 7080			Need code (Extracted) Need code (Abandoned) Need code (Reused)
[0..1]	R:ICD Existing Lead	"Returned to the Manufacturer"	ICD: 7085	CD	NA	True or False

Cardinality	Procedure Parameter Group	observation/code	Registry	HL7 v3 Data Type	Unit of Measure	Value Set
[0..1]	R:ICD Existing Lead	"Placement Issue: Dislodgement"	ICD: 7095	CD	NA	True or False
[0..1]	R:ICD Existing Lead	"Placement Issue: Perforation"	ICD: 7100	CD	NA	True or False
[0..1]	R:ICD Existing Lead	"Placement Issue: Erosion"	ICD: 7105	CD	NA	True or False
[0..1]	R:ICD Existing Lead	"Placement Issue: Faulty Connector/Head"	ICD: 7110	CD	NA	True or False
[0..1]	R:ICD Existing Lead	"Placement Issue: Pt Clinical Status"	ICD: 7115	CD	NA	True or False
[0..1]	R:ICD Existing Lead	"Placement Issue: Infection"	ICD: 7120	CD	NA	True or False
[0..1]	R:ICD Existing Lead	"Abnormal Pacing "	ICD: 7130	CD	NA	True or False
[0..1]	R:ICD Existing Lead	"Abnormal Pacing Issue - Oversensing"	ICD: 7135	CD	NA	True or False
[0..1]	R:ICD Existing Lead	"Abnormal Pacing Issue - Undersensing"	ICD: 7140	CD	NA	True or False
[0..1]	R:ICD Existing Lead	"Abnormal Pacing Issue - Failure to Pace"	ICD: 7145	CD	NA	True or False
[0..1]	R:ICD Existing Lead	"Abnormal Pacing Issue - Failure to Capture with Acceptable Safety Margin"	ICD: 7150	CD	NA	True or False
[0..1]	R:ICD Existing Lead	"Abnormal Pacing Issue - Extracardiac Stimulation"	7155	CD	NA	True or False
[0..1]	R:ICD Existing Lead	" Abnormal Defibrillation Issues "	7160	CD	NA	True or False
[0..1]	R:ICD Existing Lead	" Abnormal Defibrillation Issue -Oversensing w/Shock or ATP"	7165	CD	NA	True or False
[0..1]	R:ICD Existing Lead	" Abnormal Defibrillation Issue -Oversensing w/o Shock or ATP"	7170	CD	NA	True or False
[0..1]	R:ICD Existing Lead	" Abnormal Defibrillation Issue -Failure to Shock with Inadequate DFT Safety Margin"	7175	CD	NA	True or False
[0..1]	R:ICD Existing Lead	" Lead Integrity Issue "	7180	CD	NA	True or False
[0..1]	R:ICD Existing Lead	" Lead Integrity Issue - Insulation Failure"	7185	CD	NA	True or False
[0..1]	R:ICD Existing Lead	" Lead Integrity Issue - Conductor Failure"	7190	CD	NA	True or False

Cardinality	Procedure Parameter Group	observation/code	Registry	HL7 v3 Data Type	Unit of Measure	Value Set
[0..1]	R:ICD	" Premarket Clinical Trial"	6040	CD	NA	True or False

6.4.6.9 Cardiac EP Activity Procedures - Vocabulary Constraints

The content creator shall be capable of creating EP activity procedures selected from Value Set 1.3.6.1.4.1.19376.1.4.1.5.52, listed below.

Table 6.4.6.9-1: Cardiac EP Activity Procedures 1.3.6.1.4.1.19376.1.4.1.5.52 STATIC

Coding Scheme / Concept		SNOMED CT
Venogram	ICD	4970003
Subclavian Venography	ICD	312731002
Radiographic procedure on cardiovascular system (type of venogram)	ICD	108276004
Arm Venogram	ICD	300906006
Venogram of Lower Extremity - Bilateral	ICD	25347009
Echo	ICD	40701008
ICD Implant	ICD(6135)	233170003(ICD)
ICD Implant(1 electrode)	ICD(6135)	425435003
ICD Implant(2 electrode)	ICD(6135)	427508005
ICD Implant(3 electrode)	ICD(6135)	442249009
ICD Implant (AICD)	ICD(6135)	45965006
ICD Implant(PACEMAKER)	ICD(6135)	233174007
ICD Replacement(replace cardiac pacemaker)	ICD(6005)	444566006
ICD Replacement (replace cardioverter/defibrillator)	ICD(6005)	428625001
ICD Replacement (replacement dual chamber pulse generator)	ICD(6005)	443434006

Concept \ Coding Scheme		SNOMED CT
ICD Replacement (replacement pulse generator)	ICD(6005)	3515001
ICD Explant (Device Explant)	ICD(6225)	62881002
Lead Placement (implant into atrium)	ICD(7030)	88722002
Lead Placement (implant in cardiac atrium and ventricle)	ICD(7030)	87825006
Lead Placement (ventricular pacing lead position)	ICD(7030)	398220006
Lead Extraction (Explant)	ICD(7030/7080)	233188006
Lead Replacement (Explant/Implant)	ICD(7030)	45921003
Lead Reuse	ICD(7030/7080)	
Lead Abandon	ICD(7030/7080)	
Creation of Cardiac Device Pocket		83333004

6.4.6.10 Cardiac Procedures - Vocabulary Constraints

The content creator shall be capable of creating cardiac procedures selected from Value Set 1.3.6.1.4.1.19376.1.4.1.5.63, listed below.

