Lynn Settergren

DOCKET DATE Jul 16, 2024



John Tomkinson

MURJ ID MRN # DOB Clinic Site Following Physician 1591407 60007566543 01/26/1957 Cherry Hill Adam Zivin

SUMMARY STATEMENT

This report includes 1 total transmission that was received on 07/16/24. Battery, lead impedance, sensing amplitude and pacing threshold data was reviewed and tested.

PROGRAMMING EVALUATION PERFORMED

IMPRESSIONS

Normal In-Office: With Events

- Normal Device Function
- Events or Alerts: AFL, PMT (false)
- Battery: OK, 11.5 years
- Sensing, impedance and thresholds reviewed and tested
- Presenting Rhythm: was AP VP 80s
- Underlying Rhythm: was no P waves at 40 ppm, intact AV conduction which lengthens with increasing rate
- Heart Rate Histograms reviewed
- Pacing and Detection Parameters were evaluated

Created By: Lynn Settergren 07/16/2024 03:55 PM

Tachycardia: AFL

- Stored EGMs are consistent with or suggestive of Atrial Flutter
- AT Burden: 4%
- Total number of events: 210
- EGMs show AFL with some flutter waves falling into blanking
- recent episode of AFL was persistent from 7/6/24 with recent self-conversion on 7/10/24
- correlates with recent GI symptoms
- rates were controlled but EGMs showed some 2:1 conduction in the 150s

Created By: Lynn Settergren 07/16/2024 03:59 PM

Pacemaker Mediated Tachycardia (PMT)

- Stored EGMs are NOT consistent with or suggestive of Pacemaker Mediated Tachycardia
- Stored EGMs reviewed and show tracking at max track rate when flutter waves fall into PVAB

Created By: Lynn Settergren 07/16/2024 04:00 PM

Rate Response Suboptimal

- $\bullet \ \ \text{Rate histograms consistent with or suggestive of suboptimal rate response programming}$
- Patient Symptomatic? patient reports excessive rates for minimal movement such as bending down and stretching out arms (as to put on a shirt)
- Device Reprogrammed? Y
- had pt recreate movements that cause excessive rates and sensor driven rates were observed in the 100s
- recalibrated MV to the RV lead and pt repeated movements. sensor driven rates were still 90s-100s
- changed MV ventilatory threshold from 125-115ppm and reduced MV response factor from 11-7 and added accelerometer. rates were still in the 90s with minimal upper body movement
- programmed MV to passive with accelerometer on with med/low threshold and response factor of 9. hallwalk produced peak rate of 97ppm
- $\bullet \;\;$ contacted BSX rep to discuss case with an engineer

Created By: Lynn Settergren 07/16/2024 04:06 PM Edited By: Lynn Settergren 07/16/2024 04:08 PM

Device Reprogrammed

Device reprogrammed, changes are listed below:

- changed MV to passive after recalibrating to the RV lead
- turned on accelerometer with med/low threshold and response factor of 9

Created By: Lynn Settergren 07/16/2024 04:07 PM

PLAN

Routine remote and in-office follow up as needed

Additional Notes:

quarterly transmissions, annual office visit

맛 CPT: 93280 ICD-10: 295.0. 149.5

Boston Scientific IMPLANT DATE: 11/15/2021

IPG: L331 S/N: 959438

LEADMFRMODELIMPLANT DATERight AtriumBoston Scientific78412021-11-15Right VentricleBoston Scientific78422021-11-15

BATTERY: Battery has 11.5 years left. Battery Status: OK.

♦ On Anticoagulant

♥ Pacer Dependent

07/16/2024 ▼

07/16/2024 -

07/16/2024 -

2V @ 0.4ms

+ EF

MR Conditional

MOST RECENT IMPRESSIONS

- Device Reprogrammed (6)
- Rate Response Suboptimal (3)
- Pacemaker Mediated Tachycardia (PMT) (2) 07/16/2024 ▼
- Tachycardia: AFL (4)

PACING INDICATION
Sick Sinus Syndrome (SSS) / Sinus Node Dysfunction

LEAD	SENSING	IMPEDANCE	THRESHOLD
RA	PacedmV	630 Ω	0.7V @ 0.4ms
	Fixed 0.5mV		on 07/16/2024 2V @ 0.4ms
RV	22.4mV Fixed 2.5mV	942 Ω	0.9V @ 0.4ms on 07/16/2024

PARAMETER SUMMARY

MODE: PACED CHAMBER: LOWER RATE: DDDR 65

MODE SWITCH: TRACKING RATE: SENSOR RATE: 160 125 155

PACED AV: SENSED AV: LVRV Delay:

320 300

TYPE STATUS RATES THERAPIES

VT On 160 bpm

RECENT THERAPY COUNTS

Shocks Delivered: Shocks Aborted: ATP Delivered:



Lynn Settergren

DOCKET DATE Jul 16, 2024 **SWEDISH**

John Tomkinson

MURJ ID MRN # 1591407 60007566543 01/26/1957 Cherry Hill Adam Zivin

Clinic Site Following Physician **设** CPT: 93280 ICD-10: *Z***95.0, I49.5**

Boston Scientific

IMPLANT DATE: 11/15/2021

IPG: L331 S/N: 959438

I REVIEWED THE DATA AND AGREE WITH THE FINDINGS IN THIS REPORT. ELECTRONICALLY

Adam Zivin MD

ELECTRONICALLY SIGNED ON:

Jul 22, 2024 @ 10:44 am



LATITUDE™ Programming System **Combined Follow-up Report**

Tomkinson, John

Date of Birth 26 Jan 1957

ACCOLADE MRI EL L331/959438 Device

Report Created 16 Jul 2024

Last Office Interrogation

16 Feb 2024 Implant Date 15 Nov 2021

My Alerts

There are no alerts to display.

Events Since Last Reset (16 Feb 2024)

10 Jul 2024 02:26 ATR at 247 bpm, Avg V Rate in ATR: 68 bpm 10 Jul 2024 00:44 ATR at 252 bpm, Avg V Rate in ATR: 83 bpm

See last page for full list of Events Since Last Reset.

