See Rigel Medical at MEDICA
Hall 11 Stand C12
We looked through your eyes. And designed the electrical safety analyser of the future.

We asked you for your observations on safety analysers in the field. You saw a need for something more compact and portable than the safety analysers you’d used previously. To see the result, or to contribute your own ideas, call us on +44 (0) 191 587 8730, email us at info@rigelmedical.com or visit www.rigelmedical.com
## Welcome

As you open the pages of the second issue, you join us at an exciting time for Rigel Medical as we receive the Queen’s Award for Export and look to the future with a great portfolio of high-quality, high-performance products which not only meet customer expectations but in many aspects, exceed them. Listening to our customers and investing in product development, will ensure we continue to give you the testers, analysers and simulators that you want.

You also join us ahead of one of the biggest events in the biomed calendar – the MEDICA trade show (14 – 17 November). There’s more inside about what we’ll be showing, notably our new range of performance analysers, but the show is already gearing up to be as big as ever with thousands expected to visit to discover what’s new and catch up with friends, old and new. Visit us at Hall 11, Stand C 12.

This year also sees five years of IEC 62353, an important safety test for medical electrical equipment. We re-visit the standard in our feature lead to see what was happening in the medical devices industry prior to its publication and look at where things stand today.

MEDRAD is one of the world’s leading suppliers of medical equipment for hospitals and healthcare facilities – and also the focus of this issue’s case study. Find out how they use the Rigel Medical 288 electrical safety analysers to improve electrical safety testing throughout the UK and Western Europe.

Understanding what the important test scenarios are and the importance of testing equipment while it’s in use in a hospital or healthcare facility are covered in our ‘Q&A’ section. There’s also a chance for you to take part in our competition to win a Nexus 7 Tablet and catch the latest industry events in our ‘What’s On’ section.

We always 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 will feature some of them in future issues of Pulse.

**Best regards**

John Backes  
Editor, Pulse
Seaward has received its Queen’s Award for Enterprise following international sales success for its Rigel Medical biomedical test products.

The award, given each year to those companies demonstrating outstanding export achievement, was presented by the Lord Lieutenant of County Durham, Sir Paul Nicholson, at a special event.

The Queen's Award reflects Rigel's market growth and investment in overseas sales and marketing strategies that have successfully boosted the international profile of the brand.

Receiving the award were Rod Taylor, managing director of the Seaward Group, and John Backes, Associate Director of Rigel Medical, who said: “The Award continues to be a high profile and highly respected achievement recognised worldwide. I’m sure it will become a major marketing asset as part of our continued export drive over the coming years.”

John Backes added that MEDICA is one of the most important platforms for showcasing the benefits of the company’s product range. “I’m sure the many features and benefits of the Uni-Therm and Multi-Flo alongside all our products will be of significant interest at MEDICA to both existing and potential new users.”

Elsewhere, plans have been finalised for MEDICA where leading the way for Rigel Medical will be the Multi-Flo infusion pump analyser, which meets all the IEC 60601-2-24 requirements and can be used for high and low flow, occlusion, back pressure and bolus measurement and features variants of one, two and four independent channels.

The Rigel Uni-Therm high current electrosurgical analyser which is able to test accurately all modern low, medium and high current electrosurgical generators, will also be showing alongside the UNI-PULSE defibrillator analyser which verifies the safe operation and functionality of defibrillators and AEDs.

All the instruments can be used with Rigel Medical’s Med-eBase PC software to provide enhanced electronic recording and management of medical device safety testing programmes.

* More about the industry-leading benefits of the Multi-Flo in our ‘Product Review’ on page 10.
The UK medical device market can benefit significantly from over £200 million funds of grants that are available to UK businesses, according to the independent research organisation TBAT Innovation Ltd.

The grants include the Biomedical Catalyst funding, which since April offers support to UK small and medium-sized enterprises (SMEs) and academics developing solutions to healthcare challenges. The grants are supported by the Medical Research Council and the Technology Strategy Board (TSB).

In addition, the annual SMART programme, available from the TSB, provides £30 million of grants to SMEs in the areas of science, technology or engineering.

“The combined grant funds this year, which can be applied for throughout 2012, make it a very significant time for investment in this sector, but people need to remember the process is a competition and therefore it’s important to get it right,” said Matt Symonds, director of TBAT.

