

# the Pulse

Expert news and advice for the medical industries

## Royal reward

International sales success for its Rigel Medical biomedical test equipment has secured the prestigious Queen's Award for Enterprise for the Seaward Group.

Issue

#1

# Your ideas are at the heart of our new performance analysers



**Rigel Uni-Therm**  
Electrosurgical Analyser

**Rigel Multi-Flo**  
Infusion Pump Analyser

**Rigel Uni-Pulse**  
Defibrillator Analyser

Experts like you help us to produce the world's leading performance analysers. Your ideas inspire our continual innovation. Our compact, portable and traceable products are perfect for bedside testing, speeding up your test process, reducing downtime and boosting your efficiency.

New to the range are the Rigel Multi-Flo infusion pump analyser, Uni-Pulse defibrillator analyser and the next generation Uni-Therm electro-surgical analyser. All designed for use within the patient environment, with onboard automation and data storage as standard.

See the full range at [rigelmedical.com](http://rigelmedical.com)  
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Innovating together

Part of Seaward Group

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# Welcome

I'm personally delighted to welcome you to the first edition of our newsletter, Pulse, the ideal way to find out about the latest industry news and product launches from Rigel Medical.

I hope you enjoy it. You'll find plenty to interest you as we cast our gaze across the sector during these challenging times, when there is the need to be even more willing and flexible to adapt to rapidly changing circumstances.

The way forward continues to be led by companies like us, which have been at the forefront of technical innovation, providing customers with the tools to work smarter and more intelligently.

And to mark our international success, the Seaward Group has secured the prestigious Queen's Award for the Rigel Medical division, one of the highest accolades a company can win and reward for the innovative biomedical test equipment produced over many years.

Innovation lies at the heart of the Rigel Medical offer, and we will be continuing our commitment to new product development working closely with our customers to prove the solutions that make a difference

to their businesses. For example, find out more in this first issue about the new high performance Uni-Pulse defibrillator analyser and the Uni-Therm electrosurgical analyser.

We'd love to hear what you have to say too; so please feel free to get in touch with your views and comments. They'll be appreciated and we'll try to feature some of them in future issues of Pulse.

In the meantime, enjoy the first edition where we take an in-depth look at measuring and simulating vital signs alongside the latest industry news.

We also answer some of your questions in our 'Question Time' section and show how our customers benefit from our products. There's also a chance for you to win an Amazon Kindle Touch and catch the latest industry events in our 'What's On' section.

**Best regards**

**John Backes** Editor, Pulse





## What's On

### AAMI:

June 2 – 4th  
Charlotte Convention Center,  
North Carolina, USA

### WümeK:

June 11 – 13th  
Würzburg, Bavaria, Germany

### Electrical Safety Seminar:

June 26th  
Connolly Hospital, Dublin,  
Ireland

### Electrical Safety Seminar

June 27th  
Galway University Hospital,  
Galway, Ireland

### Welch Allyn

Completing the picture  
July 4th  
The Heritage Motor Museum,  
Gaydon, UK

### IPEM Seminar

July 25th  
York Racecourse,  
York, UK

### 16th National Biomed & Clinical Engineering Conference

October 18th  
National Motorcycle Museum,  
Birmingham, UK

### MEDICA 2012

November 14 – 17th  
Messe Düsseldorf,  
Germany

# Royal reward for international sales success



**International sales success for its Rigel Medical biomedical test equipment has secured the prestigious Queen's Award for Enterprise for the Seaward Group.**

The Award is one of the highest honours that can be bestowed on a UK-based company and is given each year to those companies demonstrating outstanding achievement - growth in export sales of Rigel Medical analysers and simulators has seen the

Seaward Group recognised in the international trade category.

John Backes, associate director – Rigel Medical, said: "Export sales are increasingly important to our business and the constant challenge is to maintain a competitive edge against much larger multi-skilled groups and the lower production costs of overseas-based manufacturing operations".

## New ISO medical devices guide

**The new International Organization for Standardisation (ISO) and International Electrotechnical Commission (IEC) have published an improved guide to help address safety aspects in medical device standards.**

The Guide to the development and inclusion of safety aspects in international standards for medical devices improves on and replaces a 1999 edition. Notably, it responds to the risk-based framework set out in ISO 14971: 2007, Medical devices – Application of risk management to medical devices.

Alfred Dolan, convenor of the team that updated the guidelines, described the benefits which the new guide brings to

users and the improvements made compared to the 1999 edition it replaces.

Compared to the 1999 version, the new guide accentuates the concept of risk and emphasizes the need to consider the relationship between hazards and the associated harms which may result. The resultant risk is what standards need to control through establishing technical or process requirements in those standards.”