The content creator shall be capable of creating EP activity procedures selected from Value Set 1.3.6.1.4.1.19376.1.4.1.5.52, listed below.

Table 6.4.6.10-1: Cardiac Procedures 1.3.6.1.4.1.19376.1.4.1.5.63 STATIC

Concept \ Coding Scheme		SNOMED CT
Include Value Set 1.3.6.1.4.1.19376.1.4.1.5.52 Cardiac EP activity procedures		
Include Value Set 1.3.6.1.4.1.19376.1.4.1.5.40 Cardiac activity procedures which is found in the CRC content profile which can be found at http://www.ihe.net/uploadedFiles/Documents/Cardiology/IHE_CARD_Suppl_CRC.pdf		

6.4.6.11 ICD Implant Sites - Vocabulary Constraints

The content creator shall be capable of including an ICD implant site selected from Value Set 1.3.6.1.4.1.19376.1.4.1.5.53, listed below.

Table 6.4.6.11-1: ICD Implant Sites 1.3.6.1.4.1.19376.1.4.1.5.53 STATIC

Concept \ Coding Scheme	SNOMED CT
Abdominal	113345001
Pectoral	251007

6.4.6.12 Cardiac EP Complications - Vocabulary Constraints

The content creator shall be capable of including complications selected from Value Set 1.3.6.1.4.1.19376.1.4.1.5.54, listed below.

Table 6.4.6.12-1: Cardiac EP Complications 1.3.6.1.4.1.19376.1.4.1.5.54 STATIC

Coding Scheme / Concept	ACC NCDR ICD Seq#	SNOMED CT
CVA/Stroke	8085-EPRC	230690007
Cardiac Arrest	8005-EPRC	410429000
Drug Reaction	8010-EPRC	62014003
Cardiac Perforation	8015-EPRC	20681005
Cardiac Valve Injury	8020-EPRC	
Conduction Block	8025-EPRC	44808001
Coronary Venous Dissection	8030-EPRC	9406001
Postoperative Hematoma Formation	8035-EPRC	213262007
Postoperative Hemothorax	8040-EPRC	428782008
Infection Requiring Antibiotics	8045-EPRC	
Lead Dislodgement (displacement)	8050-EPRC	234213008 or 234233007
Pericardial Tamponade	8060-EPRC	35304003
Peripheral Embolus	8065-EPRC	286959000
Peripheral Nerve Injury	8070-EPRC	73590005
Set Screw Problem	8075-EPRC	
Pneumothorax	8080-EPRC	36118008
Urgent Cardiac Surgery	8090-EPRC	373110003
Venous Obstruction (distal to vascular access site)	8095-EPRC	307221007

6.4.6.13 Cardiac Drug Classes and Specific Cardiac Drugs - Vocabulary Constraints

The content creator shall be capable of creating cardiac procedure Cardiac Drug Classes and Specific Cardiac Drugs from Value Set 1.3.6.1.4.1.19376.1.4.1.5.55, listed below.

2845

Table 6.4.6.13-1: Cardiac Drug Classes and Specific Cardiac Drugs 1.3.6.1.4.1.19376.1.4.1.5.55 STATIC

Coding Scheme / Concept	ACC NCDR - ICD Seq#	SNOMED CT	NDF-RT (DRUG CLASSES)	RxNorm
ACE inhibitor	9045	372733002	N0000029130	836
Angiotensin receptor blocker	9100	96308008	N0000175561	133049
Thyroid replacement		61020000	N0000029627	691804
Aspirin, other antiplatelet agents	9105	7947003	N0000145918	1191
Calcium channel blockers	9120	48698004	N0000029119	1899
Calcium channel blockers - Amlodipine		108537001	N0000148333	17767
Calcium channel blockers - Atenolol+calcium channel blocker		346330007	N0000146784	1202
Calcium channel blockers - Bepridil		108530004	N0000147724	1436
Calcium channel blockers - Calcium-channel blocker+ACE		318172002		
Calcium channel blockers - Clevidipine		439624003	N0000178415	233603
Calcium channel blockers - Diltiazem	9115	59941008	N0000147814	3443
Calcium channel blockers - Felodipine		108535009	N0000148116	4316
Calcium channel blockers - Isradipine		108533002	N0000147660	33910
Calcium channel blockers - Lacidipine		319299000	N0000171781	28382
Calcium channel blockers - Lercanidipine		356862006		135056
Calcium channel blockers - Lidoflazine		319206000		6390
Calcium channel blockers - Mibefradil		319318006	N0000022079	83213
Calcium channel blockers - Nicardipine		108526002	N0000147944	7396
Calcium channel blockers - Nifedipine		85272000	N0000146717	7417
Calcium channel blockers - Nisoldipine		108524004	N0000148422	7435
Calcium channel blockers - Perhexiline		421776000		8050
Calcium channel blockers - Prenylamine		51908007		8674
Calcium channel blockers - Verapamil	9125	47898004	N0000148054	11170
Calcium channel blockers - Other	9120	48698004	N0000029119	1899
Beta-blockers	9110	33252009	N0000029118	691779
Erectile dysfunction medication: Sildenafil		109123009	N0000022115	136411
Erectile dysfunction medication: Tadalafil		407734006	N0000148829	358263
Nitrates		31970009	N0000007647	7439
Diuretic	9135	30492008		216676

