Medtronic

5388
Temporary Pacemaker

Checkout Manual

MEDTRONIC®
MODEL 5388
DUAL CHAMBER TEMPORARY PACEMAKER
CHECKOUT MANUAL

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PURPOSE AND SCOPE OF THIS DOCUMENT

This manual is intended for use by a qualified engineer or technician for the purpose of checking the operation of a Medtronic® Model 5388 Dual Chamber Temporary Pacemaker. The instructions in this manual cover testing the electrical parameters of the Model 5388 temporary pacemaker. If checkout of a temporary pacemaker indicates improper operation, the unit should be returned to Medtronic for evaluation and repair.

Medtronic does not recommend field repair of this device. Refer to terms of the limited warranty covered in the Model 5388 Dual Chamber Temporary Pacemaker Technical Manual supplied with the device.

Also refer to the Model 5388 Dual Chamber Temporary Pacemaker Technical Manual for a complete description, operating and service instructions, and the specifications for this device.

RETURNING A TEMPORARY PACEMAKER TO MEDTRONIC

To return a damaged or malfunctioning Model 5388 Dual Chamber Temporary Pacemaker to Medtronic for evaluation and repair, write down the information requested on the Returned Product Information Report at the back of this manual. Send this information and the temporary pacemaker to:

Medtronic Inc.
7000 Central Ave., N.E.
Dock B
Minneapolis, MN 55432-3576

Attention: Instrument Service Department

If there are questions, call 1-800-638-1991 and ask for the Instrument Service Department.

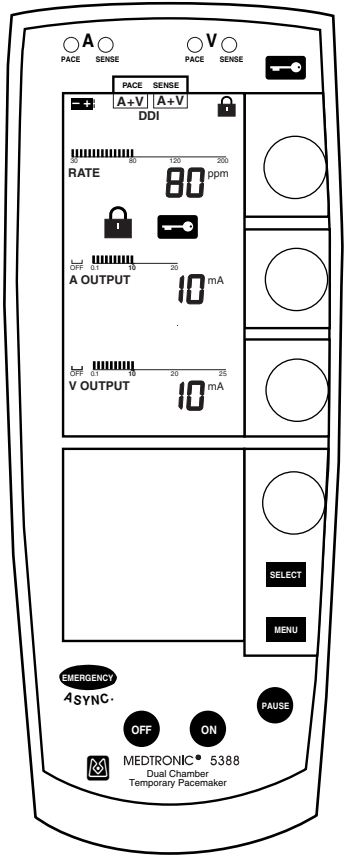


Figure 1. The Model 5388 Dual Chamber Temporary Pacemaker

TEST PARAMETER DEFINITIONS

The following paragraphs define each of the test parameters covered by the checkout procedures in this manual.

1) **Rate -** Rate is the number of output pulses per minute (ppm). It is the inverse of the time interval between output pulses, measured from leading edge to leading edge at the half-peak amplitude points. The rate control knob sets the atrial and the ventricular rates.

2) **Rapid Atrial Pacing (RAP) -** High rate is delivered only to the atrium and is measured in the same manner as the rate.

3) **Pulse Width -** Pulse width is the time interval in milliseconds (ms) between the leading and trailing edges of the output pulse measured at the half-peak amplitude points. In this pacemaker, the Atrial Pulse Width is fixed at 1.0 ms and the Ventricular Pulse Width is fixed at 1.5 ms.

4) **AV Interval -** AV interval is the interval between the atrial and ventricular output pulses. It is measured from leading edge of the atrial output to leading edge of the ventricular output at the half-peak amplitude points.

5) **Output -** Output is in milliamps (mA) and is equal to the amplitude of the output pulse in volts, measured at the mid-width point, divided by the load resistance in ohms (500 ohms is the nominal load resistance).

6) **Direct Current Leakage -** When the device is on, this test measures the DC leakage current in the time interval between output pulses.

