

# the Pulse

Expert news and advice for the medical industries

## At the heart of cardiac surgery robot testing

Issue

#4

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Innovating together

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**Publisher:** Rigel Medical, Bracken Hill, South West Industrial Est., Co. Durham, SR8 2SW

**Editor:** John Backes

**Distribution:** [www.rigelmedical.com](http://www.rigelmedical.com)

**Email:** [pulse@rigelmedical.com](mailto:pulse@rigelmedical.com)

**Tel:** +44 (0)191 587 8730



# Welcome

Welcome to the latest edition of Pulse, bringing you expert views and advice for the medical devices and equipment testing sector.

It continues to be exciting times for Rigel Medical as we build on recent successes and welcome Paul Weaver, our new sales manager. He brings more than 20 years sales experience to the position and will be instrumental in helping to develop and manage key accounts and distribution activity across the UK and Europe. It's good to have you on board Paul.

We also mark the opening of our new purpose-built commercial centre at Peterlee. This facility will enable our global customers to gain access to improved levels of service while being able to benefit from centralised product management, marketing and customer support.

Look out too for our new and automated infusion pump analyser, Multi-Flo, which will be coming very soon. There's more inside (page 8) about this IEC 60601-2-24 compliant analyser, which provides accurate back pressure simulations, occlusion alarm monitoring and bolus (PCA) measurements.

We will be updating our Med-eBase test solution software, moving it from an asset management programme to an advanced test solution as part of our fully integrated, added value solutions' package. There's also the new 'Introduction to Infusion Pump Testing' booklet to look forward to as we continue to invest in supporting customers with the very latest medical device testing expertise and information as part of our knowledge centre.

Product development continues to work hard to meet the requirements of all our customers as we look forward to further exciting new product releases this year. So, stay tuned...and don't forget we always like to hear what you have to say - please don't hesitate to get in touch with your news and views.

**Best regards**

**John Backes** Editor, Pulse



## What's On

### AAMI

May 31 – June 2 2014,  
Philadelphia, USA

### Completing the Picture 2014

July 9 2014, Heritage Motor Centre,  
Gaydon, UK

### The 18th National Biomedical & Clinical Engineering Conference

Oct 23 2014, Silverstone Circuit,  
Northamptonshire, UK

### MEDICA

Nov 12-15 2014,  
Düsseldorf, Germany

### Arab Health

26 - 29 Jan 2015,  
Dubai International Convention &  
Exhibition Centre, Dubai, UAE

# Medical device recalls nearly doubled in a decade

**Recalls of defective medical devices in the U.S nearly doubled in the decade from 2003 through 2012, according to a Food and Drug Administration report.**

The total number of recalls rose to 1,190 in 2012, up from 604 in 2003. There was a sharp increase in recalls where the defective product carried a reasonable probability of death. In 2012, there were 57 of these so-called Class I recalls - up from seven in 2003.

A recall means a product is removed from the market, or that it is corrected in response to a defect. The analysis by the FDA's centre for medical devices was undertaken in part to respond to a 2011 report by the Government Accountability Office and noted that recalls by companies often came too late to do much about the defects in products.

Steve Silverman, director of the FDA medical device centre's office of compliance, said the rate of recall lags industry growth - the numbers of medical devices increased by about 25% from 2008 through 2012.

Wanda Moebius, a senior vice president at the industry trade group AdvaMed, said: "The increase in recalls...can be attributed primarily to companies taking a more cautious, pro-active, patient-centric approach to quality, safety and reporting of events to FDA."



Diana Zuckerman, president of the National Research Center for Women & Families and a critic of FDA device regulation, said: "You have to wonder whether a more rigorous regulatory effort before devices went on the market would have avoided these recalls."

## Medical devices: better controls and traceability ensure patients' safety

**Stricter monitoring and certification procedures to ensure full compliance and traceability of medical devices have been agreed by the European Parliament.**

MEPs have also tightened up information and ethical requirements for diagnostic medical devices used for example in pregnancy or DNA testing.

The proposed legislation seeks to increase patient safety and to strengthen traceability from producer to patient, without creating additional burdens for innovative small manufacturers.

Rapporteur Dagmar Roth-Behrendt (S&D, DE), whose report was approved by 541 votes to 19, with 63 abstentions, said: "We talk about products that are supposed to help patients in their suffering, in their illness.

We should assist doctors in making sure they are using the best and safest products to help their patients...We need a much better system."

