2019 HRS/EHRA/APHRS/LAHRS focused update to 2015 expert consensus statement on optimal implantable cardioverter-defibrillator programming and testing

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Abstract

The *2015 HRS/EHRA/APHRS/SOLAECE Expert Consensus Statement on Optimal Implantable Cardioverter-Defibrillator Programming and Testing* provided guidance on bradycardia programming, tachycardia detection, tachycardia therapy, and defibrillation testing for implantable cardioverter-defibrillator (ICD) patient treatment. The 32 recommendations represented the consensus opinion of the writing group, graded by Class of Recommendation and Level of Evidence. In addition, Appendix B provided manufacturer-specific translations of these recommendations into clinical practice consistent with the recommendations within the parent document. In some instances, programming guided by quality evidence gained from studies performed in devices from some manufacturers was translated such that this programming was approximated in another manufacturer's ICD programming settings. The authors found that the data, although not formally tested, were strong,

consistent, and generalizable beyond the specific manufacturer and model of ICD. As expected, because these recommendations represented strategic choices to balance risks, there have been reports in which adverse outcomes were documented with ICDs programmed to Appendix B recommendations. The recommendations have been reviewed and updated to minimize such adverse events. Notably, patients who do not receive unnecessary ICD therapy are not aware of being spared potential harm, whereas patients in whom their ICD failed to treat life-threatening arrhythmias have their event recorded in detail. The revised recommendations employ the principle that the randomized trials and large registry data should guide programming more than anecdotal evidence. These recommendations should not replace the opinion of the treating physician who has considered the patient's clinical status and desired outcome via a shared clinical decision-making process.

Manufacturer-Specific Translation of ICD Programming Recommendations[‡]

[‡]The manufacturer-specific programming settings/choices set forth below are based on a compilation of clinical expertise and clinical trial data as reported in the *2015 HRS/EHRA/APHRS/SOLAECE Expert Consensus Statement on Optimal Implantable Cardioverter-Defibrillator Programming and Testing*, of which this Appendix B is a part. These recommended settings/choices represent a diligent and good faith effort on the part of the writing committee to translate the consensus statement recommendations to device settings/choices for the four specified clinical issues/implantable cardioverter-defibrillator (ICD) therapies where the writing committee considered that there was sufficient consensus and supporting data to make recommendations intended to improve the safety, morbidity, and mortality profile of patients with these clinical issues/ICD therapies. They are the recommendations of the writing committee only. They do not represent the position or recommendations of HRS, EHRA, LAHRS (formerly SOLAECE), or APHRS, nor are they the manufacturer's nominal settings or the precise programming tested during clinical trials of these devices, nor are they necessarily the settings/choices that would be recommended by the manufacturer. These recommended settings/choices are not applicable in all circumstances. As stated in the Introduction to the consensus statement, "The care of individual patients must be provided in context of their specific clinical condition and the data available on that patient." Each treating physician must carefully consider the circumstances of their individual patient and determine whether these recommended settings/choices are appropriate to their patient's circumstances.

Abbott (Formerly St. Jude Medical)
Settings that are not nominal are marked with an asterisk.

Brady	**Single Chamber** VVI 40bpm **Dual Chamber** DDD, consider Ventricular Intrinsic Preference (VIP) $\pm$ rate response **CRT** DDD $\pm$ rate response Consider SyncAV* (if intact AV conduction) as appropriate
Detection	**In patients with no VT history** VF: 30 intervals*[1], 240 or 250bpm* VT2: 30 intervals*[1], 187bpm* VT: Monitor, at user discretion **In patients where VT CL is known** VF: 30 intervals*[1], 240 or 250bpm VT2: 30 intervals*[1], 187bpm or 10–20bpm < VT rate* VT: Therapy at 10–20bpm < VT rate or Monitor zone

[1] Fewer intervals to detect may be reasonable due to the possibility of VT straddling 2 zones that may result in "binning" to both zones, effectively doubling time to detect. Beats that fall out of zone sometimes reset counters so patients with poor sensing should also have fewer detection intervals considered.

