RIGEL MEDICAL
TESTED, TRUSTED... WORLDWIDE.

# SafeTest 60
# USER MANUAL


rigelmedical.com

**Limited Warranty & Limitation of Liability**

Rigel Medical, guarantees this product for a period of 1 year. The period of warranty will be effective at the day of delivery.

**Calibration Statement**

The Rigel SafeTest 60 hand-held electrical safety analyzer is fully calibrated and found to be within the specified performance and accuracy at the time of production. The Seaward Group provides its products through a variety of channels, therefore it may be possible that the calibration date on the provided certificate may not represent the actual date of first use.

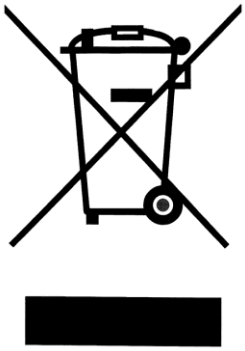
Experience has indicated that the calibration of this instrument is not effected by storage prior to receipt by the user. We therefore recommend that the recalibration period be based on a 12 month interval from the first date the unit is placed in to service.

For information on service or calibration please go to the link below.

www.rigelmedical.com/calibration

Date received into service; / / .

**Disposal of old product**



The Rigel SafeTest 60 has been designed and manufactured with high quality materials and components, which can be recycled and reused.

Please familiarise yourself with the appropriate local separate collection system for electrical and electronic products or contact your local supplier for further information.

Please dispose of this product according to local regulations. Do not dispose of this product along with normal waste material. By offering your old products for recycling, you will help prevent potential negative consequences for the environment and human health.

**User Notes**

These operating instructions are intended for the use of adequately trained personnel.

**Environmental Conditions**

The SafeTest 60 has been designed to be operated for indoor use in a dry environment, at a temperature of 0 to 40 degrees C without moisture condensation, and at an operating altitude 0 – 2000m.

The SafeTest 60 has a protection rating of IP40 and is rated for operation at pollution degree 2 according to IEC 60529.

The following symbols are used in these operating instructions and on the Rigel SafeTest 60.

**Safety Notes**


If the SafeTest 60 is used in a manner not specified by these operating instructions then the protection provided may be impaired.


Only accessories recommended or approved by the manufacturer should be used with the SafeTest 60.


Do not connect the SafeTest 60 to electrical circuits with nominal voltage greater than CAT II 300 V AC/DC.


Do not touch test probes beyond the hand barrier on the test probe.


The SafeTest 60 may apply high voltage or mains power to the appliance under test. Do not touch conductive parts of the appliance while tests are active.


Do not open the SafeTest 60, no user serviceable parts


Do not operate the SafeTest 60 in an explosive gas or dust environment.


The SafeTest 60 and all associated cables and leads must be checked for signs of damage before equipment is operated. Do not use if there are signs of damage.


Where safe operation of the SafeTest 60 is no longer possible it should be immediately shut down and secured to prevent accidental operation

It must be assumed that safe operation is no longer possible:

- if the instrument or leads show visible signs of damage or
- the instrument does not function or
- after long periods of storage under adverse environmental conditions.


To verify the correct operation of the unit, perform test functions using a known appliance or checkbox or return the unit to an approved agent for service.

# 1. Introduction

The Rigel SafeTest 60 is a dedicated medical safety analyzer, ideal for testing high volumes of basic medical and laboratory equipment. A robust and reliable design ensures that the SafeTest 60 can with-stand a busy schedule of testing medical equipment that does not require patient lead testing, such as beds, hoists, infusion pumps, CPAP's, and centrifuges etc.

With a large colour display and a colour-coded user interface, it's easy to select the required tests with a single key press, whilst a fast step-through of the test routine makes the testing process speedy and dependable. Whilst small, the SafeTest 60 includes a range of safety tests to enable compliance with a range of international safety standards, including leakage testing to IEC 60601, 62353 and 61010, earth bond testing to 62353 and 61010 (Annex F).

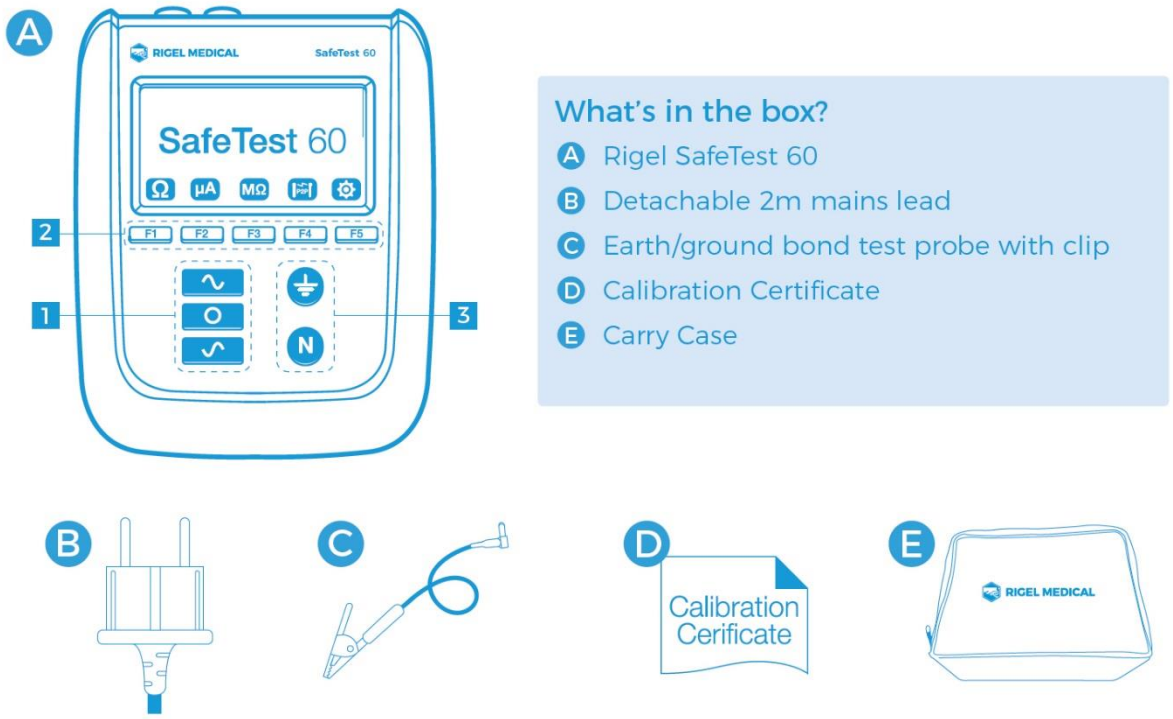
Full manual control offers the benefit of executing only those specific tests that are required and provide the user with full control of the power cycles, making testing simple, easy and fast. An automatic warning of secondary earth/ground paths ensures users are made aware when invalid readings are made, thus ensuring correct and accurate test results first time, every time.

