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

Specifications

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<th>Manual</th>
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<td>- 21 characters X 8 lines</td>
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<td></td>
<td>- Brightness/viewing angle adjustment</td>
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</tr>
<tr>
<td>Keys:</td>
<td>Eight push buttons (F-2, F-3 [UP arrow], F-4 [UP arrow], two DOWN arrows, ESCAPE, and ENTER)</td>
<td></td>
</tr>
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</table>

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): | - Normal sinus rhythm (NSR) |
| Amplitude: | - Complete P-QRS-T complex |
| Modes of Operation: | - 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); overload 300 BPM (max) |
| Active Outputs: | 5-lead ECG; ventricular test load; high-level ECG jack |
| Pacemaker Compatibility: | - 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 | - Rate: 30 to 200 PPM |
| | - Test Loads: (30) 50 Q to 1550 Q in 50-Q steps |
| Waveforms: | Square (SQU); triangle (TRI); haversine (HSN); sine square (SSQ) |
| Amplitude: | - Range: 0.05 mVpeak to 5.0 mVpeak |
| | - Accuracy: ± 5 % of setting |
| | - Resolution: 0.05-mV steps (0.05 to 0.95 mVpeak); 0.50-mV steps (1 to 5 mVpeak) |
| Width: | - Range: 0.15 mS to 300 mS |
| | - Accuracy: ± 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) |
| 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: | - Pulse Rates: 30 to 200 PPM |
| | - Intended Type: VVI (pace and sense) |
| Noise Immunity/Line Frequency Test Waveform: | Sine wave |
| | - Frequency: 50 and 60 Hz |
| | - Accuracy: 0.5 Hz |
| Amplitude Test Load Output: | - Range: 0 (OFF) to 10 mVpeak-to-peak |
| | - Accuracy: ± 5 % of setting |
| | - Resolution: 0.5-mVpeak-to-peak steps |
| | - Settings: (30) 50 Q to 1550 Q ± 1 % |
| 5-lead ECG Output: | - Range: 0 (OFF) to 10 mVpeak-to-peak |
| | - Accuracy: ± 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 |
| | - Accuracy: 5 % of reading or 1 mS (whichever is greater) |
| | - Selection: Single pulse, R Wave, SSQ |
| | - Pulse Width: 40 mS |
| Physiological Simulation: | 5-lead ECG; ventricular test load |
| Pacemaker Compatibility: | - Pulse Rates: 30 to 200 BPM |
| | - Intended Type: VVI (pace and sense) |
| Sensed Refractory Period Test (SRP) Range: | 15 mS to 500 mS |
| | ± 5 % of reading or ± 1 mS (whichever is greater) |
| | - 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: | - Pulse Rates: 30 to 200 BPM |
| | - Intended Type: VVI (pace and sense) |
### Transcutaneous Pacer:
- **Selections:** (31) 50 Ω to 1550 Ω in 50-Ω steps
- **Accuracy:** ± 1 % of selection
- **Power Rating:** 5 W (average); 40 W (peak) @ 100 Ω
- **Type:** Internal spark gap

**Input Defibrillation Protection:**
- **Episode Limit:** 5 pulses @ 360 J (10 seconds min between discharges)
- **Life Limit:** 250 pulses @ 360 J

### Transvenous Pacer Tests:

#### Output Pulse Measurement

- **Current:**
  - 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 -

- **Rate:**
  - Ranges: 10.0 PPM to 99.9 PPM; 100 PPM to 999 PPM
  - Accuracy: ± 0.5 % or 0.3 PPM (whichever is greater)

- **Width:**
  - 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)

- **Voltage:**
  - 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 -

- **Energy:**
  - Ranges: (available single channel only) 1 nJ to 999 nJ; 1 µJ to 999 µJ
  - Accuracy: ± 5 % of reading/computation

#### Display Formats:
- Atrial channel only; ventricular channel only; both A + V channels

#### AV Interval (Delay Time)

- **Measurement Ranges:** 10.0 mS to 99.9 mS; 100 mS to 999 mS
- **Start Point:** Atrial pulse leading edge
- **Stop Point:** Ventricular pulse leading edge
- **Accuracy:** 1 % of reading/computation

#### Demand/Async Mode Tests

- **Channels:** Single and dual
- **Waveform:** Sine square (SSQ)
- **Atrial Output:** Simulated P Wave
  - Width: 30 mS
  - Amplitude: 2.0 mVpeak
- **Vent Output:** Simulated R Wave
  - Width: 40 mS
  - Amplitude: 2.5 mVpeak
- **AV Interval:** 90 mS (fixed)

#### Interactive Simulated Rates

- **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

#### Output Voltage

- **Pulse Rate:** Ventricular channel test load; atrial channel test load 30 to 200 PPM

#### Intended Pacemaker Types

- **DDD (dual-channel pace and sense):**
  - 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)

#### Amplitude Sensitivity Test

- **Operation:** Single-channel operation only (atrial or ventricular)
- **Atrial Channel (Physiological)**
- **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

Available Test Loads:
200 Ω, 500 Ω (default setting) and 1000 Ω ± 1 %

Waveform Selections:
Square (SQU); triangle (TRI); haversine (HSN); sine square (SSQ) (default setting); asymmetrical triangle (ISO) – fixed width: 2 mS rise time/13 mS fall time

Sensitivity Waveform Amplitude:
- Test Load Selection:
  - 500 Ω (default setting)
    - Range: 0.05 mVpeak to 50.0 mVpeak
    - Accuracy: ± 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: ± 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: ± 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)
- Default Setting: 2.0 mVpeak

Widths:
- Range: 0.15 mS to 95.0 mS
- Accuracy: ± 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)

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

Waveform Selections:
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 Load(s):
200 Ω, 500 Ω (default setting) and 1000 Ω ± 1 %

