

Single-Chamber ICD with Atrial Sensing & AHRE Detection: *Clinical Data & EGM Review*

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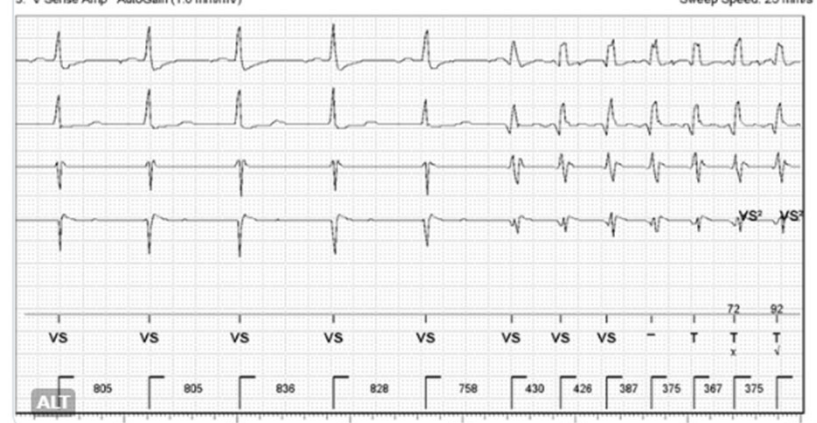
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Gregory Michaud
@DrGregMichaud

#Epeeps.. SVT with aberrancy or VT?

1: SVC-RV-coil AutoGain (0.8 mm/mV) 4: Discrimination AutoGain (1.2 mm/mV)
2: V Bipolar AutoGain (1.1 mm/mV) 5: Markers
3: V Sense Amp AutoGain (1.0 mm/mV)

Sweep Speed: 25 mm/s



VS VS VS VS VS VS VS VS VS - T T T
x v

805 805 836 828 758 430 426 367 375 367 375

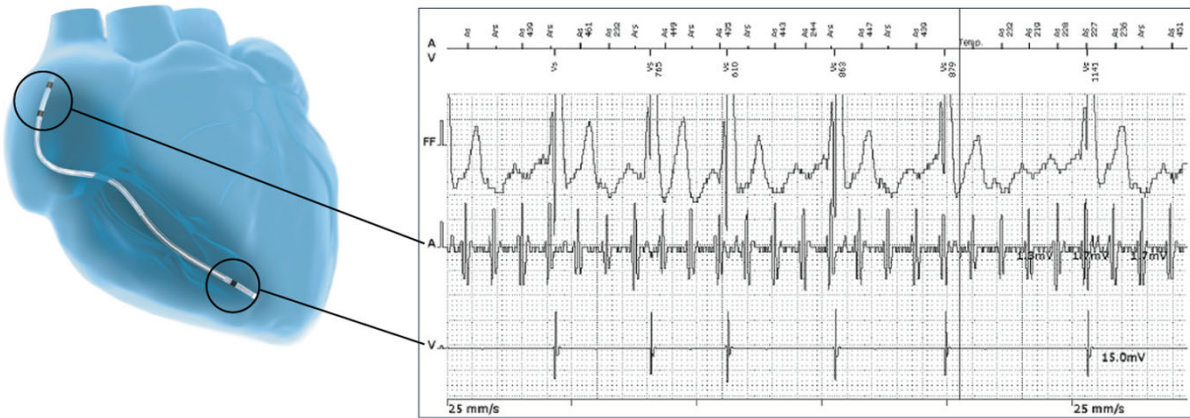
7.4 8.4 9.4 10.4 11.4 12.4 13.4

2 | FEBRUARY 26, 2024 | 12:40 PM · Jun 14, 2023 · 35.6K Views

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Evolution of ICD Therapy: DX Technology



