



# PROGRAMMING GUIDE

for Gallant™ HF CRT-D

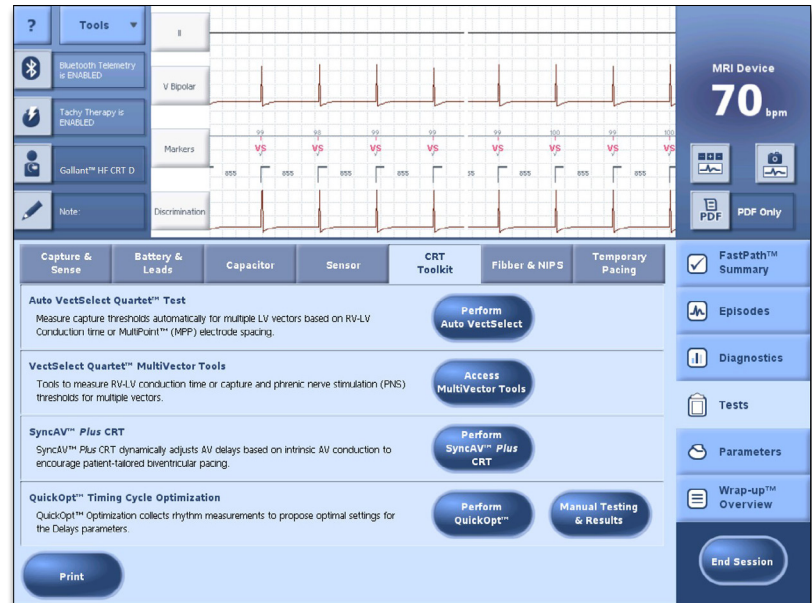




PROGRAMMING **SUMMARY MENU**

# PATIENT SELECTION AND PROGRAMMING GUIDANCE

- Programming guidance is based on the latest clinical evidence, key opinion leader presentations and best practices from the field
- Programming can occur during implant for new patients as well as follow-up for existing patients



# PATIENT SELECTION AND **PROGRAMMING GUIDANCE**

The goal of programming guidance is to improve CRT response and narrow the QRS in applicable patients with the unique tools offered by Abbott CRT systems, including:

- Multiple LV lead options with  $\geq 30$  mm electrode spacing offering a multitude of LV pacing vectors
- SyncAV™ *Plus* CRT technology
- MultiPoint™ pacing

The ideal programming for any patient may include both SyncAV *Plus* CRT technology and MultiPoint pacing, just one or neither. This programming guide will help you appropriately tailor the therapies for each individual patient.





# STEP 1 PROGRAM STANDARD SINGLE-SITE CRT

- Navigate to the CRT Toolkit tab in the Tests application
- Select **PERFORM AUTO VECTSELECT**

Perform Auto VectSelect

The screenshot displays the CRT Toolkit interface. At the top, there's a 'Tools' dropdown menu. Below it, several status indicators are shown: 'Bluetooth Telemetry is ENABLED', 'Tachy Therapy is ENABLED', and 'Gallant™ HF CRT D'. A 'Note' field is also present. The main display area shows a grid with ECG waveforms. The top waveform is labeled 'V Bipolar' and the bottom one 'Discrimination'. The grid contains numerical values and 'VS' markers. On the right side, there's a 'MRI Device' section showing a heart rate of '70 bpm' and icons for 'PDF' and 'PDF Only'. Below the grid, there's a navigation bar with tabs: 'Capture & Sense', 'Battery & Leads', 'Capacitor', 'Sensor', 'CRT Toolkit' (selected), 'Fibber & NIP S', and 'Temporary Pacing'. The 'Auto VectSelect Quartet™ Test' section is highlighted, with a green arrow pointing to the 'Perform Auto VectSelect' button. Below it, the 'VectSelect Quartet™ MultiVector Tools' section has an 'Access MultiVector Tools' button. The 'SyncAV™ Plus CRT' section has a 'Perform SyncAV™ Plus CRT' button. The 'QuickOpt™ Timing Cycle Optimization' section has 'Perform QuickOpt™' and 'Manual Testing & Results' buttons. At the bottom left is a 'Print' button, and at the bottom right is an 'End Session' button. On the far right, there's a sidebar with 'FastPath™ Summary' (checked), 'Episodes', 'Diagnostics', 'Tests', 'Parameters', and 'Wrap-up™ Overview'.



