OLYMPUS put the Uni-Therm to the test
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 enquiry@rigelmedical.com or visit www.rigelmedical.com.
Welcome to the latest edition of Pulse, the first of 2013.

However before looking ahead I would like to take a moment to reflect on 2012. It was certainly a year to remember with one of the best Olympics and Paralympics ever staged in the history of the games and the Queen’s Diamond Jubilee celebrations burning bright in the memory. Closer to home, it was also a terrific year for Rigel Medical, climaxing in winning the prestigious Queen’s Award for Enterprise.

And this year promises continued success, which started with a successful showing at Arab Health 2013 in January (more inside about this). We are planning to attend further exhibitions as the year unfolds where customers and specifiers will be introduced to our market leading range of advanced instruments, including the exciting launch of the Uni-Therm, our new high performance analyser for electrosurgical devices.

One of the biggest trends in the electrosurgery equipment market relates to safety for the patient and staff. It’s well known that the safe use of these devices is of primary importance to any facility; so we take a look at what’s involved in our special technical feature, where you can also request our free guide to find out more.

Elsewhere, there’s no doubt safety and performance will remain an important issue for anyone working with medical devices in the coming years. We take a look at the sector to find out more and answer some of your questions in our popular ‘Q&A’ feature. You can also 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
Rigel shows its quality at Arab Health

The Middle East’s largest healthcare exhibition and medical congress, Arab Health 2013, once again saw an impressive display from Rigel Medical as it showcased many of its advanced medical device performance analysers, electrical safety analysers and vital signs simulators.

Visitors from the UAE and across the region headed to the Dubai International Convention and exhibition Centre to find out about the latest news and products from Rigel. Catching the eye for many was the impressive Uni-Therm, the state-of-the-art high current electrosurgical analyser is able to test accurately all modern low, medium and high current electrosurgical generators. With a new ultra-low inductance, high resolution load bank, the Uni-Therm can accurately detail the power in response to varying loads. Automatic control of the CUT/COAG allows automatic testing and improves safety whilst reducing test times.

Also garnering considerable interest was the Multi-Flo infusion pump analyser and compact Uni-Pulse defibrillator analyser. Multi-Flo 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.

Rigel Medical’s presence at Arab Health comes as it continues to benefit from a growing presence in the Middle East market, where demand for high performance biomed device testers, featuring advanced added value capabilities, remains strong.

Associate director John Backes, reflecting on a successful exhibition said: “Our brand positioning, built around involving customers in the development of test equipment, continues to underpin our marketing push across the Middle East. We will be following up with customers and specifiers for feedback, insight and suggestions for new and future products and improvements.”

Clarity for EU medical device regulations moves closer

An update on the anticipated timetable for the parliamentary vote on the European Commission’s proposal for a revision of the Medical Devices Directive (MDD), submitted last September, has been published by MedTech Europe.

The European Parliament’s Committee for Environment, Public Health and Safety (the ENVI Committee) is charged with considering the revision of the Medical Devices Directive, and its anticipated timeline has become clear over the past month, says MedTech Europe, an alliance of European medical technology industry associations founded by EDMA and Eucomed.

An initial exchange of views took place in February alongside an ENVI workshop on medical devices. A draft report will then be considered by ENVI on April 24 before members table amendments (May 3) and final voting on the report in July.

The report is slated to be voted on by the full Parliament in a plenary session in September 2013.

Details at http://www.europarl.europa.eu
AED safety and performance critical over next five years, says Rigel

Safety and performance will remain an important issue for AEDs in the coming years, says John Backes, associate director – Rigel Medical.

Commenting in a US biomed magazine ‘TechNation’, he believes manufacturers have increasingly made AEDs successful and safer to use by people but the challenge going forward will be to make them even more widely available, which will occur when they become more cost effective.

He says: “Although manufacturers provide built-in check procedures, these are not always sufficient to warn the user in advance. Problems with equipment more often than not will only surface when cardio version is required – of course, this is far too late and patients’ lives will be placed at even more risk if equipment doesn’t work.

