

SP-SiM Handheld SpO2 Simulator



Technical Data Sheet 2009

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A new hand - held, high performance pulse oximetry simulator for the fast, accurate and efficient testing of SpO2 devices.

The lightweight and battery powered Rigel SP-Sim is the first hand - held simulator of its type and utilises new technology to eliminate the inconsistencies that can often be associated with testing using traditional methods like an optical finger.

Market leaders in oximeters specify instruments using electronic simulation for quality assurance purposes as a direct result of the high accuracy and repeatability of direct electrical simulation. However, the optical simulation method is able to take account of optical uncertainties. The Rigel SP-Sim is the first SpO2 simulator able to utilise both electronic and optical methods in a single test setup, reducing uncertainties thus improving the test time.

The SP-Sim features pulse volume adjustments, heart rate and manufacturer specific R-curves for maximum flexibility, combined with a large capacity internal memory for the data capture, storage and easy downloading to a PC via Bluetooth of test results for record keeping – details of up to 10,000 devices can be stored.

Manufacturer specific test programs can be uploaded via the Bluetooth technology while probe and monitor are tested at the same time for improved accuracy and faster results.

The SP-Sim forms part of a comprehensive range of high performance

specialist biomedical test equipment supplied by Rigel Medical, part of the Seaward Group.

Custom Test Settings

The unique setup in the Rigel SP-Sim not only allows you to configure your own test sequences or modify existing ones to suit your specific needs, it also includes a unique feature to configure your own visual or acceptance test routines prior to an electrical safety test. These could be simple instructions to the user or observations required for your own maintenance procedures such as checking for certain labels, software versions and upgrades etc.

These features make the Rigel SP-Sim a truly versatile service tool that ensures all test data is captured and processed in one single test record thus maximising traceability and allowing full flexibility in the field.

Test 'n' Tag Compatible

The Rigel Test 'n' Tag system allows customised Thermal PASS / FAIL Labels to be printed. The benefits of using the

Key features

- **Portable and Lightweight**
 Ideal for field service technicians and in-situ testing of SpO2 performance
- **Electronic and Optical Simulation**
 Ensuring the complete system is checked fast and accurately
- **Battery Operated**
 For convenient and fast testing without mains
- **Manufacturer R-curves**
 To ensure accurate simulations across a wide range of different brands and models
- **Prepared for PPM protocols**
 Configured for automatic performance testing of a variety of parameters
- **Full Keyboard**
 Easy data capturing and asset management
- **Intuitive User Interface**
 Fast and easy navigation using graphics display
- **Graphics Display**
 Allowing real-time display of test settings and simulation data
- **Bluetooth Communication**
 For PC download and future field
- **Web Updates**
 Enjoy easy updates through our website to benefit from the latest features

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Test 'n' Tag printer are:

- Tough and durable labels
- Resistant to most solvents used in the medical sector
- Opportunity to advertise your logo and company details or emergency telephone number with every item you Test 'n' Tag.
- Automatic barcode generation to enable easy use of the barcode scanner and speeds up test time.

The unique test 'n' tag label enables test status and retest due date, barcode and asset ID number, and person conducting the test.

Med-eBase PC Software

The SP-Sim is compatible with Med-eBase, a new and comprehensive download software package capable of producing asset management records and work schedules.

Use the software to configure a number of SP-Sims at the same time to ensure that all engineers work to the same test routines. Create customer test routines including test protocols for testing patient monitors (NIBP, SpO2, ECG etc.), defibrillators etc. Test protocols can be easily uploaded to the SP-Sim using the Bluetooth connection.

Use your SP-Sim during functional testing

to collect not only the electrical safety test record but also the performance of the Medical Device. The complete PPM in one single record.

Furthermore, the software allows you to produce certificates and print or email them to make sure test records are kept for future reference.

Key Features

1. Windows Explorer type user interface - layout
2. Download from SP-Sim to PC via Bluetooth
3. Upload from PC to SP-Sim via Bluetooth
4. Create test routines and configure multiple testers
5. Output of database to Excel / Access.
6. Database function
7. Test schedule function
8. Printing of test certificate
9. Store test certificate as HTML for easy email application

Rigel SP-Sim Design Philosophy

The SP-Sim has been designed to address the increasing demand for smaller more comprehensive test equipment within the healthcare industry.

The challenge was to combine the benefits of the size and weight of a smaller hand-held SpO2 Simulator with the test versatility and convenience of a larger bench-mounted

Applications

- Verify the correct performance of SpO2 – pulse oximeter monitors
- Simulation of different patient conditions through oximetry
- Testing of probe circuits

What comes in the box?

