Identifiers

Study ID _____

ECG File

Main ECG

ECG File number

_____

Is the patient paced during this electrocardiogram?

◯ No ◯ Yes ◯ Unknown

ECG Acquisition Date

_____

Second ECG

ECG File number

_____

Is the patient paced during this electrocardiogram?

◯ No ◯ Yes ◯ Unknown

ECG Acquisition Date

_____

Blinding Identifiers

First Name _____

Last Name _____

Middle Initial _____

Date of Birth _____

Subject Status

Is the subject alive at time of data entry?

◯ Yes
◯ No

Date of death? _____

Cause of death?

_____
(brief explanation)

Demographics

Sex

◯ Male
◯ Female

Race

◯ White
◯ Black
◯ Asian
◯ Native American
◯ Hispanic

Inclusion And Exclusion Criteria

Inclusion Criteria

-ICD/CRT-D implanted for primary prevention

-Collected pre-implant (digitized) 12-Lead ECG

Meets Inclusion Criteria?

◯ Yes
◯ No

Exclusion Criteriea

-Inherited cardiomyopathies and channelopathies

-Congenital heart disease

-ICD implanted for secondary prevention

Absent Exclusion Criteria?

◯ Yes
◯ No

Baseline Clinical Data Pre-Implant

Document clinical data to temporally agree with patient status at time before implant or generator change. E.g. If the patient has their first MI between de novo implant and generator change/upgrade, you would answer "No" for "History of MI" at the baseline clinical data timepoint and "Yes" during concordant timeframe.

History of MI
◯ Yes
◯ No

History of Revascularization
◯ Yes
◯ No

Type of Revascularization
☐ CABG
☐ PTCA

Hypertension
◯ Yes
◯ No

Diabetes
◯ Yes
◯ No

Atrial Fibrillation
◯ Yes
◯ No

History of Stroke
◯ Yes
◯ No

Use Anti-arrhythmic Drugs
◯ Yes
◯ No

Type of AAD
☐ Amiodarone
☐ Dronedarone
☐ Propafenone
☐ Sotalol
☐ Other

Use Beta Blockers
◯ Yes
◯ No

RAAS Modifying Medications
☐ No medications
☐ ACE inhibitor use
☐ ARB use
☐ ARNI (Angiotensin II Receptor Blocker Neprilysin Inhibitor) use
☐ Aldosterone Inhibitor Use

Use Calcium Channel Blockers
◯ Yes
◯ No

BUN (mg/dL) _____

Creatinine (mg/dL) _____

Baseline NYHA (New York Heart Association) Class
◯ I
◯ II
◯ III
◯ IV

Baseline LVEF

- ◯ >55%
- ◯ 50-55%
- ◯ 45-50%
- ◯ 40-45%
- ◯ 35-40%
- ◯ 30-35%
- ◯ 25-30%
- ◯ 20-25%
- ◯ 15-20%
- ◯ 10-15%
- ◯ < 10%

Exact LVEF (if known) _____

Date of Echocardiogram _____

Implantation Data

Device Data

ICD/CRT-D Indication

◯ Primary Prevention
◯ Secondary Prevention
(Subject screen fails if indicated for secondary prevention)

Date of Baseline (pre-implant) 12-Lead ECG

_____

Date of ICD/CRT-D Implant

_____

ICD Type

◯ Single-chamber
◯ Dual-chamber
◯ CRT-D
◯ S-ICD

LV Lead Positioning

◯ Apical
◯ Mid
◯ Basal

LV Lead Positioning

◯ Anterior
◯ Anterolateral
◯ Posterior
◯ Posterolateral

Device Manufacturer

◯ Medtronic
◯ Boston Scientific
◯ St Jude
◯ Biotronik

Device Model

_____

VT Detection Zone Programmed?

◯ Yes
◯ No

Device ATP Setting

◯ On
◯ Off

Device VT Zone (BPM)

_____
(Please list the lowest integer of the VT zone. E.g. if range is 188-200 bpm enter in 188)

Device VF Zone (BPM)

_____
(Please list the lowest integer of the VF zone. E.g. if range is 188-200 bpm enter in 188)

If Milliseconds is Reported Instead

Device VT Interval (ms) _____

Device VF Interval (ms) _____

If Programmed for Number of Intervals to Detect (NID)

Device NID for VT _____
(Optional if listed on report)

Device NID for Redetection VT _____
(Optional if listed on report)

Device NID VF Numerator _____
(Optional if listed on report)

Device NID VF Denominator _____
(Optional if listed on report)

If Programmed for Detection Duration
Example
Initial Duration: 2.5 seconds
Redetection Duration: 1.0 seconds

Device Initial Detection Duration for VT _____
(Optional if listed on report)

Device Re-detection Duration for VT _____
(Optional if listed on report)

Device Initial Detection Duration for VF _____
(Optional if listed on report)

Device Redetection Duration for VF _____
(Optional if listed on report)

Events Status-Post Implant

Events

Therapy During Device Life?
◯ Yes
◯ No

Date of Therapy _____

% Atrial Pacing at Date of Therapy _____

% Ventricular Pacing at Date of Therapy _____

% Left Ventricular Pacing at Date of Therapy _____

Charge Time at Date of Therapy _____
((seconds))