# STEP 1 PROGRAM STANDARD SINGLE-SITE CRT

The first automatic test to be completed is the RV-LV Conduction Time Test.

The screenshot displays a medical device interface with ECG waveforms and a pop-up window for measuring RV-LV conduction time. The ECG shows Bipolar, Markers (VS), and Termination waveforms. The heart rate is 70 bpm. The pop-up window includes a diagram of the heart with electrode positions (Prox. 4, Mid 3, Mid 2, Tip 1) and a table of measured times for each electrode.

LV Electrode	Measured Time
Proximal 4	---
Mid 3	---
Mid 2	---
Distal tip 1	---

**Additional Parameters**

Test Method	RV Sense
Base Rate	60 bpm
Sensed AV Delay	300 ms



# STEP 1 PROGRAM STANDARD SINGLE-SITE CRT

- Select the pacing vectors for which you would like to test capture thresholds\*
- Program preferred single-site CRT parameters

**Auto VectSelect Quartet™ Capture Test**

RVp-LV Conduction Time

Proximal 4	45 ms
Mid 3	37 ms
Mid 2	18 ms
Distal tip 1	17 ms

Additional Parameters

Mode	DDD
Base Rate	60 bpm
LV Pulse Width	0.5 ms
BiVCap™ Confirm	
Paced/Sensed AV Delay	50/25 ms

Prox 4 - RV Coil

Mid 3 - RV Coil

Mid 2 - RV Coil

Distal tip 1 - RV Coil

Prox 4 - Mid 2

Mid 3 - Prox 4

Mid 2 - Prox 4

Distal tip 1 - Prox 4

Prox 4 - Mid 3

Mid 3 - Mid 2

Mid 2 - Mid 3

Distal tip 1 - Mid 3

Distal tip 1 - Mid 2

Thresholds @ LV Pulse Width = 0.5 ms

Estimated test time: 1 min 20 secs

Measure LV Thresholds

\* Per the physician's protocol for Abbott CRT devices.



STEP 2

# ASSESS INTRINSIC RHYTHM

- Navigate to the CRT Toolkit tab in the Tests application
- Click **PERFORM SyncAV™ PLUS CRT**

The screenshot shows the MRI Device software interface. At the top, there's a 'Tools' menu and a status bar indicating 'MRI Device 70 bpm'. The main display area shows an ECG rhythm strip with markers and a 'Discrimination' section. Below the ECG, there's a 'CRT Toolkit' tab selected, which contains several test options: 'Auto VectSelect Quartet™ Test', 'VectSelect Quartet™ MultiVector Tools', 'SyncAV™ Plus CRT', and 'QuickOpt™ Timing Cycle Optimization'. The 'Perform SyncAV™ Plus CRT' button is highlighted with a green circle. A green arrow points from the text 'Perform SyncAV™ Plus CRT' to this button. The interface also includes a 'Print' button and an 'End Session' button.

Perform SyncAV™ Plus CRT





STEP 2

# ASSESS INTRINSIC RHYTHM

For initial setup, click  
**PERFORM MEASUREMENTS.**

**Setup of SyncAV™ Plus CRT includes two sets of intrinsic AV conduction measurements**

The following parameter values will be temporarily programmed to obtain intrinsic AV conduction measurements for atrial sensing and atrial pacing:

**Mode: DDD**  
**Base Rate: 40 bpm for A Sense, Sinus Rate + 15 bpm for A Pace**  
**Paced/Sensed AV Delay: 350/325 ms**

To begin, press "Perform Measurements". The measurements can be cancelled at any time.