## 1.1. Key Features

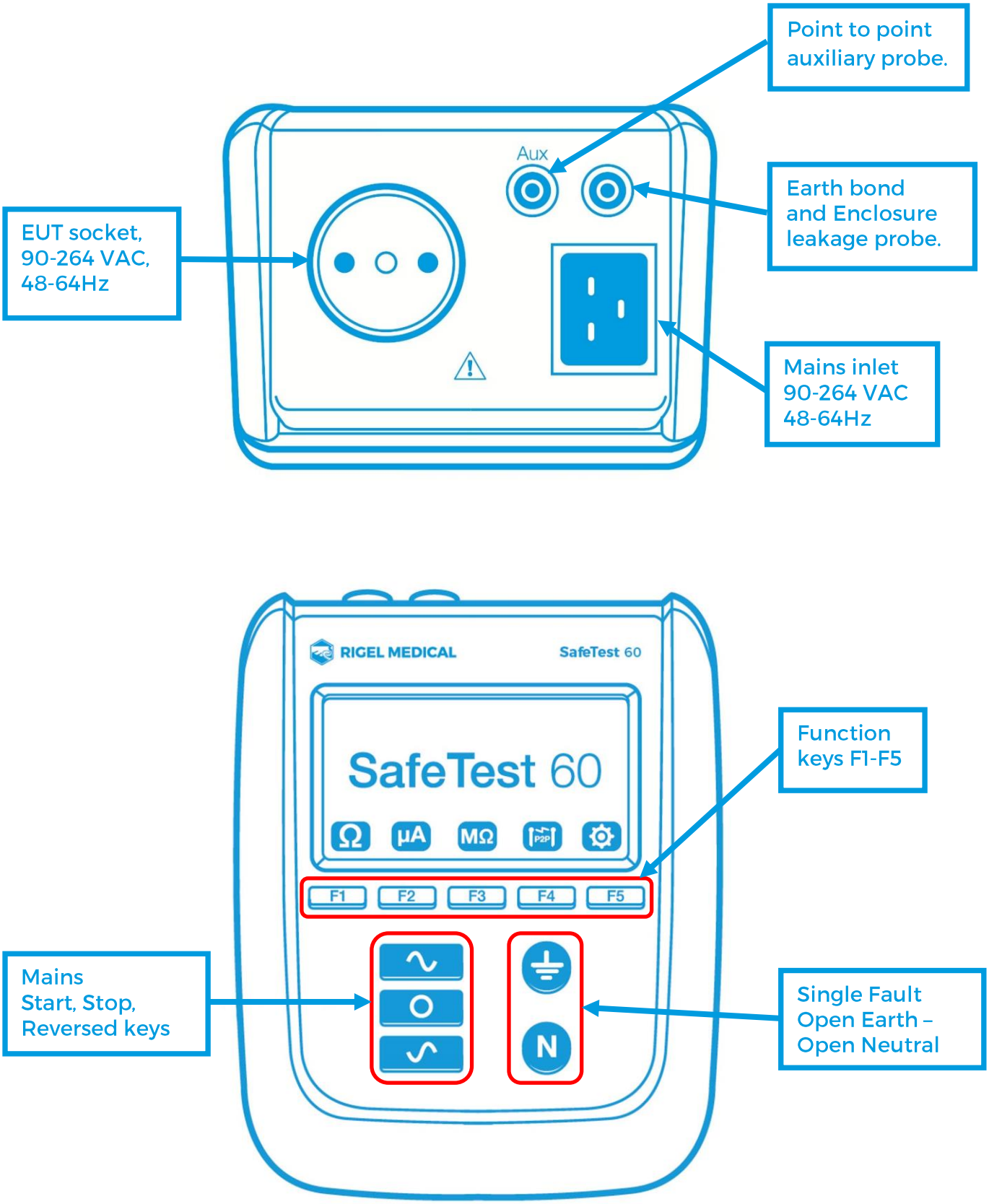
- Compact, robust and portable design
- Fast step-through of test routines with minimised power breaks
- Manual control of fault conditions
- Tests to a range of international standards including IEC 60601, 62353, 61010 and NFPA-99
- Insulation testing to IEC 62353
- Large colour display with clear read-out
- Secondary earth warnings to ensure valid test setup
- Accurate high current, low energy earth bond testing
- Supplied with free, protective carry case
- Multi voltage - operates on any mains supply between 90-264V / 48-64Hz

## 1.2. Rigel SafeTest 60 Includes:

- Calibration certificate
- Carrying case
- Bond test probe with clip
- Detachable mains cable
- Electronic instruction manual (from website)
- Quick start guide



## 1.3. Interfaces



## 1.4. Optional Accessories

| | |
|---|---|
| Earth bond cable | 44B154 |
| Carry case | 410A950 |

## 1.5. Unique use of ICONS

The Rigel SafeTest 60 features a hi resolution colour graphic back lit display provides a unique user experience and to help guide the user through the different test steps.

