2005

FUNCTIONAL TEST PROCEDURE

FOR

MODEL 4170 BEDSIDE

Pace Medical, Inc., Waltham, MA 02451

1.0 SCOPE

This procedure provides instructions for a final test of the Model 4170 Bedside. 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

Only qualified personnel should perform this procedure; 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 Frequency Counter, 8-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 -- Resistance: 500 Ohms, 2% accuracy. (Either resistance box or discrete resistor may be used.)

2.2.8 Nine volt battery -- Voltage: ≥ 8 Volts.

2.3 Functional Test Data Sheet -- (page 8 of this document.)

3.0 SETUP

3.1 Remove all batteries from the Model 4170 Bedside.

3.2 Attach a patient extension cable to the Model 4170 with a 500Ω load connected across the Active and Indiff terminals.

3.3 Connect the voltmeter negative lead to the negative lead of the power supply. Connect the voltmeter positive lead 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 CHECKS

(*For information – the device's two 9V batteries are in parallel, and it will run with one or two batteries in place. It also has internal rechargeable Lithium batteries; while these are charging they prevent Test 4.5, and when they are fully charged they prevent Test 4.4)*

4.1 Connect the ammeter positive lead to the power supply positive lead. Connect the ammeter negative lead to battery #1's (*rightmost battery*) "+" terminal inside the battery compartment. Connect the power supply negative lead to the "-" terminal of battery #1. Record **Battery #1 Standby Current** on the test data sheet. This reading should be <20µA.

4.2 Connect the ammeter positive lead to the power supply positive lead. Connect the ammeter negative lead to battery #2's (*leftmost battery*) "+" terminal inside the battery compartment. Connect the power supply negative lead to the "-" terminal of battery #1. Record **Battery #2 Standby Current** on the test data sheet. This reading should be < 20µA.

4.3 Disconnect the Power Supply. Insert a 9V Battery. Press the [ON] button to turn-on the Model 4170, and then remove the Battery. Observe the BATTERY LOW and PACE LED's.

If only the PACE LED is flashing, reconnect the Power Supply and perform Test 4.5. After that, switch off the Power Supply and leave the device running on its internal batteries until the BATTERY LOW LED starts flashing, and then perform Test 4.4.

If both LED's are flashing, reconnect the Power Supply and perform Test 4.4, then replace the Power Supply with the Battery, leave the device running for 8 hours minimum and then perform Test 4.5.

If neither LED is flashing one minute or less after the Battery is removed, perform Test 4.4 reinsert the Battery and leave the Model 4170 switched on for 8 hours minimum, and then perform Test 4.5.

4.4 Slowly decrease the output of the Power Supply from 9V until the BATTERY LOW LED begins to flash with each output pulse. Record the **Low Battery Threshold** voltmeter reading on the data sheet. The reading must be between 6.75 and 7.25 Volts.

4.5 Set the power supply output to +9.0V. Turn the Rate and Output controls fully CCW. Record the **Nominal Operating Current** on the test data sheet. The system current will deviate as processing takes place. Record the minimum level observed.

5.0 PARAMETER ACCURACY CHECKS

5.1 Attach the positive lead of the frequency counter to the Active(-) output of the Model 4170. Attach the negative lead of the counter to the Indiff(+) output. Setup the counter to measure the pulse-to-pulse interval.

5.2 Set the **RATE** panel control to 60 PPM (1000ms). Record the **60 PPM Rate Interval** on the test data sheet. Valid readings range from 930ms to 1080ms.

5.3 Set the **RATE** panel control to 180 PPM (333ms). Record the **180 PPM Rate Interval** on the test data sheet. Valid readings range from 310ms to 360ms.

5.4 Using the **RATE** panel control, set the RATE to 120 PPM. Setup the frequency counter to start counting on the falling edge of the output and end the count on the rising edge. Record the **Pulse Width** on the test data sheet. Valid readings range from 1.71ms to 1.89ms.

5.5 Set the **OUTPUT** panel control to -0.1V. Record the **-0.1 V Output** amplitude on the test data sheet. Valid readings range from –900mV to –0.11V. Ensure the **PULSE LED** flashes with each output pulse.

5.6 Set the **OUTPUT** panel control to -5.0V. Record the –**5.0 V Output** amplitude on the test data sheet. Valid readings range from –4.5V to –5.5V.

