ProSim™ 8

ProSim™ 8P

Vital Signs Simulator

Getting Started Manual

PN 3984515
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Limited Warranty and Product Support

Fluke Biomedical warrants this instrument against defects in materials and workmanship for one year from the date of original purchase. During the warranty period, we will repair or at our option replace, at no charge, a product that Fluke Biomedical determines to be defective, provided you return the product, shipping prepaid, to Fluke Biomedical. This warranty covers the original purchaser only and is not transferable. The warranty does not apply if the product has been damaged by accident or misuse or has been serviced or modified by anyone other than an authorized Fluke Biomedical service facility. NO OTHER WARRANTIES, SUCH AS FITNESS FOR A PARTICULAR PURPOSE, ARE EXPRESSED OR IMPLIED. FLUKE SHALL NOT BE LIABLE FOR ANY SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES OR LOSSES, INCLUDING LOSS OF DATA, ARISING FROM ANY CAUSE OR THEORY.

This warranty covers only serialized products and their accessory items that bear a distinct serial number tag. Recalibration of instruments is not covered under the warranty.

This warranty gives you specific legal rights and you may also have other rights that vary in different jurisdictions. Since some jurisdictions do not allow the exclusion or limitation of an implied warranty or of incidental or consequential damages, this limitation of liability may not apply to you. If any provision of this warranty is held invalid or unenforceable by a court or other decision-maker of competent jurisdiction, such holding will not affect the validity or enforceability of any other provision.

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Unpacking and Inspection

Follow standard receiving practices upon receipt of the instrument. Check the shipping carton for damage. If damage is found, stop unpacking the instrument. Notify the carrier and ask for an agent to be present while the instrument is unpacked. There are no special unpacking instructions, but be careful not to damage the instrument when unpacking it. Inspect the instrument for physical damage such as bent or broken parts, dents, or scratches.

Technical Support

For application support or answers to technical questions, either email techservices@flukebiomedical.com or call 1-800- 850-4608 or 1-440-248-9300. In Europe, email techsupport.emea@flukebiomedical.com or call +31-40-2965314.

Claims

Our routine method of shipment is via common carrier, FOB origin. Upon delivery, if physical damage is found, retain all packing materials in their original condition and contact the carrier immediately to file a claim. If the instrument is delivered in good physical condition but does not operate within specifications, or if there are any other problems not caused by shipping damage, please contact Fluke Biomedical or your local sales representative.

Returns and Repairs

Return Procedure

All items being returned (including all warranty-claim shipments) must be sent freight-prepaid to our factory location. When you return an instrument to Fluke Biomedical, we recommend using United Parcel Service, Federal Express, or Air Parcel Post. We also recommend that you insure your shipment for its actual replacement cost. Fluke Biomedical will not be responsible for lost shipments or instruments that are received in damaged condition due to improper packaging or handling.

Use the original carton and packaging material for shipment. If they are not available, we recommend the following guide for repackaging:

- Use a double–walled carton of sufficient strength for the weight being shipped.
- Use heavy paper or cardboard to protect all instrument surfaces. Use nonabrasive material around all projecting parts.
- Use at least four inches of tightly packed, industry-approved, shock-absorbent material around the instrument.

Returns for partial refund/credit:

Every product returned for refund/credit must be accompanied by a Return Material Authorization (RMA) number, obtained from our Order Entry Group at 1-440-498-2560.

Repair and calibration:

To find the nearest service center, go to www.flukebiomedical.com/service or

In the U.S.A. and Asia:
Cleveland Calibration Lab
Tel: 1-800-850-4608 x2564
Email: globalcal@flukebiomedical.com

In Europe, Middle East, and Africa:
Eindhoven Calibration Lab
Tel: +31-40-2675300
Email: ServiceDesk@fluke.com

To ensure the accuracy of the Product is maintained at a high level, Fluke Biomedical recommends the product be calibrated at least once every 12 months. Calibration must be done by qualified personnel. Contact your local Fluke Biomedical representative for calibration.

Certification

This instrument was thoroughly tested and inspected. It was found to meet Fluke Biomedical's manufacturing specifications when it was shipped from the factory. Calibration measurements are traceable to the National Institute of Standards and Technology (NIST). Devices for which there are no NIST calibration standards are measured against in-house performance standards using accepted test procedures.

