FLUKE®

Biomedical

SigmaPace™ 1000
External Pacemaker Analyzer

Technical Data

Fluke Biomedical's premier SigmaPace™ 1000 analyzes both transvenous and transcutaneous external pacemakers and comes loaded with features to save time and money. This powerful handheld tool conducts the full suite of tests specified by major pacemaker manufacturers in less than half the time it would take using originally prescribed testing methods.

Output data is displayed on three selectable screens for easy viewing, including an AV delay time readout providing a performance snapshot for both pacer channels.

With capability for long-term trend testing, the SigmaPace 1000 can interrogate a pacer for up to 11 days, capturing data pulse by pulse to detect intermittent and hard-to-find problems.

For maximum efficiency, the SigmaPace 1000 doubles as a training tool. Interactive ECG simulation lets users test patient monitoring equipment as well as teach nurses how to operate the pacemaker.

Key Features

- Transcutaneous and transvenous external pacemaker tests
- Pulse-output tests (rate, current, volts, energy, pulse width, and AV interval)
- Amplitude sensitivity and refractory tests
- Demand and asynchronous-mode tests
- DC load current test
- Output-leakage tests
- Line-frequency noise-rejection tests
- Wide range of test loads, from 50 Ω to 1500 Ω, specified by manufacturer for transcutaneous pacers
- Full range of IEC specified test loads for transvenous pacers 200, 500, and 1000 Ω
- Pacer output displayed on three different screens
- AV readout showing both pacer channels on one screen
- Long-term trend test to detect intermittent errors and hard-to-find problems
- Interactive ECG pacer simulation with 5-lead output for patient monitor evaluation and pacer operation training
- 8-line x 21-character display

Technical Specifications

Transcutaneous Pacer Tests

Output Pulse Measurement

Current
- Ranges: 4 mA to 9.99 mA; 10 mA to 99.9 mA; 100mA to 250 mA
- Accuracy: ± 2 % of reading or ± 50 µA (whichever is greater)

Rate
- Ranges: 5 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 mS to 9.99 mS; 10 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)
- Complete P–QRS–T complex

Amplitude: 1 mVpeak (lead I)

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); overdrive 300 BPM (max)

Active Outputs: 5–lead ECG; ventricular test load; high–level ECG jack

Pacemaker Compatibility
- Pulse Rates: 30 PPM to 200 PPM
- Intended Types: Demand: VVI (pace and sense); async: VOO (pace)

Amplitude Sensitivity Test

Selections: R–, S–, and T–waves
- Rate: 30 PPM 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
- Range: 0.05 mVpeak to 5 mVpeak
- Accuracy: ± 5 % of setting

Resolution: 0.05–mV steps (0.05 mVpeak to 0.95 mVpeak); 0.5–mV steps (1 mVpeak to 5 mVpeak)

Width
- Range: 0.15 mS to 300 mS
- Accuracy: ± 5 % of setting
- Selections: 50
- Resolution: 0.05–mS steps (0.15 mS to 0.95 mS); 1–mS steps (1 mS to 19 mS); 5–mS steps (20 mS to 95 mS) 25–mS steps (100 mS to 300 mS)

Active Outputs: 5–lead ECG; ventricular test load; high–level ECG jack

Pacemaker Compatibility
- Pulse Rates: 30 PPM to 200 PPM
- Intended Type: VVI (pace and sense)

Noise Immunity/Line Frequency Test

Waveform: Sine wave
- Frequency: 50 Hz and 60 Hz
- Accuracy: 0.5 Hz

Amplitude Testload Output
- Range: 0 (OFF) to 10 mVpeak–to–peak
- Accuracy: ± 5 % of setting
- Resolution: 0.5–mV peak–to–peak steps
- Settings: (30) 50 Ω to 1550 Ω ± 1 %

5–lead ECG Output
- Range: 0 (OFF) to 10 mVpeak–to–peak
- Accuracy: ± 5 % of setting
- Resolution: 0.5–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)

Physiological Simulation
- Selection: Single pulse, R–wave, SSQ
- Pulse Width: 40 mS

Outputs: 5–lead ECG; ventricular test load

Pacemaker Compatibility
- Pulse Rates: 30 BPM to 200 BPM
- Intended Type: VVI (pace and sense)

Sensed Refractory Period Test (SRP)

Range: 15 mS to 500 mS

Accuracy: ± 5 % of reading or ± 1 mS (whichever is greater)

Physiological Simulation
- 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 BPM to 200 BPM
- Intended Type: VVI (pace and sense)

Test Loads

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) @ 1000 Ω

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

Transvenous Pacer Tests

Output Pulse Measurement

Current
- Ranges: 0.05 mA to .999 mA (available single channel only); 1 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 PPM to 99.9 PPM; 100 PPM to 999 PPM
- Accuracy: ± 0.5 % or 0.3 PPM (whichever is greater)