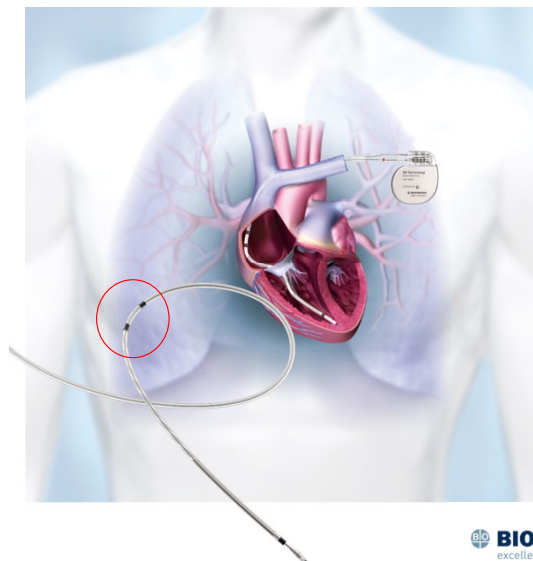
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DX: Single-Chamber ICD with Atrial Sensing and AHRE Detection

- DX provides benefits of DC-ICDs by providing atrial diagnostics without an atrial lead
- Detection of AHRE with enhanced diagnostic accuracy
- Discrimination of VT vs SVT
- Avoiding unnecessary atrial lead placement means fewer complications
- Reduced procedure complexity
- Cost savings with a single lead



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Expansive Body of Clinical Evidence Supporting DX

DX Publications

Study/Author	n	Follow-up Duration	Key Findings
Gwag, et al. ¹	86	24 months	P-waves stable at 24 months, atrial signal stabilizes greatly at 12-24 months
Mullane, et al.* ²	4,903	16 months	20% of CRT patients do not need an atrial lead
Pung, et al. ³	991**	24 months	Meta-analysis: DX superior to VR and equivalent to DR in AHRE detection
Shaik, et al. ⁴	240	6 months	CRT-DX patients fared better due to having fewer major complications and fewer inappropriate shocks
Biffi, et al. (2020) ⁵ THINGS	378	24 months	DX superior to VR in AHRE detection, OAC onset higher/earlier in DX group
Thomas, et al. ⁶ SENSE	150	12 months	DX superior to VR and equivalent to DR in AHRE detection
Kurt, et al. ⁷	212	24 months	Reduced inappropriate shocks
Biffi, et al. (2017) ⁸	37	36 months	Stable P-waves in CRT-DX
Safak, et al. ⁹	116	6 months	Appropriate atrial sensing in DX
Adria Investigators ¹⁰	249	12 months	DX can be implanted faster & is equal to DR in VT/SVT detection
Stazi, et al. ¹¹	43	12 months	Stable atrial sensing in DX, and amplification of P-wave effective
Niehaus, et al. ¹²	25	12 months	Stable detection of atrial & ventricular signals during all rhythms
Hindricks, et al. ¹³ MATRIX	2,054	24 months	High detection accuracy plus RM allows for effective subclinical AF monitoring
O'Connor, et al. ¹⁴ REACT-DX	234	16 months	Rapid intervention (within 24 days of detection) for high-risk group (81%), and >93% were not on OAC

* An analysis of atrial pacing percentage comparing CRT-DX (n = 387) to CRT-D (n = 4,516).

** A meta-analysis of SENSE, THINGS, and Statuto G, et al abstract

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SENSE Trial

Study Design

- Prospective, multi-site and cohort-controlled clinical trial
- 150 months
- Retrospective and

Results:

Zero inappropriate therapies in DX Cohort

Subclinical atrial fibrillation detection with a floating atrial sensing dipole in single lead implantable cardioverter-defibrillator systems: Results of the SENSE trial

George Thomas MD¹ | Daniel Y. Choi MD¹ | Harish Doppalapudi MD, FHRS² | Mark Richards MD, PhD, FHRS³ | Sei Iwai MD, FHRS⁴ | Emile G. Daoud MD, FHRS⁵ | Mahmoud Housse MD, FHRS⁵ | Arvindh N. Kanagasundram MD, FHRS⁶ | Sumeet K. Mainigi MD, FHRS⁷ | Steven A. Lubitz MD, MPH⁸ | Jim W. Cheung MD, FHRS¹

Thomas G et al. JCE. 2019 Oct;30(10):1994-2001.

