



## A Practical Guide to IEC 60601

Passionate about  
patient safety.



**RIGEL MEDICAL**  
TESTED, TRUSTED... WORLDWIDE.

## CONTENTS

<b>05</b>	Foreword
<b>06</b>	Introduction to IEC 60601
<b>07</b>	Local Adaptation
<b>08</b>	Commonly Used Definitions within IEC 60601
<b>10</b>	Symbols and Markings
<b>11</b>	Visual Inspection
<b>12</b>	Earth Bond (Protective Earth) Testing
<b>13</b>	Leakage Measurements
<b>15</b>	IEC 60601-1 Body Model
<b>15</b>	Single Fault Condition
<b>16</b>	Earth Leakage Test
<b>17</b>	Enclosure Leakage Test
<b>18</b>	Patient Leakage
<b>19</b>	Patient Leakage F-Type
<b>20</b>	Patient Auxiliary Current
<b>21</b>	Record Keeping

<b>22</b>	Conclusion
<b>23</b>	Appendix
<b>32</b>	Products in the Rigel Medical Range
<b>33</b>	Accessories and Services from Rigel Medical

© Copyright 2021 - All rights reserved. Nothing from this edition may be multiplied, or made public in any form or manner, either electronically, mechanically, by photocopying, recording, or in any manner, without prior written consent from Rigel Medical. This also applies to accompanying drawings and diagrams.



# Passionate about patient safety...

...accurate and fast, hand-held electrical safety analyzer.

The Rigel 288+ is the first truly handheld medical electrical safety tester to combine the features of an automatic / manual tester with data logging and asset management capability. Battery powered, ergonomic, robust and compact it's perfect for routine testing on fixed and portable medical electrical equipment.

**Features include:**

- Test to IEC/EN 62353, AAMI/IEC/EN 60601-1 and more
- Automatic testing with data storage capabilities
- Transfer your test data to asset management software
- Download data using your smartphone with The Rigel 288+ Downloader app



**RIGEL MEDICAL**  
TESTED, TRUSTED... WORLDWIDE.

To see the **Rigel 288+** for yourself, request your live online demonstration today at [rigelmedical.com/288plus](https://rigelmedical.com/288plus)

# Rigel Medical: We know about complying to IEC 60601-1.

After reading this booklet, so will you.

At Rigel Medical, we've been a pioneer of biomedical test and measurement instruments for more than four decades.

Our comprehensive suite of electrical safety analysers enable biomedical and clinical engineers to confirm their adherence to a series of industry standards, manufacturers' specifications and most importantly, keep patients, visitors, and staff safe in a healthcare environment.

Since launching the world's first IEC 601 electrical safety analyser in the 1970s, our user-focused developments continue to place us at the forefront of the industry. Today, our 288+ handheld electrical safety tester (testing to IEC 60601) is the first truly handheld tester of its kind to combine the features of an automatic/manual tester with asset management capability.

Alongside our commitment to quality, we also offer peace of mind to our customers who know that help and advice is always available.

If you need any assistance using our electrical safety testers to comply to IEC 60601 please visit [rigelmedical.com/support](https://www.rigelmedical.com/support) and raise a support ticket.

#### **European Office**

**T:** +44 (0)191 586 3511

#### **USA Office**

**T:** +1 -813-886-2775

Visit our website at [rigelmedical.com](https://www.rigelmedical.com) for more information.

## Foreword

This booklet is written as a guideline for people involved in testing medical electrical equipment and cannot be considered to replace the IEC 60601-1 standard.

Although all reasonable care has been taken to ensure accuracy of the information and reference figures and data have been taken from the latest versions of various standards, guidance notes and recognised 'best practices' to establish the recommended testing requirements, Rigel Medical, their agents and distributors, accept no responsibility for any error or omissions within this booklet, or for any misinterpretations by the user.

For clarification on any part of this booklet please contact Rigel Medical before operating any test instrument.

No part of this publication shall be deemed to form, or be part of any contract for training or equipment unless specifically referred to as an inclusion within such contract.

Rigel Medical assumes that the readers of this booklet are electronically technically competent and therefore does not accept any liability arising from accidents or fatalities resulting directly or indirectly from the tests described in this booklet.

Author: John Backes, MA

## Introduction to IEC 60601

Not all people will understand the dangers associated with the exposure to electricity. It is this danger that has triggered several discussions relating to the safety of all members of the public.

Regulatory bodies worldwide have acknowledged the dangers of electricity by producing legislation, standards and/or guidelines to control the design of electrical appliances in order to prevent any hazard to the general public.

One environment where electric currents pose an acute threat is in the medical treatment and care of patients. Often, patients are physically connected to one or more electrical medical devices for a period of time. In these circumstances it is possible that patients are unaware of their exposure to electrical currents, especially if being treated under full or local anaesthetic. During invasive treatments, the human body's natural protection organ, the skin, no longer provides basic insulation against electrical currents. It is during these treatments that electrical currents, as low as 50mA, can travel through the human body and cause the heart to fibrillate or paralyse the respiratory system.

The International Electrotechnical Committee (IEC) has produced a standard to control all aspects of safety directly or indirectly relating to the handling, use or connection to, of medical equipment. This standard is referenced as IEC 60601.

The IEC 60601 was first published in 1977, then referred to as IEC 601, and handles the electrical safety of both mechanical and electrical issues. It is constructed from 2 parts; IEC 60601-1 and IEC 60601-2, each built-up from a number of basic or collateral standards.

### Collateral Standard

IEC 60601-1-x (x representing a collateral standard number between 1-12) is the collateral standard; this is the primary standard which has a number of specific standards related directly to the safety of medical equipment.

### Specific Standards

IEC 60601-2-x (x representing a specific standard number between 1-76), are the standards specific to various types of medical equipment, providing additional information to the collateral standards. **Appendix C** and **D** provide an overview of the IEC 60101-1-x and IEC 60601-2-x standards.

