Issue 6 | May 2015

the Pulse

Expert news and advice for the medical industries

Siemens put the Rigel 288 to the test

Issue #6

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Publisher: Rigel Medical, Seaward Group USA, 6304 Benjamin Road, Suite 506, Tampa, Florida, 33634, United States
Editor: John Backes
Distribution: www.rigelmedical.com
Email: pulse@rigelmedical.com
Tel: 813-886-2775

Welcome

I'm delighted to welcome you to this edition of Pulse magazine, bringing you expert views and advice for the medical devices and equipment testing sector.

Firstly, we would like to invite you to join us at **AAMI (June 5-8 2015, in Denver, Colorado), booth 428,** a key event on the medical devices and equipment calendar.

Rigel will be showcasing the new, innovative PULS-R, which forms one half of the world's smallest all-in-one vital signs solution (more inside).

Look out too for the latest industry news from around the world and our article on how Siemens, a leading healthcare equipment manufacturer, uses Rigel technology for improved compliance testing.

We also take an in-depth look at the new edition of the IEC 62353 standard which applies to 'Medical electrical equipment – Recurrent test and test after repair of medical electrical equipment', and answer some of your questions in our regular 'Question Time' slot.

As always, we'd love to hear what you have to say, so please feel free to get in touch with your news and views. They'll be appreciated and we'll try to feature some of them in the next issue of Pulse.

In the meantime, enjoy this edition and don't forget to come and see us at AAMI in June.

Best regards

John Backes Editor, Pulse

What's On

AAMI
June 5-8 2015,
Colorado Convention Centre,
Denver, USA

MD Expo
October 21-23 2015,
Red Rock Casino Hotel,
Las Vegas, USA

Medica
November 16-19 2015,
Dusseldorf Fairgrounds,
Germany

Smallest all-in-one vital signs solution stars at AAMI

The world's smallest all-in-one vital signs solution will be the the highlight of the Rigel Medical display of advanced medical device analyzers, electrical safety testers and simulators at AAMI.

Rigel's hand-held vital signs simulator Uni-Sim - capable of undertaking six synchronised vital signs parameter tests simultaneously - has been linked with the new PULS-R SpO2 simulation finger to provide improved vital signs simulation and measurement.

Uni-Sim can check NIBP, SpO2, ECG, temperature, IBP and respiration functionality in a single test, while the compact Rigel PULS-R universal SpO2 simulation finger can produce accurate SpO2 simulations in 1% resolution from as low as 30% using the pre-programmed manufacturer specific R-curves. It can also be configured to meet customer specific R-curves via a simple-to-use configuration tool. This improves the detection of degrading and inaccurate SpO2 probes, reducing incidences of failure and providing the user with peace of mind.

The Multi-Flo infusion pump analyzer will also be on display, which leads the way in high and low flow, occlusion, back pressure and bolus measurement and meets the requirements of IEC 60601-2-24.

USA Business Development Manager, Jack Barrett said: "We are committed to investing in high performance products to provide customers with what they want. I'm sure the many features and benefits of all our products will generate significant interest among visitors to the show."

For more information on the PULS-R or to download your free copy of our in-depth guide to measuring and simulating vital signs visit **www.rigelmedical.com/puls-r.**

New FDA test to standardize medical device labels

The US Food and Drug Administration (FDA) plans to study whether it could standardize device labelling with the use of new content and format standards now under development.

At present, there are no regulations defining a standardized approach for how content should be structured or formatted for medical devices. This is considerably different than the requirements for other FDA-regulated products, such as food or pharmaceutical products, which must adhere to strict requirements regarding everything from the font size and required information to layout and required statements.

Now the agency says it wants to move forward with an additional study on standardized device labelling. It plans to compare labelling from six different types of medical devices using two different "standard content and format" labels being developed by FDA researchers.

The study is yet another indication that the FDA is seriously considering how to standardize device labels, and its second study could mean new standards could be arriving within a few years.