Coding Scheme / Concept	ACC NCDR - ICD Seq#	SNOMED CT	NDF-RT (DRUG CLASSES)	RxNorm
Hydralazine	9140	22696000	N0000147869	5470
Antiarrhythmics		67507000	N0000029121	883
Antiarrhythmics: Potassium Channel Antagonist		415151000		
Antiarrhythmics: Amiodarone	9050	69236009	N0000147701	703
Antiarrhythmics: Propafenone	9080	96300001	N0000147996	8754
Antiarrhythmics: Flecainide	9065	46576005	N0000147848	4441
Antiarrhythmics: Dofetilide	9060	392658005	N0000148648	49247
Antiarrhythmics: Sotalol	9095	96301002	N0000148334	9947
Antiarrhythmics: Disopyramide	9055	76759004	N0000147821	3541
Antiarrhythmics: Dronedarone		443310000	N0000179804	233698
Antiarrhythmics: Quinidine	9090	31306009	N0000148010	9068
Antiarrhythmics: Procainamide	9075	11959009	N0000147989	8700
Digitalis		387521006	N0000147198	91235
Long Acting Nitroglycerin	9155	71759000	N0000145909	4917
Digitalis:Digoxin	9130	387461009	N0000146388	3407
Metformin		109081006	N0000021984	6809
Lipid-lowering medication		57952007	N0000029122	969
Lipid-lowering medication - Statin	9145	96302009		
Lipid-lowering medication - Non-Statin	9150	See list below		
Other antihypertensives		318641000	N0000029427	714568
Xanthines		417953004	N0000008118	1311085
Xanthines :Aminophylline		373508009	N0000146397	689
Xanthines:Theophylline		372810006	N0000146467	10438
Dipyridamole		66859009	N0000146237	3521
Inhaler		334980009	N0000177906	992544
Diabetic medications		384953001		
Lidocaine		82573000	N0000146592	6387
Diphenhydramine		26458009	N0000147816	3498
Hydromorphone		414428000	N0000147870	3423
Midazolam		26800000	N0000147927	6960
Normal Saline		262003004		125464
Isovue				Isovue 370 155031 Isovue-M-200 217822 Isovue-M-300 262238
Anticoagulants: Fondaparinux		395236007	N0000148733	321208
Anticoagulants: Low Molecular Weight Heparin		373294004	N0000007961	5227

Concept \ Coding Scheme	ACC NCDR - ICD Seq#	SNOMED CT	NDF-RT (DRUG CLASSES)	RxNorm
Anticoagulants:Unfractionated Heparin		96382006	N0000146860	5224
Anticoagulants:Warfarin	9175	48603004	N0000148057	11289
Direct Thrombin Inhibitors: Bivalirudin		400610005	N0000148708	60819
Glycoprotein IIb/IIIa Inhibitors			N0000009962	986894
Thienopyridines		108972005	N0000182125	1031667
Thienopyridines: Clopidogrel	9160	108979001	N0000022101	32968
Thienopyridines: Ticlopidine	9170	108971003	N0000148235	10594
Thienopyridines: Prasugrel	9165	443312008	N0000179815	613391
Thienopyridines:Ticagrelor			N0000182973	1116632

6.4.6.14 EP Postprocedure Diagnoses - Vocabulary Constraints

2850 The content creator shall be capable of including EP postprocedure diagnoses selected from Value Set 1.3.6.1.4.1.19376.1.4.1.5.56, listed below.

Table 6.4.6.14-1: EPRC Postprocedure Diagnoses 1.3.6.1.4.1.19376.1.4.1.5.56 STATIC

