

2008 FYI
Implantable Cardioverter Defibrillators Registry v1.08
Data Dictionary - Definitions Only

A. Participant Administration

Field Name: Participant ID

Seq No: 1000

Definition: Participant ID is a unique number assigned to each Participant by the ACC-NCDR. An ACC-NCDR Participant is defined as one entity that signs a Participation Agreement with the ACC, submits one data submission file to the harvest, and gets back one Outcomes Report on their data.

Each Participant's data if submitted to harvest must be in one data submission file. If one Participant keeps their data in more than one file (e.g. at two sites), then the data must be combined into a single data submission file for the harvest.

If two or more Participants share a single purchased software, and enter cases into one database, then the data must be exported into different data submission files, one for each Participant ID.

Selections:

Field Name: Participant Name

Seq No: 1010

Definition: The full official hospital name of the facility where the implant procedure was performed. Values should be full, official hospital names with no abbreviations or variations in spelling for a single hospital.

Selections:

Field Name: Medicare Provider Number

Seq No: 1015

Definition: Indicate the medicare provider number of the facility at which the patient received the implant.

Selections:

Field Name: Participant NPI

Seq No: 1016

Definition: Indicate the hospital's (N)ational (P)rovider (I)dentifier. NPIs, assigned by CMS, are used to uniquely identify hospitals for Medicare billing purposes.

Selections:

Field Name: Timeframe of Data Submission

Seq No: 1020

Definition: Indicate the timeframe of data included in the data submission. Format: YYYYQQ. e.g. 2005Q4

Selections:

Field Name: Transmission Number

Seq No: 1040

Definition: A unique number created and automatically inserted by the software. It identifies the number of times the software has created data submission files. The transmission number should be incremented by one every time the data submission files are exported. The transmission number should never be repeated.

Selections:

Field Name: Software Vendor Identifier

Seq No: 1050

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Definition: Software Vendor Identification (agreed upon by mutual selection between the vendor and the ACC) to identify software vendor. Vendors must use consistent name identification across sites. Changes to Vendor Name Identification must be approved by the ACC.

Selections:

Field Name: Vendor software version **Seq No:** 1060

Definition: Vendor's software product name and version number identifying the software which created this record (assigned by vendor). Vendor controls the value in this field. Version passing certification/harvest testing will be noted at the ACC.

Selections:

Field Name: Registry Identifier **Seq No:** 1070

Definition: The ACC-NCDR Registry Identifier describes which ACC data registry these records apply. It is implemented in the software at the time the data is collected and the records are created. This is entered into the schema automatically by software.

Selections:

Field Name: Registry Version **Seq No:** 1080

Definition: Registry Version describes the version number of the Data Specifications/Dictionary, to which each record conforms. It identifies which fields should have data, and what are the valid data for each field. It is the version implemented in the software at the time the data is collected and the records are created. This is entered into the schema automatically by software.

Selections:

Field Name: Patient Population **Seq No:** 1090

Definition: Indicate the population of patients that should be included in the data export and submitted to the registry.

Selections:	Coding/Sort	Selection(Choose one)	Explanation
	1	All Patients	All patients regardless of insurance payor and ICD Indication.
	2	CMS Primary Prevention Patients	Patients with a Primary or Secondary insurance payor of "Medicare" and an ICD Indication of "Primary Prevention".

Field Name: Data Submission File Password **Seq No:** 1100

Definition: Indicates the ACC assigned password that should be applied to the data submission zip file.

Selections:

Field Name: Auxiliary 0 **Seq No:** 1110

Definition: Not for participant use. A 50 character text field that may be used to collect additional administrative information about the data submission.

Selections:

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B. Demographics

Field Name: Patient Last Name **Seq No:** 2000

Definition: Indicate the patient's last name.

Selections:

Field Name: Patient First Name **Seq No:** 2010

Definition: Indicate the patient's first name.

Selections:

Field Name: Patient Middle Name **Seq No:** 2020

Definition: Indicate the patient's middle name or middle initial.

Selections:

Field Name: Patient SSN **Seq No:** 2030

Definition: Indicate the nine digit patient's United States Social Security Number (SSN). If the patient does not have a US assigned SSN, then leave the SSN blank.

Selections:

Field Name: Unique Patient ID **Seq No:** 2040

Definition: This is an arbitrary number (not a recognizable ID like SSN or Medical Record Number) that uniquely identifies each patient. Once assigned to a patient at a health care facility, this will never be changed or reassigned to a different patient. If a patient returns to the same hospital, or for follow-up, they will receive this same unique patient identifier.

Selections:

Field Name: Other ID **Seq No:** 2045

Definition: An additional 'optional' patient identifier, such as medical record number, that can be associated with the patient.

Selections:

Field Name: Patient DOB **Seq No:** 2050

Definition: Indicate the patient's date of birth.

Selections:

Field Name: Gender **Seq No:** 2060

Definition: Indicate the patient's gender at birth.

Selections:

Coding/Sort	Selection(Choose one)	Explanation
1	Male	
2	Female	

Field Name: Race **Seq No:** 2070

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Definition: Indicate the patient's race as determined by the patient/family.

Selections:

Coding/Sort	Selection(Choose one)	Explanation
1	White	
2	Black/African American	
4	Asian	
5	American Indian/Alaska Native	
6	Native Hawaiian	
7	Other	

Field Name: Hispanic Ethnicity

Seq No: 2075

Definition: Indicate if the patient is of hispanic ethnicity.

Selections:

Coding/Sort	Selection(Choose one)	Explanation
0	No	
1	Yes	

Field Name: Auxiliary 1

Seq No: 2080

Definition: For participant use only. A 50 character text field that may be used to collect additional information about the patient or admission.

Selections:

Field Name: Auxiliary 2

Seq No: 2090

Definition: For participant use only. A 50 character text field that may be used to collect additional information about the patient or admission.

Selections:

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C. Admission

Field Name: Admission Date **Seq No:** 3000

Definition: Indicate the date on which the patient was admitted to the hospital for the current stay.

Selections:

Field Name: Date of Implant **Seq No:** 3010

Definition: Indicate the date of the ICD implant.

Note: In the event that multiple ICDs were implanted/explanted during a single admission, this is the date of the first/initial ICD implant. For clarification, see Sequence Numbers 3507, 3508.

Selections:

Field Name: Insurance Payor-Primary **Seq No:** 3020

Definition: Indicate the patient's primary insurance payor.

Selections:

Coding/Sort	Selection(Choose one)	Explanation
1	Government	Government refers to all individuals who are covered by a government health insurance plan, including Medicare and Medicaid.
2	Commercial	Commercial refers to all indemnity (fee-for-service) carriers and Preferred Provider Organizations (PPOs) (e.g. Blue Cross/Blue Shield).
3	HMO	HMO refers to a Health Maintenance Organization (HMO) characterized by coverage that provides health services for members on a pre-paid basis.
4	Non-U.S. Insurance	Non-US Insurance refers to individuals who reside in and have health insurance in another country.
5	None/Self Pay	None/Self Pay refers to individuals with no or limited health insurance; thus, the individual is the payor regardless of ability to pay.

Field Name: Government Type-Primary **Seq No:** 3025

Definition: Indicate the type of insurance if the patient's primary insurance payor is Government.

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Selections:	Coding/Sort	Selection(Choose one)	Explanation
	1	Medicare	
	2	Medicaid	
	3	TriCare	
	4	Veteran's Administration Health Plan	
	5	Federal Employee Insurance	

Field Name: Insurance Payor-Secondary

Seq No: 3027

Definition: Indicate the patient's secondary insurance payor.

