

SigmaPace™ 1000 External Pacemaker Analyzer



Overview

The SigmaPace™ 1000 is a powerful handheld analyzer with a comprehensive range of test suites, measurement algorithms and test loads – as specified by the external pacemaker manufacturers – to fulfill your testing requirements both quickly and efficiently.

Standard Features

- Unique full-featured biomedical test product
- Tests for both transcutaneous and transvenous external pacemakers
- Full range of user-selectable measurement algorithms and test loads for external pacemakers
- Dual-channel signal acquisition for capturing synchronous AV-sequential pulse data
- Interactive pacemaker and ECG simulation with 5-lead output
- Large 21-character x 8-line alphanumeric LCD readout
- Exclusive readout "HOLD" function
- Exclusive SigmaPace™ 1000 test features: DC static/dynamic leakage, and current drain

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SigmaPace™ 1000 External Pacemaker Analyzer

Specifications	
Modes of Operation	Manual Remote (via standard RS232 serial port)
User Interface	Display: - LCD readout - 21 characters X 8 lines - Brightness/viewing angle adjustment Keys: Eight push buttons (F-2, F-3 [UP arrow], F-4 [UP arrow], two DOWN arrows, ESCAPE, and ENTER)
Transcutaneous Pacer Tests:	Output Pulse Measurement Current: - Ranges: 4.00 mA to 9.99 mA; 10.0 mA to 99.9 mA; 100 mA to 250 mA - Accuracy: ± 2 % of reading or ± 50 µA (whichever is greater) Rate: - Ranges: 5.0 PPM to 99.9 PPM; 100 PPM to 300 PPM - Accuracy: ± 0.5 % of reading or ± 0.3 PPM (whichever is greater) Width: - Ranges: 1.00 mS to 9.99 mS; 10.0 mS to 99.9 mS - Accuracy: ± 0.5 % of reading or ± 14 µS (whichever is greater) Energy: - Ranges: 1 µJ to 999 µJ; 1 mJ to 999 mJ; 1.00 J to 1.99 J - Accuracy: 5 % of reading/computation Demand and Asynchronous Mode Tests

Waveform (Physiological Simulation):	<ul style="list-style-type: none"> - Normal sinus rhythm (NSR) - Complete P-QRS-T complex
Amplitude:	1.0mVpeak (lead I)
Modes of Operation:	<ul style="list-style-type: none"> - Underdrive: NSR @ 85 % of pulse interval/rate - Overdrive: NSR @ 115 % of pulse interval/rate - Auxiliary Control: NSR adjustable in 1-BPM increments - Auxiliary Rate Range: Underdrive 10 BPM (min); overdrive 300 BPM (max)
Active Outputs:	5-lead ECG; ventricular test load; high-level ECG jack
Pacemaker Compatibility:	<ul style="list-style-type: none"> - Pulse Rates: 30 to 200 PPM - Intended Types: Demand: VVI (pace and sense); async: VOO (pace)
Amplitude Sensitivity Test Selections: R, S and T Waves	<ul style="list-style-type: none"> - Rate: 30 to 200 PPM - Test Loads: (30) 50 Ω to 1550 Ω in 50-Ω steps
Waveforms:	Square (SQU); triangle (TRI); haversine (HSN); sine square (SSQ)
Amplitude:	<ul style="list-style-type: none"> - Range: 0.05 mVpeak to 5.0 mVpeak - Accuracy: \pm 5 % of setting Resolution: 0.05-mV steps (0.05 to 0.95 mVpeak); 0.50-mV steps (1 to 5 mVpeak)
Width:	<ul style="list-style-type: none"> - Range: 0.15 mS to 300 mS - Accuracy: \pm 5 % of setting - Selections: 50 - Resolution: 0.05-mS steps (0.15 to 0.95 mS); 1-mS steps (1 to 19 mS);
5-mS steps (20 to 95 mS)	25-mS steps (100 to 300 mS)
Active Outputs:	5-lead ECG; ventricular test load; high-level ECG jack
Pacemaker Compatibility:	<ul style="list-style-type: none"> - Pulse Rates: 30 to 200 PPM - Intended Type: VVI (pace and sense)
Noise Immunity/Line Frequency Test Waveform:	<ul style="list-style-type: none"> Sine wave - Frequency: 50 and 60 Hz - Accuracy: 0.5 Hz
Amplitude Testload Output:	<ul style="list-style-type: none"> - Range: 0 (OFF) to 10 mVpeak-to-peak - Accuracy: \pm 5 % of setting - Resolution: 0.5-mVpeak-to-peak steps - Settings: (30) 50 Ω to 1550 Ω \pm 1 %
5-lead ECG Output:	<ul style="list-style-type: none"> - Range: 0 (OFF) to 10 mVpeak-to-peak - Accuracy: \pm 5 % of setting - Resolution: 0.50-mV steps - Reference: Lead I (RA to LA)
Active Outputs:	5-lead ECG; ventricular test load
Paced Refractory Period Test (PRP)	
Range:	20 mS to 500 mS
Physiological Simulation:	<ul style="list-style-type: none"> - Accuracy: 5 % of reading or 1 mS (whichever is greater) - Selection: Single pulse, R Wave, SSQ - Pulse Width: 40 mS
Outputs:	5-lead ECG; ventricular test load
Pacemaker Compatibility:	<ul style="list-style-type: none"> - Pulse Rates: 30 to 200 BPM - Intended Type: VVI (pace and sense)
Sensed Refractory Period Test (SRP)	
Range:	15 mS to 500 mS
Accuracy:	\pm 5 % of reading or \pm 1 mS (whichever is greater)
Physiological Simulation:	<ul style="list-style-type: none"> - Selection: Double pulse, R Wave, SSQ - Pulse Width: 40 mS - Amplitude: 1 mVpeak lead I
Active Outputs:	5-lead ECG; ventricular test load
Pacemaker Compatibility:	<ul style="list-style-type: none"> - Pulse Rates: 30 to 200 BPM - Intended Type: VVI (pace and sense)