5.7 Set the **OUTPUT** panel control to -10.0V. Record the –**10.0 V Output** amplitude on the test data sheet. Valid readings range from –9.0V to –10.1V.

5.8 Set the **OUTPUT** panel control to -15.0V. Record the –**15.0 V Output** amplitude on the test data sheet. Valid readings range from –13.5V to –16.5V.

5.9 Connect the output of the function generator to the input of the ***Sensing Test Circuit***. Remove the 500Ω load from the patient extension cable. Attach the output of the Sensing Test Circuit to the patient extension cable (refer to Figure 1).

5.10 Set the **RATE** panel control to 60 PPM. Adjust the controls on the function generator as needed to produce a positive and negative 50Hz haversine. Set the haversine repetition rate to 500ms. Determine the following thresholds by raising and lowering the input haversine output and observing the inhibited pacing response come-and-go.
The Sensing Test Circuit is a 200:1 attenuator. To inject a 3.0mV haversine, set the generator to 600mV. (***measure sense thresholds by measuring the generator output amplitude and dividing by 200***). Ensure the **SENSE LED** flashes green with each sense event.

5.11 Set the **SENSE** panel control to 0.2mV. Apply a 0.2mV (*40mV*) positive haversine. Increase and decrease the input haversine to determine the threshold response. Record the **+0.2mV Sensitivity Threshold** on the test data sheet. Valid readings range from +0.16mV to +0.24mV.

5.12 Apply a 0.2mV (*40mV*) negative haversine. Increase and decrease the input haversine to determine the threshold response. Record the **-0.2mV Sensitivity Threshold** on the test data sheet. Valid readings range from -0.16mV to -0.24mV.

5.13 Set the **SENSE** panel control to 4.0mV. Apply a 4.0mV (*800mV*) positive haversine. Increase and decrease the input haversine to determine the threshold response. Record the **+4.0mV Sensitivity Threshold** on the test data sheet. Valid readings range from +3.2mV to +4.8mV.

5.14 Apply a 4.0mV (*800mV*) negative haversine. Increase and decrease the input haversine to determine the threshold response. Record the **–4.0mV Sensitivity Threshold** on the test data sheet. Valid readings range from –3.2mV to –4.8mV.

5.15 Set the **SENSE** panel control to 10mV. Apply a 10.0mV (*2.00V*) positive haversine. Increase and decrease the input haversine to determine the threshold response. Record the **+10.0mV Sensitivity Threshold** on the test data sheet. Valid readings range from +8.0mV to +12.0mV.

5.16 Apply a 10mV (*2.00V*) negative haversine. Increase and decrease the input haversine to determine the threshold response. Record the **–10.0mV Sensitivity Threshold** on the test data sheet. Valid readings range from –8.0mV to –12.0mV.

5.17 Set the **SENSE** panel control to 16mV. Apply a 16.0mV (*3.20V*) positive haversine. Increase and decrease the input haversine to determine the threshold response. Record the **+16.0mV Sensitivity Threshold** on the test data sheet. Valid readings range from +12.8mV to +19.2mV.

5.18 Apply a 16mV (*3.20V*) negative haversine. Increase and decrease the input haversine to determine the threshold response. Record the **–16.0mV Sensitivity Threshold** on the test data sheet. Valid readings range from –12.8mV to –19.2mV.

5.19 Lower the power supply input to +6.50V to ensure a Low Battery condition is active. Set the programmed **RATE** to 200 PPM. Increase the amplitude of the input haversine to 18mV (*3.60V*). Increase the repetition rate of the input haversine until the SENSE LED begins to flash a steady RED denoting an active noise condition. Ensure the noise condition was identified within a repetition rate range of 90 to 100ms. Ensure the output pulse rate is 200 PPM (300ms). Ensure no significant reduction of intensity is experienced within the LED flashes. Check off the **Noise Reversion Response** on the test data sheet.

5.20 Turn off the Model 4170. Return the power supply putput to +9.0V. Turn the Model 4170 back on (this is to set up for the battery backup interval). Remove the *Sensing Test Circuit* from the patient extension cable and place a 500Ω load across the patient cable Active(-) and Indiff(+) terminals. Attach the positive lead of the frequency counter to the Active(-) output. Attach the negative lead of the counter to the Indiff(+) output. Setup the counter to measure the pulse-to-pulse interval.

