



Micra® MC1VR01

MR-Conditional single chamber transcatheter pacing system with SureScan® technology (VVIR)

SPECIFICATIONS



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 medical adhesive |
| Steroid | Dexamethasone acetate, < 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 |

^aThese 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 after RRT |
| End of Service (EOS) | ≤ 2.5V on 3 consecutive daily automatic measurements |

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 min ⁻¹ | 500 Ω | 14.6 | 14.5 | |
| | 50% | 1.0 V | 60 min ⁻¹ | 500 Ω | 13.3 | 12.5 |
| | | 1.5 V | 60 min ⁻¹ | 500 Ω | 11.7 | 10.4 |
| 100% | 2.0 V | 60 min ⁻¹ | 500 Ω | 9.6 | 8.1 | |
| | 100% | 1.0 V | 60 min ⁻¹ | 500 Ω | 11.8 | 10.5 |
| | | 1.5 V | 60 min ⁻¹ | 500 Ω | 9.6 | 8.0 |
| 100% | 2.0 V | 60 min ⁻¹ | 500 Ω | 7.1 | 5.5 | |
| | 100% | 2.5 V | 60 min ⁻¹ | 500 Ω | 5.8 | 4.3 |
| | | 1.5 V | 60 min ⁻¹ | 400 Ω | 9.0 | 7.4 |
| 100% | 1.5 V | 60 min ⁻¹ | 600 Ω | 10.0 | 8.4 | |
| | | 70 min ⁻¹ | 500 Ω | 9.1 | 7.5 | |
| | 1.5 V | 100 min ⁻¹ | 500 Ω | 8.0 | 6.4 | |
| 100% | 2.5 V | 60 min ⁻¹ | 600 Ω | 6.3 | 4.7 | |
| | 3.5 V | 60 min ⁻¹ | 500 Ω | 3.6 | 2.4 | |
| | 5.0 V | 60 min ⁻¹ | 500 Ω | 1.8 | 1.2 | |

*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 5.4%.

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, Rate Histogram

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

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 ventricular pacing and sensing. This data also shows the distribution of ventricular rate for paced and sensed events recorded since the last patient session.

Device parameters

Emergency VVI settings

| Parameter | Selectable values |
|-----------------|----------------------|
| Mode | VVI |
| Lower Rate | 70 min ⁻¹ |
| Sensitivity | 2.0 mV |
| Amplitude | 5 V |
| Pulse Width | 1 ms |
| Refractory | Off |
| Blank Post VP | 240 ms |
| Blank Post VS | 120 ms |
| Rate Hysteresis | Off |

Pacing parameters

Modes, rates, and intervals

| Parameter | Programmable values |
|-----------------------------|---|
| Mode | VVIR \diamond ; VVI; VOO; OVO; Device Off |
| Lower Rate ^{a,b,c} | 30; 35; 40 ... 60 \diamond ... 80; 90 ... 170 min ⁻¹ (\pm 4%) |
| Refractory ^d | Off \diamond ; 160; 170 ... 330 ... 500 ms (+4% +10 ms)/(-4% -25 ms) |

^a The corresponding Lower Rate Interval can be calculated as follows:
Lower Rate Interval (ms) = 60,000/Lower Rate.

^b Programmable values for Lower Rate do not include 65 min⁻¹.

^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 14708-2:2012, clause 6.1.5, the escape interval is within -10 and 25 ms of the programmed lower rate interval.

^d Blank Post VP and Blank Post VS parameters must be programmed to values lower than the programmed value for Refractory. If Refractory is programmed to Off, the refractory period is determined by the programmed value for Blank Post VP or Blank Post VS.

RV sensing and pacing parameters

| Parameter | Programmable values |
|----------------------------|--|
| Amplitude | 0.13; 0.25 (\pm 0.06 V); 0.38; 0.50; 0.63; 0.75; 0.88; 1.00; 1.13 ... 1.50 \diamond ... 5.00 V (\pm 15%) |
| Pulse Width | 0.09; 0.15; 0.24 \diamond ; 0.40 (\pm 0.025 ms); 1.00 ms (\pm 0.04 ms) |
| Sensitivity ^{a,b} | 0.45; 0.60; (\pm 50%); 0.90; 1.50; 2.00 \diamond ; 2.80; 4.00; 5.60; 8.00; 11.30 mV (\pm 30%) |
| Sensing Assurance | Off \diamond ; On |

^a This setting applies to all bradycardia pacing operations.

