

# ProSim 8

## Vital Signs Simulator

### Technical Data

The 8-in-1 ProSim 8 Vital Signs Simulator offers fast and comprehensive preventative maintenance (PM) testing for your entire patient monitor fleet. Designed to get you in and out of most PM locations in minutes, this multifunction simulator tests ECG (including fetal ECG and arrhythmias), respiration, temperature, IBP, cardiac output/cardiac catheterization, NIBP, SpO<sub>2</sub>, and is capable of simulating Rainbow multi-wavelength waveforms. Featuring specialized stay-connected ECG posts for secure lead connections, physiologically-synchronized pulses across all parameters, and customizable patient pre-sets and autosequences, the ProSim 8 patient simulator provides unbeatably fast and easy complete monitor testing. Barcode-scanner compatibility and wireless PC interface, direct printing, data transfer and reporting, along with advanced, integrated technologies and works-every-time performance allow top confidence in patient monitor fleet performance and supports passing regulatory audits with ease.



### Key features

- All-in-one complete monitor testing 80 % smaller and 17 lbs/7.7 kilos lighter than predecessor technology
- 8-in-1 multifunction simulator tests ECG (including fetal ECG and arrhythmias), respiration, temperature, IBP, cardiac output/cardiac catheterization, NIBP, SpO<sub>2</sub>, and Rainbow multi-wavelength waveforms
- Stay-connected ECG posts for easy/secure ECG snap and lead connections
- Custom SpO<sub>2</sub> r-curve for accurate testing of the latest and future oximetry technologies
- Static pressure linearity testing
- Repeatable NIBP simulation (+/- 2 mmHg) for dynamic pressure repeatability testing
- Physiologically synchronized pulses across all parameters
- Barcode scanning and direct data capture and printing functionality
- Onboard, customizable patient pre-sets and autosequences for fast/easy testing
- Multi-language user interface offers choice of language selection
- Integrated, easily-replaceable long-life battery
- Optional PC-interface software offers customizable procedures/checklists to replace bulky service manuals and automated data capture/storage
- Wireless communication for remote PC control of test device, as well as data transfer and automated regulatory reporting

## Specifications

General specifications		
Temperature	Operating	10 °C to 40 °C (50 °F to 104 °F)
	Storage	-20 °C to +60 °C (-4 °F to 140 °F)
Humidity	10 % to 90 % non-condensing	
Altitude	3,000 meters (9,843 ft)	
Dimensions (L x W x H)	14.5 cm x 30.2 cm x 8.6 cm (5.7 in x 11.9 in x 3.4 in)	
Display	LCD color display	
Communication	USB device upstream port	Mini-B connector for control by a computer
	USB host controller port	Type A, 5 V output, 0.5 A max load. Connector for keyboard, barcode reader, and printer
	Wireless	IEEE 82.15.4 for control by a computer
Power	Lithium-ion rechargeable battery	
Battery charger	100 V to 240 V input, 15 V/2.0 A output. For best performance, the battery charger should be connected to a properly-grounded ac receptacle	
Battery life	9 hours (minimum), 100 NIBP cycles typical	
Weight	1.87 kg (4.2 lb)	
Safety standards	EN/IEC 61010-1:2001	
Certifications	CE, CSA, C-TICK N10140 , RoHS	
Electromagnetic compatibility (EMC)	IEC 61326-1:2006	



## Detailed specifications

### Normal-sinus-rhythm waveform

ECG reference	The ECG amplitudes specified are for Lead II (calibration), from the baseline to the peak of the R wave. All other leads are proportional
Normal sinus rhythm	12-lead configuration with independent outputs referenced to right leg (RL). Output to 10 universal ECG jacks, color-coded to AHA and IEC standards
High-level output	0.5 V/mV $\pm$ 5 % of the ECG amplitude setting available on a BNC connector
Amplitude	0.05 mV to 0.5 mV (0.05 mV steps); 0.5 mV to 5 mV (0.25 mV steps)
Amplitude accuracy	$\pm$ (2 % of setting + 0.05 mV)
ECG rate	10 BPM to 360 BPM in 1 BPM steps
Rate accuracy	$\pm$ 1 % of setting
ECG waveform selection	Adult (80 ms) or pediatric (40 ms) QRS duration
ST-segment elevation	Adult mode only. -0.8 mV to +0.8 mV (0.1 mV steps). Additional steps: + 0.05 mV and - 0.05 mV
Power-on default	60 BPM, 1.0 mV, adult QRS and ST-segment elevation of 0 mV