5.21 Set the **RAPID** panel control to 60 PPM (1000ms). Press and hold both [ENABLE] keys and record the **60 PPM Rapid Interval** on the test data sheet. Valid readings range from 925ms to 1075ms.

5.22 Set the **RAPID** panel control to 400 PPM (150ms). Press and hold both [ENABLE] keys and record the **400 PPM Rapid Interval** on the test data sheet. Valid readings range from 138.75ms to 161.25ms.

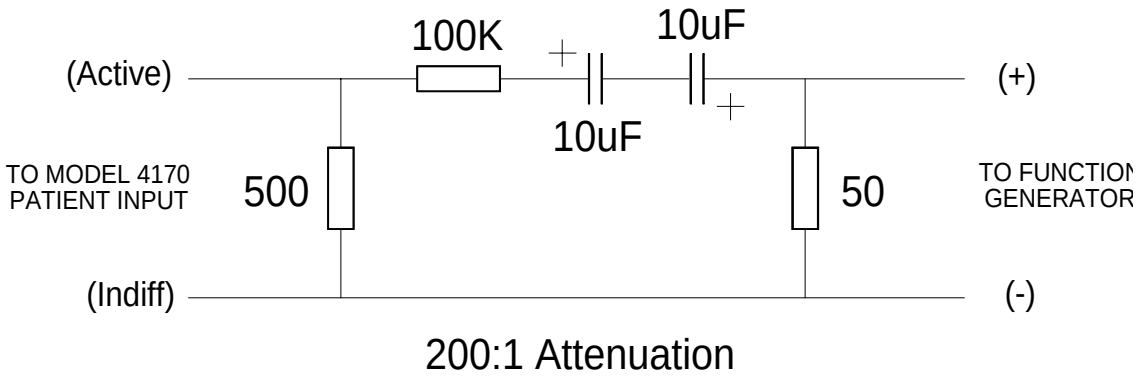
5.23 Set the **RAPID** panel control to 800 PPM (75ms). Press and hold both [ENABLE] keys and record the **800 PPM Rapid Interval** on the test data sheet. Valid readings range from 69.38ms to 80.62ms.

6.0 COMPLETING THE TEST DATA SHEET

6.1 Check the test data sheet for completeness, accuracy and legibility.

6.2 Sign your name and enter the date in the spaces provided at the bottom of the test data sheet.

Figure 1



SENSING TEST CIRCUIT

FUNCTIONAL TEST DATA SHEET

Serial Number: Unit_____

Step No.	Parameter Tested	Acceptance Limits	Measurements	
4.1	Battery #1 Standby Current	< 20uA		µA
4.2	Battery #2 Standby Current	< 20uA		uA
4.4	Low Battery Threshold	6.75 to 7.25V		V
4.5	Nominal Operating Current	< 2.5mA		mA
5.2	60 PPM Rate Interval	930 to 1080ms		ms
5.3	180 PPM Rate Interval	310 to 360ms		ms
5.4	Pulse Width	1.71 to 1.89ms		ms
5.5	-0.1V Output	-0.09 to -0.11V		V
5.6	-5.0V Output	-4.50t o -5.50V		V
5.7	-10.0V Output	-9.00 to -11.0V		V
5.8	-15.0V Output	-13.5 to -16.5V		V
5.11	+0.2mV Sensitivity Threhold	+0.16 to +0.24mV		mV
5.12	-0.2mV Sensitivity Threhold	-0.16 to -0.24mV		mV
5.13	+4.0mV Sensitivity Threhold	+3.20 to +4.80mV		mV
5.14	-4.0mV Sensitivity Threhold	-3.20 to -4.80mV		mV
5.15	+10.0mV Sensitivity Threhold	+8.00 to +12.0mV		mV
5.16	-10.0mV Sensitivity Threhold	-8.00 to -12.0mV		mV
5.17	+16.0mV Sensitivity Threhold	+12.8 to +19.2mV		mV
5.18	-16.0mV Sensitivity Threhold	-12.8 to -19.2mV		mV
5.19	Noise Reversion Response	OK	Yes No	
5.21	60 PPM Rapid Interval	930 to 1080ms		ms
5.22	400 PPM Rapid Interval	139.5 to 162.2ms		ms
5.23	800 PPM Rapid Interval	69.77 to 81.08ms		ms

Technician:_____ Date:_____