Below are of some of the icons used in the Rigel SafeTest 60:


Select **Earth Bond Testing**


Select **Leakage Testing**


Select **Insulation Testing**


Select **Point to Point Testing**

Select **Settings** menu (change **Language** and **Test Standard**)

Select to the required standard

Change to the required language

Product information, serial number

Confirm / OK


Display Line voltage, frequency and load current

Applies normal mains to EUT


Interrupts mains to EUT

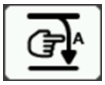

Applies reversed mains to the EUT

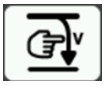

Warning, EUT socket live


Warning, 500VDC supplied to EUT


Select Earth leakage (in IEC60601 setting)


Select Enclosure leakage (in IEC60601 setting)


Select Touch Leakage (in IEC61010 setting)


Select Touch Voltage (in IEC61010 setting)


Open **Earth** single fault condition key

Open **Neutral** single fault condition key

Earth bond test lead compensated


Earth bond test running


Go to **Home screen**

# 2. Getting Started

The Rigel SafeTest 60 is pre-programmed to perform electrical safety tests in accordance with a variety of international standards. To get started, simply follow these instructions;

Switch ON:

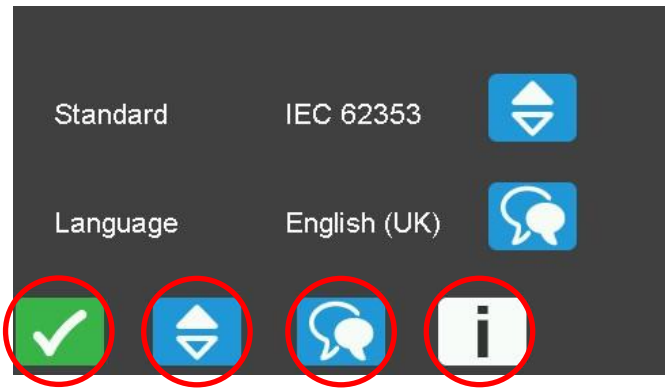
To switch on the Rigel SafeTest 60, please insert the mains cable to the power inlet, the SafeTest 60 will automatically power up in the **Home screen**.

## 2.1. Setting your Language and Preferred Test Standard

From the home screen, select **Settings** to select the required language and test standard;


**Settings menu**

Press from **Home screen** to enter **Settings menu**;




Press the key to change to the required language

Press the key to change to the required test standard

Press the i key to view the firmware and hardware information

Press the ✓ key confirm and return to the **Home menu**

Note: The Rigel SafeTest 60 will store the most recent settings in the **Settings menu**.

From the **Home screen**, select the required test;


Ω To select **Earth Bond Testing**

µA To select **Leakage Testing**

MΩ To select **Insulation Testing**

P2P To select **Point to Point Testing**

⚙ To select **Settings Menu** (change **Language** and **Test Standard**)

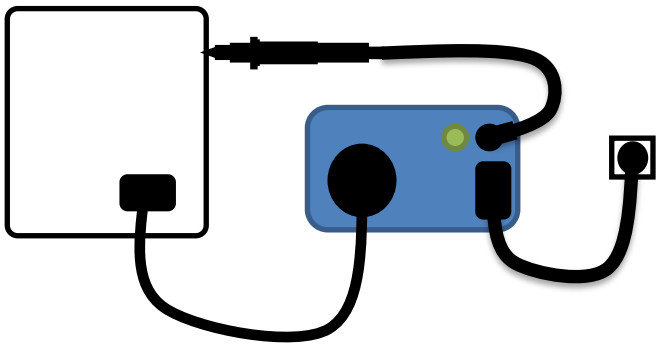
## 3. Earth Bond Testing

To perform an earth bond test, select the Ω icon from **Home screen**.


The SafeTest 60 will automatically start the test when it is selected and will automatically stop by pressing the Leakage, **Insulation, Point To Point** or **Home** icon.

**Connection Between EUT and SafeTest 60;**

**Earth Bond Testing**



Note: Each time the earth bond probe is placed on a new test point, the zap circuit will be reactivated, ensuring accurate readings at every measurement point.

**Do not exceed the maximum permitted voltage of 30 V AC/DC with respect to earth potential! Electric Shock danger!**

To compensate for the test cable resistance, connect the test cable between the black

Earth bond socket and the EUT earth, then press the button on the front panel.

When the lead compensation is activated, the Zero icon will appear on the screen.


To remove the lead compensation, remove the probe and press the button.

**When different earth bond cables are used, the Null function must be repeated for each different cable.**

Note: Switching off the Rigel SafeTest 60 will not cancel the 'probe zero'.

# 4. IEC 60601 Leakage Testing

To perform an IEC 60601 leakage test, press µA from **Home screen** to enter **Leakage test**. If the required test standard needs to change, please press Home and see **Error! Reference source not found.**.


To apply mains voltage in **Normal Polarity** and **Start** the test, press the button on the front panel. The test will run until the button is pressed.

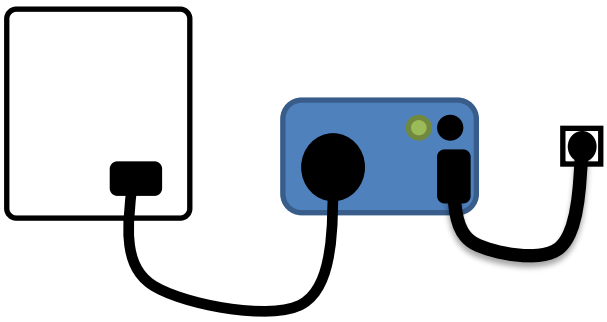
To apply mains in **Reversed Polarity** and **Start** the test, press the button on the front panel. The test will run until the button is pressed.

To minimise the power breaks during your tests, please see **Error! Reference source not found.**.

