MAT DOCKET: IN-OFFICE

Lynn Settergren

DOCKET DATE Jul 30, 2024



John Tomkinson

1591407 60007566543 01/26/1957 Cherry Hill

Clinic Site

Following Physician

Adam Zivin

SUMMARY STATEMENT

This report includes 1 total transmission that was received on 07/30/24. Battery, lead impedance, sensing amplitude and pacing threshold data was reviewed and tested.

PROGRAMMING EVALUATION PERFORMED

IMPRESSIONS

Normal In-Office: No Events

- Normal Device Function
- Alerts or events: None
- Battery: OK, 11.5 years
- Sensing, impedance and thresholds reviewed and tested
- Presenting Rhythm: was AP VS 60s
- Underlying Rhythm: historically no P waves at 40 ppm, intact AV conduction
- · Heart Rate Histograms reviewed
- Pacing and Detection Parameters were evaluated

Additional Notes:

BSX rep present to offer programming options from tech support engineers

Created By: Lynn Settergren 07/30/2024 03:24 PM Edited By: Lynn Settergren 07/30/2024 03:40 PM

Rate Response Suboptimal

- $\bullet \ \ \text{Rate histograms consistent with or suggestive of suboptimal rate response programming}$
- Patient Symptomatic? reports inadequate HR response for cycling with accelerometer only. Accelerometer only provided adequate HR for walking.
- Device Reprogrammed? Y
- 24 hr sensor trend playback with MV ON would increase sensor rates approximately 20ppm with VT threshold ON and response factor of 8

Created By: Lynn Settergren 07/30/2024 03:31 PM

Device Reprogrammed

Device reprogrammed, changes are listed below:

- MV ON without Ventilatory Threshold response factor.
- MV response factor of 7 by pt's preference instead of proposed response factor of 5, so not to accelerate rate too quickly
- min paced AV delay shortened from 200-140ms
- min sensed AV delay shortened from 190-130ms

Created By: Lynn Settergren 07/30/2024 03:36 PM Edited By: Lynn Settergren 07/30/2024 03:38 PM

PLAN

Routine remote and in-office follow up as needed

Additional Notes:

quarterly transmissions, annual office visit

የታ CPT: 93280 ICD-10: 295.0. I49.5

Boston Scientific

IMPLANT DATE: 11/15/2021

IPG: L331 S/N: 959438

LEAD MFR MODEL **IMPLANT DATE** Right Atrium **Boston Scientific** 7841 2021-11-15 Right Ventricle Boston Scientific 7842 2021-11-15

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

• On Anticoagulant

Pacer Dependent

MR Conditional

RA

RV

PARAMETER SUMMARY

MOST RECENT IMPRESSIONS

- Normal In-Office: No Events (2)
- Device Reprogrammed (7) 07/30/2024 -
- Rate Response Suboptimal (4)
- 07/30/2024 -
- Pacemaker Mediated Tachycardia (PMT) (2)
- 07/16/2024 -

2V @ 0.4ms

+ EF

07/30/2024 🔻

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

IMPEDANCE SENSING THRESHOLD 8.5mV 608 Ω Fixed 0.5mV 2V @ 0.4ms 20.8mV 903 Ω --

Fixed 2.5mV

PACED CHAMBER: LOWER RATE: DDDR 65

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

PACED AV: SENSED AV: LVRV Delay: 320 300

STATUS RATES THERAPIES 160 bpm On

RECENT THERAPY COUNTS

Shocks Delivered: Shocks Aborted: ATP Delivered:



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

Adam Zivin MD

FI FCTRONICAL LY SIGNED ON:

Jul 31, 2024 @ 01:59 pm



LATITUDE™ Programming System
Combined Follow-up Report

Tomkinson, John

Date of Birth 26 Jan 1957

Device ACCOLADE MRI EL L331/ 959438

Report Created 30 Jul 2024

Last Office Interrogation

16 Jul 2024 Implant Date 15 Nov 2021

My A	leri	ts
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There are no alerts to display.

Events Since Last Reset (16 Jul 2024)

27 Jul 2024 03:02 APM RT at 76 bpm

Battery OK

Approximate time to explant: 11.5 years

Magnet Rate 100 ppm

One Year Remaining	
Explant	

		Explaint -	
Leads Data	Implant 15 Nov 2021	Previous Session	Most Recent
Atrial			
Intrinsic Amplitude	4.0 mV	/ Paced mV	8.5 mV
Pace Impedance	700 Ω	630 Ω	608 Ω
Pace Threshold	0.7 V @ 0.5 ms	0.7 V @ 0.4 ms	No data collected
Ventricular			
Intrinsic Amplitude	14.0 mV	22.4 mV	20.8 mV
Pace Impedance	1100 Ω	942 Ω	903 Ω
Pace Threshold	0.7 V @ 0.5 ms	0.9 V @ 0.4 ms	No data collected
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	140 - 320 ms	Ventricular	Fixed 2.5 mV
Sensed AV Delay	130 - 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	

