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# **Customer Test Procedure**

## **Model 4570 External Pacemaker**

## 1.0) SCOPE

This document describes the electrical tests to check the operation and calibration of MICROPACE Model 4570 Cardiac Pulse Generators. 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 user serviceable so if a Device is found to be out of specification it must 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 Duration required is 20ms (i.e. 50Hz wave). Pulse amplitudes in the range 0 to 1V before attenuation. The Function Generator to be internally triggered at a 500ms repetition interval.
- 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: 500R  $\pm$  2% Resistor. (Two required).
- 3.5) Attenuator/Coupling Capacitor: 2x 10 microFarad  $\pm$  10% in series with 100K  $\pm$  2% used to couple the Function Generator to the Device and the Standard Load. (See Figure No. 1 on Page 4).
- 3.6) Nine Volt Batteries (Two): Capable of >8V at 10mA load.

The tests to be performed are described in paragraph 4 below. The specific measurements to be made are listed on the form which is Page 5 of this document. The tester should make copies of this Form and use them to record the measured results.

## 4.0) GENERAL TEST INSTRUCTIONS

All test are performed with the 500R Standard Load resistors connected, one to the Ventricle Output Terminals, the other to the Atrium Output Terminals. In order to avoid channel interaction DO NOT connect test equipment so that the two Red (+) Terminals are shorted together. The tests described are sequential, i.e. the status of the Device at the start of each test is derived from the previous test.

The amplitude of the signal which 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. For example, if the Generator amplitude needed to inhibit the Device is 400mV then the Sensitivity is recorded as 2.0mV, and etc.

#### **4.1) BATTERY SWITCHING**

Insert one 9V battery in the Device Battery Compartment. Slide the OFF/ON/LOCK Switch to ON. When the Device has completed its self-test routines and is displaying its normal DDD mode, change the RATE to 70ppm. Press the [SPECIAL PARAMS] Key twice to get the 'MEMORISE' display and the [+] Key to store the current values. Insert the second battery and remove the first. Check the Device is still pacing at 70ppm and record on the Form.

#### **4.2) MEMORY FUNCTION**

Switch the Device OFF; wait 10 seconds minimum; switch the Device ON again and recall the memorised DDD values by pressing [SPECIAL PARAMS] twice to display the MEMORISE function and then [-]. Check the RATE changes from 60ppm to 70ppm and record on the Form.

#### **4.3) KEYPAD AND LOCK FUNCTION**

Slide the OFF/ON/LOCK Switch to the LOCK position. Press each of the twelve Keys in turn. Verify that each time the message "KEYS LOCKED: NO CHANGES ALLOWED" is displayed, and the Device emits a Bleep! Wait for the display to return to normal status each time before pressing the next Key. Record that all Keys function and the Bleeper functions on the Form.

#### **4.4) RATE**

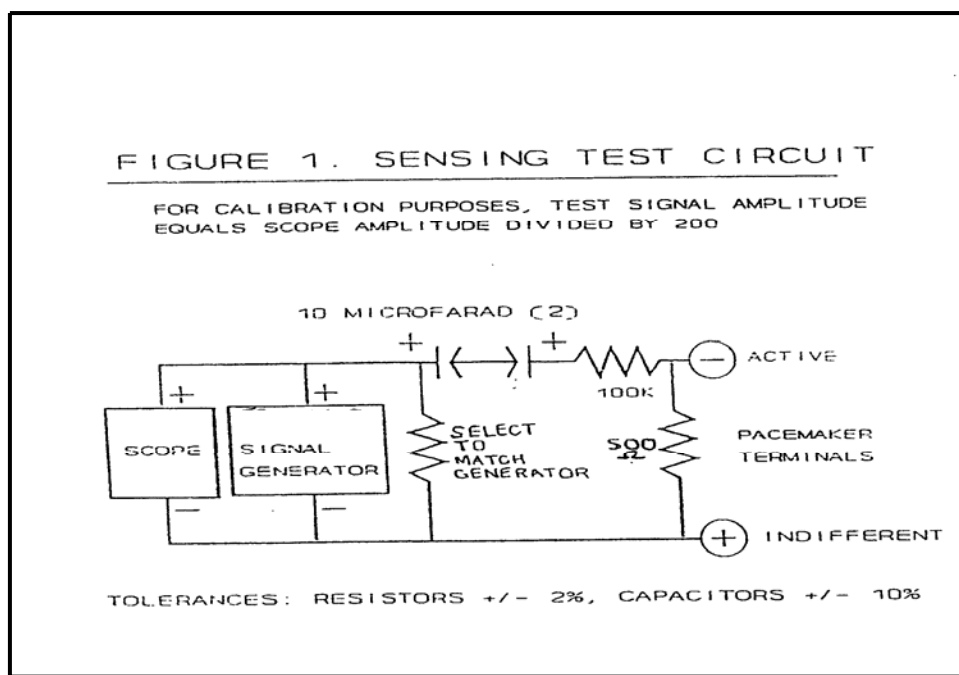
Slide the OFF/ON/LOCK Switch back to ON. Change the pacing mode to VOO. Connect the Counter to the Ventricular channel, Ground to V+, Counter Signal to V- Terminals. Measure and record the pacing pulse interval. Change the pacing mode to AAI and connect the Counter to the Atrial channel Ground to A+, Counter Signal to A- Terminals. Measure and record the pacing pulse interval. Press the [SPECIAL PARAMS] Key repeatedly until the RAPID STIMULATION option is displayed. Press and hold the [+] Key until the display reaches the maximum value at 800ppm. Press and hold the RATE Key to initiate the rapid stimulation output. Measure and record the rapid stimulation pacing pulse interval. Disconnect the Counter.