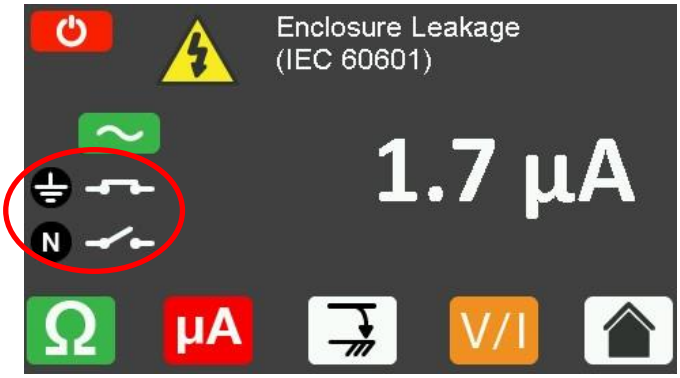
will appear on the screen when the DUT socket is activated.

**Connection Between EUT and SafeTest 60;**

**Earth Leakage**



When the SafeTest 60 is set to test to IEC 60601, the will go to **Enclosure Leakage** and to **Earth Leakage**.

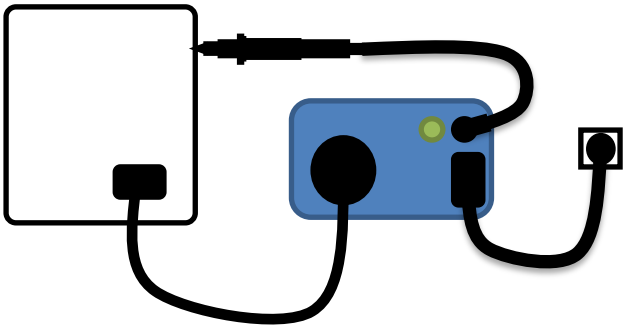



To activate single fault conditions, use the ⏚ and N buttons on the front panel. ⏚ opens the **Earth fault condition relay** whilst the N opens the **Neutral fault condition relay**.

The leakage screen will indicate the current state of the selected fault conditions;

**Connection Between EUT and SafeTest 60;**

**Enclosure Leakage**



| | All Applied Parts | |
|---|---|---|
| Leakage Current Type | NC | SFC |
| Earth Leakage (3rd edition)* | 5mA | 10mA |
| Earth Leakage (General) | 0.5mA | 1mA |
| Enclosure Leakage | 0.1mA | 0.5mA |

* 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.

## 4.1. Displaying Mains Voltage, Frequency and Load Current

During a leakage test, the mains voltage, frequency and load current can be displayed by pressing the V/I.

# 5. IEC 62353 Leakage Testing

To perform an IEC 62353 leakage test, press µA from **Home screen** to enter **Leakage test**.
If the required test standard needs to change, please press Home and see **Error! Reference source not found.**.


To apply mains voltage in **Normal Polarity** and START the test, press the button on the front panel. The test will run until the O button is pressed.

To apply mains in **Reversed Polarity** and START the test, press the button on the front panel. The test will run until the O button is pressed.

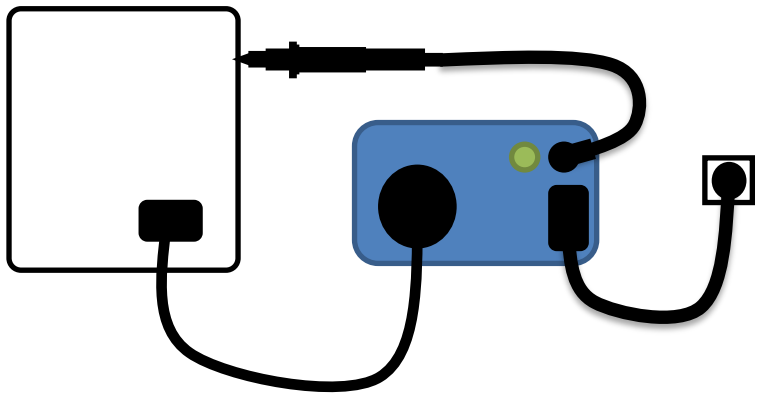
To minimise the power breaks during your tests, please see **Error! Reference source not found.**.

will appear on the screen when the DUT socket is activated.

When the SafeTest 60 is set to test to IEC 62353, the **Single Fault** buttons and N are deactivated in order to perform the test as per IEC 62353 requirements.

**Connection Between EUT and SafeTest 60;**

**Equipment Leakage IEC 62353**

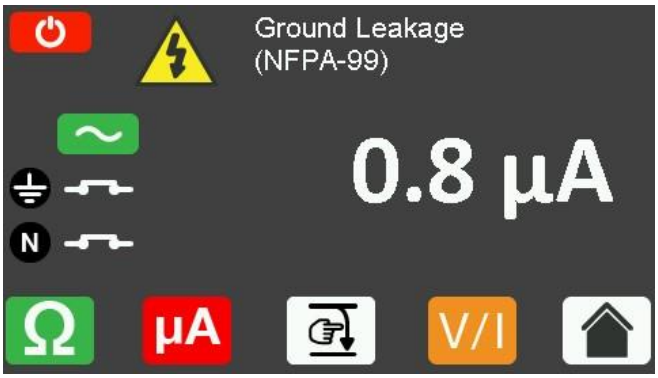


| Current in µA (RMS) | All Applied Parts |
|---|---|
| Equipment leakage – direct method. | |
| • Class I Equipment<br>• Class II Equipment (touch current) | 0.5mA<br>0.1mA |

## 6. NFPA-99 Leakage Testing

To perform an NFPA-99 leakage test, press µA from **Home** screen to enter **Leakage** test.

If the required test standard needs to change, please press Home and see **Error! Reference source not found.**.




To apply mains voltage in **Normal Polarity** and START the test, press the button on the front panel. The test will run until the button is pressed.