**Go to [www.iso.org](http://www.iso.org)**



**Two market leaders in biomedical device testing have formed a new alliance to extend the range of products and services available to UK and Ireland customers.**

The move follows Rigel Medical reaching an exclusive agreement with imtmedical ag for the distribution of their respiratory test equipment in the UK and Ireland.

This will see Rigel providing sales, technical and after sales support for the Switzerland-based company's respiratory test equipment range, which includes ventilator testers including the latest hand-held Citrex and test lung devices.

imtmedical's biomedical testing devices meet the requirements for the field

## Market leaders new biomedical alliance boosts UK and Ireland offering

measurement and calibration of ventilators and anaesthesia devices and are distinguished from other calibration tools by combining a simple, intuitive user interface with precise sensor technology.

Rigel already offers a range of analysers and simulators for UK and international markets so the inclusion of imtmedical's testers will enable it to offer a comprehensive suite of industry-leading biomedical testing devices for hospital and healthcare facilities customers.

John Backes, Rigel Medical's associate director, said imtmedical's products will benefit from Rigel's strong market identity and reputation, adding: "There are a lot of synergies between both companies, so being able to include their products as an

integral part of our offering makes sense".

"We look forward to introducing our customers to the benefits of imtmedical's products and explaining how they can be included as part of our Med-eKit system to offer one of the best and most advanced biomed field service kits available."

imtmedical's range features the compact Citrex, a mobile instrument used primarily in the verification and calibration of hospital and homecare ventilators. The FlowAnalyser instruments can be used to measure pressure, flow and volume with analysis undertaken using FlowLab software. The company's test lung models cover a variety of purposes including the quick and easy calibration of ventilators and anaesthetic equipment.

## US senators move to make medical devices safer

**US senators have introduced a bill that would give the Food and Drug Administration the power needed to improve the oversight of medical devices.**

Defective medical devices have been associated with thousands of deaths in recent years in the US, the bipartisan Ensuring Safe Medical Devices for Patients

Act will give the FDA and its Center for Devices and Radiologic Health (CDRH) the tools needed to protect patients and keep harmful devices off the market.

The legislation builds on important initiatives to improve the oversight of medical devices and has been endorsed by the Consumers Union, Health Care

Supply Chain Association, the Premier Healthcare Alliance, Association of American Medical Colleges, Alliance for Advancing Nonprofit Health Care and MedicAlert Foundation, Public Citizen among others.

**More details at [www.merkley.senate.gov](http://www.merkley.senate.gov)**



## EU standards move

The EU has issued a revised and updated list of standards that can be used to demonstrate conformity with the essential requirements of its Directive 93/42/EEC concerning medical devices.

The Directive defines a 'medical device' as "any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application....to be used for human beings for the purpose of:

- 1) diagnosis, prevention, monitoring, treatment or alleviation of disease.
- 2) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap.
- 3) investigation, replacement or modification of the anatomy or of a physiological process; or
- 4) control of conception."

It has also published an updated list of standards that can be used to demonstrate compliance with the essential requirements of its Directive 98/79/EC, dealing with in-vitro diagnostic medical devices.

More at: [www.eur-lex.europa.eu](http://www.eur-lex.europa.eu)



## Rigel Shows New Products at AAMI 2012 (June 2-4th)

**The benefits of the new Rigel Uni-Therm high current electrosurgical analyser, Uni-Pulse hand-held defibrillator tester and the new Multi-Flo infusion pump analyser will be the highlights of Rigel Medical's presence at this year's AAMI in Charlotte, North Carolina.**

The new high power Rigel Uni-Therm accurately verifies and calibrates the performance of electrosurgical generators. Measurements include high frequency leakage, high current, power distribution and patient return plate alarm testing. A large color screen, onboard data storage and test automation make the Uni-Therm ideal for field and workshop based testing.

The Multi-Flo infusion pump analyser offers accurate and instant high and low flow measurements, occlusion, back pressure and bolus measurement. Available in one, two and four independent channels, tested simultaneously from as low 100 L (microlitre) with results stored in the instrument's large internal memory. The innovative Rigel Uni-Pulse defibrillator analyser is the most compact and versatile instrument on the market, able to accurately verify all mono- and bi-phasic

defibrillators and AED's. Features include: onscreen waveform capture, built-in 12-lead ECG simulator, onboard memory and optional variable load box ensuring the Rigel Uni-Pulse meets all the requirements of IEC 60601-2-4.

Andrew Upton, Vice President of the Seaward Group USA, said: "We are committed to bringing innovative new products to market to meet customer requirements and we're sure the many new features and benefits of Uni-Pulse and Multi-Flo will attract significant interest."