Concept \ Coding Scheme	SNOMED CT	ICD9 Codes	Section
Abnormal EKG	102594003	79431	Signs and Symptoms
Abnormal Echocardiogram	169241000	7932	Signs and Symptoms
Abnl pain: general		78907	Signs and Symptoms
Murmur	88610006	7852	Signs and Symptoms
Dizziness	404640003	7804	Signs and Symptoms
Syncope and collapse	271594007	7802	Signs and Symptoms
Syncope: Carotid sinus		33701	Signs and Symptoms
Palpitation	80313002	7851	Signs and Symptoms
Ventricular Tachycardia	25569003	7850	Signs and Symptoms
Atrial Tachycardia	276796006	7850	Signs and Symptoms
Alteration Aware, transient		78002	Signs and Symptoms
Chest pain: precordial	29857009	78651	Signs and Symptoms
Chest pain: unspecified	29857009	78650	Signs and Symptoms
Chest tightness/pressure	29857009	78659	Signs and Symptoms
Bacteremia	5758002	7907	Signs and Symptoms
Cardiogenic Shock	89138009	78551	Signs and Symptoms
Sleep apnea	73430006	78057	Signs and Symptoms
Fatigue: malaise	367391008	78079	Signs and Symptoms
Orthopnea	62744007	78602	Signs and Symptoms

Coding Scheme / Concept	SNOMED CT	ICD9 Codes	Section
Dyspnea	267036007	78605	Signs and Symptoms
Edema	267038008	7823	Signs and Symptoms
Fever	386661006	7806	Signs and Symptoms
AV Block: Complete	27885002 164906009	4260	Rhythm Block
1st degree	164947007	42611	Rhythm Block
2nd degree: Mobitz I	164905008	42613	Rhythm Block
2nd degree: Mobitz II	426183003	42612	Rhythm Block
Left Hemiblock	445118002	4262	Rhythm Block
LBBB	63467002 164909002	4263	Rhythm Block
RBBB	59118001 164907000	4264	Rhythm Block
RBBB/LAFB	30667004 445263008	42652	Rhythm Block
RBBB/LPFB	46319007 445393004	42651	Rhythm Block
Trifascicular Block	445309007	42654	Rhythm Block
Other Heart Block	164898000	4266	Rhythm Block
Conduction Disorder Unspecified	44808001	4269	Rhythm Block
AV Block Unspecified		42610	Rhythm Block
Sinoatrial Dysfunction	164901004	42781	Rhythm Block
Bifascicular Block	445481009	42653*	Rhythm Block
Atrial Fibrillation	49436004 164889003	42731	Rhythm-Supraventricular
Atrial Flutter	5370000 164890007	42732	Rhythm-Supraventricular
Supraventricular premature beats	63593006	42761	Rhythm-Supraventricular
SVT Supraventricular Tachycardia	426761007	4270	Rhythm-Supraventricular
Wolff-Parkinson-White	74390002 251116002 251117006	4267	Rhythm-Supraventricular
Sick Sinus Syndrome/Tachybrady	36083008	42781	Rhythm-Supraventricular
Bradycardia	426627000	42789	Rhythm-Supraventricular
Paroxys Tach, Unspecified	67198005	4272	Rhythm-Supraventricular
Card Dysrhyth Unspecified		4279	Rhythm-Supraventricular
Premature beats Unspecified	29717002	42760	Rhythm-Supraventricular
Long QT syndrome	111975006	42682	Rhythm-Supraventricular
Cardiac Arrest	410429000	4275	Rhythm-Ventricular

Coding Scheme / Concept	SNOMED CT	ICD9 Codes	Section
Ventricular premature beats	17338001	42769	Rhythm-Ventricular
Ventricular Fibrillation	164896001	42741	Rhythm-Ventricular
Ventricular Flutter	111288001	42742	Rhythm-Ventricular
Ventricular Tachycardia	164895002	4271	Rhythm-Ventricular
Peripheral vascular disease	400047006	4439	Rhythm-Ventricular
Congestive Failure	42343007	4280	Heart Failure
Left Vent Failure	195114002	4281	Heart Failure
Acute systolic	443254009	42821	Heart Failure
Chronic systolic	441481004	42822	Heart Failure
Acute diastolic	443343001	42831	Heart Failure
Chronic diastolic	441530006	42832	Heart Failure
Acute combined		42841	Heart Failure
Chronic combined		42842	Heart Failure
Acute/chronic systolic	443253003	42823	Heart Failure
Acute/chronic diastolic	443344007	42833	Heart Failure
Acute/chronic combined		42843	Heart Failure
Primary Idiopathic	63183009	4254	Myopathy
Alcoholic	19303008	4255	Myopathy
Postpartum	62377009	6748	Myopathy
Hypertrophic obstructive cardiomyopathy	45227007	4251	Myopathy
Ischemic	281091000	4148	Myopathy
Acute Myocarditis	46701001	42290	Myopathy
Cardiomegaly	8186001	4293	Myopathy
Benign Hypertension	10725009	4011	Hypertension
Malignant Hypertension	70272006	4010	Hypertension
Hypertension HD w/o CHF	77970009	40210	Hypertension
Hypertension HD w/ CHF	77737007	40211	Hypertension
Renal Hypertension	28119000	40511	Hypertension
Orthostatic Hypotension	28651003	4580	Hypotension
Chronic Hypotension	77545000	4581	Hypotension
Heart Transplant	119762001	V421	Heart Transplant
Failure	233934000	99683	Heart Transplant
Rejection	233933006	99683	Heart Transplant
Failure and Rejection	213151004	99683	Heart Transplant
Angina, unstable	4557003	4111	Coronary Disease
Angina, stable exertion	233819005	4139	Coronary Disease
Angina, Prinzmetal	87343002	4131	Coronary Disease
MI-anterior wall -MI-< 8 weeks	54329005	4101	Coronary Disease