Selections:	Coding/Sort	Selection(Choose one)	Explanation
	1	Government	
	2	Commercial	Commercial refers to all indemnity (fee-for-service) carriers and Preferred Provider Organizations (PPOs) (e.g. Blue Cross/Blue Shield).
	3	HMO	HMO refers to a Health Maintenance Organization (HMO) characterized by coverage that provides health services for members on a pre-paid basis.
	4	Non-U.S. Insurance	Non-US Insurance refers to individuals who reside in and have health insurance in another country.
	5	None/Self Pay	None/Self Pay refers to individuals with no or limited health insurance; thus, the individual is the payor regardless of ability to pay.

Field Name: Government Type-Secondary

Seq No: 3029

Definition: Indicate the type of insurance if the patient's secondary insurance payor is Government.

Selections:	Coding/Sort	Selection(Choose one)	Explanation
	1	Medicare	
	2	Medicaid	
	3	TriCare	
	4	Veteran's Administration Health Plan	
	5	Federal Employee Insurance	

Field Name: Reason for Admission

Seq No: 3030

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Definition: Indicate the primary reason the patient was hospitalized for this admission.

Selections:

Coding/Sort	Selection(Choose one)	Explanation
1	Admitted for this Procedure	Admitted for ICD implantation.
2	Cardiac-CHF	Admitted for management of heart failure other than implantation of an ICD.
3	Cardiac-Other	Admitted for a cardiac reason other than heart failure or implantation of an ICD.
4	Non-Cardiac	Admitted for a non-cardiac reason other than implantation of an ICD.

Field Name: Auxiliary 3

Seq No: 3040

Definition: For participant use only. A 50 character text field that may be used to collect additional information about the patient or admission.

Selections:

Field Name: Auxiliary 4

Seq No: 3050

Definition: For participant use only. A 50 character text field that may be used to collect additional information about the patient or admission.

Selections:

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D. History and Risk Factors

Field Name: Syncope

Seq No: 3060

Definition: Indicate if the patient had a sudden loss of consciousness, including loss of postural tone (not related to anesthesia) with spontaneous recovery as reported by the patient or an observer. Patient may experience syncope when supine.

Note: Patient history is defined as any time prior to the date of implant.

Selections:	Coding/Sort	Selection(Choose one)	Explanation
	0	No	
	1	Yes	

Field Name: Family Hx Sudden Death

Seq No: 3070

Definition: Indicate if the patient has a known family history (parent or sibling) of sudden cardiac death.

Sudden cardiac death is defined as a natural death due to cardiac causes heralded by abrupt loss of consciousness, occurring before 75 years of age. The time and mode of death are unexpected even though preexisting heart disease may have been known to be present. Traumatic death subsequently proven to be due to sudden loss of control due to a cardiac problem is included. Coding Exception: If the patient is adopted, or the family history is unavailable, code "No".

Note: Patient history is defined as prior to the current admission.

Selections:	Coding/Sort	Selection(Choose one)	Explanation
	0	No	
	1	Yes	

Field Name: CHF

Seq No: 3080

Definition: Indicate if the patient has a history of congestive heart failure (CHF), as documented in the medical record. Besides physician documentation of the CHF history, CHF can also be defined by one of the following:

1. Paroxysmal nocturnal dyspnea (PND);
2. Dyspnea on exertion (DOE) due to heart failure; or
3. Chest X-Ray (CXR) showing pulmonary congestion;
4. Pedal edema or dyspnea treated with medical therapy for heart failure.

Note: Patient history is defined as any time prior to the date of implant.

Selections:	Coding/Sort	Selection(Choose one)	Explanation
	0	No	
	1	Yes	

Field Name: CHF Duration

Seq No: 3090

Definition: Indicate the time since the initial CHF diagnosis.

Note: This includes any time prior to date of implant.

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Selections:	Coding/Sort	Selection(Choose one)	Explanation
	1	Within the past 3 months	
	2	3 to 9 months	
	3	Greater than 9 months	

Field Name: Prior CHF Hospitalization

Seq No: 3095

Definition: Indicate if the patient has ever been hospitalized for CHF prior to this admission. Indicate the timeframe associated with that hospitalization.

Note: This timeframe does NOT include this admission. The intent of this field is to capture hospitalizations for CHF excluding the current admission.

Selections:	Coding/Sort	Selection(Choose one)	Explanation
	0	Not Hospitalized	
	1	Yes-Within 6 months	
	2	Yes-Greater than 6 months	

Field Name: NYHA Class - Current Status

Seq No: 3100

Definition: Indicate the patient's New York Heart Association (NYHA) classification.

NOTE: For patients with no symptoms, code "Class 1".

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Selections:

Coding/Sort	Selection(Choose one)	Explanation
1	Class I	Patient has cardiac disease but without resulting limitations of ordinary physical activity. Ordinary physical activity (e.g., walking several blocks or climbing stairs) does not cause undue fatigue, palpitation, dyspnea, or anginal pain. Limiting symptoms may occur with marked exertion.
2	Class II	Patient has cardiac disease resulting in slight limitation of ordinary physical activity. Patient is comfortable at rest. Ordinary physical activity such as walking more than two blocks or climbing more than one flight of stairs results in limiting symptoms (e.g., fatigue, palpitation, dyspnea, or anginal pain).
3	Class III	Patient has cardiac disease resulting in marked limitation of physical activity. Patient is comfortable at rest. Less than ordinary physical activity (e.g., walking one to two level blocks or climbing one flight of stairs) causes fatigue, palpitation, dyspnea, or anginal pain.
4	Class IV	Patient has dyspnea at rest that increases with any physical activity. Patient has cardiac disease resulting in inability to perform any physical activity without discomfort. Symptoms may be present even at rest. If any physical activity is undertaken, discomfort is increased.

Field Name: Cardiac Arrest

Seq No: 3110

Definition: Indicate if the patient experienced cardiac arrest due to arrhythmia.

Note: Patient history is defined as any time prior to the date of implant.

Selections:

Coding/Sort	Selection(Choose one)	Explanation
0	No Arrest	
1	Brady Arrest	
2	Tachy Arrest	

Field Name: Brady Arrest Reason

Seq No: 3111

Definition: Indicate the reason(s) for the Brady Arrest.

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Selections:

Coding/Sort	Selection(Choose multiple)	Explanation
1	Acute MI	
2	Severe Electrolyte Disturbance	
3	Drug Induced Arrhythmia	
4	Sinus Node Dysfunction/AV Block	
5	Unknown Etiology	

Field Name: Tachy Arrest Reason

Seq No: 3112

Definition: Indicate the reason(s) for the Tachy Arrest.

Selections:

Coding/Sort	Selection(Choose multiple)	Explanation
1	Acute MI	
2	Severe Electrolyte Disturbance	
3	Drug Induced Arrhythmia	
4	Primary VT/VF	
5	Unknown Etiology	

Field Name: Atrial Fibrillation/Atrial Flu

Seq No: 3120

Definition: Indicate if the patient has a documented history of atrial fibrillation or flutter.

Note: Patient history is defined as any time prior to the date of implant.

Selections:

Coding/Sort	Selection(Choose one)	Explanation
0	No	
1	Yes	

Field Name: Ventricular Tachycardia

Seq No: 3130

Definition: Indicate if the patient has a history of ventricular tachycardia (either spontaneous or induced) that led to the placement of the ICD. Ventricular tachycardia is defined as a cardiac arrhythmia of 3 or more consecutive complexes in duration emanating from the ventricles at a rate greater than 100 bpm (cycle length less than 600 msec).

Note: Patient history is defined as any time prior to the date of implant.

