

# 62353 Electrical Medical Safety Analyser



Technical Data Sheet 2009

Tried. Tested. Trusted.



# The Rigel 62353 is a hand-held medical electrical safety tester to combine an automatic / manual tester with a data logging / asset management facility.

The Rigel 62353's compact lightweight design and long life battery power reduces downtime between tests, making the instrument practical and highly portable for multi-site use.

The Rigel 62353 tests to the new standard for in-service and after repair testing of medical electronic devices, the IEC 62353 (2007).

The Rigel 62353'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. 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 62353 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. Newer faster and easier test methods can be maintained using the IEC 62353 standard.

The Rigel 62353 combines the requirements for the IEC 62353 and AAMI/NFPA or AS/NZ3551 leakage currents (local variants only) as well as the new IEC 62353.

The Rigel 62353 is the first dedicated IEC 62353 safety analyser that is able to provide automatic sequencing, onboard data storage and data entry in a ergonomic hand-held enclosure. This will allow for high flexibility in the field.

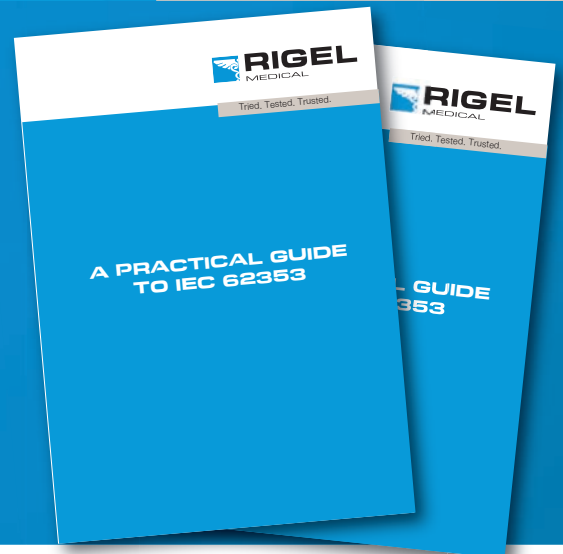
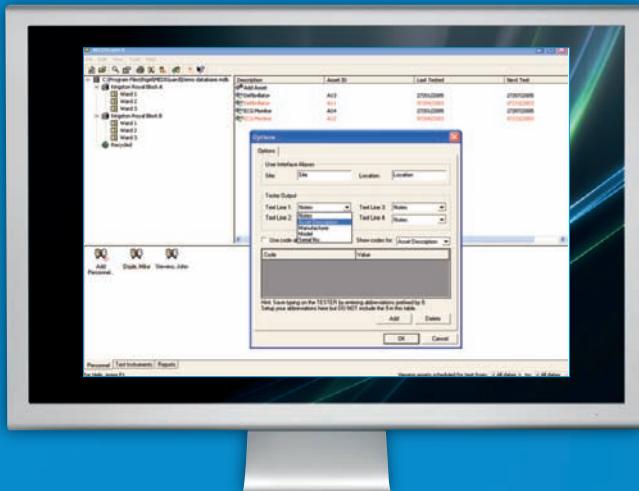
## Custom Test Settings

The unique setup in the Rigel 62353 not only allows you to configure your own test sequences or modify existing ones to suit your specific needs, the Rigel 62353 also

## Key features

- **Versatile**  
Test in Accordance with the leakage requirements of IEC/EN 62353 and NFPA 99 or AS/NZ3551 in respective local versions.
- **Hand-held**  
With its purpose designed robust enclosure, the Rigel 62353 is compact. It is easy to hold single-handedly enabling one handed 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**  
The 62353 is 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 to test up to 2 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 a PC.

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includes a unique feature to allow visual or acceptance test routines to be configured 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.

In addition, you can configure post safety test procedures such as recording readings during a performance test on a patient monitor (SpO<sub>2</sub>, NiBP, ECG, Temperature, IBP etc) or defibrillators (energy, synch time, charge time etc) and so on.

These features make the Rigel 62353 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.

### Med-eBase PC Software

The Rigel 62353 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 62353s 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, SpO<sub>2</sub>, ECG tc.), defibrillators etc. Test protocols can be easily uploaded to the Rigel 62353.

Use the Rigel 62353 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 62353 to a PC
3. Upload from PC to Rigel 62353
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

### 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 lead
- 2 applied part adaptors
- Detachable 2 meter mains cable
- Instruction manual
- Application software

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### Rigel 62353 Design Philosophy

The Rigel 62353 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 money. These factors have been taken into account during the development of the Rigel 62353. 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 62353 leakage tests, up to 2 patient connections, alpha-numeric keyboard, graphic user interface, large internal memory, PC communication, asset management facilities, user configurable performance tests and more.

We believe that the new Rigel 62353 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 62353 hand held electrical medical safety analyser.

The innovative new Rigel 62353 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 62353 meets the in-service and post-repair test demands of the IEC 60601 and IEC 62353 standard for in-service testing of Medical Devices.

# Biomed testing on the move.



### 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

## 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        |
| Accuracy                     | ± 3% of reading + 10 m ohms                   |

### Insulation Resistance

|                       |  |
|-----------------------|--|
| Measurement           | EUT to Earth / Ground, EUT to AP, AP to Ground |
| 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 @ 100% of mains     |
| Measuring Device      | As per IEC 60601-1 requirements |
| Measurement Type      | True RMS                        |

### Differential Leakage Measurement

|                                  |  |
|----------------------------------|--|
| Measuring Range                  | 75µA to 9999µA   |
| Accuracy                         | ±5% of reading + 5 counts                                  |
| Measurement / display resolution | 1µA  |
| 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    |
| Measurement Range      | 4µA to 9999µA             |
| Measurement Resolution | 1µA                       |
| Measurement Accuracy   | ±5% of reading + 2 counts |
| Measurement Type       | True RMS                  |
| Measuring Device       | As per IEC 60601-1        |

## Additional Information

### Unique use of Icons

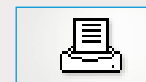
The Rigel 62353 features a hi-resolution graphic backlit display which not only provides highly visible and easy to follow menu structures but also allows the user to operate the tester using intuitive icons to speed up their test routines. Below are of some of the icons used in the Rigel 62353:



Settings



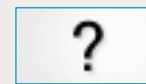
Edit



Print



Delete



Help



Save



Patient Connection



Single Fault Condition

### Electrical Safety Tests performed:

- Earth bond\*
- Insulation

### Specific to IEC 62353 – VDE 0751:

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

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

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

### Power Measurement

|          |                 |
|----------|-----------------|
| Method   | VA rating.      |
| Range    | 0.1KVA – 4KVA   |
| Accuracy | ±10% + 2 counts |

### Mains Outlet Test

|                      |                            |
|----------------------|----------------------------|
| Input voltage range: | 0-300V AC, max current 16A |
| Measures             | L – E, N – E & L – N       |
| Accuracy             | ± 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   |

### Also available

#### Accessories:

- PC Download software
- Pelican case
- RS 232 download cable

#### From Rigel Medical

- Rigel 266 Plus Manual Safety Analyser
- Rigel 277 Plus Automatic Safety Analyser
- Rigel 288 Electrical Medical Safety Analyser
- Rigel BP-SiM NIBP Simulator
- Rigel SP-SiM SPO2 Simulator
- Rigel UNI-SiM Vital Signs 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
- Microhmmeters

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