Parliament's amendments would strengthen the procedure for placing new medical devices on the market so as to ensure that unsafe products or devices that have undergone insufficient controlled trials on patients can no longer be used on or in them.

MEPs say that in future, notified bodies should have a permanent team of in-house experts who meet up-to-date qualification requirements. A new group of bodies should assess devices considered 'high risk' – those, that for instance, can be implanted in the human body.

## India consulting stakeholders on Bill on drugs and medical devices



India's Government does not want to rush through legislation aimed at regulating trade, manufacture and sale of drugs and medical devices and is instead carrying out consultations with various stakeholders, according to a report in the Economic Times.

The report quoted Minister of State for Health, Abu Hasem Khan Choudhury: "For the Bill to have maximum impact, it is important for us to consider the views of other ministries, the industry and the civil society. We do not wish to hastily push forward a draft Bill without listening to the views of all stakeholders."

The Drugs and Cosmetics (Amendment) Bill, 2013, proposes changes in the regulation of the import, export, manufacture, distribution and sale of drugs, cosmetics and medical devices and to ensure safety, efficacy and quality in conduct of clinical trials.

The Bill, which seeks to set up the Central Drugs Authority, was introduced in Parliament in August 2013 and later referred to the Standing Committee on Health and Family Welfare. The Committee came up with its recommendations last December.

The minister claimed that once finalised, the Bill would ensure the highest standards of safety and efficacy.

In the report, Choudhury refers to the concerns of the medical devices industry: "Medical devices and drugs are very different and we want to ensure that the distinction in their regulation is taken to the last mile."

## New FDA guidance on medical devices submissions

The Food and Drug Administration (FDA) has released guidance to help European manufacturers of Class II and Class III medical devices seeking clarification from U.S. regulators before or after applications are sent to the FDA for new or modified medical devices, including IVDs, mobile medical apps, and accessories.

Included in the guidance is information on how to receive written feedback from FDA, as well as setting up teleconference and

in-person meetings to exchange information in real-time and receive verbal feedback.

Because of differences between EU and U.S. regulatory processes, manufacturers in Europe have various reasons for seeking direct feedback from FDA, and at different times during the product application process. The new FDA guidance outlines the steps and timing that apply to this feedback process, as well as several specific examples of situations.

The move comes as the FDA continues to standardise the methods for its activities, and these new rules for interaction with the agency are important to understand and conduct correctly. Doing so can help get a company's new device through the FDA's regulatory process and onto the U.S. market.

## Eyes east for growth, says medtech intelligence provider



While BRIC markets offer outstanding growth opportunities for medical device companies, there are other smaller markets in Turkey, Indonesia and Iran that have quietly been growing beyond the spotlight.

Currently, these countries are seeing a strong rise in healthcare spending and with 85% or more of devices imported, there is little domestic competition to challenge international medical device manufacturers.

Turkey has been attracting a lot of interest, according to pharmaceutical and medtech intelligence provider Espicom. The country's medical device market is worth

about US\$2.2 billion, and if it was able to join the European Union, it could see its economy boosted by increased healthcare spending.

Further east, Indonesia's economy and healthcare is improving to meet the demands of 240 million people with rising incomes and more demand for healthcare while political bluster should not dissuade an objective evaluation of Iran's potential as a medical device market.

Iran has roughly the same population as Turkey (about 75 million people) and its economy has grown briskly - primarily due to a burgeoning oil and gas sector. Between 2001 and 2011, per capita

spending on healthcare increased 163%, due partly to increased government investment in healthcare infrastructure.

Medical device manufacturers would be wise to invest their time in exploring these under-served, yet growing, markets. Individually, they are relatively small now but healthcare spending is growing two to three times faster than in the United States, Japan or most countries in Europe. As was the case with China, 10 years from now you might wish you were one of the forward thinking companies who established an early foothold.

# Testing times for infusion devices

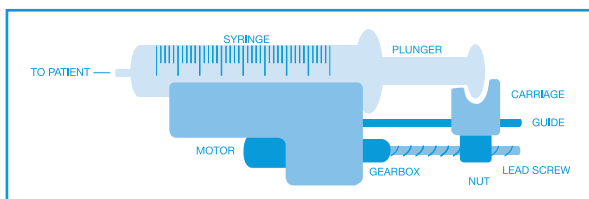


## Introduction

Like most medical equipment, infusion devices need to be checked regularly for accuracy and performance to ensure they are operating correctly. Katherine Summers MEng, Product Specialist – Rigel Medical, looks at what's involved and the advantages of using automatic flow analysers.