Also showing will be the Rigel 288 electrical safety analyser and the Rigel UNI-SIM, the industry's first hand-held automated safety analyser and vital signs simulator. The UNI-SIM is capable of undertaking synchronised vital signs parameter tests simultaneously: NIBP, SpO2, ECG, temperature, IBP and respiration functionality tests.

Make an appointment to find out more from Rigel during the show by emailing [info@rigelmedical.com](mailto:info@rigelmedical.com) or visit us at booth 915.

## Med-eBase software for enhanced test recording



The Med-eBase PC software V2 can be used with Rigel Medical's comprehensive range of medical device testers and advanced simulators.

Upgraded features provide enhanced electronic recording and management of medical device safety testing programmes using vital signs simulators, performance analysers and electrical safety testers.

Med-eBase helps medical equipment companies and service firms to verify the status of electrical medical equipment in line with IEC 60601-1 and the new IEC62353 in-service safety testing standard. The latest version enables the user to quickly create bespoke test protocols on a PC before uploading them to the Rigel tester or simulator.

It is fully compatible with the Microsoft Windows 7 operating platforms and features an enhanced interface to allow the user to easily manage the transfer of data using Bluetooth connectivity. Test results can be stored on a local or remote database depending on the needs of individual biomedical service departments, enabling quick and easy access for service technicians and engineers via PCs.

Importantly, the new multi lingual program uses SQL compatible databases (SQLite and Microsoft SQL Server) and is therefore suitable for use by test engineers and medical facilities managers that utilise advanced database structures to hold medical equipment records.

Med-eBase V2.0 can be networked and facilitates a customisable test certificate generator to confirm that the medical device under test is safe for use.

## Uni-Pulse – hand-held defibrillator analyser



### Features at a glance

- Compact and lightweight for ease of carrying
- Bluetooth and USB improved connectivity
- Full range of automatic test programs
- Integrates with Med-eBase software for comprehensive record management

Rigel Medical's new compact, lightweight and portable Uni-Pulse defibrillator analyser features advanced measurement technology to verify the safe operation and functionality of all defibrillators.

The battery powered analyser offers both manual and automatic test programs for testing of all mono-phasic, bi-phasic and pulsed waveform defibrillators.

Bluetooth and USB has been incorporated for improved connectivity, enhanced memory capacity for the storage of results, defibrillator waveforms and test programmes and a clear, easy-to-read colour graphics display screen. An optional paddle adaptor box includes a version with variable loads from 25 – 200 Ohms for compliance with IEC 60601-2-4 requirements.

The colour LCD provides easy navigation around the functions and simulations including defibrillator waveform capture,

accurate energy measurements, cardio synch times, peak voltage and current.

A 12-lead ECG simulation with substantial variation of atrial and ventricular arrhythmias and performance wave forms provides faster, easier and more accurate testing of defibrillators with built-in monitoring functions. Automatic test programs for AED's (Automatic External Defibrillator) leads to fast and effective testing of AED response, interpretation and performance.

Uni-Pulse can also be used with Rigel Medical's Med-eBase PC software to provide enhanced electronic recording and management of medical device safety testing programmes.



# Checking those vital signs



By John Backes,  
Associate Director, Rigel Medical

**Medical devices and equipment used to check for and monitor people's vital signs needs to be checked regularly to ensure they work accurately and safely and do not pose a risk to operators and patients alike. This has led to the development of high performance simulators to undertake vital signs performance testing and verification. To help people understand what's involved, Rigel Medical has produced a free illustrative 'Introduction to measuring and simulating vital signs' booklet, covering the critical issues and explaining ways of testing the accuracy of vital signs**

The main vital signs described are blood pressure (invasive or non-invasive methods), temperature, electro cardiogram (ECG), respiration and blood oxygen saturation (SpO2). All vital signs are related to the operation and functioning of the respiratory system. While the ECG shows the electrical activity of the human heart pumping the oxygenated blood around the arteries, blood pressure is generated. Respiration rates might show any

obstruction in the airways thus affecting the oxygen absorption in the lungs. The core body temperature, together with blood pressure being the most commonly measured vital signs, is maintained through good blood circulation.

To ensure the correct treatment, diagnoses or monitoring of patient's vital signs, it is of critical importance that the vital signs monitor is able to provide accurate data

across all available vital signs. Such accuracy is verified on a regular basis, based on risk assessment, manufacturer recommendations and stages of the monitor's life cycle.

The 'Introduction to measuring and simulating vital signs' booklet covers the performance tests (also referred to as quality or functional tests) that are typically executed using calibrated simulators across a number of applications and are all part of an acceptance test, preventative maintenance cycle or repair.

A typical test cycle for a vital signs monitor might include a visual inspection, self tests (where applicable), electrical safety testing (earth bonding, leakage currents), integrity of the device under test (i.e. leak test, over pressure test), parameter accuracy (temperature, pressure, SpO2, time etc), check alarms (pitch, frequency, volume),



physiological simulations (dynamic patient simulation).

