

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, NIBP, SpO₂, and is capable of testing 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, NIBP, SpO₂, and Rainbow multi-wavelength waveforms
- Stay-connected ECG posts for easy/secure ECG snap and lead connections
- Custom SpO₂ 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*



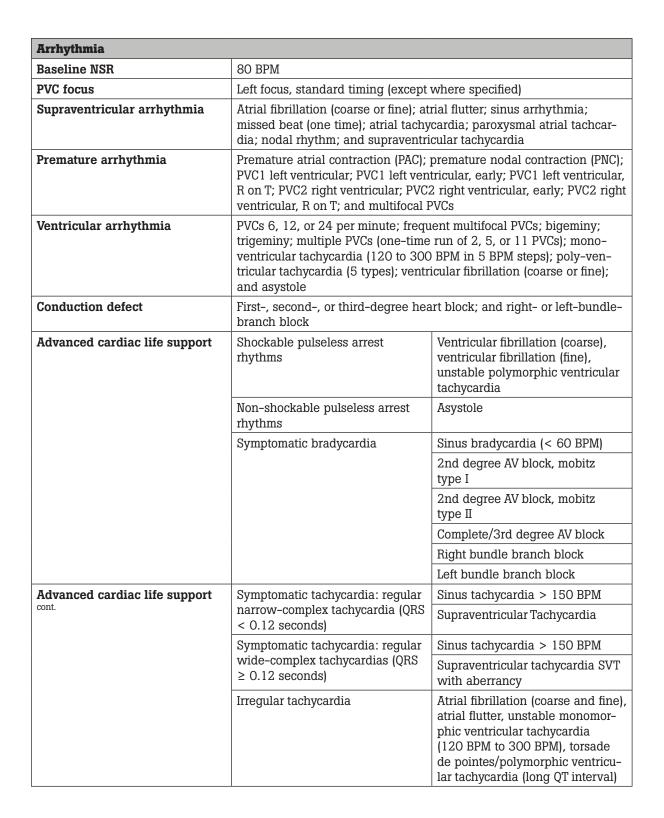
Specifications

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	IEC/EN 61010-1 3rd Edition; Pollution degree 2 CAT None	
Certifications	CE, CSA, C-TICK N10140, RoHS	
Electromagnetic compatibility (EMC)	IEC 61326-1:2006	

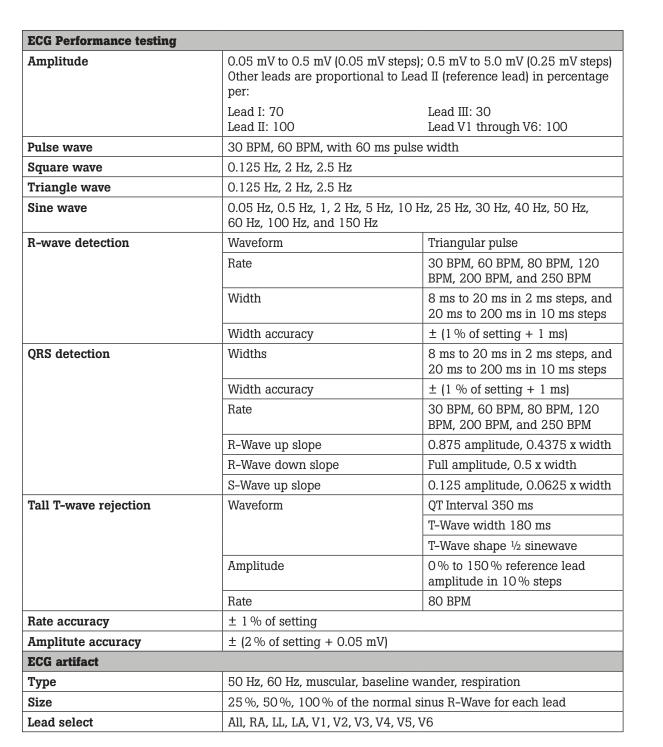




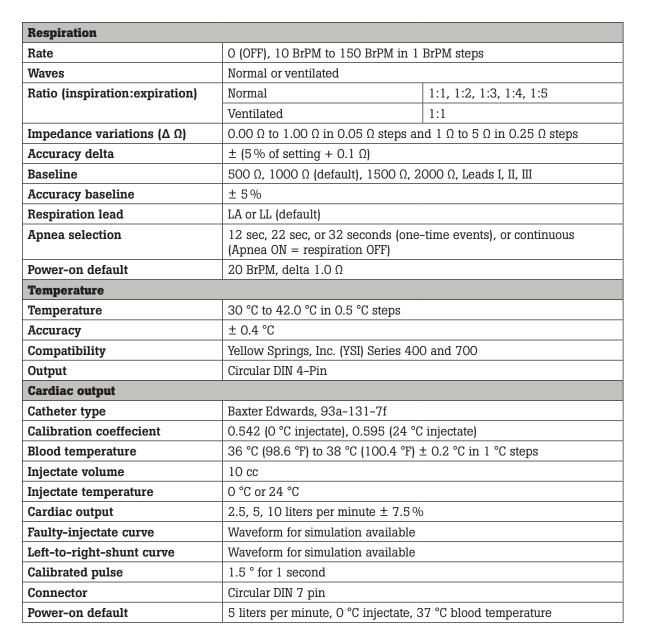
Detailed specifications		
Normal-sinus-rhythm waveform		
ECG reference	The ECG amplitudes specified are for Lead II (calibration), from the baseline to the peak of the R wave. All other leads are proportional	
Normal sinus rhythm	12-lead configuration with independent outputs referenced to right leg (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:	
	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), ± 2 , ± 4 , ± 6 , ± 8 , ± 10 , ± 12 , ± 14 , ± 16 , ± 18 , ± 20 , ± 50 , ± 100 , ± 200 , ± 500 , and ± 700 mV for lead II (reference lead)
	Accuracy	Reference lead II: ± (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 ± 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	