WARNING

Unauthorized user modifications or application beyond the published specifications may result in electrical shock hazards or improper operation. Fluke Biomedical will not be responsible for any injuries sustained due to unauthorized equipment modifications.

Restrictions and Liabilities

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Manufacturing Location

The ProSim™ 8 /ProSim™ 8P Vital Signs Simulator is manufactured at Fluke Biomedical, 6920 Seaway Blvd., Everett, WA, U.S.A.

Introduction

The Fluke Biomedical ProSim™ 8/ProSim™ 8P Vital Signs Simulator (hereafter the Product) is a full-featured, compact, portable simulator, used to measure the performance of patient monitors.

Intended Use

The Product is intended to be used to test and verify the basic operation of patient monitoring devices or systems used to monitor various physiological parameters of a patient, including ECG, Respiration, Invasive blood pressure, Non-invasive blood pressure, Temperature, and Cardiac output. Additionally, the Devices provide an optical signal to verify that the electronics within the pulse oximeter probe are functional.

The intended user is a trained biomedical equipment technician who performs periodic preventative maintenance checks on patient monitors in service. Users can be associated with hospitals, clinics, original equipment manufacturers and independent service companies that repair and service medical equipment. The end user is an individual, trained in medical instrumentation technology.

This Product is intended to be used in the laboratory environment, outside of the patient care area, and is not intended for use on patients, or to test devices while connected to patients. This Product is not intended to be used to calibrate medical equipment. It is intended for over the counter use.

Safety Information

In this manual, a **Warning** identifies hazardous conditions and actions that could cause bodily harm or death. A **Caution** identifies conditions and actions that could damage the Product, the equipment under test, or cause permanent loss of data.

⚠⚠ Warnings

To prevent personal injury, use the Product only as specified, or the protection supplied by the Product can be compromised.

To prevent possible electrical shock, fire, or personal injury:

- **Read all safety Information before you use the Product.**
- **Do not alter the Product and use only as specified, or the protection supplied by the Product can be compromised.**
- **Carefully read all instructions.**
- **Do not use the Product if it operates incorrectly**
- **Do not touch voltages >30 V ac rms, 42 V ac peak, or 60 V dc.**
- **Do not use the Product around explosive gas, vapor, or in damp or wet environments.**
- **Examine the case before you use the Product. Look for cracks or missing plastic. Carefully look at the insulation around the terminals.**
- **Do not use the Product if it is damaged.**
- **Disable the Product if it is damaged.**
- **Use this Product indoors only.**
- **Do not connect directly to mains.**
- **Use the correct terminals, function, and range for measurements.**
- **Use only current probes, test leads, and adapters supplied with the Product.**
- **Remove all probes, test leads, and accessories that are not necessary for the measurement.**

- **Remove all probes, test leads, and accessories before the battery door is opened.**
- **The battery door must be closed and locked before you operate the Product.**
- **Replace the batteries when the low battery indicator shows to prevent incorrect measurements.**
- **Remove the batteries if the Product is not used for an extended period of time, or if stored in temperatures above 50 °C. If the batteries are not removed, battery leakage can damage the Product.**
- **Use only the mains power cord and connector approved for the voltage and plug configuration in your country and rated for the Product.**
- **Replace the mains power cord if the insulation is damaged or if the insulation shows signs of wear.**
- **Use only the external mains power supply included with the Product.**
- **Connect the battery charger to the mains power outlet before the Product.**
- **Do not put metal objects into connectors.**
- **Do not connect the Product to a patient or equipment connected to a patient. The Product is intended for equipment evaluation only and should never be used in diagnostics, treatment, or any other capacity where the Product would come in contact with a patient.**

- **Batteries contain hazardous chemicals that can cause burns or explode. If exposure to chemicals occurs, clean with water and get medical aid.**
- **Do not disassemble the battery.**
- **Do not disassemble or crush battery cells and battery packs.**
- **Do not put battery cells and battery packs near heat or fire. Do not put in sunlight.**
- **Do not short the battery terminals together.**
- **Do not keep cells or batteries in a container where the terminals can be shorted.**
- **Remove the input signals before you clean the Product.**
- **Use only specified replacement parts.**
- **Have an approved technician repair the Product.**