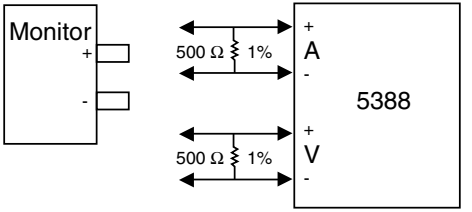
7) **Sensitivity -** This parameter represents the signal level that the amplitude of an intrinsic atrial or ventricular depolarization signal must exceed to be detected as a sensed event. Sensitivity is tested by determining the amplitude of sine-squared pulses (simulated P- or R-waves) that will inhibit pacing. This test first injects a sub-threshold signal (the device paces), then the amplitude is slowly increased until it is above threshold (the device senses).

8) **Refractory Period -** Refractory period is the time interval following a paced or sensed event in a channel during which a sensed event does not affect pacing timing. However, an event sensed inside refractory but outside blanking restarts blanking and refractory periods. This test injects a timed sequence of square waves and measures the affected lower rate.

9) **Off Current Drain -** When the device is turned off, but with the battery inserted, this test verifies no unacceptable current leakage.

10) **On Current Drain -** When the device is turned on and operating, this test measures the current drawn by the device.

11) **Emergency -** The test verifies maximum atrial and ventricular output in mA at the current Rate setting, when the Emergency key is depressed.



Test Function	Monitor
Rate, RAP AV Interval and Pulse Width	Digital Counter
Output Current	Oscilloscope - differential input must be used if the scope is connected to both pulse generator outputs simultaneously
DC Leakage current	DC millivoltmeter/oscilloscope

Figure 2. Setup for Testing Rate, RAP, Pulse Width, Output Current, and DC Current Leakage

For accurate measurement of device parameters, test instrument inaccuracy should not exceed 10 percent of the tolerance for that particular parameter. An analog oscilloscope may be used, but due to instrument tolerances, measured values should be considered relative rather than exact.

Measurements are to be made under the following conditions and at the specified parameter settings.

TEST CONDITIONS

- All unspecified tolerances +/- 5%
- Temperature 70 +/- 5 degrees F
- Relative humidity 80% or less
- Normal output load 500 ohms +/- 1%
- Battery voltage 9 +/- 0.5 volts
- Simulated P-wave 30 ms (33 Hz), sine-squared pulse at 500 ms intervals
- Simulated R-wave 40 ms (25 Hz), sine-squared pulse at 500 ms
- Device settings shall be the default settings in DDD mode unless otherwise specified.

MODE	DDD
LOWER RATE	80 ppm
UPPER RATE	110 ppm (base rate + 30 ppm)
A OUTPUT	10.0 mA
V OUTPUT	10.0 mA
A SENSITIVITY	0.5 mV
V SENSITIVITY	2.0 mV
A PULSE WIDTH	1.0 ms
V PULSE WIDTH	1.5 ms
A REFRACTORY	250 ms (after Atrial event) 300 ms (after Ventricular event)
AV INTERVAL	170 ms

TEST PROCEDURES

GENERAL
To change a parameter value, adjust the appropriate control knob for the required parameter value while observing the LCD bar graph.

The pacing load for this device consists of a 500 ohm, +/- 1% resistor installed across the atrial and/or ventricular outputs.

1) RATE

a) Test Setup
Using a digital counter as per Figure 2, trigger only on the positive-going slope of the output pulse.

b) Change the mode to AAI by setting the V OUTPUT to OFF. Adjust the A OUTPUT to 10 mA. Set Atrial Rate to the values listed below, and verify that the measured atrial pulse intervals are within specified tolerances.

Rate Setting	Specified Tolerance	Pulse Interval Specified Range
30 ppm	+/- 5%	1900-2100 ms
80 ppm	+/- 5%	712-788 ms
120 ppm	+/- 5%	475-525 ms
200 ppm	+/- 5%	285-315 ms

c) Change the mode to VVI by setting the A OUTPUT to OFF. Adjust the V OUTPUT to 10 mA. Set Ventricular Rate to the values listed above, and verify that the measured ventricular pulse intervals are within specified tolerance.