Amplitude:
- Pacer Load Selection:
  - 500 Ω
    - Range: 0.05 to 50.0 mVpeak
    - Accuracy: ± 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: ± 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: ± 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)
- Default Setting: 2.5 mVpeak

Widths:
- Range: 0.15 mS to 300 mS
- Accuracy: ± 5 % of setting
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<th>VVI (atrial pace and sense only)</th>
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<td>ECG Signal:</td>
<td>ECG signal can be added to the selected channel,</td>
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<tr>
<td>Atrial:</td>
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<td>Ventricular:</td>
<td>1.5 mVpeak</td>
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<td>Accuracy: ± 5 % of setting</td>
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<tr>
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<td>Accuracy: ± 5 % of setting</td>
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<td></td>
<td>Resolution: 5-mVpeak-to-peak steps</td>
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<tr>
<td>- Pacer Load Selection:</td>
<td>1000 Ω</td>
</tr>
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<td>Range: 0 (OFF) to 200 mVpeak-to-peak</td>
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<td>Accuracy: ± 5 % of setting</td>
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<td>Resolution: 5-mVpeak-to-peak steps</td>
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<td>Period:</td>
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<td>Physiological Simulation:</td>
<td>Selection: Square wave (default setting)</td>
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<td>Atrial Channel: Simulated P Wave</td>
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<td>Width: 1 mS</td>
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<td>Amplitude: 20 mVpeak</td>
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<td>Test Selections:</td>
<td>20 to 500 mS</td>
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<tr>
<td>Period:</td>
<td>± 1 LSD</td>
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<tr>
<td>Physiological Simulation:</td>
<td>Selection: Square wave (default setting)</td>
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<tr>
<td></td>
<td>Ventricular Channel: Simulated R Wave</td>
</tr>
<tr>
<td></td>
<td>Width: 1 mS</td>
</tr>
<tr>
<td></td>
<td>Amplitude: 20 mVpeak</td>
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</tbody>
</table>
### 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:
- **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)
- **Default setting:** 20 mVpeak

**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

### Intended Pacemaker Types:
- VVI

### Pacemaker Rates:
- 20 to 200 PPM

### DC Leakage Current Measurement Range:
- 0.1 µA to 99.9 µA

### Input Polarity:
- Positive and negative

### Resolution:
- 1 LSD (0.1 µA)

### Test Selections:
- Static: Continuous (power OFF)
- Dynamic: Gated (power ON)

### Test Load/Input Configurations:
- Atrial+ and atrial-
- Ventricular+ and ventricular–
- Atrial+ and ventricular+

### Baseline/Test Selection:
- 500 Ω

### Dynamic Test Gating Algorithm:
- 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

### Specified Applied Pacemaker Rate:
- 80 PPM

### 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
- Polarity: Positive or negative
- Indicator: + or – symbol
- Resolution: ± 1 LSD
- Display Format: 3 digits plus decimal point
- Accuracy: ± 5 % of reading ± 10 µA
- 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

### Selectable Testloads:
- 200 Ω, 500 Ω, and 1000 Ω

### Battery Test Fixture:
- 9 V battery supply included, to facilitate connection of analyzer to recessed battery terminals within Medtronic 5388 and 5348 Temporary Pacemakers

### Test Loads
- **Atrial Channel:**
  - Selections: 200 Ω, 500 Ω, and 1000 Ω
  - Accuracy: ± 1 % of selection
  - Power Rating: 2 W
- **Ventricular Channel:**
  - Selections: 200 Ω, 500 Ω, and 1000 Ω
  - Accuracy: ± 1 % of selection
  - Power Rating: 2 W

### Tracking:
- Identical atrial and ventricular channel settings

### Input Defibrillation Protection:
- Type: Internal spark gap
- Episode Limit: 5 pulses @ 360 J (10 seconds min between discharges)
- Life Limit: 250 pulses @ 360 J

### Long-Term Test
### Test Configuration:
- 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 (hh:mm:ss)
- Maximum Error Count: 200
- Test Termination: Manual; or upon max error count
- Testloads: 200 Ω, 500 Ω, and 1000 Ω

### Interactive Pacer ECG Simulation
Simulation of demand, continuous, noncapture, and nonfunction patient

Additional user-selectable parameters:
- NSR Heart Rate: Asystole and 20 to 250 BPM (1-BPM steps)
- NSR PR Interval: 0.05 to 0.30 s (6 settings)
- Transcutaneous: 10 to 250 mA (10-mA steps)
- Transvenous: 1 to 25 mA (1-mA steps)

### Pacemaker Capture/Threshold:
- Transcutaneous: 10 to 250 mA (10-mA steps)
- Transvenous: 1 to 25 mA (1-mA steps)

### General Specifications

#### Serial Port:
- Type: RS232
- Connector Type: DB-9 (male)
- Baud Rates: 2400, 9600, and 19200
- Data Control: Xon/Xoff

#### Power Requirements:
- External battery charger source/power supply
- 100 to 240 Vac, 50/60 Hz operation
- Auto power-off feature during battery operation

#### Battery Life:
- 20 hours (min)

### Environmental Specifications

#### Temperature Range:
- Operating: 15 °C to 35 °C (59 °F to 95 °F)
- Storage: 0 °C to 50 °C (32 °F to 122 °F)

#### Humidity Range:
< 90% noncondensing

#### Size:
8" L X 4" W X 2" H (approx) (203 mm L X 101 mm W X 50 mm H)

#### Weight:
2 lb (approx) (0.90 kg)

### CE Mark

#### User Safety:
- EN61326-1.1997
- UL STD 3101-1
- CAN/USA STD C22.2 No.1010

#### ETL Listed
- Device has received FDA 510(k) clearance (on file)