### Pacemaker waveform

Pacer pulse	Amplitude	0 (off), $\pm$ 2, $\pm$ 4, $\pm$ 6, $\pm$ 8, $\pm$ 10, $\pm$ 12, $\pm$ 14, $\pm$ 16, $\pm$ 18, $\pm$ 20, $\pm$ 50, $\pm$ 100, $\pm$ 200, $\pm$ 500, and $\pm$ 700 mV for lead II (reference lead)
	Accuracy	Reference lead II: $\pm$ (5 % setting + 0.2 mV)
		All other leads: $\pm$ (10 % setting + 0.4 mV)
Pacer pulse width	0.1 ms, 0.2 ms, 0.5 ms, 1 ms, and 2 ms $\pm$ 5 %	
Paced arrhythmias	Atrial 80 BPM	
	Asynchronous 75 BPM	
	Demand with frequent sinus beats	
	Demand with occasional sinus beats	
	Atrio-ventricular sequential	
	Noncapture (one time)	
	Nonfunction	
Power-on default	Amplitude 5 mV, width 1 ms, atrial waveform	



<b>Arrhythmia</b>		
<b>Baseline NSR</b>	80 BPM	
<b>PVC focus</b>	Left focus, standard timing (except where specified)	
<b>Supraventricular arrhythmia</b>	Atrial fibrillation (coarse or fine); atrial flutter; sinus arrhythmia; missed beat (one time); atrial tachycardia; paroxysmal atrial tachycardia; nodal rhythm; and supraventricular tachycardia	
<b>Premature arrhythmia</b>	Premature atrial contraction (PAC); premature nodal contraction (PNC); PVC1 left ventricular; PVC1 left ventricular, early; PVC1 left ventricular, R on T; PVC2 right ventricular; PVC2 right ventricular, early; PVC2 right ventricular, R on T; and multifocal PVCs	
<b>Ventricular arrhythmia</b>	PVCs 6, 12, or 24 per minute; frequent multifocal PVCs; bigeminy; trigeminy; multiple PVCs (one-time run of 2, 5, or 11 PVCs); monoventricular tachycardia (120 to 300 BPM in 5 BPM steps); polyventricular tachycardia (5 types); ventricular fibrillation (coarse or fine); and asystole	
<b>Conduction defect</b>	First-, second-, or third-degree heart block; and right- or left-bundle-branch block	
<b>Advanced cardiac life support</b>	Shockable pulseless arrest rhythms	Ventricular fibrillation (coarse), ventricular fibrillation (fine), unstable polymorphic ventricular tachycardia
	Non-shockable pulseless arrest rhythms	Asystole
	Symptomatic bradycardia	Sinus bradycardia (< 60 BPM)
		2nd degree AV block, mobitz type I
		2nd degree AV block, mobitz type II
		Complete/3rd degree AV block
		Right bundle branch block
		Left bundle branch block
<b>Advanced cardiac life support</b> cont.	Symptomatic tachycardia: regular narrow-complex tachycardia (QRS < 0.12 seconds)	Sinus tachycardia > 150 BPM
		Supraventricular Tachycardia
	Symptomatic tachycardia: regular wide-complex tachycardias (QRS ≥ 0.12 seconds)	Sinus tachycardia > 150 BPM
		Supraventricular tachycardia SVT with aberrancy
	Irregular tachycardia	Atrial fibrillation (coarse and fine), atrial flutter, unstable monomorphic ventricular tachycardia (120 BPM to 300 BPM), torsade de pointes/polymorphic ventricular tachycardia (long QT interval)