2) RAPID ATRIAL PACING TEST (RAP)

a) Test Setup

Connect the temporary pacemaker according to the setup shown in Figure 2.

b) Select RAP mode from Menu 3. Set the RAP rate to 350 ppm with the Menu Parameter Dial. To deliver RAP, depress and hold the Select Key. The A Pace LED will flash at the RAP rate. The V Pace LED will stop flashing, indicating no V Pace. Verify on the counter that the atrial rate is 350 ppm +/- 5% (163-180 ms). Release the Select Key to discontinue RAP.

3) PULSE WIDTH

a) Test Setup

Connect the temporary pacemaker according to the setup shown in Figure 2. Using the counter "Time Interval, A to B" (or equivalent), trigger channel A on the positive-going slope and channel B on the negative-going slope, at the half-peak point. As an alternative, a scope can be used with the time base set to 0.2 ms/division.

b) Set the mode to AAI by turning V OUTPUT off. Adjust the A OUTPUT to 10 mA. Connect the counter or scope across the atrial output. The Atrial Pulse Width is fixed at 1.0 ms +/- 5% (0.95 - 1.05 ms). Verify the Atrial Pulse Width on the counter or scope.

c) Change the mode to VVI mode by setting A OUTPUT off. Adjust the V OUTPUT to 10 mA. Connect the counter or scope across the ventricular output. The Ventricular Pulse width is fixed at 1.5 ms +/- 5% (1.425 - 1.575 ms). Verify the Ventricular Pulse Width on the counter or scope.

4) AV INTERVAL

a) Test Setup

With the temporary pacemaker in the DDD mode, connect the temporary pacemaker according to the setup shown in Figure 2. Using a digital counter, trigger on the positive-going slope of channel A (connected to the atrial output), and on the positive-going slope of channel B (connected to the ventricular output) at the half-peak points. Measure the time interval between an atrial output pulse and the following ventricular output pulse.

Alternatively, a scope may be used by setting the sensitivities to ASYNC and parallel the outputs across a single 500 ohm resistor load. Adjust the time base of the scope to observe the interval between the leading edge of the atrial pulse to the leading edge of the ventricular pulse.

b) Set the device to the following AV intervals and verify that the readings meet the specifications.

AV Interval	Spec.	Range
20 ms	+/- 5 ms	15-25 ms
150 ms	+/- 5%	142-158 ms
300 ms	+/- 5%	285-315 ms

5) OUTPUT

a) Setup

Set the mode to VVI by turning the A OUTPUT to OFF. Adjust the V OUTPUT to 10 mA. Using the setup in Figure 2, but substituting an oscilloscope for the digital counter, set the ventricular output to the values listed below and measure the ventricular output amplitude at the mid-width point of the output pulse. Divide this value by the load resistance (500 ohms) to get the value for output current and verify that the measured outputs are within specified limits.

Ventricular Current Output specifications

Output Range	Specified Tolerance	Specified Range (mA)
0.2 mA	+/- 0.1 mA	0.1-0.3
5.0 mA	+/- 10%	4.5-5.5
25.0 mA	+/- 10%	22.5-27.5

b) Set the mode to AAI by turning the V OUTPUT to OFF. Adjust the A OUTPUT to 10 mA. Using the setup in Figure 2, but substituting an oscilloscope for the digital counter, set the atrial output to the values listed below and measure the atrial output amplitude at the mid-width point of the output pulse. Divide this value by the load resistance (500 ohms) to get the value for output current and verify the measured outputs are within specified limits.

Atrial Current Output specifications

Output Range	Specified Tolerance	Specified Range (mA)
0.2 mA	+/- 0.1 mA	0.1-0.3
5.0 mA	+/- 10%	4.5-5.5
20.0 mA	+/- 10%	18.0-22.0

6) DIRECT CURRENT LEAKAGE

a) Test Setup

Connect the temporary pacemaker according to the setup shown in Figure 2 with the monitor being a DC voltmeter or scope as indicated.

b) With the device turned off, measure the DC voltage across the 500 ohm atrial load resistor, then across the 500 ohm ventricular load resistor. Verify that the value is as specified below.