FLUKE



Fetal heart rate (fixed)60 BPM to 240 BPM in 1 BPM stepsFetal heart rate (IUP)140 BPM at beginning, then varies with pressure		
Fetal heart rate (IUP) 140 BPM at beginning, then varies with pressure		
	140 BPM at beginning, then varies with pressure	
Intrauterine-pressure Early deceleration, late deceleration, and acceleration waveforms Early deceleration	Early deceleration, late deceleration, and acceleration	
Wave duration90 seconds, bell-shaped pressure curve, from 0 mmHg to 90 m and returning to 0	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 140 BPM, early deceleration wave, manual		
Invasive blood pressure		
Channels 2, each independently settable with identical parameters and a individually electrically isolated from all other signals	2, each independently settable with identical parameters and are individually electrically isolated from all other signals	
Input/output impedance $300 \Omega \pm 10 \%$		
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 \pm (1 % of setting + 1 mmHg) accuracy guaranteed for dc excitat only	tion	
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 (1	10/2)	
Right atrium (central venou CVP) (15/10)	is or	
Pressure variability Systolic and diastolic press are independently variable mmHg steps		
Swan-Ganz sequence Right atrium, right ventrical (RV), pulmonary artery (PA), pulmor artery wedge (PAW)	nary	
Cardiac catheterization Chambers Aortic, pulmonary valve, an mitral valve	ıd	
Respiration artifactArterial, radial artery, and left ventricle5 % to 10 % multiplication		
Other 5 mmHg or 10 mmHg		
BP output Circular DIN 5-Pin	Circular DIN 5-Pin	
Power-on default 0 mmHg	0 mmHg	





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	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
NIBP simulations cont.	Repeatability	Within \pm 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 contrac- tion (PVC), atrial fibrillation, and missed beat
Leak test	Target pressure	20 mmHg to 400 mmHg
	Elapse time	0:30 min to 5:00 minutes: sec- onds in 30 second steps
	Leakage rate	0 mmHg/minute to 200 mmHg/ minute
Pressure relief test range	100 to 400 mmHg	·





Oximeter SpO_2 optical emitter a	nd detector (optional)	
% 0 ₂	Range	30% to 100%
	Resolution	1%
% 0 ₂ accuracy	With oximeter manufacturer's R-curve	Saturation within UUT specific range: ± (1 count + specified ac- curacy of the UUT)
		Saturation outside UUT specific range: monotonic with unspeci- fied accuracy
	With Fluke Biomedical R-curves	91 % to 100 % \pm (3 counts + specified accuracy of the UUT)
		81% to $90\% \pm (5 \text{ counts } + \text{specified accuracy of the UUT})$
		71 % to 80 % \pm (7 counts + specified accuracy of the UUT)
		Below 71 % monotonic with un- specified accuracy
Heart rate	30 BPM to 300 BPM in 1 BPM steps. Oximeter SpO_2 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,	Resolution	0.01 ppm
expressed 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 products	With manufacturer R-curve	Nellcor, Masimo, Nonin, and Nihon Kohden
	With Fluke R-curve	Mindray, GE-Ohmeda, Philips/HP, and BCI

Pre-Defined Simulations
Normal
Hypertensive
Hypotensive
Tachycardic
Bradycardic
Ventricular fibrillation
Asystole
Autosequences (default)
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

3979409 ProSim 8 Vital Signs Simulator **3985658** ProSim SpO₂ Test Module **4034609** ProSim Rainbow Test Cable

Standard accessories

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

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 4034611 NIBP Rigid Test Chamber 500ML 4034627 Ansur Test Software ProSim 8 Plug-In 3341333 USB Wireless Dongle



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/Phillips intellivue Cable Set (includes: 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 (Includes: 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), PROSIM8-4402GEC0, Din cardiac Output Marq Eagle (4022300)

3984946 ProSim 8 SpaceLabs Ultraview Cable Set (Includes: 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 (Includes: 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 (Includes: 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 (Includes: 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)

Blood pressure cables

 BCI International TK-1 (6M) Criticare Systems Inc. (1100) TK-1 (6M) Critikon (Dinamap Plus) TK-1 (6M) Datascope DS-1 (6F) Datex (AS/3, CS/3, Compact, Cardio Cap II, Critical Care, Light) DX-1 (10F) Fakuda Denshi (DS3300 series) FD-2 (12M) GE Marquette Medical Corametrics (115, 116, 142, 145, 556) CM-3 (Nicolet round – 12M) 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 μ V)

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 µV)

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 (Propag 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)

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)

4022300 DIN Cardiac Output MARQ EAGLE

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

Biomedical

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

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. We
CE Certified, where required
NIST Traceable and Calibrated

- UL, CSA, ETL Certified, where required