^b With a 40 ms sine² waveform. When using the waveform, according to the standard ISO 14708-2:2012, clause 6.1.3, the sensing threshold value is 1.5 times the sine² sensing threshold.

RV Capture Management parameters

| Parameter | Programmable values |
|--------------------------------------|--|
| Capture Management | Adaptive \diamond ; Monitor; Off |
| Amplitude Safety Margin ^a | 0.25; 0.50 \diamond ; 0.75; 1.00; 1.25; 1.50 V |
| RV Acute Phase Remaining | Off; Device Repositioned (112 days) \diamond |

^a Amplitude safety margin is 1.5V during RV Acute Phase

Blanking periods

| Parameter | Programmable values |
|-------------------------------|--|
| V. Blank Post VP ^a | 150; 160 ... 240 \diamond ... 450 ms (+4% +10 ms)/(-4% -25 ms) |
| V. Blank Post VS ^a | 120 \diamond ; 130 ... 350 ms (+4% +10 ms)/(-4% -25 ms) |

^a Blank Post VP and Blank Post VS must be programmed to values lower than the programmed value for the Refractory parameter. If Refractory is programmed to Off, the refractory period is determined by the programmed value for Blank Post VP or Blank Post VS.

Rate response pacing parameters

| Parameter | Programmable values |
|--------------------------------|--|
| Upper Sensor Rate ^a | 80; 90; 100 ... 120 \diamond ... 170 min ⁻¹ (\pm 4%) |
| ADL Rate | 60; 65 ... 95 \diamond ... 160 min ⁻¹ (\pm 4%) |
| Rate Profile Optimization | On \diamond ; Off |
| ADL Response | 1; 2; 3 \diamond ; 4; 5 |
| Exertion Response | 1; 2; 3 \diamond ; 4; 5 |
| Activity Acceleration | 15; 30 \diamond ; 60 s |
| Activity Deceleration | Exercise \diamond ; 2.5; 5; 10 min |

Exercise test parameters^b

| | |
|-----------------|--|
| Activity Vector | Vector 1 \diamond ; 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 If Rate Response is enabled, the Upper Sensor Rate must be greater than the ADL Rate, which must be greater than the Lower Rate.

^b Exercise test parameters, Activity Vector and rate-response setpoints, can be programmed only from the Exercise test screen.

MRI SureScan parameters

| Parameter | Programmable values |
|-----------------|--|
| MRI SureScan | On; Off |
| MRI Pacing Mode | VOO; OVO |
| MRI Pacing Rate | 60; 70; 75; 80; 90 ... 120 min ⁻¹ |

Additional pacing features

| Parameter | Programmable values |
|------------------------------|---------------------------------------|
| Rate Hysteresis ^a | Off ; 30; 40 ... 80 min ⁻¹ |

^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 min ⁻¹ |
| 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 ^c | 150; 160 ... 450 ms |

Sensing test parameters

| | |
|------------|--|
| Mode | VVI; OVO |
| Lower Rate | 30; 35 ... 60; 70; 75; 80; 90 ... 170 min ⁻¹ |

Exercise test parameters

| | |
|-----------------|--------------------------------------|
| Duration | 5 min; 20 min |
| 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 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 The selectable values for V. Pace Blanking depend on the programmed value for the Refractory parameter.

Temporary test parameters

Temporary test parameters

| Parameter | Selectable values |
|-------------|---|
| Mode | VVI; VOO; OVO |
| Lower Rate | 30; 35; 40 ... 60; 70; 75; 80; 90 ... 170 min ⁻¹ |
| 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 |
| Refractory | Off; 250; 260; 270 ... 500 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 | Value |
|---|------------------------------|
| Pacing rate limit (runaway pacing rate protection) | 195 min ⁻¹ (± 8%) |
| Minimum input impedance | 150 k Ω |
| Pacing output capacitance | 2.2 μF (± 15%) |

Brief Statement

See the device manual for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events.



www.medtronic.com/manuals

Consult instructions for use at this website. 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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