

Biomedical

# Technical data ProSim 8 Vital Signs Simulator



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, NIBP, SpO2, and is capable of testing Rainbow multiwavelength 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 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, 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\*
- Remote PC control of test device, as well as data transfer and automated regulatory reporting\*

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\*Bipolar leakage testing performed with 200 ohm fixed load.



# **Specifications**

General specifications			
Temperature	Operating	10 °C to 40 °C (50 °F to 10	4 °F)
	Weight	-20 °C to +60 °C (-4 °F to 1	40 °F)
Humidity	10 % to 90 % non-condensin	Ig	
Altitude	3,000 meters (9,843 ft)		
Dimensions (L $\times$ W $\times$ 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 contr	rol by a computer
	USB host controller port	Type A, 5 V output, 0.5 A board, barcode reader, an	max load. Connector for key- Id printer
Power	Lithium-ion rechargeable ba	attery	
Battery charger	100 V to 240 V input, 15 V/2 should be connected to a pr	.0 A output. For best perforoperly-grounded ac recep	rmance, the battery charger tacle
Battery life	9 hours (minimum), 100 NIB	P cycles typical	
Weight	1.87 kg (4.2 lb)		
Safety standards	IEC/EN 61010-1 3rd Edition; I	Pollution degree 2 CAT No	ne
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 5.0 mV (0.25 mV steps) Other leads are proportional to Lead II (reference lead) in percentage per:		0.25 mV steps) i in percentage per:	
	Lead I: 70 Lead II: 100 Lead III: 30	Lead V1: 24 Lead V2: 48 Lead V3: 100	Lead V4: 120 Lead V5: 112 Lead V6: 80
Amplitude accuracy	± (2 % of setting + 0.05 mV)		
ECG rate	10 BPM to 360 BPM in 1 BPM steps		
Rate accuracy	±1% of setting		
ECG waveform selection	Adult (80 ms) or pediatric (40 ms) QRS duration		
ST-segment elevation	Adult mode only0.8 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: ± (5 % setting + 0.2 mV)
		All other leads: ± (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
Arrhythmia		
Baseline NSR	80 BPM	
PVC focus	Left focus, standard timing (	except where specified)
Supraventricular arrhythmia	Atrial fibrillation (coarse or fine); atrial flutter; sinus arrhythmia; missed beat (one time); atrial tachycardia; paroxysmal atrial tachcardia; nodal rhythm; and supraventricular tachycardia	
Premature arrhythmia	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	
Ventricular arrhythmia	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); poly-ventricular tachycardia (5 types); ventricular fibrillation (coarse or fine); and asystole	
Conduction defect	First-, second-, or third-degree heart block; and right- or left-bundlebranch block	
Advanced cardiac life support	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
	Symptomatic tachycardia: regular narrow-complex	Sinus tachycardia > 150 BPM
	tachycardia (QRS < 0.12 seconds)	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 5.0 mV (0.25 mV steps) Other leads are proportional to Lead II (reference lead) in percentage per:	
	Lead 1: 70	
	Lead II: 100	Lead V1 through V6: 100
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	
Amplitute accuracy	± (2 % of setting + 0.05 mV)	
ECG artifact		
Туре	50 Hz, 60 Hz, muscular, basel	ine wander, respiration
Size	25 %, 50 %, 100 % of the normal sinus R-Wave for each lead	
Lead select	AII, 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	d manual
Default settings	FHR 140 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) accu	racy 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 ventrical (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	
BP output	Circular DIN 5-Pin		
Power-on default	0 mmHg		
Respiration			
Rate	0 (OFF), 10 BrPM to 150 BrPM ir	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	± (5 % of setting + 0.1 Ω)		
Baseline	500 Ω, 1000 Ω (default), 1500 Ω, 2000 Ω, Leads I, II, III		
Accuracy baseline	± 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 O		



Temperature			
Temperature	30 °C to 42.0 °C in 0.5 °C steps		
Accuracy	± 0.4 °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 coeffecient	0.542 (0 °C injectate), 0.595 (24	°C injectate)	
Blood temperature	36 °C (98.6 °F) to 38 °C (100.4 °F	) ± 0.2 °C in 1 °C steps	
Injectate volume	10 cc		
Injectate temperature	0 °C or 24 °C		
Cardiac output	2.5, 5, 10 liters per minute ± 7.5 9	%	
Faulty-injectate curve	Waveform for simulation availab	le	
Left-to-right-shunt curve	Waveform for simulation availab	le	
Calibrated pulse	1.5 ° for 1 second		
Connector	Circular DIN 7 pin		
Power-on default	5 liters per minute, 0 °C injectate	e, 37 °C blood temperature	
Non-invasive blood pressure			
Pressure units	mmHg or kPa		
Manometer (pressure meter)	Range	10 mmHg to 400 mmHg	
	Resolution	0.1 mmHg	
	Accuracy	± (0.5 % reading + 0.5 mmHg)	
Pressure source	Target pressure range	20 mmHg to 400 mmHg	
	Resolution	1 mmHg	
NIBP simulations	Pulse		
	Volume of air moved		
	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	
	Repeatability	Within ± 2 mmHg (at maximum pulse size independent of device under test)	
	Synchronization: normal Sinus heart rates:	Maximum rate at 1 ml: 240 BPM achievable with pulses up to 1 ml	
	30 BPM to 240 BPM	Maximum rate at 1.25 ml: 180 BPM	
	Synchronization: arrhythmias	Premature atrial contraction (PAC), premature ventricular contraction (PVC), atrial fibrillation, and missed beat	
Leak test	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	
Pressure relief test range	100 to 400 mmHg		