Read in full at: **www.raps.org**

EU move on medical devices' Directives

The European Parliament has voted on new legislation to replace the current directives on medical devices and in vitro diagnostic medical devices. The draft text reflects many of the concerns put forward by the European Office on behalf of the NHS and will include the following changes:

- Wider, clearer scope for EU legislation on medical devices – extended to include, for example, implants for aesthetic purposes, and clarified as regards genetic tests
- Stronger supervision of independent assessment bodies by national authorities
- More powers for assessment bodies to ensure thorough testing and regular checks on manufacturers, including unannounced factory inspections
- Clearer rights & responsibilities for manufacturers, importers and distributors, which would also apply to diagnostic services and internet sales
- Extended European database on medical devices (Eudamed), will provide comprehensive information on products available on the EU market. Non-confidential data will also be publicly available
- Better traceability of medical devices throughout the supply chain – enabling a swift and effective response to safety problems (e.g. recalls)
- Stricter requirements for clinical evidence to support assessments of medical devices
- Updated classification rules dividing medical devices into four different risk categories and health & safety requirements, including labelling rules – to keep pace with technological and scientific progress
- Better coordination between national surveillance authorities, with the commission providing scientific, technical and logistic support
- Existing international guidelines to be incorporated into EU law.

Once adopted, the new regulations will replace the existing medical devices and in vitro diagnostic medical devices Directives.

Read in full at **www.nhsconfed.org**

Global refurbished medical equipment market to hit more than $9 billion by 2019

The global refurbished medical equipment market is expected to grow at a compound annual growth rate (CAGR) of 12.5 percent and reach $9.37 billion by 2019, according to a new MarketsandMarkets report.

The market includes operating room, medical imaging, cardiology, intravenous therapy systems, endoscopy equipment, patient monitors, defibrillators, intravenous therapy systems, intensive care and neonatal intensive care units, blanket warmers, autoclaves, suction pumps, sequential compressor devices, stretchers, cath labs, stress test systems, heaters/coolers, dry imagers and beds.

Financial challenges are increasing the global interest in low-cost refurbished medical equipment and growing privatization in the health care sector is also driving the market. But at the same time, the market is restricted by the lack of standard policies for the sale and use of refurbished medical equipment and a public institutional stance against purchasing the equipment.

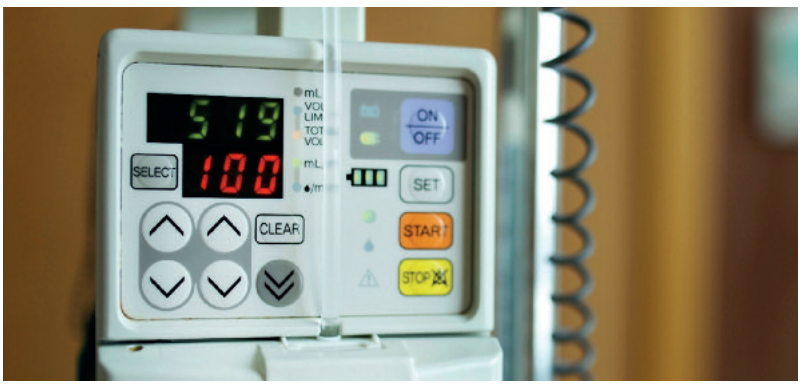
In 2014, North America made up most of the global market, followed by Europe, but the Asia-Pacific region is projected to gain momentum and grow at a CAGR of 13.7 percent from 2014 to 2019. That is being driven by privatization, reduced reimbursement rates, a growing population base and an increase in low budget hospitals and clinics.

The emerging markets, including India, Brazil, and Mexico hold great potential for refurbished medical equipment companies.

Medical tourism is growing in those regions and there is also an increase in the population bases and privatization.

As of 2014, the global refurbished medical equipment market was dominated by GE Healthcare (UK), Philips Healthcare (Netherlands), and Siemens Healthcare (Germany), which together accounted for about 41% of the market.

More at **www.dotmed.com**



Introducing IEC 62353: 2014

John Backes, Associate Director – Rigel Medical, looks at IEC 62353 - and the 2014 additions - and how it compares against IEC 60601 for medical electrical equipment testing.

For decades, medical electrical equipment (ME equipment) has been subject to extensive approval processes, from clinical trials, to type testing, all the way through to end of production line testing, to ensure its safety and performance. In addition, manufacturers recommend regular inspections to ensure there's no risk or harm[i] to the patient and operator during its useful life.

Figure 1: Safety test stages

In 2007, the IEC (International Electrotechnical Commission) published the dedicated IEC 62353 standard for "Recurrent test and test after repair of medical electrical equipment". Since being introduced, the IEC 62353 standard has been followed by many of the leading manufacturers of ME equipment and is now commonly used for routine electrical safety inspections.