Battery

Approximate time to explant: 11.5 years

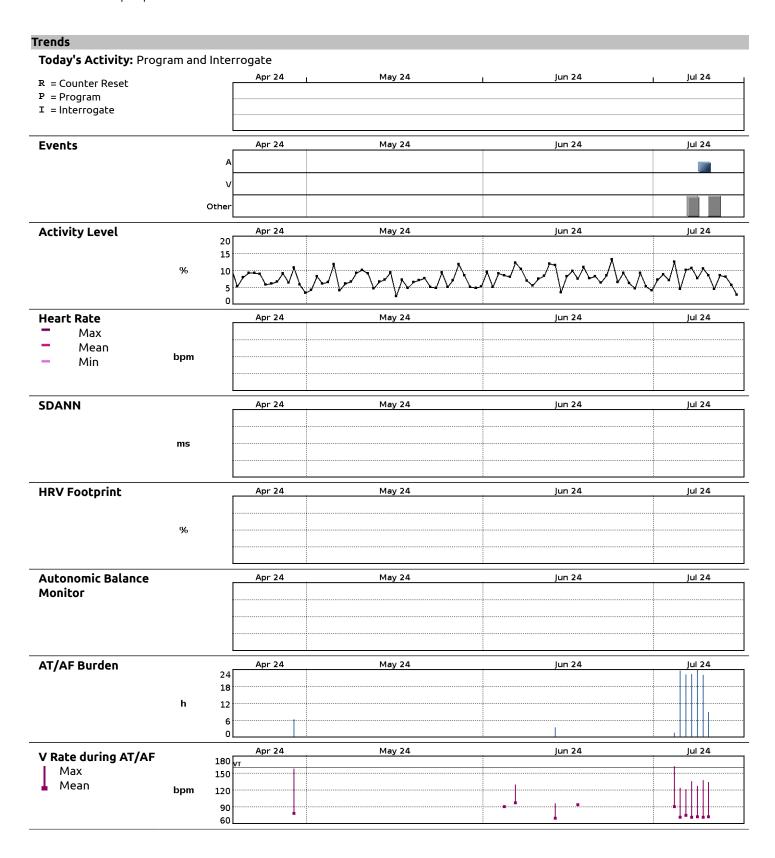
Magnet Rate 100 ppm One Year Remaining

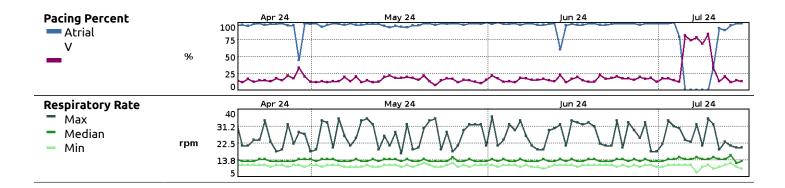
		Explant	
Leads Data	Implant 15 Nov 2021	Previous Session	Most Recent
Atrial			
Intrinsic Amplitude	4.0 mV	/ Paced mV	Paced mV
Pace Impedance	700 Ω	718 Ω	630 Ω
Pace Threshold	0.7 V @ 0.5 ms	0.8 V @ 0.4 ms	0.7 V @ 0.4 ms
Ventricular			
Intrinsic Amplitude	14.0 mV	23.0 mV	22.4 mV @ 40 bpm
Pace Impedance	1100 Ω	922 Ω	942 Ω
Pace Threshold	0.7 V @ 0.5 ms	0.6 V @ 0.4 ms	0.9 V @ 0.4 ms
Settings			
Ventricular Tachy Settings		Atrial Tachy Settings	
Ventricular Tachy EGM Storage	On	ATR Mode Switch 160 bpm DDIR	
Detection Rate	160 bpm		
Brady Settings			
Mode	DDDR	Pacing Output	
RYTHMIQ™	Off	Atrial	2.0 V @ 0.4ms
Lower Rate Limit	65 ppm	Ventricular	2.0 V @ 0.4ms
Maximum Tracking Rate	125 ppm	Sensitivity	
Maximum Sensor Rate	155 ppm	Atrial	Fixed 0.5 mV
Paced AV Delay	200 - 320 ms	Ventricular	Fixed 2.5 mV
Sensed AV Delay	190 - 300 ms	Leads Configuration (Pace/Sense)	
A-Refractory (PVARP)	240 - 340 ms	Atrial	Bipolar
V-Refractory (VRP)	190 - 250 ms	Ventricular	Bipolar
		Rate Adaptive Pacing	-
		Minute Ventilation	Passive

