

Micra™ AV

Transcatheter Pacing System
MC1AVR1

PRODUCT SPECIFICATIONS

Physical characteristics

Volume	0.8 cc
Length	25.9 mm
Outer diameter	6.7 mm (20.1 Fr)
Mass	1.75 g
Materials in chronic contact with human tissue ^a	Titanium, titanium nitride, parylene C, primer for parylene C, PEEK, siloxane, nitinol, platinum, iridium, liquid silicone rubber, and silicone medical adhesive
Steroid	Dexamethasone acetate, < 1.0 mg, MCRD release mechanism
Fixation mechanism	Nitinol FlexFix™ Tines
Nominal pacing cathode	2.5 mm ² , Pt sintered, TiN coated
Minimum pacing anode	22 mm ² , TiN coated
Cathode to anode spacing	18 mm

^a These materials have been successfully tested for the ability to avoid biological incompatibility. The device does not produce an injurious temperature in the surrounding tissue during normal operation.

Battery characteristics

Manufacturer	Medtronic Energy and Component Center
Model	M957651A001
Chemistry	Lithium-hybrid CFx silver vanadium oxide
Initial voltage	3.2 V
Mean usable capacity	120 mAh
Estimated time from RRT to EOS	6 months (180 days)

Replacement indicators

Recommended Replacement Time (RRT)	6 months (180 days) before EOS
Elective Replacement Indicator (ERI)	3 months (90 days) after RRT
End of Service (EOS)	≤ 2.5 V on 3 consecutive daily automatic measurements



- Designed to provide AV Synchrony (VDD)¹
- Approved for 1.5T and 3T MRI use
- 8-13 year battery longevity^{2,3}

1. Medtronic Micra™ AV MC1AVR1 Reference Manual. January 2020.

2. Pender J, Whiting J. Micra AV Battery Longevity. January 2020. Medtronic data on file.

3. Medtronic Micra™ AV MC1AVR1 Device Manual. January 2020.

Longevity

Projected service life in years*					
Pacing	Amplitude	Pacing Rate	Impedance	Predicted Service Life	
				Pulse width 0.24 ms	Pulse width 0.4 ms
VDD, 0%	1.5 V	60 bpm	500 ohms	15.1	15.1
	1.0 V	60 bpm	500 ohms	14.8	14.7
	1.5 V	60 bpm	500 ohms	14.6	14.4
VDD, 5%	2.0 V	60 bpm	500 ohms	14.3	14.0
	1.0 V	60 bpm	500 ohms	11.9	11.2
	1.5 V	60 bpm	500 ohms	10.8	9.7
VDD, 50%	2.0 V	60 bpm	500 ohms	9.5	8.1
	1.0 V	60 bpm	500 ohms	10.2	9.2
	1.5 V	60 bpm	500 ohms	8.6	7.3
VDD, 100%	2.0 V	60 bpm	500 ohms	6.9	5.4
	2.5 V	60 bpm	500 ohms	5.8	4.3
	1.5 V	60 bpm	400 ohms	8.1	6.7
VDD, 100%	1.5 V	60 bpm	600 ohms	9.0	7.7
	1.5 V	70 bpm	500 ohms	8.0	6.7
	1.5 V	100 bpm	500 ohms	6.8	5.5
VDD, 100%	2.5 V	60 bpm	600 ohms	6.3	4.8
	3.5 V	60 bpm	500 ohms	3.7	2.5
	5.0 V	60 bpm	500 ohms	2.0	1.4

* Projected service life estimates are based on accelerated battery discharge data and device modeling as specified. Do not interpret these values as precise numbers.

Note: The longevity projections are based on typical shelf storage time. Assuming worst-case shelf storage time (18 months), longevity is reduced by approximately 5.8%.

Stored data and diagnostics

Battery and device measurement data
The device automatically and continuously monitors its battery, pacing, and sensing performance throughout the life of the device. You can view the following data on the programmer screens and print reports:
Battery and Device Measurements: Battery Voltage, Remaining Longevity, Sensing Integrity Counter, Electrode Impedance, Capture Threshold, Sensing Electrode Impedance Trend, Capture Threshold Trend, R-Wave Amplitude Trend, A4 Amplitude Trend, Rate Histogram (Ventricular, Atrial Ventricular)

Device performance trend data
The device stores the daily measurements for 15 days. After 15 days, the device stores the weekly high and low measurements up to 80 weeks. Beyond 80 weeks, the data is maintained on a first collected, first-deleted basis.
Electrode Impedance Trend, Capture Threshold Trend, R-Wave Amplitude Trend, A4 Amplitude Trend

Rate Histogram data
Rate histogram data is available to view on the programmer and print as a printed report. The Rate histogram data shows the percent of total time for atrial mechanical sensed-ventricular paced (AM-VP) events, atrial mechanical sensed-ventricular sensed (AM-VS) events, ventricular sensed (VS) only events, and ventricular paced (VP) only events. This data also shows the distribution of AM-VP events, AM-VS events, VS only events, and VP only events recorded since the last patient session.