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Selections:	Coding/Sort	Selection(Choose one)	Explanation
	0	No	No history of spontaneous ventricular tachycardia.
	1	Yes-VT, Non-Sustained	Three or more consecutive beats of ventricular origin, terminating spontaneously in less than 30 seconds.
	2	Yes-Monomorphic Sustained VT	VT greater than 30 seconds in duration and/or requiring termination due to hemodynamic compromise in less than 30 seconds.
	3	Yes-Polymorphic Sustained VT	VT with a constantly changing morphology lasting greater than 30 seconds in duration and/or requiring termination due to hemodynamic compromise in less than 30 seconds.

Field Name: Sinus Node Function

Seq No: 3140

Definition: Indicate if the patient's sinus node function was normal or abnormal.

Note: Timeframe includes any time prior to the date of implant.

Selections:	Coding/Sort	Selection(Choose one)	Explanation
	1	Normal	
	2	Abnormal	Abnormal - History of any pause longer than 3 seconds OR Tachy/Brady Syndrome.

Field Name: Cardiac Transplant

Seq No: 3150

Definition: Indicate if the patient had a history of cardiac transplant surgery.

Note: Patient history is defined as any time prior to the date of implant.

Selections:	Coding/Sort	Selection(Choose one)	Explanation
	0	No	
	1	Yes	

Field Name: Non-Ischemic Dilated Cardiomyopathy

Seq No: 3160

Definition: Indicate if the patient has a history of non-ischemic dilated cardiomyopathy documented by heart failure and reduced systolic function.

Note: Patient history is defined as any time prior to the date of implant.

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Selections:	Coding/Sort	Selection(Choose one)	Explanation
	0	No	
	1	Yes-Within the past 3 months	
	2	Yes-3 to 9 months	
	3	Yes-Greater than 9 months	

Field Name: Ischemic Heart Disease

Seq No: 3180

Definition: Indicate if the patient shows evidence of ischemic heart disease as documented by any of the following conditions:
 -At least one major epicardial artery with more than 70% obstruction by coronary angiography.
 -Other Diagnostic Tests: History of myocardial infarction associated with wall motion abnormality as shown by echocardiography or other cardiac imaging. Stress testing diagnostic of coronary artery disease with or without imaging; ECG with evidence of MI; history of chest pain associated with cardiac enzyme abnormality.

Note:

1. Patient history is defined as any time prior to the date of implant.
2. At least one major epicardial artery with more than 70% obstruction by coronary angiography takes precedence over other diagnostic tests if ischemic heart disease has been documented.

Selections:	Coding/Sort	Selection(Choose one)	Explanation
	0	No	
	1	Yes-At Least 1 Epicardial artery greater than 70% Obstruction	At least one epicardial artery greater than 70% obstruction (Angiography).
	2	Yes-Other Diagnostic Tests	History of myocardial infarction associated with wall motion abnormality as shown by echocardiography or other cardiac imaging. Stress testing diagnostic of coronary artery disease with or without imaging; ECG with evidence of MI; history of chest pain associated with cardiac enzyme abnormality.

Field Name: Previous MI

Seq No: 3190

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Definition: Indicate if the patient had a MI prior to the device implant.

The patient had at least one documented STEMI or NSTEMI. This can be coded based on physician documentation or history noted in the medical record.

Definitions: NON ST ELEVATION MYOCARDIAL INFARCTION (NSTEMI)

The patient was hospitalized for a myocardial infarction documented in the medical record.

AT LEAST ONE OF THE FOLLOWING BIOCHEMICAL INDICATORS for detecting myocardial necrosis must be present (see below for a definition of Reference Control Limits):

1) Troponin T or I:

a) Maximal concentration of troponin T or I > the MI decision limit on at least one occasion during the first 24 hours after the index clinical event.

2) CK-MB:

a) Maximal value of CK-MB > 2 x the upper limit of normal on one occasion during the first hours after the index clinical event. OR

b) Maximal value of CK-MB, preferable CK-MB mass, > upper limit of normal on two successive samples.

3) Total CK:

a) In the absence of availability of a troponin or CK-MB assay, total CK > 2 x the upper limit of normal, or the B fraction of CK may be employed, but these last two biomarkers are considerably less satisfactory than CK-MB.

AND ONE OF THE FOLLOWING:

1) Either ST segment depression or T wave abnormalities; or

2) Ischemic symptoms in the presence or absence of chest discomfort. Ischemic symptoms may include:

a) unexplained nausea and vomiting; or

b) persistent shortness of breath secondary to left ventricular failure; or

c) unexplained weakness, dizziness, lightheadedness, or syncope.

ST ELEVATION MYOCARDIAL INFARCTION (STEMI)

Indicate whether the patient was hospitalized for an ST Elevation Myocardial Infarction (STEMI) documented in the medical record.

AT LEAST ONE OF THE FOLLOWING BIOCHEMICAL INDICATORS for detecting myocardial necrosis must be present (see below for a definition of Reference Control Limits):

1) Troponin T or I:

a) Maximal concentration of troponin T or I > the MI decision limit on at least one occasion during the first 24 hours after the index clinical event.

2) CK-MB:

a) Maximal value of CK-MB > 2 x the upper limit of normal on one occasion during the first hours after the index clinical event; OR

b) Maximal value of CK-MB, preferable CK-MB mass, > upper limit of normal on two successive samples.

3) Total CK

a) In the absence of availability of a troponin or CK-MB assay, total CK > 2 x the upper limit of normal, or the B fraction of CK may be employed, but these last two biomarkers are considerably less satisfactory than CK-MB.

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Definition:

AND ONE OF THE FOLLOWING ECG CHANGES:

- 1) ST-segment elevation: New or presumed new ST segment elevation at the J point in two or more contiguous leads with the cut-off points ≥ 0.2 mV in leads V1, V2, or V3, or ≥ 0.1 mV in other leads; OR
- 2) Development of any Q wave in leads V1 through V3, or the development of a Q-wave \geq or = to 30 ms (0.03s) in leads I, II, aVL, aVF, V4, V5, or V6. (Q wave changes must be present in any two contiguous leads, and be \geq or = to 1mm in depth.)

Defining Reference Control Values (MI Diagnostic Limit and Upper Limit of Normal):

Reference values must be determined in each laboratory by studies using specific assays with appropriate quality control, as reported in peer-reviewed journals. Acceptable imprecision (coefficient of variation) at the 99th percentile for each assay should be defined as $<$ or = to 10%. Each individual laboratory should confirm the range of reference values in their specific setting.

Note: If more than one MI occurred, code the most recent event.

Selections:	Coding/Sort	Selection(Choose one)	Explanation
	0	No	
	1	Yes-Within 40 Days of ICD Implant	
	2	Yes-Greater than 40 Days prior to ICD Implant	
	3	Yes-Both Within 40 days/Greater than 40 days	

Field Name: Previous CABG

Seq No: 3200

Definition: Indicate if the patient had Coronary Bypass Graft Surgery by any approach.

Note: Patient history is defined as any time prior to the current admission. Timeframe does NOT include the current admission. CABGs performed during this admission should be coded within Sequence Number 3590: CABG During this Admission.

Selections:	Coding/Sort	Selection(Choose one)	Explanation
	0	No	
	1	Yes	

Field Name: Previous CABG Date

Seq No: 3210

Definition: Indicate the date of the most recent CABG. If month and/or day are not known enter 01.

Note: In the case of multiple CABGs prior to this admission, indicate the most recent.

Selections:

Field Name: Previous PCI

Seq No: 3220

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Definition: Indicate if the patient had a previous percutaneous coronary intervention (PCI) (even if unsuccessful) of any type (balloon angioplasty, stent or other), performed prior to the current admission.