“No doubt manufacturers will be able to address some of these concerns and perhaps even consider letting their users have remote (wireless) access using public (wifi) hotspots to monitor AED status.”

However, the necessity for testing defibrillators will remain no matter what level of self-testing is incorporated into future defibrillator technology says John, adding that the automotive industry is a good analogy because innovation has dramatically increased the reliability of cars.

“Most modern cars are fitted with several self-test and alarm features but this hasn’t eliminated the need for regular check-ups in the garage or by the owners. Wear and tear is difficult to monitor and visual damage always requires human interpretation. It’s the same for AEDs.”

Read John Backes’ interview with the editor at: www.1technation.com/roundtable-defibrillator-equipment/

Japanese medical device market improves

Japan’s medtech market is showing marked signs of improvement, thanks to efforts by the regulatory body to reduce product approval lag times and the government’s targeting of the industry as a key growth sector.

A report in the trade journal European Medical Device Technology claims that Japan’s ageing population could benefit foreign companies, in particular. According to the Ministry of Health, Labour and Welfare, all artificial cardiac valves (worth €141 million), 99.6% of artificial hearts (€256 million), 98.4% of artificial respirators (€376 million) and 81.4% of artificial respirators (€1.6 billion) sold in Japan are manufactured abroad.

Overall Japan accounts for 10% of the total global market for medical devices, and ranks as the third largest after the United States and the European Union. It is reported that high-end medical technology from the United States and Europe continues to be in great demand.

Historically, Japan’s rigid regulatory system has been a barrier to entry, but the government now appears to be more receptive to streamlining the product approval process and encouraging innovation. For example, the Ministry of Health, Labour and Welfare has more than doubled the number of reviewers at the Pharmaceuticals and Medical Devices Agency (PMDA) in the past three years.

More details at www.emdt.co.uk

New US guidance on home-use medical devices

The latest FDA guidance for medical devices highlights risk management processes as particularly important, notably important environmental issues that manufacturers should bear in mind, including:

Location - do different physical structures affect the device’s intended use?

Temperature - can the device function during temperature fluctuations?

Dampness/humidity - how do variable humidity levels impact the device’s functionality?

Contaminants - how would non-sterile settings impact the device’s functionality?

Water supply - tap versus distilled

Child proofing - whether or not the device is designed for use by children?

Travel/international use - how would air travel, security screening technology and voltage rates affect the device?

For devices that use electricity, FDA advises manufacturers to consult ANSI/AAMI/ES 60601-1-2:2005 on medical electrical equipment safety and performance.

Read the full report and find links at: www.emergogroup.com

Home-use medical device manufacturers should now have a clearer idea of which issues the Food and Drink Administration (FDA) staff will focus on most keenly during registration reviews and audits, says the Emergo Group in its latest regulatory update.

www.rigelmedical.com
Introduction

Electrosurgery uses high frequency alternating (AC) current to electrically induce heat to cut biological tissue, Figure 1. Heat production is a function of the current per unit area, known as current density, resistance and time period. The principle of heat production via current through tissue can be modified to produce a variety of effects including cutting and coagulation using monopolar and bipolar delivery techniques. It was first developed by William Bovie in 1928.

Electrosurgery

The electrosurgical circuit is composed of a generator providing electron flow, an active electrode, the patient and the patient return electrode. Current enters the patient and the tissue provides impedance which produces heat as electrons overcome this. Electrosurgical circuits use two electrodes in contact with a substance or dielectric that has reduced electrical conductivity, such as human tissue, which is known as a dipole circuit. For patient safety radio waves are used to eliminate any possible neuromuscular stimulation or risk of electrocution which can be seen at lower frequencies, Figure 1. The electrosurgical generator is used to convert electricity to over 200 KHz [1].