Type of Therapy
☐ Shock (Joules)
☐ ATP

Total Amount of Joules Delivered _____
(Please calculate total amount of joules. E.g. if interrogation lists 41 J x 4, then enter 164 into this box)

Total Frequency of Shocks Delivered During Therapy _____
(Do not include ATP in this sum)

Adjudication of Therapy
◯ Appropriate
◯ Inappropriate

Programming Changes After Therapy
◯ Yes
◯ No

Type of Ventricular Arrhythmia
◯ Monomorphic VT
◯ Polymorphic VT / Ventricular Fibrillation

Average Cycle Length of Arrhythmia (ms) _____

Pre-Generator Change or Device Upgrade Clinical Data

Document clinical data to temporally agree with patient status at time before implant or generator change. E.g. If the patient has their first MI between de novo implant and generator change/upgrade, you would answer "No" for "History of MI" at the baseline clinical data timepoint and "Yes" during concordant timeframe.

History of MI
◯ Yes
◯ No

History of Revascularization
◯ Yes
◯ No

Type of Revascularization
☐ CABG
☐ PTCA

Hypertension
◯ Yes
◯ No

Diabetes
◯ Yes
◯ No

Atrial Fibrillation
◯ Yes
◯ No

History of Stroke
◯ Yes
◯ No

Use Anti-arrhythmic Drugs
◯ Yes
◯ No

Type of AAD
☐ Amiodarone
☐ Dronedarone
☐ Propafenone
☐ Sotalol
☐ Other

Use Beta Blockers
◯ Yes
◯ No

RAAS Modifying Medications
☐ No medications
☐ ACE inhibitor use
☐ ARB use
☐ ARNI (Angiotensin II Receptor Blocker Neprilysin Inhibitor) use
☐ Aldosterone Inhibitor Use

Use Calcium Channel Blockers
◯ Yes
◯ No

BUN (mg/dL) _____

Creatinine (mg/dL) _____

NYHA (New York Heart Association) Class Prior to Generator Change/Upgrade
◯ I
◯ II
◯ III
◯ IV

LVEF Prior to Generator Change/Upgrade

◯ >55%
◯ 50-55%
◯ 45-50%
◯ 40-45%
◯ 35-40%
◯ 30-35%
◯ 25-30%
◯ 20-25%
◯ 15-20%
◯ 10-15%
◯ < 10%

Exact LVEF (if known - e.g. Biplane Simpson's Method) _____

Date of Echocardiogram _____

Generator Change or Device Upgrade

Device Data

Date of Pre-Generator Change 12-Lead ECG _____

Date of Generator Change or Upgrade _____

ICD Type
- ◯ Single-chamber
- ◯ Dual-chamber
- ◯ CRT-D
- ◯ S-ICD
- ◯ Downgrade to Pacemaker

LV Lead Positioning
- ◯ Apical
- ◯ Mid
- ◯ Basal

LV Lead Positioning
- ◯ Anterior
- ◯ Anterolateral
- ◯ Posterior
- ◯ Posterolateral

Device Manufacturer
- ◯ Medtronic
- ◯ Boston Scientific
- ◯ St Jude
- ◯ Biotronik

Device Model _____

VT Detection Zone Programmed?
- ◯ Yes
- ◯ No

Device ATP Setting
- ◯ On
- ◯ Off

Device VT Zone (BPM) _____
(Please list the lowest integer of the VT zone. E.g. if range is 188-200 bpm enter in 188)

Device VF Zone (BPM) _____
(Please list the lowest integer of the VF zone. E.g. if range is 188-200 bpm enter in 188)

If Milliseconds is Reported Instead

Device VT Interval (ms) _____

Device VF Interval (ms) _____

If Programmed for Number of Intervals to Detect (NID)

Device NID for VT

_____
(Optional if listed on report)

Device NID for Redetection VT

_____
(Optional if listed on report)

Device NID VF Numerator

_____
(Optional if listed on report)

Device NID VF Denominator

_____
(Optional if listed on report)

If Programmed for Detection Duration
Example
Initial Duration: 2.5 seconds
Redetection Duration: 1.0 seconds

Device Initial Detection Duration for VT

_____
(Optional if listed on report)

Device Re-detection Duration for VT

_____
(Optional if listed on report)

Device Initial Detection Duration for VF

_____
(Optional if listed on report)

Device Redetection Duration for VF

_____
(Optional if listed on report)

Events Status-Post Generator Change or Device Upgrade

Events

Therapy During Device Life?
◯ Yes
◯ No

Date of Therapy
_____

% Atrial Pacing at Date of Therapy
_____

% Ventricular Pacing at Date of Therapy
_____

% Left Ventricular Pacing at Date of Therapy
_____

Charge Time at Date of Therapy
_____
(seconds)

Type of Therapy
☐ Shock (Joules)
☐ ATP

Total Amount of Joules Delivered
_____
(Please calculate total amount of joules. E.g. if interrogation lists 41 J x 4, then enter 164 into this box)

Total Frequency of Shocks Delivered During Therapy
_____
(Do not include ATP in this sum)

Adjudication of Therapy
◯ Appropriate
◯ Inappropriate

Programming Changes After Therapy
◯ Yes
◯ No

Type of Ventricular Arrhythmia
◯ Monomorphic VT
◯ Polymorphic VT / Ventricular Fibrillation

Average Cycle Length of Arrhythmia (ms)
_____