Medtronic

Micra™ VR2 Leadless Pacemaker

Model MC2VR01

- Single chamber
- SureScan™ technology

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, PEEK, nitinol, platinum-iridium alloy, and silicone rubber
Steroid	Dexamethasone acetate,[b] < 1.0 mg, MCRD release mechanism
Fixation mechanism	Nitinol FlexFix™ Tines
Battery	Lithium-hybrid CFx silver vanadium oxide
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.

[b] Steroid (International Nonproprietary Name [INN]): Dexamethasone acetate.

Battery characteristics

Manufacturer	Medtronic Energy and Component Center
Chemistry	Lithium-hybrid CFx silver vanadium oxide
Initial voltage	3.2 V
Mean usable capacity	142 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 (approximately 3 months [90 days] after ERI)

Longevity

Projected service life in years

VVIR or VVI Pacing %	Amplitude	Pacing Rate	Impedance	Longevity in years	
				Pulse width 0.24 ms	Pulse width 0.4 ms
0%	1.5 V	60 bpm	500 Ω	19.8	19.8
5%	1.0 V	60 bpm	500 Ω	19.6	19.4
	1.5 V	60 bpm	500 Ω	19.3	19.0
	2.0 V	60 bpm	500 Ω	18.9	18.4
50%	1.0 V	60 bpm	500 Ω	17.4	16.2
	1.5 V	60 bpm	500 Ω	15.3	13.6
	2.0 V	60 bpm	500 Ω	13.2	11.1
100%	1.0 V	60 bpm	500 Ω	15.4	13.6
	1.5 V	60 bpm	500 Ω	12.4	10.2
	2.0 V	60 bpm	500 Ω	9.7	7.4
	2.5 V	60 bpm	500 Ω	7.6	5.7
100%	1.0 V	60 bpm	400 Ω	14.7	12.8
	1.0 V	60 bpm	600 Ω	15.9	14.3
100%	1.5 V	60 bpm	400 Ω	11.5	9.3
	1.5 V	60 bpm	600 Ω	13.2	11.0
100%	1.5 V	70 bpm	500 Ω	11.6	9.3
	1.5 V	100 bpm	500 Ω	9.5	7.4
100%	2.5 V	60 bpm	600 Ω	8.4	6.3
	3.5 V	60 bpm	500 Ω	4.8	3.4
	5.0 V	60 bpm	500 Ω	2.7	1.8

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	Selectable values
Mode	VVIR ◆; VVI; VOO; OVO; Device Off
Lower Rate[a,b,c]	30; 35; 40 … 60 ◆ … 80; 90 … 170 bpm

[a] The corresponding pulse interval can be calculated as follows: pulse interval (ms) = 60,000/Lower Rate.

[b] Programmable values for Lower Rate do not include 65 bpm.

[c] If an EMI source interferes with the R-wave detection, the device starts pacing at the programmed lower rate in the VVI mode and at the programmed lower rate or sensor rate in the VVIR mode. When measured according to the standard ISO 14708-2, clause 6.1.5, the escape interval is within –10 and 25 ms of the programmed lower rate interval.

RV sensing and pacing 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
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

[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

Blanking periods

Parameter	Programmable values
Blank Post VP	150; 160 … 240 ◆ … 420 ms
Blank Post VS	120 ◆; 130 … 350 ms

Rate response pacing parameters

Parameter	Programmable values
Upper Sensor Rate	80; 90 … 120 ◆ … 170 bpm
ADL Rate	60; 65 … 95 ◆ … 160 bpm
Rate Profile Optimization	On ◆; Off
ADL Response	1; 2; 3 ◆; 4; 5
Exertion Response	1; 2; 3 ◆; 4; 5
Activity Acceleration	15; 30 ◆; 60 s
Activity Deceleration	Exercise ◆; 2.5; 5; 10 min
Exercise test parameters[a]	
Activity Vector	Vector 1; Vector 2; Vector 3
LR Setpoint	0; 1; 2 … 40; 42 … 50
ADL Setpoint	5; 6 … 40; 42 … 80; 85 …100
UR Setpoint	15; 16 … 40; 42 … 80; 85 … 200

[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 data are determined by the Device Date/Time clock.

Test parameters

System test parameters

Parameter	Selectable values
Pacing Threshold Test parameters	
Threshold Test	Capture Management 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 … 420 ms
SensingTest parameters	
Mode	VVI; OVO
Lower Rate	30; 35 … 60; 70; 75; 80; 90 … 170 bpm
Exercise Test parameters	
Duration	5; 20 min
Activity Vector[a]	Vector 1; Vector 2; Vector 3
LR Setpoint[a]	0; 1; 2 … 40; 42 … 50
ADL Setpoint[a]	5; 6 … 40; 42 … 80; 85 …100
UR Setpoint[a]	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.