Visual inspections form a critical part of the general safety and performance inspections during the functional life of medical equipment. Visual inspections are a relatively easy procedure to ensure that the medical equipment in use, is in the expected and intended condition as released by the manufacturer and has not suffered from any external damage and / or contamination.

These inspections can include the following: Housing (enclosure; look for damage, cracks etc); contamination, checking for obstruction of moving parts, connector pins, etc; cabling (supply, applied parts and accessories etc); look for cuts, wrong connections, etc; fuse rating; check correct values after replacement; markings and labelling; check the integrity of safety markings and integrity of mechanical parts (check for any obstructions).

The correct function and operation of medical equipment is equally as important as the function it performs.

An incorrect reading or missed condition might have considerable consequences

for the patient therefore the person carrying out the maintenance must be technically competent, appropriately trained and aware of the various parameters being verified.

Planned preventative maintenance is also covered in the vital signs booklet, highlighting how this is an important aspect to prolong the useful life of a medical electronic device. To ensure safety of both the patient and operator, procedures are required to cover visual inspection, electrical safety testing (see IEC 62353), performance or functional testing and record keeping.

Without fully understanding the function and / or operation, any visual inspections, electrical safety tests or functional tests could be incorrect or incomplete. So, ensure that the function and operation of the device under test (DUT) is fully understood before commencing and also, prior to any testing, confirm that the manufacturer's recommendations are available as they often supercede any general inspection guidelines.

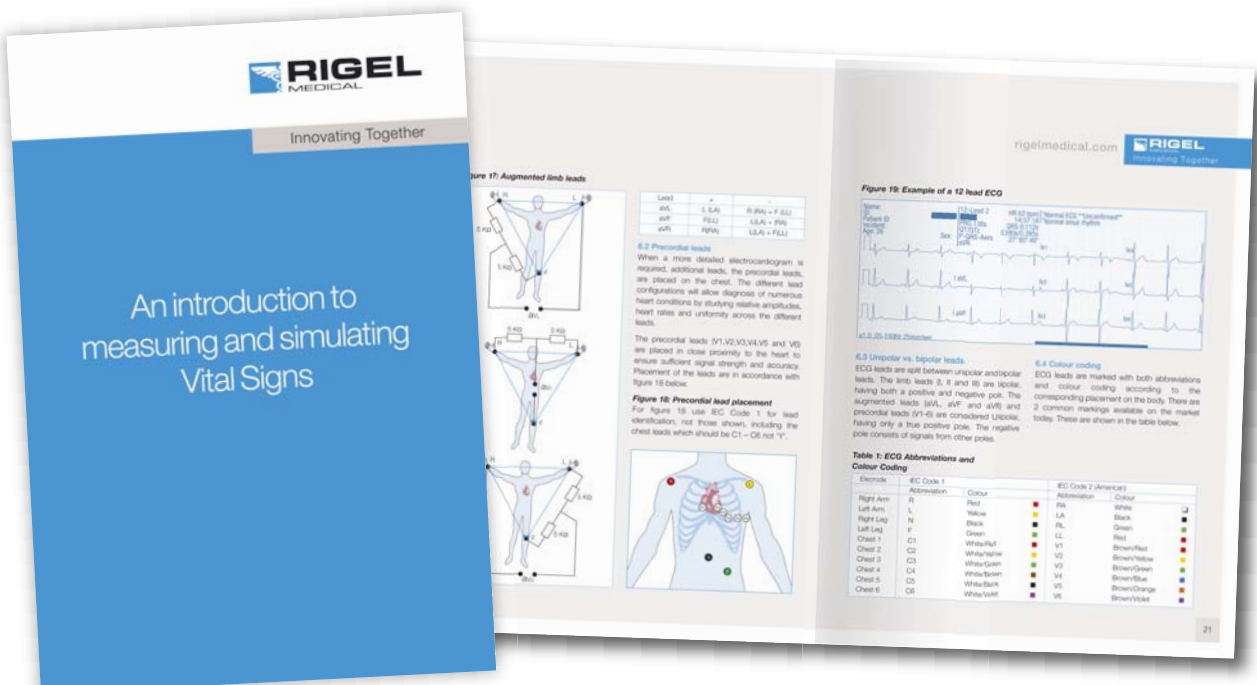
Ensure also that the operator of test equipment is properly trained on both the test equipment and the DUT to get valid measurements and prevent unnecessary danger during the safety test. Always

ensure that the DUT does not pose any danger to the user and/or people within the vicinity of the safety test (e.g. moving parts, open conductors, live components, heat etc).