	<p>Test Loads Transcutaneous Pacer:</p> <ul style="list-style-type: none"> - Selections: (31) 50 Ω to 1550 Ω in 50-Ω steps - Accuracy: ± 1 % of selection - Power Rating: 5 W (average); 40 W (peak) @ 1000 Ω <p>Input Defibrillation Protection:</p> <ul style="list-style-type: none"> - Type: Internal spark gap - Episode Limit: 5 pulses @ 360 J (10 seconds min between discharges) - Life Limit: 250 pulses @ 360 J
<p>Transvenous Pacer Tests:</p>	<p>Output Pulse Measurement</p> <p>Current:</p> <ul style="list-style-type: none"> - Ranges: 0.05 mA to .999 mA (available single channel only); 1.00 mA to 9.99 mA; 10 mA to 30 mA - Accuracy: ± 2 % of reading or ± 50 μA (whichever is greater) - Polarity Indicator: + or - <p>Rate:</p> <ul style="list-style-type: none"> - Ranges: 10.0 PPM to 99.9 PPM; 100 PPM to 999 PPM - Accuracy: ± 0.5 % or 0.3 PPM (whichever is greater) <p>Width:</p> <ul style="list-style-type: none"> - Ranges: 0.020 mS to .999 mS; 1.00 mS to 9.99 mS; 10.0 mS to 99.9 mS - Accuracy: 0.5 % or ± 14 μS (whichever is greater) - Resolution: ± 1 LSD or ± 4 μS (whichever is greater) <p>Voltage:</p> <ul style="list-style-type: none"> - Ranges: (available single channel only) 0.050 Vpeak to .999 Vpeak; 1.00 Vpeak to 9.99 Vpeak; 10 Vpeak to 30 Vpeak - Accuracy: ± 2 % of reading or ± 0.05 Vpeak (whichever is greater) - Polarity Indicator: + or - <p>Energy:</p> <ul style="list-style-type: none"> - Ranges: (available single channel only) 1 nJ to 999 nJ; 1 μJ to 999 μJ - Accuracy: ± 5 % of reading/computation <p>Display Formats: Atrial channel only; ventricular channel only; both A + V channels</p> <p>AV Interval (Delay Time) Measurement Ranges: 10.0 mS to 99.9 mS; 100 mS to 999 mS</p> <p>Start Point: Atrial pulse leading edge</p> <p>Stop Point: Ventricular pulse leading edge</p> <p>Accuracy: 1 % of reading/computation</p> <p>Demand/Async Mode Tests</p> <p>Channels: Single and dual</p> <p>Waveform: Sine square (SSQ)</p> <p>Atrial Output: Simulated P Wave</p> <ul style="list-style-type: none"> - Width: 30 mS - Amplitude: 2.0 mVpeak <p>Vent Output: Simulated R Wave</p> <ul style="list-style-type: none"> - Width: 40 mS - Amplitude: 2.5 mVpeak <p>AV Interval: 90 mS (fixed)</p> <p>Interactive Simulated Rates:</p> <ul style="list-style-type: none"> - Default Settings: Underdrive = NSR @ 85 % of pulse interval/rate; overdrive = NSR @ 115 % of pulse interval/rate - Manual: NSR simulations adjustable in 1-BPM increments - Limits: Underdrive (min) = 10 BPM; overdrive (max) = 300 BPM <p>Output: Ventricular channel test load; atrial channel test load</p> <p>Pulse Rate: 30 to 200 PPM</p> <p>Intended Pacemaker Types:</p> <ul style="list-style-type: none"> - Demand: VVI (V-channel pace and sense); AAI (A-channel pace and sense); - Async/Continuous: VOO (V-channel pace and sense); AOO (A-channel pace and sense); DOO (dual-channel pace and sense) <p>DDD (dual-channel pace and sense)</p> <p>Amplitude Sensitivity Test Operation: Single-channel operation only (atrial or ventricular)</p> <p>Atrial Channel (Physiological)</p> <ul style="list-style-type: none"> - Selection: P Wave