Note: Timeframe does NOT include the current admission. PCIs performed during this admission should be coded within Sequence Number 3610: PCI During this Admission.

Selections:

Coding/Sort	Selection(Choose one)	Explanation
0	No	
1	Yes-Within the past 3 months	
2	Yes-Greater than 3 months	

Field Name: Previous Valvular Surgery **Seq No:** 3230

Definition: Indicate if the patient had a previous surgical replacement and/or repair of a cardiac valve, by any approach.

Note: Patient history is defined as any time prior to the date of implant.

Selections:

Coding/Sort	Selection(Choose one)	Explanation
0	No	
1	Yes	

Field Name: Permanent Pacemaker **Seq No:** 3240

Definition: Indicate if the patient had a Pacemaker inserted prior to current ICD implant. If yes, indicate the type of pacemaker.

Selections:

Coding/Sort	Selection(Choose one)	Explanation
0	No	
1	Yes-Atrial Chamber	
2	Yes-Ventricular Chamber	
3	Yes-Dual Chamber	Both atrial and ventricular chambers.
4	Yes-Biventricular	

Field Name: Previous ICD **Seq No:** 3250

Definition: Indicate if the patient had an ICD Implant procedure prior to this admission.

Note: Timeframe does NOT include the current admission. This device is coded within Sequence Number 3570: ICD Explant Device ID.

Selections:

Coding/Sort	Selection(Choose one)	Explanation
0	No	
1	Yes-Single Chamber	
2	Yes-Dual Chamber	
3	Yes-Biventricular	

Field Name: Previous ICD Date **Seq No:** 3260

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Definition: Indicate the date of the most recent previous ICD implant. If month and/or day are not known, enter 01.

Note: In the case of multiple implants prior to this admission, code the most recent.

Selections:

Field Name: Previous ICD Reason

Seq No: 3280

Definition: Indicate the previous ICD indication (reason for ICD implant).

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Selections:

Coding/Sort	Selection(Choose multiple)	Explanation
1	Primary Prevention	Primary Prevention was the original indication for patients who were at risk for sudden death but had not suffered from a spontaneous life-threatening ventricular arrhythmia, syncope, or sudden cardiac death.
2	Syncope with Inducible VT	Syncope: Sudden loss of consciousness with loss of postural tone, not related to anesthesia. Inducible VT refers to performance of electrophysiological testing with resulting induction of VT.
3	Spontaneous Monomorphic Sustained VT	VT with a constant morphology greater than 30 seconds in duration and/or requiring termination due to hemodynamic compromise in less than 30 seconds.
4	Spontaneous Polymorphic Sustained VT	VT with a constantly changing morphology lasting greater than 30 seconds in duration and/or requiring termination due to hemodynamic compromise in less than 30 seconds.
5	Ventricular Fibrillation	Rapid, usually more than 300 bpm (cycle length 180 msec or less), grossly irregular ventricular rhythm with marked variability in cycle length, lack of discernible discrete QRS complex.
6	Cardiac Arrest/Arrhythmia - Etiology Unknown	Sudden loss of consciousness requiring cardioversion or defibrillation to restore hemodynamic stability.
7	Syncope and High Risk Characteristics	Syncope: Sudden loss of consciousness with loss of postural tone, not related to anesthesia, and High Risk Characteristics specific for non-ischemic dilated cardiomyopathy, or ischemic heart disease with significant ventricular dysfunction, hypertrophic cardiomyopathy, Brugada Syndrome, Long QT Syndrome.

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Selections:	8	AFib	A cardiac arrhythmia arising from the atrium with an atrial rate greater than 300 bpm and an irregular ventricular response in the presence of conduction. AF can be further characterized as: First detected AF Paroxysmal AF: AF is self-terminating within 7 days of recognized onset. Persistent AF: AF is not self-terminating within 7 days, or is terminated electrically or pharmacologically. Chronic AF: AF lasting more than 6 months.
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Field Name: Previous ICD Implant Site

Seq No: 3290

Definition: Indicate the previous ICD implant site.

Selections:	Coding/Sort	Selection(Choose one)	Explanation
	1	Pectoral	
	2	Abdominal	

Field Name: Cerebrovascular Disease

Seq No: 3310

Definition: Indicate if the patient had cerebrovascular disease (CVD) prior to device implant, defined as any one of the following:

- Cerebrovascular Accident (CVA): Patient has a history of stroke, i.e., loss of neurological function with residual symptoms at least 72 hours after onset.
- Reversible Ischemic Neurologic Deficit (RIND): Patient has a history of loss of neurological function with symptoms at least 24 hours after onset but with complete return of function within 72 hours.
- Transient Ischemic Attack (TIA): Patient has a history of loss of neurological function that was abrupt in onset but with complete return of function within 24 hours.
- Non-invasive/invasive carotid test with greater than 75% occlusion.
- Previous carotid artery surgery. This does not include neurological disease processes such as metabolic and/or anoxic ischemic encephalopathy.

Note: Patient history is defined as any time prior to the date of implant.

Selections:	Coding/Sort	Selection(Choose one)	Explanation
	0	No	
	1	Yes	

Field Name: Chronic Lung Disease

Seq No: 3320

Definition: Indicate if the patient has a documented history of chronic lung disease prior to this admission (i.e. chronic obstructive pulmonary disease, emphysema, asthma, chronic bronchitis), or has been or is currently being treated with pharmacologic therapy.

Selections:	Coding/Sort	Selection(Choose one)	Explanation
	0	No	
	1	Yes	

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Field Name: Diabetes

Seq No: 3330

Definition: Indicate if the patient has a history of diabetes, regardless of duration of disease or need for antidiabetic agents. It does not include gestational diabetes.

Note: Patient history is defined as any time prior to the date of implant.

Selections:	Coding/Sort	Selection(Choose one)	Explanation
	0	No	
	1	Yes	

Field Name: Hypertension

Seq No: 3340

Definition: Indicate if the patient has a history of hypertension defined as any one of the following:
 1. History of hypertension diagnosed and treated with medication, diet and/or exercise.
 2. Blood pressure greater than 140 systolic or 90 diastolic on at least 2 occasions.
 3. Currently on antihypertensive pharmacologic therapy.

Note: Patient history is defined as any time prior to the date of implant.

Selections:	Coding/Sort	Selection(Choose one)	Explanation
	0	No	
	1	Yes	

Field Name: Renal Failure-Dialysis

Seq No: 3350

Definition: Indicate if the patient received or is receiving dialysis as a result of renal failure.

Note: Patient history is defined as any time prior to the date of implant.

Selections:	Coding/Sort	Selection(Choose one)	Explanation
	0	No	
	1	Yes	

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Implantable Cardioverter Defibrillators Registry v1.08
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E. Diagnostic Studies

Field Name: Ejection Fraction Assessed

Seq No: 3360

Definition: Indicate if the patient's ejection fraction was assessed before or during the EP lab visit via invasive (i.e. LV gram) or non-invasive testing (i.e. Echo).

Selections:	Coding/Sort	Selection(Choose one)	Explanation
	0	No	
	1	Yes	

Field Name: EF %

Seq No: 3370

Definition: Indicate the lowest Ejection Fraction percent that led to the decision to implant the ICD. The Ejection Fraction percent is the percentage of blood that has emptied from the ventricle at the end of the contraction.

Selections:

Field Name: EF Timeframe

Seq No: 3380

Definition: Indicate the timeframe of the Ejection Fraction percent that led to the decision to implant the ICD.