This booklet describes the electrical safety requirements for compliance with IEC 60601-1. Although a type of test standard, most of these tests are used to test medical devices, both regularly and following service or repair.

## Local Adaptation

In many cases the IEC 60601 standard has been adapted into local standards for use in countries around the world. Some examples are EN 60601 (EU), ANSI/AAMI ES60601 (USA), UL60601-1 (USA), CSA C22.2 no 60601-1 (Canada), JIS T 0601-1 (Japan) and AS/NZ 60601.1 (Australia/New Zealand).

Safety testing at the design stage and at the end of the production line is vitally important, but what about when the equipment enters service?

IEC 62353 Medical Electrical Equipment - Recurrent Test and Test After Repair of Medical Equipment defines the requirements for electrical safety testing of medical electrical (ME) equipment and systems during routine intervals.

Following the need for a unified approach to routine testing, the first edition of IEC 62353 brought together a set number of tests to allow its users to test means of operator protection (MOOP) and means of patient protection (MOPP) dielectric integrity via two distinct leakage current tests.

In meeting this requirement the IEC 62353 incorporates tests beyond those of type testing. Specifically, it seeks to provide a uniformed and unambiguous means of assessing the safety of medical equipment, whilst maintaining the relevance to IEC 60601-1 and minimising the risks to the person conducting the assessment.

Some countries have also produced standards or guidelines for the safety testing of newly-delivered medical devices, referred to as acceptance testing; testing during regular intervals, referred to as preventive maintenance tests; and testing following service or repair. Some examples are DIN VDE 0751 (Germany), AS/NZ 3551 (Australia/New Zealand), and AAMI/NFPA 99 (USA).

Countries without a national guidance or code of practice mainly follow the manufacturer's instructions or guidelines, which most commonly refer to the IEC 60601-1 test requirements. In essence, all standards have one thing in common: to control the safety of medical devices for use in the treatment, care and diagnosis of patients and/or individuals.



## Commonly Used Definitions within IEC 60601

### Equipment Under Test (EUT)

The equipment which is the subject of testing.

### Device Under Test (DUT)

The device which is the subject of testing.

### Applied Part

Part of the medical equipment which is designed to, or likely to, come into physical contact with the patient.

### Patient Connection

Individual physical connections and/or metal parts intended for connection with the patient which form (part of) an applied part.

### Patient Environment

Volumetric area in which a patient can come into contact with medical equipment or contact can occur between other persons touching medical equipment and the patient, both intentionally and unintentionally (see Appendix E).

### F-Type Applied Part

Applied part which is electrically isolated from earth and other parts of the medical equipment i.e. floating F-Type applied parts are either type BF or type CF applied parts.

### Type B Applied Part

Applied part complying with specified requirements for protection against electric shock. Type B applied parts are those parts, which are usually earth referenced. Type B applied parts are those parts not suitable for direct cardiac application.

### Type BF Applied Part

F-Type applied part complying with a higher degree of protection against electric shock than type B applied parts. Type BF applied parts are those parts not suitable for direct cardiac application.

### Type CF Applied Part

F-Type applied part complying with the highest degree of protection against electric shock. Type CF applied parts are those parts suitable for direct cardiac application.

### Medical Electrical Equipment

Electrical equipment designed for treatment, monitoring or diagnoses of patients, powered from one connection to mains supply. Does not necessarily require physical or electrical contact with the patient, transfer energy to or from the patient, or detect such energy transfer to or from the patient.

### Medical Electrical System

A combination of equipment of which at least one is classed as medical electrical equipment and is specified by the manufacturer to be connected by functional connection or use of a multiple portable socket outlet.

### Class I

Equipment protection against electric shock by (earthed) additional protection to basic insulation through means of connecting exposed conductive parts to the protective earth in the fixed wiring of the installation.



### Class II

Also referred to as 'double insulated'. Equipment protection against electric shock by additional protection to basic insulation through supplementary insulation. There is no provision for the connection of exposed metalwork of the equipment to a protective conductor and no reliance upon precautions to be taken in the fixed wiring of the installation.

**Note:** Class II equipment may be provided with a functional earth terminal or a functional earth conductor.

## Symbols and Markings

The IEC 60601 has defined the requirements for information/data to be present on the medical equipment's nameplate, in order to form an unambiguous identification of the equipment.

Information must include specific manufacturer and equipment information, including manufacturer's name, model number, serial number, and electrical requirements.

The IEC 60601 standard refers to a large variety of symbols for use on medical equipment, medical systems, accessories and other related parts. A full overview of the symbols used in IEC 60601 is provided in the standard. For the purpose of this booklet, a selection of the most commonly used symbols is displayed below:



Class I



Class II



Earth reference point



i.e.  
"Conformité  
Européenne"



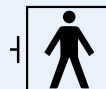
Type B applied part



Defibrillation  
proof type B  
applied part



Type BF applied part



Defibrillation  
proof type BF  
applied part



Type CF applied part



Defibrillation  
proof type CF  
applied part

## Visual Inspection

The process of visual inspection is not clearly defined by IEC 60601, however visual inspections form a critical part of the general safety inspections during the functional life of medical equipment. Around 70% of all faults are detected during visual inspection.

Visual inspection is a relatively easy procedure to support your assessment that the medical equipment in use still conforms to the specifications as released by the manufacturer and has not suffered from any external damage and/or contamination.

These can include the following inspections:

- Housing enclosure – look for damage, cracks etc.
- Contamination – look for obstruction of moving parts, connector pins etc.
- Cabling (supply, applied parts etc.) – Look for cuts, wrong connections etc.
- Fuse rating – check correct values after replacement
- Markings and labelling – check the integrity of safety markings
- Integrity of mechanical parts – check for any obstructions

## Earth Bond (Protective Earth) Testing

Earth bond testing, also referred to as ground bond testing, earth resistance, earth continuity or protective earth testing, tests the integrity of the low resistance connection between the earth conductor and any metal conductive parts, which may become live in case of a fault on Class I medical devices.