**Perform Measurements**





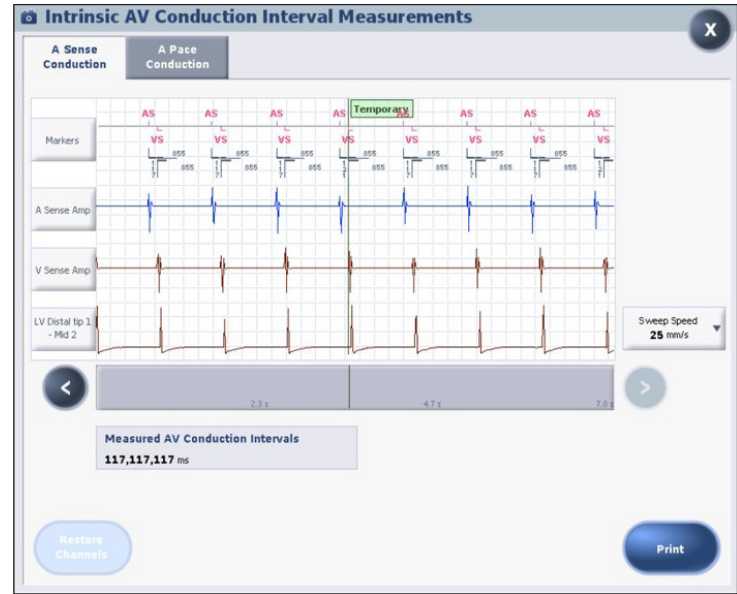
STEP 2

# ASSESS INTRINSIC RHYTHM

This test will measure the AV conduction time from both paced and sensed atrial events.

To view the measurements and ensure the patient has intact intrinsic conduction, click

**VIEW MEASUREMENTS.**

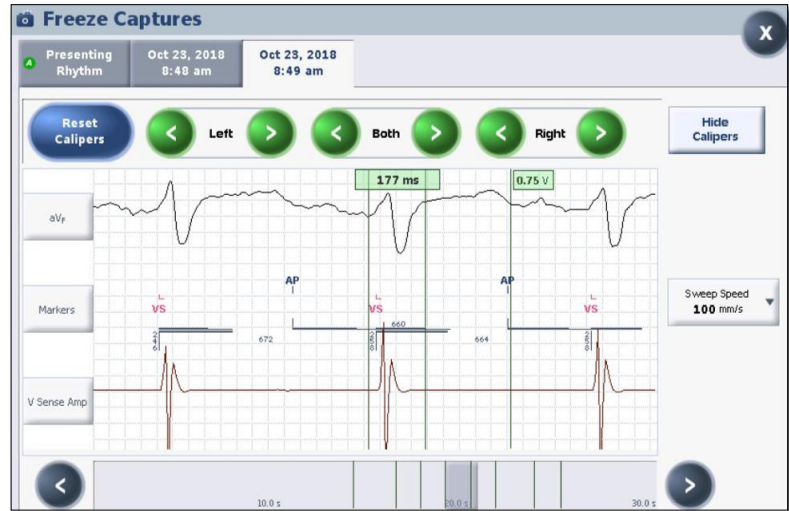




## STEP 2

# ASSESS INTRINSIC RHYTHM

- Connect surface ECG to the programmer and pull up the corresponding channel in the EGM Display
- Take a Freeze Capture of the rhythm with the camera icon
- Utilizing the electronic calipers, measure the QRS duration



## REMINDER

Before evaluating different SyncAV™ Plus CRT Technology Deltas, it is important to measure intrinsic QRS duration and single-site CRT QRS duration to establish a baseline.



### STEP 3

# PROGRAM SyncAV™ PLUS CRT TECHNOLOGY

SyncAV™ Plus CRT technology patient selection criteria include:

- Intact AV conduction
- PR <300 ms
- Left Bundle Branch Block
- Minimal ventricular ectopy (PVCs)
- Low AT/AF burden

If above criteria are not met, go to STEP 4.

**Setup of SyncAV™ Plus CRT includes two sets of intrinsic AV conduction measurements**

The following parameter values will be temporarily programmed to obtain intrinsic AV conduction measurements for atrial sensing and atrial pacing.

**Mode: DDD**  
**Base Rate: 40 bpm for A Sense, Sinus Rate + 15 bpm for A Pace**  
**Paced/Sensed AV Delay: 350/325 ms**

To begin, press "Perform Measurements". The measurements can be canceled at any time.

**Perform Measurements**

## REMINDER

SyncAV Plus CRT technology is not intended for patients with heart block where 1:1 conduction is not present.