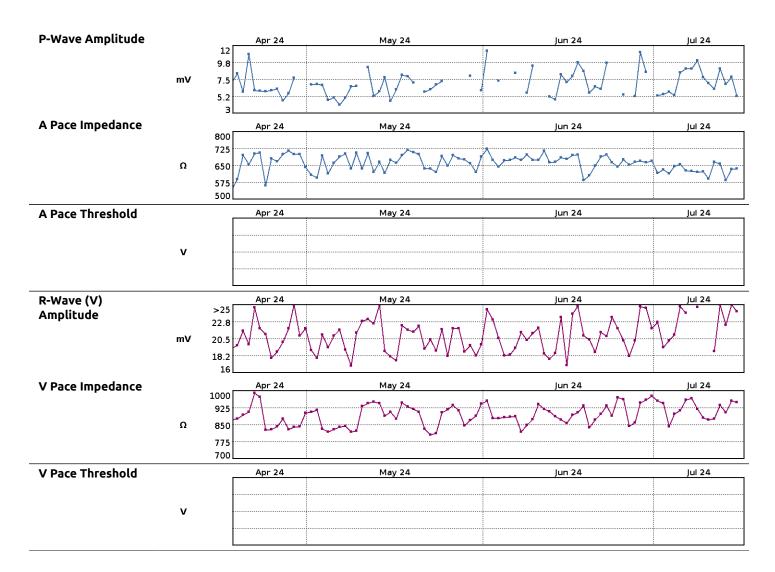
Accelerometer

3869 Software Version: 1.10 L331 Firmware Version: F_v1.00.00(2.01) Clinician Signature:

On

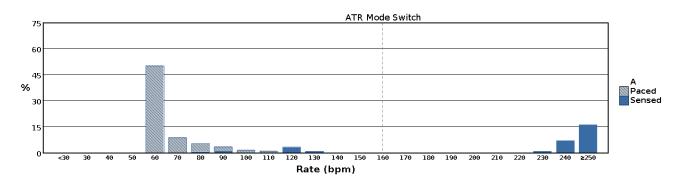


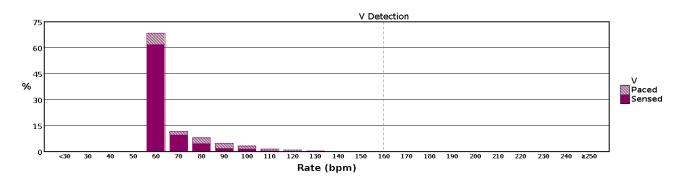


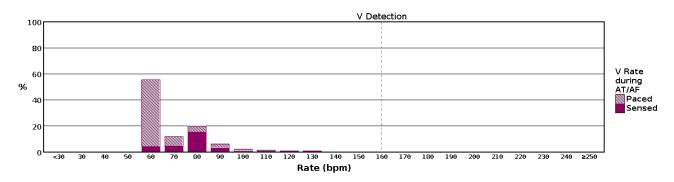


Ventricular Tachy Counters		Since Last Reset 16 Feb 2024	Device Totals	
Ventricular Episode Coun	ters			
Total Episodes		0	4	
VT Episodes (V>A)		0	1	
SVT Episodes (V<=A)		0	0	
Nonsustained Episodes		0	3	
Brady Counters		Reset Before Last 358 day(s) 23 Feb 2023 to 16 Feb 2024	Since Last Reset 150 day(s) 16 Feb 2024 to Today	
Counters				
% A Paced		70	86	
% V Paced		20	18	
Intrinsic Promotion				
AV Search +				
% Successful		69	100	
Rate Hysteresis				
% Successful		0	0	
Atrial Arrhythmia				
% AT/AF		<1	4	
(One Year of Data)				
Total Time in AT/AF (days)		<0.1	6.5	
(One Year of Data)				
Episodes by Duration				
< 1 minute		347	93	
1 min - < 1 hr		216	89	
1 hr - < 24 hr		159	28	
24 hr - < 48 hr		1	0	
> 48 hr		0	0	
Total PACs		129.4K	31.3K	
Ventricular Counters				
Total PVCs		57.4K	477	
Three or More PVCs		0	0	
AT/AF Overview: Since Las	t Reset (16 Feb 2024 to $^{ extsf{T}}$			
AT/AF: 4 %	AT/AF Events: 210	Total Time in AT/AF (c		
Most Recent:	10 Jul 2024 02:26	Avg V Rate: 68 bpm	Duration: 06:35:46 hh:mm:ss	
Longest:	07 Jul 2024 00:24	Avg V Rate: 69 bpm	Duration: 17:10:25 hh:mm:ss	
Fastest VS Rate:	04 Jul 2024 23:44	Max V Rate: 161 bpm	Duration: 00:17:32 hh:mm:ss	
AT/AF Overview: Reset Bel				
Longest:	16 Арг 2023 21:28	Avg V Rate: 86 bpm	Duration: 25:54:14 hh:mm:ss	
Fastest VS Rate:	06 Apr 2023 22:37	Max V Rate: 167 bpm	Duration: 00:00:10 hh:mm:ss	

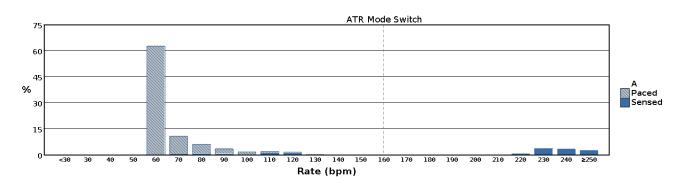
Histograms Reset Before Last (23 Feb 2023)







Histograms Since Last Reset (16 Feb 2024)

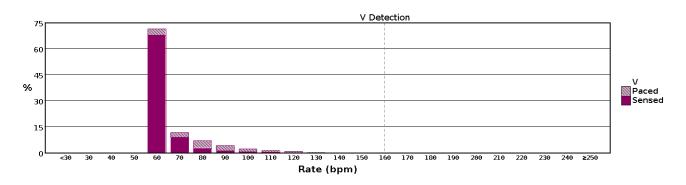


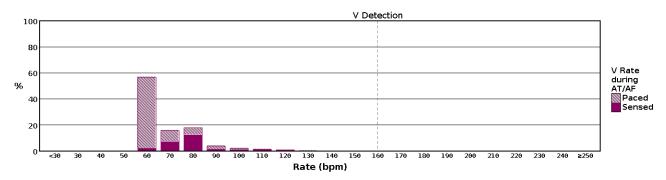
3869 Software Version: 1.10 L331 Firmware Version: F_v1.00.00(2.01) © 2014-2019

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Page 6 of 7

Histograms Since Last Reset (16 Feb 2024)





Heart Rate Variability

Last Measured:

HRV data unavailable because device was reprogrammed in the last 24 hours.

Reference:

HRV data unavailable because device was reprogrammed in the last 24 hours.

All Events Since Last Reset (16 Feb 2024)

11 Jul 2024 18:	:56	APM RT at 79 bpm	
10 Jul 2024 02:	:26	ATR at 247 bpm, Avg V	Rate in ATR: 68 bpm
10 Jul 2024 00:	:44	ATR at 252 bpm, Avg V	Rate in ATR: 83 bpm
10 Jul 2024 00:	:25	ATR at 263 bpm, Avg V	Rate in ATR: 86 bpm
10 Jul 2024 00:	:24	ATR at 213 bpm, Avg V	Rate in ATR: 121 bpm
10 Jul 2024 00:	:20	ATR at 210 bpm, Avg V	Rate in ATR: 107 bpm
10 Jul 2024 00:	:20	ATR at 209 bpm, Avg V	Rate in ATR: 121 bpm
10 Jul 2024 00:	:19	ATR at 261 bpm, Avg V	Rate in ATR: 116 bpm
10 Jul 2024 00:	:18	ATR at 261 bpm, Avg V	Rate in ATR: 118 bpm
10 Jul 2024 00:	:15	ATR at 208 bpm, Avg V	Rate in ATR: 102 bpm
10 Jul 2024 00:	:13	ATR at 260 bpm, Avg V	Rate in ATR: 120 bpm
09 Jul 2024 23:	:17	PMT at 125 bpm	
09 Jul 2024 23:	:17	PMT at 125 bpm	
09 Jul 2024 23:	:17	PMT at 125 bpm	
07 Jul 2024 22:	:51	PMT at 125 bpm	
07 Jul 2024 22:	:50	PMT at 125 bpm	