Selections:	Coding/Sort	Selection(Choose one)	Explanation
	1	0 to 1 month	0 to 1 month (up to 30 days)
	2	1 to 2 months	1 to 2 months (31-60 days)
	3	2 to 3 months	2 to 3 months (61-90 days)
	4	3 to 6 months	3 to 6 months (91-180 days)
	5	6 to 12 months	6 to 12 months (181-365 days)
	6	Greater than 12 months	Greater than 12 months (366 days and greater)

Field Name: Electrophysiology Study Done

Seq No: 3390

Definition: Indicate if the patient had an EP Study prior to the ICD implant.

Selections:	Coding/Sort	Selection(Choose one)	Explanation
	0	No	
	1	Yes	

Field Name: EPS Timeframe

Seq No: 3400

Definition: Indicate the timeframe of the most recent Electrophysiology study.

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Selections:	Coding/Sort	Selection(Choose one)	Explanation
	1	0 to 1 month	0 to 1 month (up to 30 days)
	2	1 to 2 months	1 to 2 months (31-60 days)
	3	2 to 3 months	2 to 3 months (61-90 days)
	4	3 to 6 months	3 to 6 months (91-180 days)
	5	6 to 12 months	6 to 12 months (181-365 days)
	6	Greater than 12 months	Greater than 12 months (366 days and greater)

Field Name: EPS Findings

Seq No: 3410

Definition: Indicate the findings associated with the most recent Electrophysiology Study. If "No Arrhythmias Induced" is selected, no other selections may be chosen.

Selections:	Coding/Sort	Selection(Choose multiple)	Explanation
	0	No Arrhythmias Induced	
	1	VT Induced	
	2	Non-sustained VT	
	3	Sustained Monomorphic	
	4	Sustained Polymorphic	
	5	Ventricular Flutter Induced	
	6	Ventricular Fibrillation Induced	
	7	Results Unattainable	The results of the EP Study could not be obtained or located.

Field Name: QRS Duration

Seq No: 3420

Definition: Indicate the patient's QRS duration in milliseconds from simultaneous (preferably 3 or more) ECG leads, including I, II, and VI, from the onset to the termination of the QRS.

Note: Indicate the most recent EKG findings prior to the ICD implant.

Selections:

Field Name: PR Interval Attainable

Seq No: 3429

Definition: Indicate if the patient's PR Interval was attainable. No should be answered when a patient has Afib, a greater than 1st Degree Heart block or has a Ventricular Paced rhythm.

Selections:	Coding/Sort	Selection(Choose one)	Explanation
	0	No	
	1	Yes	

Field Name: PR Interval

Seq No: 3430

Definition: Indicate the patient's longest measured time in milliseconds from onset of P wave to onset of QRS complex in any given ECG lead.

Note: Indicate the most recent EKG findings prior to the ICD implant.

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Selections:

Field Name: AV Conduction

Seq No: 3440

Definition: Indicate the patient's Atrioventricular Conduction rhythm.

Note: Indicate the EKG findings leading to the decision to implant the ICD.

Selections:	Coding/Sort	Selection(Choose one)	Explanation
	1	Normal	
	2	Abnormal-1st Degree Heart Block Only	
	3	Abnormal-Heart Block 2nd or 3rd Degree (not paced)	
	4	Paced(any)	

Field Name: Intraventricular Conduction

Seq No: 3450

Definition: Indicate the patient's Intraventricular Conduction.

Note: Indicate the EKG findings leading to the decision to implant the ICD.

Selections:	Coding/Sort	Selection(Choose one)	Explanation
	1	Normal	
	2	Abnormal-Left Anterior Fascicular Block	
	3	Abnormal-Left Posterior Fascicular Block	
	4	Abnormal-LBBB	
	5	Abnormal-RBBB	
	6	Abnormal-Intraventricular Conduction Delay, Nonspecific	
	7	Paced	
	8	Abnormal-Bifascicular Block (RBBB Plus LAF)	
	9	Abnormal-Bifascicular Block (RBBB Plus LPF)	

Field Name: Creatinine Level

Seq No: 3460

Definition: Indicate the patient's most recent preoperative Creatinine level prior to the ICD implant. The creatinine level is measured in mg/dL.

Selections:

Field Name: BUN Level

Seq No: 3470

Definition: Indicate the patient's most recent preoperative BUN (Blood Urea Nitrogen) level prior to the ICD implant. The BUN level is measured in mg/dL.

Selections:

Field Name: Sodium Level

Seq No: 3480

Definition: Indicate the patient's most recent preoperative Sodium level prior to the ICD implant. The Sodium level is measured in mEq/L.

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Selections:

Field Name: BNP Drawn

Seq No: 3485

Definition: Indicate if the patient had a preoperative BNP (B-type Natriuretic Peptide) drawn prior to the ICD implant.

Selections:

Coding/Sort	Selection(Choose one)	Explanation
0	No	
1	Yes	

Field Name: BNP Level

Seq No: 3490

Definition: Indicate the patient's most recent preoperative BNP (B-type Natriuretic Peptide) prior to the ICD implant. The BNP is measured in pg/mL.

Selections:

Field Name: Systolic BP

Seq No: 3500

Definition: Indicate the patient's systolic blood pressure on day of implant prior to sedation. Measured in mm-Hg.

Selections:

2008 FYI Update
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F. ICD Procedure(s)

Field Name: ICD Indication

Seq No: 3505

Definition: Indicate the reason for the first ICD implantation in this patient's lifetime.

Selections:

Coding/Sort	Selection(Choose one)	Explanation
1	Primary Prevention	Primary prevention is an indication for patients who are at risk for sudden death but have not yet suffered from a spontaneous life-threatening ventricular arrhythmia, syncope, or sudden cardiac death. (This includes patients who have never experienced syncope or cardiac arrest but have inducible ventricular tachycardia during electrophysiologic testing for risk stratification.)
2	Secondary Prevention	Secondary prevention is an indication for patients who have already experienced a spontaneous life-threatening ventricular arrhythmia, a cardiac arrest, or unexplained syncope with workup suggesting a high probability that a ventricular tachyarrhythmia was the cause of the syncope.

Field Name: Reason(s) for Re-implantation

Seq No: 3506

Definition: Indicate the reason(s) why device was re-implanted.

Note: Applicable only if Sequence Number 3250: Previous ICD, is "Yes".

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Selections:	Coding/Sort	Selection(Choose multiple)	Explanation
	1	End of Battery Life	The manufacturer's designation that the pulse generator battery has reached the end of its service life.
	2	Device Upgrade	Replacement of a pulse generator with a model with additional pacing capabilities such as an upgrade from a single to a dual chamber device, or the replacement of a non-CRT device with a CRT device.
	3	Device Infection	Replacement of a device because of an infection involving a previously implanted device
	4	Device Malfunction	Replacement of a device because of a malfunction involving a previously implanted device
	5	Device Under Manufacturer Advisory/Recalled	A device model recognized by the manufacturer as demonstrating a recurring performance failure resulting in an advisory letter to physicians. This may or may not reach the level of an FDA designated recall.

Field Name: Mult ICDs implanted during admit

Seq No: 3507

Definition: Indicate if multiple ICD devices were implanted during the current admission.

Note: This field is meant to capture whether an ICD was implanted AND explanted during the current admission. Code "No" if the patient had only one implant during the current admission.

Selections:	Coding/Sort	Selection(Choose one)	Explanation
	0	No	
	1	Yes	

Field Name: Reason for Device Repl during admit

Seq No: 3508

Definition: Indicate the reason(s) for multiple implants during the current admission.

Note: Applicable only if Sequence Number 3507: Multiple ICDs implated during this admission, is "Yes".

