Abbott

PROGRAMMING GUIDE

for Gallant™ HF CRT-D

PROGRAMMING **SUMMARY MENU**

1

Program
Single-site CRT

2

Assess Intrinsic
Rhythm

3

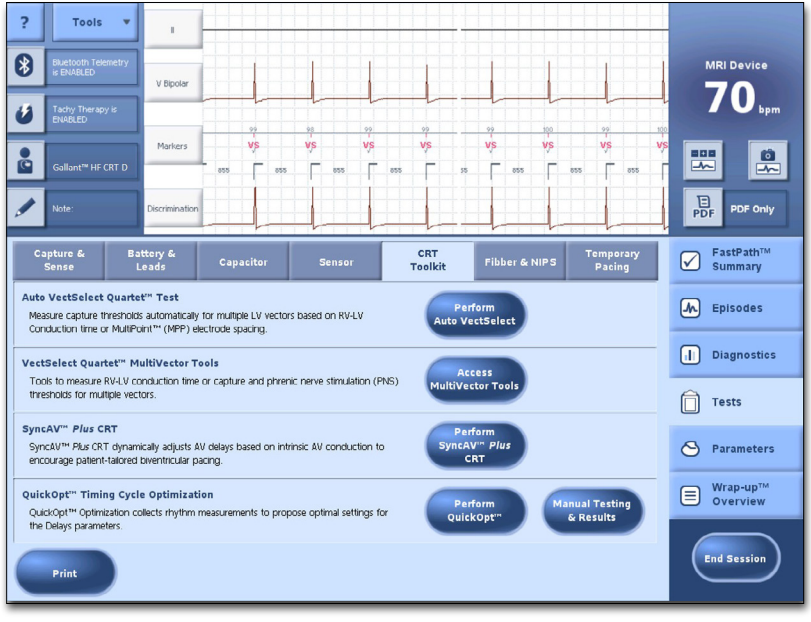
If Applicable,
Optimize
SyncAV™ *Plus* CRT
Technology

4

If Applicable,
Program
MultiPoint™
Pacing ON

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:

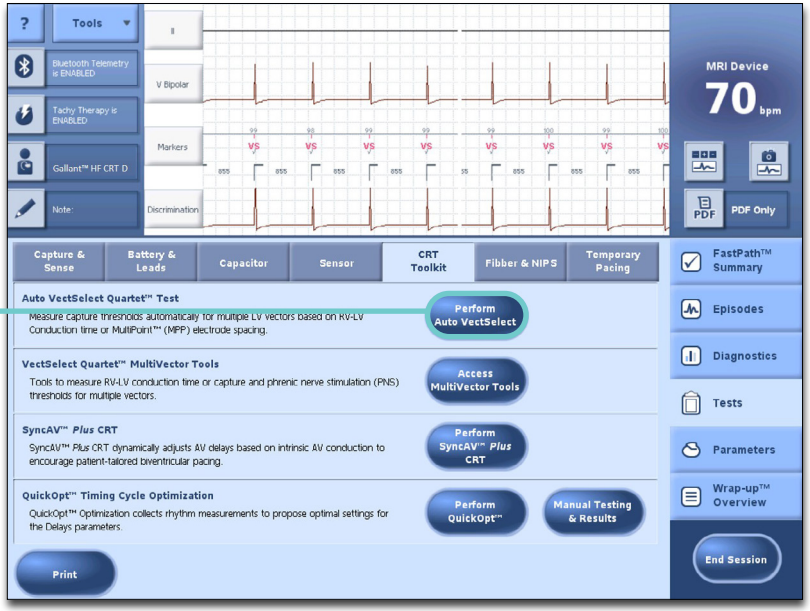
- Multiple LV lead options with ≥30 mm electrode spacing offering a multitude of LV pacing vectors
- SyncAV™ *Plus* CRT technology
- MultiPoint™ pacing