TBAT offers its clients help applying for funding sources and, in the past 12 months, has leveraged over £6 million worth of grants for clients. More at www.tbat.co.uk

The EU directive on the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment (RoHS) is a fine example of why device manufacturers making instrument and equipment purchasing decisions today must anticipate the medical device designs of the future, commented blogger Dave Selin.

He says RoHS restricts the use of lead and other potentially hazardous substances such as cadmium and mercury that historically have been at the heart of electronic products of all kinds. The medical device industry has been exempted from compliance for now by the EU because of product failures that might occur if substitute materials prove unreliable over the long term in real-world conditions.

Many agency reviewers are now at work to determine if implanted devices should be permanently excluded from RoHS restrictions. Meanwhile, research continues on the likes of lead-free alloys for use in device electronics. In other words, nobody really knows what the future holds and how product designs will need to change in the coming years or decades.

This is one of many examples showing why purchasing decisions must take into account much more than the grid of products being made today. Test instruments and assembly equipment must be evaluated in terms of how flexible they are in adapting to product specs of the future.

Read in full at http://medtechinsider.com

Manufacturers have the option to implement e-labeling for medical devices following the final wording of draft regulations gets the stamp of approval.

The news follows the publication of the EU Council and European Parliament regulation on the use of e-labelling - or electronic instructions for use (IFU) as it is sometimes called.

The scope of the regulation means that only devices for professional users are able to use e-labelling and is applicable to Medical Devices Directive 93/42/EEC (as amended by 207/47/EC) and Active Implantable Medical Devices Directive 90/385/EEC.

This includes standalone software, devices and accessories with a built-in system displaying IFUs, fixed installed medical devices and accessories and active implantable devices. The use and provision of e-labelling is set to remain at the discretion of the manufacturer and will not be mandatory for all medical devices.

Go to www.standards.org for more information.

The EU vigilance system for medical devices must be further developed in order to allow a coordinated analysis and a coherent EU-wide response to safety issues.

That’s one of the findings noted in the Council of the European Union conclusion on innovation in the medical device sector.

The Council also says it is desirable to consider a European coordination mechanism founded on a clear legal basis and mandate in order to ensure efficient and effective coordination between national authorities while creating a level playing field.

Synergies with existing bodies and relevant expertise should also be explored when deciding on the mechanisms for such coordination. Consideration should also be given to which activities are best carried out in cooperation between member states.

Read the full conclusion at www.europa.eu
As its full title implies, IEC 62353 Medical Electrical Equipment – recurrent test and test after repair of medical electrical equipment, defines the test requirements to ensure the in-service electrical safety of electromedical equipment and systems. But five years on from initial publication where do we stand? To understand this - and the benefits provided by IEC 62353 - we must look at what was happening in the medical devices industry before publication.

Prior to 2007 there was no internationally accepted standard for electrical safety testing during preventative maintenance and few local standards existed to cover this subject but today, leading medical device manufacturers and hospitals have incorporated the test philosophy of IEC 62353 or are in the process of doing so. Uniform test procedures and practical approaches to testing medical devices once in-use, have lead to an unambiguous and correct approach to safety testing, giving peace of mind. The following is a brief description of the most common tests from IEC 62353 and where their strengths have come into play.

### Protective Earth Bond Test

An earth bond test proves the low resistance integrity between the ground pin of the mains plug and any touchable metal conductive parts on the enclosure, which may become live during fault situations in Class I medical devices. Manufacturers of medical devices have welcomed the reduction in test current requirements in IEC 62353, which now specifies a minimum test current of 200mA, either AC or DC instead of the high current 25A test in IEC 60601 which are meant to stress the protective earth path.

Unlike low test currents, high test currents do provide a practical problem during the preventative maintenance, leading to potential damage to functional earth circuits and masking of poor contact resistance in older mains cabling. Protective earth problems are common, caused by either partial or complete restriction in the current path due to mechanical damage or wear and tear.

### Protection against electrical shock

In today’s world, electricity is taken for granted and its benefits far outweigh the dangers – it would be difficult to envisage modern life without electricity. And so it must be accepted that electrical currents referred to as functional current - are a necessary part of modern medical devices. IEC 60601-1:2006 defines leakage current as ‘current that is not functional’ and is an unavoidable aspect of electronic designs. However, the risk of unacceptably high leakage currents can be managed through effective levels of electrical insulation/isolation.

