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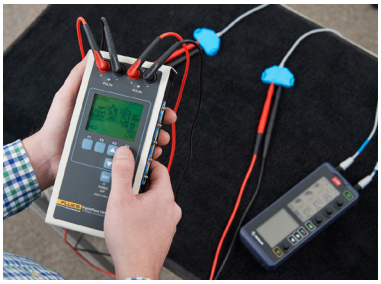
SigmaPace™ 1000
External Pacemaker Analyzer

Technical data

The Fluke Biomedical premier SigmaPace™ 1000 is a powerful stand-alone handheld tool with a comprehensive range of test suites, measurement algorithms and test loads to fulfill your testing requirements both quickly and efficiently.



Full range testing

The SigmaPace™ 1000 analyzes both transvenous and transcutaneous external pacemakers and comes loaded with features to save time and money. The full range of capabilities allows users to perform a wide range of tests with the added benefit of running remote command sets and uploading results to a computer.

Parameter tests

This powerful handheld tool conducts the full suite of tests, including Demand Mode and Asynchronous Mode tests, specified by major pacemaker manufacturers, in less than half the time it would take using originally prescribed testing methods. The SigmaPace 1000 will also allow you to conduct DC Leakage Current and Current Drain tests without the need for a separate testing device. Manufacturer Medtronic has standardized their external pacemaker tests using the SigmaPace 1000 for their 5388, 5391 and 5392 models.

Long-term troubleshooting

With capability for long-term trend testing, the SigmaPace 1000 can record pacer output for up to 11 days, capturing data pulse-by-pulse to detect intermittent and hard-to-find problems. For enhanced output, the SigmaPace can connect to an oscilloscope using an RS232 port to view detailed waveform data.

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Benefits and features

- Have confidence that the pacemaker is ready for the next patient with the highly accurate ppm pulse rate and mA current parameter settings.
- Efficiently conduct both transcutaneous and transvenous external pacemaker tests with one analyzer.
- Ensure patient safety by detecting pacemaker problems before intermittent errors or a failure occurs with long-term trend testing.
- Accurately determine that the heart beat functionality of the pacemaker is performing properly with demand mode testing.
- Stop and record charge delivery readings with the exclusive readout "HOLD" function.
- Visually see the pacemaker waveform output during connection to an oscilloscope using the RS232 port.
- Streamline your testing procedure, reduce errors and quicken your test time with the remote command set.
- Test to manufacturer and IEC requirements on all types of patients with transcutaneous test loads from 50 Ω to 1500 Ω and transvenous test loads of 200 Ω, 500 Ω, and 1000 Ω.
- Accurately capture synchronous AV, sequential pulse data with the dual-channel signal acquisition mode.
- Easily track three output readings at once with the 8 line by 21 selectable three-screen display.

Specifications

Transcutaneous pacer tests		
Output pulse measurement		
Current	Ranges	4 mA to 9.99 mA; 10 mA to 99.9 mA; 100 mA 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 mV peak (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: V00 (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 mV peak to 5 mV peak
	Accuracy	± 5 % of setting
Resolution	0.05-mV steps (0.05 mV peak to 0.95 mV peak); 0.5-mV steps (1 mV peak to 5 mV peak)	

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 mV peak-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 mV peak-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 mV peak 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 0.999 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 0.999 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 V peak to 0.999 V peak; 1 V peak to 9.99 V peak; 10 V peak to 30 V peak
	Accuracy	± 2 % of reading or ± 0.05 V peak (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 mV peak
Vent output	Simulated R-wave	
	Width	40 mS
	Amplitude	2.5 mV peak 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	V00 (V-channel pace and sense); A00 (A-channel pace and sense); D00 (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	