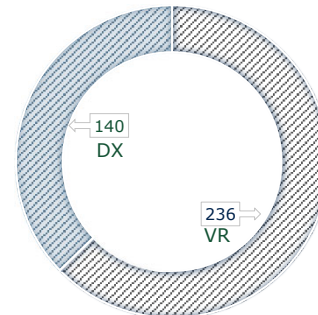
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The THINGS Registry (THE sINGLE-lead reGiStry): Study Design

Prospective, observational and multicenter study comparing clinical outcomes of patients implanted with a conventional single-chamber ICD (ICD VR group) to those implanted with a DX ICD (ICD DX group)

561 subjects @ 15 participating Italian centers

- 236 (62.8%) subjects in ICD VR cohort
- 140 (37.2%) subjects in ICD DX cohort
- Followed for a median of 27 months
- Pts were excluded due to early study drop-out (n = 35) or history of AF (n = 148)



Biffi M, et al. J Cardiovasc Electrophysiol. 2020 Apr;31(4):846-853

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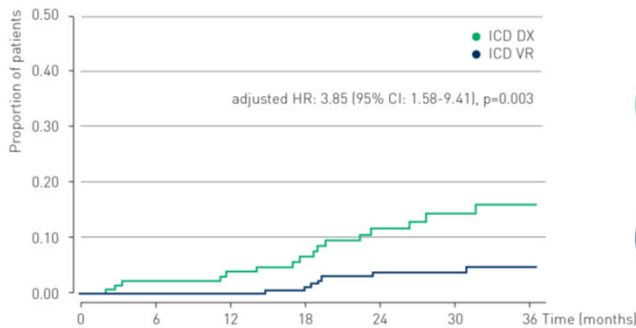


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THINGS Registry: New-onset AT/AF Diagnoses

Incidence of AT/AF Diagnosis: Significantly Higher with ICD DX Compared to Single-Chamber ICDs

New-Onset AT/AF Diagnosis



Number at risk	0	6	12	18	24	30	36
ICD DX	140	130	117	100	80	53	28
ICD VR	236	213	194	166	134	94	55

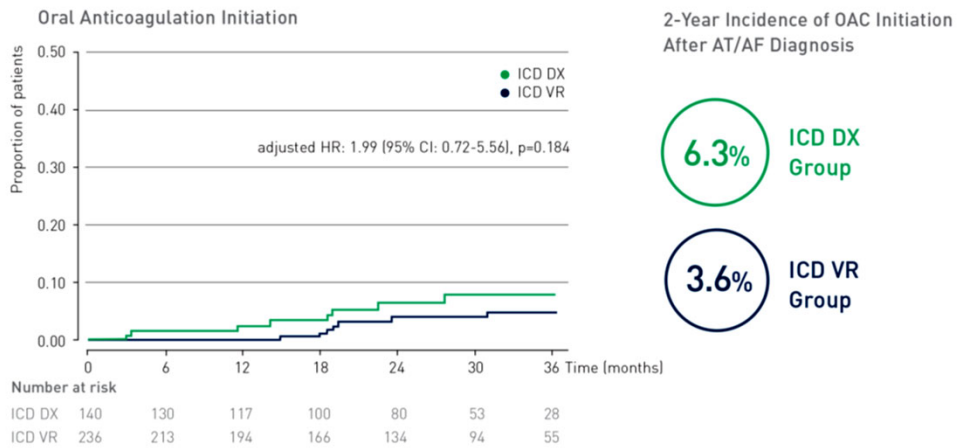
2-Year Incidence of New-Onset AT/AF Diagnosis



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THINGS Registry Results: New-onset OAC