ECG Performance testing		
Amplitude	0.05 mV to 0.5 mV (0.05 mV steps)	
	0.5 mV to 5 mV (0.25 mV steps)	
Pulse wave	30 BPM, 60 BPM, with 60 ms pulse width	
Square wave	0.125 Hz, 2 Hz, 2.5 Hz	
Triangle wave	0.125 Hz, 2 Hz, 2.5 Hz	
Sine wave	0.05 Hz, 0.5 Hz, 1, 2 Hz, 5 Hz, 10 Hz, 25 Hz, 30 Hz, 40 Hz, 50 Hz, 60 Hz, 100 Hz, and 150 Hz	
R-wave detection	Waveform	Triangular pulse
	Rate	30 BPM, 60 BPM, 80 BPM, 120 BPM, 200 BPM, and 250 BPM
	Width	8 ms to 20 ms in 2 ms steps, and 20 ms to 200 ms in 10 ms steps
	Width accuracy	± (1 % of setting + 1 ms)
QRS detection	Widths	8 ms to 20 ms in 2 ms steps, and 20 ms to 200 ms in 10 ms steps
	Width accuracy	± (1 % of setting + 1 ms)
	Rate	30 BPM, 60 BPM, 80 BPM, 120 BPM, 200 BPM, and 250 BPM
	R-Wave up slope	0.875 amplitude, 0.4375 x width
	R-Wave down slope	Full amplitude, 0.5 x width
	S-Wave up slope	0.125 amplitude, 0.0625 x width
Tall T-wave rejection	Waveform	QT Interval 350 ms
		T-Wave width 180 ms
		T-Wave shape ½ sinewave
	Amplitude	0 % to 150 % reference lead amplitude in 10 % steps
	Rate	80 BPM
Rate accuracy	± 1 % of setting	
Amplitude accuracy	± (2 % of setting + 0.05 mV)	
ECG artifact		
Type	50 Hz, 60 Hz, muscular, baseline wander, respiration	
Size	25 %, 50 %, 100 % of the normal sinus R-Wave for each lead	
Lead select	All, RA, LL, LA, V1, V2, V3, V4, V5, V6	

Fetal/Maternal ECG		
Fetal heart rate (fixed)	60 BPM to 240 BPM in 1 BPM steps	
Fetal heart rate (IUP)	140 BPM at beginning, then varies with pressure	
Intrauterine-pressure waveforms	Early deceleration, late deceleration, and acceleration	
Wave duration	90 seconds, bell-shaped pressure curve, from 0 mmHg to 90 mmHg and returning to 0	
IUP period	2 min, 3 min, or 5 minutes; and manual	
Default settings	FHR 120 BPM, early deceleration wave, manual	
Invasive blood pressure		
Channels	2, each independently settable with identical parameters and are individually electrically isolated from all other signals	
Input/output impedance	300 Ω ± 10 %	
Exciter input range	2 to 16 V peak	
Exciter-input frequency range	DC to 5000 Hz	
Transducer sensitivity	5 (default) or 40 μV/V/mmHg	
Pressure accuracy	± (1 % of setting + 1 mmHg) accuracy guaranteed for dc excitation only	
Static pressure	- 10 to + 300 mmHg in 1 mmHg steps	
Pressure units	mmHg or Kpa	
Dynamic waveforms	Types (default pressures	Arterial (120/80)
		Radial artery (120/80)
		Left ventricle (120/00)
		Right ventricle (25/00)
		Pulmonary artery (25/10)
		Pulmonary-artery wedge (10/2)
		Right atrium (central venous or CVP) (15/10)
	Pressure variability	Systolic and diastolic pressures are independently variable in 1 mmHg steps
Swan-Ganz sequence	Right atrium, right ventricle (RV), pulmonary artery (PA), pulmonary artery wedge (PAW)	
Cardiac catheterization	Chambers	Aortic, pulmonary valve, and mitral valve
Respiration artifact	Arterial, radial artery, and left ventricle	5 % to 10 % multiplication
	Other	5 mmHg or 10 mmHg
BP output	Circular DIN 5-Pin	
Power-on default	0 mmHg	