Therapy	VF: ATP While Charging, 8 pulses at 85% VT CL
	        All shocks: Maximum output (unless DFT guided)
	        Note: 1st shock 4–6J lower than full output
	VT2: ATP, $\geq$1 bursts of 8 pulses at 85% VT CL
	        Scan step 10ms, Re-adaptive ON, Minimum CL 200ms
	        All shocks ON
	VT: As for VT2, favoring more ATP[2]

[2] Rarely, hemodynamically stable slow VT can be treated without programming a back-up shock.

SVT Discriminators[3]	**Single Chamber** Far-Field Morphology: All others:	 ON, 90%, 3 of 10 "Passive"
	Dual Chamber/CRT-D Far-Field Morphology: Arrhythmia onset: Interval Stability: If ALL	 ON, 90%, 3 of 10 ON (default settings) ON (default settings)
	For CRT: Template Auto Update 30 days and Template Pacing Hysteresis ON *or* Far-Field Morphology Auto Update OFF	
	SVT Upper Limit: SVT Discrimination Timeout: VT Therapy Timeout:	230bpm OFF OFF

[3] SVT Discriminators are not required in Complete Heart Block.

Oversensing Rejection	Low Frequency Attenuation: SecureSense RV Lead Noise Discrimination:	ON ON

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BIOTRONIK

Settings that are not nominal are marked with an asterisk.

Brady	<u>Single Chamber</u> VVI 40bpm <u>Dual Chamber</u> DDD, consider IRS Plus* / I OPT* ± Closed Loop Stimulation (CLS)* <u>or</u> DDD with Vp Suppression* ± rate response <u>CRT</u> DDD; optional DDD-CLS* <u>or</u> rate response* at user discretion
Detection	<u>In patients with no VT history[1]</u> VF: 30/40 intervals* (if programmable, otherwise 24/30), 231bpm* VT2: 30 intervals*, 188bpm* VT1: Monitor zone* at user discretion <u>In patients where VT CL is known</u> VF: 24/30 intervals*, 231bpm* VT2: 30 intervals*, 188bpm* (or 10–20bpm < VT rate) VT1: Therapy* at 10–20bpm < VT rate or Monitor zone* at user discretion

[1] SVT discriminators are linked to Detection Zones. An alternative configuration would be VF 250bpm, VT2 231bpm and VT1 188bpm with therapy (i.e., no Monitor zone) if >1 ATP attempt desired up to 250bpm.

Therapy	VF:	ATP One-Shot, 1 burst of 8 pulses at 88%[2] CL*, full output shocks (unless DFT guided)
	VT2:	ATP ≥1 bursts* of 8 pulses* at 88%[2] CL*, 10ms scan decrement*, All shocks ON
	VT1:	Monitor zone* or Therapy* as for VT2 (favoring more ATP)[3]

[2] If programmable, otherwise 85%.
[3] Rarely, hemodynamically stable slow VT can be treated without programming a back-up shock.

SVT Discriminators[4]	<u>Single Chamber</u>	
	MorphMatch[5]	ON(*)
	Onset[6]	OFF
	Stability	OFF*
	Sustained VT Timer	OFF
	<u>Dual Chamber/CRT-D</u>	
	SMART	ON (at default settings or adapted to known VT)

[4] SVT Discriminators are not required in Complete Heart Block.
[5] MorphMatch is recommended for patients with narrow QRS complexes and sufficient far-field amplitude. Otherwise, Onset 20% and Stability 48ms is a recommended alternative.
[6] If Onset is programmed ON, the performance of this discriminator is enhanced with a Monitoring Zone enabled.