Incidence of OAC Initiation: Trend for Higher Use with ICD DX



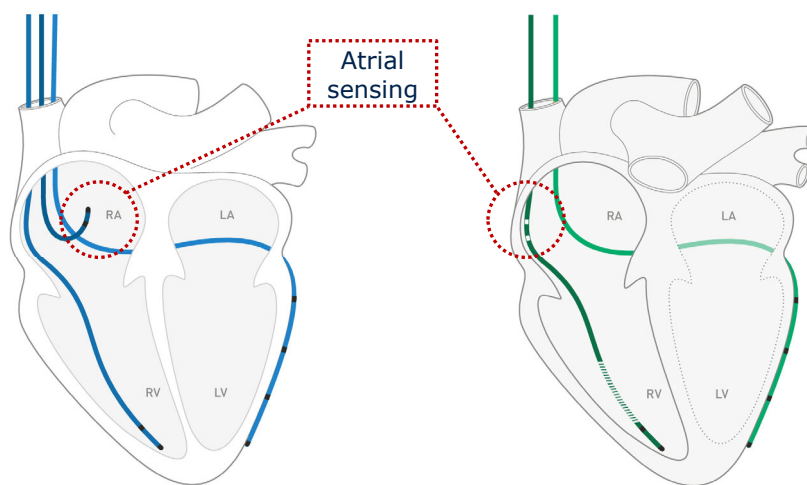
Biffi M, et al. J Cardiovasc Electrophysiol. 2020 Apr;31(4):846-853

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CRT-DX Offers 2-lead CRT



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QP ExCELS Lead Registry: 3-Lead CRT c/w DX CRT

Novel two-lead cardiac resynchronization therapy system provides equivalent CRT responses with less complications than a conventional three-lead system: Results from the QP ExCELS lead registry

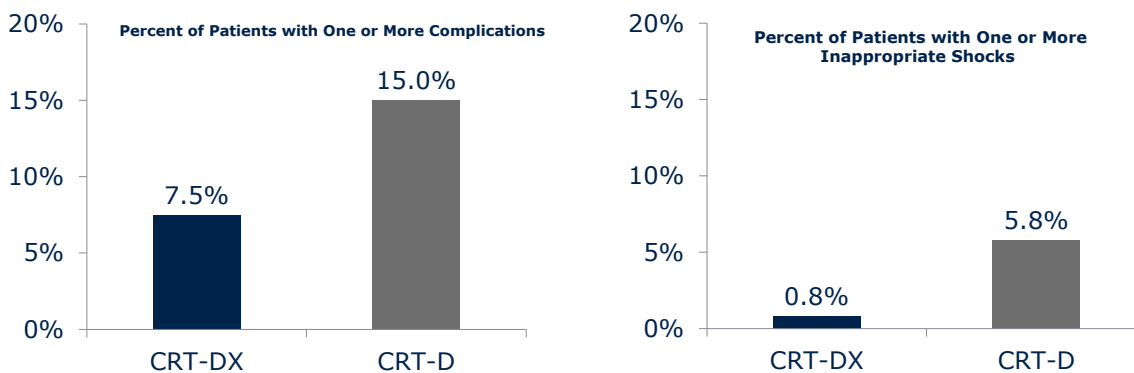
Naushad A. Shaik MD¹ | Michael Drucker MD² | Christopher Pierce MD³ | Gabor Z. Duray MD⁴ | Shane Gillett RN, BSN⁵ | Crystal Miller MS⁵ | Camden Harrell MS⁵ | George Thomas MD⁶

Shaik NA, et al. J Cardiovasc Electrophysiol. 2020 Jul;31(7):1784-1792.
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CRT-DX Patients Had Fewer Complications and Fewer Shocks



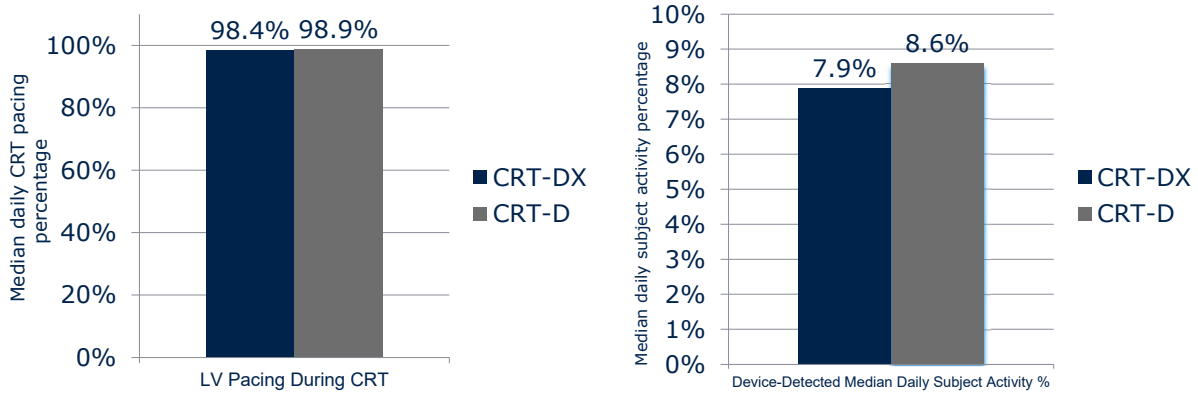
Complication-free survival favored the CRT-DX group with 92.5% of patients without a major complication compared to 85.0% in the CRT-D cohort (P=0.0495; 95% CI 0.1%–14.9%) over a mean follow-up of 1.3 and 1.4 years, respectively.