Tomkinson, John

Date of Birth 26 Jan 1957 Device ACCOLADE

ACCOLADE MRI EL L331/959438

Report Created 16 Jul 2024

Last Office Interrogation

16 Feb 2024 Implant Date **15 Nov 2021**

Event ATR-1080: 10 Jul 2024 00:25

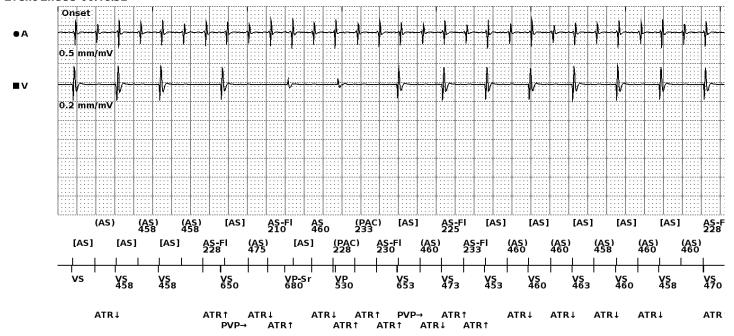
25mm/s

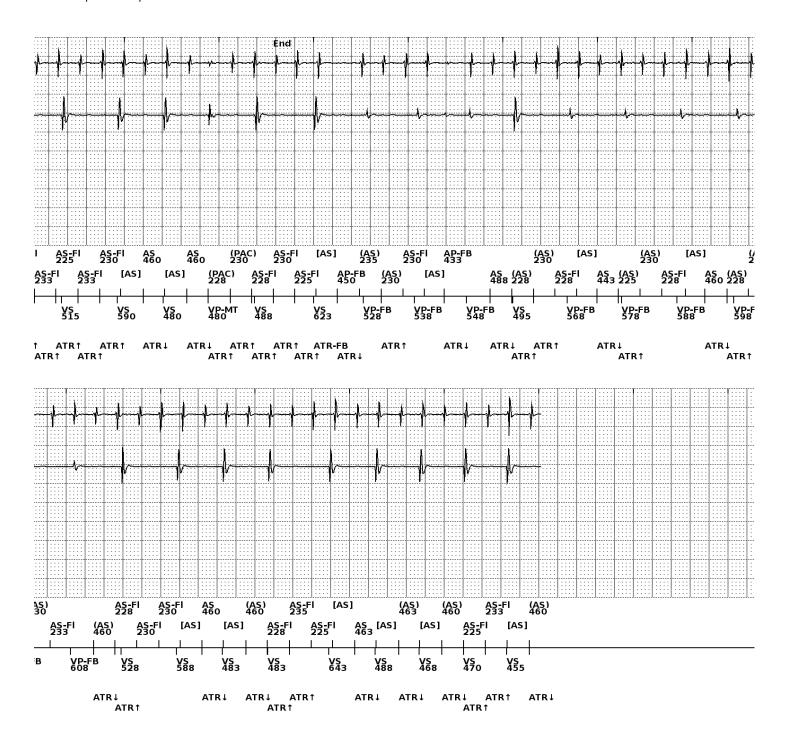
ATR Event Onset Avg A Rate: 263 bpm Avg V Rate: 116 bpm

