

277 Plus Electrical Medical Safety Analyser



Technical Data Sheet 2009

Tried. Tested. Trusted.



A compact, easy-to-use electrical medical safety analyser designed to test in accordance with IEC/EN 60601-1 and IEC/EN 61010.

The Rigel 277 Plus combines IEC/EN 60601-1 compliance with additional test facilities for IEC/EN 61010 (Laboratory Equipment) including Touch Leakage, Voltage Measurement and dedicated IEC 61010 Measuring Device (Body Model).

In addition, test routines are preset for MDA DB9801 and VDE 0751. Customised test routines can be created to group Applied Parts, measure multi class Medical Equipment in one single test routine (eg Defibrillators Bf/Cf), meet local standards and variants of safety test standards such as EN60601-2-4, AS/NZ 3200 and previous editions of IEC / EN 60601 standards.

The Rigel 277 plus performs manual, automatic and semi automatic test routines allowing full control of power up and power down delay times. The combination of a full graphics display, large internal memory and integral QWERTY- keyboard provides a complete stand alone test system to prove the electrical safety of both medical and laboratory equipment.

The Rigel 277 plus is designed to increase the efficiency of test routines and to reduce the overall test time.

Rigel 277 plus Design Philosophy

The Rigel 277 plus is designed to provide the industry with a full IEC 60601-1 compliant International Leakage Tester

combined with full 25A regulated Earth Bond Test Current to meet the most demanding test environments and requirements yet not compromising the portability of such tester. The outset of the design was to make sure such tester would not rely on any external PC control to ensure its portability would be guaranteed in practise.

The enclosure used on the Rigel 277 plus was designed by the Seaward Group as part of a Navy Contract who required a rugged portable tester with small footprint to test in confined spaces but with full Integrated Electronics, Keyboard and Data Storage Capability.

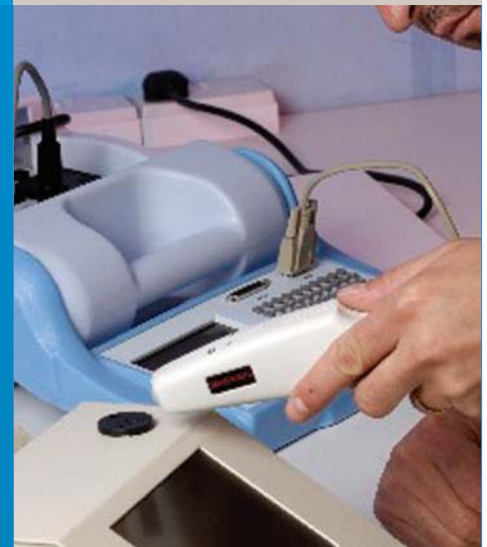
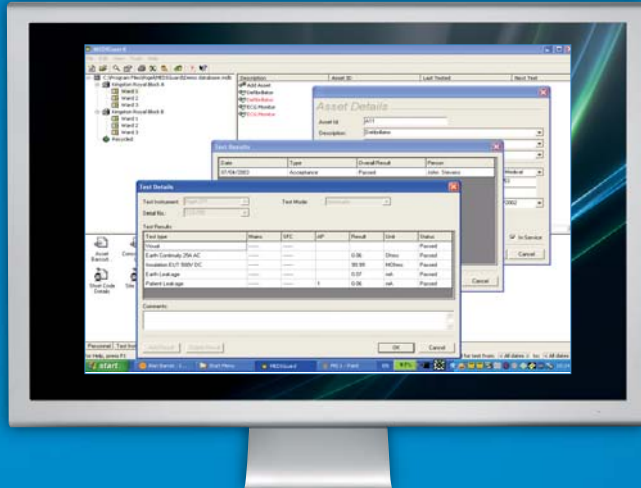
The design of the Rigel 277 plus won several awards for its functionality and innovation. Today over 11,000 testers have been manufactured using this design, a true Industry standard.

Today, the Rigel 277 plus remains one of the few Electrical Medical Safety Analysers able to fully meet the test requirements as described in the IEC 60601-1 standard. Its portable design is favoured by Users demanding full portability and ease of use.