Oximeter SpO2 optical emitter an	d detector (optional)	
% 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. Oximeter SpO2 optical emitter and detector is synchronized with ECG rate delayed by 150 ms.	
Transmission: ratio of detector	Range	0 ppm to 300.00 ppm
current to LED current, expressed	Resolution	0.01 ppm
in parts per million (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.
Pulse amplitude	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	Masimo Rainbow technology with an optional adapter cable supplied by Masimo that allows the ProSim two wavelength to test the Rainbow multiple wavelength system	
Compatible manufacturer	With manufacturer R-curve	Nellcor, Masimo, Nonin, and Nihon Kohden
products	With Fluke R-curve	Mindray, GE-Ohmeda, Philips/HP, and BCI







# Ordering information

Part number	Description
3979409	ProSim 8 Vital Signs Simulator
3985658	ProSim SpO <sub>2</sub> Test Module
4034609	ProSim Rainbow Test Cable

#### **Standard Accessories**

Part number	Description	
3980671	ProSim 6/8 Users Manual	
3980667	ProSim 6/8 Getting start manual	
4021085	ProSim 6/8 Battery Pack	
4034393	USB Cable	
2392173	IBP Cable, unterminated	
4034597	ProSim 6/8 Carrying Case	
4308086	ProSim NIBP Mandrel Set	
2391882	Set of NIBP Cuff Adapters	
2184298	AC/DC Power Supply Power cord (country-specific)	





#### **AC Power cords**

Part number	Description
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**

Part number	Description
2392199	CI-3 Cardiac Output Box
3408564	Mini-DIN to DIN IBP Adapter
4034611	NIBP Rigid Test Chamber 500ML
4034627	Ansur Test Software ProSim 8 Plug-In

### Cable kits

Part number	Model	Includes
3984910	ProSim 8 Accessory Kit	DIN to minDin adapter, HP/Philips Intellivue IBP cable, GE Marquette Eagle/Dash/Solar IBP cable, Welch Allyn Propaq/SpaceLabs Ultraview IBP cable, YSI400 series temperature cable, YSI700 series temperature cable, CI-3 Cardiac Output Box, spare battery pack)
3984922	HP/Phillips intellivue Cable Set	HP-3 BP Cable (2198902) two, HPT-2 Tamp/C.O. Injct Cable Assembly (2199257), COA-1 Cable Assembly (2199240), UT-4, Low profile 1/4 inch phone plug, YSI 400 Series Compatible 2 conductor (2523334)
3984968	GE Marquette Eagle/Dash/ Solar Cable Set	MQ-3 BP Cable (2199627) two, UT-4 Low profile 1/4 inch phone plug, YSI 400 series Compatible 2 conductor (2523334), UT-2 Tamp Cable 700 series YSI (2199019), PROSIM8- 4402GECO, Din cardiac Output Marq Eagle (4022300)
3984946	ProSim 8 SpaceLabs Ultraview Cable Set	TK-1 BP Cable (2198879) two, UT-4 Low profile 1/4 inch phone plug, YSI 400 series compatible 2 conductor (2523334), UT-2 Tamp Cable 700 Series YSI (2199019)
3984979	Welch Allyn/Propaq Cable Set	TK-1 BP Cable (2198879) two, UT-4 Low profile 1/4 inch phone plug, YSI 400 Series Compatible 2 conductor (252334), UT-2 Tamp cable 700 series YSI (2199019)
3984993	Drager Infinity Cable Set	SM-1 BP Cable (2198925) two, UT-4, Low profile 1/4 inch phone plug, YSI 400 series compatible 2 conductor (2523334)
3985009	ProSim 8 Nihon Kohden Cable Set	Nihon Kohden-NK-1, BP Cable (5M) (2462263) two, DIN to mindin adapter (3408564), UT-4, Low profile 1/4 inch phone plug, YSI 400 Series Compatible 2 conductor (2523334)

The ProSim 8 does not provide simulation for all types of fetal heart rate tracings and contraction patterns, including the following:

- variable decelerations
- sinusoidal pattern
- reactive tracing
- variations in FHR variability
- tachysystole



## **Blood pressure cables**

Part number	Description
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 TRAMAR 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 $\mu$ V)
2198916	Hewlett Packard/Philips (78-300, 78- 500, 78-800, Merlin/Viridia/Omnicare) HP-4 (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)
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)
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)
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)
5226108	PS8IUP-8001, Corometrics IUP Simulation Cable
5226113	PS8IUP-8000,HP/AG/PH, 50 & 8040 SER, IUP SIMU CABLE

#### **Temperature cables**

Part number	Description
2199019	UT-2 standard 1/4 in phone plug (compatible with YSI 700 series – 3 conductor)
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

Part number	Description
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)
4022300	DIN Cardiac Output MARQ EAGLE



#### **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**

We empower our everyday heroes to focus only on protecting lives.

Fluke Biomedical

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