Shaik NA, et al. J Cardiovasc Electrophysiol. 2020 Jul;31(7):1784-1792.
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No Meaningful Difference in LV Pacing Percentage or Patient Activity



Device-detected median LV pacing during CRT was similar for both CRT-DX and CRT-D cohorts at 98.4% and 98.9%, respectively (P=0.2025). Device-detected median daily subject activity % in the CRT-DX cohort was 7.9% compared with 8.6% in the CRT-D cohort . (P=0.1647).

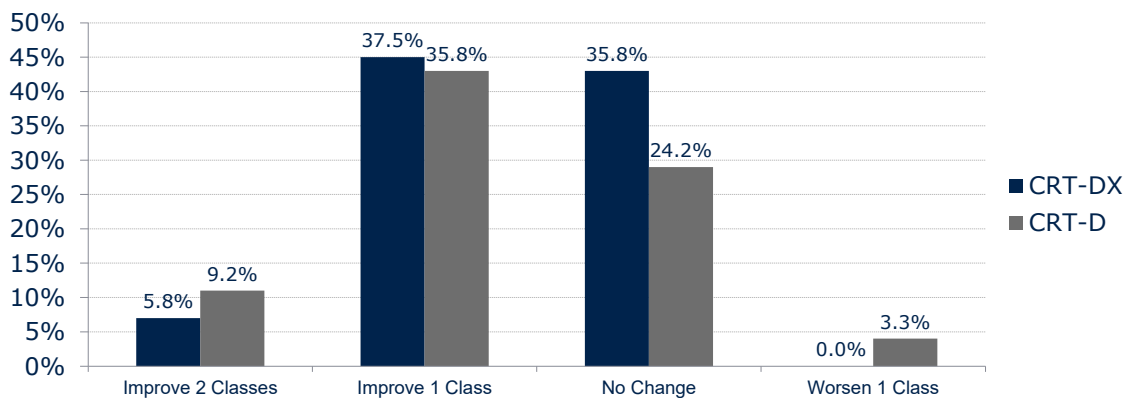
Shaik NA, et al. J Cardiovasc Electrophysiol. 2020 Jul;31(7):1784-1792.

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Similar NYHA Class Improvement at 6 Months



NYHA changes at 6 months follow-up. NYHA was not obtained at baseline and/or 6 months for 25 and 33 subjects in the CRT-DX and CRT-D cohorts, respectively. All percentages are displayed as absolute percentages (out of 120 subjects).

Shaik NA, et al. J Cardiovasc Electrophysiol. 2020 Jul;31(7):1784-1792.

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MATRIX

Using DX + HM to Remotely Monitor for Subclinical AF

- International, multicenter registry at **119 sites** in **24 countries**
- **Enrolled 2,054 DX-ICD patients and followed for 24 months**
- Key Takeaways
 - **99.6% detection accuracy** for AHRE lasting ≥ 1 hour
 - **92.5% Home Monitoring®** transmission performance
 - AF found in 8.2% of patients with no known history of AF, and these patients were often at high-risk of stroke (**80% high CHA₂DS₂-VASC scores of which 69.5% no OAC**)

"A 99.7% detection accuracy for AHRE lasting for ≥ 1 h, and 97.5% accuracy for AF ≥ 6 min, in combination with a 92.5% Home Monitoring® transmission performance allows a reliable guideline-recommended remote monitoring of subclinical AF in the vast majority of patients treated with a single-chamber ICD with atrial sensing capabilities (DX ICD)."