Respiration		
Rate	0 (OFF), 15 BrPM to 150 BrPM in 1 BrPM steps	
Waves	Normal or ventilated	
Ratio (inspiration:expiration)	Normal	1:1, 1:2, 1:3, 1:4, 1:5
	Ventilated	1:1
Impedance variations ( $\Delta \Omega$ )	0.00 $\Omega$ to 1.00 $\Omega$ in 0.05 $\Omega$ steps and 1 $\Omega$ to 5 $\Omega$ in 0.25 $\Omega$ steps	
Accuracy delta	$\pm$ (5 % of setting + 0.1 $\Omega$ )	
Baseline	500 $\Omega$ , 1000 $\Omega$ (default), 1500 $\Omega$ , 2000 $\Omega$ , Leads I, II, III	
Accuracy baseline	$\pm$ 5 %	
Respiration lead	LA or LL (default)	
Apnea selection	12 sec, 22 sec, or 32 seconds (one-time events), or continuous (Apnea ON = respiration OFF)	
Power-on default	20 BrPM, delta 1.0 $\Omega$	
Temperature		
Temperature	3.0 $^{\circ}\text{C}$ to 42.0 $^{\circ}\text{C}$ in 0.5 $^{\circ}\text{C}$ steps	
Accuracy	$\pm$ 0.4 $^{\circ}\text{C}$	
Compatibility	Yellow Springs, Inc. (YSI) Series 400 and 700	
Output	Circular DIN 4-Pin	
Cardiac output		
Catheter type	Baxter Edwards, 93a-131-7f	
Calibration coefficient	0.542 (0 $^{\circ}\text{C}$ injectate), 0.595 (24 $^{\circ}\text{C}$ injectate)	
Blood temperature	36 $^{\circ}\text{C}$ (98.6 $^{\circ}\text{F}$ ) to 38 $^{\circ}\text{C}$ (100.4 $^{\circ}\text{F}$ ) $\pm$ 0.2 $^{\circ}\text{C}$ in 1 $^{\circ}\text{C}$ steps	
Injectate volume	10 cc	
Injectate temperature	0 $^{\circ}\text{C}$ or 24 $^{\circ}\text{C}$	
Cardiac output	2.5, 5, 10 liters per minute $\pm$ 5 %	
Faulty-injectate curve	Waveform for simulation available	
Left-to-right-shunt curve	Waveform for simulation available	
Calibrated pulse	1.5 $^{\circ}$ for 1 second	
Connector	Circular DIN 7 pin	
Power-on default	5 liters per minute, 0 $^{\circ}\text{C}$ injectate, 37 $^{\circ}\text{C}$ blood temperature	



<b>Non-invasive blood pressure</b>		
<b>Pressure units</b>	mmHg or kPa	
<b>Manometer (pressure meter)</b>	Range	10 mmHg to 400 mmHg
	Resolution	0.1 mmHg
	Accuracy	± (0.5 % reading + 0.5 mmHg)
<b>Pressure source</b>	Target pressure range	20 mmHg to 400 mmHg
	Resolution	1 mmHg
<b>NIBP simulations</b>	Pulse	2 mmHg max into 500 ml NIBP system
	Volume of air moved	1.25 ml max
	Simulations (systolic/diastolic [MAP])	Adult: 60/30 (40), 80/50 (60); 100/65 (77); 120/80 (93); 150/100 (117); and 200/150 (167) and 255/195 (215)
		Neonatal: 35/15 (22); 60/30 (40); 80/50 (60); 100/65 (77); 120/80 (93) and 150/100
		Pressure variability: systolic and diastolic pressures are variable by 1 mmHg
<b>NIBP simulations</b> cont.	Repeatability	Within ± 2 mmHg (at maximum pulse size independent of device under test)
	Synchronization: normal Sinus heart rates: 30 BPM to 240 BPM	Maximum rate at 1 ml: 240 BPM achievable with pulses up to 1 ml
		Maximum rate at 1.25 ml: 180 BPM
	Synchronization: arrhythmias	Premature atrial contraction (PAC), premature ventricular contraction (PVC), atrial fibrillation, and missed beat
<b>Leak test</b>	Target pressure	20 mmHg to 400 mmHg
	Elapse time	0:30 min to 5:00 minutes: seconds in 30 second steps
	Leakage rate	0 mmHg/minute to 200 mmHg/minute
<b>Pressure relief test range</b>	100 to 400 mmHg	