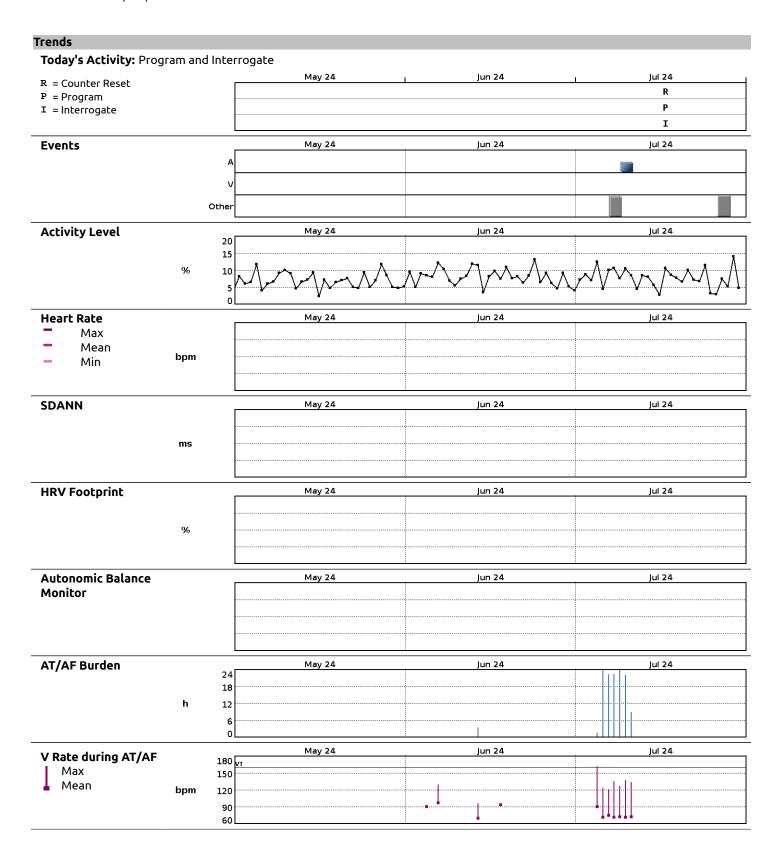
Minute Ventilation

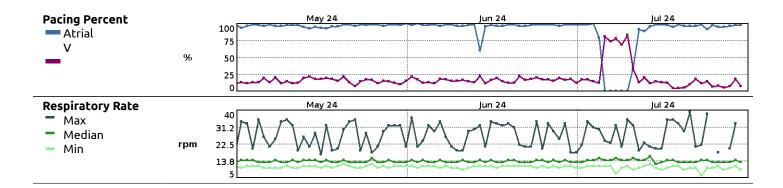
Accelerometer

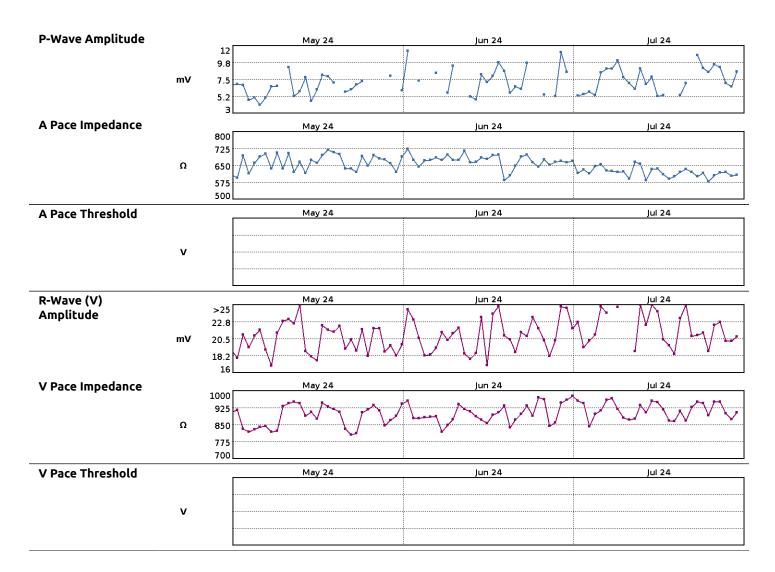
3869 Software Version: 1.10 L331 Firmware Version: F_v1.00.00(2.01) Clinician Signature:

On

On







Ventricular Tachy Counters	Since Last Reset 16 Jul 2024	Device Totals	
Ventricular Episode Counters			
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 150 day(s)	Since Last Reset 13 day(s)	
	16 Feb 2024 to 16 Jul 2024	16 Jul 2024 to Today	
Counters	33 13 33 23 23 2		
% A Paced	86	97	
% V Paced	18	9	
Intrinsic Promotion			
AV Search +			
% Successful	100	0	
Rate Hysteresis			
% Successful	0	0	
Atrial Arrhythmia			
% AT/AF	4	0	
Total Time in AT/AF (days)	6.5	0.0	
Episodes by Duration			
< 1 minute	93	0	
1 min - < 1 hr	89	0	
1 hr - < 24 hr	28	0	
24 hr - < 48 hr	0	0	
> 48 hr	0	0	
Total PACs	31.3K	1.9K	
Ventricular Counters			
Total PVCs	477	42	
Three or More PVCs	0	0	
AT/AF Overview: Since Last Res			
AT/AF: 0 % AT/A	F Events: 0 Total Time in AT/A	vF (days): 0.0	

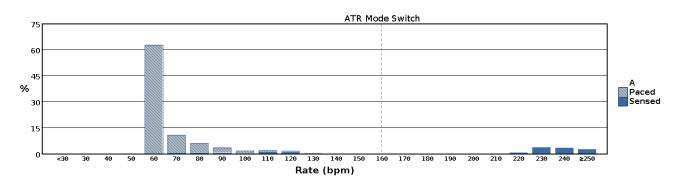
There are no ATR events to display.

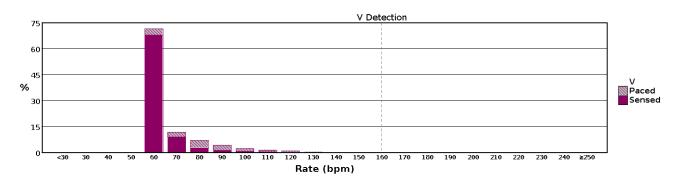
AT/AF Overview: Reset Before Last (16 Feb 2024 to 16 Jul 2024)

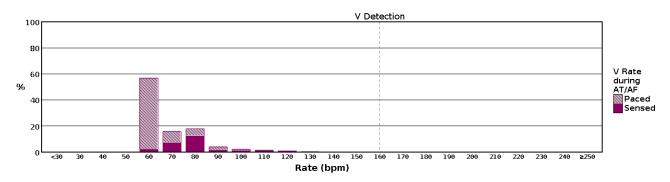
 Longest:
 07 Jul 2024 00:24
 Avg V Rate: 69 bpm
 Duration: 17:10:25 hh:mm:ss

 Fastest VS Rate:
 04 Jul 2024 23:44
 Max V Rate: 161 bpm
 Duration: 00:17:32 hh:mm:ss

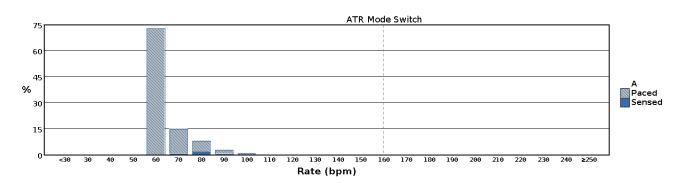
Histograms Reset Before Last (16 Feb 2024)







Histograms Since Last Reset (16 Jul 2024)

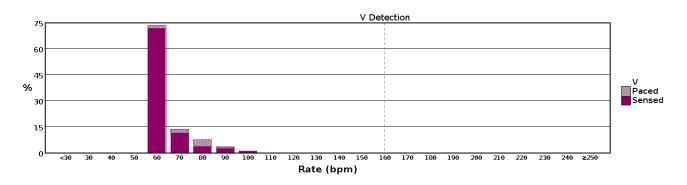


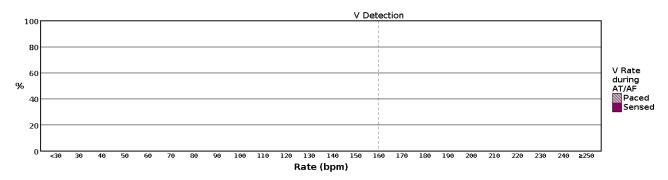
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Histograms Since Last Reset (16 Jul 2024)





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.