Make sure manufacturer's instructions are followed and that performance levels are checked against original documentation. Ensure high accuracy and repeatability of simulations and measurement readings (some manufacturers might specify full scale accuracy which will affect the accuracy of low value readings or measurements) and when determining the correct means of testing a specific medical device, make sure that the chosen test procedures are applicable to the DUT and are clearly documented for future use.

Rigel Medical offers a range of test equipment to cover simulation and performance testing as well as a range of electrical safety analysers to meet the IEC 62353 and IEC 60601 requirements. Visit [www.rigelmedical.com](http://www.rigelmedical.com) for a full overview of Rigel's product offering or register online for our free newsletter on future product releases and product innovations.

**For a pdf or hard copy of the booklet, please register online at [www.rigelmedical.com/pulse](http://www.rigelmedical.com/pulse) ↓**



# Vital Signs Simulators Selection Guide

Rigel Medical offers the best range of simulation test equipment to suit your needs.



| ▼ Features             | BP-Sim | SP-Sim | 333 | UNI-Sim |
|------------------------|--------|--------|-----|---------|
| <b>NIBP Simulation</b> | ■      |        |     | ■       |
| Leak test              | ■      |        |     | ■       |
| Over pressure test     | ■      |        |     | ■       |
| Manometer              | ■      |        |     | ■       |
| <b>SpO2 Simulation</b> |        | ■      |     | ■       |
| Artefacts              |        | ■      |     | ■       |
| Chronometer function   |        | ■      |     | ■       |
| <b>ECG Waveforms</b>   |        |        | ■   | ■       |
| Arrhythmias            |        |        | ■   | ■       |
| IBP simulation         |        |        | ■   | ■       |
| Temperature simulation |        |        | ■   | ■       |
| Respiration simulation |        |        | ■   | ■       |
| Manual mode            | ■      | ■      | ■   | ■       |
| Automatic mode         | ■      | ■      |     | ■       |
| Custom test sequencing | ■      | ■      |     | ■       |
| Battery operation      | ■      | ■      | ■   | ■       |
| Data storage           | ■      | ■      |     | ■       |
| Data entry             | ABCD   | ABCD   |     | ABCD    |
| Barcode scanning       | ■      | ■      |     | ■       |
| PC download            | ■      | ■      |     | ■       |
| Direct print facility  | ■      | ■      |     | ■       |
| Weight (kg)            | <1.5   | <1     | <1  | <1.5    |

# Rigel 62353 helps operating table manufacturer improve

A leading supplier of medical equipment has turned to Rigel Medical's 62353 safety analyser to improve the electrical testing of its powered operating room tables and boost service times.

TRUMPF Medical Systems Ltd, based in Luton UK, manufactures and supplies operating room tables to hospitals and healthcare facilities. These have to be regularly tested to ensure compliance with IEC 62353, the standard for in-service and after repair testing of medical electronic devices.

Using the Rigel 62353 enables the nationwide team of field service engineers to carry out electrical safety testing to ensure the operating tables are safe for use by both patients and staff. This means that important electrical safety tests are being undertaken as an integral part of TRUMPF's after sales support, saving time and boosting customer service levels.

Five units are being used by TRUMPF's UK operation, combining the benefits of an automatic and manual tester with advanced data logging to provide improved asset management capability.

Additional units have been supplied to the company's head office in Germany, reflecting strong demand for Rigel products in important European markets.

Alasdair Owen, service manager for TRUMPF Medical Systems Ltd, said the Rigel 62353 was an excellent instrument which has been easy to integrate into the engineering maintenance schedule.

"The Rigel 62353 enables us to comply properly with the requirements of the European standard for in service testing of products.

"It's a very intuitive instrument, offering a single-button test solution which engineers, who have busy service schedules to complete, really appreciate.

"This means that they don't have to stay on site any longer than absolutely necessary, avoiding any inconvenience to hospital staff and services.

"Rigel's after sales service is also very responsive, ensuring we get the best possible advice on how to use the instruments for maximum benefit."

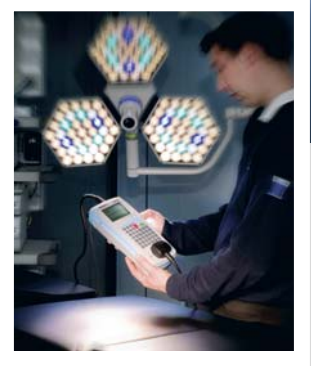
It is the first analyser of its type offering automatic sequencing, onboard data storage and data entry in a lightweight,

easy-to-carry enclosure. Improved battery power provides extended operating life while the instrument's lightweight feature makes it extremely practical and easy-to-transport from site-to-site.