Although many Class I medical devices are supplied with an earth reference point, most medical devices require multiple earth bond tests to validate the connections of additional metal accessible parts on the enclosure.

The test current is applied between the earth pin of the mains supply plug and any accessible metal part, including the earth reference point, with a dedicated earth bond test lead using a crocodile clip or probe.

The IEC 60601-1 (clause 8.6.4) requires a minimum test current of either 25A AC or 1.5 times the highest rated current of the relevant circuit(s), whichever is greater. The open circuit voltage of the current source should not exceed 6V.

A test current of 25A AC is most commonly used. Due to the exposure of high current, some parts of the equipment could be damaged and therefore requires a lower test current. However, the earth bond test is designed to stress the connection under fault conditions.

Faults in the detachable power cord account for 80-90% of all Earth bond failures, as most moulded power cables are prone to stress when the cables are dropped.

For fixed installations, such as MRI or x-ray equipment) a point-to-point continuity measurement can be made. The resistance is then measured between two probes: one connected to the incoming earth reference point and one placed on accessible, metal parts of the medical installation.

Test limits are set at 0.1  $\Omega$  for fixed power cords and 0.2  $\Omega$  for equipment with a detachable power cord. See **Appendix A** for a full overview of the IEC 60601-1 test limits.

Prolonged use of testing at high currents can lead to a high probe temperature. Care should be taken to avoid touching the probe tip under these conditions.

## Leakage Measurements

It takes only a small amount of current to cause major consequences. Research has shown that current, not voltage, is often the source of injury or death.

When an electrical current flows through the human body the effect is influenced by two main factors: Firstly, the amount of current, and secondly, the length of time the current flows.

For example, the heart stops if the current persists for 250mS at 40mA, 100mS at 100mA, or 50mS at 200mA.

Consider the following examples of the effect of current on the human body when applied to the skin (non-invasive):

**0.9 - 1.2mA** Current just perceptible.

**15.0 - 20.0mA** Release impossible. Cannot be tolerated over 15 minutes.

**50.0 - 100.0mA** Ventricular fibrillation. Respiratory arrest, leading directly to death.

**100.0 - 200.0mA** Serious burns and muscular contraction of such a degree that the thoracic muscles constrict the heart.

For this reason, the IEC 60601 committee has set stringent rules on the design of medical equipment to prevent any patient or operator being exposed to currents not part of the functional operation of the device. These currents are referred to as leakage currents.

IEC 60601 defines leakage current of three different sources:

**Earth leakage:** current flowing down the protective earth conductor of the mains inlet lead.

**Enclosure leakage:** current flowing to Earth through a person by touching the medical equipment/system or part of.

**Applied part or patient leakage:** current flowing through a person to earth from the applied part, or current flowing from a person to earth through the applied part by applying unintended voltage from an external source.

Applied part/patient leakage can be classed into number of measurements such as:

- Patient leakage (please refer to the corresponding paragraph)
- Patient F-Type leakage (please refer to the corresponding paragraph)
- Patient auxiliary leakage (please refer to the corresponding paragraph)

Compare these values to the fact that 250mA of current is required to power a 25 watt lamp.

Applied part or patient leakage is the most important part of leakage measurement on any medical device. Applied parts are directly in contact with the patient or, in the case of invasive devices, placed under the patient's skin. Currents applied under the skin, which forms our natural protection against electrical currents, can result in far greater consequences, with currents as low as 15  $\mu$ A resulting in fatality.

The limits for leakage currents within the IEC 60601-1 requirements are set to minimising the probability of ventricular fibrillation to a factor as low as 0.002 – the limit of 10  $\mu$ A for CF applied part under normal condition. See **Appendix A** for a full overview of the IEC 60601-1 test limits.

The following tests find their origin from the IEC 60601-1 but are specific to the AAMI and NFPA 99 standards (USA):

- **Patient leakage (applied part to ground):** Similar to patient leakage (see description above).
- **Patient leakage (applied part to case):** Similar to patient leakage (see description above) with leakage current path coming from the applied parts, through the patient, to the casing of the EUT/DUT.
- **Patient auxiliary (applied part to applied part or lead to lead):** Similar to patient auxiliary current (see description above).
- **Patient auxiliary (applied part to all):** Similar to patient auxiliary current (see description above). For the purpose of this booklet, the focus will be on the directly related leakage measurements as per IEC 60601-1.

**Warning:**

**Mains voltage applied to appliance.**

It is important to verify that a medical device with moving parts (such as a motor or pump) is safely mounted to allow movement, without causing damage to people or equipment. Secondary earth paths will affect the leakage measurements and can give false PASS readings. Always make sure that the device under test is positioned safely and isolated from earth when measuring leakage.

## IEC 60601-1 Body Model Single Fault Condition

To ensure a traceable simulation of current as if passing through a human body, measurement circuits have been designed to simulate the average typical electrical characteristics of the human body. These measurement circuits are referred to as body models or measuring devices (MD in IEC 60601-1).

Some standards such as the AAMI/NFPA 99 and the IEC 61010 (Safety requirements for electrical equipment for measurement, control, and laboratory use) specify different electrical characteristics to that of the IEC 60601-1.

The IEC 60601-1 body model or measuring device is shown in **Appendix B**.

To maintain a medical device's high level of protection during its operational life and maintain the integrity of the device's electrical safety, a number of design features are taken into account. This is done by introducing conditions that could occur under normal use, such as reversed mains supply or voltage on signal input/output terminals (SIP/SOP), and conditions that can occur under a single fault condition (SFC).

IEC 60601-1 specifies a number of single fault conditions (SFCs) under its clause 8.1. For the purpose of this booklet, the only highlighted SFCs are the interrupted earth connection (open earth) and interruption of any of the supply conductors (open neutral).

