





Tried. Tested. Trusted.

The Rigel 288 is a hand-held medical electrical safety tester to combine an automatic / manual tester with a data logging / asset management facility.

The Rigel 288's compact lightweight design and long life battery power reduces downtime between tests, making the instrument practical and highly portable for multi-site use.

In addition to IEC 60601-1 and AAMI / NFPA 99, the Rigel 288 tests to the new standard for in-service and after repair testing of medical electronic devices, the IEC 62353 (2007).

The Rigel 288's large internal memory facilitates the storage of test results for safety audit and traceability purposes.

Comprehensive database software is available to ensure fast and easy download of test results, managing your asset database, creation of test sequences, scheduling of Preventative Product Maintenance and producing test certificates. Wireless connection means that stored data can be transferred immediately and directly from the tester to PC-based record keeping systems at the touch of a button.

The highly versatile Rigel 288 represents the next generation of electrical medical safety analysers.

The Market Place

With the introduction of the IEC 62353 standard for in-service and after-repair testing of medical electronic devices, the market for hand-held medical safety testers has changed. The globally recognised IEC 62353 has become the general guideline for routine testing for many leading medical device manufacturers. Whilst at present, the IEC 60601-1 standard is still used as a reference in many countries, newer faster and easier test methods can be maintained using the IEC 62353 standard.

The Rigel 288 combines the requirements for the IE60601-1 and AAMI/NFPA leakage currents as well as the new IEC 62353. The Rigel 288 is the first hand-held tester to combine graphics with an alphanumeric keyboard and Bluetooth connection to various peripherals such as Label Printers, barcode scanners and PC's. This will allow for high flexibility in the field.

Custom Test Settings

The unique setup in the Rigel 288 not only allows you to configure your own test sequences or modify existing ones to suit your specific needs, the Rigel 288 also includes a unique feature to allow visual or acceptance test routines to be configured prior to an

Key features

Versatile

Test in Accordance with the leakage requirements of IEC/EN 62353, IEC/EN 60601-1, AAMI, NFPA, AS/NZS 3551 and VDE 0751-1using separate IEC 60601 and AAMI Body Model.

Hand-held

With its purpose designed robust enclosure, the Rigel 288 is truly handheld. It is easy to hold single-handedly and enables one hand operation and navigation.

Easy to use

A full graphic, monochrome LCD display (1/4 VGA minimum) in combination with an integral alpha-numeric ABCD-key-board.

Manual and Automatic test modes

Able to perform UTS (Unique Test Sequence) and allows fully automatic, semi automatic and fully manual testing.

User definable test routines

Users have the ability to amend the default programs or create new programs by copying the preset test programs. Each program will have a unique Identifier.

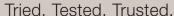
Multiple Applied Part Function

This feature gives the user the capability of testing up to 10 individual Applied Parts from different Modules or classes e.g. BF and CF class, or Bf ECG and Bf SPO2 module.

Internal Asset management facilities

Store up to 10,000 test records, custom test routines, visual inspections and performance tests and download to and from PC via Bluetooth Interface.







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. In addition, you can configure post safety test procedures such as recording readings during a performance test on a patient monitor (SpO2, NIBP, ECG, Temperature, IBP etc) or defibrillators (Energy, Synch time, Charge time etc) and so on.

These features make the Rigel 288 a truly versatile service tool to ensure 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 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 enables 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 Rigel 288 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 Rigel 288s 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 tc.), defibrillators etc. Test protocols can be easily uploaded to the Rigel 288 using either the Bluetooth or RS 232 connection.

Use the Rigel 288 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 Rigel 288 to PC via Bluetooth or RS 232

Applications

- Routine testing of Medical Electrical Equipment
- Service tool for Performance Testing
- Asset Management
- Fast and efficient testing of IEC leads
- Earth bond testing on (Medical)
 Installations and non Medical Equipment

What comes in the box?

- Calibration Certificate
- Carrying Case
- Earth bond test probe with clip
- Earth bond clip lead
- Patient Applied part module
- 10 Applied part adaptors
- Detachable 2 meter mains cable
- Bluetooth USB dongle
- Instruction Manual
- Application Software



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- 3. Upload from PC to Rigel 288 via Bluetooth or RS 232
- 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 288 Design Philosophy

The Rigel 288 has been designed to address the increasing demand for smaller more comprehensive test equipment within the healthcare Industry. What better way than to combine such a tester with the International In-Service Test required as per IEC 62353.

The challenge was to unite the benefits of the size and weight of a smaller hand-held and portable analyser with the test power and convenience of a larger bench-mounted automatic safety analyser. Today's industry demands test equipment that can save time and cost. These factors have been taken into account during the development of the Rigel 288. The test capabilities and functionality exceed that of most common bench mounted safety analysers, yet the instrument is only a fraction of the size and weight.

No other safety tester on the market offers a hand-held enclosure with the test capabilities of an automatic safety analyser; including IEC 60601 and IEC 62353 leakage tests, up to 10 patient connections, alpha-numeric keyboard, graphic user interface, large internal memory, Bluetooth communication, asset management facilities, user configurable Performance Tests and more.

We believe that the new Rigel 288 is set to become the new standard in electrical medical safety testing.

Seaward Group files patent for new **Earth Continuity test**

Seaward Group, parent company of Rigel Medical, has developed a new method of carrying out earth continuity tests undertaken as part of the process to verify the electrical safety of portable medical and domestic appliances.

The Seaward Group has filed a patent application for the new test technology that uses a dual current high intensity test to overcome contact resistance problems or other situations where weak conductor connections may inhibit protective earth testing with conventional test currents such as 1A or 200mA.