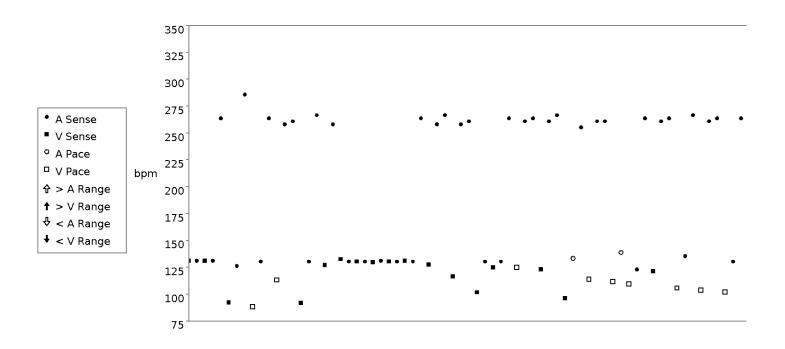
In ATR

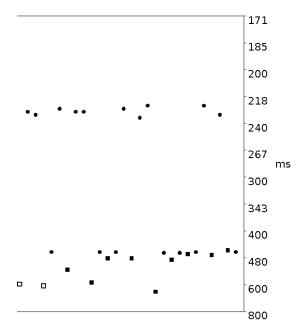
Avg V Rate: 86 bpm

Event Ended 00:18:52











Tomkinson, John

Date of Birth 26 Jan 1957

Device ACCOLADE MRI EL L331/ 959438

Report Created 16 Jul 2024

Last Office Interrogation

16 Feb 2024 Implant Date **15 Nov 2021**

Event ATR-1082: 10 Jul 2024 02:26

25mm/s

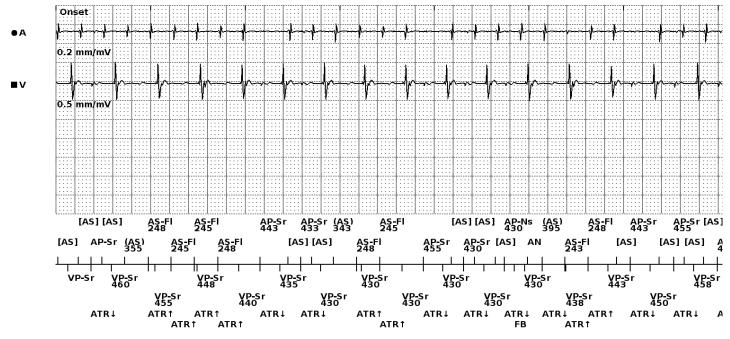
ATR Event Onset

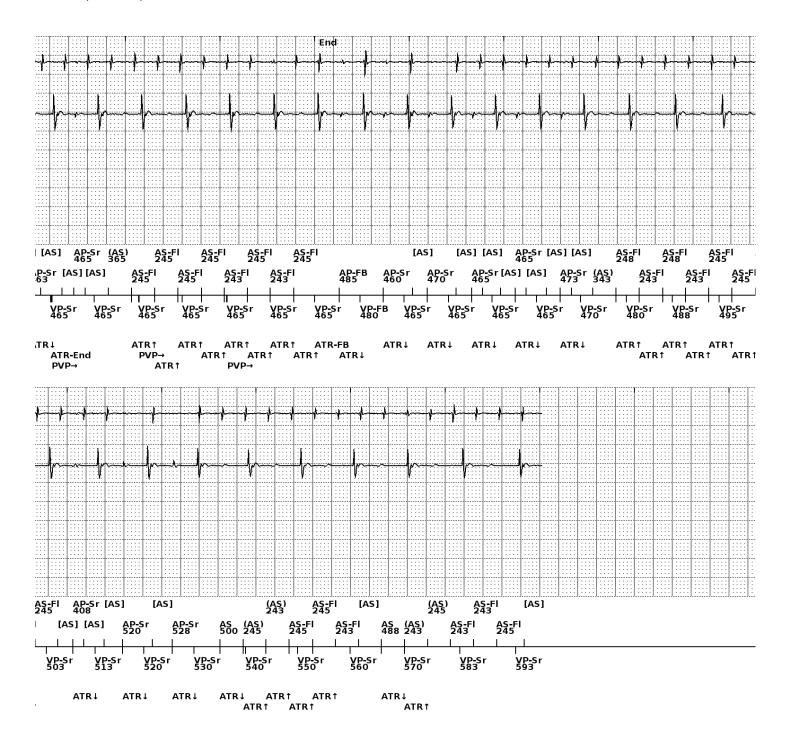
Avg A Rate: 247 bpm Avg V Rate: 129 bpm

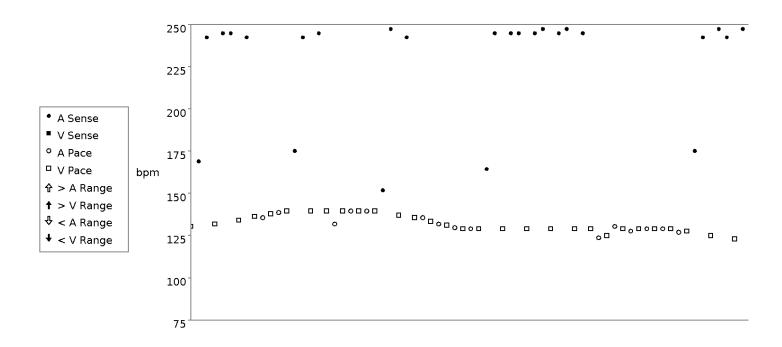
In ATR

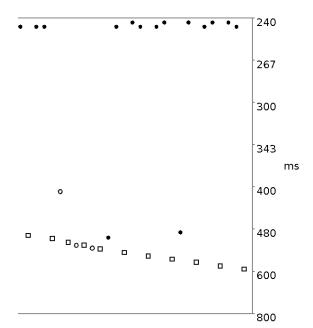
Avg V Rate: 68 bpm

Event Ended 06:35:46











Tomkinson, John

Date of Birth 26 Jan Device ACCOL

ACCOLADE MRI EL L331/ 959438

Report Created 16 Jul 2024

Last Office Interrogation

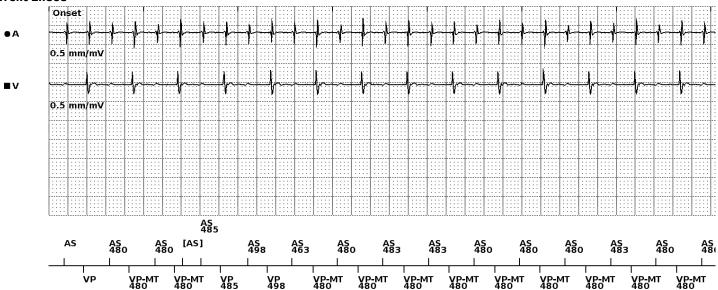
16 Feb 2024 Implant Date 15 Nov 2021

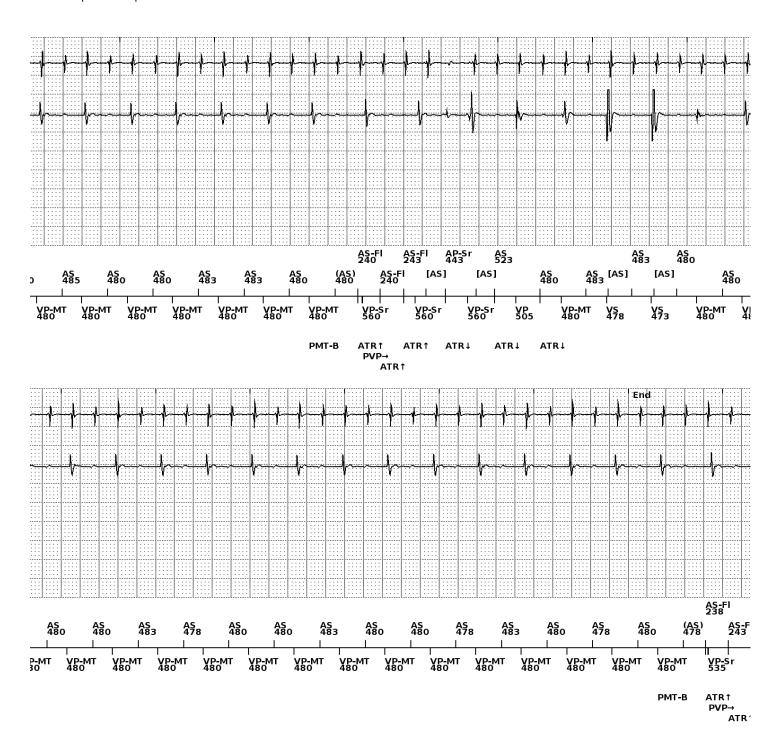
Event PMT-48: 09 Jul 2024 23:17

25mm/s

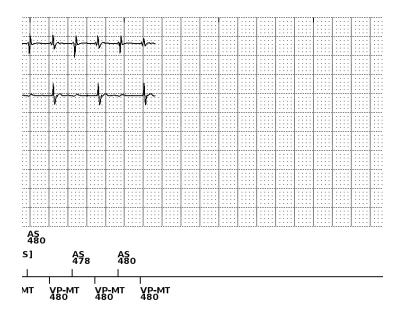


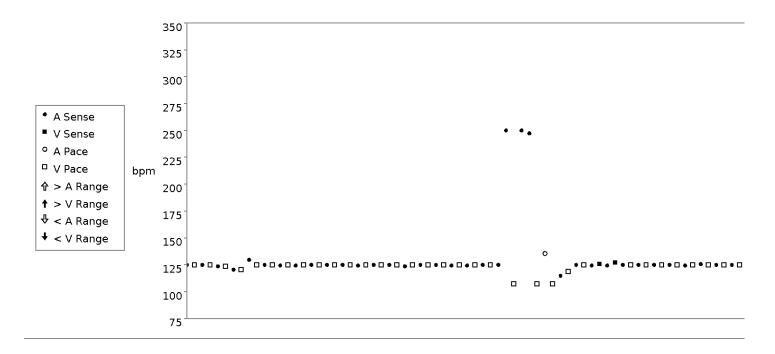




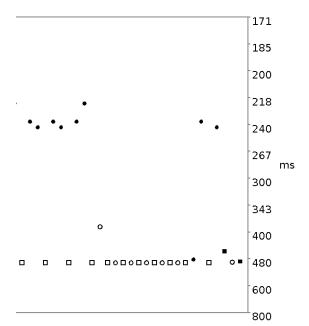














Tomkinson, John

Date of Birth 26 Jan 1957 Device ACCOLADE MRI EL L331/ 959438 Report Created 16 Jul 2024