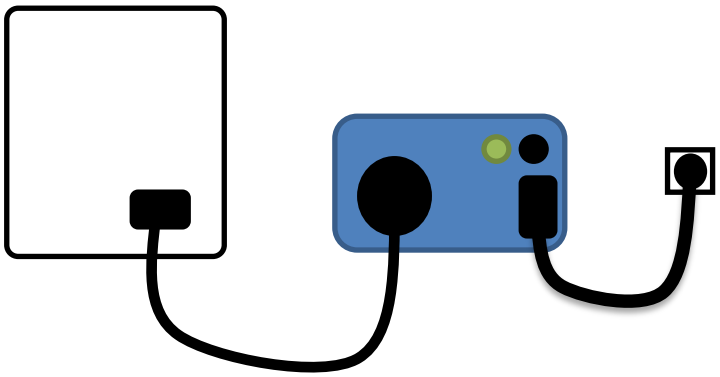
To apply mains in **Reversed Polarity** and START the test, press the button on the front panel. The test will run until the button is pressed.

To minimise the power breaks during your tests, please see **Error! Reference source not found.**.

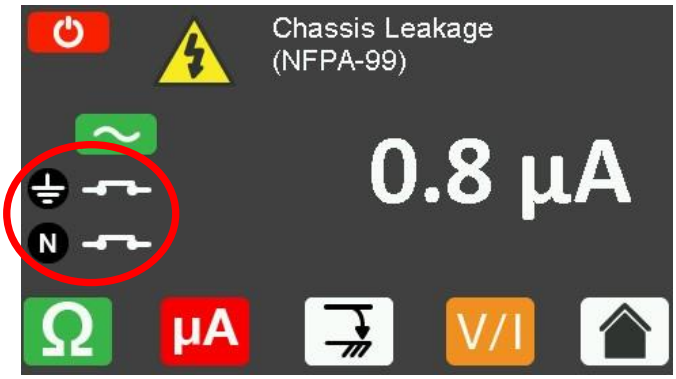
will appear on the screen when the DUT socket is activated.

**Connection Between EUT and SafeTest 60;**

**Ground Leakage NFPA-99**



When the SafeTest 60 is set to test to NFPA-99, the will go to **Chassis leakage** and to **Ground leakage**.

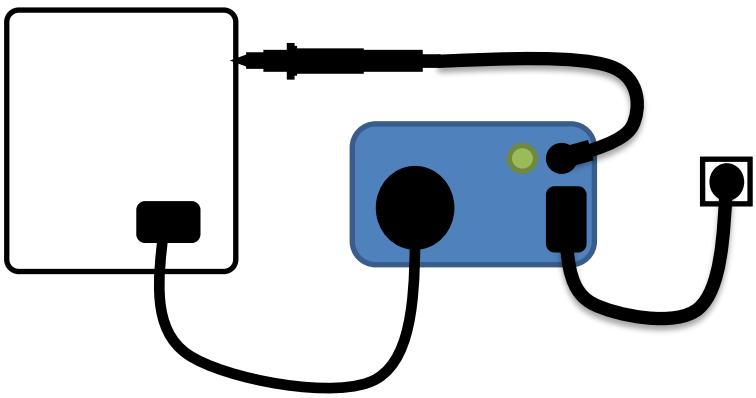



To activate single fault conditions, use the and buttons on the front panel. opens the **Earth fault condition relay** whilst the opens the **Neutral fault condition relay**.

The leakage screen will indicate the current state of the selected fault conditions;

**Connection Between EUT and SafeTest 60;**

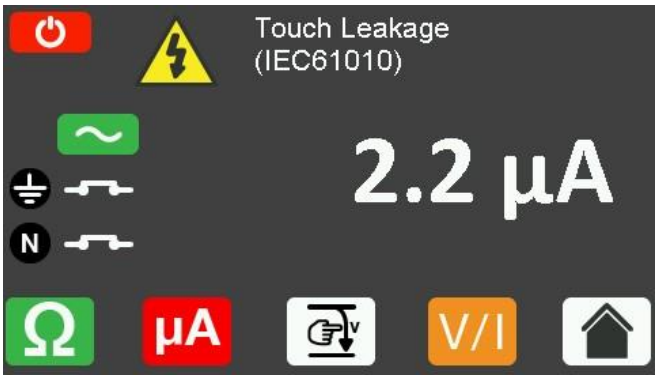
**Chassis Leakage NFPA-99**



| | For All Applied Parts | |
|---|---|---|
| Leakage Current Type | NC | SFC |
| Ground Leakage | 0.3mA | 1mA |
| Chassis Leakage | 0.1mA | 0.5mA |

# 7. IEC 61010 Touch Leakage & Voltage Testing

To perform an IEC 61010 touch leakage test, press µA from **Home screen** to enter **Leakage test**. If the required test standard needs to change, please press Home and see **Error! Reference source not found.**.



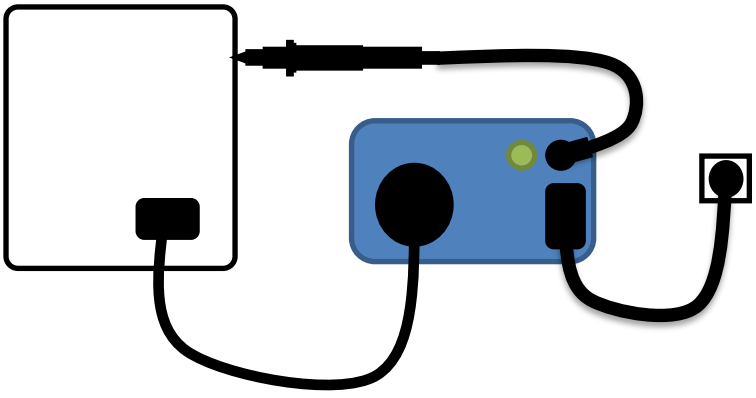

To apply mains voltage in **Normal Polarity** and START the test, press the button on the front panel. The test will run until the button is pressed.