Increased leakage currents can occur due to reduced insulation quality as a result of component failure (inevitable), mechanical damage leading to reduced creepage distances, evident and non-evident spillage of liquids inside the medical device, degrading of insulation materials due to ageing or abrasion and environmental conditions and unintentional misuse of the medical device.

Considering that electrically conductive parts can be placed in close proximity to the heart, and that electrically conductive parts from a medical device can be connected to a patient for hours even up to several days or weeks during treatment or monitoring, the risk of micro and macro shocks cannot be understated, especially when considering that the patient might be vulnerable or have impaired ability to move or communicate.

The following table provides an overview of the different means of protection against electrical shock and how the effectiveness is tested.

<table>
<thead>
<tr>
<th>Means /Stage</th>
<th>Human</th>
<th>Design</th>
<th>In use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protection</td>
<td>Skin</td>
<td>Isolation &amp; Bonding</td>
<td>Leakage &amp; Bonding</td>
</tr>
<tr>
<td>Means</td>
<td>60k~100kΩ</td>
<td>IEC 60601</td>
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</tr>
<tr>
<td>Kind</td>
<td>Dependent on patient condition</td>
<td>Type testing till destruction</td>
<td>Routine testing</td>
</tr>
<tr>
<td>Considerations</td>
<td>Type of treatment: invasive</td>
<td>Test environment</td>
<td>Alternatives to type testing</td>
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Five years of IEC 62353

By John Backes, Associate Director, Rigel Medical
Human skin acts as an electrical insulator and can limit the amount of current passing through the muscle tissues and vital organs like the heart. Body impedance (hand-to-hand or hand-to-foot) is considered 1kΩ but this drops significantly when the current path is reduced i.e. when the current path starts and exits closer to the heart (microshock). In such cases, body impedance can drop to 10Ω.

To standardise the leakage measurements, a common measuring device (body model) is specified in IEC 60601 and IEC 62353: See figure 1.

The effectiveness of electrical insulation is tested through electric leakage measurements (results in mA or µA).

IEC 62353 defines two different kinds of leakage current tests: the equipment leakage current is the total leakage deriving from the applied parts, chassis and mains parts combined to ground. This can also be referred to as leakage on the input of the medical device as leakage is predominately generated in the power supply.

The applied part leakage current is the total leakage deriving from the combined patient leads within an applied part to ground and any conductive or non-conductive parts on the chassis. This can also be referred to as leakage on the output of the medical device.

During this test, the effectiveness of the dielectrics of the floating applied parts is determined.

The strength of IEC 62353 is that leakage measurements are done primarily under single fault condition, reducing the need for repeated measurements - as is done under IEC 60601. Furthermore, IEC 62353 measurements in patient environments are always ideal. Secondary ground due to functional grounding or connections in a medical system can lead to invalid readings (false pass) caused by the internal resistance of the measuring device. Leakage currents are primarily referenced to ground as this is the most common danger to humans. When measuring on an isolated mains supply, high leakage currents in medical devices can be masked by the line isolators in hospitals. As such, a false pass might occur when a medical device has generated a fault. This will only become apparent when the medical device left the isolated mains location.

Testing leakage under these conditions is not covered by IEC 60601 but is considered in IEC 62353 by offering different methods for testing leakage: the direct leakage, differential leakage and the alternative methods.

The direct leakage method places the measuring device directly in the leakage current path, to mimic the current path through an operator or patient. This method is a direct comparison with the IEC 60601-1 tests and can measure lower leakage values typically of less than 10-50µA.

However, one of the main disadvantages of this method is that the 1kΩ resistor (body model) is connected in series with the protective ground conductor which will form an ‘equal’ parallel connection with the human body thus forming a potential hazard to the operator.

Another disadvantage is that secondary ground connections will produce a lower reading, thus potentially allowing a faulty equipment to pass the test. The Direct Method does therefore require a fully isolated Device Under Test (DUT) and must be performed on a TN (Terre Neutral) supply and in both polarity of the incoming mains to guarantee measurements are taken at the maximum potential leakage current. The method is applicable to both equipment and applied part leakage. See figure 2 & 3.

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**Expert advice (cont.)**

The differential leakage method is based on inductance, the same principles and an RCD (Residual Current Detector), measuring the imbalance between the line conductors. The advantage is that no additional impedance is used in the test setup, allowing the possibility to measure leakage even when a secondary earth is present. A possible disadvantage is the reduced accuracy at lower leakage values in the region of 10-50 A. This method is applicable to equipment leakage only. See figure 4.-

Similar to an insulation test done at mains frequency and potential, the benefit of the alternative leakage method over a DC insulation test is that it gives a realistic indication of expected capacitive leakage and test voltages do not exceed the design limits of the electronic designs unlike the 500VDC used in insulation testing.