IEC 60601-1 specifies that all leakage measurements should be carried out using normal and single fault conditions. A typical part of the electrical safety testing procedures is to perform the test as follows:

1. Normal supply voltage (No SFC)
2. Normal supply voltage (Open neutral)
3. Normal supply voltage (Open earth)
4. Reversed supply voltage (No SFC)
5. Reversed supply voltage (Open neutral)
6. Reversed supply voltage (Open earth)

In addition to these tests, some manufacturers may choose to include voltage on the signal input/output terminals (i.e. communication ports such as USB or RS 232). As this test can be destructive, it is not commonly used other than during type testing of the medical electrical equipment.



## Earth Leakage Test

The earth leakage test shows the current flowing through the medical device or its insulation into the protective earth conductor. The earth leakage test is important as it demonstrates the total leakage from the EUT/ DUT.

IEC 60601-1 specifies that the measurements are done under normal and reverse operation and single fault condition (neutral open circuit). The earth leakage test is valid for Class I equipment with Type B, Type BF and Type CF applied parts. **Appendix A** shows the pass/fail limits as per IEC 60601-1 requirements.

**Note:** SFC 'open earth' cannot be performed as this would result in zero leakage measurements under all circumstances.

**Diagram A** shows a schematic interpretation of the earth leakage measurement including the relays operating the single fault conditions.

### Earth leakage, normal conditions

This test measures the earth leakage current under normal conditions. The current is measured through the measuring device with **S1 closed**, S5 normal, and then S5 reversed.

### Earth leakage, single fault, supply open

This test measures the earth Leakage current with a single fault condition (supply open). The current is measured through the measuring device with **S1 open**, S5 normal, and then S5 reversed.

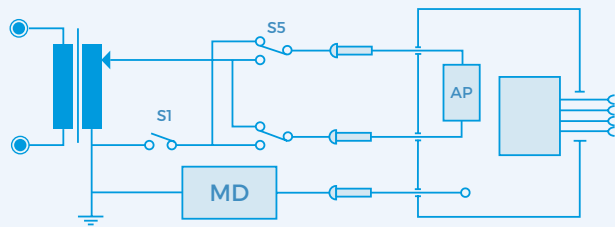


Diagram A - Test circuit for earth leakage

## Enclosure Leakage Test

In general, enclosure leakage displays the current that would flow if a person came into contact with the housing (or any accessible part not intended for treatment or care) of the medical device.

IEC 60601-1 specifies that the measurements are done under normal and reverse operation of the mains supply and single fault conditions open neutral circuit and open earth. The enclosure leakage test is valid for both Class I and II equipment with Type B, Type BF and Type CF applied parts. **Appendix A** shows the pass/fail limits as per IEC 60601-1 requirements.

**Note:** For Class II equipment, the single fault earth open tests are not required.

**Diagram B** shows a schematic interpretation of the earth leakage measurement including the relays operating the single fault conditions.

### Enclosure leakage, normal condition

This test measures the enclosure leakage current under normal conditions. The current is measured through the measuring device with S1 and S8 closed and S5 normal and reversed.

### Enclosure leakage, single fault, supply open

This test measures the enclosure leakage current with a single fault condition (earth open). The current is measured through the measuring device with S1 open, S8 closed and S5 in normal and then S5 reversed.

### Enclosure leakage, single fault, earth open

This test measures the enclosure leakage current with a single fault condition (earth open). The current is measured through the measuring device with S1 closed, S8 open and S5 in normal and then S5 reversed.

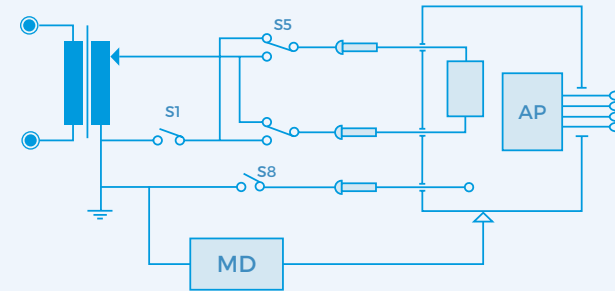


Diagram B - Test circuit for enclosure leakage

## Patient Leakage

The patient leakage current is the current flowing from the applied part via the patient to earth, or flowing from the patient via an applied part to earth originating from an unintended voltage appearing on an external source.

IEC 60601-1 specifies that the measurements must be done under normal and reverse operation of the mains supply and single fault conditions open neutral circuit and open earth. The patient leakage test is valid for both Class I and Class II equipment with Type B, Type BF and Type CF applied.

**Appendix A** shows the pass/fail limits as per IEC 60601-1 requirements.

**Note:** For Class II equipment, the single fault earth open tests are not required.

For Type CF equipment the patient leakage current is measured from each applied part separately. However, for Type B and Type BF equipment, the patient leakage current is measured with all applied parts connected together.

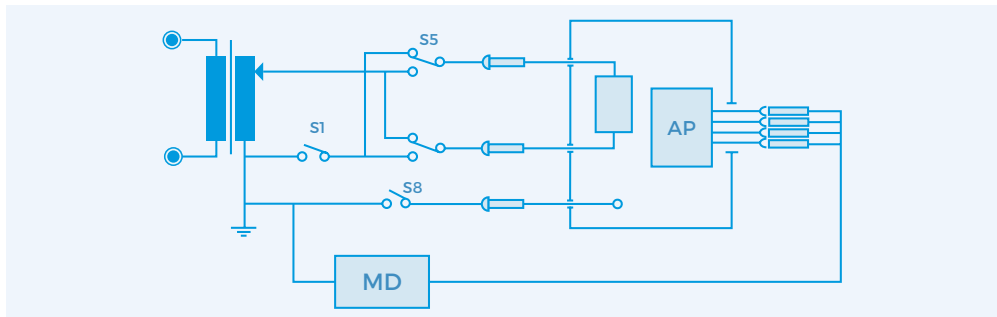


Diagram C - Test circuit for patient leakage current

**Diagram C** shows a schematic interpretation of the patient leakage measurement, including the relays operating the single fault conditions.