To apply mains in **Reversed Polarity** and START the test, press the button on the front panel. The test will run until the button is pressed.

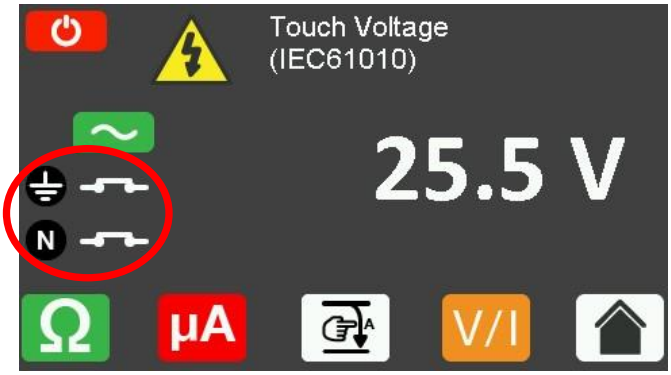
will appear on the screen when the DUT socket is activated.

**Connection Between EUT and SafeTest 60;**

**Touch Leakage and Touch Voltage IEC 61010**



When the SafeTest 60 is set to test to IEC 61010, the will go to **Touch Voltage** and to **Touch Leakage**.




To activate single fault conditions, use the  and  buttons on the front panel.  opens the **Earth fault condition relay** whilst the  opens the **Neutral fault condition relay**.

The leakage screen will indicate the current state of the selected fault conditions.

| IEC 61010 Tests | | |
|---|---|---|
| Tests | NC | SFC |
| Touch Leakage | 0.5mA | 3.5mA |
| Touch Voltage | 33V | 55V |

# 8. Minimise your Power Breaks in IEC 60601

Certain medical equipment can be sensitive to sudden power breaks or have a long power-up cycle. To protect your equipment or to reduce the overall test time, we suggest you run the SafeTest 60 in the following sequence;

To minimise the power breaks to the EUT, all leakage measurements should be grouped by Single Fault Condition (SFC).

As such, all leakage measurements are carried out for a specific SFC, leakage measurements are then repeated for the next SFC. This is to minimise the power breaks and power ups.

**Normal Polarity Testing – Power Up**

1. **Earth Leakage** Normal Supply
2. **Enclosure Leakage** Normal Supply, Earth CLOSED
3. **Enclosure Leakage** Normal Supply, Earth OPEN

**Normal Polarity Testing – Power Down**

4. **Enclosure Leakage** Normal Supply, **Neutral OPEN**
5. **Earth Leakage** Normal Supply, **Neutral OPEN**

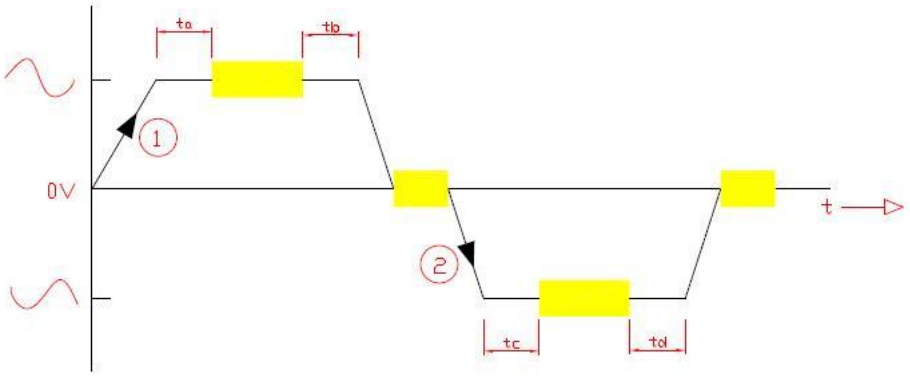
**Reversed Polarity Testing – Power Up**

6. **Earth Leakage** Reversed Supply
7. **Enclosure Leakage** Reversed Supply, **Earth CLOSED**
8. **Enclosure Leakage** Reversed Supply, **Earth OPEN**

**Reversed Polarity Testing – Power Down**

9. **Enclosure Leakage** Reversed Supply, **Neutral OPEN**
10. EARTH LEAKAGE Reversed Supply, **Neutral OPEN**

Below is a graph highlighting the Grouping of Single Fault Conditions ( ) and the delays which are manually controlled by the User (ta, tb, tc & td) and the time in which the safety analyzer performs the automatic test routines.



# 9. Insulation Testing

To perform an insulation test, press MΩ from **Home screen**.

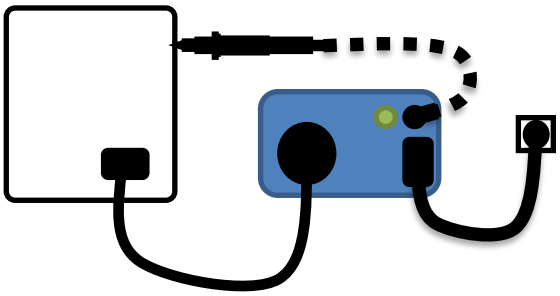

The SafeTest 60 will automatically start the test and will automatically stop by pressing the **Earth bond**, **Leakage**, **Insulation**, **Point to Point** or **Home** icon.

**During this test, 500V D.C. is applied between the black socket on the back panel as well as earth pin in the EUT socket and both the live and neutral pins of the EUT.**

The **Insulation Voltage** will be applied between **L-N to Earth** for class 1 equipment or L-N to the black socket for class 2 equipment.

**Connection Between EUT and SafeTest 60;**

**Insulation Testing IEC 62353**



Do not exceed the maximum permitted voltage of 30 V AC/DC with respect to earth potential! Electric Shock danger!