STEP 3

# PROGRAM SyncAV™ PLUS CRT TECHNOLOGY

- Choose to program SyncAV™ Plus CRT Technology Delta as either a percentage or fixed value
- The optimal SyncAV Plus CRT Technology Delta can be determined by measuring the QRS duration for multiple delta options

**SyncAV™+ CRT setup is complete**

SyncAV™+ CRT is now ready to dynamically synchronize pacing based on patient-specific sensed and paced AV intervals.

SyncAV™+ CRT Delta: **-20%**

For LV-first pacing, the dynamic SyncAV™+ AVD includes the interventricular delay.

Repeat Measurements | View Measurements | Preview 3 | Program SyncAV



### STEP 3

## PROGRAM SyncAV™ PLUS CRT TECHNOLOGY

AV delays will now adjust to patient.

- 1 Every 256<sup>†</sup> cycles the AV delay is set to 350 ms for AP-VS and 325 ms for AS-VS
- 2 Intrinsic AV Conduction occurs and SyncAV™ Plus CRT technology measures the conduction time
- 3 SyncAV Plus CRT technology adjusts the Paced and Sensed AV Delays for the next 256<sup>†</sup> cycles using the following equation:  
**AVD = (Intrinsic Conduction Time for AP or AS) – (SyncAV Plus CRT technology Delta)**



### REMINDER

In SyncAV Plus CRT, the calculated AV delays are based on RA to RV conduction times. For LV-first pacing, the VV delay is then subtracted from each calculated AV delay.

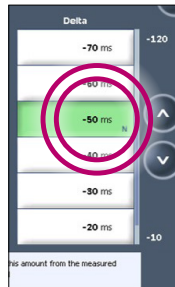
<sup>†</sup> The 256-beat search interval doubles with every consecutive identification of conduction block, up to a maximum of 18 hours.



### STEP 3

# PROGRAM SyncAV™ PLUS CRT TECHNOLOGY

- Program different SyncAV™ Plus CRT technology Deltas in percentage or ms
- Measure and print, if necessary or desired, to compare QRS durations



## RECOMMENDATION

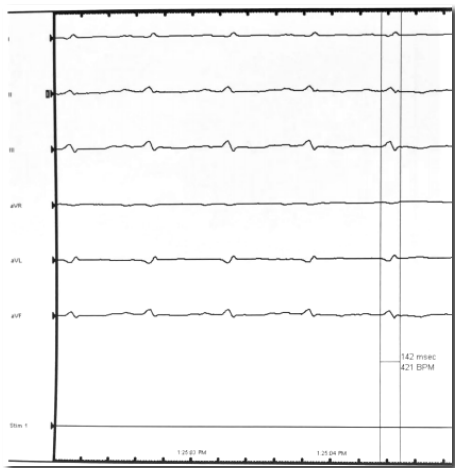
After -15% (or -50 ms), go to -20% (or -60 ms) then to -10% (or -40 ms) and evaluate QRS duration versus 15% (or -50 ms) to determine directionality. Then step up or step down in 5% (or 10 ms) increments to find the narrowest QRS.



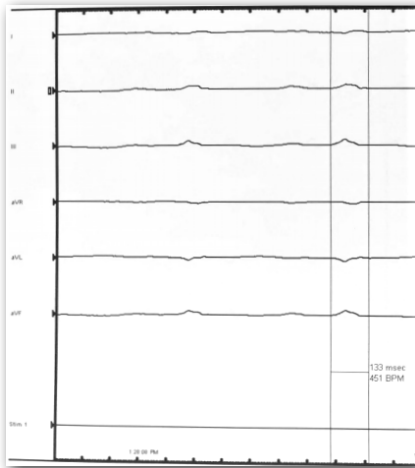
STEP 3

# PROGRAM SyncAV™ PLUS CRT TECHNOLOGY

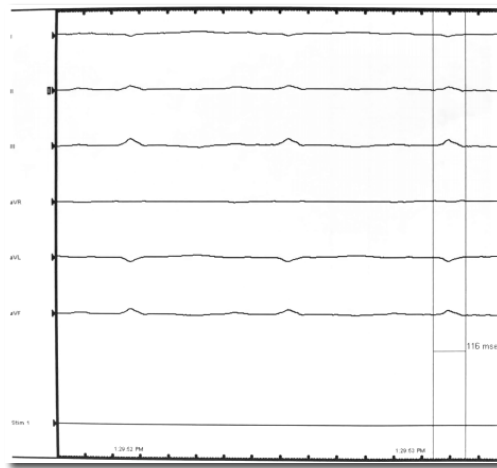
Permanently program SyncAV™ Plus CRT technology Delta to the value that yields the narrowest QRS. In the example pictured, a delta of -50 ms was selected based on this criteria.