### Patient leakage, normal condition

This test measures the patient leakage current under normal conditions. The current is measured through the measuring device with S1 and S8 closed, S5 normal, and then S5 reversed.

### Patient leakage, single fault, supply open

This test measures the patient leakage current with a single fault condition (earth open). The current is measured through the measuring device with S1 closed, S8 open, S5 normal, and then S5 reversed.

### Patient leakage, single fault, earth open

This test measures the patient leakage current with a single fault condition (earth open). The current is measured through the measuring device with S1 closed, S8 open, S5 normal, and then S5 reversed.

## Patient Leakage: F-Type

The patient leakage F-Type Test (also known as mains on applied part test) displays the current that would flow if a mains potential was applied to the applied part which was attached to a patient (i.e. a single fault condition). This test is applied only to Type BF and Type CF equipment.

This test involves applying a current limited mains potential (110% of mains input voltage) to the applied part connections. Due to the requirements for IEC 60601-1, this test current can be in excess of 5mA under short circuit conditions, and is therefore hazardous to the user. Caution should be taken when conducting this test. Current limiting is achieved with a limiting resistor in series with the measurement circuit.

IEC 60601-1 specifies that leakage current for Type CF applied parts is measured from each of the patient connection/applied parts separately. For Type BF equipment, the leakage current is measured with all parts of the same type of applied part connected together, shown in **Diagram D**.

The F-Type leakage test is valid for both Class I and Class II equipment. It is measured under mains normal or reverse and source voltage normal or reverse conditions. **Appendix A** shows the pass/fail limits as per IEC 60601-1 requirements.

**Diagram D** shows a schematic interpretation of the F-Type leakage measurement including the relays operating the single fault conditions.

The current is measured through the measuring device with S1 and S8 closed, S5 and S9 are switched between normal and reversed.

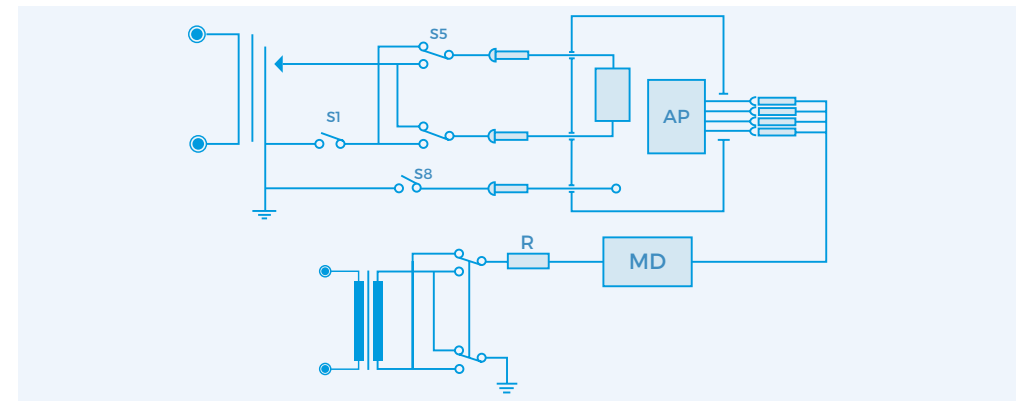


Diagram D - Test circuit for patient leakage current mains on applied part

## Patient Auxiliary Current

The patient auxiliary current displays the leakage current that would flow between applied parts under normal and fault conditions. For these tests, current is measured between a single part of the applied part and all other applied parts connected together. This test should be repeated until all combinations have been tested. This is also referred to as applied part to all.

IEC 60601-1 specifies that the measurements be carried out under normal and reverse operation of the mains supply and single fault conditions open neutral circuit and open earth. The patient auxiliary leakage test is valid for both Class I and II equipment with Type B, Type BF, and Type CF applied.

**Note:** For Class II equipment, the single fault earth open tests are not required.

**Diagram E** shows a schematic interpretation of the patient auxiliary leakage measurement including the relays operating the single fault conditions.

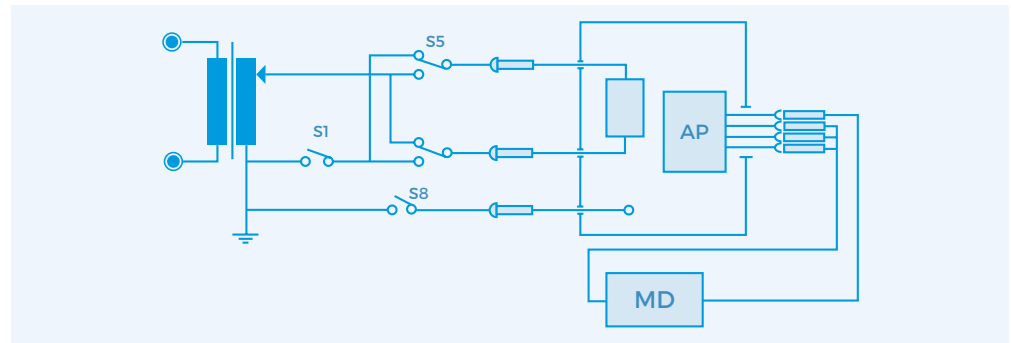


Diagram E - Test circuit for patient auxiliary current

### Patient auxiliary, normal condition

This test measures the patient auxiliary current under normal conditions. The current is measured through the measuring device with S1 and S8 closed, S5 normal, and then S5 reversed.

### Patient auxiliary, single fault, supply open

This test measures the patient auxiliary current under a single fault condition (supply open). The current is measured through the measuring device with S1 open, S8 closed, S5 normal, and then S5 reversed.

### Patient auxiliary, single fault, earth open

This test measures the patient auxiliary current under a single fault condition (earth open). The current is measured through the measuring device with S1 closed, S8 open, S5 normal, and then S5 reversed.

## Record Keeping

There are two paths for tracking preventative maintenance (PM) activity. First is a manual data capture process of test data. The other option is use of a computerised maintenance management software (CMMS).