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

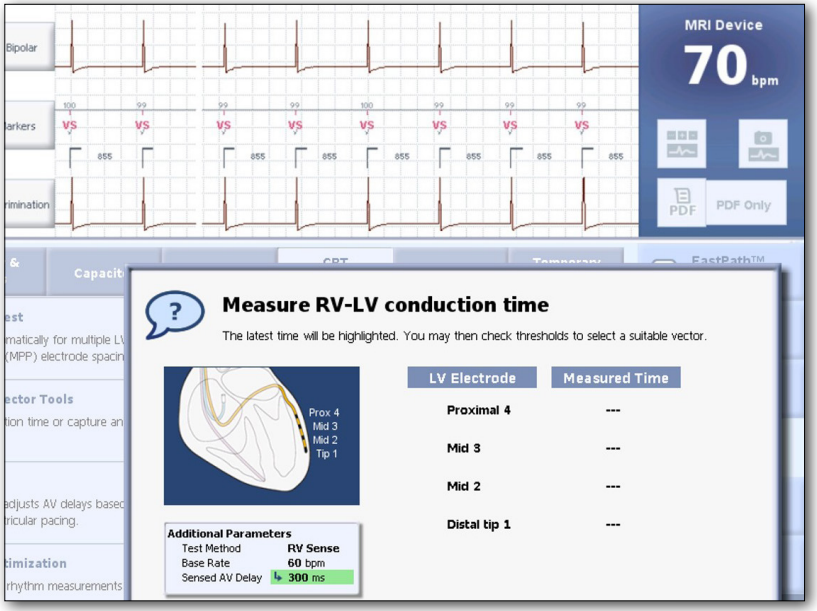
- Navigate to the CRT Toolkit tab in the Tests application
- Select **PERFORM AUTO VECTSELECT**



STEP 1

PROGRAM STANDARD SINGLE-SITE CRT

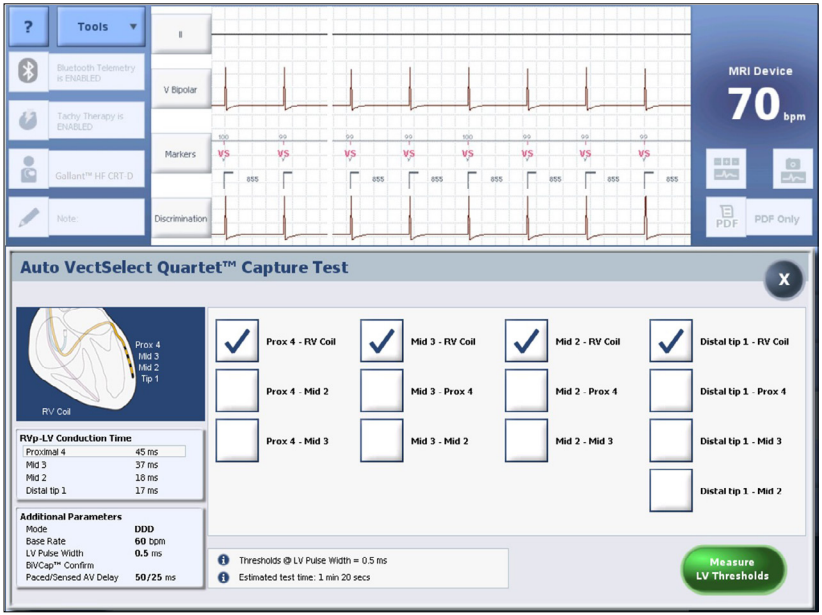
The first automatic test to be completed is the RV-LV Conduction Time Test.



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

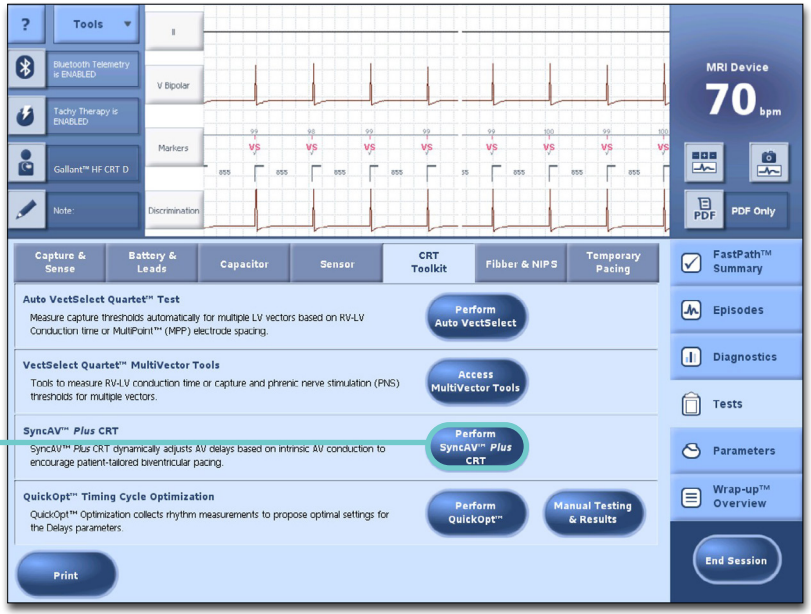


* Per the physician's protocol for Abbott CRT devices.