IEC 60601

ME equipment must meet the safety and performance requirements as set out by the IEC 60601 (a harmonized standard), which has been adopted by all IEC member states. All tests relating to the electrical safety of ME Equipment can be categorized into two categories:

- **MEANS OF OPERATOR PROTECTION (MOOP)** - Means of protection for reducing the risk of electric shock to persons other than the patient
- **MEANS OF PATIENT PROTECTION (MOPP)** - Means of protection for reducing the risk of electric shock to the patient

ME equipment must be designed to reduce the amount of leakage current to an acceptable and safe level - as low as 10μA.[ii] This is achieved by separating high electrical potentials from any conductive parts, accessible to the operator or patient. Dielectric strength is proven by applying a high voltage between high and low electrical potentials. However, this could lead to a breakdown of the isolation and would therefore be referred to as a destructive test.

A safer way to test the effectiveness of dielectrics is to perform a number of electrical leakage tests, such as leakage originating from the power supply to the enclosure (MOOP) or protective ground wire (MOOP & MOPP) or even to the patient connected parts (MOPP).

Testing the protective ground circuit design for sufficient current carrying capability is achieved by stressing the design, passing a minimum test current of 25 Ampere RMS through the circuit for a minimum of 10 seconds. At these current levels and time duration, enough energy will be created to convert current into thermal heat. By observing the thermal profile of a design, one can establish parts of the design that might need to alter in order to reduce the electrical resistance and thus the converted energy;

$$E = I^2 \times R \times T$$

Conducting such tests during the development and approval stage of a product, provides sufficient levels of confidence that the ME equipment meets the design requirements of IEC 60601.

Once a design is approved for manufacturing and marketing, one can argue that a subset of tests will suffice to ensure the product has been built and assembled to the required product quality and safety requirements. This subset of tests is commonly referred to as routine tests and are not clearly defined in IEC 60601 thus can vary between manufacturers and product designs. It's for this reason that the new IEC 62353:2014 makes a recommendation that IEC 62353 can be used during final testing and testing before putting a piece of ME equipment into service.

IEC 62353:2014

Following the need for a unified approach to routine testing, the first edition of IEC 62353 brought together a number of tests to provide an appropriate approach to test for MOOP and MOPP dielectric integrity via two distinct leakage current tests:

- **EQUIPMENT LEAKAGE** - Testing the total leakage generated from the incoming mains to the rest of the equipment (confirming integrity of the MOOP)
- **APPLIED PART LEAKAGE** - Testing that the floating applied parts (BF&CF) remain at an acceptable floating level (confirming integrity of the MOPP)

Each leakage current is undertaken under single fault condition "open ground" for equipment leakage and "mains on applied parts" for applied part leakage.

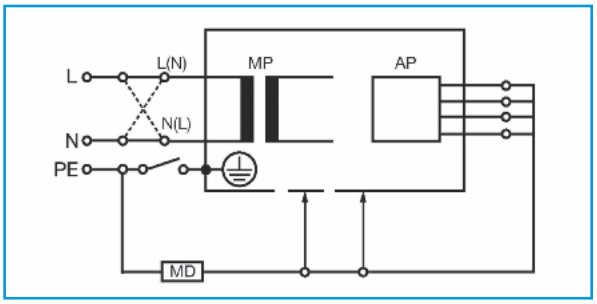


Figure 2: Example of an equipment leakage test (class 1)

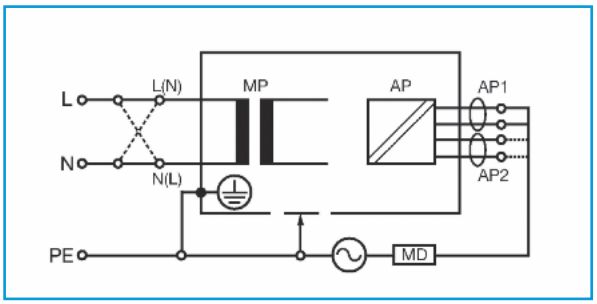
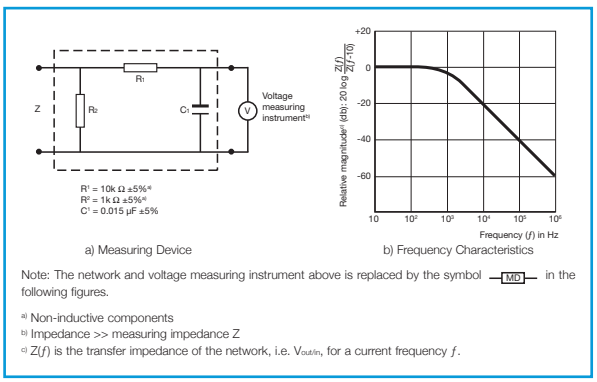


Figure 3: Example of an applied part leakage test (class 1)



Note: The network and voltage measuring instrument above is replaced by the symbol —MD— in the following figures.