**Do not connect any probe combination to voltages in excess of 30 V AC/DC with respect to earth potential when performing non-power tests. This can cause damage to the equipment.**

| Insulation resistance limit MΩ | |
|---|---|
| Class I Equipment | >2MΩ |
| Class II Equipment | >7MΩ |

# 10. Point to Point Testing

To perform a **Point to Point** test, press  from **Home screen**.


Select  to perform a **point to point earth bond test**

Select  to perform a **point to point leakage test**

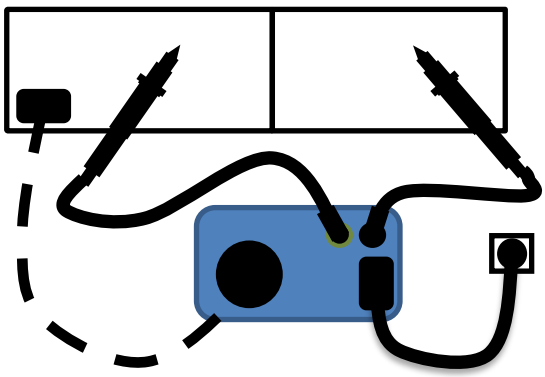
Select  to exit the **point to point function** and return to the **Home screen**

Select  will perform a standard insulation test

Connect the **Point to Point probes** between the BLACK and GREEN socket on the back panel. The EUT socket will power up during leakage tests however the mains cable is not part of the measurement circuit hence it is shown as optional and not required. The **Point to Point test** is ideal for earth bond testing on larger and or fix installed installations.

**Connection Between EUT and SafeTest 60;**

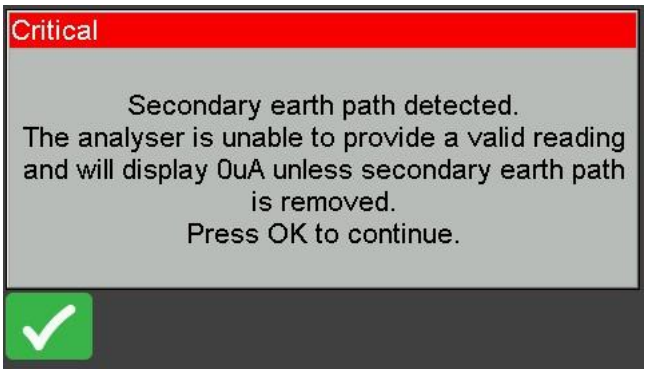
**Point to Point Testing**



# 11. Warning Messages

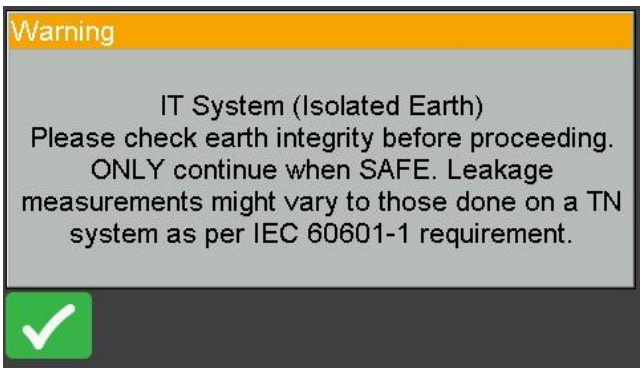
The Rigel SafeTest 60 will automatically warn the user of possible incorrect test setups such as secondary earthing and isolated mains supply (mains voltage isolated from earth).

**Secondary Earth Warning:**




To perform a valid test, the secondary earth must be removed. Testing with a secondary earth will lead to invalid readings as the leakage current will flow through the low resistance secondary earth rather than the high resistance (1kΩ) body model in the Safetest 60.

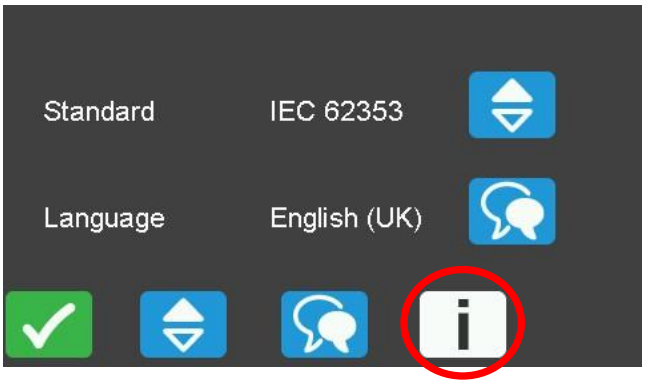
**Isolated Earth Error:**

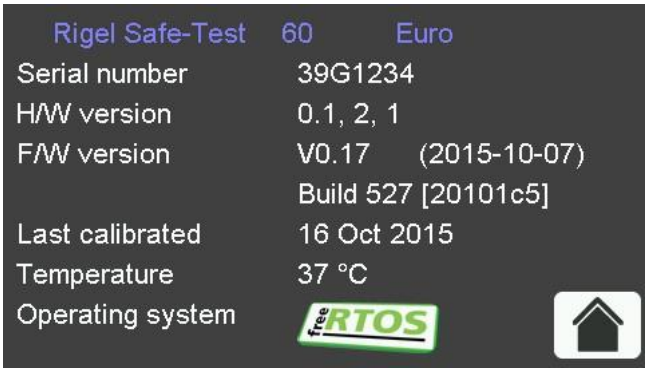



Please note that leakage values can appear at half the value as would be expected under a normal mains configuration.

# 12. About

From the **Home screen**, select **Settings**, then the i key to view the firmware and hardware information.


- Firmware version
- Serial Number

Ensure you have this information available when contacting Rigel Medical for Technical Support or Service.

# 13. Maintaining the Rigel SafeTest 60

## 13.1. Cleaning the Analyzer

The Rigel SafeTest 60 case can be cleaned with a damp cloth with, if necessary, a small amount of mild detergent. Prevent excessive moisture around the socket panel or in the lead storage area.