STEP 2
ASSESS INTRINSIC RHYTHM

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

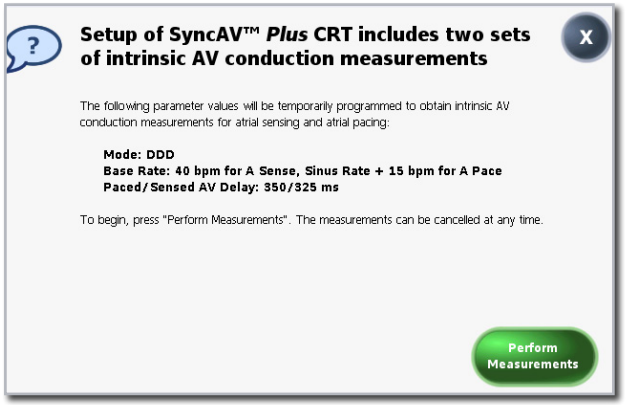
Perform SyncAV™ *Plus* CRT

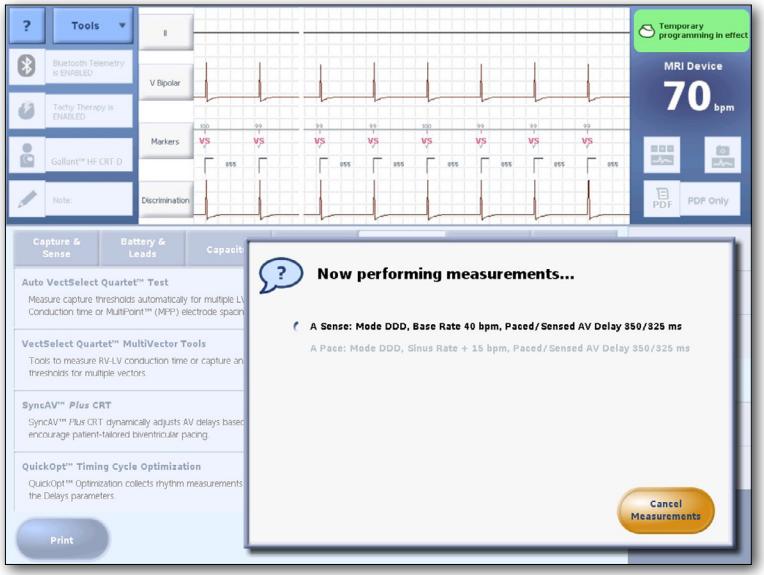


STEP 2

ASSESS INTRINSIC RHYTHM

For initial setup, click
PERFORM MEASUREMENTS.