⚠⚠ Warnings

For safe operation and maintenance of the Product:

- **Repair the Product before use if the battery leaks.**
- **Use only Fluke Biomedical approved power adapters to charge the battery.**

Symbols

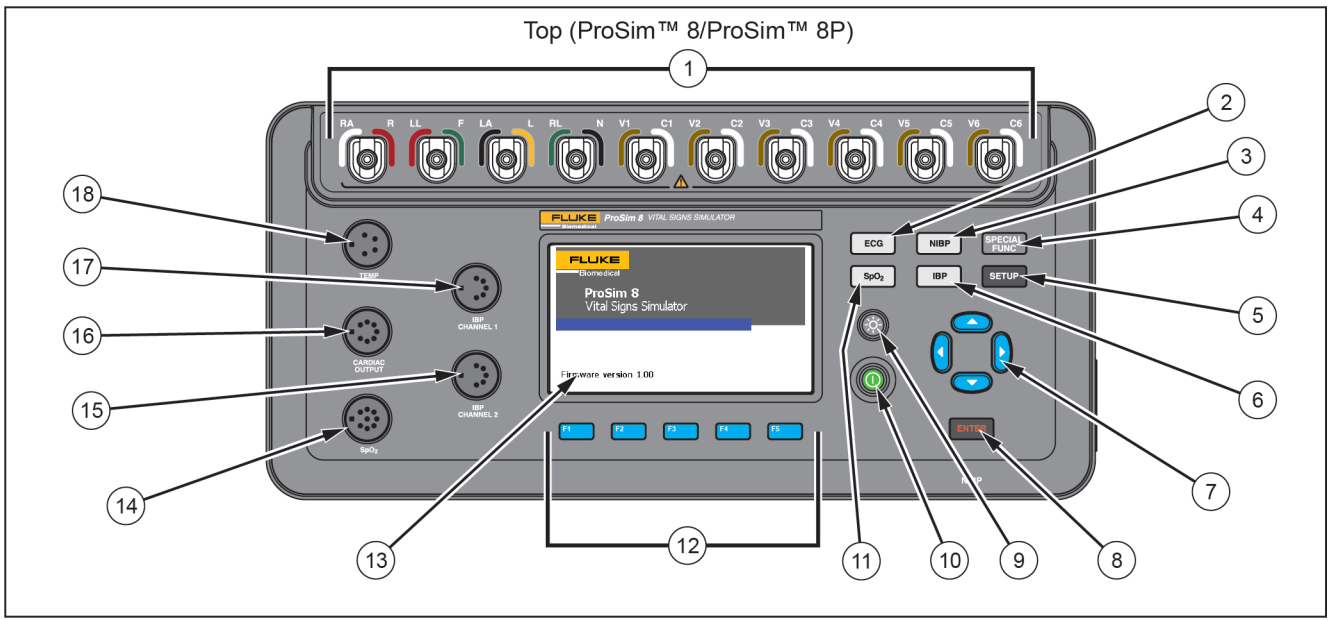
Table 1 describes symbols used in association with the Product.

Table 1. Symbols

Symbol	Description	Symbol	Description
	WARNING - RISK OF DANGER. Consult user documentation.		WARNING. HAZARDOUS VOLTAGE. Risk of electric shock.
	Magnetic Field		Input jack for the DC output of the AC-DC supply connector.
	Conforms to European Union directives.		Consult user documentation.
	This product complies with the WEEE Directive marking requirements. The affixed label indicates that you must not discard this electrical/electronic product in domestic household waste. Product Category: With reference to the equipment types in the WEEE Directive Annex I, this product is classed as category 9 "Monitoring and Control Instrumentation" product. Do not dispose of this product as unsorted municipal waste.		Spent Lithium batteries should be disposed of by a qualified recycler or hazardous materials handler per local regulations. Contact your authorized Fluke Service Center for recycling information.

