

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 Ω , 500 Ω , 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

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) | <ul style="list-style-type: none"> • 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: 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 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) |

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| 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 | 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 | | |
| 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 to 100 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) |
| | Default setting | 2.5 mV peak |
| 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) to 100 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 μ A) | |
| 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 | \pm 1 LSD | |
| Display format | 3 digits plus decimal point | |
| Accuracy | \pm 5 % of reading \pm 10 μ A | |
| Input dc voltage | Nominal | \pm 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 | \pm 1 % of selection |
| | Power rating | 2 W |
| Ventricular channel | Selections | 200 Ω , 500 Ω , and 1000 Ω |
| | Accuracy | \pm 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 | CE Mark; 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) | |

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)

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. Highly credentialed and equipped with a NVLAP Lab Code 200566-6 accredited laboratory, Fluke Biomedical also offers the best in quality and customer service for all your equipment calibration needs.

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 test device manufacturer, we recognize and follow certain quality standards and certifications when developing our products. We are ISO 9001 certified and our products are:

- CE Certified, where required
- NIST Traceable and Calibrated
- UL, CSA, ETL Certified, where required
- NRC Compliant, where required

Fluke Biomedical.

Better products. More choices. One company.

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