Width
- Ranges: 0.02 mS to .999 mS; 1 mS to 9.99 mS; 10 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) 0.05 Vpeak to .999 Vpeak; 1 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 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: Ventricular channel test load; atrial channel test load

Pulse Rate: 30 PPM to 200 PPM

Intended Pacemaker Types
- Demand: VVI (V–channel pace and sense); AAI (A–channel pace and sense); DDD (dual–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 Simulation)
- Selection: P–wave
- Rate: 30 BPM 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

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Sensitivity Waveform Amplitude
- Test Load Selection: 500 Ω (default setting)
  - Range: 0.05 mVpeak to 50 mVpeak
  - Accuracy: ± 5 % of setting
  - Resolution: 0.05 mVpeak (0.05 mVpeak to 0.95 mVpeak); 0.5 mVpeak (1 mVpeak to 50 mVpeak)
- Test Load Selection: 200 Ω
  - Range: 0.05 mVpeak to 20 mVpeak
  - Accuracy: ± 5 % of setting
  - Resolution: 0.05 mVpeak (0.05 mVpeak to 0.95 mVpeak); 0.50 mVpeak (1 mVpeak to 20 mVpeak)
- Test Load Selection: 1000 Ω
  - Range: 0.05 mVpeak to100 mVpeak-to-peak
  - Accuracy: ± 5 % of setting
  - Resolution: 0.05 mVpeak (0.05 mVpeak to 0.95 mVpeak); 0.5 mVpeak (1 mVpeak to 49.5 mVpeak); 5 mVpeak (50 mVpeak to 100 mVpeak)
- Default Setting: 2 mVpeak

Widths
- Range: 0.15 mS to 95 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)
- Pulse Rates: 30 PPM to 200 PPM

Ventricular Channel (Physiological Simulation)
- Selection: R-wave, S-wave, and T-wave
- Rate: 30 BPM 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 mVpeak to 50 mVpeak
  - Accuracy: ± 5 % of setting
  - Resolution: 0.05 mVpeak (0.05 mVpeak to 0.95 mVpeak); 0.5 mVpeak (1 mVpeak to 50 mVpeak)
- Pacer Load Selection: 200 Ω
  - Range: 0.05 mVpeak to 20 mVpeak
  - Accuracy: ± 5 % of setting
  - Resolution: 0.05 mVpeak (0.05 mVpeak to 0.95 mVpeak); 0.5 mVpeak (1 mVpeak to 20 mVpeak)
- Pacer Load Selection: 1000 Ω
  - Range: 0.05 mVpeak to100 mVpeak-to-peak
  - Accuracy: ± 5 % of setting
  - Resolution: 0.05 mVpeak (0.05 mVpeak to 0. 95 mVpeak); 0.5 mVpeak (1.0 mVpeak to 49.5 mVpeak); 5 mVpeak (50 to 100 mVpeak)
- Default Setting: 2.5 mVpeak

Widths
- Range: 0.15 mS to 300 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); 25 mS (100 mS to 300 mS)

Intended Pacemaker Type(s): VVI (atrial pace and sense only)
- Pulse Rates: 30 PPM to 200 PPM

Noise Immunity Test

Channels: Single, atrial, or ventricular only

Waveform: Sine wave

Frequency: 50 Hz 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.

Amplitude:
- Pacer Load Selection: 500 Ω
  - Range: 0 (OFF) to100 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

Refractory Period Test (Atrial Channel)

Test Selections: Paced refractory period; sensed refractory period

Period: 20 mS 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

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 mVpeak
- Accuracy: ± 5 % of setting
- Resolution: 0.05 mVpeak (0.05 mVpeak to 0.95 mVpeak); 0.5 mVpeak (1 mVpeak to 49.5 mVpeak)

Width
- 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 to 95 mS)

Active Outputs: Atrial channel (4 mm banana jacks) only

Intended Pacemaker Types: AAI (atrial pace and sense only)

Pacemaker Rates: 30 PPM to 200 PPM

Available Test Load: 500 Ω ± 1 %

Refractory Period Test (Ventricular Channel)

Test Selections: Paced refractory period; sensed refractory period

Period: 20 mS 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
- Active Outputs: Ventricular channel (4mm banana jacks) only

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: 0.05 mVpeak to 50 mVpeak
  - Accuracy: ± 5 % of setting
  - Resolution: 0.05 mVpeak (0.05 mVpeak to 0.95 mVpeak); 0.5 mVpeak (1.0 mVpeak 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 mS to 0.95 mS); 1 mS (1 mS to 19 mS); 5 mS (20 mS to 95 mS); 25 mS (100 mS to 300 mS)
- Default setting: 30 mS