Coding Scheme / Concept	SNOMED CT	ICD9 Codes	Section
MI-inferior wall - MI-< 8 weeks	73795002	4104	Coronary Disease
MI-lateral wall - MI-< 8 weeks	58612006	4105	Coronary Disease
MI-posterior wall - MI-< 8 weeks	233838001	4106	Coronary Disease
MI-nontransmural - MI-< 8 weeks		4107	Coronary Disease
Left Ventricular Aneurysm - Old MI > 8 weeks	297160003	41410	Coronary Disease
Left Ventricular Mural Thrombus - Old MI > 8 weeks	309519009	42979	Coronary Disease
CAD Native Vessel	1641000119107	41401	Coronary Disease
CAD-SVG		41402	Coronary Disease
CAD- Artery Bypass	371805005	41404	Coronary Disease
Acute idiopathic pericarditis	266235007	42091	Pericardial Disease
Constrictive pericarditis	85598007	4232	Pericardial Disease
Effusion or Tamponade	373945007	4239	Pericardial Disease
Transient ischemic attack (TIA)	266257000	4359	Cerebrovascular Disease
Vertebral Syndrome	34781003	4351	Cerebrovascular Disease
Basilar Syndrome	64009001	4350	Cerebrovascular Disease
Subclavian Steal	15258001	4352	Cerebrovascular Disease
Cerebrovascular accident (CVA)	230690007	436	Cerebrovascular Disease
Cerebral Embolism	75543006	43411	Cerebrovascular Disease
Prosthetic Valve		V433	Prosthetic Valves
Thrombus, Stenosis	234185004	99671	Prosthetic Valves
Leakage, Breakdown	234181008	99602	Prosthetic Valves
Infection	213038007	99661	Prosthetic Valves
Anemia-unspecified	271737000	2859	MISCELLANEOUS
Cardiac Contusion	17414004	86101	MISCELLANEOUS
Chest Wall Injury	65978000	9591	MISCELLANEOUS
NIDDM-Controlled (noninsulin-dependent diabetes mellitus, Type 2)	444110003	25000	MISCELLANEOUS
NIDDM-Uncontrolled (noninsulin-dependent diabetes mellitus, Type 2)	443694000	25002	MISCELLANEOUS
IDDM-Controlled (insulin-dependent diabetes mellitus, Type 1)	444074000	25001	MISCELLANEOUS
IDDM-Uncontrolled (insulin-dependent diabetes mellitus, Type 1)	444073006	25003	MISCELLANEOUS
Electrolyte Disorder	237840007	2769	MISCELLANEOUS

Coding Scheme / Concept	SNOMED CT	ICD9 Codes	Section
Hypercholesterolemia	13644009	2720	MISCELLANEOUS
Hypertriglyceridemia	302870006	2721	MISCELLANEOUS
Mixed Hyperlipidemia	267434003	2722	MISCELLANEOUS
Hyperkalemia	14140009	2767	MISCELLANEOUS
Hypokalemia	43339004	2768	MISCELLANEOUS
Hyponatremia	89627008	2761	MISCELLANEOUS
Hyperthyroidism	34486009	24290	MISCELLANEOUS
Hypothyroidism	40930008	2449	MISCELLANEOUS
Obesity	414916001	27800	MISCELLANEOUS
Obesity-Morbid	238136002	27801	MISCELLANEOUS
Postop Cardiac Complication	233816003	9971	MISCELLANEOUS
Renal Failure-chronic	90688005	585	MISCELLANEOUS
Renal Insufficiency	42399005	5939	MISCELLANEOUS
Wound- open, chest	127314000	8750	MISCELLANEOUS
Status Post CABG		V4581	PERSONAL HISTORY
Status Post PTCA		V4582	PERSONAL HISTORY
Diabetes mellitus	160303001	V180	FAMILY HISTORY
Ischemic Heart Disease	297242006	V173	FAMILY HISTORY
Other CV Disease	266894000	V174	FAMILY HISTORY
Sudden Cardiac Arrest		V12.53	FAMILY HISTORY
Congenital ventricular septal defect (VSD)	30288003	745.4	Congenital VSD
Congenital atrial septal defect (ASD)	405752007	745.5	Congenital VSD
Congenital Heart Block	46619002	746.86	Congenital VSD
Tetralogy of Fallot	86299006	745.2	Congenital VSD
Unspecified Congential Heart	30288003	746.9	Congenital VSD
Brugada Syndrome	418818005	746.89	Congenital VSD

6.4.6.15 VT Types - Vocabulary Constraints

The content creator shall be capable of including one the VT types selected from Value Set 1.3.6.1.4.1.19376.1.4.1.5.57, listed below.