It can store and manage thousands of test records - highly beneficial to field service engineers moving quickly from site-to-site. Also, the capacity to customise test routines, visual inspections and performance tests, which can be downloaded to and from a PC, improves in-service testing capacity.

Make sure you keep abreast of the all the latest news and developments and join in the debate by becoming a member of IEC 62353 on LinkedIn. To become a member, please go to [www.rigelmedical.com/pulse](http://www.rigelmedical.com/pulse) and follow the link for LinkedIn - 62353

**To get your booklet on the IEC 62353 standard, please email [pulse@rigelmedical.com](mailto:pulse@rigelmedical.com) or go to [www.rigelmedical.com/pulse](http://www.rigelmedical.com/pulse)**





## Getting technical

with John Backes

# No comparison: The alternatives for medical device insulation testing

Rigel Medical's John Backes looks at the latest tests used to assess the integrity of insulation in electrical appliances.

It is accepted that electrical currents are a necessary part of medical electrical devices and therefore the electrical industry has implemented stringent procedures and requirements to ensure the safe and effective operation of medical devices, enshrined in the IEC 60601 standard for medical electronic devices.

The risk of unacceptably high electrical fault currents can be minimised through good design i.e. through effective levels of electrical isolation between operator, patient and live parts during normal and fault condition.

The effectiveness of electrical insulation is tested through electric leakage measurements (results in mA or  $\mu$ A) while the level of isolation is often tested using a dielectric or insulation test. A dielectric, or hipot test stresses the isolation by applying up to 4000V AC across different parts of the electronic design. An insulation resistance test applies a lower DC voltage, typically between 250-500V DC, across different parts of the electronic design. The results are displayed in Mega ohms ( $M\Omega$ ).

Despite the traditional merits of a 500V DC insulation test to verify the level of insulation, it has also been recognised this method can be problematic in some circumstances causing damage to the equipment under test and also not indicate the true state of the insulation when presented with an alternating voltage.

Therefore there is a new alternative leakage test within IEC 62353 that applies a typical line voltage (~230V) and frequency (50Hz) as the insulation test source rather than DC. Both have their relative merits and place in periodic testing, provided the different limitations of each test method are understood.

### Insulation resistance

Insulation resistance is normally checked by applying 500V DC between:

1. Input (live conductors, phase and neutral, connected together) and enclosure (protective earth in class 1)
2. Output (Applied Parts) and enclosure (protective earth in class 1)
3. Input (phase and neutral) and output (Applied Parts) for floating type applied parts (BF and CF)

The resistance is measured and compared with the minimum acceptable value to assess pass or fail conditions, which can vary greatly depending on design and test voltage variations.

However, since the insulation resistance test does not power up the appliance, which could be seen as an advantage (reducing the time taken to test and eliminating the danger of moving hazardous parts), extra care should be taken to ensure the equipment switch is in

the 'on' position to complete a meaningful test.

While the outcome of a 500V DC insulation test is quick and safe to do so, in most cases it does not provide a real indication of the effectiveness of the insulation in modern medical devices or the expected leakage values that may be experienced during normal or typical operation. This is due to the increased use of switch mode power supplies that may indicate very high DC insulation resistances ( $>100M\Omega$ ) but when measured with AC, might indicate high leakage due to the greater influence of capacitive and inductive leakage.

Finally, in some electrical equipment, components connected to the live/neutral conductors for EMC filtering or surge protection can significantly influence the measurement, indicating an erroneous failure of the test. On the plus side, the insulation resistance test is relatively quick and easy to perform, which is why it is probably the most widely used.

### Alternative leakage

To verify the effectiveness of insulation while maintaining the speed and safety of a traditional insulation test, an alternative leakage method is contained in the recently published IEC 62353 standard for routine testing of medical devices. The alternative

leakage test is similar in setup as the dielectric strength test (high voltage) and DC insulation test.

The alternative leakage test is done at mains potential and frequency thus representing operational conditions unlike the 500V DC insulation test. This effective and safe method involves the application of a test voltage between the input and output of a medical device.

### Equipment leakage (alternative method)

The Equipment Leakage is performed by placing an AC voltage (~230V, 50Hz) between the mains Input (live conductors, phase and neutral, connected together and protective earth in class 1) against Output (Applied Parts) including the enclosure as shown in the diagrams below (figures 1 and 2).