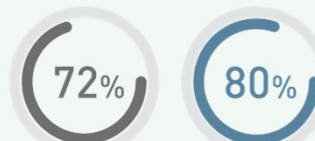
Highly Accurate AHRE Detection



Progression is common



of patients with new-onset AF showed progression. (AHRE durations $\geq 1h$)



Patients with new-onset AHRE who were not on OAC therapy at baseline (86/119)

Patients with new-onset AHRE with a high CHA₂DS₂-VASC score (95/119)

Hindricks G et al. EP Europace, 2023 Apr 11; euad061; doi: 10.1093/europace/euad061

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Journal of the American Heart Association

ORIGINAL RESEARCH

Single- Versus Dual-Chamber Implantable Cardioverter-Defibrillator for Primary Prevention of Sudden Cardiac Death in the United States

Gilad Margolis, MD; Nashed Hamuda, MD; Ofer Kobo, MD, MHA; Gabby Elbaz Greener, MD, MHA; Offer Amir, MD; Munther Homoud, MD; Christopher Madias, MD; Edwin Kevin Heist, MD, PhD; Jeremy N. Ruskin , MD; Mark Kazatsker, MD; Ariel Roguin , MD, PhD; Eran Leshem , MD, MHA; Guy Rozen , MD, MHA

Margolis, et al. JAHA 2023;12

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Single-Chamber vs Dual-Chamber ICD for Primary Prevention

- Dual-chamber ICD complication rate = 12.8%
- Single-chamber ICD complication rate = 10.7% ($p < 0.001$)
- Complication difference driven by:
 - \uparrow hemothorax in DC-ICD (4.6% v 3.4%, $p < 0.001$)
 - \uparrow lead dislodgement in DC-ICD (3.6% v 2.3%, $p < 0.001$)
- Atrial lead addition was an independent predictor for any complication, pneumo/hemothorax and atrial lead dislodgement

monitoring unjustifiable.¹⁹ In the subset of patients who may benefit from long-term atrial rhythm monitoring such as those with a markedly elevated stroke risk, the option of implanting a single ventricular implantable cardioverter-defibrillator lead with a floating atrial dipole was shown to be comparable to dICD in detecting atrial high-rate episodes.³³

As an sICD system does not provide atrial backup pacing, patients who are anticipated to meet a pacing

Margolis, et al. JAMA 2023;12 - Highlighted text summarized from Thomas G, et al., 2019

33. Thomas G, et al. Subclinical atrial fibrillation detection with a floating atrial sensing dipole in single lead implantable cardioverter-defibrillator systems: results of the SENSE trial. JCE. 2019; 30:1994-2001

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Interpreting Multiple Ventricular Rhythms in a Patient with a Single-Lead ICD

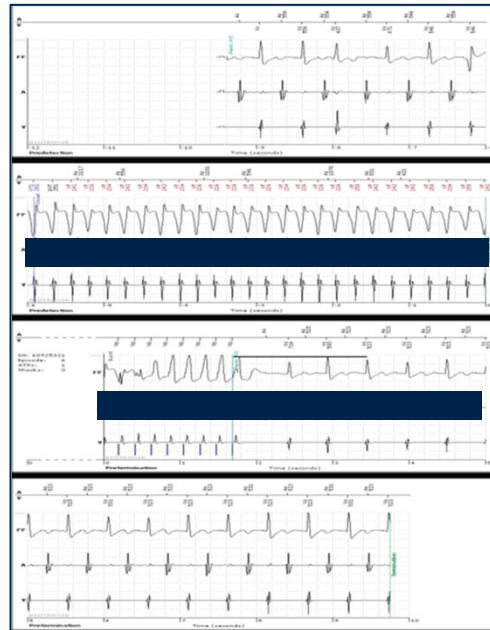
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What is the Rhythm?