Table 6.4.6.15-1: VT Types 1.3.6.1.4.1.19376.1.4.1.5.57 STATIC

Coding Scheme / Concept	SNOMED CT
Non-Sustained	444658006

Coding Scheme / Concept	SNOMED CT
Sustained monomorphic	251158004
Sustained polymorphic	251159007

6.4.6.16 Cardiovascular Family History - Vocabulary Constraint

The content creator shall be capable of creating a family history including concepts selected from Value Set 1.3.6.1.4.1.19376.1.4.1.5.58, listed below.

Table 6.4.6.16-1: Cardiovascular Family History 1.3.6.1.4.1.19376.1.4.1.5.58 STATIC

Coding Scheme / Concept	SNOMED CT
Family history of coronary artery disease	430091005
Family history: Diabetes mellitus	160303001
Family history of myocardial infarction	266897007
No Family history of Diabetes	160274005
No Family history of Cardiovascular disease	160270001
Family History Unknown	407559004
Family History of Sudden Death	430283008
Family history of Arrhythmias	429958001
Family history of recurrent syncope	430815001
Family history of ischemic heart disease	297242006
Familial cardiomyopathy	35728003
Acquired long QT syndrome	442946007
Congenital long QT syndrome	442917000
Short-QT Syndrome	77867006
Brugada syndrome	418818005
Overlap SCN5A Syndromes	
Arrhythmogenic right ventricular cardiomyopathy	281170005
Arrhythmogenic right ventricular dysplasia	253528005
Wolff-Parkinson-White pattern	74390002
Primary familial hypertrophic cardiomyopathy	83978005
Family history of atrial fibrillation	433276002
Catecholaminergic polymorphic ventricular tachycardia	419671004
Family history of aneurysm of artery	430102007
Family history of cardiovascular disease in first degree female relative less than 65 years of age	438825005
Family history of cardiovascular disease in first degree male relative less than 55 years of age	439724007

Concept \ Coding Scheme	SNOMED CT
Family history of cerebral artery occlusion	430674005
Family history of congenital anomaly of cardiovascular system	266908007
Family history of pulmonary embolism	430801003
Family history of stroke	275104002
Family history of transient ischemic attack	160363004
Family history of coronary arteriosclerosis	430091005
Family history of syncope	430815001
Family history: Hypertension	160357008
Family history: Migraine	160342001
Family history: premature coronary heart disease	134439009
FH: Cardiac disorder	275120007
FH: Thrombosis	310247005

6.4.6.17 Cardiac Lab Results - Vocabulary Constraints

The content creator shall be capable of creating cardiac lab results selected from Value Set 1.3.6.1.4.1.19376.1.4.1.5.59, listed below.

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Table 6.4.6.17-1: Cardiac Lab Results 1.3.6.1.4.1.19376.1.4.1.5.59 STATIC

Concept \ Coding Scheme	ACC NCDR - ICD 2.01 Seq#	units	LOINC	SNOMED
Cholesterol in HDL		mg/dL	2085-9	102737005
Cholesterol in LDL		mg/dL	2089-1	102739008
Total Cholesterol		mg/dL	2093-3	301860006
Cholesterol LDL/HDL ratio		ratio	16616-5	250743005
Triglyceride		mg/dL	2571-8	365795001
High sensitivity C reactive protein		mg/L	30522-7	55235003
Creatine kinase MB	PCI(7300/7325)	ng/mL	13969-1	250736004
Natriuretic peptide B (BNP)	PCI(5140)	pg/mL	30934-4	412905009
Natriuretic peptide B prohormone (NT-proBNP)	PCI(5145)	pg/mL	33762-6	407060002
Cardiac Troponin T		ug/L	6598-7	121871002
Cardiac Troponin I		ug/L	10839-9	121870001
Creatinine	PCI(5130)	mg/dL	2160-0	365756002
Hemoglobin A1c	PCI(5120)	g/dL	41995-2	43396009
Urea nitrogen (BUN)	PCI(5115)	mg/dL	3094-0	105011006
Fasting glucose		mg/dL	1557-8	271062006

Concept \ Coding Scheme	ACC NCDR - ICD 2.01 Seq#	units	LOINC	SNOMED
Platelets [Morphology] in Bone marrow			11126-0	488930013
Platelets Large/Platelets in Blood		%	48386-7	61928009/365632008
Potassium	PCI(5135)	mEq/L	11148-4	59573005/365760004
Prothrombin Time		s	5964-2	415184000
International Normalized Ratio (INR)		INR	34714-6	440685005
Red Blood Count (Erythrocytes)		10*12/L	26453-1	14089001
White Blood Count (Leukocytes)		10*3/uL	26464-8	767002
Albumin		g/dL	1747-5	26758005
Albumin/creatinine ratio		ug/mg	9318-7	250745003
Sodium	PCI(5125)	mEq/L	2950-4	25197003
Calcium		mmol/L	50837-4	71878006
Magnesium		mg/dL	29365-4	38151008
Thyroid stimulating hormone (TSH/Thyrotropin)		mlU/L	3015-5	61167004
Inflammatory markers				

6.4.6.18 Vital Signs Results - Value Set

The content creator shall be capable of creating vital signs organizers selected from Value Set 1.3.6.1.4.1.19376.1.4.1.5.60, listed below.