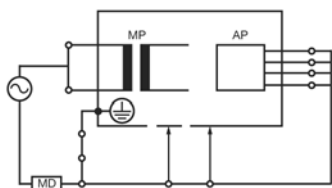


Figure 1 Equipment Leakage Class I Alternative Method

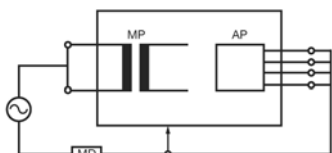


Figure 2 Equipment Leakage Class II Alternative Method

### Applied part leakage (alternative method)

Applicable to Floating Applied Parts (BF & CF) only, the Applied Part Leakage is performed by placing the test voltage (~230V, 50Hz) between the Output

(Applied Parts only) and Enclosure (protective earth in class 1) and Input (phase and neutral) together. This is shown in the diagrams below (figures 3 and 4).

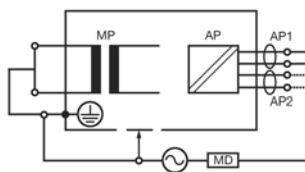


Figure 3 Applied Part Leakage Class I Alternative Method

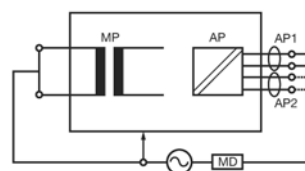


Figure 4 Applied Part Leakage Class II Alternative Method

The test voltage is at mains potential and frequency of 50 Hz (UK mains frequency) which means the leakage paths will be similar to those present when the equipment is in operation. This avoids the problems associated with EMC filtering or surge protection affecting DC insulation tests and provides a more accurate reading of the true insulation taking into account capacitive and inductive elements.

However, the alternative leakage test still has some limitations because any electronic switches present will not be on (as with insulation testing) and relays or other active circuitry that may effect measurements may not be activated.

The results measured with the alternative test can be compared to the IEC 60601 leakage measurements performed with 'open neutral' single fault condition. During a comparison between IEC 60601 earth leakage and the IEC 62353 alternative method, results showed a consistent relationship between the two measurements and are roughly twice the expected earth leakage during normal conditions.

As the equipment under test is not powered up, the alternative method is therefore a safe and quick method of verifying the effectiveness of the insulation and thus the expected safety. As both mains phases are shorted together during the test no mains reversal needs to be performed saving time. This coupled with the more accurate and realistic data make for a safer and reliable test method.

| DC insulation test method |  |
|---------------------------|--|
| Pros                      | Cons   |
| Quick and simple          | May cause damage to device under test                        |
|                           | Frequent infinity readings may mask unit is not switched on! |
|                           | Not suitable for use with 'active' power circuits            |

| IEC 62353 alternative method                                      |   |
|---|---|
| Pros  | Cons  |
| Quick and simple  | Not suitable for use with 'active' power circuits |
| Unlikely to damage device under test                              |   |
| Results relate to real world leakage measurements                 |   |
| zero reading indicates unit is not on or has active power circuit |   |

Although the onus will remain on the manufacturers of medical devices to advise on appropriate tests for their equipment, the new standard will clearly have a significant impact on medical service companies, biomed and clinical engineering departments in the healthcare sector.

Request a full copy of this article from [www.rigelmedical.com/pulse](http://www.rigelmedical.com/pulse)

Rigel Medical's 'A Practical Guide to IEC 62353' is also available at [www.rigelmedical.com/pulse](http://www.rigelmedical.com/pulse) and summarises the standard's methods and requirements.

# New Rigel analyser for electrosurgical devices

Faster and  
easier testing  
and  
calibration



The new high performance Rigel Uni-Therm accurately measures the performance of electrosurgical generators including high frequency leakage, high current, power distribution and patient return plate alarm testing.

Compliant with IEC 60601-2-2\*, the Uni-Therm is capable of verifying and calibrating all major electrosurgical generators whilst guiding the user through all test procedures automatically and most of all safe.

A high power load bank enables performance testing up to 6A RMS with a duty cycle of up to 100% making the analyser an extremely versatile test instrument for calibrating and performance testing of conventional and high power electrosurgical generators.

The large array of internal resistors, ranging from 0-5100 $\Omega$  in 5 $\Omega$  steps provide not only the most accurate and detailed power curves, the Rigel Uni-Therm also advocates safe working practise by providing all necessary resistors within a single enclosure.

Return electrode monitoring capability is carried out using a rotary encoder, which also controls the potentiometer, scaling up and down in manual or automatic mode to capture the alarm using the on-screen dedicated fast key. Data can be stored onboard for future traceability.

Product features include built-in memory, test automation, comprehensive data management facilities and a wide range of in-built resistors, while a large full colour screen displays easy-to-follow, step-by-step instructions to ensure the correct connection to the device under test.

Bluetooth-enabled technology allows wireless connectivity to PCs and other equipment for the fast and convenient downloading of test data and the uploading of the electrosurgical device's power curves and the manufacturer's test specific programmes. Output waveforms can be examined through a built-in scope output which allows for easy confirmation of the desired waveform shape.