#### **4.5) OUTPUT PULSE AMPLITUDE AND DURATION**

Connect the Oscilloscope to the Atrial Terminals (Ground to '+') and adjust to display the negative pacing pulse waveform. Press the [STAT PACE] Key which will switch the device to DDI mode. Change Atrial and Ventricular pulse durations to 2.0ms using the [SPECIAL PARAMS] and [+] Keys. Reset the Oscilloscope if required and use it to measure and record the Atrial and Ventricular pacing pulse Leading Edge amplitudes, Trailing Edge amplitudes, and Pulse Durations. (Note that the output transformer on the Ventricular channel results in a small excursion positive of Ground at the end of the pacing pulse but that the amplitudes are measured relative to Ground). Disconnect the Oscilloscope.

#### 4.6) SENSITIVITY

Connect the Function Generator to the Ventricular channel as shown in Figure No. 1 below. Set the Function Generator to give a 50Hz haversine at 500ms repetition interval. Measure and record the Ventricular Sensitivity for positive and negative haversine waves. Select VVI mode, 2mV Sensitivity, 60ppm Rate. The technique to measure Sensitivity is to slowly increase the amplitude of the Function Generator to the point where the display consistently indicates sensed 'R' waves by flashing **R** at the rate of two per second and with no missed beats. At that point the amplitude of the Function Generator is measured, divided by 200, and the result recorded as the Device Sensitivity. After measuring the Ventricular channel for both positive and negative waves, change the device to AAI mode, reduce the Atrial Sensitivity to 2mV, and repeat the Sensitivity measurement on the Atrial Channel. After that, increase the Atrial Sensitivity to 0.3mV and repeat the Sensitivity measurement. Finally, disconnect the Function Generator, connect the Counter to the Ventricular channel, change the mode to DDD, increase the Ventricular Sensitivity to 1.0mV. Repeatedly press each of the first two rows of Keys (Atrial Output to Special Params) and confirm there are no 'False Inhibits', i.e. the counter consistently displays the set 60ppm or 1000ms pacing interval.



End of Test Procedure

**Customer Test Procedure - Model 4570 External Pacemakers**

DEVICE SERIAL No. _____ TESTED BY: _____ DATE _____			
<b>APC RECOMMENDS THAT THESE DEVICES ARE TESTED AT LEAST ONCE EVERY SIX MONTHS</b>			
	TEST MEASUREMENT	TEST LIMITS	RESULT
4.1)	<u>BATTERY SWITCHING</u>	(Still in 70ppm)	Yes____ No____
4.2)	<u>MEMORY FUNCTION</u>	(70ppm recalled)	Yes____ No____
4.3)	<u>KEYPAD AND LOCK</u>	(All Keys work)	Yes____ No____
		(Lock works)	Yes____ No____
		(Bleeper works)	Yes____ No____
4.4)	<u>RATE</u>		
	Ventricular at 70ppm	841ms to 874ms	_____ ms
	Atrial at 70ppm	841ms to 874ms	_____ ms
	Atrial at 800ppm	73ms to 77ms	_____ ms
4.5)	<u>OUTPUT PULSE</u>		
	Atrial Leading Edge	-9V to -11V	_____ V
	Atrial Trailing Edge	-7V to -10V	_____ V
	Atrial Pulse Duration	1.9.ms to 2.1ms	_____ ms
	Ventricular Leading Edge	-9V to -11V	_____ V
	Ventricular Trailing Edge	-7V to -10V	_____ V
	Ventricular Pulse Duration	1.9ms to 2.1ms	_____ ms
4.6)	<u>SENSITIVITY</u>		
	Ventricular 50Hz Positive (2mV)	1.6mV to 2.4mV	_____ mV
	Ventricular 50Hz Negative(2mV)	1.6mV to 2.4mV	_____ mV
	Atrial 50Hz Positive (2mV)	1.6mV to 2.4mV	_____ mV
	Atrial 50Hz Negative (2mV)	1.6mV to 2.4mV	_____ mV
	Atrial 50Hz Positive (0.3mV)	0.24mV to 0.36mV	_____ mV
	Atrial 50Hz Negative (0.3mV)	0.24mV to 0.36mV	_____ mV
	No False Inhibits		Yes____ No____