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Selections:	Coding/Sort	Selection(Choose multiple)	Explanation
	1	Device Upgrade	Replacement of a pulse generator with a model with additional pacing capabilities such as an upgrade from a single to a dual chamber device, or the replacement of a non-CRT device with a CRT device.
	2	Device Infection	Replacement of a device because of an infection involving a previously implanted device
	3	Device Malfunction	Replacement of a device because of a malfunction involving a previously implanted device
	4	Device Under Manufacturer Advisory/Recalled	A device model recognized by the manufacturer as demonstrating a recurring performance failure resulting in an advisory letter to physicians. This may or may not reach the level of an FDA designated recall.

Field Name: Implant Operator UPIN

Seq No: 3510

Definition: Indicate the implanting physician's (U)nique (P)hysician (I)dentification (N)umber. UPINs, assigned by CMS, are used to uniquely identify physicians for Medicare billing purposes and may contain any letter or number character combination. The UPIN should be specified for the physician implanting the device, not the physician placing the leads. Implanting physician is determined by the individual institution.

Selections:

Field Name: Implant Operator NPI

Seq No: 3515

Definition: Indicate the physician's (N)ational (P)rovider (I)dentifier. NPIs, assigned by CMS, are used to uniquely identify physicians for Medicare billing purposes. The NPI should be specified for the physician implanting the device, not the physician placing the leads.

Selections:

Field Name: Implant Operator First Name

Seq No: 3520

Definition: Indicate the implant operator's first name.

Selections:

Field Name: Implant Operator Middle Name

Seq No: 3525

Definition: Indicate the implant operator's middle name or middle initial.

Selections:

Field Name: Implant Operator Last Name

Seq No: 3530

Definition: Indicate the implant operator's last name.

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Selections:

Field Name: ICD Type **Seq No:** 3540

Definition: Indicate the type of ICD implanted.

Selections:	Coding/Sort	Selection(Choose one)	Explanation
	1	Single Chamber	
	2	Dual Chamber	
	3	Biventricular	

Field Name: LV Lead Implantation Method **Seq No:** 3550

Definition: Indicate the method for implanting the LV lead.

Selections:	Coding/Sort	Selection(Choose one)	Explanation
	1	Coronary Sinus	
	2	Epicardial Lead	
	3	Other	

Field Name: ICD Manufacturer **Seq No:** 3560

Definition: Indicate the manufacturer of the implanted or explanted ICD.

Selections:

Field Name: ICD Model Name **Seq No:** 3561

Definition: Indicate the model name of the implanted or explanted ICD.

Selections:

Field Name: ICD Model Number **Seq No:** 3562

Definition: Indicate the model number of the implanted or explanted ICD.

Selections:

Field Name: ICD Implant Device ID **Seq No:** 3565

Definition: Indicate the unique ACC assigned identification number associated with the implanted device. The ACC will assign a unique identification number for each unique ICD device manufacturer, model and model number. The list of ICDs will be maintained by the ACC and added to the data entry tool as each new device receives FDA approval. Third party software vendors certified by the ACC will be required to download and import the ICD master list so that newly approved devices can be specified and submitted to the ACC. Only one ICD Implant Device can be specified. Note: In the event of multiple implantations, code the final/last device implanted during the current admission.

Selections:

Field Name: ICD Implant Serial Number **Seq No:** 3566

Definition: Indicate the ICD Device Serial Number associated with the implanted device.

Selections:

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Data Dictionary - Definitions Only

Field Name: ICD Explant Device ID

Seq No: 3570

Definition: Indicate the unique ACC assigned identification number associated with the explanted device. The ACC will assign a unique identification number for each unique ICD device manufacturer, model and model number. The list of ICDs will be maintained by the ACC and added to the data entry tool as each new device receives FDA approval. Third party software vendors certified by the ACC will be required to download and import the ICD master list so that newly approved devices can be specified and submitted to the ACC. Only one ICD Explant Device can be specified.

Note(1): Applicable only if Sequence Number 3250: Previous ICD, is "Yes". The intent of this field is to record the device in the patient at the time of admission for the current hospital stay.

Note(2): This field is NOT to be used in the event of multiple implantations (Sequence Number 3507:Multiple ICDs implanted during this admission, is "Yes").

Selections:

Field Name: ICD Explant Serial Number

Seq No: 3571

Definition: Indicate the ICD Device Serial Number associated with the explanted device.

Selections:

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Data Dictionary - Definitions Only

G. Adverse Events

Field Name: Available Adverse Events **Seq No:** 3575

Definition: Indicate the Adverse Events that were downloaded from the ACC website and imported into the ICD data collection tool. This element will be used to determine if the participant has the right adverse events in the ICD data collection tool for every admission.

Selections:

Field Name: Adverse Events Exist **Seq No:** 3580

Definition: Indicate if the patient had any adverse events during or after the EP lab visit up until discharge. If "Yes" then complete the Adverse Events section.

Selections:

Coding/Sort	Selection(Choose one)	Explanation
0	No	
1	Yes	

Field Name: Adverse Event **Seq No:** 3581

Definition: Indicate the Adverse Event that occurred during or after the EP lab visit up until discharge. The same adverse event can be repeated with a different adverse event date.

Note: The initial set of Adverse Events that should be collected are documented in Appendix A of the data dictionary. These Adverse Events may be updated periodically by the ACC. When the Adverse Events have been updated, participants utilizing non-ACC software will be instructed to download and import the latest version of Adverse Event file into their data collection tool.

Selections:

Field Name: Adverse Event Date **Seq No:** 3583

Definition: Indicate the date that the Adverse Event occurred.

Selections:

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Data Dictionary - Definitions Only

H. Discharge

Field Name: CABG During This Admission

Seq No: 3590

Definition: Indicate if the patient had a CABG (Coronary Artery Bypass Graft Surgery) during the current admission.

Note: If multiple CABGs are performed during this admission, code the date of the CABG performed closest to the date of implant.

Selections:	Coding/Sort	Selection(Choose one)	Explanation
	0	No	
	1	Yes	

Field Name: CABG Date

Seq No: 3600

Definition: Indicate the date Coronary Artery Bypass Graft (CABG) Surgery was performed during the current admission.

Selections:

Field Name: PCI During This Admission

Seq No: 3610

Definition: Indicate if the patient had a PCI during this admission.

Note: If multiple PCIs are performed during this admission, code the date of the PCI performed closest to the date of implant.

Selections:	Coding/Sort	Selection(Choose one)	Explanation
	0	No	
	1	Yes	

Field Name: PCI Date

Seq No: 3620

Definition: Indicate the date PCI was performed during the current admission.

Selections:

Field Name: Vital Status

Seq No: 3630

Definition: Indicate if the patient expired during the hospital stay. If "Yes," indicate the cause of death.

Selections:	Coding/Sort	Selection(Choose one)	Explanation
	1	Alive	
	2	Deceased-Cardiac Death	
	3	Deceased-Non-Cardiac Death	

Field Name: Date of Death This Admit

Seq No: 3640

Definition: Indicate the date the patient expired during this hospitalization.

Selections:

Field Name: Death in Lab

Seq No: 3645

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Definition: Indicate if the patient's death occurred in the lab where the device was implanted

Selections:

Coding/Sort	Selection(Choose one)	Explanation
0	No	
1	Yes	

Field Name: Date of Discharge

Seq No: 3650

Definition: Indicate the patient's date of discharge.

Selections:

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Data Dictionary - Definitions Only

I. Discharge Medications

Field Name: Discharge Medication

Seq No: 3660

Definition: Indicates the discharge medication.

Note: The initial set of discharge medications that should be collected are documented in Appendix B of the data dictionary. These medications may be updated periodically by the ACC. When the discharge medications have been updated, participants utilizing non-ACC software will be instructed to download and import the latest version of medication file into their data collection tool.