Test instrument manufacturers offer test instruments capable of storing test results for the subsequent downloading to printers and digital applications.

Test instrument manufacturers have already responded with the introduction of instruments capable of storing test results for subsequent downloading to printers and digital applications.

Overall, the area of risk assessment and the creation of risk management files has become a growing feature of routine safety testing decisions, with different organisations and departments drawing-up individual plans to deal with specific safety hazards.

For the future, therefore, determining the appropriate levels of electrical testing to be taken without compromising the safety of staff or patients will be central to the introduction of cost effective yet reliable preventative maintenance campaigns.



## Conclusion

Electrical safety testing of medical electronic devices remains a crucial part of the overall safety validation of medical devices and requires specialised test equipment.

When choosing your electrical safety analyser, make sure it can be used to test in accordance with the IEC 60601-1 requirements and secondly that your analyser will enable you to accurately and repeatedly produce the results you require.

Essential requirements for electrical safety analysers are:

- User safety – this must never be compromised
- 25Ampere AC earth bond (ground bond) testing up to loads exceeding 0.2 Ω
- The measuring device meets the frequency response of the IEC 60601-1 body model
- High accuracy and repeatability of leakage measurement readings. Some manufacturers may specify accuracy of full scale reading which will affect the accuracy of low leakage measurements
- Traceability of measurement results. Do you require data storage?
- Test convenience, including test duration, user interface, time efficiency

Rigel Medical offers a range of test equipment in line with the IEC 60601 requirements.

Please visit our website, [rigelmedical.com](http://rigelmedical.com) for a full overview of our product offering or register online for our free newsletter on future product releases and product innovations.

If you need any assistance using our electrical safety testers to comply to IEC 60601 please visit [rigelmedical.com/support](http://rigelmedical.com/support) and raise a support ticket.

### European Office

T: +44 (0)191 586 3511

### USA Office

T: +1 -813-886-2775

## Appendix A: IEC 60601-1 Test Limits (3rd Edition)

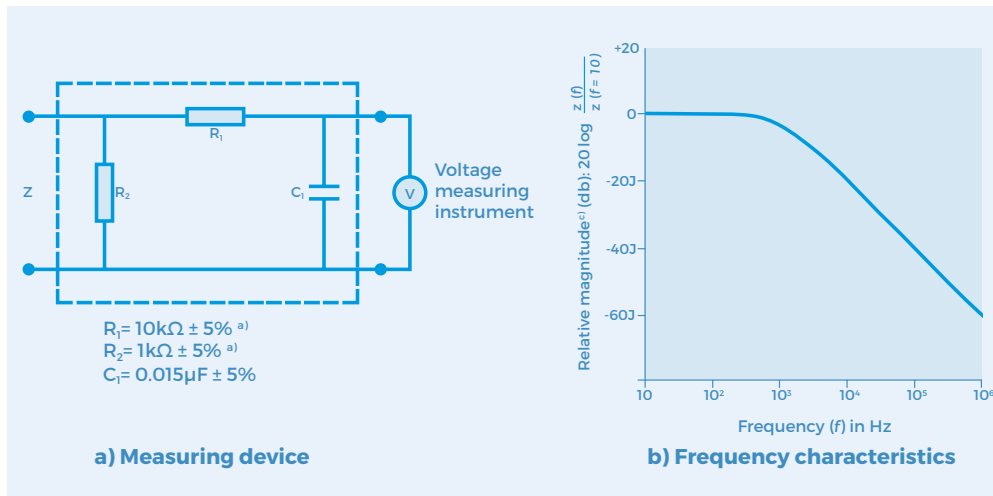
### Earth bond test limit at 25A, 50Hz


ME Equipment Type	Measurement	Limits
<b>Permanently Installed</b>	Between protectively earthed parts and PE terminal	<0.1Ω
<b>Detachable cord</b>	Between protectively earthed parts and earth pin on appliance inlet	<0.1Ω
<b>Non-detachable cord</b>	Between protectively earthed parts and earth pin on mains plug	<0.2Ω

Leakage Current Type	Type B Applied Parts		Type BF Applied Parts		Type CF Applied Parts	
	NC	SFC	NC	SFC	NC	SFC
<b>Earth Leakage</b>	5000µA	10000µA	5000µA	10000µA	5000µA	10000µA
<b>Enclosure Leakage</b>	100µA	500µA	100µA	500µA	100µA	500µA
<b>Patient Leakage (DC)</b>	100µA	500µA	100µA	500µA	10µA	50µA
<b>Patient Leakage (AC)</b>	100µA	500µA	100µA	500µA	10µA	50µA
<b>Patient Leakage (F-Type)</b>	NA	NA	NA	5000µA	NA	50µA
<b>Patient Leakage (mains on SIP/SOP)</b>	NA	500µA	NA	NA	NA	NA
<b>Patient Auxiliary Current (DC)</b>	10µA	50µA	10µA	50µA	10µA	50µA
<b>Patient Auxiliary Current (AC)</b>	100µA	500µA	100µA	500µA	10µA	50µA

\* The pass/fail limit for Earth Leakage in the 3rd edition of IEC 60601 has been increased from 500µA under normal condition to 5000µA for Class I equipment with NO exposed metal parts that may become live when a fault appears.