Others	Lead Integrity check	ON (if available)
	HomeMonitoring	ON* (if available)

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Boston Scientific
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Brady	<u>Single Chamber</u> VVI, 40bpm* <u>Dual Chamber</u> DDD, consider RYTHMIQ* or AV Search +* ± rate response <u>CRT</u> DDD ± rate response Consider Smart Delay optimization of AV delays
Detection	<u>In patients with no VT history</u> *Option 1* – delayed therapy VF: 8 of 10 intervals plus 5-second duration*, 250bpm* VT: 8 of 10 intervals plus 12-second duration*, 185bpm* VT-1: Monitor, at user discretion *Option 2* – high-rate therapy VF: 8 of 10 intervals plus 2.5-second duration*, 200bpm* VT-1: Monitor, at user discretion <u>In patients where VT cycle length is known</u> VF: 5-second duration*, 250bpm* VT: 12-second duration*, 185bpm* or 10–20bpm < VT rate VT-1: Monitor Zone or Therapy at ≥12-second duration*, 10–20bpm < VT rate

Therapy	VF: QuickConvert ON to 300bpm* (if available)
	        All shocks: Maximum output (unless DFT guided)
	VT: ATP-1: Scan, ≥1 bursts, 8 pulses* at 84%* coupling interval and cycle
	        length (Minimum 200ms*), 10ms decrement*
	        ATP-2: OFF*
	        All shocks: ON
	VT-1: As for VT, favoring more ATP[1]
	[1] Rarely, hemodynamically stable slow VT can be treated without programming a back-up shock.

SVT Discriminators[2]	<u>ICD</u> RhythmID: ON <u>CRT-D</u> Onset/Stability: ON *or* RhythmID: ON* Sustained Rate Duration (SRD): OFF* SVT Discriminators apply only up to 230bpm [2] SVT Discriminators are not required in Complete Heart Block.
Oversensing Rejection	Nonphysiological Signal Detected: ON (Latitude)
Others	Turn on "Beep When Out-of-Range" Daily Lead Measurements* RV Pacing Impedance Abrupt Change alert ON (Latitude) Single Chamber: Consider %RV pacing alert ON (Latitude) Dual Chamber: Consider %RV pacing alert in non-AVB patients ON (Latitude) CRT-D: Consider CRT % pacing alert ON (Latitude)
SUBCUTANEOUS ICD Settings:	Shock Zone: ≥230bpm Conditional Zone: ≥200bpm or 10–20bpm < VT CL (if known) Consider post-shock pacing ON

Manufacturer-Specific Translation of ICD Programming Recommendations[‡]

Medtronic

Settings that are not nominal are marked with an asterisk

Brady	Single Chamber VVI 40bpm Dual Chamber DDD, consider Managed Ventricular Pacing (MVP; AAI↔DDD) ± rate response CRT DDD ± rate response Patient with intact AV conduction and LBBB—Consider Adaptive BiV & LV*
Detection	In patients with no VT history VF: 30/40 intervals, 188bpm FVT: OFF[1] VT: OFF VT Monitor: User discretion In patients where VT CL is known VF: 30/40 intervals, 188bpm FVT: OFF[1] VT: 24* intervals[2], 10–20bpm < VT rate VT Monitor: User discretion

[1] Use of ATP Before/During Charging in the VF zone achieves similar functionality as use of the FVT zone. Multi-zone programming using FVT may allow tiered ATP therapy.
[2] Consecutive count in VT zone; hence, lower NID as per PainFree SST data.

Therapy	VF:	ATP Before* Charging; ChargeSaver ON All shocks: Full output shocks (unless DFT guided)
	VT (if ON):	Rx1: ATP, ≥1 bursts of 8 pulses at 88% VT CL, 10ms Decrement Rx2-6: All Shocks ON[3]

[3] Rarely, hemodynamically stable slow VT can be treated without programming a back-up shock.

SVT Discriminators[4]	Single Chamber	
	Wavelet:	ON
	Limit:	260ms (230bpm)
	Stability:	OFF
	Onset:	OFF
	Dual Chamber/CRT-D	
	PR Logic:	ON (Other 1:1 OFF until lead stabilized at ∼3 months)
	Wavelet:	ON (if available)
	SVT Limit:	260ms (230bpm)
	Stability:	OFF
	Onset:	OFF

[4] SVT Discriminators are not required in Complete Heart Block.

