FINAL TEST PROCEDURE

FOR

4580 SERIES

04-001-016
Revision 2

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Approved by: _____ Date:_____
Quality Assurance

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Production

REVISION RECORD

REV	ECN #	DESCRIPTION	DRAWN	DATE	APP'D	DATE
1	1684	Originate and release.	DMD	19 Jan 09	DMD	19 Jan 09
2	1686	Optimized test sequencing.	DMD	20 Aug 09	APPROVED	

1.0 SCOPE

This procedure provides instructions for a final test of the Model 4580. This test is intended to verify the integrity of the electronic circuitry in the unit and assumes that validated software has been programmed into the EPROM contained within the unit.

2.0 MATERIALS NEEDED

2.1 Personnel

This procedure should be performed only by qualified personnel; typically a test technician, engineering technician, or anyone experienced in the use of the equipment listed below.

2.2 Equipment (all specifications are minimum required)

2.2.1 Digital voltmeter, 3.5 digit -- Voltage: 1 mV to 10 V range, 1% accuracy.

2.2.2 Digital ammeter, 3.5 digit -- Current: 1 μA to 100 mA range, 5% accuracy.

2.2.3 Function generator -- Frequency: 1 Hz to 1 MHz range, 5% accuracy. Amplitude: 100 mV to 10 V (peak-to-peak) range, 5% accuracy. Waveform: haversine (one full sine wave cycle starting and ending at 270° [positive pulse] or 90° [negative pulse]) or $\sin^2$.

2.2.4 Oscilloscope -- Time base: 1 μs to 1 s / div range, 5% accuracy. Amplifier: 100μV to 5V/div range, 5% accuracy.

2.2.5 Counter, 4 digit -- Input frequency: 0.5 Hz to 100 KHz range, 1% accuracy.

2.2.6 DC Power Supply -- Output: 0 to 10 V, continuously variable. Output current capability to 100 mA.

2.2.7 Output load (2) -- Resistance: 500 Ohms, 2% accuracy. (Either resistance boxes or discrete resistors may be used.)

2.2.8 Output load (2) -- Resistance: 200 Ohms, 2% accuracy. (Either resistance boxes or discrete resistors may be used.)

2.2.9 Patient extension cables (2) with Redel™ patient connectors.

2.2.10 Battery drawer power plug.

2.3 Final Test Data Sheet -- (Last page of this document.)

3.0 SETUP

3.1 Connect one 500Ω output load across the extension cable terminals associated with the atrial output connector. Connect one 500Ω output load across the extension cable terminals associated with the ventricular output connector.

3.2 Insert the battery drawer power plug into the leftmost battery drawer. Connect the voltmeter negative lead to the negative lead of the power supply. Connect the voltmeter positive to the power supply positive lead. Adjust the power supply output voltage to 9.0 Volts. (The output must be between 8.9 and 9.1 Volts.)

4.0 BATTERY / SUPPLY CIRCUITRY

4.1 Connect the ammeter positive lead to the power supply positive lead. Connect the ammeter negative lead to the (+) terminal of the battery drawer power plug. Connect the power supply negative lead to the (-) terminal of the battery drawer power plug.

4.2 Press the [DDD ON] key and wait until the device completes self-test diagnostics and beeps indicating the device is ready. Press and hold both the [DDD ON] and [OFF] keys for at least one-second to turn off the device. Wait until the ammeter reading stabilizes. Record the standy current (BATT1) ammeter reading on the data sheet. Reading must be <= 30 μA.

4.3 Press the [DDD ON] key and wait until the device completes self-test diagnostics and beeps indicating the device is ready. Wait until the ammeter reading stabilizes. Observe the lowest reading (not actively pacing). Record the active current (BATT1) ammeter reading on the data sheet. Reading must be <= 3.2 mA.

4.4 Press and hold both the [DDD ON] and [OFF] keys for at least one-second to turn off the device. Move the battery drawer power plug from the leftmost battery drawer to the rightmost battery drawer. Press the [DDD ON] key and wait until the device completes self-test diagnostics and beeps indicating the device is ready. Press and hold both the [DDD ON] and [OFF] keys for at least one-second to turn off the device. Wait until the ammeter reading stabilizes. Record the standy current (BATT2) ammeter reading on the data sheet. Reading must be <= 30 μA.

4.5 Press the [DDD ON] key and wait until the device completes self-test diagnostics and beeps indicating the device is ready. Wait until the ammeter reading stabilizes. Observe the lowest reading (not actively pacing). Record the active current (BATT2) ammeter reading on the data sheet. Reading must be <= 3.2 mA.

4.6 Slowly decrease the output of the power supply until the low battery indicator located in the lower right corner of the display ("L") begins to flash (***be patient, do not decrease input voltage too quickly, repeat processs until an accurate threshold value is achieved***). Record the low battery threshold voltage reading on the data sheet. The low battery threshold voltage reading must be between 6.30 and 6.5 Volts.

4.7 Slowly decrease the output of the power supply until the device ceases operation. (***be patient, do not decrease input voltage too quickly, repeat processs until an accurate threshold value is achieved***). Record the No Battery Threshold voltmeter reading on the data sheet. The reading must be between 4.70 and 4.95 Volts.

5.0 KEYPAD AND LOCK FUNCTION

5.1 Adjust the power supply output voltage to 9.0 Volts. (The output must be between 8.9 and 9.1 Volts.) Press the [DDD ON] key and wait until the device completes self-test diagnostics and beeps indicating the device is ready. Ensure the keypad lock switch located on the front panel is in the UNLOCK position.

5.2 Press each of the keypad keys and ensure proper function. If all keys operate as expected, checkoff YES on the test data sheet, else checkoff NO.

5.3 Slide the keypad lock switch located on the front panel to the LOCK position. Press the [RATE] key. Verify that the message "KEYS LOCKED: NO CHANGES ALLOWED" is displayed and that a short beep is emitted. If keypad lock is verified, checkoff YES on the test data sheet, else checkoff NO. If the expected short beep was emitted, checkoff YES for beeper operation, else checkoff NO.

5.4 Slide the keypad lock switch located on the front panel to the UNLOCK position.

6.0 RATE

6.1 The device should be pacing DDD mode nominal values. Connect the frequency counter ground lead to the atrial indifferent (+) terminal located on the patient entension cable. Connect the counter signal lead to the atrial active (-) terminal. Record the counter reading on the data sheet. The reading must be between 950 and 1050 ms.

6.2 Using the [MENU] key, select rapid stimulation mode. Increase the rapid stimulation rate to 800 ppm. Initiate rapid stimulation by pressing and holding the [RATE] key. While holding the [RATE] key, observe the counter reading and record it on the data sheet. Reading must be between 71.25ms and 78.75 ms.

7.0 OUTPUT AND PULSE WIDTH

7.1 Disconnect both counter leads from the patient extension cables and ensure 500Ω output loads remain connected across the extension cable terminals associated with the atrial and ventricular output connectors.

7.2 Connect the scope ground lead to the atrial indifferent (+) terminal. Connect the scope signal lead to the atrial active (-) terminal. Adjust atrial output for –14V. Record the leading edge amplitude of the atrial output pulse on the data sheet. The reading must be between -13.3 and -14.3 Volts.

7.3 Adjust atrial output for –0.1V. Record the leading edge amplitude of the atrial output pulse on the data sheet. The reading must be between –90mV and -110 mV.

7.4 Adjust atrial output for –10V and replace the 500Ω load with a 200Ω load. Record the leading edge amplitude of the atrial output pulse on the data sheet. The reading must be between –9.0V and -11.0 V.

7.5 Remove the scope leads and attach the frequency counter (+) lead to the atrial active terminal (-) and attach the frequency counter (-) lead to the atrial indifferent (+) terminal. Setup the frequency counter to measure period. Using the [MENU] key, select atrial pulse width and set it to 2.00 ms. Record the atrial pulse width reading on the test data sheet. The reading must be between 1.90ms and 2.10ms.

7.6 Remove the frequency counter from the atrial leads. Connect the scope ground lead to the ventricular indifferent (+) terminal. Connect the scope signal lead to the ventricular active (-) terminal. Adjust ventricular output for –14V. Record the leading edge amplitude of the ventricular output pulse on the data sheet. The reading must be between -13.3 and -14.3 Volts.

7.7 Adjust ventricular output for –0.1V. Record the leading edge amplitude of the ventricular output pulse on the data sheet. The reading must be between –90mV and -110 mV.

7.8 Adjust ventricular output for –10V and replace the 500Ω load with a 200Ω load. Record the leading edge amplitude of the ventricular output pulse on the data sheet. The reading must be between –9.0V and -11.0 V.

7.9 Remove the scope leads and attach the frequency counter (+) lead to the ventricular active terminal (-) and attach the frequency counter (-) lead to the ventricular indifferent (+) terminal. Setup the frequency counter to measure period. Using the [MENU] key, select ventricular pulse width and set it to 2.00 ms. Record the ventricular pulse width reading on the test data sheet. The reading must be between 1.90ms and 2.10ms.

8.0 SENSING

8.1 Ensure output loads are removed from both patient extension cables and connect the test equipment as shown in Figure 1, "Sensing Test Circuit". Connect the *Sensing Test Circuit* as indicated to the terminals of the patient extension cable associated with the ventricular output of the device. Ensure the device is pacing VVI mode nominal values resulting in a ventricular sensitivity setting of 2.0mV.

8.2 NOTE: ACTUAL PACEMAKER SENSITIVITY IS DETERMINED BY MEASURING THE HAVERSINE AMPLITUDE AT THE SIGNAL GENERATOR OUTPUT AND DIVIDING THIS MEASUREMENT BY 200. FOR EXAMPLE, IF THE MEASURED SIGNAL GENERATOR AMPLITUDE WERE 500 MV, THE PACEMAKER SENSITIVITY ENTERED ON THE TEST DATA SHEET WOULD BE 2.5 MV.

8.3 Adjust the controls on the function generator as needed to produce a positive 50 Hz haversine output with a repetition interval of 500 ms. Adjust the function generator amplitude as low as possible while maintaining consistent sensing. Calculate and record the pacemaker sensitivity on the data sheet. The calculated sensitivity must be between 1.60mV and 2.40mV.

8.4 Adjust the controls on the function generator as needed to produce a negative 50 Hz haversine output with a repetition interval of 500 ms. Adjust the function generator amplitude as low as possible while maintaining consistent sensing. Calculate and record the pacemaker sensitivity on the data sheet. The calculated sensitivity must be between 1.60mV and 2.40mV.

8.5 Remove the sensing test circuit from the patient cable associated with the ventricular output of the device and attach it as indicated to the patient cable associated with the atrial output of the device. Change the pacing mode to AAI. Change the atrial sensitivity to 2.0 mV.

8.6 Adjust the controls on the function generator as needed to produce a positive 50 Hz haversine output with a repetition interval of 500 ms. Adjust the function generator amplitude as low as possible while maintaining consistent sensing. Calculate and record the pacemaker sensitivity on the data sheet. The calculated sensitivity must be between 1.60mV and 2.40mV.

8.7 Adjust the controls on the function generator as needed to produce a negative 50 Hz haversine output with a repetition interval of 500 ms. Adjust the function generator amplitude as low as possible while maintaining consistent sensing. Calculate and record the pacemaker sensitivity on the data sheet. The calculated sensitivity must be between 1.60mV and 2.40mV.

9.0 MEMORIZE / RECALL EXAMINATION

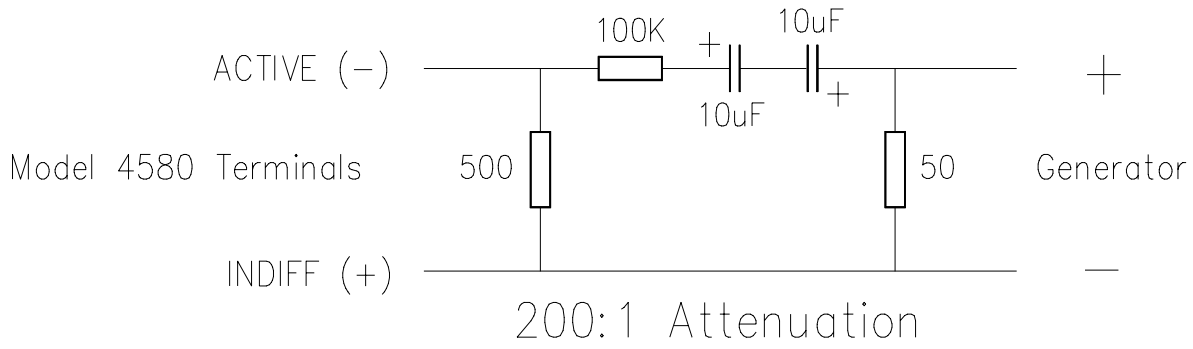
Select DDD mode and press the [NOMINAL] key to establish DDD mode pacing nominal values. Using the [MENU] key, select the Memorize/Recall screen. Press the [+] key to memorize existing values. Press the [RATE] key to select the rate function and return to the normal status screen. Adjust rate for 200 PPM. This will cause a range of values to be auto-programmed. Using the [MENU] key, select the Memorize/Recall screen once again. Press the [-] key to recall memorized values. Ensure DDD mode is restored pacing nominal values. Check off observations on the test data sheet.

10.0 INTERNAL ERROR CONDITIONS

Press and hold both the [DDD ON] and [OFF] keys for at least one-second to turn off the device. Press and hold the [ATRIAL OUTPUT], [VENT SENSE], [STAT PACE], and [-] keys. While still holding these four keys, press either the [RESUME ON] or [DDD ON] keys. The display will show a sequential list of all the possible internal error conditions. As soon as the list begins, the four keys may be released. (***If the display shows the normal self-test message, perform this step from the beginning, ensuring that all four keys are being held.***) When the error list reaches the end a message is displayed for a moment allowing the user to press the [-] key to clear all errors. Press the [-] key to clear all error codes when the message prompt is displayed. Once all error codes are cleared, the device will automatically shutdown. Press the [DDD ON] key and wait until the device completes self-test diagnostics and beeps indicating the device is ready. Ensure normal status display is active and the device is pacing DDD mode nominal values.

Figure 1

Sensing Input Circuit



400mV Output From The Generator Produces 2.0mV Input To Model 4580

FINAL TEST DATA SHEET

Step #	Parameter Tested	Acceptance Limits	Measurements
4.2	Standby Current (BATT1)	<= 30 μA	μA
4.3	Active Current DDD nominals (BATT1)	<= 3.2mA	mA
4.4	Standby Current (BATT2)	<= 30 μA	μA
4.5	Active Current DDD nominals (BATT2)	<= 3.2mA	mA
4.6	Low Battery Threshold	6.30 to 6.50V	V
4.7	No Battery Threshold	4.70 to 4.95 V	V
5.2	Keypad Operation	All Keys Work	Yes No
5.3	Keypad Lock Function	Key Lock Works	Yes No
5.3	Beeper Operation	Beeper Works	Yes No
6.1	Rate (DDD nominal values)	950 to 1050 ms	ms
6.2	Atrial Rapid Stimulation Rate	72.25 to 78.75 ms	ms
7.2	Atrial Output -14V (LE w/500Ω)	-13.3 to -14.3 V	V
7.3	Atrial Output -0.1V (LE w/500Ω)	-90 to -110 mV	mV
7.4	Atrial Output -10V (LE w/200Ω)	-9.0 to -11.0 V	V
7.5	Atrial Pulse Width	1.90 to 2.10 ms	ms
7.6	Ventricular Output -14V (LE w/500Ω)	-13.3 to -14.3 V	V
7.7	Ventricular Output -0.1V (LE w/500Ω)	-90 to -110 mV	mV
7.8	Ventricular Output -10V (LE w/200Ω)	-9.0 to -11.0 V	V
7.9	Ventricular Pulse Width	1.90 to 2.10 ms	ms
8.3	Ventricular Sensitivity (50Hz Pos)	1.60 to 2.40 mV	mV
8.4	Ventricular Sensitivity (50Hz Neg)	1.60 to 2.40 mV	mV
8.6	Atrial Sensitivity (50 Hz Pos.)	1.60 to 2.40 mV	mV
8.7	Atrial Sensitivity (50 Hz Neg.)	1.60 to 2.40 mV	mV
9.0	Memorize/Recall Function	Recall OK	Yes No
10.0	Error Conditions	Errors Cleared	Check Off:

Module S/N: _____

Test Technician:_____ Date:_____

Test Data Inspected By:_____ Date:_____