[a] Non-inductive components
[b] Impedance >> measuring impedance Z
[c] $Z(f)$ is the transfer impedance of the network, i.e. $V_{out/in}$, for a current frequency f.

Figure 4: Example body model

The leakage current is measured using an electrical circuit, referred to as the "measuring device" or more commonly known as the "body model", which consists of a 1000 Ω resistor and a parallel RC network to reflect a certain frequency response of the human body (>1kHz).

Differential leakage and secondary ground errors

When several medical devices are connected with each other (e.g. via detachable leads), leakage measurements with a 1kΩ body model could result in near zero values. This is due to the lower resistance of secondary ground paths compared to the 1kΩ measuring device. When secondary ground paths are present, IEC 62353 offers a differential method for checking equipment leakage to avoid false positives.

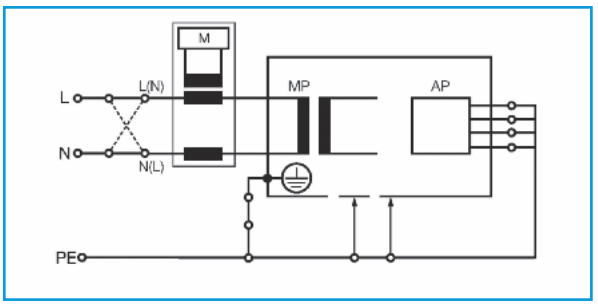


Figure 5: Example of equipment leakage, differential method (class 1)

Alternative leakage

The alternative leakage method is offered when testing can, or needs to be done without powering up the ME equipment. By shortening the hot and neutral wires, this test provides supplied mains potential on both the hot and neutral parts of the circuit. This results in roughly double the expected leakage value when compared to tests under normal mains conditions. The source for the supplied mains voltage is current limited (3.5mA), allowing for a safe approach to leakage testing when high leakage currents are expected.

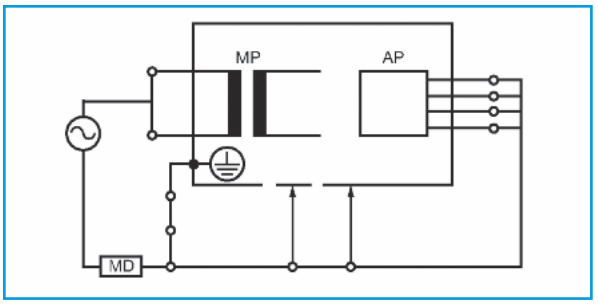


Figure 6: Example of equipment leakage, alternative method (class 1)

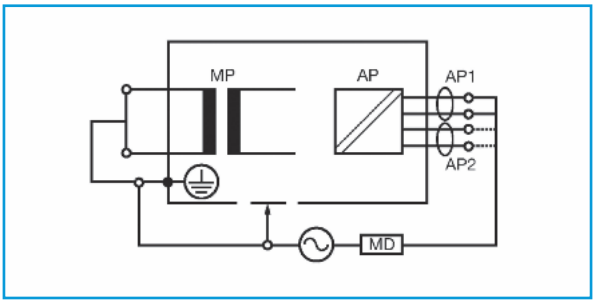


Figure 7: Example of applied part leakage, alternative method (class 1)

Introducing IEC 62353:2014 (cont.)

Ground continuity measurement and common errors

Checking the protective ground during routine testing is different from that undertaken during the type test approval. During routine testing, the focus is on the quality of the protective ground. Testing using a high current can temporarily repair poor mechanical contacts[iii] and therefore mask any quality problems caused by aging.

Lower test currents, typically less than 8A RMS, are unable to temporarily overcome contact resistance and thus highlight quality problems due to aging. Therefore, IEC 62353 recommends that protective ground connections are tested with a 200mA test current. When a DC source is used, the resistance must be measured for both the polarity of the DC test current and the highest test recorded.