Selections:

Field Name: Discharge Medication Prescribed

Seq No: 3665

Definition: Indicate if discharge medication was prescribed, not prescribed, contraindicated or blinded.

Note: "Blinded" should be specified if the patient was in a research study and the prescribing of this specific medication is unknown.

Selections:

Coding/Sort	Selection(Choose one)	Explanation
0	No	
1	Yes	
2	Contraindicated	
3	Blinded	

Appendix A - Adverse Events

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Implantable Cardioverter Defibrillators Registry v1.08

Adverse Events

Field Name: Cardiac Arrest

Adverse Event Seq No: ae001

Adverse Event ID: 1

Effective Date: 01/01/2004

Expiration Date:

Definition: Indicate if the patient experienced a cardiac arrest as documented by sudden cessation of cardiac activity so that the patient became unresponsive, with no normal breathing and no signs of circulation.

Field Name: Drug Reaction

Adverse Event Seq No: ae002

Adverse Event ID: 2

Effective Date: 01/01/2004

Expiration Date:

Definition: Indicate if the patient experienced a drug reaction as documented by anaphylaxis, rash, etc.

Field Name: Cardiac Perforation

Adverse Event Seq No: ae003

Adverse Event ID: 3

Effective Date: 01/01/2004

Expiration Date:

Definition: Indicate if the patient experienced a cardiac perforation as documented by migration of pacing or defibrillator lead to epicardial surface, resulting in pain, pericardial effusion, failure to capture, capture of diaphragm, phrenic nerve, or intercostals muscle of sufficient magnitude to require repositioning.

Field Name: Cardiac Valve Injury

Adverse Event Seq No: ae004

Adverse Event ID: 4

Effective Date: 01/01/2004

Expiration Date:

Definition: Indicate if the patient experienced a cardiac valve injury as documented by manipulation of pacing or defibrillating leads that may tear a valve leaflet or chordae tendinae (usually manifests as a new regurgitant murmur appearing after the procedure).

Field Name: Conduction Block

Adverse Event Seq No: ae005

Adverse Event ID: 5

Effective Date: 01/01/2004

Expiration Date:

Definition: Indicate if the patient experienced a conduction block as documented by manipulation of pacing or defibrillating leads that may injure parts of the specialized cardiac conducting system. (Usually manifest as a new RBBB or new onset of complete heart block in a person with preexisting LBBB).

Field Name: Coronary Venous Dissection

Adverse Event Seq No: ae006

Adverse Event ID: 6

Effective Date: 01/01/2004

Expiration Date:

Appendix A - Adverse Events

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Implantable Cardioverter Defibrillators Registry v1.08

Definition: Indicate if the patient experienced a coronary venous dissection as documented by manipulation of pacing or defibrillating leads in the coronary sinus (CS) may result in a tear of the CS endothelium, with dissection into the CS wall. This may occasionally result in perforation of the CS.

Field Name: Hematoma

Adverse Event Seq No: ae007

Adverse Event ID: 7

Effective Date: 01/01/2004

Expiration Date:

Definition: Indicate if the patient experienced hematoma resulting in reoperation or transfusion.

Field Name: Lead Dislodgement

Adverse Event Seq No: ae008

Adverse Event ID: 8

Effective Date: 01/01/2004

Expiration Date:

Definition: Indicate if the patient experienced a lead dislodgement as documented by movement of lead sufficient to require repositioning.

Field Name: Hemothorax

Adverse Event Seq No: ae009

Adverse Event ID: 9

Effective Date: 01/01/2004

Expiration Date:

Definition: Indicate if the patient experienced a hemothorax as documented by accumulation of blood in thorax.

Field Name: Pneumothorax

Adverse Event Seq No: ae010

Adverse Event ID: 10

Effective Date: 01/01/2004

Expiration Date:

Definition: Indicate if the patient experienced a pneumothorax as documented by air in thorax sufficient to require chest tube.

Field Name: Peripheral Nerve Injury

Adverse Event Seq No: ae011

Adverse Event ID: 11

Effective Date: 01/01/2004

Expiration Date:

Definition: Indicate if the patient experienced peripheral nerve injury as documented by sensory or motor loss of peripheral nerve function. This may result from external nerve compression as a result of positioning during an implantation procedure, internal compression (e.g. secondary to hematoma formation) or direct nerve.

Field Name: Peripheral Embolus

Adverse Event Seq No: ae012

Adverse Event ID: 12

Effective Date: 01/01/2004

Expiration Date:

Definition: Indicate if the patient experienced a peripheral embolus as documented by acute occlusion of an artery resulting from embolization of a cardiac or proximal arterial thrombus.

Field Name: Phlebitis - Superficial

Adverse Event Seq No: ae013

Appendix A - Adverse Events

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Adverse Event ID: 13

Effective Date: 01/01/2004

Expiration Date:

Definition: Indicate if the patient experienced superficial phlebitis as documented by signs of superficial venous inflammation, such as local erythema, tenderness or swelling.

Field Name: Phlebitis - Deep

Adverse Event Seq No: ae014

Adverse Event ID: 14

Effective Date: 01/01/2004

Expiration Date:

Definition: Indicate if the patient experienced deep phlebitis as documented by occlusion of deep vein resulting in extremity swelling, plus or minus signs of inflammation.

Field Name: TIA

Adverse Event Seq No: ae015

Adverse Event ID: 15

Effective Date: 01/01/2004

Expiration Date:

Definition: Indicate if the patient experienced a TIA as documented by loss of neurological function that was abrupt in onset but with complete return of function within 24 hours.

Field Name: CVA/Stroke

Adverse Event Seq No: ae016

Adverse Event ID: 16

Effective Date: 01/01/2004

Expiration Date:

Definition: Indicate if the patient experienced a cerebrovascular accident (CVA) as documented by a central neurological deficit persisting for > 72 hours.

Field Name: MI

Adverse Event Seq No: ae017

Adverse Event ID: 17

Effective Date: 01/01/2004

Expiration Date:

Appendix A - Adverse Events

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Implantable Cardioverter Defibrillators Registry v1.08

Definition: Indicate if the patient experienced an MI during the EP lab visit or after lab visit until discharge (or before any subsequent lab visits) as documented by:
Definitions: NON ST ELEVATION MYOCARDIAL INFARCTION (NSTEMI)
The patient was hospitalized for a myocardial infarction documented in the medical record.
AT LEAST ONE OF THE FOLLOWING BIOCHEMICAL INDICATORS for detecting myocardial necrosis must be present (see below for a definition of Reference Control Limits):

1) Troponin T or I:

a) Maximal concentration of troponin T or I > the MI decision limit on at least one occasion during the first 24 hours after the index clinical event.

2) CK-MB:

a) Maximal value of CK-MB > 2 x the upper limit of normal on one occasion during the first hours after the index clinical event. OR

b) Maximal value of CK-MB, preferable CK-MB mass, > upper limit of normal on two successive samples.

3) Total CK:

a) In the absence of availability of a troponin or CK-MB assay, total CK > 2 x the upper limit of normal, or the B fraction of CK may be employed, but these last two biomarkers are considerably less satisfactory than CK-MB.

AND ONE OF THE FOLLOWING:

1) Either ST segment depression or T wave abnormalities; or

2) Ischemic symptoms in the presence or absence of chest discomfort. Ischemic symptoms may include:

a) unexplained nausea and vomiting; or

b) persistent shortness of breath secondary to left ventricular failure; or

c) unexplained weakness, dizziness, lightheadedness, or syncope.