Leakage current measurements achieved using the alternative method are highly repeatable and provide a good indication of deterioration in the dielectrics of the medical device under test. Typically, the alternative leakage will result in double the amount of leakage when the DUT is powered on. This is due to the mains test voltage being present on both the live and neutral parts of the circuit.

The alternative equipment leakage provides identical results to the IEC 60601 ground leakage under open neutral fault condition and is applicable to both Equipment and Applied Part leakage. See figure 5 & 6.

**No compromise**

IEC 62353 plays a seminal role in providing an easy way to assess the electrical safety of medical devices by providing a summary of leakage tests aimed at giving quick and easy comparison with previous and or expected reference values. And thanks to IEC 62353, electrical safety testing has become affordable, manageable, accurate and quicker, creating more time for equally important aspects of preventative maintenance. Updates to IEC 62353 are expected in the coming years with perhaps greater emphasis on applying the standard even as part of acceptance and end-of-line production testing.

There are still ways to improve our safety and wellbeing by collecting and analysing data in standard formats. This is now possible with IEC 62353, providing concise information for manufacturers and operators which can lead to improvements in product design and provide an important reference when evaluating new medical devices.

A free guidance booklet on IEC 62353 is available for download at www.rigelmedical.com/pulse
One of the world’s leading suppliers of contrast injectors is using Rigel Medical 288 electrical safety analysers to improve the safety throughout the UK and Western Europe.

MEDRAD UK Ltd is a manufacturer and supplier of medical contrast injectors for hospitals and other healthcare facilities, which enable or enhance diagnostic and therapeutic medical procedures for computed tomography, magnetic resonance, and cardiovascular applications.

The company’s field service engineers use the 288 analysers as a highly cost effective, versatile and portable testing solution, enabling them to quickly and accurately undertake over 1,500 safety tests a year in the UK alone during the routine service and maintenance of MEDRAD’s installed base of contrast injectors.

These are used to inject a contrast agent during a CT or MRI scan to intensify the image and, currently, MEDRAD has more than 15,000 on its UK and Europe installed base.

A further benefit is that the tester can easily interface with the engineers’ portable printers, which are carried in their laptop bags. Using the Bluetooth facility enables test results to be printed out while the engineer is onsite and left with the customer as part of the field service report.

The 288s are also used for testing the electrical safety of MEDRAD’s MRI compliant Veris range of vital signs patient monitors. Adam Reid, the company’s UK Service Manager, said:

“The 288 is an excellent instrument, providing a cost effective, high end testing solution. The engineers find it easy-to-use and appreciate the fact that it’s compact enough to carry around with them.

“It incorporates a good range of features for a tester of its size, while the connectivity benefits are particularly impressive.

“The ability to import and export data is also a particularly beneficial feature, enabling us to store test information which can then be easily retrieved and used for audit purposes.

“Rigel provides excellent aftersales support, which is another important reason why we use their products. Product training has been very good while they have been very responsive to our needs.”

The Rigel 288 incorporates easy-to-follow menu driven instructions for simple operation and test control of all IEC 62353 required electrical safety tests in manual, semi automatic or fully automatic test modes.

Available as part of a special test kit is the new battery operated Test ‘n’ Tag Elite printer which provides an easy way to generate tamper proof barcode pass-fail labels or result print outs.

The Elite printer also has the additional ability to design and print customised logos or contact details on every label printed. This not only gives a clear indication of the electrical safety of the medical equipment, but also a simple way of providing contact details in the event of unexpected service requirements.

Each label offers a cost effective way of enhancing customer service and is unique to the Rigel 288. The Elite can also be used with thermal paper for on the spot printing of test results using the industry standard 50mm wide paper.

For traceability and safety audit purposes, wireless connection also means that data from the Rigel 288’s large internal memory can be transferred immediately and directly from the tester to PC-based record keeping systems at the touch of a button.

The Rigel 288 forms part of a range of Safety Analysers from Rigel Medical. For more information visit www.rigelmedical.com/pulse
The high performance Multi-Flo infusion pump analyser meets the requirements of IEC 60601-2-24 and provides high and low flow, occlusion, back pressure and bolus measurement.