<b>SpO<sub>2</sub> simulations (optional)</b>		
% O <sub>2</sub>	Range	30 % to 100 %
	Resolution	1 %
% O <sub>2</sub> accuracy	With oximeter manufacturer's R-curve	Saturation within UUT specific range: ± (1 count + specified accuracy of the UUT)
		Saturation outside UUT specific range: monotonic with unspecified accuracy
	With Fluke Biomedical R-curves	91 % to 100 % ± (3 counts + specified accuracy of the UUT)
		81 % to 90 % ± (5 counts + specified accuracy of the UUT)
		71 % to 80 % ± (7 counts + specified accuracy of the UUT)
		Below 71 % monotonic with unspecified accuracy
Heart rate	30 BPM to 300 BPM in 1 BPM steps. SpO <sub>2</sub> simulation is synchronized with ECG rate delayed by 150 ms.	
Transmission: ratio of detector current to LED current, expressed in parts per million (ppm)	Range	0 ppm to 300.00 ppm
	Resolution	0.01 ppm
	Accuracy	+ 50 %/- 30 % for compatible monitors, unspecified for others. Selected by finger size and color: dark, thick finger, medium finger, light, thin finger, neonatal foot.
Perfusion	Range	0 % to 20.00 %
	Resolution	0.01 %
Artifact	Respiration	Range: 0 % to 5 % of transmission
		Resolution: 1 %
		Rate: all ProSim respiration simulation settings
	Ambient light	Range: 0 to 5X transmitted light
		Resolution: 1X
		Frequency: DC, 50 Hz, 60 Hz, and 1 kHz to 10 kHz in 1 kHz steps
Masimo Rainbow technology	Simulate Masimo Rainbow technology with an optional adapter supplied by Masimo that allows the ProSim two wavelength simulation to test the Rainbow multiple wavelength system	
Compatible manufacturer products	With manufacturer R-curve	Nellcor, Masimo, Nonin, and Nihon Kohden
	With Fluke R-curve	Mindray, GE-Ohmeda, Philips/HP, and BCI

<b>Pre-Defined Simulations</b>
Normal
Hypertensive
Hypotensive
Tachycardic
Bradycardic
Ventricular fibrillation
Asystole
<b>Autosequences (default)</b>
Monitor testing sequence
Medical training sequence
Oximeter testing sequence
Cardiac failure sequence
Arrhythmia sequence
Exercise sequence
Respiration sequence
Performance wave test
IBP testing sequence
Temperature sequence

## Ordering information

### Models/descriptions

**ProSim 8** ProSim 8 Vital Signs Simulator

**ProSim SPOT** ProSim SpO<sub>2</sub> Test Module

**ProSim RAINBOW** ProSim Rainbow Sensor

### Standard accessories

**3980671** ProSim 6/8 Users Manual

**3980667** ProSim 6/8 Getting start manual

**3938110** ProSim 6/8 Battery Pack

**1626219** USB Cable

**2392173** IBP Cable, unterminated

**3987170** ProSim 6/8 Carrying Case

**2392370** Adult Cuff Mandrel End Blocks

**2392381** Adult Cuff Mandrel Spacer Blocks

**2392328** Neonatal Cuff Mandrel

**2391882** Set of NIBP Cuff Adapters

**2184298** AC/DC Power Supply

Power cord (country-specific)

### AC Power cords

**2201437** ProSim 8 AC power cord Schuko

**2201455** ProSim 8 AC power cord USA

**2201428** ProSim 8 AC power cord UK

**2201419** ProSim 8 AC power cord Japan

**2201443** ProSim 8 AC power cord Australia

**3930831** ProSim 8 AC power cord Brazil

### Optional accessories

**2392199** CI-3 Cardiac Output Box

**3408564** Mini-DIN to DIN IBP Adapter

**3890640** NIBP Test Chamber 500ML

**4034627** Ansur Test Software ProSim 8 Plug-In

### Cable kits

**3984910** ProSim 8 Accessory Kit (includes DIN to minDin adapter, HP/Philips Intellivue IBP cable, GE Marquette Eagle/Dash/Solar IBP cable, Welch Allyn Propaq/SpaceLabs Ultraview IBP cable, USB wireless dongle, YSI400 series temperature cable, YSI700 series temperature cable, CI-3 Cardiac Output Box, spare battery pack)