Additions in IEC 62353:2014

One of the most significant additions to the 2014 edition is the recommendation to test to IEC 62353 at the final production line stage and before equipment goes into service. This will allow recurrent testing to be directly comparable with factory tests, providing easier observation of any variations. New in the IEC 62353:2014 edition are a number of suggested leakage tests that would isolate the touch leakage current or patient leakage current should a manufacturer identify a need to isolate a particular leakage current. Both tests form part of the equipment leakage current.

The 500V DC insulation tests have also been supplied with recommended pass/fail limits, taken from internationally accepted practices for insulation testing of electrical equipment. While insulation tests are optional, it's recommended to check with the equipment manufacturer to ensure these can be conducted without damaging the equipment under test.

Comparing data

Testing to IEC 62353 has reduced the time taken to conduct an electrical safety test – down from five minutes to less than 15 seconds[iv] in some cases. In addition, a direct outcome from reducing the amount of individual tests is that results can be easily compared against previous readings; tests in different polarities of the incoming mains rarely result in a significant difference in readings, so under IEC 62353 only an equipment leakage and applied part leakage value has to be observed, making comparison easy and quick. Comparing data also makes it possible to monitor leakage against expected values rather than the test limits in the IEC 62353.

Test frequency

To ensure safety and performance is managed throughout the lifecycle of ME equipment, manufacturers must specify the intervals for testing and inspecting their devices. The basis for this is risk assessment, based on the likelihood of occurrence and severity of incorrect operation. Consideration has to also be given to the application of the product, frequency of use, the operational environment and operator competency. IEC 62353:2014 recommends following the manufacturer's instructions on test intervals. If this is not available, a test interval of between six to 36 months is suggested depending on the risk assessment carried out.

Conclusion

There's no doubt IEC 62353 has made an impact on improving testing standards and raising safety levels. The 2014 edition elevates this to another level, making for a more complete document for manufacturers and medical device end-users. Those who wish to test according to IEC 60601 will appreciate that most of the conventional safety analyzers on the market today provide only a small subset of the IEC 60601 requirements and that careful consideration must be given to ensuring that the test setup is correct and that equipment is not damaged during any of the tests done.

The recommendation that IEC 62353 can be used as a standard for end of line testing and testing before going into service is new within the 2014 edition. Uniformity in test procedures, time (and cost) savings and a simplified means of analyzing test data are among other significant benefits[v] for those who have made the transition to testing in accordance with IEC 62353.

	Design	In use
Standard	IEC 60601	IEC 62353
Operator Safety	MOOP	Equipment leakage
Patient Safety	MOPP	Applied part leakage
Considerations	Elevated and isolated mains, preconditioning	Visual inspection, mains voltages, secondary grounding, functional testing

Figure 8: IEC standard comparison table

Rigel Medical has produced a free guide to testing in accordance with IEC 62353:2014.

Visit www.rigelmedical.com/IEC62353 to download an electronic copy.

i. 'Harm' is defined in ISO 14971:2000 as "physical injury or damage to the health of people or animals, or damage to property or the environment'

ii. In IEC 60601, safe levels of current are defined as 10µA AC / DC for CF applied parts and 100µA AC / DC for B / BF applied parts and touch current'. Ground leakage limits are higher at '500µA RMS for equipment with conductive accessible parts that may become hot under a fault condition and 5000µA RMS for ground devices with no conductive accessible parts. Under fault conditions, higher values are allowed.

iii. A free application note on this subject is available at; www.rigelmedical.com/rigel-downloads

iv. Comparing the tests of a 12 lead ECG (CF) monitor which requires 290 AC and DC leakage readings under IEC 60601 (excluding SIP-SOP) and only 4 leakage readings in IEC 62353.

v. Information gathered by Rigel Medical during over 40 international seminars on IEC 62353.

Improved safety analyzer from Rigel Medical makes for faster testing

Hospital and healthcare facilities require high performance products that can provide ever faster and safer testing of medical devices and installed equipment. The improved battery powered 288 from Rigel Medical delivers this and more.

The 288 is one of the most recognized electrical safety analyzers on the market today, renowned as the smallest, most compact tester of its type in the world. It incorporates unique technologies and features to provide enhanced performance and improved electrical safety testing of equipment to the appropriate standards including IEC/EN 62353 and IEC/EN 60601.