Device:	Intica 7 VR-T DX
Implantation:	04/2018
Episode:	
Description:	

- Analyze the Ventricular channel
- Assess Morphology of Far-field channel
- Now analyze with visualizing the Atrium
 1. What is the V to A ratio?
 2. Are the V-V and A-A intervals stable?
 3. Are the A and V associated?



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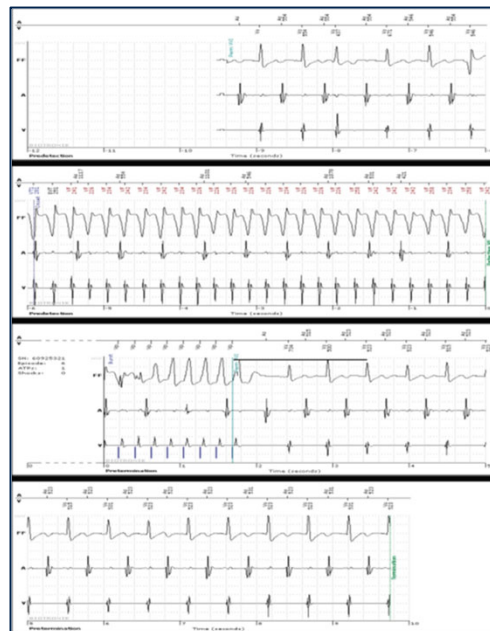
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What is the Rhythm?

Device:	Intica 7 VR-T DX
Implantation:	04/2018
Episode:	VF from 04/2018
Description:	Fast VT at 248 bpm detected in the VF Zone. ATP One Shot delivered after 24 cycles, successfully terminating rhythm. Device begins charging, but aborts a full charge after confirmation of VT termination.

- Analyze the Ventricular channel
- Assess Morphology of Far-field channel
- Now analyze with visualizing the Atrium
 1. What is the V to A ratio?
 2. Are the V-V and A-A intervals stable?
 3. Are the A and V associated?



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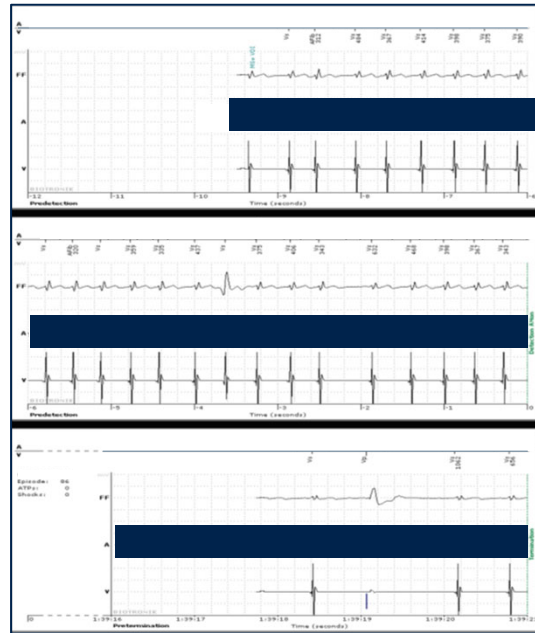
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What Is the Rhythm?

Device:	Intica 7 VR-T DX
Implantation:	01/2019
Episode:	
Description:	

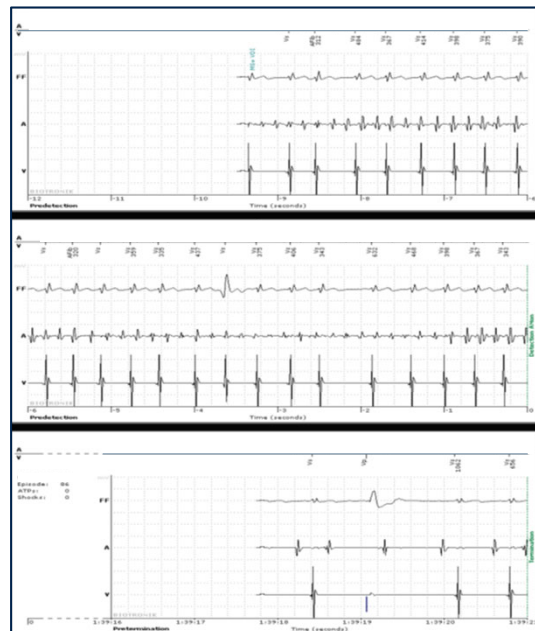
- Analyze the ventricular channel
- Assess morphology of far-field channel
- Now analyze with visualizing the atrium
 1. What is the V to A ratio?
 2. Are the V-V and A-A intervals stable?
 3. Are the A and V associated?