Infusion devices are capable of delivering medication such as insulin or hormones, antibiotics, chemotherapy drugs, pain relief and feeding at rates from 0.1 millilitres per hour (ml/hr) where other methods would be impractical or unreliable. It is estimated that there are millions of devices in use around the world, primarily in hospitals, and that every year, more than 80% of hospitalised patients receive some form of IV therapy reinforcing the paramount role they play as essential tools for providing preoperative care, critical care and pain management.

There are several different types of infusion devices which use a variety of mechanisms to control the flow and volume being infused for a range of purposes and environments. The most common are elementary gravity controllers which use a clamping action to vary the flow; volumetric pumps which employ a linear peristaltic pumping mechanism; and syringe pumps which work by pushing a plunger to drive a syringe at a predetermined rate (Fig. 1).

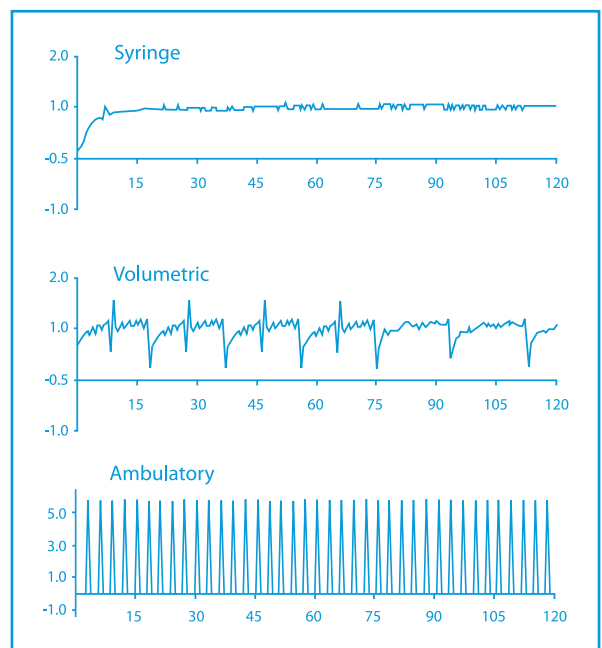


**Figure 1: Syringe pump**

The pattern of fluid delivery is dependent on the type of pump used and typical flow patterns for volumetric, syringe and ambulatory pumps at a flow rate of 1 ml/hr (Fig. 2). Each pump can deliver accurate average flow rates (within manufacturer specifications) over long periods of infusion. However, syringe pumps can deliver fluid accurately over shorter periods of time.

While the vast majority work safely, there have been adverse incidents involving pumps - at least 1000 investigated by the Medicines and Healthcare Products Regulatory Agency (MHRA) between 2005 and 2010 in the UK alone. The majority of these relate to over-infusion of drugs due primarily to user error with dosage and patient data but also some caused through product

design and engineering or software malfunction. So it is important that those with responsibility for medical device safety and performance arrange for IV devices to be regularly tested and evaluated to ensure that they are functioning to the manufacturer's specification and within clinical and environmental expectations.



**Figure 2: Fluid delivery pattern for volumetric, syringe and ambulatory pumps**

## Flow measuring principles

The primary aim of testing is to verify that the device delivers the required flow rate, volume and bolus accurately, that occlusion alarms are activated when necessary, and to determine that the device is safe for patient and operator use. It's important that testing conditions mirror real life settings - it should reflect what the manufacturer recommends ensuring that the equipment is working within its specification. Testing can involve a variety of methods but the essential criterion is to measure the accuracy of the delivered volume and flow rate over a range of time periods (typically between 10 minutes and one hour and conducted over several days).

Common flow measuring principles are:

- **Volumetric** - flow calculated after a certain volume has been delivered. The greater the volume over a certain time, the greater the flow.
- **Mass** - flow is calculated based on temperature difference between two points within the sensor, the greater the temperature difference the lower the flow.
- **Bubble tracking** - flow is calculated based on the displacement of an inserted air bubble into the flow sensor part. The greater the displacement, the greater the flow.
- **Pressure based** - flow is regulated within the flow sensor to a set line pressure. The greater the potential pressure built-up in the line, the greater the flow rate.
- **Displacement of syringe plunger** – Flow rate is calculated based on volume displaced by the syringe plunger over time. The syringe type and volume are required to provide an accurate calculation.

Occlusion alarm pressures and also bolus delivery have to be tested to maintain the performance of the infusion device especially in PCA devices where the bolus is self-medicated. A visual inspection and electrical safety test should also be considered to make sure all aspects of patient safety and instrument reliability are covered during the test procedure.