While most conventional testers rely on mains power, the improved battery powered 288 retains operational integrity, even without mains connection, using standard AA battery power compatibility. This provides greater user flexibility and makes it quicker to complete in-service testing of point-to-point leakage as well as ground continuity and insulation resistance.

And, because the 288 does not require a lengthy power cord to operate, there are no trailing cables to cause potential trip hazards, making it even safer and more convenient to set-up and use on-site. Further time saving benefits are achieved because the analyzer's battery power back-up avoids the need for lengthy start-up times between tests.

Up to 10 individual patient leakage circuits can be checked in a single test routine, while a further benefit is the ability to automatically warn users of incorrect test set-ups, helping to avoid incorrect readings – it is the only tester of its type providing automated verification of secondary ground paths and incoming mains configuration.

The 288 features Rigel's unique ground bond technology, which combines high and low test currents to ensure the accuracy of the protective ground path, helping to precisely identify any potential wear and tear. This can help to avoid the need for any unnecessary cable replacement, providing further cost savings.

An integrated keyboard enables the user to quickly input equipment details alongside electrical safety test results for improved electronic data storage and traceability. The information can be downloaded into Med-eBase – the easy-to-use test solutions software – which enables the user to trace and manage test results, set-up standardized templates, email html test certificates to clients and schedule new work orders among other customized functions.

Katherine Summers, Product Manager at Rigel Medical said: "Our customers want even more flexibility by testing medical installations and fixed installed equipment for ground continuity and leakage current using batteries alone. We have responded to their needs, and now they can benefit from faster and safer testing programs using the enhanced Rigel 288."

The Rigel 288 forms part of a comprehensive range of high performance specialist biomedical test equipment supplied by Rigel Medical. More at **www.rigelmedical.com/288**

Rigel electrical safety analyzers put to the test at Siemens

Leading healthcare equipment manufacturer Siemens Healthcare has equipped its nationwide team of mobile service engineers with 100 new Rigel Medical 288 electrical safety analyzers.

The move will significantly reduce the time it takes for engineers to carry out electrical safety checks on Siemens MR, CT, nuclear, PET, ultrasound and radiotherapy equipment.

The handheld devices will replace larger testing, which are both cumbersome and heavy to transport from site to site.

The lightweight portability and versatility of the Rigel 288 will enable engineers to move more swiftly, completing electrical safety testing in a more expedient and cost effective way.

The battery powered 288 ensures Siemens meets the recurrent and post repair test requirements of the IEC 62353 standard.

The tester features Bluetooth connection of barcode scanners, label printers and other accessories, enabling engineers to carry out cable-free data transfer and safety labelling, without the cumbersome plugging and unplugging of leads and cords.

As well as storing the results of electrical tests, the instrument also has the ability to record user defined inspections and measurements from specialist electro-medical equipment such as SpO2, NIBP, ECG and other patient devices.

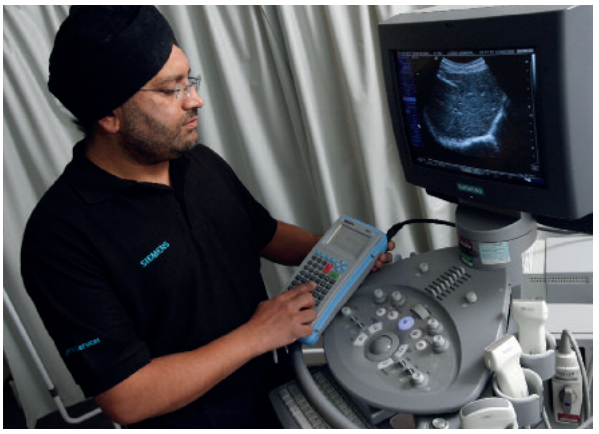
The Rigel 288 incorporates easy-to-follow instructions for simple operation and test control of all IEC 62353 electrical safety tests in manual, semi-automatic or fully automatic test modes.

Siemens Healthcare is one of the world's largest suppliers to the healthcare industry, offering core competence and innovative strength in diagnostic and therapeutic technologies as well as in knowledge engineering, including information technology and system integration.

The company employs more than 49,000 people worldwide and operates in 130 countries. In the fiscal year 2007 (Sept. 30), it reported sales of €9.85 billion with orders of €10.27 billion and group profit of €1.32 billion.