**Intrinsic**  
QRS Duration: 142 ms



**Single-site CRT**  
QRS Duration: 133 ms



**SyncAV™ CRT technology -50ms**  
QRS Duration: 116 ms





STEP 3

# PROGRAM SyncAV™ PLUS CRT TECHNOLOGY

When programming SyncAV™ Plus CRT technology ON, Rate-Responsive AV Delay (RRAVD) is automatically turned OFF. This should remain OFF and can be found on the Delays screen.



The screenshot shows the device's programming interface. At the top, there are ECG waveforms for V Spolar, Markers, and Discrimination. The Markers section shows a sequence of VS (Ventricular Sense) and OS (Oversense) events. On the right, the MRI Device heart rate is displayed as 70 bpm. Below the waveforms is the 'Delays' screen, which includes the following settings:

- Paced AV Delay: 200 ms
- Sensed AV Delay: 150 ms
- Rate Responsive AV Delay: Off
- Shortest AV Delay: 100 ms
- Ventricular Intrinsic Preference (VIP™): n/a
- VIP™ Settings: VIP™ Extension: n/a, Search Interval: n/a, Search Cycles: n/a
- Encourage intrinsic conduction: or Encourage ventricular pacing
- SyncAV™ Plus CRT Delta: -20 %

At the bottom left, the 2:1 Block Rate is set to 103 bpm. At the bottom right, there are 'Preview' and 'Program' buttons.



## STEP 4

# PROGRAM MULTIPOINT™ PACING

- If appropriate for the patient, evaluate MultiPoint™ pacing options
- Navigate to the CRT Toolkit tab in the Tests application
- Click on **ACCESS MULTIVECTOR TOOLS**

Access MultiVector Tools

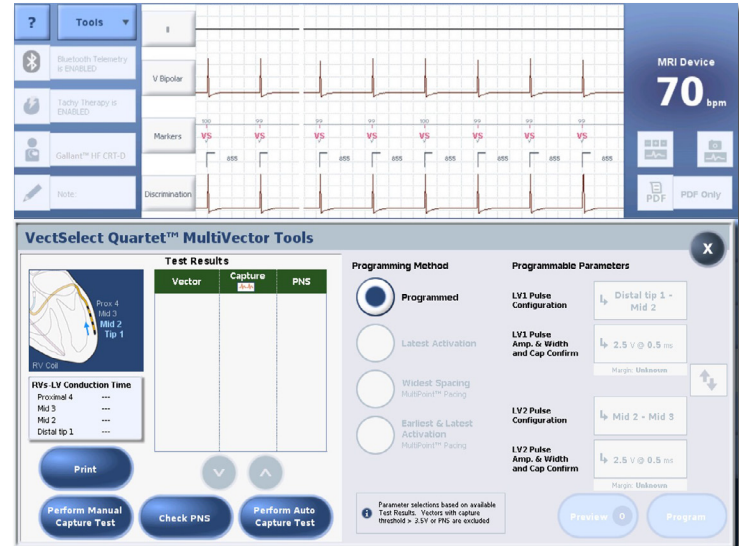
The screenshot displays the CRT Toolkit interface. At the top, there are status indicators for Bluetooth Telemetry (ENABLED), Tachy Therapy (ENABLED), and Gallont™ HF CRT D. The main display shows ECG waveforms for Lead I and V Bipolar, with markers indicating V/S points. A heart rate of 70 bpm is shown in the top right corner. The interface includes a navigation menu on the left with options like 'Tools', 'Markers', and 'Note'. The main content area features a 'CRT Toolkit' tab with several tool options: 'Auto VectSelect Quartet™ Test', 'VectSelect Quartet™ MultiVector Tools' (highlighted with a red circle and a red arrow from the text 'Access MultiVector Tools'), 'SyncAV™ Plus CRT', and 'QuickOpt™ Timing Cycle Optimization'. Each tool has a corresponding 'Perform' button. A 'Print' button is located at the bottom left, and an 'End Session' button is at the bottom right. The right sidebar contains a 'FastPath™ Summary' section with a checkmark, and a list of options: 'Episodes', 'Diagnostics', 'Tests', 'Parameters', and 'Wrap-up™ Overview'.