Designed to fully meet the IEC 60601-2-24 test requirements, the Rigel Multi-Flo is a truly valuable test tool for those requiring fast and accurate assessments and calibration of flow rates, pressure and volume - fast and error-free asset information can be directly entered into the Multi-Flo via a compact Bluetooth barcode scanner or an optional keyboard.

Multi-Flo features variants of one, two and four independent channels - each channel can be tested simultaneously across a range of 100 µL (microlitre) to 1,500 mL per hour with results stored in the instrument's large internal memory. Trumpet curves and test programmes can also be stored while an upgraded colour graphic screen ensures test results can be displayed and read easily.

Instantaneous flow measurement gives the benefit of faster test times at low flow rates while the ability to detect flow rates from 10µL/hour, makes the Multi-Flo infusion pump analyser a versatile tool for all types of infusion.

A rugged and compact all-in-one housing with integrated infusion program memory makes the Multi-Flo completely stand-alone. Onboard memory stores test data and allows fast transfer to the PC for traceability. An upgraded version of Rigel’s Med-eBase software provides test templates, custom test certificates and the ability to control and configure the Multi-Flo infusion pump analyser.

The Multi-Flo is the latest addition to Rigel Medical’s product offering and is part of a range of advanced, high performance analysers, simulators, testers and accessories from Rigel Medical.

Find out more about the Multi-Flo infusion pump analyser and the other products in Rigel’s performance analyser range by visiting: www.rigelmedical.com/pulse
Need to know something about the requirements for the electrical safety testing of medical devices and equipment?

A third – after service and repair test – is done following a repair or upgrade. This is often part of a service carried out by a hospital’s own mechanical or clinical engineering team. More rigorous electrical safety testing may be required following the replacement of components or reconfiguration of medical devices.

Q It’s important to test equipment while it’s in use in a hospital or healthcare facility, so can you tell me what are the main in-service tests?

Gary, Scotland

A After an initial visual inspection is undertaken to check for damage, integrity of enclosure and patient connections etc to the device under test, there are three electrical safety tests that should be completed: an earth bond test, an insulation resistance test and leakage measurements.

Q Electrical current leakage, even a small amount, can be a source of injury or death, so does IEC 62353 define leakage and, if so, how’s it measured?

Craig, Bristol

A IEC 62353 defines two different kinds of leakage current tests: equipment leakage current and applied part leakage current. Equipment Leakage is in affect the leakage produced by the whole equipment and is predominately as a result of leakage in the power supply. Equipment Leakage can thus be considered as leakage currents produced as a result of insulation / dielectrics on the input. - Applicable to floating applied parts (BF & CF only), the Applied Parts leakage, is the leakage as a result of insulation / dielectrics on the Applied Parts, or considered as output.

There are three ways to measure leakage currents as defined by IEC 62353. The direct leakage method measures the true leakage directly in the path of the current through a body model (measuring device) to earth and is highly accurate when compared to other methods. The differential leakage method determines the leakage current by measuring the imbalance in current between the live and neutral conductor. This method measures the total equipment leakage current. The third is the alternative method which is similar to the insulation test but carried out at actual mains frequency instead of a DC voltage. The live and neutral conductors are shorted together and a floating, current limited mains voltage is applied between the mains parts and other parts of the equipment.

Q I understand that there are some important test scenarios. What are they?

Stewart, by email

A The acceptance test, or initial reference test, is carried out before a new medical device can be judged fit-for-purpose and approved for use by the user. It’s not just limited to an electrical safety test – other basic functions are checked to confirm the device operates correctly. Routine testing is done at fixed time intervals depending on the manufacturer’s recommendations. Again, testing is not necessarily limited to safety and often includes others to verify that the device under test continues is functioning correctly.

Thanks for these questions. We’re here to help with any concerns you may have so get in touch with your questions and look out for future articles covering these and other topics. Send it to pulse@rigelmedical.com for a chance to win a Nexus 7 Tablet.

Got a question? Send it to pulse@rigelmedical.com for your chance to win a Nexus 7.
Introducing the Rigel Uni-Pulse defib analyser.

The Rigel Medical Uni-Pulse quickly and safely tests the performance of all defibs and AEDs. It displays full waveforms in colour. Handheld with on-board memory, the Uni-Pulse is the ultimate way to cut downtime for your life saving equipment.

For further information please visit www.rigelmedical.com or call us on +44 (0)191 587 8730

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