What Is the Rhythm?

Device:	Intica 7 VR-T DX
Implantation:	01/2019
Episode:	Atrial monitoring episode from 03/2020
Description:	Afib with rapid ventricular rate at 152 bpm

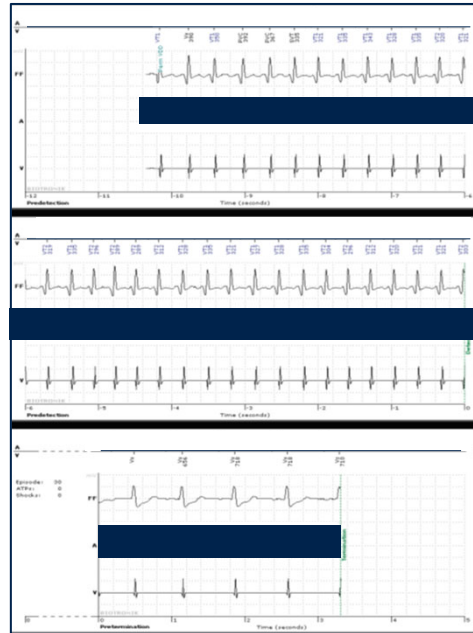
- Analyze the ventricular channel
- Assess morphology of far-field channel
- Now analyze with visualizing the atrium
 1. What is the V to A ratio?
 2. Are the V-V and A-A intervals stable?
 3. Are the A and V associated?



What Is the Rhythm?

Device:	Intica 7 VR-T DX
Implantation:	12/2018
Episode:	
Description:	

- Analyze the ventricular channel
- Assess morphology of far-field channel
- Now analyze with visualizing the atrium
 1. What is the V to A ratio?
 2. Are the V-V and A-A intervals stable?
 3. Are the A and V associated?



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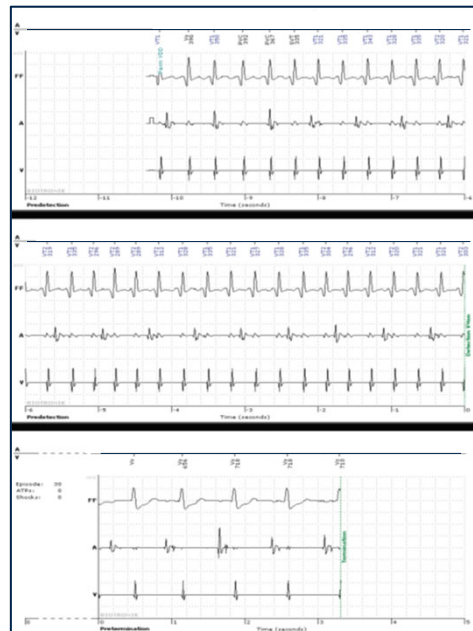


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What Is the Rhythm?

Device:	Intica 7 VR-T DX
Implantation:	12/2018
Episode:	VT from 08/2019
Description:	VT in monitoring zone with narrow morphology that is almost indistinguishable from sinus. The atrial channel indicates that this rhythm is ventricular driven.

- Analyze the ventricular channel
- Assess morphology of far-field channel
- Now analyze with visualizing the atrium
 1. What is the V to A ratio?
 2. Are the V-V and A-A intervals stable?
 3. Are the A and V associated?



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Summary

- Large and expanding evidence base supporting clinical advantages of DX to SC-ICD and advantages to DC-ICD when atrial pacing not indicated
- Margolis, et al, demonstrated significantly higher complication rate in patients receiving atrial pacing leads when no clinical need for atrial support
- Higher detection of AHRE and faster clinical response, e.g. initiation of OAC, with DX compared to SC-ICD
- Fewer inappropriate shocks in multiple studies



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Thank you!

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