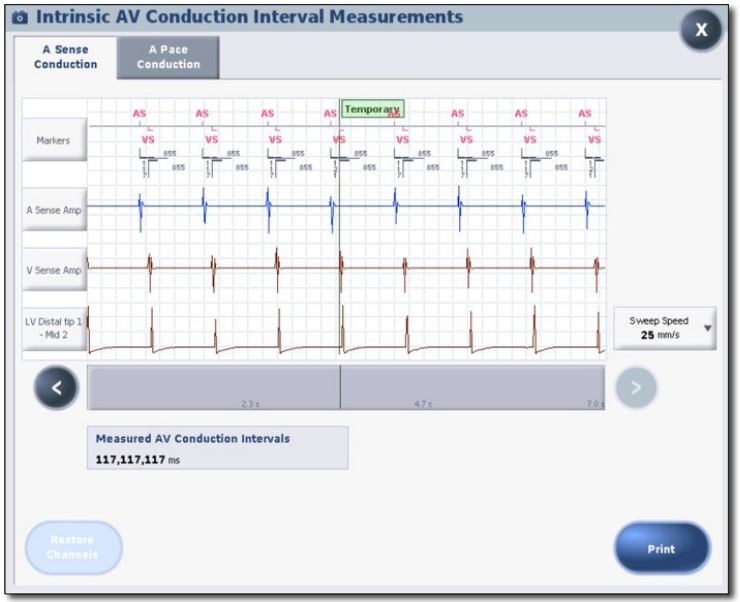


STEP 2

ASSESS INTRINSIC RHYTHM

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

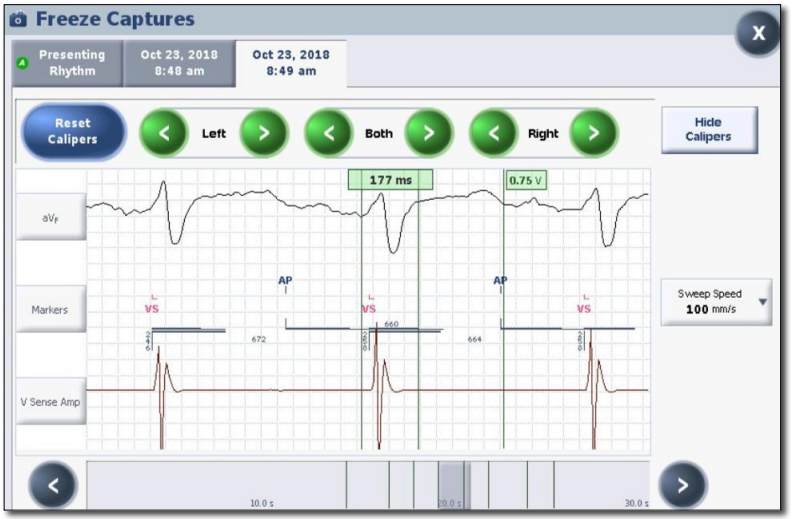
To view the measurements and ensure the patient has intact intrinsic conduction, click **VIEW MEASUREMENTS.**



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.

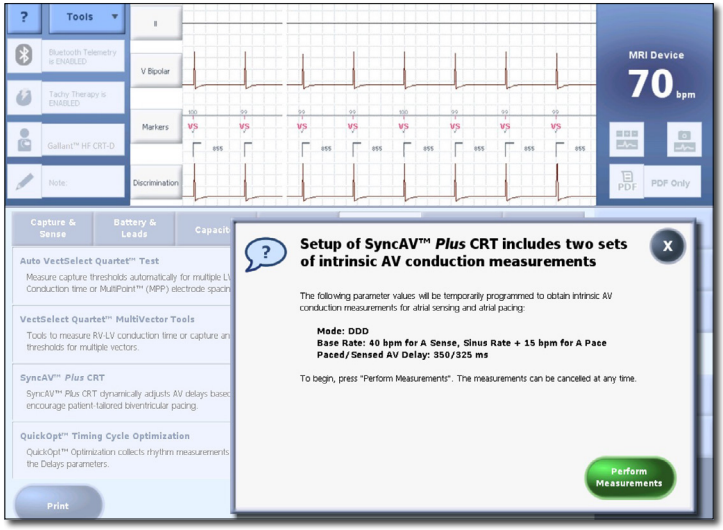
STEP 3

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.



