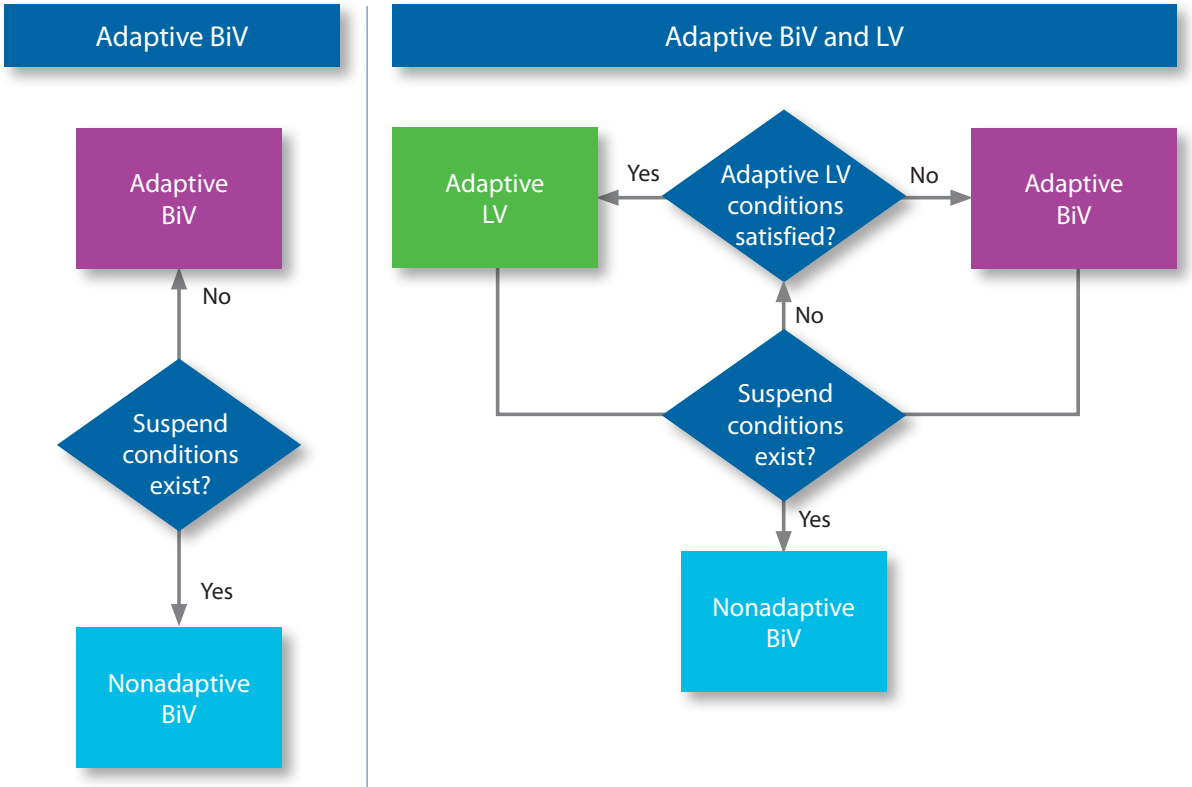
AdaptivCRT™ Algorithm

for Viva™ XT CRT-D

AdaptivCRT* Programmable Settings



* AdaptivCRT is available in DDD/R modes.

Reference

Medtronic Viva™ XT Manual.

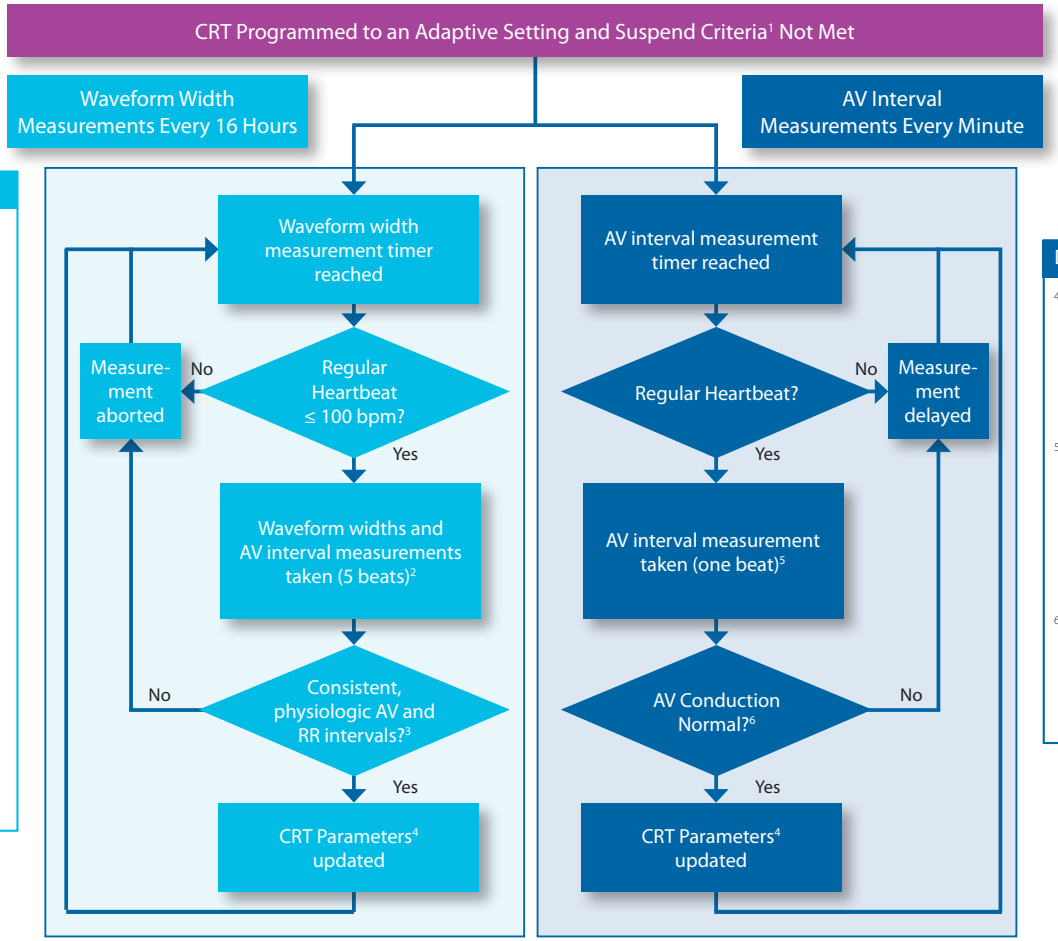
Adaptive LV Conditions:
(Checked at AV Interval Measurements)