## STEP 4

# PROGRAM MULTIPOINT™ PACING

- Based on the RV-LV conduction times and LV capture thresholds determined in Step 1, evaluate electrode options for MultiPoint™ pacing
- Consider choosing electrodes with  $\geq 30$  mm anatomical spacing and an offset of 5 ms



## REMINDER

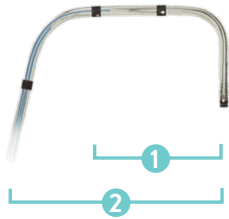
In the U.S. IDE, when  $\geq 30$  mm anatomical spacing and a 5 ms offset were selected, the patient response rate was 87%.<sup>1</sup>



## STEP 4

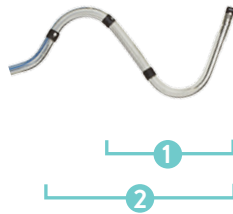
# PROGRAM MULTIPOINT™ PACING

**QUARTET™ 1457Q  
DOUBLE BEND LEAD**



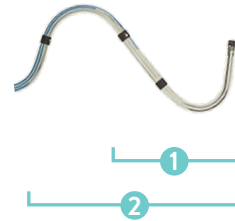
1. 30mm
2. 47mm

**QUARTET™ 1456Q  
SMALL S-CURVE LEAD**



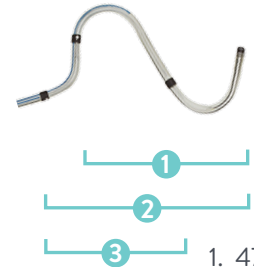
1. 30mm
2. 40mm

**QUARTET™ 1458Q  
TRADITIONAL S-CURVE LEAD**



1. 30mm
2. 47mm

**QUARTET™ 1458QL  
LARGE S-CURVE LEAD**



1. 47mm
2. 60mm
3. 40mm

The Quartet Family of LV Leads was designed to enable more electrode spacing options  $\geq 30$  mm for MultiPoint™ pacing



## STEP 4

# PROGRAM MULTIPOINT™ PACING

Program MultiPoint™ pacing with the following criteria

- $\geq 30$  mm electrode spacing
- 5 ms LV1 – LV2 pulse separation (Nominal)

The screenshot displays the VectSelect Quartet™ MultiVector Tools software interface. The top section shows ECG waveforms for V Bipolar, Markers (VS), and Discrimination. The right side indicates MRI Device status and a heart rate of 70 bpm. The bottom section is divided into Test Results, Programming Method, and Programmable Parameters.

**Test Results**

Vector	Capture	PNS

**Programming Method**

- Programmed
- Latest Activation
- Widest Spacing MultiPoint™ Pacing
- Earliest & Latest Activation MultiPoint™ Pacing

**Programmable Parameters**

- LV1 Pulse Configuration**: Distal tip 1 - Mid 2
- LV1 Pulse Amp. & Width and Cap Confirm**: 2.5 V @ 0.5 ms (Margin: Unknown)
- LV2 Pulse Configuration**: Mid 2 - Mid 3
- LV2 Pulse Amp. & Width and Cap Confirm**: 2.5 V @ 0.5 ms (Margin: Unknown)

**RV's-LV Conduction Time**

Prox 4	Mid 3	Mid 2	Distal tip 1
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**Parameter selections based on available Test Results. Vectors with capture threshold  $> 3.5V$  or PNS are excluded.**

Buttons: Print, Perform Manual Capture Test, Check PNS, Perform Auto Capture Test, Preview, Program.



PROGRAMMING **SUMMARY MENU**

1. Niazi, et al. Safety and efficacy of multipoint pacing in cardiac resynchronization therapy—the multipoint pacing trial. *JACC*. 2017. <http://dx.doi.org/10.1016/j.jacep.2017.06.022>.