Instrument Familiarization

Table 2 is a list of Product top-panel controls and connections shown in Figure 1.



glh034.bmp

Figure 1. Top-Panel Controls and Connections

Table 2. Top-Panel Controls and Connections

Item	Name	Description
①	ECG Posts	Connection posts for Device Under Test (DUT) ECG leads.
②	ECG Function	Accesses the ECG waveforms (adult, pediatric, and arrhythmias), and ECG test functions (performance waves, QRS detection, Tall T wave rejection, and R wave detection).
③	NIBP Button	Accesses the Non-Invasive Blood Pressure (NIBP) functions.
④	Special Functions	Accesses the temperature, respiration, cardiac output, fetal simulation, autosequences, and view memory functions.
⑤	SETUP Button	Accesses the setup controls.
⑥	IBP Button	Accesses the Invasive Blood Pressure (IBP) functions.
⑦	Navigation Buttons	Cursor control buttons for navigating menus and lists.
⑧	Enter Button	Sets the highlighted function.
⑨	Backlight Button	Adjusts the brightness of the backlight.
⑩	Power Button	Turns the Product on and off.
⑪	SpO2 Button	Accesses the SpO2 functions.
⑫	Function Softkeys	Keys F1 through F5 are used to select from several selections that appear in the LCD display above each function softkey.

Table 2. Top-Panel Controls and Connections (cont.)

Item	Name	Description
⑬	LCD Display	Color display.
⑭	SpO2 Connector	Connector to the SpO2 accessory.
⑮	IBP Channel 2 Connector	Connector to an IBP input of the patient monitor.
⑯	Cardiac Output Connector	Connector to the Cardiac input of the patient monitor.
⑰	IBP Channel 1 Connector	Connector to the IBP input of the patient monitor.
⑱	Temperature Connector	Connector to the Temperature input of the patient monitor.

Table 3 is a list of Product controls and connections shown in Figure 2.