1. HR ≤ 100 bpm
2. Intrinsic AV conduction normal (AS-VS ≤ 200 ms or AP-VS ≤ 250 ms)
3. LV capture confirmed by LVCM

Suspend Conditions:
(Checked every beat)

1. Evidence of tachyarrhythmia
2. Incompatible device operation which affects patient's rhythm

AdaptivCRT Measurements



Definitions

[1] Suspend Conditions:
- Evidence of tachyarrhythmia
- Incompatible device operation which affects patient's rhythm

[2] Waveform Width and AV Interval Measurement:
- Five consecutive beats
- Sensed and Paced AVs extended to 300 ms
- P-wave and QRS widths measured on far-field EGM
- AV Intervals measured
- VSR is disabled

[3] Consistent AV/RR Intervals:
- Atrial paced or atrial sensed for the duration of the test (five beats).
- RR intervals cannot vary by more than 200 ms

Physiologic AV Intervals:
- AS-VS interval > 80 ms
- AP-VS interval > 100 ms
- AV interval does not contain PVCs, PACs
- A VP does not occur within 300 ms of the AP/AS due to pacemaker functions

Definitions

[4] CRT Parameters:
- V. Pacing configuration (LV→RV, RV→LV)
- V-V Pace Delay
- Sensed AV
- Paced AV

[5] AV Interval Measurement:
- One beat
- Sensed and Paced AVs extended to 300 ms
- AV interval measured
- VSR pace will occur after a ventricular sense if programmed

[6] Normal AV Conduction:
- AV intervals are physiologic
- No evidence of AV Block (3 consecutive AV interval measurements end with a VP)

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Reference
Medtronic Viva™ XT Manual.

Viva XT CRT-D Brief Statement
Viva XT CRT-D Model DTBA1D4, Viva XT CRT-D Model DTBA1D1
Indications for Use: The Viva XT CRT-D system is indicated for ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life threatening ventricular arrhythmias and for providing cardiac resynchronization therapy in heart failure patients who remain symptomatic despite optimal medical therapy and meet any of the following classifications: New York Heart Association (NYHA) Functional Class III or IV and who have a left ventricular ejection fraction ≤ 35% and a prolonged QRS duration. Left bundle branch block (LBBB) with a QRS duration ≥ 130 ms, left ventricular ejection fraction ≤ 30%, and NYHA Functional Class II. The system is also indicated for use in patients with atrial tachyarrhythmias, or those patients who are at significant risk for developing atrial tachyarrhythmias.
Lead Integrity Alert
The RV Lead Integrity Alert feature is intended primarily for patients who have a Medtronic ICD or CRT-D device and a Sprint Fidelis lead (Models 6949, 6948, 6931, and 6930). At the discretion of the clinician, the feature may be used with other RV leads manufactured by Medtronic.

Contraindications: The Viva XT CRT-D system is contraindicated for patients experiencing tachyarrhythmias with transient or reversible causes including, but not limited to, the following: acute myocardial infarction, drug intoxication, drowning, electric shock, electrolyte imbalance, hypoxia, or sepsis. The device is contraindicated for patients who have a unipolar pacemaker implanted. The device is contraindicated for patients with incessant VT or VF. The device is contraindicated for patients whose primary disorder is chronic atrial tachyarrhythmia with no concomitant VT or VF.
Warnings and Precautions: Changes in a patient's disease and/or medications may alter the efficacy of the device's programmed parameters. Patients should avoid sources of magnetic and electromagnetic radiation to avoid possible underdetection, inappropriate sensing and/or therapy delivery, tissue damage, induction of an arrhythmia, device electrical reset, or device damage. Do not place transthoracic defibrillation paddles directly over the device. Certain programming and device operations may not provide cardiac resynchronization.

Potential Complications: Potential complications include, but are not limited to, rejection phenomena, erosion through the skin, muscle or nerve stimulation, oversensing, failure to detect and/or terminate tachyarrhythmia episodes, acceleration of ventricular tachycardia, and surgical complications such as hematoma, infection, inflammation, and thrombosis.

See the Device Manual for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and potential complications/adverse events. For further information, please call Medtronic at 1 (800) 328-2518 and/or consult Medtronic's website at www.medtronic.com.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

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Every Patient Optimized. **Every Minute.**