Device parameters

Emergency VVI settings	
Parameter	Selectable values
Mode	VVI
Lower Rate	70 bpm
Sensitivity	2.0 mV
Amplitude	5 V
Pulse Width	1 ms
Blank Post VP	240 ms
Blank Post VS	120 ms
Rate Hysteresis	Off

Pacing parameters

Modes, rate, and intervals	
Parameter	Programmable values
Mode	VDD ; VDI; VVIR; VVI; VOO; ODO; OVO; Device Off
Lower Rate ^{a,b,c}	30; 35; 40 ... 50 55; 60; 70; 75; 80; 90 ... 170 bpm
Upper Tracking Rate	80; 90; 95; 100; 105 110; 115 bpm
Activity Mode Switch	On ; Off
AV Conduction Mode Switch	On ; Off

^a The corresponding pulse interval can be calculated as follows: pulse interval (ms) = 60,000/Lower Rate.
^b The escape interval is within -10/+25 ms of the programmed rate, measured in accordance with ISO 14708-2:2012 (Clause 6.1.5).
^c Programmable values for Lower Rate do not include 65 bpm.

Atrial parameters	
Parameter	Programmable values
A. Sensing Vector	1; 2; 3; 1+2 ; 1+3; 2+3; 1+2+3
Live Waveform Display	Rectified ; Vector 1 Source; Vector 2 Source; Vector 3 Source
A3 Threshold	1.0; 1.2; 1.4 ... 4.0 ; 4.5; 5.0 ... 10.0; Max m/s ²
Auto	On ; Off
A3 Window End	600; 625 ... 775 ... 1,000 ms
Auto	On ; Off
Min Auto A3 Window End	600; 625 ... 750 ; 775; 800 ms
Max Auto A3 Window End	650; 675 ... 900 ; 925 ... 1,000 ms
A4 Threshold ^a	0.7; 0.8; 0.9; 1.0; 1.2 ; 1.4 ... 3.0; 3.5; 4.0 ... 8.0 m/s ²
Auto	On ; Off
Min Auto A4 Auto Threshold	0.7; 0.8 ; 0.9; 1.0; 1.2; 1.4; 1.6 m/s ²
Sensed AV (AM-VP)	20 ; 30 ... 200 ms
PVAB	450; 500; 550 ; 600 ms
PVARP	Auto ; 500; 550 ... 750 ms
Max PVARP	500; 550; 600 ... 750 ms
Rate Smoothing	On ; Off
Smoothing Delta	50; 100 ; 150; 200 ms
Tracking Check ^b	On ; Off
Tracking Check Rate	90; 100 ; 110 bpm
Atrial Sensing Setup ^c	On/Restart; Off/Complete

^a The range of values for this parameter can also be considered the atrial sensitivity range for the device.

^b Tracking Check will extend PVARP and limit tracking when programmed to On.

^c Check atrial sensing parameters after atrial sensing setup has completed.

RV parameters	
Parameter	Programmable values
RV Amplitude	0.13; 0.25; 0.38; 0.50; 0.63; 0.75; 0.88; 1.00; 1.13; 1.25; 1.38; 1.50 ; 1.63; 1.75; 1.88; 2.00; 2.13; 2.25; 2.38; 2.50; 2.63; 2.75; 2.88; 3.00; 3.13; 3.25; 3.38; 3.50; 3.63; 3.75; 3.88; 4.00; 4.13; 4.25; 4.38; 4.50; 4.63; 4.75; 4.88; 5.00 V
RV Pulse Width	0.09; 0.15; 0.24 ; 0.40; 1.00 ms
RV Sensitivity	0.45; 0.60; 0.90; 1.50; 2.00 ; 2.80; 4.00; 5.60; 8.00; 11.30 mV ^{a,b}
Acute Phase Remaining	Device Repositioned (112 days) ; Off
RV Blanking	
Blank Post VP	150; 160 ... 240 ; ... 450 ms
Blank Post VS	120 ; 130 ... 350 ms

^a Carefully evaluate the possibility of increased susceptibility to EMI and oversensing before changing the sensitivity threshold to its minimum (most sensitive) setting. When susceptibility to interference is tested under the conditions specified in ISO 14708-2 clause 27.4 and EN 45502-2-1 clause 27.5.1, the device may sense the interference if the sensitivity threshold is programmed to the minimum value. The device complies with the requirements of 14708-2 clause 27.4 and EN 45502-2-1 clause 27.5.1 when the sensitivity threshold is programmed to 0.6 mV or higher.

^b Patients who require the lowest sensitivity threshold (0.45 mV) should be under medical direction.