## Abbott

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Cardiovascular.Abbott

## Rx Only

**Brief Summary:** This product is intended for the use by or under the direction of a Physician. Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

**Intended Use:** The Implantable Cardioverter Defibrillator (ICD) and Cardiac Resynchronization Therapy Defibrillator (CRT-D) devices are intended to provide ventricular antitachycardia pacing and ventricular cardioversion/defibrillation. The CRT-D devices are also intended to resynchronize the right and left ventricles.

**Indications:** The ICD and CRT-D devices are indicated for automated treatment of life-threatening ventricular arrhythmias. CRT-D devices are also indicated to treat symptoms in patients who have congestive heart failure with ventricular dyssynchrony. In addition, dual chamber ICD and CRT-D devices with the AT/AF detection algorithm are indicated in patients with atrial tachyarrhythmias or those patients who are at significant risk of developing atrial tachyarrhythmias. MR Conditional ICDs and CRT-Ds are conditionally safe for use in the MRI environment when used in a complete MR Conditional system and according to instructions in the MRI-Ready Systems manual. Scanning under different conditions may result in severe patient injury, death or device malfunction.

**Contraindications:** Contraindications for use of the pulse generator system include ventricular tachyarrhythmias resulting from transient or correctable factors such as drug toxicity, electrolyte imbalance, or acute myocardial infarction.

**Adverse Events:** Possible adverse events associated with the implantation of the pulse generator system include the following: Arrhythmia (for example, accelerated or induced), Bradycardia, Cardiac or venous perforation, Cardiac tamponade, Cardiogenic shock, Death, Discomfort, Embolism, Endocarditis, Erosion, Exacerbation of heart failure, Excessive fibrotic tissue growth, Extracardiac stimulation (phrenic nerve, diaphragm, pectoral muscle), Extrusion, Fluid accumulation within the device pocket, Formation of hematomas, cysts, or seromas, Heart block, Hemorrhage, Hemothorax, Hypersensitivity, including local tissue reaction or allergic reaction, Infection, Keloid formation, Myocardial damage, Nerve damage, Occlusion/Thrombus, Pericardial effusion, Pericarditis, Pneumothorax, Pulmonary edema, Syncope, Thrombosis, Valve damage. Complications reported with direct subclavian venipuncture include pneumothorax, hemothorax, laceration of the subclavian artery, arteriovenous fistula, neural damage, thoracic duct injury, cannulation of other

vessels, massive hemorrhage and rarely, death. Among the psychological effects of device implantation are imagined pulsing, depression, dependency, fear of premature battery depletion, device malfunction, inappropriate pulsing, shocking while conscious, or losing pulse capability. Possible adverse device effects include complications due to the following: Abnormal battery depletion, Conductor fracture, Device-programmer communication failure, Elevated or rise in defibrillation/cardioversion threshold, Inability to defibrillate or pace, Inability to interrogate or program due to programmer or device malfunction, Incomplete lead connection with pulse generator, Inhibited therapy including defibrillation and pacing, Inappropriate therapy (for example, shocks and antitachycardia pacing [ATP] where applicable, pacing), Interruption of function due to electrical or magnetic interference, Intolerance to high rate pacing (for example dyspnea or discomfort), Lead abrasion, Lead fracture, Lead insulation damage, Lead migration or lead dislodgement, Loss of device functionality due to component failure, Pulse generator migration, Rise in DFT threshold, Rise in pacing threshold and exit block, Shunting of energy from defibrillation paddles, System failure due to ionizing radiation. Additionally, potential adverse events associated with the implantation of a coronary venous lead system include the following: Allergic reaction to contrast media, Breakage or failure of implant instruments, Prolonged exposure to fluoroscopic radiation, Renal failure from contrast media used to visualize coronary veins. Refer to the User's Manual for detailed intended use, indications, contraindications, warnings, precautions and potential adverse events.

## Quartet™ Leads

**Indications and Usage:** The Quartet lead has application as part of an Abbott's biventricular system.

**Contraindications:** The use of the Quartet lead is contraindicated in patients who:

- Are expected to be hypersensitive to a single dose of 1.0 mg of dexamethasone sodium phosphate.
- Are unable to undergo an emergency thoracotomy procedure.
- Have coronary venous vasculature that is inadequate for lead placement, as indicated by venogram.

Refer to the User's Manual for detailed indications, contraindications, warnings, precautions and potential adverse events.

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