**Testing methods**

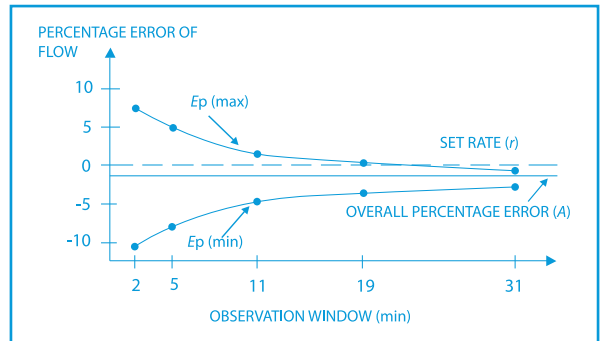
Optimal infusion is the ability of a device to reliably deliver the prescribed dosage and volume to the patient, at a pressure which overcomes all baseline and intermittent resistance, whilst causing no harm to the patient (3). The reliability of infusion pumps is extremely important because these devices are used for patients who could be in a critical condition; also, due to incidents associated with infusion devices there is a need to adequately validate the accuracy and performance of such devices (4).

There are several methods for testing reliability but increasingly users are moving away from basic measurements such as weighing scales and burettes, where continuous user input is required to ensure accuracy, towards automatic flow analysers which record real time results graphically and comply with both the IEC 60601-2- 24 standard, and manufacturer’s specifications as outlined in a service manual. Furthermore, it is important to ensure the accuracy of an infusion system is looked at in its entirety, taking into account all possible inaccuracies. For example, the syringe used and other external equipment, including the tubing set, could increase the inaccuracy to 10%; so it is generally accepted that the testing method and equipment has to be more accurate than the equipment under test (2).

Common methods for measuring volume or flow rate are:

- **Direct volumetric** - using either graduated cylinders or burettes.
- **Derived mass measurement** - using a measurement vessel and weighing scales.
- **Vernier callipers and dial gauges** - to provide a direct reading of the distance measured with high accuracy and precision.

Trumpet curves show the accuracy performance of an infusion device at set intervals in the second hour of infusion and during the final hour of infusion, as required by IEC 60601-2-24. (Fig. 3).



**Figure 3: Example of a trumpet curve**

The migration towards automatic solutions has seen growing interest in systems like the Rigel Medical Multi-Flo. This uses a pressure based system to provide instantaneous flow readings and realises a quick verification of the infusion devices’ accuracy and performance to a resolution of 10µl/hr. By controlling the line pressure, the Multi-Flo is not only capable of measuring the flow but is also able to control the different back pressure settings as required by IEC 60601-2-24.

The real time graphical data detects peak and minimal flow rates giving the benefit of faster test times at low flow rates. The ability to detect low flow rates makes the Multi-Flo infusion pump analyser a versatile tool for all types of infusion. Custom tests and sequences can be created on remote control software, and user-definable limits and expected values help clearly indicate whether the infusion is within the manufacturer’s specification, Fig. 4.



**Figure 4: Real-time graphical data in Med-eBase shows whether infusion is within manufacturer’s specification**

## Testing times for infusion devices (cont.)

The Rigel Multi-Flo is a fully-featured device measuring instantaneous flow, average flow, occlusion pressure and PCA to meet requirements of IEC 60601-2-24. Real time measurement curves are displayed graphically in either a manual mode on screen, or using the Med-eBase remote control PC software which enhances the assessment of the performance of the infusion device under test.

### Reliability and accuracy

Whether it is with a burette (direct volumetric measurement), weighing scales (derived mass measurement) or through the use of automatic analysers, the most important consideration when selecting the preferred method of testing is that it provides reliable and accurate results.

Direct volume measurements are techniques which provide a good degree of accuracy without the need to worry about the design or performance accuracy of another piece of equipment. However, they are quite labour intensive and require continuous user input. Automated electronic devices combine the various manual test methods with the ease-of-use of one analyser that offers the ability to conduct the most important aspects of infusion device performance accuracy analysis with little user input and the ability to test multiple devices simultaneously.

The volume of fluid delivered is used to measure the system's volumetric accuracy and other tests determine the performance accuracy of the device to maintain safety for staff and patients who will use the equipment. Most manufacturers specify system accuracy under stated test conditions including the giving set, temperature of test, flow rates, etc. this indicates that there are a number of elements that can affect the accuracy and therefore the device under test must be used within the recommended specification to maintain the given limits of accuracy.