Last Office Interrogation **16 Feb 2024**

Implant Date
15 Nov 2021

Event PMT-49: 09 Jul 2024 23:17

25mm/s



Event Ended -----



ATR↑ ATR↓

ATR↑ PVP→

ATR↓

ATR↓

ATR↓

3869 Software Version: 1.10 L331 Firmware Version: F_v1.00.00(2.01)

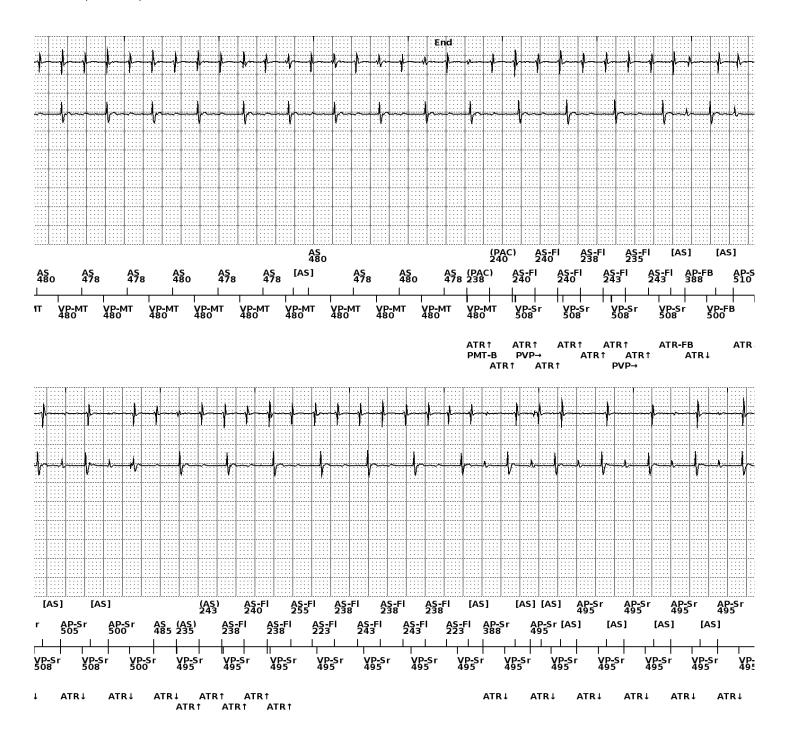
РМТ-В

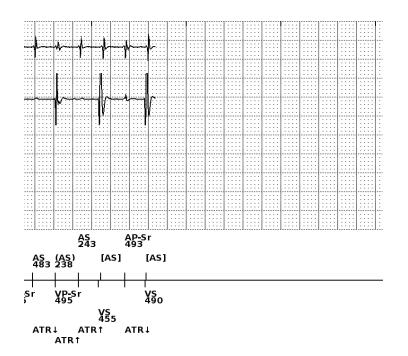
ATR1

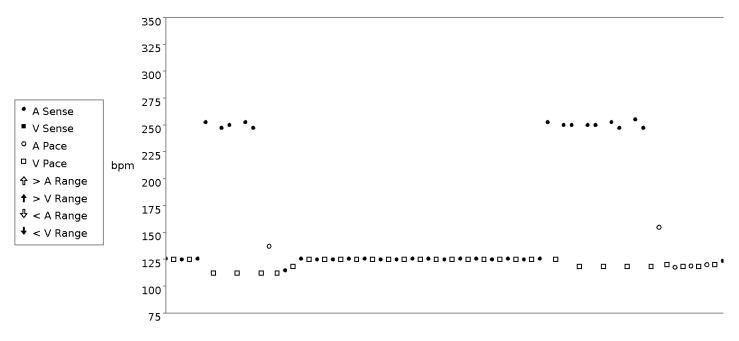
ATR↑

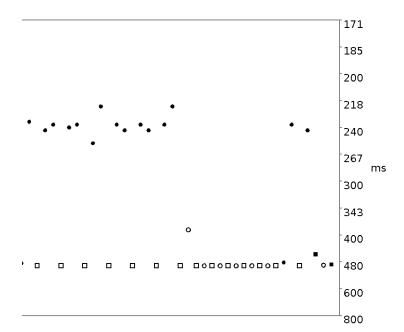
ATR1

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Page 1 of 4









LATITUDE™ Programming System

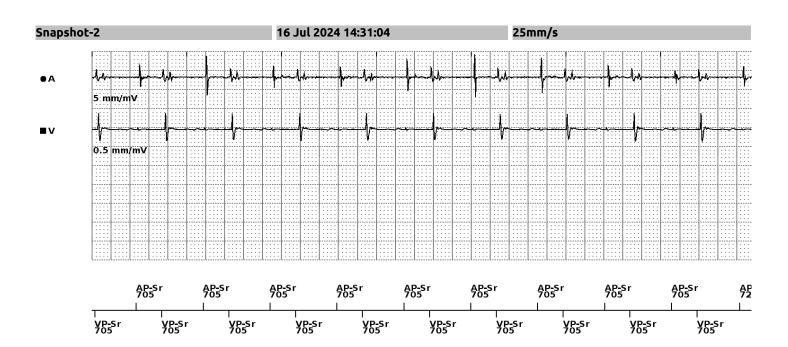
Real-time Log Report Tomkinson, John

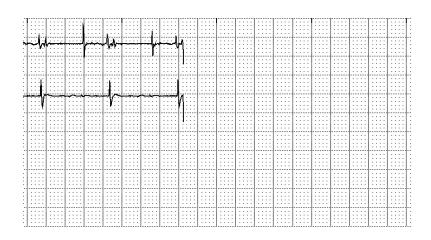
Date of Birth 26 Jan 1957

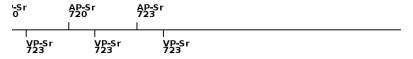
Device ACCOLADE MRI EL L331/ 959438

Report Created 16 Jul 2024

Last Office Interrogation







LATITUDE™ Programming System

Real-time Log Report Tomkinson, John

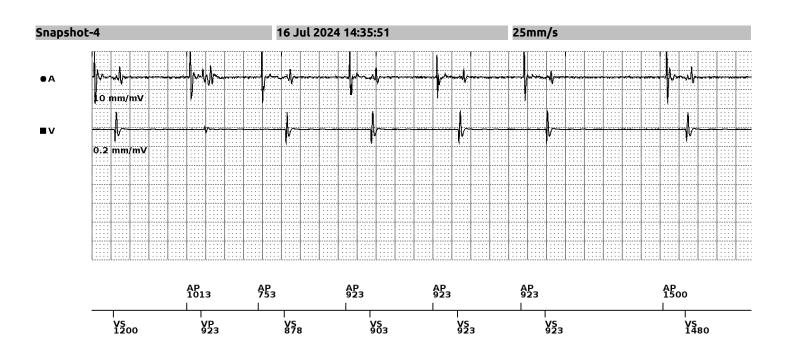
Date of Birth

26 Jan 1957

Device ACCOLADE MRI EL L331/ 959438

Report Created 16 Jul 2024

Last Office Interrogation





LATITUDE™ Programming System