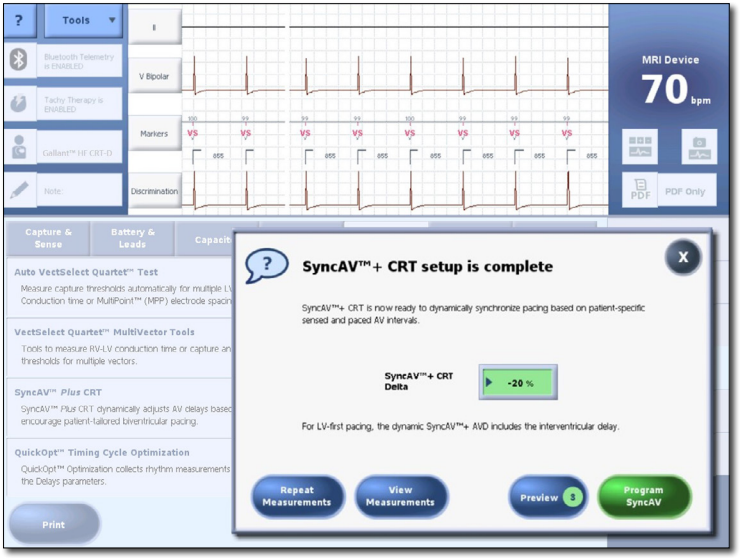
REMINDER

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

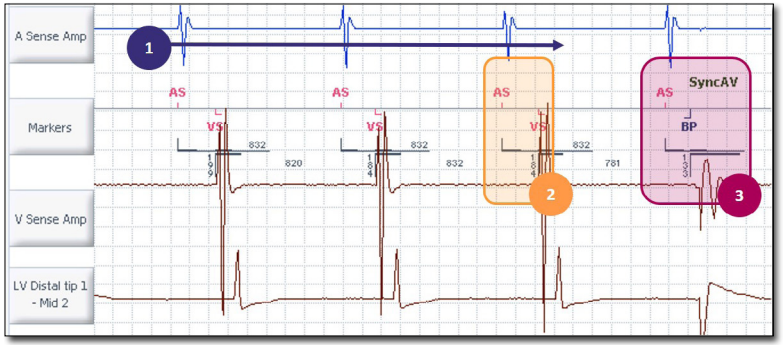
- Choose to program SyncAV™ *Plus* CRT Technology Delta as either a percentage or fixed value
- The optimal SyncAV *Plus* CRT Technology Delta can be determined by measuring the QRS duration for multiple delta options



STEP 3

PROGRAM SyncAV™ *PLUS* CRT TECHNOLOGY

AV delays will now adjust to patient.



1. Every 256† 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† cycles using the following equation:
   AVD = (Intrinsic Conduction Time for AP or AS) – (SyncAV Plus CRT technology Delta)

REMINDER

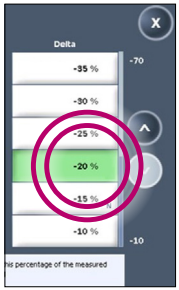
In SyncAV *Plus* CRT, the calculated AV delays are based on RA to RV conduction times. For LV-first pacing, the VV delay is then subtracted from each calculated AV delay.

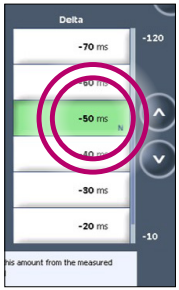
† The 256-beat search interval doubles with every consecutive identification of conduction block, up to a maximum of 18 hours.

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





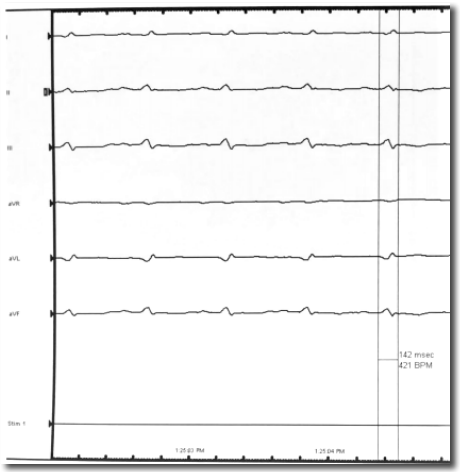
RECOMMENDATION

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.