Most adverse incidents are eventually identified as user error. Good design can contribute to minimising user error. Work has been initiated to develop a formal ergonomic testing procedure for application to all devices. At present, user instructions are assessed for clarity and readability, conciseness, and indexing. Procedures for using the device are systematically worked through on the bench after other testing is completed. Any hazardous potential misuse is noted. For all available alarms, the reliability, readability of text displayed, the alarm tone quality, the positioning of alarm lights, and methods of silencing alarms are tested as part of the ergonomic assessment of the device (5).

The technological advances in infusion pumps during the past forty years have transformed the treatment of patients in hospitals, as well as afforded the ability to infuse fluids on an outpatient basis or in a home environment and enable patients to receive treatment while going about their daily lives (6). Therefore, measuring performance accuracy needs to keep up with the changing and advancing technology of new pumps, which can infuse very low volumes and for extended periods, to be able to satisfactorily evaluate them in terms of volume/flow rate, occlusion and bolus measurements.



For you FREE copy of the full version of the 'Introduction to Infusion Pump Testing' guidance booklet, go to:  
[www.rigelmedical.com/infusion-guide](http://www.rigelmedical.com/infusion-guide)

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# Want to know how to save valuable time testing your infusion devices?

Infusion devices such as peristaltic pumps and syringe drives are among the most common devices in the healthcare industry. Each year, healthcare professionals in hospitals, manufacturers and independent service providers spend thousands of hours, testing and confirming the performance of devices like these, especially when conformance is tested at low flow rates (<10ml/h).

To help reduce test times of infusion devices, Rigel Medical has introduced the easy-to-use and feature-packed Multi-Flo infusion pump analyser, offering highly accurate readings right from the start.

Available in single or multi-channel configuration, the Multi-Flo channels can be tested simultaneously across a range of 10 µL (microlitre) to 1,500 mL per hour and the results stored in the instrument's large internal memory. With a sampling rate of 1Hz, the Multi-Flo can accurately detail any variations in flow or pressure, providing a real-time picture of the quality of infusion.

The Multi-Flo's unique instantaneous flow measurements are directly comparable with tests using the traditional scales method, but without the typical associated challenges such as setup time, recording of data, vibration, air-pressure variations and evaporation at low flow rates.

Tests have demonstrated that on typical low flow rates, users can reduce testing time by up to 50%, providing significant annual cost savings.

## IEC 60601-2-24 requirements

To meet the requirements of IEC 60601-2-24, the Multi-Flo also provides accurate back pressure simulations, occlusion alarm monitoring and bolus (PCA) measurements. A large colour screen presents the data in both numerical and graphical format, giving the user the flexibility to monitor acquired volume, flow delivery profiles, pressure changes and bolus volumes.

Manufacturer specific test routines can be programmed and automatically executed, removing the need for manual recording of data, reducing duplication of work and reduces the risk of data errors.



A remote control interface is available via Rigel's proprietary test solution software Med-eBase, allowing the complete control of the Multi-Flo's features from the comfort of a PC. Requiring just a single USB connection per Multi-Flo, users can connect as many multi-channel Multi-Flo's to a PC as they have USB ports, increasing the test capacity in high volume test environments.

Med-eBase software also provides an easy way to create default templates, producing real time and high resolution graphs including trumpet curves, and storage of test data. Thanks to its database structure, the software builds a complete history of each asset including functional and electrical safety test results along with user definable visual inspections. Customised PDF test certificates can be included to form a corporate identity on each individual certificate.

Med-eBase provides a total solution from test and inspection through to record management and certification and together with Multi-Flo, is part of a range of advanced analysers, simulators, testers and accessories from Rigel Medical.

Find out more about the Multi-Flo infusion pump analyser at:  
[www.rigelmedical.com/multi-flo](http://www.rigelmedical.com/multi-flo)



# At the heart of cardiac surgery robot testing



**A ground breaking project in Poland to create a new generation of advanced cardiac surgery robots is utilising the latest in portable analysers to improve electrical safety testing during product development.**

Robin Heart, instigated by the Professor's Zbigniew Religa Foundation of Cardiac Surgery Development, is Europe's first medical robot for cardiac surgery with semi-automatic movements, an advanced human-machine interface and a 3D virtual training system.

There are an estimated four million minimally-invasive surgeries undertaken annually around the world, and the robot technology aims to reduce the risk factor by using advancements in precision robotics to improve surgical accuracy and manoeuvrability.