## Appendix B: IEC 60601 Body Model



**Note:** The network and voltage measuring instrument above are replaced by the symbol  in the following figures:

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

Diagram F - Example of a measuring device according to IEC 60601-1 and its frequency characteristics

## Appendix C:

**Table 1 - IEC 60601 Collateral Standards (© IEC Geneva, Switzerland)**

- IEC 60601-1  
Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2  
Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-1-3  
Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment
- IEC 60601-1-6  
Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 60601-1-8  
Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
- IEC 60601-1-9  
Medical electrical equipment - Part 1-9: General requirements for basic safety and essential performance - Collateral Standard: Requirements for environmentally conscious design
- IEC 60601-1-10  
Medical electrical equipment - Part 1-10: General requirements for basic safety and essential performance - Collateral Standard: Requirements for the development of physiologic closed-loop controllers
- IEC 60601-1-11  
Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- IEC 60601-1-12  
Medical electrical equipment - Part 1-12: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment



## Appendix D:

**Table 2 - IEC 60601 Specific Standards (© IEC Geneva, Switzerland)**

IEC 60601-2-1 Medical electrical equipment - Part 2-1: Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV	IEC 60601-2-17 Medical electrical equipment - Part 2-17: Particular requirements for the basic safety and essential performance of automatically-controlled brachytherapy after loading equipment
IEC 60601-2-2 Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories	IEC 60601-2-18 Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
IEC 60601-2-3 Medical electrical equipment - Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment	IEC 60601-2-19 Medical electrical equipment - Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators
IEC 60601-2-4 Medical electrical equipment - Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators	IEC 60601-2-20 Medical electrical equipment - Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators
IEC 60601-2-5 Medical electrical equipment - Part 2-5: Particular requirements for the basic safety and essential performance of ultrasonic physiotherapy equipment	IEC 60601-2-21 Medical electrical equipment - Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers
IEC 60601-2-6 Medical electrical equipment - Part 2-6: Particular requirements for the basic safety and essential performance of microwave therapy equipment	IEC 60601-2-22 Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment
IEC 60601-2-8 Medical electrical equipment - Part 2-8: Particular requirements for the basic safety and essential performance of therapeutic X-ray equipment operating in the range 10 kV to 1 MV	IEC 60601-2-23 Medical electrical equipment - Part 2-23: Particular requirements for the basic safety and essential performance of transcutaneous partial pressure monitoring equipment
IEC 60601-2-10 Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators	IEC 60601-2-24 Medical electrical equipment - Part 2-24: Particular requirements for the basic safety and essential performance of infusion pumps and controllers
IEC 60601-2-11 Medical electrical equipment - Part 2-11: Particular requirements for the basic safety and essential performance of gamma beam therapy equipment	IEC 60601-2-25 Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs
IEC 60601-2-16 Medical electrical equipment - Part 2-16: Particular requirements for basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment	IEC 60601-2-26 Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs
	IEC 60601-2-27 Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment

## IEC 60601-2-28

Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis

## IEC 60601-2-29

Medical electrical equipment - Part 2-29: Particular requirements for the basic safety and essential performance of radiotherapy simulators

## IEC 60601-2-31

Medical electrical equipment - Part 2-31: Particular requirements for the basic safety and essential performance of external cardiac pacemakers with internal power source

## IEC 60601-2-33

Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis

## IEC 60601-2-34

Medical electrical equipment - Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment

## IEC 60601-2-36

Medical electrical equipment - Part 2-36: Particular requirements for the basic safety and essential performance of equipment for extra corporeally induced lithotripsy

## IEC 60601-2-37

Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment

## IEC 60601-2-39

Medical electrical equipment - Part 2-39: Particular requirements for basic safety and essential performance of peritoneal dialysis equipment

## IEC 60601-2-40

Medical electrical equipment - Part 2-40: Particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment

## IEC 60601-2-41

Medical electrical equipment - Part 2-41: Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis

## IEC 60601-2-43

Medical electrical equipment - Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures

## IEC 60601-2-44

Medical electrical equipment - Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography

## IEC 60601-2-45

Medical electrical equipment - Part 2-45: Particular requirements for basic safety and essential performance of mammographic X-ray equipment and mammographic stereotactic devices

## IEC 60601-2-46

Medical electrical equipment - Part 2-46: Particular requirements for the basic safety and essential performance of operating tables

## IEC 60601-2-47

Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems

## IEC 60601-2-50

Medical electrical equipment - Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment

## IEC 60601-2-52

Medical electrical equipment - Part 2-52: Particular requirements for the basic safety and essential performance of medical beds

## IEC 60601-2-54

Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy

## IEC 60601-2-57

Medical electrical equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use

## IEC 60601-2-62

Medical electrical equipment - Part 2-62: Particular requirements for the basic safety and essential performance of high intensity therapeutic ultrasound (HITU) equipment

## IEC 60601-2-63

Medical electrical equipment - Part 2-63: Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment

## IEC 60601-2-64

Medical electrical equipment - Part 2-64: Particular requirements for the basic safety and essential performance of light ion beam medical electrical equipment

IEC 60601-2-65

Medical electrical equipment - Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment

IEC 60601-2-66

Medical electrical equipment - Part 2-66: Particular requirements for the basic safety and essential performance of hearing instruments and hearing instrument systems

IEC 60601-2-68

Electrical medical equipment - Part 2-68: Particular requirements for the basic safety and essential performance of X-ray-based image-guided radiotherapy equipment for use with electron accelerators, light ion beam therapy equipment and radionuclide beam therapy equipment

IEC 60601-2-75

Medical electrical equipment - Part 2-75: Particular requirements for the basic safety and essential performance of photodynamic therapy and photodynamic diagnosis equipment

IEC 60601-2-76

Medical electrical equipment - Part 2-76: Particular requirements for the basic safety and essential performance of low energy ionized gas haemostasis equipment