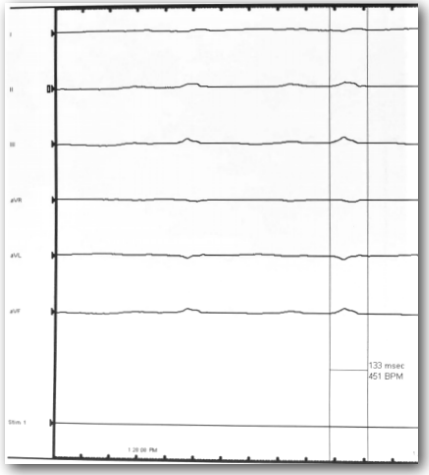
STEP 3

PROGRAM SyncAV™ *PLUS* CRT TECHNOLOGY

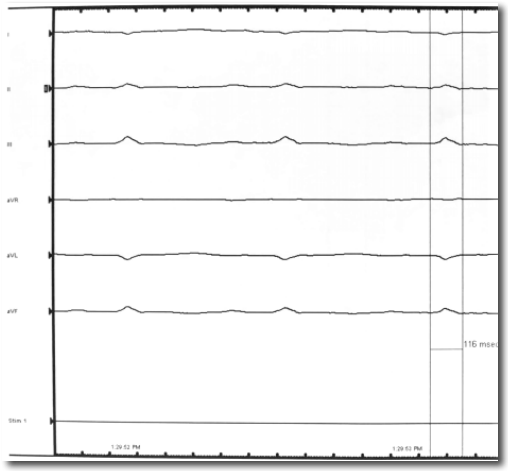
Permanently program SyncAV™ *Plus* CRT technology Delta to the value that yields the narrowest QRS. In the example pictured, a delta of -50 ms was selected based on this criteria.



Intrinsic
QRS Duration: 142 ms



Single-site CRT
QRS Duration: 133 ms

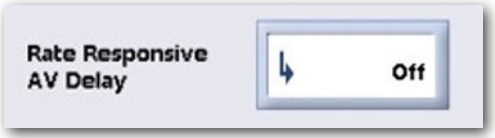


SyncAV™ CRT technology -50ms
QRS Duration: 116 ms

STEP 3

PROGRAM SyncAV™ *PLUS* CRT TECHNOLOGY

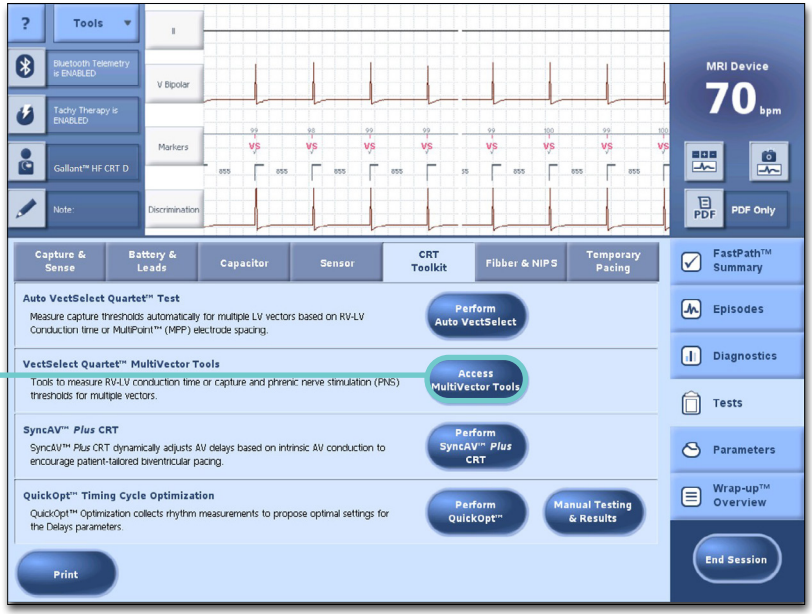
When programming SyncAV™ *Plus* CRT technology ON, Rate-Responsive AV Delay (RRAVD) is automatically turned OFF. This should remain OFF and can be found on the Delays screen.



STEP 4

PROGRAM MULTIPOINT™ PACING

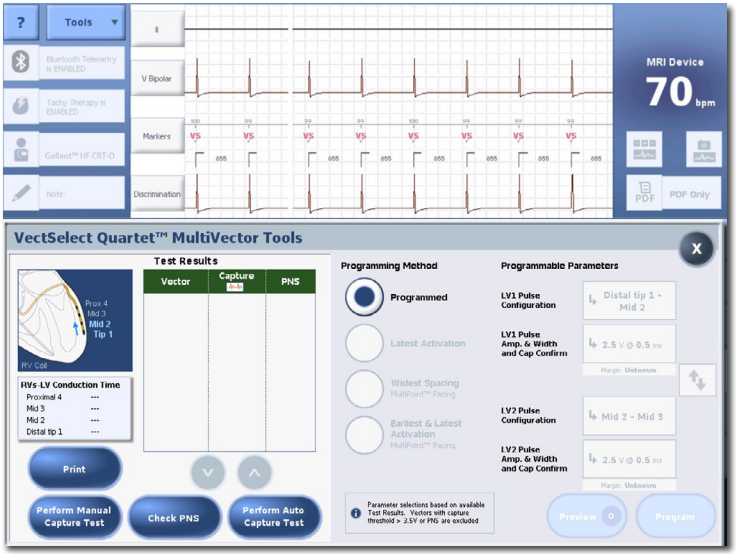
- If appropriate for the patient, evaluate MultiPoint™ pacing options
- Navigate to the CRT Toolkit tab in the Tests application
- Click on **ACCESS MULTIVECTOR TOOLS**