Techniques of Delivery

In monopolar electrosurgery current flows from the active electrode at the surgical site to the tissue, through the patient, to the return electrode which disperses the electrical current and returns it back to the generator to complete the electrical circuit. In bipolar electrosurgery the active and return electrodes are located at the surgical site, within the instrument tip, Figure 2. The current is confined to the tissue situated between the forcep tines which minimises damage to the surrounding tissue as the patient’s body is not part of the circuit, Figure 2.
Electrosurgical Waveforms

The electrosurgical generator output can be varied by altering either the voltage to drive more or less current through the tissue or by modifying the waveform which influences the tissue effect.

Cutting currents use a sinusoidal waveform with high average power and current density, allowing for precise cutting without extensive thermal damage, Figure 3. The electrode is held away from the tissue to create a spark gap and discharge arc at a specific location to produce sudden concentrated heating to vaporize cells.

A blended current is a modification of the duty cycle and operates at voltages between cutting and coagulation which allows tissue division with a maintained degree of hemostasis. The total energy remains the same; however, the ratio of voltage and current is modulated by interrupted current and increased voltage which delivers intermittent bursts of the waveform, Figure 3.

Coagulation currents are characterized by intermittent bursts of dampened sine waves with high voltage to drive the current through the tissue and low current which reduces the duty cycle to as little as 6%, Figure 3. Tissue is heated when the waveform spikes and in between spikes, the generated heat travels through the tissue, reducing the cutting effect whilst enhancing the coagulation during the 94% off cycle, Figure 3 [1-4].

Figure 3: Pure Cutting, Blended and Coagulation currents

Electrosurgical Tissue Effects

The tissue effect of an electrosurgical current depends upon the size and shape of the electrode and the output mode of the generator. The amount of current that flows through the tissue and current density significantly alters the tissue effect.

Electrosurgical cutting divides tissue using electrical sparks which produce maximum current concentration and focused heat at the surgical site. The spark gap produces a greater amount of heat over a very short period of time which causes vaporization. Modifications and reduction of the duty cycle from blends 1 to 3 produce less heat; with blend 1 vaporising with minimal haemostasis and blend 3 having maximum haemostasis but limited cutting ability, Figure 3.

The coagulation waveform can be used in two ways: dissection or fulguration, resulting in the creation of a coagulum rather than vaporization. Desiccation is a direct contact form of coagulation where 100% of the electrical energy is converted into heat. Desiccation uses low current density over a broad area. Fulguration is a non-contact form of coagulation, where an electric discharge arc produces a spray effect causing shallow tissue destruction at various regions [1-4].

Electrosurgical Units [ESU’s]

The active electrode delivers high frequency AC current from the generator to the surgical site. At the tip of the active electrode electron flow is high over a relatively small area and as resistance increases, heat is produced. The current density is high but differs depending on the type, size and shape of the tip. The monopolar active electrode is typically a small flat blade with the edges of the blade shaped to easily initiate discharge arcs, Figure 4.

To control the waveform, footswitches or switches on the active electrode handle allow the surgeon to alternate between cutting and coagulation modes. Needle tips require a lower power setting than blade or ball electrodes because the current is concentrated on a very small area. The function of the patient return electrode in monopolar electrosurgery is to collect the high frequency current and safely return it to the electrosurgical generator. The large electrode area and small contact impedance reduce the current density to minimise skin heating, Figure 4.

Figure 4: Active and Patient Return Electrode

To combat electrode failure and subsequent patient injury, contact quality monitoring (CQM) systems were developed to monitor the quantity and quality of contact and impedance between the pad and the patient. The CQM system will alarm and deactivate the generator.

Typical Example

High Voltage

COAG

6% on

94% off

LOW VOLTAGE

50% on

50% off

PURE CUT

100% on

BLEND 1

40% on

60% off

BLEND 2

25% on

75% off

BLEND 3

50% on

50% off

100% on

Figure 3: Pure Cutting, Blended and Coagulation currents

Typical Example
Expert advice (cont.)

if the contact is interrupted or beyond a preselected limit to prevent skin burns or potential injury.

ESU Hazards
An electric current needs a closed circuit for electricity to flow and therefore current has the potential to travel along alternative pathways of least resistance to earth which can cause undesired affects. This can expose patients and staff to potential hazards such as electric shocks and skin burns. The patient return electrode is a common site of injury mainly due to insufficient size and interrupted or reduced contact which can cause skin burns due to increased current density.

Conclusion

Electrosurgery is the principle of producing heat by high frequency electrical current for coagulation and cutting of tissue developed by Bovie. The evolution of electrosurgery since the 1920s has been rapid and still continuously develops. Electrosurgical devices minimise blood loss, allow for precision cutting and decrease operative times. However, a thorough understanding of each energy modality, waveform and tissue effect is critical in reducing potential complications and hazards. The performance and safety of these electrosurgical devices must be regularly verified (every 3 - 6 months), for instance, using the Rigel Uni-Therm electrosurgical analyser.

Uni-Therm

The Rigel Uni-Therm offers the latest technology in high frequency power measurement. It’s small, easy-to-use, has a large colour display and innovative navigation making it a fast, efficient and accurate measuring tool for testing the performance of electrosurgical generators. A large internal memory and PC communication provide traceability of the test data. The main features of the Uni-Therm include:

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<td>HF leakage test</td>
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<td>On-board data storage</td>
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<td>Duty cycle 100% up to 60 seconds</td>
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<tr>
<td>Contact quality monitoring (CQM)</td>
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<tr>
<td>■ Current measurement</td>
<td>0 to 8A (RMS)</td>
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<td>■ Power rating</td>
<td>0 to 500W (RMS)</td>
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<td>0 to 10kV (Peak)</td>
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<td>■ Voltage</td>
<td>0 to 700V (RMS)</td>
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<td>■ Crest factor</td>
<td>1.4 to 20 (V peak / V RMS)</td>
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<td>■ CQM test</td>
<td>1 to 475Ω, steps at 1Ω steps</td>
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References


To register your interest for a FREE copy of the Introduction to Electrosurgery booklet, available in April 2013, go to: www.rigelmedical.com/pulse
Uni-Therm passes the test

Reduce the complexity of ESU testing

The new Uni-Therm from Rigel Medical accurately measures the performance of electrosurgical generators including high frequency leakage, high current, power distribution and contact quality monitoring (CQM) alarm testing.

Compliant with IEC 60601-2-2*, the high performance 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 safely.

A high power load bank enables performance testing up to 8A 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 0-5115Ω in 5Ω steps provide not only the most accurate and detailed power curves, the Rigel Uni-Therm also advocates safe working practice by providing all necessary resistors within a single enclosure.

Contact quality monitoring (CQM) 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.

Find out more about the Uni-Therm electrosurgical analyser and the other products in Rigel’s performance analyser range by visiting: www.rigelmedical.com/pulse
Field engineers at Olympus KeyMed Ltd have turned to Rigel Medical’s Uni-Therm analyser for improved medical device compliance and safety testing.

Olympus, which has been at the forefront of designing endoscopy and microscopy products, medical and industrial equipment for over 90 years, uses the advanced Uni-Therm for in-service performance testing of its electrosurgical devices.

These items of equipment use electricity to produce enough heat to enable surgeons to cut body tissue or seal bleeding vessels during operations.

Twenty Uni-Therm units have been specified to allow automation of the performance testing of Olympus’s electrosurgical equipment, resulting in greater efficiencies. Already, the new testers have enabled engineers working at sites across the UK to accurately measure the performance of each device and complete high frequency leakage, high current, power distribution and contact quality monitoring (CQM) alarm testing.

Compliant with IEC 60601, the high performance Uni-Therm is capable of verifying and calibrating the electrosurgical equipment while guiding the engineer through all test procedures automatically and most of all safely.

Olympus is a leading manufacturer of advanced optical and digital equipment for the healthcare and consumer electronics sectors, leading the way in designing endoscopy and microscopy products among others.

Martin Wallace, head of field service at the Southend-on-Sea based company, said: “Rigel supplies us with a range of high performance, high quality instruments, which provide the engineers with convenient, easy-to-use and accurate testing solutions.

“The engineers appreciate the fact that they are compact enough to carry around with them and offer full automation of test procedures, leading to more efficient testing schedules and improved standards of customer service and care.