ST ELEVATION MYOCARDIAL INFARCTION (STEMI)

Indicate whether the patient was hospitalized for an ST Elevation Myocardial Infarction (STEMI) documented in the medical record.

AT LEAST ONE OF THE FOLLOWING BIOCHEMICAL INDICATORS for detecting myocardial necrosis must be present (see below for a definition of Reference Control Limits):

1) Troponin T or I:

a) Maximal concentration of troponin T or I > the MI decision limit on at least one occasion during the first 24 hours after the index clinical event.

2) CK-MB:

a) Maximal value of CK-MB > 2 x the upper limit of normal on one occasion during the first hours after the index clinical event; OR

b) Maximal value of CK-MB, preferable CK-MB mass, > upper limit of normal on two successive samples.

3) Total CK

a) In the absence of availability of a troponin or CK-MB assay, total CK > 2 x the upper limit of normal, or the B fraction of CK may be employed, but these last two biomarkers are considerably less satisfactory than CK-MB.

AND ONE OF THE FOLLOWING ECG CHANGES:

1) ST-segment elevation: New or presumed new ST segment elevation at the J point in two or more contiguous leads with the cut-off points ≥ 0.2 mV in leads V1, V2, or V3, or ≥ 0.1 mV in other leads; OR

2) Development of any Q wave in leads V1 through V3, or the development of a Q-wave $>$ or $=$ to 30 ms (0.03s) in leads I, II, aVL, aVF, V4, V5, or V6. (Q wave changes must be present in any two contiguous leads, and be $>$ or $=$ to 1mm in depth.)

Defining Reference Control Values (MI Diagnostic Limit and Upper Limit of Normal):

Appendix A - Adverse Events

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Implantable Cardioverter Defibrillators Registry v1.08

Definition: Reference values must be determined in each laboratory by studies using specific assays with appropriate quality control, as reported in peer-reviewed journals. Acceptable imprecision (coefficient of variation) at the 99th percentile for each assay should be defined as < or = to 10%. Each individual laboratory should confirm the range of reference values in their specific setting.

Field Name: Pericardial Tamponade

Adverse Event Seq No: ae018

Adverse Event ID: 18

Effective Date: 01/01/2004

Expiration Date:

Definition: Indicate if the patient experienced fluid in the pericardial space compromising cardiac filling, and requiring intervention as documented by either: 1) Echo showing pericardial fluid and signs of tamponade such as right heart compromise, or 2) Systemic hypotension due to pericardial fluid compromising cardiac function.

Field Name: AV Fistula

Adverse Event Seq No: ae019

Adverse Event ID: 19

Effective Date: 01/01/2004

Expiration Date:

Definition: Indicate if the patient experienced an AV fistula as documented by a connection between the access artery and the accompanying vein that is demonstrated by arteriography or ultrasound and most often characterized by a continuous bruit.

Field Name: Infection Related to Device

Adverse Event Seq No: ae020

Adverse Event ID: 20

Effective Date: 01/01/2004

Expiration Date:

Definition: Indicate if the patient experienced an infection related to the device.

Appendix B - Medications

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Implantable Cardioverter Defibrillators Registry v1.08

Medications

Field Name: ACE-Inhibitor (any)

Medication Seq No: m001

Category: Ace Inhibitor

Medication ID: 1

Effective Date: 01/01/2004

Expiration Date:

Field Name: Amiodarone

Medication Seq No: m002

Category: Antiarrhythmic Agent

Medication ID: 2

Effective Date: 01/01/2004

Expiration Date:

Field Name: Disopyramide

Medication Seq No: m003

Category: Antiarrhythmic Agent

Medication ID: 3

Effective Date: 01/01/2004

Expiration Date:

Field Name: Dofetilide

Medication Seq No: m004

Category: Antiarrhythmic Agent

Medication ID: 4

Effective Date: 01/01/2004

Expiration Date:

Field Name: Flecainide

Medication Seq No: m005

Category: Antiarrhythmic Agent

Medication ID: 5

Effective Date: 01/01/2004

Expiration Date:

Field Name: Mexiletine

Medication Seq No: m006

Category: Antiarrhythmic Agent

Medication ID: 6

Effective Date: 01/01/2004

Expiration Date:

Field Name: Procainamide

Medication Seq No: m007

Category: Antiarrhythmic Agent

Medication ID: 7

Effective Date: 01/01/2004

Expiration Date:

Field Name: Propafenone

Medication Seq No: m008

Category: Antiarrhythmic Agent

Medication ID: 8

Effective Date: 01/01/2004

Expiration Date:

Field Name: Quinidine

Medication Seq No: m009

Category: Antiarrhythmic Agent

Medication ID: 9

Effective Date: 01/01/2004

Expiration Date:

Appendix B - Medications

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Implantable Cardioverter Defibrillators Registry v1.08

Field Name: Sotalol	Medication Seq No: m010
Category: Antiarrhythmic Agent	Medication ID: 10
Effective Date: 01/01/2004	Expiration Date:

Field Name: Other Anti. Arrhy.	Medication Seq No: m011
Category: Antiarrhythmic Agent	Medication ID: 11
Effective Date: 01/01/2004	Expiration Date:

Field Name: Hydralazine	Medication Seq No: m012
Category: Antihypertensive	Medication ID: 12
Effective Date: 01/01/2004	Expiration Date:

Field Name: ARB (any)	Medication Seq No: m013
Category: ARB	Medication ID: 13
Effective Date: 01/01/2004	Expiration Date:

Field Name: ASA	Medication Seq No: m014
Category: ASA	Medication ID: 14
Effective Date: 01/01/2004	Expiration Date:

Field Name: Beta-Blocker (any)	Medication Seq No: m015
Category: Beta Blocker	Medication ID: 15
Effective Date: 01/01/2004	Expiration Date:

Field Name: Diltiazem	Medication Seq No: m016
Category: Calcium Channel Blocker	Medication ID: 16
Effective Date: 01/01/2004	Expiration Date:

Field Name: Verapamil	Medication Seq No: m017
Category: Calcium Channel Blocker	Medication ID: 17
Effective Date: 01/01/2004	Expiration Date:

Field Name: Other CCB	Medication Seq No: m018
Category: Calcium Channel Blocker	Medication ID: 18
Effective Date: 01/01/2004	Expiration Date:

Field Name: Coumadin	Medication Seq No: m019
Category: Coumadin	Medication ID: 19

Appendix B - Medications

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Implantable Cardioverter Defibrillators Registry v1.08

Effective Date: 01/01/2004	Expiration Date:
Field Name: Digoxin	Medication Seq No: m020
Category: Digoxin	Medication ID: 20
Effective Date: 01/01/2004	Expiration Date:
Field Name: Diuretic (any)	Medication Seq No: m021
Category: Diuretic	Medication ID: 21
Effective Date: 01/01/2004	Expiration Date:
Field Name: Nitroglycerin SL, PRN	Medication Seq No: m022
Category: Nitrate	Medication ID: 22
Effective Date: 01/01/2004	Expiration Date:
Field Name: Nitroglycerin Long Acting	Medication Seq No: m023
Category: Nitrate	Medication ID: 23
Effective Date: 01/01/2004	Expiration Date:
Field Name: Clopidogrel	Medication Seq No: m024
Category: Platelet Aggregation Inhibitor	Medication ID: 24
Effective Date: 01/01/2004	Expiration Date:
Field Name: Ticlopidine	Medication Seq No: m025
Category: Platelet Aggregation Inhibitor	Medication ID: 25
Effective Date: 01/01/2004	Expiration Date:
Field Name: Statin (any)	Medication Seq No: m026
Category: Statin	Medication ID: 26
Effective Date: 01/01/2004	Expiration Date:
