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Customer Test Procedure

Model EV4542 and EV4543
Miniature External Pacemakers

1.0) SCOPE

This document describes the electrical tests to check the operation and calibration of MINIATURE Cardiac Pulse Generators Model Numbers EV4542 and EV4543 that have Serial Numbers prefixed 'MVAX' and 'MVBX' respectively. (Note that separate Test Procedures are available for earlier versions of these pacers, i.e. those whose Serial Number prefixes are MVAS, MVBS, MVA, MVB, and the very old devices whose prefixes begin 'ME…'. It is recommended that these tests are performed at six-monthly intervals, or following suspicion that the Device may have suffered damage, misuse, or is not operating correctly.

2.0) PERSONNEL

The tests may be performed by persons qualified to use the test equipment specified and familiar with the function and operation of Cardiac Pulse Generators or by sending the Device back to APC Medical. Please note that these Devices cannot be regarded as customer serviceable so if a Device is found to be out of specification it should be taken out of use without delay and returned to the factory for repair.

3.0) EQUIPMENT

3.1) Function Generator: Able to generate positive and negative haversine pulses of variable amplitude. The Pulse Durations required are from 200µs (5kHz wave) to 200ms (5Hz wave). Pulse amplitudes in the range 0 to 16V before attenuation. The Function Generator to be internally triggered at a 100 to 500ms repetition intervals or externally via the Delay Unit.

3.2) Oscilloscope: Time base 0.001ms to 1s per division. Amplifier 50mV to 5V per division.

3.3) Counter/Timer: DC to 100kHz.

3.4) Standard Load: 500Ω ± 2% Resistor.

3.5) Multimeter: 10V and 10mA ranges.

3.6) DC Power Supply: 5-10V continuously variable, 10mA.

3.7) Attenuator/Coupling Capacitor: 2x 10µF ± 10% in series with 100KΩ ± 2% used to couple the Function Generator to the Device and the Standard Load. (See Figure No. 1 on Page 4).

3.8) Delay Unit: Able to trigger the Function Generator after being triggered by the Pacer with a delay period in the range 250 to 350ms.

The tests to be performed are described in paragraph 4) below. The specific measurements to be made are listed on the form that is Page 5 of this document. The tester should make copies of this Form and use them to record the measured results. All tests should be performed using the device's internal Battery unless otherwise specified.

4.0) GENERAL TEST INSTRUCTIONS

When measuring the parameter value for any setting, use the following procedure:
Adjust the front panel Control Knob until the closest measured value to the nominal value is achieved but without moving beyond the Range Band printed on the front panel Label.
Record the value thus measured as the Test Result.

4.0) GENERAL TEST INSTRUCTIONS (CONTINUED)

The amplitude of the signal that is sufficient to cause the Device to inhibit is recorded as that which is calculated by dividing the amplitude of the Function Generator Signal by 200. In practice this will be a larger value than the amplitude of the signal at the Device Terminals due to the loading caused by the Device input impedance; however, this method of measuring Sensitivity follows International Standards.

As an example of these instructions , suppose it is desired to measure the Inhibit Sensitivity at the 12 mV setting: Set the Function Generator amplitude to 2.4V (i.e. 12mV times 200). Rotate the Sensitivity Control Knob till the Device is just able to Sense consistently, i.e. where further counter-clockwise rotation results in the occasional missed pulse of the SENSE LED. If the index mark on the Knob is within the 12 mV range band on the Label then record the Test Result as *12mV*. If it is outside the 12 mV range band, then move it to the nearest end of the range band, and adjust the Function Generator amplitude to the lowest value which is sufficient to give consistent inhibition. Record one two-hundredth of the Function Generator amplitude as the Test Result value.

4.1) SENSITIVITY

Set the Device RATE to 70-90ppm, DEMAND, maximum OUTPUT. Connect the Standard Load and the Function Generator via the Attenuator/Coupler across its Output Terminals. (Note that the Red Positive is the Ground connection for Pacemakers). Set the Function Generator to give a 25Hz haversine pulse internally triggered at 500ms repetition rate. Measure the Sensitivity at the settings specified on Page 5 with the method described above.

After completing the 25Hz measurements, similarly make measurements for 5Hz and 5kHz haversine waves.

4.2) PULSE RATE

Set the Device to ASYNC, maximum OUTPUT. Connect the Standard Load and Counter/ Timer. Rotate the RATE Control to obtain the pulse repetition intervals specified on Page 5. If the Index is within the range band applicable then record the nominal period as the Test Result. Otherwise, rotate the Knob to the nearest end of the applicable range band and record the interval actually measured. Perform a spot check at 150ppm to confirm the Rate does not change as the Device is switched between ASYNC and DEMAND.

4.3) REVERSION AND PACED REFRACTORY

Set the Device RATE to 30ppm, DEMAND, 1mV SENSITIVITY, maximum OUTPUT. Connect the Standard Load and the Function Generator set to 50Hz 240mV positive haversine pulse internally triggered at 200ms interval through the Attenuator/Coupler to the Device. Check it is Sensing reliably. Reduce the pulse interval until the device starts to revert, i.e. the PACE LED starts to flash as well as the SENSE and BATTERY ones. Measure and record this interval as the Noise Reversion Period. Reduce the Function Generator pulse interval further to 100ms. Measure and record the Pacing Pulse periods at the three specified dial settings. Set the Function Generator to externally triggered mode. Set the Delay Unit to trigger the Function Generator about 340ms after each Device Pacing Pulse.

4.3) REVERSION AND PACED REFRACTORY (CONTINUED)

Observe the device detects a Sensed pulse from the Function Generator following each Paced pulse from the Device. Slowly decrease the Delay period until the SENSE LED no longer flashes after the Pacing Pulse. Measure this Delay Period, add 20ms to it, and record this as the Pace Refractory.

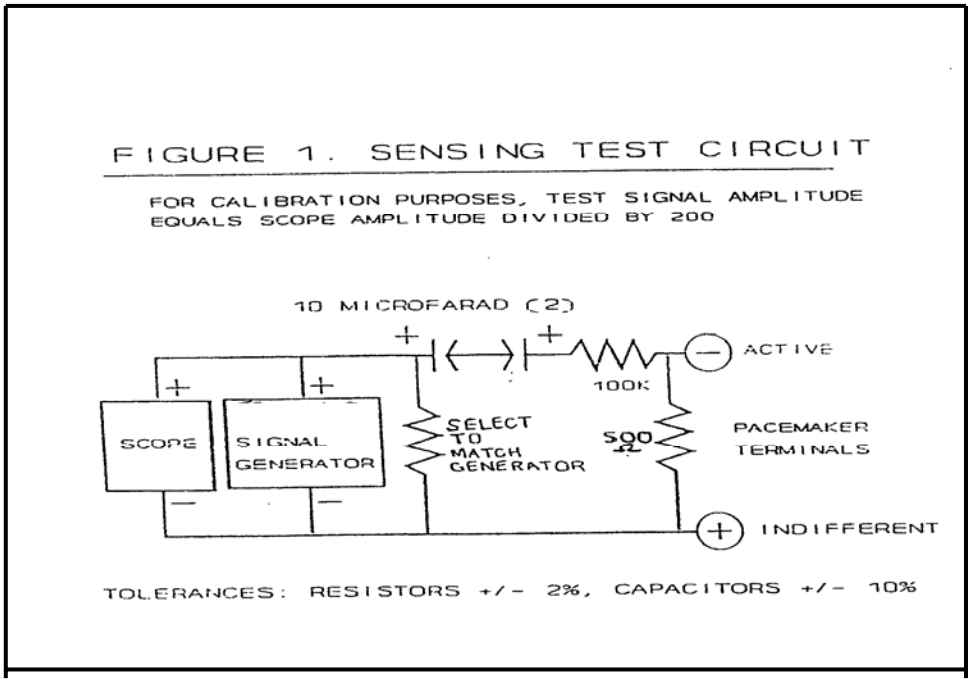
4.4) OUTPUT PULSE AMPLITUDE AND DURATION

Set the Device RATE to 150ppm, ASYNC. Connect the Standard Load and Oscilloscope to the Terminals. Adjust the OUTPUT control so that the Leading Edge of the Output negative pulse corresponds to the settings specified on Page 5. If the index marking is within the applicable range band record the nominal value as the Test Result. If not, rotate the Knob to the nearest end of the applicable range band and record the amplitude of the pulse Leading Edge actually measured. Finally, at maximum Output, use the Oscilloscope to measure and record the Duration of the Output Pulse at 50% of its total amplitude.

4.5) BATTERY DRAIN AND BATTERY LOW

Remove the Battery and connect to the PSU set at 9V. Set the Device to ASYNC. With Rate and Output at maximum, and connect the Standard Load. Use the Multimeter to measure and record the average current consumption. Set the controls to minimum. Reduce the PSU Voltage until and observe the BATTERY LED becomes dimmer. Measure and record the Voltage at which the Battery LED dims to indicate that Battery replacement is necessary.

End of Test Procedure



DEVICE SERIAL No._____ TESTED BY:_____ DATE_____

APC RECOMMENDS THAT THESE DEVICES ARE TESTED AT LEAST ONCE EVERY SIX MONTHS

PARAMETER	DIAL SETTING	MEASURED VALUE	min	LIMITS	max
(Test 4.1)					
SENSITIVITY	SENSITIVITY		**mV**		**mV**
POSITIVE 25Hz WAVE	12mV	_____	10.2		13.8
	8mV	_____	6.8		9.2
	4mV	_____	3.4		4.6
	2mV	_____	1.7		2.3
	1mV	_____	0.85		1.15
NEGATIVE 25Hz WAVE	2mV	_____	1.4		2.6
NEGATIVE 5Hz WAVE	2mV	_____	25		N/A
POSITIVE 5Hz WAVE	2mV	_____	25		N/A
NEGATIVE 5kHz WAVE	2mV	_____	35		N/A
POSITIVE 5kHz WAVE	2mV	_____	35		N/A
(Test 4.2)					
PULSE INTERVAL	RATE		**ms**		**ms**
2000ms	30ppm	_____	1739		2353
1200ms	50ppm	_____	1043		1412
857ms	70ppm	_____	745		1008
667ms	90ppm	_____	580		784
545ms	110ppm	_____	474		642
462ms	130ppm	_____	401		543
400ms	150ppm	_____	348		471
133ms (Model EV4543 only)	150 × 3	_____	116		157
222ms (Model EV4543 only)	90 × 3	_____	193		261
667ms (Model EV4543 only)	30 × 3	_____	580		784
(Test 4.3)					
REVERSION & PACE REFRACTORY			**ms**		**ms**
NOISE REVERSION PERIOD	30ppm	_____	150		195
REVERTED PACING PERIOD	30ppm	_____	1500		1850
	70ppm	_____	678		793
	150ppm	_____	316		370
PACED REF. PERIOD	90ppm	_____	300		330
(Test 4.4)					
PULSE AMPLITUDE AND DURATION			**V**		**V**
	OUTPUT				
OUTPUT VOLTS	0.2V	_____	0.15		0.25
	0.4V	_____	0.32		0.48
	1.0V	_____	0.8		1.2
	2.0V	_____	1.6		2.4
	4.0V	_____	3.2		4.8
	12.0V	_____	9.6		14.4
PULSE DURATION	12.0V	_____	1.35ms		1.65ms
(Test 4.5)					
BATTERY DRAIN AND BATTERY LOW					
DEVICE CURRENT DRAIN AT 9V		_____	N/A		2.0mA
BATTERY LED DIMMED VOLTAGE		_____	6.5V		7.5V