Scientific

LATITUDE™ Programming System

Real-time Log Report Tomkinson, John

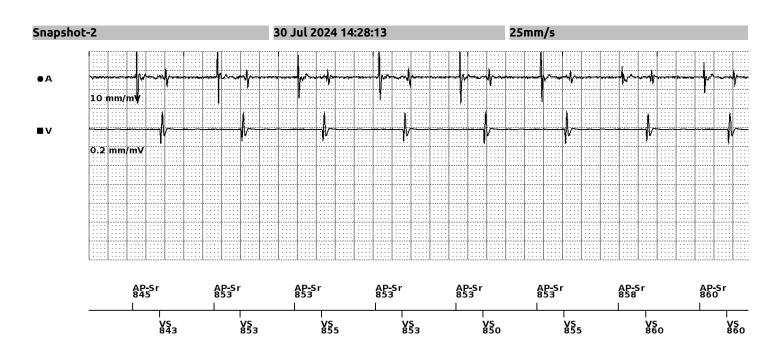
Date of Birth 26 Jan 1957

Device ACCOLADE MRI EL L331/ 959438

Report Created 30 Jul 2024

Last Office Interrogation

16 Jul 2024 Implant Date 15 Nov 2021







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

Date of Birth 26 Jan 1957

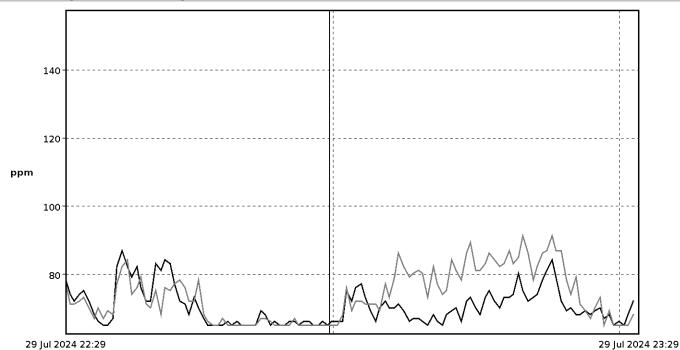
Device ACCOLADE MRI EL L331/959438 Report Created 30 Jul 2024

Last Office Interrogation

16 Jul 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	On
Response Factor		8
Fitness Level		Endurance Sports
Ventilatory Threshold		115 ppm
Ventilatory Threshold Response		70 %
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+Sensed)

Sensor Replay —— 65 ppm

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LATITUDE™ Progr		Report Created 30 Jul 2024
Device Settings	s Report	
Tomkinson, Jo	hn	Last Office Interrogation
Date of Birth	26 Jan 1957	16 Jul 2024
Device	ACCOLADE MRI EL L331/ 959438	Implant Date
		15 Nov 2021

30 Jul 2024		
On		
160 bpm (375 ms)		
	Atrial Tachy Response	
On	Atrial Flutter Response	On
160 bpm	Trigger Rate	160 bpm
0 cycles	PMT Termination	On
8 cycles		
8 cycles		
DDIR		
00:30 mm:ss		
65 ppm		
Off		
	On 160 bpm (375 ms) On 160 bpm 0 cycles 8 cycles 8 cycles DDIR 00:30 mm:ss 65 ppm	On 160 bpm (375 ms) Atrial Tachy Response On Atrial Flutter Response 160 bpm Trigger Rate 0 cycles PMT Termination 8 cycles 8 cycles DDIR 00:30 mm:ss 65 ppm

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	140 - 320 ms	■V	Fixed 2.5 mV
Sensed AV Delay	130 - 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	On
Rate Enhancements		Response Factor	7
Rate Smoothing		Fitness Level	Endurance Sports
Up	Off %	Ventilatory Threshold	125 ppm
Down	Off %	Ventilatory Thresh. Response	Off %
Sudden Brady Response	Off	Accelerometer	On
		Response Factor	9
		Activity Threshold	Medium Low
		Reaction Time	30 s
		Recovery Time	4 min
		Minute Ventilation Sensor Settings	
		Minute Ventilation Sensor	On
		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

Recording Method 30 Second Average
Duration 25 hours
Data Storage Continuous

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

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LATITUDE™ Pro	ogramming System	Report Created 30 Jul 2024
Settings Changes Report		
Tomkinson,	John	Last Office Interrogation
Date of Birth	26 Jan 1957	16 Jul 2024
Device	ACCOLADE MRI EL L331/ 959438	Implant Date
		15 Nov 2021

Status	Parameter	Old Value	New Value
Programmed	Derive from Patient Attributes		Off
Programmed	Minute Ventilation Response Factor		7
Programmed	Minute Ventilation Sensor	Passive	On
Programmed	Normal Brady Minimum Paced AV Delay	200 ms	140 ms
Programmed	Normal Brady Minimum Sensed AV Delay	190 ms	130 ms
Programmed	Patient's Fitness Level		Endurance Sports
Programmed	Patient's Fitness Level	Active	Endurance Sports
Programmed	Ventilatory Threshold		125 ppm
Programmed	Ventilatory Threshold Response		Off

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