## Appendix E: Patient Environment

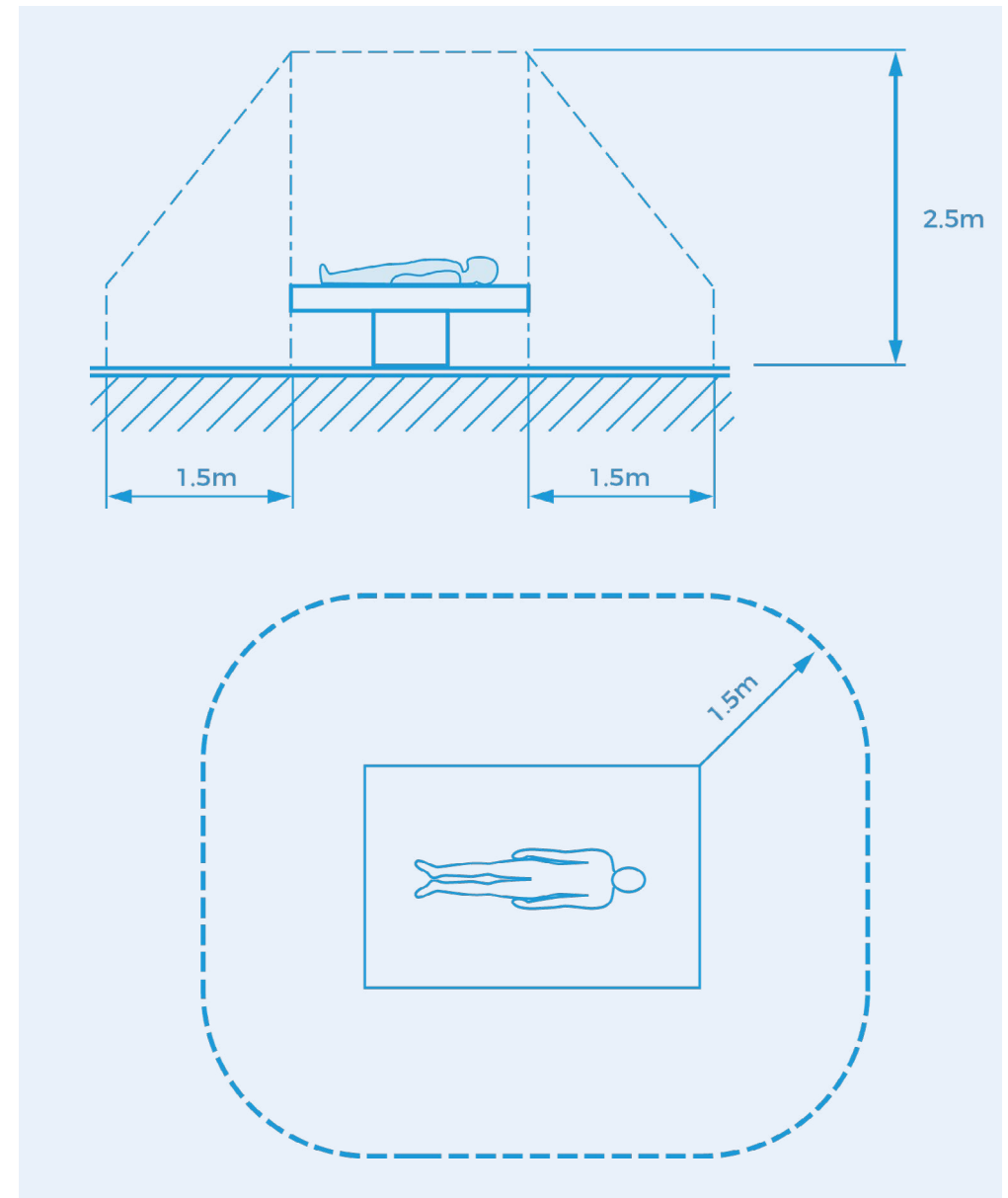


Diagram C - Patient environment

## Products in the Rigel Medical Range

### 288+

Accurate and fast electrical safety tester

- Light, handheld, battery operation\*
- Conforms to IEC 62353 / 60601 / VDE 0751 / NFPA-99 / AS-NZS 3551
- Memory for up to 5,000 devices
- Bluetooth communication
- Full, semi-automatic and manual testing
- Straightforward data transfer with the Rigel 288+ Downloader app



### SafeTest 60

A robust medical safety tester

- Small and compact
- Fully compliant (tests to a range of international standards including IEC 60601, 62353, 61010 and NFPA-99)
- Extremely flexible - manual control of fault conditions
- Versatile multi voltage - operates on any mains supply between 90-264V / 48-64Hz

View our full range of biomedical test equipment at  
[rigelmedical.com/products](https://rigelmedical.com/products)

## Accessories and services from Rigel Medical

### Accessories

Having the right accessories can streamline your testing processes and help you get the most from your instrument. Our range of accessories includes scanners, Bluetooth enabled printers, a variety of leads and adaptors, pass/fail labels and verification units.

To see the full range of Rigel Medical accessories available, visit:

[rigelmedical.com/accessories](https://rigelmedical.com/accessories)

### Training

Alongside our commitment to quality, we also offer peace of mind to our customers who know that help and advice is always available. Part of that offering includes training to support and help you get the most from your instrument.

Contact us directly to find out more.

### Online resources & support

At Rigel Medical we take pride in giving you all of the tools to make your life easier. We have a host of online resources and technical support features on our website including, FAQs, interactive videos and helpful how-to guides.

Most of our live webinars are CPD certified, meaning you can get 1 hour towards your Continuous Professional Development portfolio. Please look for the CPD mark when signing up to see if that webinar is eligible.

[rigelmedical.com/support](https://rigelmedical.com/support)



### Service, calibration & repair

Rigel Medical can also take care of your test and measurement equipment by providing calibration services (including on-site calibration), service, spares and repairs. Extend the life and quality of your instruments by contacting us for a no-obligation quote, wherever you are in the world.

[rigelmedical.com/service-centre](https://rigelmedical.com/service-centre)





Passionate about patient safety.



**RIGEL MEDICAL**

TESTED, TRUSTED... WORLDWIDE.

**European Office**

15 -18 Bracken Hill, South West Industrial Estate,  
Peterlee, County Durham, SR8 2SW. United Kingdom

**T:** +44 (0) 191 586 3511 **E:** sales@rigelmedical.com

**USA Office**

6304 Benjamin Road, Suite 506, Tampa, FL 33634, United States

**T:** +1 813 886 2775 **E:** sales@rigelmedical.com

[rigelmedical.com](http://rigelmedical.com)