Intended Pacemaker Types: VVI

Pacemaker Rates: 20 PPM 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)

Display Format: 3 digits

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: 0.1 mA to 0.999 mA; 1 mA to 9.99 mA; 10 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 V to 10.5 V
- Input Protection: Short-circuit protection
- Protection Type: Internal in-line fast-acting 1/2 A fuse

Selectable Test loads: 200, 500, 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

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

Ventricular Channel
- Selections: 200, 500, 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 sec minimum 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 (hhh:mm:ss)
- Maximum Error Count: 200
- Test Termination: Manual; or upon max error count
- Testloads: 200, 500, and 1000 Ω

Interactive Pacer ECG Simulation
Simulation of demand, continuous, noncapture, and nonfunction patient-ECG activity
Additional user-selectable parameters
- NSR Heart Rate: Asystole and 20 BPM to 250 BPM (1-BPM steps)
- NSR PR Interval: 0.05 s to 0.3 s (6 settings)

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

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

Humidity Range
< 90 % noncondensing

Modes of Operation
Manual, remote (via standard RS232 serial port)

User Interface
Display: 21-character x 8-line LCD readout; brightness/viewing angle adjustment

Keys
Eight push buttons [F-2, F-3 (UP arrow), F-4 (UP arrow), two DOWN arrows, ESCAPE, and ENTER]

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

Power
External battery charger source/power supply 100 to 240 VAC, 50/60 Hz operation
Auto power-off feature during battery operation
Battery Life: 20 hrs (min)

Dimensions
8 in L x 4 in W x 2 in H
(20.3 cm x 10.1 cm x 5 cm)

Weight
2 lb (0.9 kg)

CE Mark
User Safety:
EMC: EN61326-1.1997
Conforms to: UL STD 3101-1
Certified to: CAN/USA STD C22.2 No.1010
ETL Listed
Device has received FDA 510(k) clearance (on file)

FLUKE®

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Ordering Information

Model
2247700: SIGMAP1K-USA120V
2394548: SIGMAP1K-JPN100V
2394553: SIGMAP1K-SHK250V
2394566: SIGMAP1K-UK250V
(Pending) SIGMAP1K-AUS250V

Standard Accessories
2243306: User/service manual
2392906: Soft-sided vinyl carrying case
2201166: Transvenous pacer test leads (2 sets, red)
2201153: Transvenous pacer test leads (2 sets, black)
2392272: SigmaPace 9 VDC load test cable
2392260: Serial PC interface cable
2184298: Universal-input battery charger
2198724: Power cord set USA 120 VAC

Optional Accessories
2245006: Electrode adapters (including the brand/model-specific interface connector and a pair of 4 mm "safety-type" banana plugs)
2201109: Agilent (HP) CodeMaster series
2201111: GE Marquette Medical
2201127: Medical Data Electronics (MDE); Medical Research Laboratories (MRL)
2201095: Medtronic Physio-Control Quick Combo
2201088: Medtronic Physio-Control Quick Pace
2201323: Philips / Agilent Codemaster Series
2201130: Zoll Medical NTP Series
2201148: Zoll Medical PD Series & M Series
2200102: Interface cable (RS232; female DB9 to female DB25; medTester to SigmaPace™ 1000/PC/Index 2XL/IDA 4 Plus; Impulse 4000 to PC)
2201419: Detachable cord set – Japan (IEC 320 C6 type 3-pin inlet)
2201437: Detachable cord set – Schuko / Euro (IEC 320 C6 type 3-pin inlet)
2201428: Detachable cord set – UKI (IEC 320 C6 type 3-pin inlet)
2201455: Detachable cord set – USA (IEC 320 C6 type 3-pin inlet)
2201443: Detachable cord set – Australia (IEC 320 C6 type 3-pin inlet)

About Fluke Biomedical
Fluke Biomedical is the world's leading manufacturer of quality biomedical test and simulation products. In addition, Fluke Biomedical provides the latest medical imaging and oncology quality-assurance solutions for regulatory compliance.

Today, biomedical personnel must meet the increasing regulatory pressures, higher quality standards, and rapid technological growth, while performing their work faster and more efficiently than ever. Fluke Biomedical provides a diverse range of software and hardware tools to meet today's challenges.

Fluke Biomedical Regulatory Commitment
As a medical device manufacturer, we recognize and follow certain quality standards and certifications when developing our products. We are ISO 9001 certified and our products are:
- FDA Compliant
- CE Certified, where required
- NIST Traceable and Calibrated
- UL, CSA, ETL Certified, where required

Fluke Biomedical.
Better products. More choices. One company.

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