Real-time Log Report Tomkinson, John

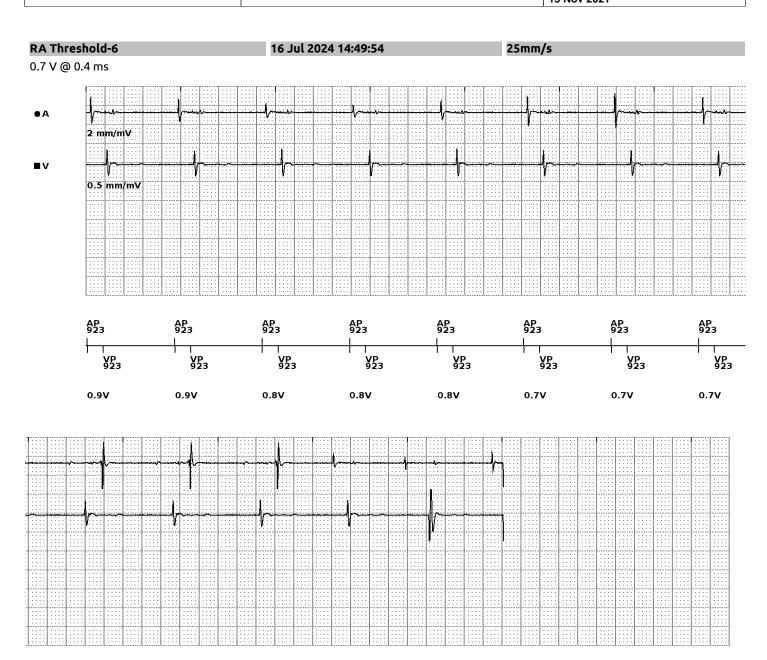
Date of Birth 26 Jan 1957

Device ACCOLADE MRI EL L331/ 959438

Report Created 16 Jul 2024

Last Office Interrogation

16 Feb 2024 Implant Date **15 Nov 2021**



AP 923

0.6V

VP 923

(PAC) 378 AP 545

0.6V

VP 923

(PAC) 380 AP 543

> VP 923

(AS) 383 AP 560

> VP 923

AP 753

> VS 888

AP 923

LATITUDE™ Programming System

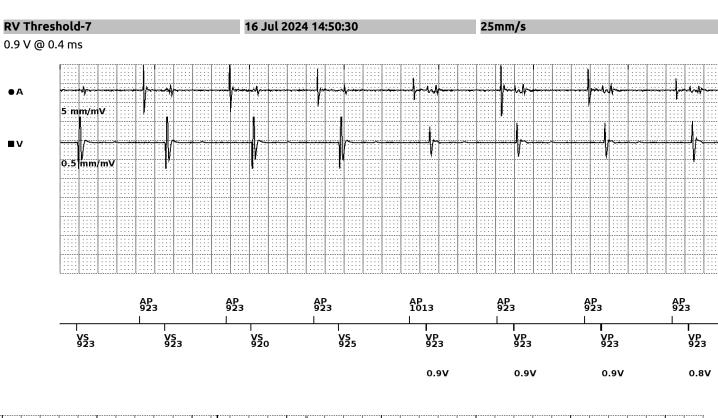
Real-time Log Report Tomkinson, John

Date of Birth Device

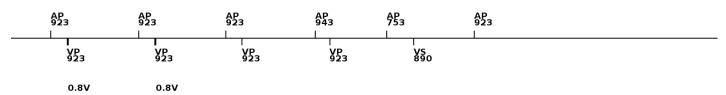
ACCOLADE MRI EL L331/959438

Report Created 16 Jul 2024

Last Office Interrogation







LATITUDE™ Programming System

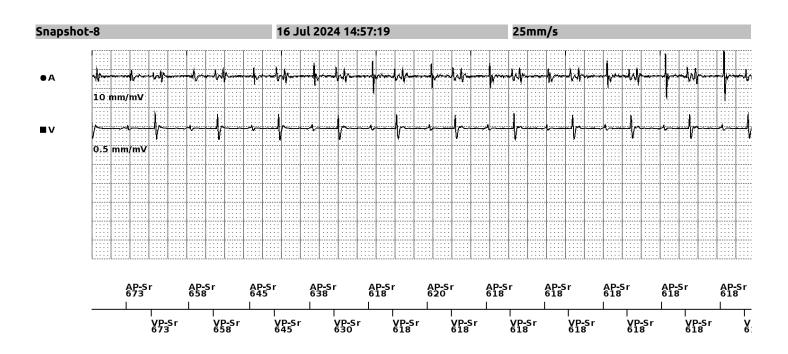
Real-time Log Report Tomkinson, John

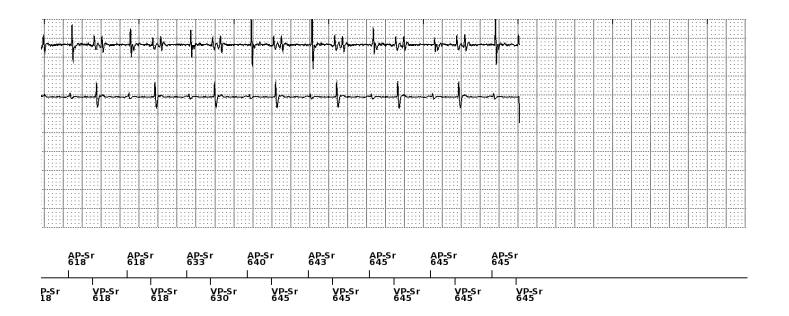
Date of Birth 26 Jan 1957

Device ACCOLADE MRI EL L331/ 959438

Report Created 16 Jul 2024

Last Office Interrogation





LATITUDE™ Programming System

Real-time Log Report Tomkinson, John

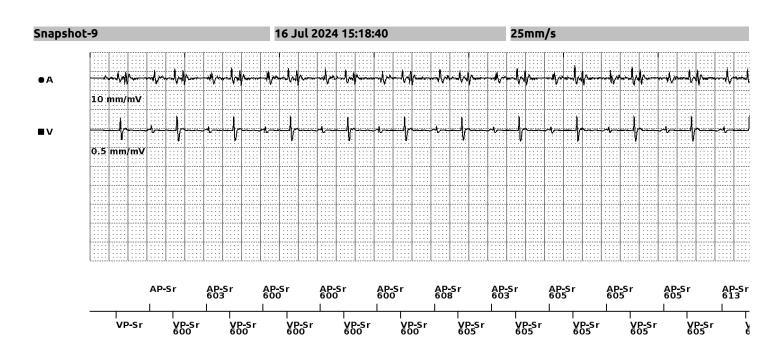
Date of Birth 26 Jan 1957 Device ACCOLADE