Ensuring that all the vital electrical components of the robot system function properly and safely during the various stages of product development is a critical part of this research project that could radically alter the future shape of medical surgery.

Testing has to be undertaken in accordance with IEC 60601-1 medical electrical equipment - Part 1: General requirements for basic safety and essential performance. The components also have to be regularly inspected and tested to make sure they comply with IEC 62353, the standard for in-service and after repair testing of medical electronic devices.

The 288 analyser has been supplied by Rigel Medical's distributor in Poland, SAMSO, and features multi-lingual menu driven instructions, with download report, for simple operation and test control of all electrical safety tests in manual, semi automatic or fully automatic test modes.

It is the industry's smallest automatic safety analyser, providing fast and accurate testing of patient, enclosure and earth leakage as well earth continuity and insulation resistance.

The compact design is particularly beneficial for the technicians involved in the Robin Heart project, providing improved portability and ease-of-use during completion of electrical safety checks.

Kamil Rohr, engineer at the Foundation of Cardiac Surgery Development, has been impressed by the reliability and accuracy of the tester.

He said: "It provides a higher degree of measurement accuracy than other testers, while the advanced software is impressive, allowing us in particular to plot trends in measurement values.

"It incorporates a good range of features for a tester of its size, while the connectivity benefits are particularly impressive. The ability to create our own test sequences is particularly useful while we find it easy-to-use and appreciate the fact that it's compact enough to carry around our research facility.

"The multi-lingual functions are also a beneficial feature, while importing and exporting data capabilities is also helpful, enabling us to store test information which can then be easily retrieved and used for audit purposes."

The 288 offers an accurate solution for testing devices for electrical safety to appropriate standards including IEC/EN 62353, IEC/EN60601-1, VDE 0751-1, AS/NZS 3551, AAMI, NFPA-99, MDA DB 9801-2006.

For more information on the Rigel 288 go to [www.rigelmedical.com/288](http://www.rigelmedical.com/288)



In our regular spot, **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](mailto:pulse@rigelmedical.com)

**Q** I am just about to upgrade my PC from Windows XP to windows 7. Can I continue to use my Med-eBase software with the Rigel product range?

*Luciano, Malta*

**A** Yes, Med-eBase is fully compatible with Windows 7 and you will be able to continue benefiting from the program's features on your new operating system. Enhanced security settings in Windows 7 do require certain settings to be changed in both the software and during pairing the Rigel devices via Bluetooth. Please visit our support section on [www.rigelmedical.com/rigel-downloads](http://www.rigelmedical.com/rigel-downloads) and read application notes 0041 and 0058.

IEC 61010 states that touch leakage measurements are only required if the touch voltage is greater than 33V or 55V under SFC however, as leakage current is the ultimate pass or fail, using the Rigel 288 earth resistance and touch leakage tests, will indicate any safety issues.

Please visit our support section on [www.rigelmedical.com/rigel-downloads](http://www.rigelmedical.com/rigel-downloads) and read application note 0017 for further information.

**Q** I recently tested a medical device for earth leakage and although the readings were below the pass/fail limits, it was significantly different from the previous reading. Do you recommend to 'pass' this equipment as the manufacturer service manual refers to the limit in IEC 60601?

*Ryan, Northern Ireland*

**A** Pass fail limits in the IEC 60601 standard, are maximum allowable values which must be met during the design stage of a medical device. These limits are then often used during production and set in the service manuals. Typical values (provided they are below the pass / fail criteria) make a much better indicator for pass / fail as it encourages people to look at the previous or expected results. Med-eBase software can help by automatically comparing current results with previous results so the user can be made aware should a particular device leakage have drifted over time, which can be a possible imminent failure.

**Q** Is there a way to conduct safety testing on non-medical devices including IEC 61010 equipment using the Rigel 288 electrical safety tester?

*David, France*

**A** Yes, using the 1kΩ body model for medical devices, the Rigel 288 can be configured to perform most of the routine tests of non-medical equipment including laboratory equipment which can include; insulation tests, earth resistance and earth or touch leakage tests. Certain tests may also require a single fault condition (SFC).

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](mailto:pulse@rigelmedical.com).



Got a question? Send it to [pulse@rigelmedical.com](mailto:pulse@rigelmedical.com) for your chance to be in the next issue.

# Double your test capacity

Save time, save money



## Introducing the NEW Rigel Multi-Flo Infusion Pump Analyser

The only multi-channel infusion pump tester that provides instant flow rate, volume and pressure measurements for unbeatable speed and accuracy.

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Innovating Together