Siemens's Michael Bernard, who is helping to deliver the engineer training program for electrical safety testing utilizing the Rigel equipment, said:

"We are very happy with the 288. It can perform any test required on portable medical equipment to any standard currently in operation throughout the world.



"It is the smallest and lightest unit on the market and very reasonably priced.

"After training, it is easier to use than other devices on the market, and has many features that would allow for future expansion."

Available as part of a 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.

For service firms, 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.

More at **www.rigelmedical.com/288**.

If you're interested in being involved in a case study, then Rigel would welcome the opportunity to speak to you and hear about your experience of working with their products. Please email pulse@rigelmedical.com to find out how to get involved.

Q&A

In our regular feature, **John Backes**, Associate Director, answers some of your questions.

For your chance to be included in the next issue
send your questions to:
pulse@rigelmedical.com

Q What are the methods and how easy is it to download results from Rigel testers?
Agnes, Sweden

A There are two download methods available to you when using a Rigel tester:

a) Data transfer (a program included in the utility disk with all products), is a free HyperTerminal program which enables results to be downloaded in txt or CSV formats.

b) Med-eBase is Rigel's test solution software program which has been designed to bring out the full potential of all Rigel products. Once results are downloaded into the software you have the ability to generate professional test certificates that can then either be printed or saved in a PDF format. Results are saved using an Asset ID, therefore, electrical safety and performance analyzer results can also be saved in the same location. A free Med-eBase trial is available at, www.rigelmedical.com/med-ebase.

Q I am in the process of changing computers and was wondering if and how Med-eBase can be moved between PCs?
James, United States

A Yes, Med-eBase can be moved to a new PC very easily. Please email the Rigel technical support team with your Med-eBase serial number at support@rigelmedical.com. Once the support team have accessed your serial number you will be able to install and activate Med-eBase on your new PC using your existing serial number and activation key information.

Q I have been using a Rigel Uni-Therm for preventative maintenance on my surgical generators, including the Covidien ForceTriadTM. Can I perform a calibration on the ForceTriadTM using the Uni-Therm as well?
Frank, Canada

A Yes, the Uni-Therm can be used to complete a calibration. Please visit www.rigelmedical.com/rigel-downloads and read application note 0066 for further guidance.

Q I am trying to test an infant NIBP monitor with the Rigel Uni-Sim. I see the adult default O-Curve, but how would I do the needed test?
Jason, United States

A There is a default adult O-Curve, but an O-Curve would need to be developed for an infant. Please visit www.rigelmedical.com/rigel-downloads and read application note 0036 for further information on how to create and upload O-Curves to the Uni-Sim.

Please note: confirmed and unconfirmed O-Curves are included on the following link (www.rigelmedical.com/customisable-o-curves). Unconfirmed O-Curves are those created by end users, which are yet to be verified by three separate parties.

Q Can a test sequence be created using the PC and uploaded into the Rigel Uni-Sim?
Max, Canada

A Yes, test sequences can be created using Rigel's Med-eBase test solution software and uploaded to the Uni-Sim via Bluetooth. Custom NIBP O-curves and SPO2 R-curves can be created for your individual needs. All Rigel products (excluding Uni-Pulse) can have a test sequence uploaded from Med-eBase.

To create your own O and R curves please see the application notes section of our website www.rigelmedical.com/rigel-downloads

Got a question? Send it to **pulse@rigelmedical.com** for your chance to be in the next issue.

The quickest and easiest way to test all leading electrosurgical devices

Introducing the new Rigel Uni-Therm electrosurgical analyzer

This all in one device is packed with features which reduce the complexity of ESU testing.

- Maximum test current of 8A RMS for calibration of high current vessel sealing modes
- Highly accurate load bank in 5Ω resolution to meet all manufacturer's requirements
- Tests all HF leakage tests as per IEC 60601-2-2 requirements
- Cut testing times with easy, step-by-step, color instructions on-screen
- No need to connect to a laptop; tests run automatically to save more time
- All-in-one test for contact quality monitoring (CQM) to within 1Ω resolution
- Footprint is 50% smaller than competitors; easier to use, transport and store

Free
Introductory Guide to Electrosurgery
For your free copy visit
www.seaward-groupusa.com/uni-therm

You need to see it to believe it

Visit www.seaward-groupusa.com/uni-therm
Or call us on 813 886 2775

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