Simulation):

- Rate: 30 to 120 BPM
 - Timing: Waveform delayed by 80 % of the pulse-to-pulse interval or 400 mS (whichever is shorter)
 - Active Output: Atrial test load
- 200 Ω , 500 Ω (default setting) and 1000 $\Omega \pm 1 \%$
Square (SQU); triangle (TRI); haversine (HSN); sine square (SSQ) (default setting); asymmetrical triangle (ISO) – fixed width: 2 mS rise time/13 mS fall time

**Available Test Loads:
Waveform Selections:**

Sensitivity Waveform Amplitude:

- Test Load Selection:

- 500 Ω (default setting)
- Range: 0.05 mVpeak to 50.0 mVpeak
- Accuracy: $\pm 5 \%$ of setting
- Resolution: 0.05 mVpeak (0.05 to 0.95 mVpeak); 0.50 mVpeak (1 to 50 mVpeak)

- Test Load Selection:

- 200 Ω
- Range: 0.05 mVpeak to 20.0 mVpeak
- Accuracy: $\pm 5 \%$ of setting
- Resolution: 0.05 mVpeak (0.05 to 0.95 mVpeak); 0.50 mVpeak (1 to 20 mVpeak)

- Test Load Selection:

- 1000 Ω
- Range: 0.05 mVpeak to 100 mVpeak-to-peak
- Accuracy: $\pm 5 \%$ of setting
- Resolution: 0.05 mVpeak (0.05 to 0.95 mVpeak); 0.50 mVpeak (1.0 to 49.5 mVpeak); 05.0 mVpeak (50 to 100 mVpeak)

Widths:

- Default Setting: 2.0 mVpeak
- Range: 0.15 mS to 95.0 mS
- Accuracy: $\pm 5 \%$ of setting
- Resolution: 0.05 mS (0.15 mS to 0.95 mS); 1 mS (1 mS to 19 mS); 5 mS (20 mS to 95 mS)

Intended Pacemaker Types:

- AAI (atrial pace and sense)
- Pulse Rates: 30 to 200 PPM
- Selection: R Wave, S Wave and T Wave

**Ventricular Channel
(Physiological Simulation):**

- Rate: 30 to 120 BPM
 - Timing: Waveform delayed from the ventricular demand pacemaker pulse by 80 % of the pulse-to-pulse interval or 400 mS (whichever is shorter)
 - Active Output: Selected ventricular test load
- Square (SQU); triangle (TRI); haversine (HSN); sine square (SSQ) (default setting); asymmetrical triangle (ISO) – fixed width: 2 mS rise time/13 mS fall time
200 Ω , 500 Ω (default setting) and 1000 $\Omega \pm 1 \%$

Waveform Selections:

**Available Test Load(s):
Amplitude:**

- Pacer Load Selection:

- 500 Ω
- Range: 0.05 to 50.0 mVpeak
- Accuracy: $\pm 5 \%$ of setting
- Resolution: 0.05 mVpeak (0.05 to 0.95 mVpeak); 0.50 mVpeak (1 to 50 mVpeak)

- Pacer Load Selection:

- 200 Ω
- Range: 0.05 mVpeak to 20.0 mVpeak
- Accuracy: $\pm 5 \%$ of setting
- Resolution: 0.05 mVpeak (0.05 to 0.95 mVpeak); 0.50 mVpeak (1 to 20 mVpeak)

- Pacer Load Selection:

- 1000 Ω
- Range: 0.05 mVpeak to 100 mVpeak-to-peak
- Accuracy: $\pm 5 \%$ of setting
- Resolution: 0.05 mVpeak (0.05 to 0.95 mVpeak); 0.50 mVpeak (1.0 to 49.5 mVpeak); 05.0 mVpeak (50 to 100 mVpeak)

Widths:

- Default Setting: 2.5 mVpeak
- Range: 0.15 mS to 300 mS
- Accuracy: $\pm 5 \%$ of setting

	<p>Intended Pacemaker Type(s): - Resolution: 0.05 mS (0.15 to 0.95 mS); 1 mS (1 to 19 mS); 5 mS (20 mS to 95 mS); 25 mS (100 mS to 300 mS) VVI (atrial pace and sense only) - Pulse Rates: 30 to 200 PPM</p> <p>Noise Immunity Test Channels: Single, atrial or ventricular only Waveform: Sine wave Frequency: 50 and 60 Hz Accuracy: ± 0.5 Hz Active Output(s): Atrial- or ventricular-channel test load Output Selections: Atrial channel only; ventricular channel only ECG Signal: ECG signal can be added to the selected channel. Atrial: 1 mVpeak Ventricular: 1.5 mVpeak Noise Line Amplitude: - Pacer Load Selection: 500 Ω -- Range: 0 (OFF) to 100 mVpeak-to-peak -- Accuracy: ± 5 % of setting -- Resolution: 5-mVpeak-to-peak steps - Pacer Load Selection: 200 Ω -- Range: 0 (OFF) to 40 mVpeak-to-peak -- Accuracy: ± 5 % of setting -- Resolution: 5-mVpeak-to-peak steps - Pacer Load Selection: 1000 Ω -- Range: 0 (OFF) to 200 mVpeak-to-peak -- Accuracy: ± 5 % of setting -- Resolution: 5-mVpeak-to-peak steps</p> <p>Refractory Period Test (Atrial Channel) Test Selections: Paced refractory period; sensed refractory period Period: 20 to 500 mS Accuracy: ± 5 % of reading (or ± 1 mS, whichever is greater) Resolution: ± 1 LSD Physiological Simulation: - Selection: Square wave (default setting) - Atrial Channel: Simulated P Wave - Width: 1 mS - Amplitude: 20 mVpeak - Active Outputs: Atrial channel (4mm banana jacks) only</p> <p>Additional Waveform Selections: Square (SQU); triangle (TRI); haversine (HSN); sine square (SSQ); asymmetrical triangle (ISO) – fixed width: 2 mS rise time/13 mS fall time Amplitude: - Range: .05 mVpeak to 50.0 mVpeak - Accuracy: ± 5 % of setting - Resolution: 0.05 mVpeak (0.05 to 0.95 mVpeak); 0.50 mVpeak (1.0 to 49.5 mVpeak) Width: - Range: 0.15 mS to 95.0 mS - Accuracy: ± 5 % of setting - Resolution: 0.05 mS (0.15 to 0.95 mS); 1 mS (1 to 19 mS); 5 mS (20 to 95 mS) Active Outputs: Atrial channel (4mm banana jacks) only Intended Pacemaker Types: AAI (atrial pace and sense only) Pacemaker Rates: 30 to 200 PPM Available Test Load: 500 Ω ± 1 %</p> <p>Refractory Period Test (Ventricular Channel) Test Selections: Paced refractory period; sensed refractory period Period: 20 to 500 mS Accuracy: ± 5 % of reading (or ± 1 mS, whichever is greater) Resolution: ± 1 LSD Display Format: 3 digits Physiological Simulation: - Selection: Square wave (default setting) - Ventricular Channel: Simulated R Wave - Width: 1 mS - Amplitude: 20 mVpeak</p>
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	<p>- Active Outputs: Ventricular channel (4mm banana jacks) only</p> <p>Additional Waveform Selections: Square (SQU); triangle (TRI); haversine (HSN); sine square (SSQ); asymmetrical triangle (ISO) – fixed width: 2 mS rise time/13 mS fall time</p> <p>Amplitude:</p> <p>- Pacer Load Selection: 500 Ω -- Range: .05 mVpeak to 50.0 mVpeak -- Accuracy: ± 5 % of setting -- Resolution: 0.05 mVpeak (0.05 to 0.95 mVpeak); 0.50 mVpeak (1.0 to 49.5 mVpeak)</p> <p>- Default setting: 20 mVpeak</p> <p>Width: - Range: 0.15 mS to 300.0 mS - Accuracy: ± 5 % of setting - Resolution: 0.05 mS (0.15 to 0.95 mS); 1 mS (1 to 19 mS); 5 mS (20 to 95 mS); 25 mS (100 to 300 mS) - Default setting: 30 mS</p> <p>Intended Pacemaker Types: VVI</p> <p>Pacemaker Rates: 20 to 200 PPM</p> <p>DC Leakage Current Measurement Range: 00.1 μA to 99.9 μA</p> <p>Input Polarity: Positive and negative</p> <p>Resolution: 1 LSD (0.1 μA)</p> <p>Display Format: 3 digits</p> <p>Test Selections: - Static: Continuous (power