DC leakage	Spec. 10 uA Max.
(5 mV across 500 ohms)	

c) Turn the device on and set it to AAI mode by setting the ventricular output to OFF. Using the scope or DC voltmeter and a 500 +/- 1% ohm resistor across the atrial terminals, measure the voltage across the load just prior to the pacing pulse. Verify that the value is as stated below.

DC leakage	Spec. 10 uA Max.
(5 mV across 500 ohms)	

d) Turn the device on and set it to VVI mode by setting the atrial output to OFF. Using the scope or DC voltmeter and a 500 +/- 1% ohm resistor across the ventricular terminals, measure the voltage across the load just prior to the pacing pulse. Verify that the value is as stated below.

DC leakage	Spec. 10 uA Max.
(5 mV across 500 ohms)	

e) Connect a third 500 +/- 1% ohm resistor between the A+ and V+ terminals. Set the pacing mode to DDD. The measured voltage across this resistor during the non-paced period must not exceed 5mV.

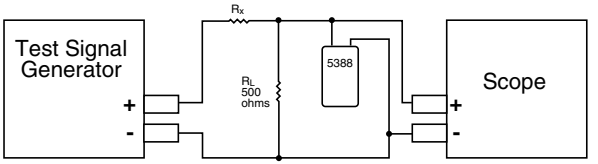


Figure 3. Setup for Testing Sensitivity

7) SENSITIVITY

a) Test Setup

Connect the device according to the test setup shown in Figure 3.

b) For measuring atrial sensitivity, use a simulated P-wave input (30 ms [33 Hz] sine-squared pulse at 500 ms intervals). For measuring ventricular sensitivity, use a simulated R-wave input (40 ms [25 Hz] sine-squared pulse at 500 ms intervals).

c) Set the sensitivity control, via Menu 1, to the values listed in the table. For measuring atrial sensitivity, set the device to AAI mode by setting the ventricular output to OFF. At each setting, increase the output from the signal generator (simulated p-wave for the atrial channel) from below sensing threshold (device paces) to above threshold (device senses a minimum of four consecutive input signals). The sensing threshold must fall within the range specified for each setting.

SENSITIVITY ATRIAL	SPEC.	THRESHOLD
0.4 mV	+/- 0.25 mV	0.15-0.65 mV
1.6 mV	+/- 25%	1.20-2.00 mV
3.0 mV	+/- 25%	2.25-3.75 mV
5.0 mV	+/- 25%	3.75-6.25 mV
10 mV	+/- 25%	7.5-12.5 mV

d) Set the sensitivity control, via Menu 1, to the values listed in the table. For measuring ventricular sensitivity, set the device to VVI mode by setting the Atrial output to OFF. At each setting increase the output from the signal generator (simulated R-wave for the ventricular channel) from below sensing threshold (device paces) to above threshold (device senses a minimum of four consecutive input signals). The sensing threshold must fall within the range specified for each setting.

SENSITIVITY VENTRICULAR	SPEC.	THRESHOLD
0.8 mV	+/- 0.25 mV	0.55-1.05 mV
2.0 mV	+/- 25%	1.50-2.50 mV
4.0 mV	+/- 25%	3.00-5.00 mV
12 mV	+/- 25%	9.0-15.0 mV
20 mV	+/- 25%	15-25 mV