The Uni-Therm high performance electrosurgical analyser forms part of a comprehensive range of high performance specialist biomedical test equipment supplied by Rigel Medical.

*\*IEC 60601-2-2 specifies the requirements for the safety of high frequency surgical equipment and HF surgical accessories used in medical practice.*





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July 2012.

## Need to know something about the requirements for the electrical safety testing of medical devices and equipment?

**Q** The requirement for the electrical safety testing of medical equipment is essential to ensure that devices are safe to use by operators and patients alike. Is that why medical devices need to be tested for electrical safety?

*Stephen, London*

**A** Research<sup>1</sup> has indicated that fault currents as low as 10 micro Amp ( $\mu\text{A}$ ) can lead to increased risk of ventricular fibrillation. Such fault currents are only approximately 1% of the current level perceivable by human beings<sup>2</sup>. Many medical devices require a functional electric current to operate, so fault currents or excessive currents can cause a serious hazard to the patient, operator or medical device. The regular and competent electrical safety testing of medical devices is therefore required to ensure that equipment is safe to use.

**Q** Surely there must be some important standards involved in electrical safety testing to ensure user safety? If so, can you tell me what they are?

*Michael, by email*

**A** Electrical safety is standardised throughout the life cycle of medical equipment. From the development stage (type and conformance testing) to testing during preventative maintenance and after repair, test standards cover individual stages of the medical device. There are two important internationally recognised standards to be aware of and understood when considering electrical safety testing: IEC 60601 and IEC 62353.

**Q** I have heard about the importance of IEC 60601 and IEC62353 but am a little bit confused. Can you explain what they are and how they differ?

*Colin, Manchester*

**A** First released in 1977 as IEC 601, the IEC 60601 standard is a type test standard which governs the design and manufacture of electrical medical equipment. It controls all aspects of safety directly or indirectly relating to the handling, use or connection to, of medical equipment. Published in May 2007, the IEC 62353 is the standard by which the recurrent test and test after repair of medical electrical equipment is undertaken. It also provides guidance on how in-service electrical safety testing of

electro medical equipment and systems should take place to ensure they are safe to operate and use.

Although the IEC 60601, which is essentially a design and manufacturing standard, is used by some biomedical and clinical engineering departments and medical service companies as the basis for the testing of medical devices, it does not specifically describe the test requirements for the in-service testing of medical devices. This area of potential uncertainty has been addressed by IEC 62353, which provides a uniform standard for the electrical safety testing of devices in use at operators' premises and covers several potential test scenarios.

**Q** Ground bond testing is important but I have heard that it is the same as earth bond testing? Can you confirm if that's correct?

*Martin, Chelmsford*

**A** Yes, they are one and the same. Sometimes referred to as ground bond testing, this tests the integrity of the low resistance connection between the protective earth conductor and a metal conductive part which might become live in case of a fault on Class I medical devices. A test current (minimum 200mA AC/DC) is applied between the earth pin of the mains supply plug and any accessible metal part via a dedicated earth bond test lead (clip/probe)

N.B It must be noted that high test currents (10A or more) might damage the device under test using functional earth circuits, while low test currents (<8A) could influence the reading due to constriction, pressure, film resistance affecting contact resistance.

**Thanks for some great questions. Please keep them coming and look out for future articles covering these and other topics.**

**If we publish your question you could be in for a chance to win an Amazon Kindle Touch.**

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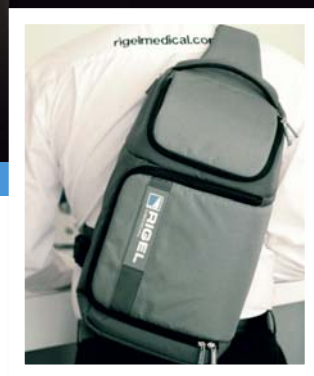
All entrants whose questions are received by email up to and including 31/7/12 will be entered into a prize draw to win an Amazon Kindle. The winner will be drawn at random and notified by email. Rigel reserves the right to publish questions in future Pulse issues and other company literature including websites.

1. Hochberg, Howard M., *Effects of Electrical Current on Heart Rhythm*, *The American Journal of Nursing*, Vol. 71, No. 7 (Jul., 1971), pp. 1390-1394

2. *A healthy human being is able to sense electric currents (feeling of shock) when the level of such current passing through the human body exceeds approximately 1 milli Amp (mA).*

✉ Got a question? Send it to [pulse@rigelmedical.com](mailto:pulse@rigelmedical.com)

# Your hard work just got easier



At Rigel Medical we understand how hard biomedical service engineers and medical physics staff work. Moving biomedical test instruments around shouldn't make your job harder. We've designed the Med-eKit Lite to store and transport all the equipment and accessories you need. Secure, comfortable, durable.

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