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 µF

Combined Micra VR2 and Micra AV2
Brief Statement

Indications (or Intended Use)
Micra VR2 Model MC2VR01 is indicated for use in patients who have experienced one or more of the following conditions:

- paroxysmal or permanent high-grade AV block in the presence of AF
- paroxysmal or permanent high-grade AV block in the absence of AF, as an alternative to dual chamber pacing, when a dual-chamber transvenous pacing system is considered difficult, high risk, or not deemed necessary for effective therapy
- symptomatic bradycardia-tachycardia syndrome or sinus node dysfunction (sinus bradycardia or sinus pauses), as an alternative to atrial or dual chamber pacing, when a dual-chamber transvenous pacing system is considered difficult, high risk, or not deemed necessary for effective therapy

Rate-responsive pacing is indicated to provide increased heart rate appropriate to increasing levels of activity. The device is designed to be used only in the right ventricle.

Micra AV2 Model MC2AVR1 is indicated for VDD pacing in patients when a dual chamber transvenous pacing system is considered a poor option or not deemed necessary for effective therapy, and when a right ventricular transcatheter pacing system promoting AV synchrony at rest is acceptable. Conditions when a patient is considered a poor candidate for transvenous pacing may include, but are not limited to, tortuous anatomy, a need to preserve venous access, or increased risk of infection. The device provides AV synchrony at rest and rate responsive (VVIR) pacing during periods of high patient activity.

Device-mediated AV synchrony can vary depending on patient condition and activity levels, and it can be limited at high sinus rates. During periods of intermittent AV synchrony, the device will provide ventricular pacing support with an increased potential for pacing rate variability. Micra AV2 is indicated for use in patients who have experienced one of the following:

- Paroxysmal or permanent high-grade AV block in the absence of AF
- Paroxysmal or permanent high-grade AV block in the presence of paroxysmal AF
- Paroxysmal or permanent high-grade AV block in the presence of persistent AF when attempts at restoring sinus rhythm are still planned

The device is designed to be used only in the right ventricle.

Contraindications
Micra VR2 Model MC2VR01 and Micra AV2 Model MC2AVR1 are contraindicated for patients who have the following types of medical devices implanted: an implanted device that would interfere with the implant of the Micra device in the judgment of the implanting physician, an implanted inferior vena cava filter, a mechanical tricuspid valve, or an implanted cardiac device providing active cardiac therapy that may interfere with the sensing performance of the Micra device.

The device is contraindicated for patients who have the following conditions: femoral venous anatomy unable to accommodate a 7.8 mm (23 French) introducer sheath or implant on the right side of the heart (for example, due to obstructions or severe tortuosity), morbid obesity that prevents the implanted device from obtaining telemetry communication within ≤12.5 cm (4.9 in), or known intolerance to the materials listed in the Instruction for Use, or to heparin, or sensitivity to contrast media that cannot be adequately premedicated, or if the steroid dose from this device cannot be tolerated.

Warnings and Precautions
End of Service (EOS) – When the EOS condition is met, the clinician has the option of permanently programming the device to Off and leaving it in the heart, or retrieving the device, provided the device has not yet become encapsulated. Removal of the Micra device after it has become encapsulated may be difficult because of the development of fibrotic tissue. If removal of the device is required, it is recommended that the removal be performed by a clinician who has expertise in the removal of implanted leads.

MRI conditions for use – Before an MRI scan is performed on a patient implanted with the Micra device, the cardiology and radiology professionals involved in this procedure must understand the requirements specific to their tasks as defined in the device manuals.

Rate-responsive mode may not be appropriate for patients who cannot tolerate pacing rates above the programmed Lower Rate. The patient's age and medical condition should be considered by physicians and patients as they select the pacing system, mode of operation, and implant technique best suited to the individual. Precautions should be taken before administering anticoagulant agents, antiplatelet agents, or contrast media in patients with known hypersensitivity to these agents.

The use of deactivated Micra devices in situ and an active Micra device, or an active transvenous pacemaker or defibrillator, has not been clinically tested to determine whether EMI or physical interaction is clinically significant. Bench testing supports that implantation of an active Micra device, or an active transvenous pacemaker or defibrillator, next to an inactivated Micra device is unlikely to cause EMI or physical interaction. Post-approval studies are planned to characterize risks of co-implanted, deactivated Micra devices. Currently recommended end of device life care for a Micra device may include the addition of a replacement device with or without explanation of the Micra device, which should be turned off.

For Micra AV2 Model MC2AVR1, patient activities and environments which present mechanical vibrations to the patient can interfere with the mechanical sensing of atrial contractions. This can result in a loss of AV synchrony.

Potential Adverse Events or Potential Complications
Potential complications include, but are not limited to, toxic/allergic reaction, oversensing, pacemaker syndrome, cardiac arrest, necrosis, and surgical complications such as cardiac perforation, pericardial effusion, cardiac tamponade, device embolization, hematoma, AV fistula, vessel dissection, infection, cardiac inflammation, and thrombosis.

See the device manuals for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, MRI conditions for use, and potential complications/adverse events. For further information, please call Medtronic at 1-800-328-2518 and/or consult Medtronic's website at www.medtronic.com.

Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.

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