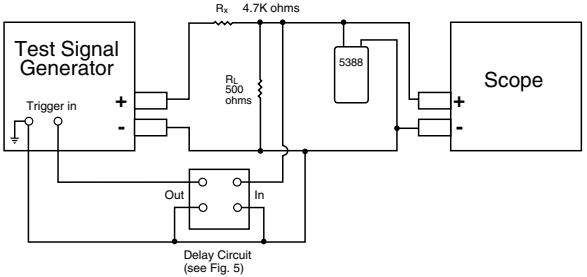


Figure 4. Setup for Testing Refractory Period

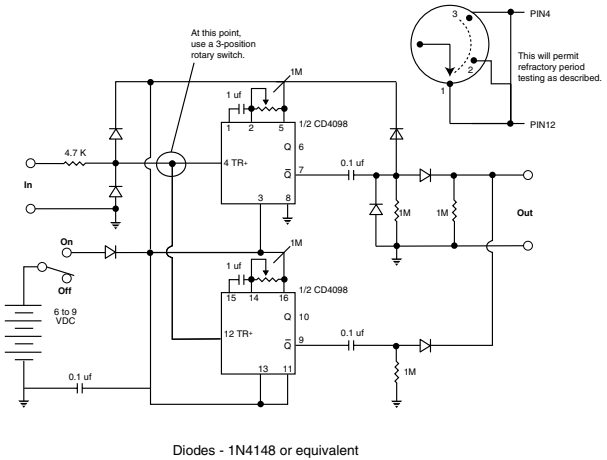


Figure 5. Example Schematic for Test Setup Delay Circuit

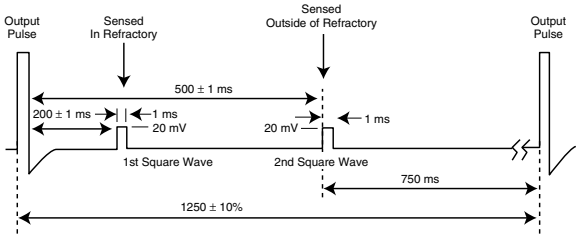


Figure 6a. Atrial Refractory Period Test Timing Diagram

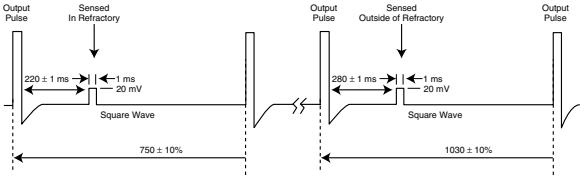


Figure 6b. Ventricular Refractory Period Test Timing Diagram

8) REFRACTORY PERIOD TEST

a) Test Setup

Connect the temporary pacemaker according to the test setup shown in Figure 4. Refer to Figure 5 for an example of a delay circuit.

b) To test the atrial refractory period, set the temporary pacemaker as follows:

MODE	AAI
RATE	80 BPM
OUTPUT	10 mA
ATR SENSITIVITY	0.5 mV
ATR REFRACTORY	250 ms

Set the signal generator to produce squarewaves of 20 mV amplitude (as measured across the 500 ohm atrial load resistor) and 1 ms width at the following intervals (refer to Figure 6a). Use switch position 2 as diagrammed in Figure 5:

First squarewave	Delayed 200 +/- 1 ms following temporary pacemaker output pulse. The atrial sense light should come on.
Second squarewave	Delayed 500 +/- 1 ms following a temporary pacemaker output pulse. The atrial sense light should come on.

Verify that the temporary pacemaker output interval is at 1250 +/- 10% (1125 - 1375 ms). Refer to Figure 6a for the pulse diagram.

Explanation: The first squarewave input falls inside the atrial refractory period and does not affect rate timing. The second squarewave falls outside the atrial refractory period and is sensed, resetting the atrial rate interval.

c) To test the ventricular refractory period, set the temporary pacemaker as follows:

MODE	VVI
RATE	80 BPM
OUTPUT	10 mA
VEN SENSITIVITY	1.0 mV
VEN REFRACTORY	250 ms

Set the signal generator to produce squarewaves of 20 mV amplitude (as measured across the 500 ohm atrial load resistor) and 1 ms width at the following intervals (refer to Figure 6b):

First squarewave	Use switch position 1 as diagrammed in Figure 5. Delayed 220 +/- 1 ms following temporary pacemaker output pulse. The ventricular sense light should not come on.

Second squarewave	Use switch position 3 as diagrammed in Figure 5. Delayed 280 +/- 1 ms following the previous temporary pacemaker output pulse. The ventricular sense light should come on.