OFF) - Dynamic: Gated (power ON) - Atrial+ and atrial- - Ventricular+ and ventricular- - Atrial+ and ventricular+</p> <p>Test Load/Input Configurations: 500 Ω</p> <p>Baseline/Test Selection: Measurement made 400 mS prior to the pacemaker pulse leading edge; 16 measurements averaged at a 4 mS rate for a total of 64 mS</p> <p>Dynamic Test Gating Algorithm: 80 PPM</p> <p>Specified Applied Pacemaker Rate:</p> <p>Current Drain Test DC Current Ranges: 0.100 mA to 0.999 mA; 1.00 mA to 9.99 mA; 10.0 mA to 99.9 mA</p> <p>Polarity: Positive or negative</p> <p>Indicator: + or – symbol</p> <p>Resolution: ± 1 LSD</p> <p>Display Format: 3 digits plus decimal point</p> <p>Accuracy: ± 5 % of reading ± 10 μA</p> <p>Input DC Voltage: - Nominal: ± 9 V - Range: 5.0 V to 10.5 V - Input Protection: Short-circuit protection - Protection Type: Internal in-line fast-acting 1/2 A fuse 200 Ω, 500 Ω, and 1000 Ω</p> <p>Selectable Testloads: 9 V battery supply included, to facilitate connection of analyzer to recessed battery terminals within Medtronic 5388 and 5348 Temporary Pacemakers</p> <p>Battery Test Fixture:</p> <p>Test Loads</p> <p>Atrial Channel: - Selections: 200 Ω, 500 Ω, and 1000 Ω - Accuracy: ± 1 % of selection - Power Rating: 2 W</p> <p>Ventricular Channel: - Selections: 200 Ω, 500 Ω, and 1000 Ω - Accuracy: ± 1 % of selection - Power Rating: 2 W</p> <p>Tracking: Identical atrial and ventricular channel settings</p> <p>Input Defibrillation Protection: - Type: Internal spark gap - Episode Limit: 5 pulses @ 360 J (10 seconds min between discharges) - Life Limit: 250 pulses @ 360 J</p> <p>Long-Term Test</p>
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	<p>Test Configuration:</p> <ul style="list-style-type: none"> - Transvenous Pacer: Atrial or ventricular channel only - Transcutaneous Pacer: Ventricular channel - Pulse Count Range: 999,999 (max) - Rate: 2 % to 20 % (default setting, 10 %) - Amplitude: 2 % to 20 % (default setting, 10 %) - Test Time (max): 999:59:59 (hhh:mm:ss) - Maximum Error Count: 200 - Test Termination: Manual; or upon max error count - Testloads: 200 Ω, 500 Ω, and 1000 Ω <p>Interactive Pacer ECG Simulation Simulation of demand, continuous, noncapture, and nonfunction patient Additional user -selectable parameters:</p> <ul style="list-style-type: none"> - ECG activity - NSR Heart Rate: Asystole and 20 to 250 BPM (1-BPM steps) - NSR PR Interval: 0.05 to 0.30 s (6 settings) <p>Pacemaker Capture/Threshold:</p> <ul style="list-style-type: none"> - Transcutaneous: 10 to 250 mA (10-mA steps) - Transvenous: 1 to 25 mA (1-mA steps) <p>General Specifications Serial Port:</p> <ul style="list-style-type: none"> - Type: RS232 - Connector Type: DB-9 (male) - Baud Rates: 2400, 9600, and 19200 - Data Control: Xon/Xoff <p>Power Requirements:</p> <ul style="list-style-type: none"> - External battery charger source/power supply - 100 to 240 Vac, 50/60 Hz operation - Auto power-off feature during battery operation <p>Battery Life: Environmental Specifications Temperature Range:</p> <ul style="list-style-type: none"> - Operating: 15 °C to 35 °C (59 °F to 95 °F) - Storage: 0 °C to 50 °C (32 °F to 122 °F) <p>Humidity Range: Dimensions Size:</p> <ul style="list-style-type: none"> < 90 % noncondensing 8" L X 4" W X 2" H (approx) (203 mm L X 101 mm W X 50 mm H) <p>Weight: CE Mark User Safety: EMC: Conforms to: Certified to: ETL Listed Device has received FDA 510(k) clearance (on file)</p> <ul style="list-style-type: none"> 2 lb (approx) (0.90 kg) EN61326-1.1997 UL STD 3101-1 CAN/USA STD C22.2 No.1010
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