- Carrying Case
- SpO2 Adaptor cable
- Power Supply
- Instruction Manual
- Bluetooth USB Adaptor
- Calibration Certificate
- Application Software

Other products in the range

- Rigel BP-Sim NIBP Simulator
- Rigel 333 ECG Simulator



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simulator. Today's industry demands test equipment that can save time and cost, thus offering greater flexibility. These factors have all been taken into account during the development of the SP-Sim. The test capabilities and functionality exceed that of most common SpO2 Simulator yet the instrument is only a fraction of the size and weight.

No other SpO2 simulator on the market offers a hand-held enclosure with test capabilities equal to most bench marked versions. Features include graphic user interface, large internal memory, Bluetooth

communication, asset management facilities, user configurable Performance Tests and more.

We believe that the SP-Sim is set to become the new standard in SpO2 performance Testing.

Biomed testing on the move.



Tests in detail



Integrated Keypad

The integrated keypad provides an easy solution to the increasing requirements or asset management. It enables you to capture the performance of the SpO2 monitor on the SP-Sim and store results in the onboard memory, including information regarding make, model, serial number, site & location. Using the Bluetooth interface, the data can be easily downloaded to a PC application.



Displaying the simulation parameters

Thanks to its large 1/4 VGA display, the SP-Sim is able to display all the simulated parameters into a single and easy to read screen.

The real time battery charge indicator ensures clear indication of the remaining battery life.



Custom simulation settings

The Rigel SP-Sim is able to simulate a wide variety of aspects associated with Pulse oximetry such as; R-curves, saturation levels, heart rate, skin colour, perfusion and artefacts. An easy to use overview screen is instantly available in manual mode simulation.



Probe adaptor box

A variety of adaptor boxes are available to ensure connectivity with a wide range of SpO2 probes. Specify the make / model of the SpO2 probes when enquiring about the Rigel SP-Sim.

Rigel's Med-eKit can include the following:



288 Electrical Safety Analyser

- Light, hand-held, battery operation
- Conform IEC 62353 / 60601 / VDE 0751 / NFPA-99 / AS-NZS 3551
- Memory for up to 10,000 devices
- Bluetooth communication
- Full, semi automatic & manual tests



BP-Sim NIBP Simulator

- Light, hand-held, battery operation
- Adult & Paediatric NIBP Simulations
- Manufacturer specific O-curves
- Overpressure and leak test
- Memory for up to 10,000 devices



SP-Sim SpO2 Simulator

- Light, hand-held, battery operation
- Tests probe and monitor all at once
- User configurable simulations
- Manufacturer R-curves
- Memory for up to 10,000 devices

As well as:

- Patient Simulator
- Flow Analyser
- Defib Analyser
- Printer
- Barcode Scanner
- Asset Management Software
- Non-Rigel Test Equipment

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SPECIFICATIONS

Technical Specifications

| | |
|------------------|--|
| Simulation | Optronic (Electronic & Optical), indirect via probe adaptor box |
| Simulation via | probe & full chain |
| Range | 50 to 100% |
| Accuracy | ± 0.5% of reading between 80 - 100% SpO2 ± 1% of reading between 50 - 79% SpO2 |
| Heart rate | 20-300 bpm |
| Accuracy | ± 1 bpm |
| R-curves | Datex, Datex Ohmeda, Nellcor, N.Oximax, Masimo, Criticare, Datascope, Philips (HP), CSI, Novamatrix, Nihon Kohden, Nonin, SensorMedics (upgradeable) |
| Perfusion Index | 0-20% (5% default) |
| Arrhythmias | Tachycardia, Bradycardia, (upgrade) |
| Artefacts | Motion, light (AC-DC) (upgrade) |
| Direct interface | to Probe adaptor box. |
| Chronometer | test option to test response time SpO2 monitor |

General

| | |
|--------------------------|------------------------------|
| Operation | Battery cell, insitu charge |
| Mains supply | 230V/110V AC +/- 10% 50/60Hz |
| Battery life | >10 hours testing |
| Weight | <1 kilo |
| Dimensions | 26 x 10 x 5.5 cm |
| Operating conditions | 10-30°C, 0-90% RH - NC |
| Storage environment | -15° - +60°C |
| Environmental Protection | IP 40 |

Part number: 370A920

Also available

From Rigel Medical

- Rigel 266 Plus Manual Safety Analyser
- Rigel 277 Plus Automatic Safety Analyser
- Rigel 288 Hand - held Safety Analyser
- Rigel BP - Sim NIBP Simulator
- Rigel 333 Patient Simulator
- Rigel 344 Defibrillator Tester
- Rigel 355 Ventilator Tester
- Rigel 377 Electrosurgical Analyser
- Rigel 601 Checkbox
- Med-eBase – Software Application

From the Seaward Group:

- Portable Appliance Testers
- IEC Lead Tester
- Insulation Resistance Testers
- RCD Testers
- Earth Loop Impedance Testers
- Installation Testers
- Multimeters
- Current Clamps
- Hipot Testers
- Earthbond Testers
- Micro Ohmmeters