ACCOLADE MRI EL L331/ 959438

Report Created 16 Jul 2024

Last Office Interrogation **16 Feb 2024**

Implant Date
15 Nov 2021







LATITUDE™ Programming System
Sensor Trending and Replay Report
Tomkinson, John

Date of Birth 26 Jan 1957

Device ACCOLADE MRI EL L331/ 959438

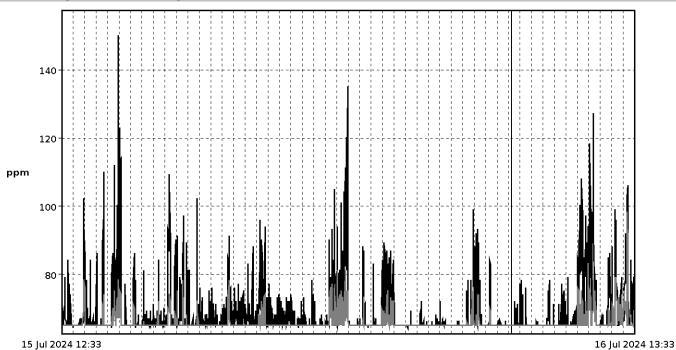
Report Created 16 Jul 2024

Last Office Interrogation

16 Feb 2024 Implant Date 15 Nov 2021

Sensor Trending and Replay Settings	Present	Replay
Lower Rate Limit	65	65 ppm
Max Sensor Rate	155	155 ppm
Minute Ventilation	Passive	Passive
Response Factor		
Fitness Level		
Ventilatory Threshold		
Ventilatory Threshold Response		
Accelerometer	On	On
Response Factor	9	9
Activity Threshold	Medium Low	Medium Low
Reaction Time	30	30 s
Recovery Time	4	4 min

Sensor Trending - 30 Second Average



Actual Rate —— 65 ppm (Paced)
Sensor Replay —— 65 ppm

•



Ventricular Rate Regulation

LATITUDE™ Programming SystemReport Created 16 Jul 2024Device Settings ReportLast Office InterrogationTomkinson, JohnLast Office InterrogationDate of Birth26 Jan 195716 Feb 2024DeviceACCOLADE MRI EL L331/ 959438Implant Date

15 Nov 2021

Programming Last Programmed 16 Jul 2024 **Ventricular Tachy** Ventricular Tachy EGM Storage On 160 bpm (375 ms) **Detection Rate Atrial Tachy** Therapy **Atrial Tachy Response ATR Mode Switch Details** ATR Mode Switch On Atrial Flutter Response On Trigger Rate 160 bpm Trigger Rate 160 bpm Duration 0 cycles **PMT Termination** On **Entry Count** 8 cycles Exit Count 8 cycles Fallback Mode **DDIR** Time 00:30 mm:ss ATR Fallback LRL 65 ppm

Off

3869 Software Version: 1.10 L331 Firmware Version: F_v1.00.00(2.01)

Brady			
Settings			
Mode	DDDR	Output	
RYTHMIQ™	Off	●A	2.0 V @ 0.4ms
Lower Rate Limit	65 ppm	■V	2.0 V @ 0.4ms
Maximum Tracking Rate	125 ppm	Sensitivity	
Maximum Sensor Rate	155 ppm	●A	Fixed 0.5 mV
Paced AV Delay	200 - 320 ms	■V	Fixed 2.5 mV
Sensed AV Delay	190 - 300 ms	Leads	
A-Refractory (PVARP)	240 - 340 ms	●A	
V-Refractory (VRP)	190 - 250 ms	Pace	Bipolar
PVARP after PVC	400 ms	Sense	Bipolar
AV Search +	Off	Safety Switch	On
Blanking		■V	
A-Blank after V-Pace	125 ms	Pace	Bipolar
A-Blank after V-Sense	45 ms	Sense	Bipolar
V-Blank after A-Pace	65 ms	Safety Switch	On
Magnet Response	Pace Async	Rate Adaptive Pacing	
Noise Response	DOO	Minute Ventilation	Passive
Rate Enhancements		Accelerometer	On
Rate Smoothing		Response Factor	9
Up	Off %	Activity Threshold	Medium Low
Down	Off %	Reaction Time	30 s
Sudden Brady Response	Off	Recovery Time	4 min
		Minute Ventilation Sensor Settings	
		Minute Ventilation Sensor	Passive
		Excitation Current	320 µA
		Vector Selection	V Only
		Signal Artifact Monitor	On
		Minute Ventilation Sensor Status	
		Status	Calibrated
		Current Vector	V

Setup

Telemetry

Enable use of ZIP™ telemetry On

Trending Setup

30 Second Average Recording Method Duration 25 hours Continuous Data Storage

Leads Status Setup

	•	Daily Intrinsic	Daily	Impedance	e Limits	Pace Threshold
		Amplitude	Impedance	Low	High	
●A	Pace/Sense	On	On	200 -	2000 Ω	Off
V	Pace/Sense	On	On	200 -	2000 Ω	Off

Page 3 of 3



LATITUDE™ Programming System		Report Created 16 Jul 2024
Settings Cha	nges Report	
Tomkinson, John		Last Office Interrogation
Date of Birth 26 Jan 1957		16 Feb 2024
Device ACCOLADE MRI EL L331/ 959438		Implant Date
		15 Nov 2021

Status	Parameter	Old Value	New Value
Programmed	Accelerometer	Passive	On
Programmed	Accelerometer Activity Threshold		Medium Low
Programmed	Accelerometer Reaction Time		30 s
Programmed	Accelerometer Recovery Time		4 min
Programmed	Accelerometer Response Factor		9
Programmed	Minute Ventilation Sensor	On	Passive
Programmed	MV Sensor Vector Selection	Auto Select	V Only
Programmed	Patient's Fitness Level	Endurance Sports	Active

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Page 1 of 1