Key features

- **Full IEC 60601 Leakage Tests**
Earth, Enclosure, Patient, Patient Auxiliary and F-type leakage tests
- **Full IEC 61010 Leakage Tests**
Earth and Touch leakage tests via dedicated Measuring device
- **Up to 25A AC Test Current**
Unique choice of 100mA, 1A, 10A or 25A Regulated Test Current
- **Multi Class Applied Part**
Single Test Routines for Equipment with both BF & CF Applied Parts
- **Large Graphic LCD**
Fast and Easy interpretation of test results, PASS/FAIL limits, test condition and more
- **Automatic & Manual Control**
Fast and Accurate control of Safety Tests when most required
- **Integral QWERTY Keyboard**
For easy and fast data entry
- **On-board Database System**
Stores test results and sequences of over 2500 Medical Devices
- **Built-in Printer**
For easy printing of test results, PASS / FAIL labels and summary
- **11 Patient Connections**
Provide an easy and fast way of testing Medical Electronic Equipment with patient connections
- **Dedicated IEC Lead Test**
For easy testing of IEC power cables

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Semi Automatic Mode Explained

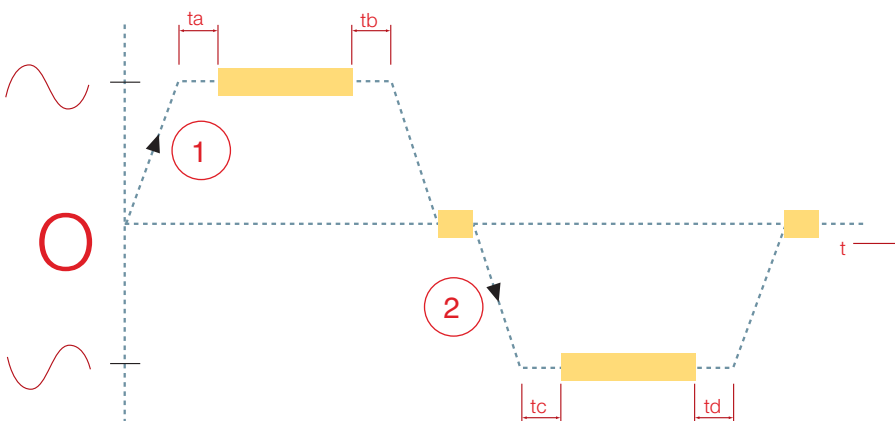
When testing Medical Devices, it is important that measurements are taken once the Device Under Test (DUT) is fully operational as required by the IEC 60601-1 and subsequent standards. To ensure measurements are taken during this condition, the safety analyser must first power-up the DUT and delay the measurements until the right conditions are met.

The Rigel 277 plus has a unique Semi Automatic Mode that allows manual control of power-up and power-down of the DUT as well as controlling the automatic test sequence.

This ensures that correct measurements are performed and provide sufficient time to power-down any device which is sensitive to power-breaks e.g. Ultrasound Equipment and PC based ME Equipment.

By grouping the Single Fault Conditions, the DUT is only powered-up twice and will significantly reduce test times on equipment with a long start-up time such as Dialyse and Imaging Equipment.

Below is a graph highlighting the Grouping of Single Fault Conditions (in Yellow) and the delays which are manually controlled by the User (t_a , t_b , t_c & t_d) and the time in which the safety analyser performs the automatic test routines.



Applications

Electrical Safety testing During:

- Pre-compliance & R&D
- Type Testing
- End of Production Line testing
- In-Service Safety Testing
- Preventive Product Maintenance (PPM)

Of Portable and Fixed Wired:

- Medical, Non-Medical & Laboratory Electronic Equipment

What comes in the box?

- Calibration Certificate
- Operation Manual
- Earth bond lead + clip
- 11 Applied part Adaptors
- RS 232 download lead
- 3 rolls of Printer Paper
- 2 rolls of labels
- MediGuard 30 day trial software

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MediGuard – Medical Appliance Testing Software

Each Rigel 277 plus is supplied with a 30 day trial version of our MediGuard Medical Appliance Testing software.

Test Software has never been easier to use due to MEDIGuard's unique presentational program layout and extensive schematic display. MEDIGuard allows automatic creation of a powerful device database direct from the downloaded data of the Rigel 277 plus.