“The Uni-Therm incorporates an excellent range of features for a tester of its size, while the added value benefits, like improved connectivity and ease-of-use, 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 quality control purposes at a later date.”

He also said that Rigel’s after sales support is very good, which is another reason why he chooses to use its products - in particular, product training is very good while the company is also responsive to his needs.

The Rigel Uni Therm forms part of a range of Safety Analysers from Rigel Medical. For more information visit www.rigelmedical.com/pulse
Q&A

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

Q We test ESU’s using external “Dale” loads and a current transformer. What clear benefits will the Rigel Uni-Therm offer me?

Marcel, Amsterdam, Netherlands

A Testing ESU’s using external resistors has been a typical way of testing ESU’s however, the risk of being exposed to HF electrical current is a serious consideration for each departmental manager. The time it takes to manually configure each test setup also leads to lengthy test routines. And finally, using separate loads and test leads, CT and RMS meter requires significant physical space which is not always available.

The Rigel Uni-Therm has all required test loads built-in and independent tests have shown that Rigel’s load bank has a lower inductance than the industry reference loads (Dale Loads). By ensuring that the test setup leaves no metal accessible parts, the Rigel Uni-Therm makes testing of ESU’s safer and faster. It’s small footprint make the Rigel Uni-Therm a unique tool to take into test environments where space is very limited. Built-in automation speeds up testing and can reduce ESU test times by over 50%. Test results are recorded as the test progresses and can be downloaded to a PC, removing the need for manual recording of data, eliminating human error and leading to direct time saving.

Q Can I perform an automatic test sequence on equipment sensitive to power breaks?

Mr Nashimoto, Tokyo, Japan

A Equipment sensitive to power breaks (PC based systems in particular like ultrasound), require consideration when power is applied and removed in order to allow the PC part to properly power up and power down. Removing the power automatically whilst the PC has not completed its boot-down process, may lead to damage to the PC or operating software. The Rigel electrical safety testers provide a semi-automatic mode whereby the user is in control of when power is applied, when measurements are taken and when power can be removed. The individual leakage readings are grouped together as much as possible to reduce the number of power breaks to 2, leading to direct time saving compared to other safety analysers on the market. Single fault conditions and measurements are processed automatically until the test routine calls for a power break. The user can manually remove and allow power to ensure the tests are completed as soon as possible whilst posing no risk to the equipment under test.

Q Hi, I am new to the electrical safety testing world and am wondering can you explain the difference between a standard PAT Test and an electrical safety test for medical equipment?

Declan, Ireland

A Portable appliance testing (PAT) is an electrical safety test (EST) intended for domestic equipment i.e. white goods or IT equipment which are in short term contact with members of the public. EST of Medical Devices on the other hand must be more stringent as this kind of equipment is often connected to weakened patients and electrical leakage currents as low as 10µA (micro) are considered a risk.

For this reason specialised test equipment is required to measure such low currents as well as providing single fault conditions which are a requirement (not part of normal PAT).

Therefore PAT testing is not suitable for medical equipment as it doesn’t carry out all of the appropriate tests. All medical equipment should be electrical safety tested to procedures based on IEC60601 (type testing) or IEC62353 (routine) standard.

Q Will the new Rigel Uni-Therm be able to test and calibrate the Covidien ForceTriad?

Brian, Dallas, Texas

A Yes, the ForceTriad has high current vessel sealing functions which produce a very high current.

To calibrate and test the ForceTriad, you require an ESU analyser that can measure around 5A RMS into a short-circuit in order to calibrate the output. In addition, the REM test (return electrode monitoring) requires 1Ω steps to ensure the various test conditions are met. The Rigel Uni-Therm can perform all the required tests for routine maintenance and calibration.

Q Can I perform an automatic test sequence on equipment sensitive to power breaks?

Mr Nashimoto, Tokyo, Japan

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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.

Terms & Conditions: Rigel reserves the right to publish questions in future issues of Pulse and other company literature, including websites.

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 analyser

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, colour 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

You need to see it to believe it

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