Oversensing Rejection	Lead Integrity Alert:	ON
	T-wave Oversensing:	ON (if available)
	RV Lead Noise:	ON* without timeout (if available)

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MicroPort CRM (Formerly LivaNova and Sorin Group)
*Settings that are not nominal are marked with an asterisk.

Brady	Single Chamber VVI 40bpm* Dual Chamber SafeR (AAI↔DDD) ± rate response, consider DDD* in complete heart block CRT DDD ± rate response, consider weekly AV + VV SonR optimization ON[1]

[1] Requires SonRtip atrial lead with integrated hemodynamic sensor.

Detection	In patients with no VT history VF: 20 cycle* + 6/8 majority >255bpm* FVT: 20 cycle* + 6/8 majority 230bpm VT: 20 or 30 cycle* + 6/8 majority 185bpm Slow VT: Monitor zone at user discretion In patients where VT CL is known VF: 20 cycle* + 6/8 majority >255bpm* FVT: 20 cycle*+ 6/8 majority 230bpm VT: ≥20 cycle* + 6/8 majority 185bpm (or 10–20bpm < VT rate) Slow VT: Monitor zone at user discretion

Therapy	VF: 6 x 42J* FVT: If stable[2]: 1 x ATP (Burst @ 85% x 8 beats) then 6 x 42J* (unless DFT guided) If unstable: 6 x 42J* (unless DFT guided) VT: ≥1 x ATP (Burst + Scan @ 85% x 8 beats; Scan 8ms) then all Shocks ON*[3]

[2] Satisfaction of stability (nominal value = 30ms) in the Fast VT zone will not prevent therapy but rather activate programmable burst pacing prior to shock therapy.
[3] Rarely, hemodynamically stable slow VT can be treated without programming a back-up shock.

SVT Discriminators[4]	Single Chamber Single button programming; Stability+/Acc *Rate, Stability, Degree of Onset, VT long cycle search* Nominal settings: Onset 19%, Stability 65ms (Slow VT, VT); Long cycle extension 10 cycles; Long cycle gap 170ms Dual Chamber/CRT-D Single button programming; PARAD+ *Rate, Stability, AV association analysis, Degree and Chamber of Onset, VT long cycle search* Nominal settings: Onset 25%, Stability 65ms (Slow VT, VT); Long cycle extension 10 cycles; Long cycle gap 170ms

[4] SVT Discriminators are not required in Complete Heart Block.

Oversensing Rejection	Daily check Lead impedance ON* Daily check Lead coil continuity ON* Daily check V oversensing alerts ON* T-wave filtering and noise detection are hardcoded in firmware

Appendix 1   Author disclosure table

Writing group member	Employment	Honoraria/ Speaking/ Consulting	Speakers' bureau	Research*	Fellowship support*	Ownership/ Partnership/ Principal/ Majority stockholder	Stock or stock options	Intellectual property/ Royalties	Other
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Number value: **0** = $0; **1** = ≤ $10,000; **2** = > $10,000 to ≤ $25,000; **3** = > $25,000 to ≤ $50,000; **4** = > $50,000 to ≤ $100,000; **5** = > $100,000.
*Research and fellowship support are classed as programmatic support. Sources of programmatic support are disclosed but are not regarded as a relevant relationship with industry for writing group members or reviewers.

Appendix 2   Reviewer disclosure table

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Number value: **0** = $0; **1** = ≤ $10,000; **2** = > $10,000 to ≤ $25,000; **3** = > $25,000 to ≤ $50,000; **4** = > $50,000 to ≤ $100,000; **5** = > $100,000. ABIM = American Board of Internal Medicine.

*Research and fellowship support are classed as programmatic support. Sources of programmatic support are disclosed but are not regarded as a relevant relationship with industry for writing group members or reviewers.