RV Capture Management™ parameters	
Parameter	Programmable values
RV Capture Management	Adaptive ; Monitor; Off
RV Amplitude Safety Margin	0.25; 0.50 ... 1.50 V

Rate Response parameters	
Parameter	Programmable values
Rates	
ADL Rate	60; 65 ... 95 ... 160 bpm
Upper Sensor Rate	80; 90 ... 120 ... 170 bpm
Rate Profile Optimization	On ; Off
Adjust Rate Response	
ADL Response	1; 2; 3 ; 4; 5
Exertion Response	1; 2; 3 ; 4; 5
Rate Response Additional Parameters ^a	
Activity Acceleration	15; 30 ; 60 s
Activity Deceleration	Exercise ; 2.5; 5; 10 min

^a The following parameters and their programmed values are shown in the Rate Response Additional Parameters window, but they must be adjusted in the Tests - Exercise screen: Activity Vector, LR Setpoint, ADL Setpoint, UR Setpoint. Tap Tests > Exercise to access these parameters.

MRI SureScan parameters	
Parameter	Programmable values
MRI SureScan	On; Off
MRI Pacing Mode	VOO; OVO
MRI Pacing Rate	60; 70; 75; 80; 90 ... 120 bpm

Additional pacing features	
Parameter	Programmable values
Rate Hysteresis ^a	Off ; 30; 40 ... 80 bpm

^a The programmed value for Rate Hysteresis must be lower than the Lower Rate value unless Rate Hysteresis is programmed to Off.

Data collection parameters

Data collection parameters	
Parameter	Programmable values
Device Date/Time ^a	(enter current date and time)
Holter Telemetry	Off ; 0.5; 1; 2; 4; 8; 16; 24; hr

^a The times and dates stored in episode records and other data are determined by the Device Date/Time clock.

System test parameters

System test parameters	
Parameter	Selectable values
Pacing Threshold Test parameters	
Threshold Test	Capture Management ^a Amplitude — Auto Decrement
Decrement after	2; 3 ... 15 pulses
Mode ^b (RV test)	VVI; VOO
Lower Rate	30; 35 ... 60; 70; 75; 80; 90 ... 170 bpm
Amplitude	0.13; 0.25; 0.38; 0.50; 0.63 ... 5.00 V
Pulse Width	0.09; 0.15; 0.24; 0.40; 1.00 ms
V. Pace Blanking	150; 160 ... 450 ms
Sensing test parameters	
Mode	VVI; OVO
Lower Rate	30; 35 ... 60; 70; 75; 80; 90 ... 170 bpm
Exercise test parameters	
Duration	5 min; 20 min
Activity Vector ^c	Vector 1; Vector 2; Vector 3
LR Setpoint ^c	0; 1; 2 ... 40; 42 ... 50
ADL Setpoint ^c	5; 6 ... 40; 42 ... 80; 85 ... 100
UR Setpoint ^c	15; 16 ... 40; 42 ... 80; 85 ... 200

^a If the permanently programmed pacing mode is VOO, Capture Management is not available for selection.

^b The selectable test values for this parameter depend on the permanently programmed pacing mode.

^c These are the rate response additional parameters; however, they can only be programmed from the Tests — Exercise screen. To see these parameters in the Rate Response Additional Parameters window, tap Params > Rate Response... > Additional Parameters....

Temporary test parameters

Temporary test parameters	
Parameter	Selectable values
Mode	VVI; VOO; OVO
Lower Rate	30; 35; 40 ... 60; 70; 75; 80; 90 ... 170 bpm
Amplitude	0.13; 0.25; 0.38; 0.50; 0.63 ... 5.00 V
Pulse Width	0.09; 0.15; 0.24; 0.40; 1.00 ms
Sensitivity	0.45; 0.60; 0.90; 1.50; 2.00; 2.80; 4.00; 5.60; 8.00; 11.30 mV

Nonprogrammable parameters

Nonprogrammable parameters	
Parameter	Selectable values
Pacing rate limit (runaway pacing rate protection)	195 bpm
Minimum input impedance	150 k Ω
Pacing output capacitance	2.2 μ F

Manual atrial mechanical test parameters

Manual Atrial Mechanical test parameters	
Parameter	Selectable values
Temp. Mode	VDD; VDI; ODO
Temp. Lower Rate	30; 35; 40 ... 60; 70; 75; 80; 90 ... 170 bpm
Temp. A Sensing Vector	1; 2; 3; 1+2; 1+3; 2+3; 1+2+3
Temp. A3 Threshold	1.0; 1.2; 1.4 ... 4.0; 4.5; 5.0 ... 10.0; Max m/s ²
Temp. A3 Window End	600; 625; 650 ... 1,000 ms
Temp. A4 Threshold	0.7; 0.8; 0.9; 1.0; 1.2; 1.4 ... 3.0; 3.5; 4.0 ... 8.0 m/s ²

See the device manual for detailed information regarding the instructions for use, the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events. If using an MRI SureScan® device, see the MRI SureScan® technical manual before performing an MRI. For further information, contact your local Medtronic representative and/or consult the Medtronic website at medtronic.eu.

For applicable products, consult instructions for use on www.medtronic.com/manuals. Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat® Reader with the browser.

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