Sensitivity waveform amplitude	Test load selection	500 Ω (default setting)
	Range	0.05 mV peak to 50 mV peak
	Accuracy	± 5 % of setting
	Resolution	0.05 mV peak (0.05 mV peak to 0.95 mV peak); 0.5 mV peak (1 mV peak to 50 mV peak)
	Test load selection	200 Ω
	Range	0.05 mV peak to 20 mV peak
	Accuracy	± 5 % of setting
	Resolution	0.05 mV peak (0.05 mV peak to 0.95 mV peak); 0.50 mV peak (1 mV peak to 20 mV peak)
	Test load selection	1000 Ω
	Range	0.05 mV peak to 100 mV peak-to-peak
	Accuracy	± 5 % of setting
	Resolution	0.05 mV peak (0.05 mV peak to 0.95 mV peak); 0.5 mV peak (1 mV peak to 49.5 mV peak); 5 mV peak (50 mV peak to 100 mV peak)
	Default setting	2 mV peak
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 mV peak to 50 mV peak
	Accuracy	± 5 % of setting
	Resolution	0.05 mV peak (0.05 mV peak to 0.95 mV peak); 0.5 mV peak (1 mV peak to 50 mV peak)
	Pacer load selection	200 Ω
	Range	0.05 mV peak to 20 mV peak
	Accuracy	± 5 % of setting
	Resolution	0.05 mV peak (0.05 mV peak to 0.95 mV peak); 0.5 mV peak (1 mV peak to 20 mV peak)
	Pacer load selection	1000 Ω
	Range	0.05 mV peak to100 mV peak-to-peak
	Accuracy	± 5 % of setting
	Resolution	0.05 mV peak (0.05 mV peak to 95 mV peak); 0.5 mV peak (1.0 mV peak to 49.5 mV peak); 5 mV peak (50 to 100 mV peak)
	Default setting	2.5 mV peak
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 mV peak-to-peak
	Accuracy	± 5 % of setting
	Resolution	5 mV peak-to-peak steps
	Pacer load selection	200 Ω
	Range	0 (OFF) to 40 mV peak-to-peak
	Accuracy	± 5 % of setting
	Resolution	5 mV peak-to-peak steps
	Pacer load selection	1000 Ω
	Range	0 (OFF) to 200 mV peak-to-peak
	Accuracy	± 5 % of setting
	Resolution	5 mV peak-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 mV peak
	Active outputs	Atrial channel (4 mm 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	0.05 mV peak to 50 mVpeak
	Accuracy	± 5 % of setting
	Resolution	0.05 mV peak (0.05 mV peak to 0.95 mV peak); 0.5 mV peak (1 mV peak to 49.5 mV peak)
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 mV peak
	Active outputs	Ventricular channel (4 mm 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 mV peak to 50 mV peak
	Accuracy	± 5 % of setting
	Resolution	0.05 mV peak (0.05 mV peak to 0.95 mV peak); 0.5 mV peak (1.0 mV peak to 49.5 mV peak)
	Default setting	20 mV peak
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 dating 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 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 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 Ω, 500 Ω, 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)

General information		
Temperature	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	
Modes of operation	Manual, remote (via standard RS-232 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	RS-232
	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 V ac, 50/60 Hz operation Auto power-off feature during battery operation	
	Battery life	20 hours
Dimensions (WxDxH)	10.1 cm x 20.3 cm x 5 cm (4 in x 8 in x 2 in)	
Weight	0.9 kg (2 lb)	
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)	

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Ordering information

Model numbers/descriptions

SigmaPace 1000 External Pacemaker Analyzer

SIGMAP1K-USA120V United States, 120 V

SIGMAP1K-JPN100V Japan, 100 V

SIGMAP1K-SHK250V Schuko, 250 V

SIGMAP1K-UK250V United Kingdom, 250 V

Standard accessories

9508-0295 Operators Manual

9530-0069FG Nylon Carrying Case

3010-0611 Transvenous Pacer Test Leads (2 sets, red)

3010-0610 Transvenous Pacer Test Leads (2 sets, black)

3010-0602FG SigmaPace 9 V dc Load Test Cable

3010-0585FG Serial PC Interface Cable

POWER SUPPLY Universal-Input Battery Charger

LINE CORD Power Cord Set USA 120 V ac

Optional accessories

9513-0202 Electrode Adapters (including the brand/model-specific interface connector and a pair of 4 mm "safety-type" banana plugs)

3010-0605 Agilent (HP) CodeMaster Series

2201111 GE Marquette Medical

3010-0607 Medical Data Electronics (MDE); Medical Research Laboratories (MRL)

3010-0604 Medtronic Physio-Control Quick Combo

3010-0603 Medtronic Physio-Control Quick Pace

3010-0639 Philips/Agilent Codemaster Series

3010-0608 Zoll Medical NTP Series

3010-0609 Zoll Medical PD Series and M Series

3010-0441 Interface Cable (RS-232; female DB9 to female DB25; medTester to SigmaPace™ 1000/PC/Index 2XL/ IDA 4 Plus; Impulse 4000 to PC)

3010-0654 Detachable Cord Set, Japan (IEC 320 C6 type 3-pin inlet)

3010-0656 Detachable Cord Set, Schuko/Euro (IEC 320 C6 type 3-pin inlet)

3010-0655 Detachable Cord Set, UKI (IEC 320 C6 type 3-pin inlet)

3010-0658 Detachable Cord Set, USA (IEC 320 C6 type 3-pin inlet)

3010-0657 Detachable Cord Set, Australia (IEC 320 C6 type 3-pin inlet)

Fluke Biomedical.
Trusted for the measurements that matter.

Fluke Biomedical
6045 Cochran Road
Cleveland, OH 44139-3303 U.S.A.

For more information, contact us:
(800) 850-4608 or
Fax (440) 349-2307
Email: sales@flukebiomedical.com
Web access: www.flukebiomedical.com

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