The patent recognises that a 200mA test current is rapidly becoming the international standard for in-service testing and testing after repair of medical electronic equipment such as the IEC 62353.

However, the new concept has been specially designed to help overcome variations in measurement that can be caused by contact resistance between the test probe and the device under test, for example, when measuring continuity of tarnished or corroded parts often seen in the commonly used detachable IEC power cable.

The unique technology introduced by Seaward Group enables valid earth continuity tests to be carried out using battery powered testers and is being incorporated into the new Rigel 288 hand held electrical medical safety analyser.

The innovative new Rigel 288 has been specifically designed to provide a hand-held test solution for those demanding versatility and portability yet not compromising the validity of tests being carried out. The Rigel 288 meets the in-service and post-repair test demands of the IEC 60601 and IEC 62353 standard for in-service testing of Medical Devices.



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

Earth Continuity

Method 2 wire technique, using 'zero' lead function. Test Current >+200mA, -200mA DC into 2 ohms Max Test Voltage 4-24V rms o/c (6V for IEC 60601 tests) Measuring Range (low range) 0.001 - 0.999 ohms @ 0.001 ohms resolution Measuring Range (mid range) 1.00 - 9.99 ohms /@ 0.01 ohms resolution Measuring Range (high range) 10.0 - 19.9 ohms @ 0.1 ohms resolution

Insulation Resistance

Accuracy

Measurement EUT to Earth / Ground, EUT to AP, AP to

Ground

± 3% of reading + 10 m ohms

Voltage 250V DC, 500 V DC @1mA. Range (low range) 0.01Mohms - 20 Mohms Accuracy (low range) ± 5% of reading +2 counts Range (high range) 20Mohms - 100Mohms Accuracy (high range) ±10% +2 counts

Resolution 0.01Mohms

Direct Leakage Measurement

Measuring Range 4µA to 9999µA

Accuracy ± 5% or reading +2 counts Mains on A.P. voltage F-type only @ 110% of mains As per IEC 60601-1 requirements Measuring Device Measurement Type Separate AC & DC for Patient (-Auxiliary) True RMS for all remaining Leakage tests Leakage to IEC 60601

Differential Leakage Measurement

Measuring Range 75µA to 9999µA

±5% of reading + 5 counts Accuracy

Measurement / display resolution 1μΑ Measurement Type True RMS

Measuring Device Similar frequency response characteristics to

IEC 60601-1.

Alternative Leakage Measurements

Test Voltage 250V at mains frequency Test Current 3.5 mA current limited 4µA to 9999µA Measurement Range

Measurement Resolution 1μΑ

Measurement Accuracy ±5% of reading + 2 counts

True RMS Measurement Type

Measuring Device As per IEC 60601-1

Additional Information

Unique use of Icons

The Rigel 288 features a hi-resolution graphic backlit display which not only provides highly visible and easy to follow menu structures but also allows the user to operate the tester using intuitive icons to speed up their test routines.

Below are of some of the icons used in the Rigel 288:





Print



Help



Patient Connection



Edit



Delete



Save



Single Fault

Electrical Safety Tests performed:

- Earth bond*
- Insulation

Specific to IEC 60601-1:

- Earth Leakage
- Enclosure Leakage
- Patient Leakage
- Patient Auxiliary
- Patient F-type

Specific to pr IEC 62353 - VDE 0751:

- Equipment Leakage (Direct, Differential and Alternative Method)
- Applied Part Leakage (Direct and Alternative Method)

Specific to AAMI & NFPA:

- Patient Leakage AP-GND
- Patient Leakage AP-CASE
- Patient Leakage AP- AP
- Patient Leakage AP- ALL (AAMI / NFPA)

Custom tests can be created using a variation or combination of the above.

* Using unique patented technology proving hi-current (>25A) test capability



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Power Measurement

Method VA rating.

Range 0.1 KVA - 4 KVAAccuracy $\pm 10\% + 2 \text{ counts}$

Mains Outlet Test

Input voltage range: 0-300V AC, max current 16A

Measures L-E, N-E&L-N

Accuracy \pm 5% of reading + 2 counts

IEC Mains Lead Test

Test Duration: 2s

Test: Continuity of all conductors, Earth bond,

Insulation & Polarity

General

Mains power 230 VAC ±10%, 50Hz +/- 1Hz 120 VAC ±10%,

60Hz +/- 1Hz (USA model)

Battery 6 x 1.5V Alkaline AA
Weights 1.6 kg including batteries

Size (L x W x D) 270 x 110 x 75 mm / 10.5 x 4 x 3"

Operating conditions 0' - 40'C, 0-90% RH - NC

Storage environment -15' - +60'C
Environmental Protection IP 40

Part number: 331A910 UK (13A)

331A912 Australian (10A) 331A913 Schuko (16A)

331A914 USA (15A-120V-60Hz)

331A915 Danish (13A) 331A917 French (16A)

331A918 Czech / Polish (16A) 331A919 German (16A)

Also available

Accessories:

- PC Download software
- Barcode scanner with embedded Bluetooth
- Bluetooth Test 'n' Tag System
- Bluetooth results printer
- Bluetooth Serial Adaptor
- Pelican case

From Rigel Medical

- Rigel 266 Plus Manual Safety Analyser
- Rigel 277 Plus Automatic Safety Analyser
- Rigel BP-Sim NIBP Simulator
- Rigel SP-Sim SPO2 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
- Earth bond Testers
- Micro Ohmmeters