**3984922** HP/Philips Intellivue Cable Set

**3984968** GE Marquette Eagle/Dash/Solar Cable Set

**3984946** ProSim 8 SpaceLabs Ultraview Cable set

**3984979** Welch Allyn/Propaq Cable Set

**3984993** Drager Infinity Cable Set

**3985009** ProSim 8 Nihon Kohden Cable Set

### Blood pressure cables

**2198879** BCI International TK-1 (6M)

**2198879** Criticare Systems Inc. (1100) TK-1 (6M)

**2198879** Critikon (Dinamap Plus) TK-1 (6M)

**2198887** Datascope DS-1 (6F)

**2200955** Datex (AS/3, CS/3, Compact, Cardio Cap II, Critical Care, Light) DX-1 (10F)

**2199387** Fakuda Denshi (DS3300 series) FD-2 (12M)

**2199682** GE Marquette Medical Corametrics (115, 116, 142, 145, 556) CM-3 (Nicolet round – 12M)

**2198893** GE Marquette Medical (PPG/E for M DR) EM-1 (6F)

**2198978** GE Marquette Medical (7000 and TRAM-AR series only) MQ-2 (8M round)

**2199627** GE Marquette Medical (Dash, Eagle, Solar, Tram, and MacLab) MQ-3 (rectangular – 11M)

**2198902** Hewlett Packard/Philips (78-300, 78-500, 78-800, Merlin/Viridia/ Omnicare (HP/Philips M1006B iBP module has a sensitivity of 5 uV/V/ mmHg only. The HP-3 cable should be selected for this application.) HP-3 (12M 5 µV)

**2198916** Hewlett Packard/Philips (78-300, 78-500, 78-800, Merlin/Viridia/Omnicare) HP-4 (12M 40 µV)



**2199694** Hewlett Packard/Philips (8040A, M1350A) HP-8 (intrauterine pressure only – 12M 40  $\mu$ V)  
**2198879** Invivo Research TK-1 (6M)  
**2198879** Ivy Biomedical (400 and 700 series) TK-1 (6M)  
**2198940** Medical Data Electronics (Escort series) PC-1 (6M)  
**2198933** Mennen Medical (Horizon series) MM-1 (6M)  
**2198879** North American Drager (Vitalert 2000) TK-1 (6M)  
**2198940** Physio Control (VSM series) PC-1(6M)  
**2198879** Protocol System (Propaq series) TK-1 (6M)  
**2190955** Puritan Bennett PB 240 DX-1 (10F)  
**2199176** Quinton (Q Cath series) QM-1 (6M)  
**2198925** Siemens (SIRECUST series) [SM-1 and Siemens Medical Transducer Adapter (3368-383-E530U) used to run a single invasive BP channel on the Siemens Medical SC6000 and SC9000 series monitors] SM-1 (10M)  
**2199666** Siemens (Micor/Mingo) SM-3 (15M)  
**2198879** SpaceLabs (1050, 1700, PCMS series) (SpaceLabs adapters 700-0028-00 and 0120-0551-00 with TK-1 used when testing the new UltraView Command Module) TK-1 (6M)

**2392173** Universal unterminated UU-1 (5-Pin DIN one end only)  
**2198893** Witt Biomedical EM-1 (6F)  
**DIN PB IBP, Schiller PB Series IBP Cable** (5M DIN)

#### Temperature cables

**2199019** UT-2 standard 1/4 in phone plug (compatible with YSI 700 series – 3 conductor)  
**2199291** UT-3 unterminated cable (DIN plug on one end only)  
**2523334** UT-4 Low profile, 1/4 in phone plug, YSI 400 series compatible, two conductor  
**2199257** HPT-2 temperature adapter (Hewlett Packard) (2 pin, used with UT-1 for HP monitors)

#### Cardiac output bath/injectate adapters

**2392199** CI-3 cable assembly  
**2392158** General purpose connector  
**2199240** COA-1 Cardiac output adapter (Hewlett Packard) (HPT-2 also required for cardiac output simulation on HP patient-monitoring systems)  
**2199257** HPT-2 Temperature adapter (Hewlett Packard) (2 pin) (COA-1 also required for cardiac output simulation on HP patient-monitoring systems)

#### 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 200566-0 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 and ISO 13485 medical device 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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