Recall that the ventricular refractory period cannot be adjusted and is preset at 250 ms +/- 10% (225 - 275 ms). The ventricular refractory test will be performed as shown in figure 6b. Verify that the first temporary pacemaker output interval is 750 +/- 10% (675 - 825 ms). The first sensed squarewave is within the ventricular refractory period so it does not affect rate timing. Verify that the temporary pacemaker output interval for the second squarewave is 1030 +/- 10% (927 - 1133 ms). The second sensed squarewave is outside the ventricular refractory period so delays the next output pulse by 280 ms.

9) OFF CURRENT DRAIN

a) Test Setup

A special fixture is needed to test this parameter. The battery contacts inside the 5388 must be accessed to perform this test. To accomplish this, a battery simulator must be fabricated. This can be done by removing the cells from an expended 9V battery and connecting wires to the battery contacts as shown in Figure 7. The preferred type of monitor is an analog milliammeter.

b) The device should draw no more than 150 uA.

10) ON CURRENT DRAIN

a) Test Setup

Same as for Off Current Drain.

Backlight off

b) Turn the device on and after 5 minutes the device should draw no more than 3.0 mA. Disregard the current excursions due to the temporary pacemaker pacing outputs.

c) With the backlight and menu on, the current drain should be at least 20.0 mA.

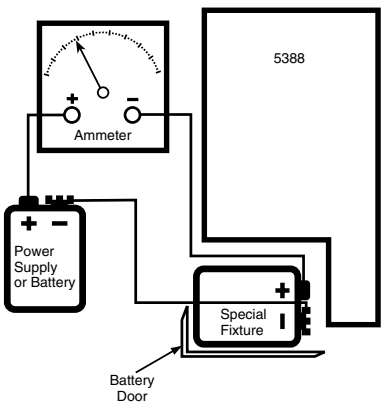


Figure 7. Setup for Current Drain Test

11) EMERGENCY

a) Test Setup

Set the temporary pacemaker to the DDD mode. The test is conducted using the setup in Figure 2. Depress the EMERGENCY key.

b) Using the scope, measure the atrial output at the half-width point of the output pulse. Divide the voltage obtained by the value of the pacing load (500 ohms) and verify the output current as 20 mA +/- 10% (18 - 22 mA).

c) Using the scope, measure the ventricular output at the half-width point of the output pulse. Divide the voltage obtained by the value of the pacing load (500 ohms) and verify the output current as 25 mA +/- 10% (22.5 - 27.5 mA).

TESTING THE 5388 WITH THE 5311/5311B PACING SYSTEM ANALYZER

The 5311/5311B Pacing System Analyzer (PSA) may be used for performance testing of the 5388 Dual Chamber DDD Temporary Pacemaker. Use a jumper wire to connect the V+ and A+ outputs of the 5388. Then connect the positive (+) probe of the PSA to this jumper wire. Connect the (- Atrial) probe of the PSA to the A- output and the (- Vent) probe to the V- output of the temporary pacemaker. Activate ALL IPG test, and then press MEASURE on the PSA. When measurements are complete, press PRINT on the PSA to obtain a printout of the test results.

Ventricular sensitivity measurements with the PSA will be numerically higher than the actual sensitivity of the 5388. This difference can be as high as 25%.

RETURNED PRODUCT INFORMATION REPORT

Please supply the following information whenever you return a Model 5388 Dual Chamber Temporary Pacemaker to Medtronic for evaluation or service. For convenience, use the Returned Product Information Report supplied with your temporary pacemaker or make a photocopy of this page.

Please Print or Type

1) Name of Hospital _____

   Street Address _____

   City _____State _____ZIP Code _____

2) Customer Purchase Order Number_____

3) Serial Number of Model 5388_____

4) Reason for Instrument Return _____

   _____

   _____

   _____

5. Name and telephone number of a person to contact for additional information.

   Name _____Phone ( )_____

6) This report was completed by _____Date_____

Medtronic

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