Table 6.4.6.18-1: Vital Signs Results 1.3.6.1.4.1.19376.1.4.1.5.60 STATIC

Concept \ Coding Scheme	Coding System	Code
Respiratory Rate	LOINC	9279-1
Heart Rate	LOINC	8867-4
O2 % BldC Oximetry	LOINC	2711-0
Oxygen measure site(like arm, leg) should be modeled as targetSiteCode for the vital sign observation	LOINC	8856-7
Cerebral oximetry (site) baseline should be modeled as targetSiteCode for the vital sign observation	LOINC	57801-3
BP Systolic	LOINC	8480-6
BP Diastolic	LOINC	8462-4
BP Mean	LOINC	8478-0
Body Temperature	LOINC	8310-5
Site for body temp (like Esophogeal, forehead, etc.) should be a	LOINC	8327-9

Concept \ Coding Scheme	Coding System	Code
targetSiteCode or methodCode for the vital sign observation		
Height	LOINC	8302-2
Height (Lying)	LOINC	8306-3
Height percentile	LOINC	8303-0
Head Circumference	LOINC	8287-5
Head circumference percentile	LOINC	8289-1
Weight Measured	LOINC	3141-9
Weight percentile	LOINC	8336-0
BMI (Body Mass Index)	LOINC	39156-5
BSA (Body Surface Area)	LOINC	3140-1
CO2 end tidal volume	LOINC	19889-5

6.4.6.19 Procedure Indications - Vocabulary Constraints

2880 The content creator shall be capable of creating procedure indications selected from Value Set 1.3.6.1.4.1.19376.1.4.1.5.61, listed below.

Table 6.4.6.19-1: Procedure Indications 1.3.6.1.4.1.19376.1.4.1.5.61 STATIC

Concept \ Coding Scheme	SNOMED CT
Chest Pain	29857009
Pre-operative Cardiovascular Exam	444733009
Coronary Artery Disease	53741008
Heart failure	84114007
Heart disease risk factors	171224000
Dyspnea	267036007
Post PTCA	373108000
History of CABG	399261000
Abnormal exercise tolerance test	165084003
Abnormal ECG	102594003
Arrhythmia	44808001
Angina pectoris	194828000
Hypertension	38341003
Palpitations	80313002
Supraventricular tachycardia	6456007
Syncope	271594007
History of Myocardial Infarction	399211009

Coding Scheme / Concept	SNOMED CT
Left bundle branch block	63467002
Valvular heart disease	368009
Occupational requirement	429060002
cardiogenic shock	89138009
ischemic heart disease	414545008
cardiac function test abnormal	165076002
heart transplant	32413006
heart disease - congenital	13213009
Cardiomyopathy	85898001
heart disease	56265001
Perioperative Evaluation	430091005
structural disorder of heart	128599005
Pericardial disease	55855009
Re-Implantation: End of battery life	
Re-Implantation: Replaced at time of lead revision	
Re-Implantation: Upgrade	
Re-Implantation: Infection	
Re-Implantation: Under Manufacturer Warranty	
Re-Implantation: Faulty Connector/Header	
Re-Implantation: Device relocation	
Manufacturer Recall: Generator	
Manufacturer Recall: Lead	
Primary Prevention	
Secondary Prevention	
Re-Implantation Generator Malfunction: Atrial Pacing	
Re-Implantation Generator Malfunction: LV Pacing	
Re-Implantation Generator Malfunction: RV Pacing	
Re-Implantation Generator Malfunction: Defibrillation	
Re-Implantation Generator Malfunction: Premature Battery Depletion	

6.4.6.20 Rx Recommendation - Vocabulary Constraints

The content creator shall be capable of creating an Rx recommendation selected from Value Set 1.3.6.1.4.1.19376.1.4.1.5.62, listed below.

Table 6.4.6.20-1: Rx Recommendation 1.3.6.1.4.1.19376.1.4.1.5.62 STATIC

Coding Scheme / Concept	SNOMED CT
Medical therapy	243121000
Counseling about disease	445142003
percutaneous coronary intervention (implicitly without planned CABG, unless there is a separate plan of care item for CABG)	415070008
coronary artery bypass graft	232717009
cardiac rehabilitation	313395003
Removal of dressing (after a certain amount of days)	118489002
Recommendation to avoid functional activity : Avoid lifting elbow above shoulder	304508008
Dressing change/wound care surveillance (in a number of days or weeks)	410379003
Pain control (as needed-perhaps a list here?)	225782006
Observe on telemetry unit, pressure dressing overnight	118414001
Keep wound dry (for a number of days or weeks)	
IV Antibiotics (for some number of doses)	
PA and lateral CXR to document lead position (like in am)	171229005
Device check (in a number of days or weeks)	
Chest X-Ray to rule out Pneumothorax	399208008
ECG (upon arrival to the floor)	29303009
Resume prior medications	
Follow-up (x number of weeks) at location	185389009
Bed Rest (x4 hours)	17535004