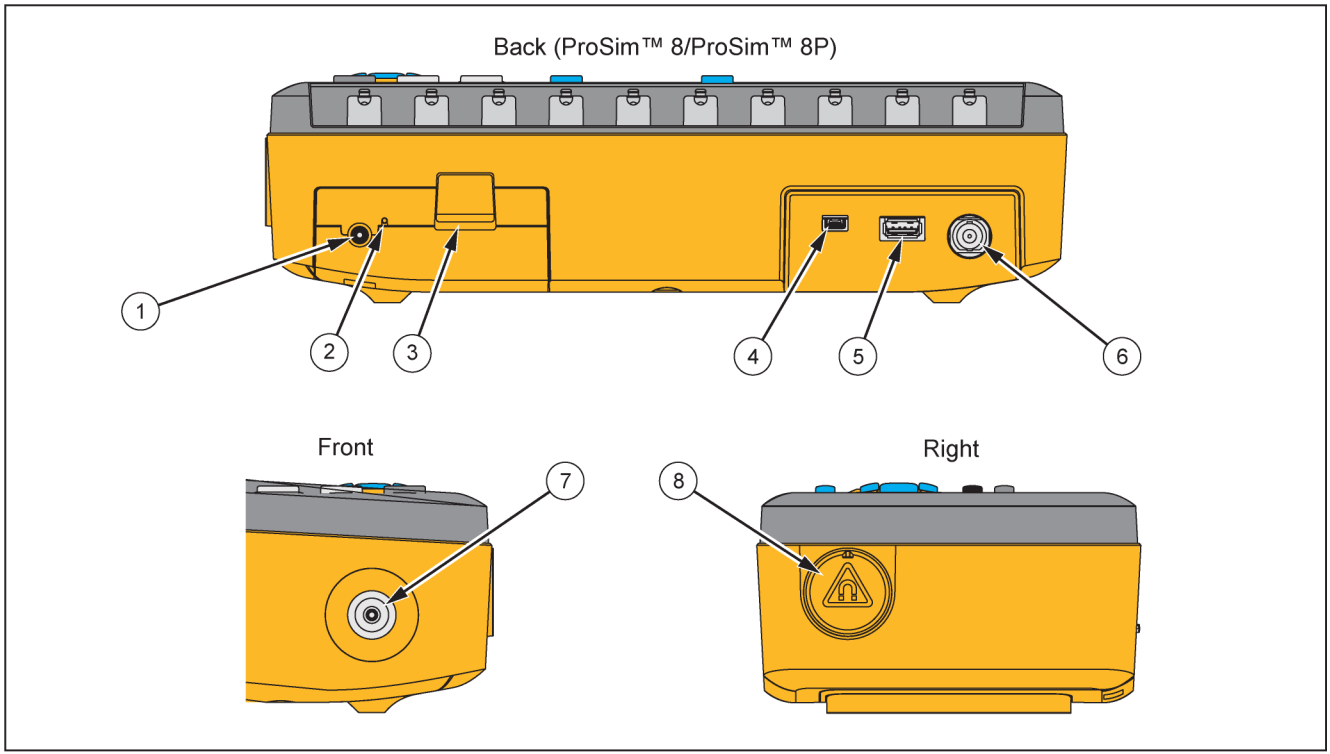


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Figure 2. Back, Front, and Side Panel Connections

Table 3. Back, Front, and Side Panel Connections

Item	Name	Description
①	AC/DC Supply Connector	Input jack for the DC output of the AC/DC supply connector.
②	Battery Charge LED	Battery charges when LED shows red. Green shows battery charge is complete.
③	Battery Latch	Locks the battery pack into the Product. Push down to remove the battery pack.
④	Mini B USB Device Port	Used to connect to a PC for remote control or download test results data to a PC.
⑤	USB A Controller Port	For external keyboard, barcode reader, or printer.
⑥	ECG BNC Connector	High-level output of ECG signal.
⑦	Air Port Connector	Pressure port for NIBP cuff and monitor.
⑧	Magnetic Holder for SpO2 Finger Module	Holds the SpO2 Optical Emitter and Detector finger module in two orientations.

How to Turn the Product On

After you unpack and inspect the Product, fully charge the battery before the first use. Afterwards, charge the battery when the Product shows the low battery message. See the Users Manual for detailed instructions.

How to Set the Display Language

The Product can be set to display text and messages in many different languages. To change the language:

1. Push SETUP.
2. Push ▲ or ▼ to highlight **Instrument Information**, and push ENTER.
3. Push ENTER to open the list of languages.
4. Push ▲ or ▼ to highlight a language in the list.

   Below is a list of the display languages.

English	Español
Français	日本語
Italiano	中文
Deutsch	Português

5. Push ENTER to change the language to the one highlighted.

Push ⏻ on the front panel to turn the Product on. The startup screen shows on the display. When the self-test is complete and no errors are sensed, the Home screen shows in the display. The Product is ready to use. See the Users Manual for detailed instructions.

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	3000 meters (9843 ft)
Wireless Module Listing	
FCC (United States) compliant (Class A)	FCC ID: OUR-XBEE
IC (Industry Canada) compliant	IC: 4214A-XBEE
CE (European) certified	CE0051
USB Device Virtual COM Port Settings	
Baud Rate	115 200 bps
Data bits	8 data bits
Stop Bits	1 stop bit
Flow Control	Hardware (RTS/CTS)
Power	Lithium-Ion rechargeable, 7.2 V, 31 Wh battery, 4300 mAh
Battery Charger	100 V to 240 V, 50/60 Hz 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	1.81 kg (4 lb)
Wireless Radio	
Frequency Range	2412 MHz to 2462 MHz
Output Power	<1 mW
Safety	IEC 61010-1 Overvoltage Category II, Pollution Degree 2.

Electromagnetic Compatibility (EMC) .....IEC 61326-1: Portable Electromagnetic Environment; IEC 61326-2-2 CISPR 11: Group 1, Class A

Group 1: Equipment has intentionally generated and/or use conductively coupled radio frequency energy which is necessary for the internal functioning of the equipment itself.

Class A: Equipment is suitable for use in all establishments other than domestic and those directly connected to a low voltage power supply network which supplies buildings used for domestic purposes. There may be potential difficulties in ensuring electromagnetic compatibility in other environments, due to conducted and radiated disturbances.

Caution: *This equipment is not intended for use in residential environments and may not provide adequate protection to radio reception in such environments.*

USA (FCC) .....47 CFR 15 Intentional Radiators: This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. (15.19). Changes or modifications not expressly approved by Fluke could void the user's authority to operate the equipment. (15.21)

Korea (KCC) .....Class A Equipment (Industrial Broadcasting & Communication Equipment)

Class A: Equipment meets requirements for industrial electromagnetic wave equipment and the seller or user should take notice of it. This equipment is intended for use in business environments and not to be used in homes.