The database enables a full historical record of testing to be maintained including acceptance tests and routine maintenance tests, as well as full device details such as manufacturer, model, serial number, purchase and warranty details and electrical information.

Retesting schedules for PPM testing can easily be created to ensure full compliance to safety procedures and plan workloads. Information about devices can also be reported by a number of different filters including device ID number, site, location or test date range.

The drag and drop action within the software also allows for easy relocation of assets from one location to another as in accordance with the movement of appliances.

Key Features

- Network compatible
- Comprehensive acceptance record linked to test record
- Unique presentational layout
- Creates complete record system automatically from download
- Test schedule to plan re-tests

Have you got BRAINCELLS?

The innovative new BRAINCELL technology uses 'smart' RF data tags to store test information and ensure that a test data record stays with an appliance throughout its lifetime.

The new BRAINCELL Smart Tag

Technology works with the Rigel 277 plus and extends the concept of conventional barcode labels.

Simply scan the BRAINCELL using the read / write module and start testing without the need of entering any further data.

Thanks to the RFID technology, the BRAINCELL does not rely on line of sight and can therefore be placed within the Medical Device to ensure the information is kept safely for future reference.

The BRAINCELL is two-way programmable and has the capacity to store test data transmitted back onto the tag directly from the Rigel 277 plus. As a result, test data can be easily updated after each test routine.

The BRAINCELL can store:

- Asset ID Number
- Asset Description, Make, Model & Serial Number
- Test Class & Program
- Location and Site information
- Previous Test Data
- Applied Part Configuration

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

AC Earth Bond Test

Test Current	100mA, 1A, 10A, 25A
Current Source	Regulated
Open Test Voltage	6V rms nominal
Range	0.01ohms - 19.99ohms / 0.01ohms counts
Accuracy	± 5% of reading, ± 2 counts
Measurement	4-wire, floating earth
Insulation Test	
Test Voltage	350 / 500V d.c. nominal
Auto Ranging	100kohms - 20 Mohms (L) / 0.01Mohms counts 20Mohms - 100Mohms (H) / 0.01Mohms counts
Accuracy	± 5% of reading, ± 2 counts (L) ±10% of reading, ± 2 counts (H)
Open Circuit Voltage	<750VDC

IEC 60601 Leakage Test

Supply Voltage	Incoming mains (230/110VAC)
F-Type Open Circuit Voltage	110% +/-20% of Mains Input Voltage
Maximum Load	16A (13A for UK model)
Input Impedance	1Kohm - as per 60601 MD
Frequency Response	as per IEC 60601-1 requirements
Range	0.000mA - 9.999mA / 0.001 counts
Accuracy.	± 3% of reading, ± 4 counts

IEC 61010 Leakage Test

Supply Voltage	Incoming mains (230/110VAC)
Maximum Load	16A (13A for UK model)
Input Impedance	2Kohms - as per 61010 MD
Frequency Response	DC - 2.5kHz (as per IEC 61010)
Range	0.10mA - 3.50 mA / 0.01 counts
Accuracy.	± 3% of reading, ± 4 counts

Load Test

Measured Load	0.06 - 4kVA
Measured Voltage	Mains Supply +/-10%

IEC Lead Test

Test	40V a.c., 1mA nominal
Detects	Good, Open, Short, Reverse

General

Size	400mm x 320mm x 160 mm
Weight	appr. 9 kg
Operating	0°C to 40°C (non condensing)
Storage	-10°C to 50°C (non condensing)
Maximum R.H	90%

Part number: 350A910	UK / Ireland
350A913	Euro - Schuko
350A917	French
350A915	Danish
350A918	Czech / Polish
350A914	US (110V - 60Hz)
350A912	Australian

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Also available

Accessories:

- MediGuard Download Software
- Carry Case
- Barcode scanner
- RFID scanner
- BrainCell RFID Chips
- Blue Tooth Converter
- PASS / FAIL Labels
- ASSET ID Labels
- BARCODE Labels
- Rigel 601 Checkbox

From Rigel Medical

- Rigel 266 Plus Manual Safety Analyser
- Rigel 288 Hand - held Safety Analyser
- Rigel BP-Sim SpO2 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
- Earthbond Testers
- Micro Ohmmeters