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 ≥30 mm anatomical spacing and an offset of 5 ms



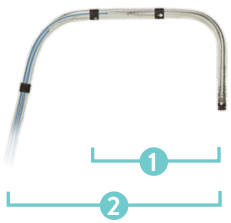
REMINDER

In the U.S. IDE, when ≥30 mm anatomical spacing and a 5 ms offset were selected, the patient response rate was 87%.[1]

STEP 4

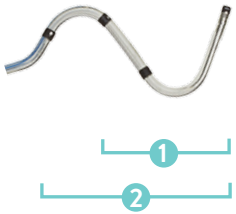
PROGRAM MULTIPOINT™ PACING

QUARTET™ 1457Q DOUBLE BEND LEAD



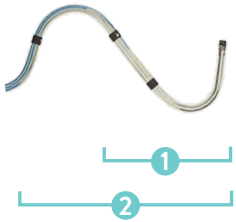
1. 30mm
2. 47mm

QUARTET™ 1456Q SMALL S-CURVE LEAD



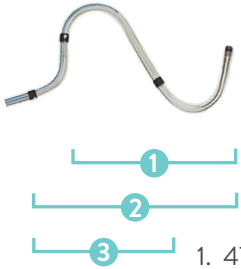
1. 30mm
2. 40mm

QUARTET™ 1458Q TRADITIONAL S-CURVE LEAD



1. 30mm
2. 47mm

QUARTET™ 1458QL LARGE S-CURVE LEAD



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

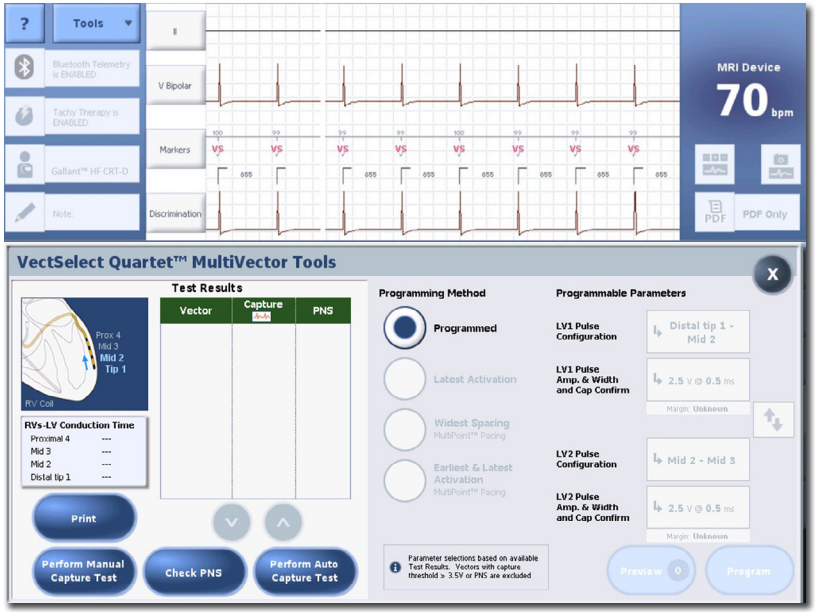
The Quartet Family of LV Leads was designed to enable more electrode spacing options ≥30 mm for MultiPoint™ pacing

STEP 4

PROGRAM MULTIPOINT™ PACING

Program MultiPoint™ pacing with the following criteria

- ≥30 mm electrode spacing
- 5 ms LV1 – LV2 pulse separation (Nominal)



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Pacing ON

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
One St. Jude Medical Dr., St. Paul, MN 55117 USA, Tel: 1-651-756-2000
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.

MAT-1900102 v1.0 | Item approved for Global use.

Abbott