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Volume 3 Namespace Additions

Add the following terms to the IHE Namespace:

Level (e.g., Section/Document/Entry)	Template id	Name
Document template id	1.3.6.1.4.1.19376.1.4.1.**1.**3	Electrophysiology Implant/Explant Report Content (EPRC-IE)
Section template id	1.3.6.1.4.1.19376.1.4.1.**2.16**	Document Summary
Section template id	1.3.6.1.4.1.19376.1.4.1.**2.17**	Medical History - Cardiac
Section template id	1.3.6.1.4.1.19376.1.4.1.**2.19**	Procedure Description - Cardiac
Section template id	1.3.6.1.4.1.19376.1.4.1.**2.20**	Procedure Results - Cardiac
Section template id	1.3.6.1.4.1.19376.1.4.1.**2.21**	Key Images - Cardiac
Section template id	1.3.6.1.4.1.19376.1.4.1.**2.22**	Plan of Care - Cardiac
Section template id	1.3.6.1.4.1.19376.1.4.1.**2.23**	Pre-Procedure Results – Cardiac
Section template id	1.3.6.1.4.1.19376.1.4.1.**2.24**	Procedure Description – Cardiac EPIE
Section template id	1.3.6.1.4.1.19376.1.4.1.**2.25**	Procedure Results – Cardiac EPIE
Section template id	1.3.6.1.4.1.19376.1.4.1.**2.26**	Document Summary - EPRC
Entry template id	1.3.6.1.4.1.19376.1.4.1.**4.9**	Problem Observation – Cardiac
Entry template id	1.3.6.1.4.1.19376.1.4.1.**4.10**	Lesion Observation
Entry template id	1.3.6.1.4.1.19376.1.4.1.**4.11**	Result Organizer – Cardiac
Entry template id	1.3.6.1.4.1.19376.1.4.1.**4.12**	Procedure Device Organizer – Cardiac
Entry template id	1.3.6.1.4.1.19376.1.4.1.**4.13**	Device Observation
Entry template id	1.3.6.1.4.1.19376.1.4.1.**4.14**	Procedure Activity Procedure - Cardiac
Entry template id	1.3.6.1.4.1.19376.1.4.1.**4.15**	Procedure Results Organizer - Cardiac
Entry template id	1.3.6.1.4.1.19376.1.4.1.**4.16**	Result Observation – Cardiac
Entry template id	1.3.6.1.4.1.19376.1.4.1.**4.17**	Plan of Care Activity Act – Cardiac
Entry template id	1.3.6.1.4.1.19376.1.4.1.**4.18**	Device Observation - EPIE
Entry template id	1.3.6.1.4.1.19376.1.4.1.**4.19**	Procedure Activity Procedure – Cardiac EPIE
Entry template id	1.3.6.1.4.1.19376.1.4.1.**4.20**	Procedure Device Organizer – Cardiac EPIE
Entry template id	1.3.6.1.4.1.19376.1.4.1.**4.21**	Not yet allocated.
Entry template id	1.3.6.1.4.1.19376.1.4.1.**4.22**	Result Observation – Cardiac EPIE
Entry template id	1.3.6.1.4.1.19376.1.4.1.**4.23**	Procedure Results Organizer – Cardiac EPIE
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.**5.31**	Cardiac Problems / Concerns
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.**5.32**	Coronary Anatomy
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.**5.33**	Cardiovascular Family History
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.**5.34**	Contrast Agent Classes for Adverse Reactions
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.**5.35**	Cardiac Lab Results

Level (e.g., Section/Document/Entry)	Template id	Name
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.**5.36**	Vital Sign Result
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.**5.37**	Procedure Indications
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.**5.38**	Result Observations
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.**5.39**	Contrast Agents
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.**5.40**	Cardiac Cath LabActivity Procedures
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.**5.41**	Drug Classes and Specific Cardiac Drugs
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.**5.42**	Rx Recommendations
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.**5.43**	CRC Procedure Finding Types
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.**5.44**	CRC Postprocedure Diagnoses
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.**5.45**	Supported File Types
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.**5.46**	Complications
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.5.47	Anginal Class
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.5.48	NYHA Classes
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.5.49	Cardiac EP Problems/Concerns
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.5.50	ICD Device Types
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.5.51	EP Result Observations
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.5.52	Cardiac EP Activity Procedures
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.5.53	ICD Implant Site
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.5.54	Cardiac EP Complications
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.5.55	Cardiac Drug Classes and Specific Cardiac Drugs
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.5.56	EPRC Postprocedure Diagnoses
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.5.57	VT Types
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.5.58	Cardiovascular Family History
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.5.59	Cardiac Lab Results
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.5.60	Vital Signs Results
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.5.61	Procedure Indications
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.5.62	Rx Recommendations
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.5.63	Cardiac Procedures

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Volume 4 – National Extensions

Add appropriate country section

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