Do not allow liquid inside the Rigel SafeTest 60 or near the sockets. Do not use abrasives, solvents or alcohol.

If any liquid is spilt into the Rigel SafeTest 60 case, the Analyzer should be returned for repair, stating the cause of the defect.

## 13.2. User Maintenance

The Rigel SafeTest 60 is a rugged quality instrument. However, care should always be taken when using, transporting and storing this type of equipment. Failure to treat the product with care will reduce both the life of the instrument and its reliability.

If the Rigel SafeTest 60 is subject to condensation, allow the Analyzer to completely dry before use.

- Always check the Rigel SafeTest 60 and all test leads for signs of damage and wear before use.
- Do not open the Rigel SafeTest 60 under any circumstances.
- Keep the instrument clean and dry.
- Avoid testing in conditions of high electrostatic or electromagnetic fields.
- Maintenance should only be performed by authorised personnel.
- There are no user replaceable parts in the Rigel SafeTest 60.
- The unit should be regularly calibrated (at least annually).

## 13.3. Return Instructions

Prior to returning your unit for service, please contact our service department to obtain a Returns Number.

By obtaining a Returns Number, your service request can be booked in advance thus reducing the down time of your equipment.

When asking for a Returns Number, please quote:

- Instruments name and model
- Serial number (see section **Error! Reference source not found.**)
- Firmware version (see section **Error! Reference source not found.**)

**Service, Calibration and Repair**
Tel: +44 (0) 191 587 8739
Fax: +44 (0) 191 518 4666
Email: info@calibrationhouse.com

CalibrationHouse
11 Bracken Hill
South West Industrial Estate
Peterlee, County Durham
SR8 2SW, United Kingdom

# 14. Technical Specifications

| | |
|---|---|
| **Earth Continuity** | |
| Pre-pulse | 65-25A peak current,<br>(0.1 to 0.8Ω respectively) |
| Pulse Shape | Exponential Decay |
| Decay Time | 200 – 550µs to 5% of peak current,<br>(0.1 to 0.8Ω respectively) |
| Method | 2 wire, |
| Measurement Current | >± 200mADC into 2Ω |
| Max Test Voltage | 4-24Vrms o/c |
| Measuring Range (Low Range) | 0.001 – 0.999Ω |
| Resolution | 0.001Ω |
| Measuring Range (Mid Range) | 1.00 – 9.99Ω |
| Resolution | 0.01Ω |
| Measuring Range (High Range) | 10.0 – 19.9Ω |
| Resolution | 0.1Ω |
| Accuracy | ± 1% of value, ± 5mΩ<br>± 1% of value, ± 5mΩ |
| Circuit Protection | Test inhibited if ≥ 30VAC or DC at 4mm inputs |
| **Insulation Resistance** | |
| Measurement | EUT to Earth |
| Voltage | 500VDC @1mA |
| Maximum O/C Voltage | <600VDC |
| Range | 100K – 20MΩ ± 5% ± 2 digits |
| Resolution | 0.01MΩ |
| Short Circuit Current | <2mA |
| **Powered Leakage Measurements** | |
| IEC 62353 | Equipment Leakage (Direct) |
| IEC / AAMI 60601 | Earth + Enclosure Leakage |
| NFPA-99 | Ground + Chassis Leakage |
| IEC 61010 | Touch Leakage, Touch Voltage |
| Test Voltage | Mains Supply Voltage |
| Measuring Range | 0.1 - 9999µA<br>(0.1 - 8000µA typical for IEC61010) |
| Measurement/Display Resolution | 0.1 µA |
| Accuracy | ± 2%, ± 5 µA |
| Mains Reversal | Soft Key |
| Single Fault Conditions | Open Neutral and Open Earth Via Soft Key |
| Frequency Response | IEC 60601 – 62353, NFPA-99, and IEC 61010 selectable |

| | |
|---|---|
| **Voltage Measurement** | |
| Application | L-N, L-E, N-E and touch voltage (IEC 61010) |
| Range | 0.0V – 300VAC |
| Resolution | 0.1V |
| Accuracy | ± 2% ± 5 digits (between 10V – 270VAC) |
| Mains frequency | 45.0 – 66.0Hz |
| Resolution | 0.1Hz |
| Accuracy | Unspecified |
| **EUT Load Current Measurement** | |
| Range | 0.0A – 20.0A |
| Resolution | 0.1A |
| Accuracy | ±5% ± 2 digits |
| **Power Source** | |
| Maximum Current Rating | 20A @ 120V / 16A @ 230V |
| Duty cycle (@21˚C ambient) | 16A to 20A, 3 min. on/ 10 min. off<br>10A to 15A, 3 min. on/ 5 min. off<br>0A to 10A, continuous |
| Mains Power | 90-264V 48-64Hz |

## 14.1. General Specifications

| | |
|---|---|
| Weight | 1.1kg/2lbs (unit)<br>2.2kg/5lbs (complete with accessories) |
| Size (L x W x D) | 225 x 150 x 100mm / 9 x 6 x 4” |

# 15. Environmental Conditions

| | |
|---|---|
| Operating Temperature | 0 to 40˚C |
| Humidity | 0 -98% Relative humidity, non-condensating |
| Storage Temperature | -10 to 50˚C |
| Altitude | 0 – 2000m |
| Ingress Protection | IP 40 |
| Operating Pollution Degree | 2, according to IEC 60529 |
| Overvoltage Category | CAT II 300V |

# Appendix A Pass / Fail Limits of IEC 60601-1

| Earthbond test limit at 25A, 50Hz | |
|---|---|
| Excluding power cord | < 0.1 Ω |
| Including power cord | < 0.2 Ω |

| | Type B Applied Parts | | Type BF Applied Parts | | Type CF Applied Parts | |
|---|---|---|---|---|---|---|
| **Leakage Current Type** | **NC** | **SFC** | **NC** | **SFC** | **NC** | **SFC** |
| Earth Leakage (3rd edition)* | 5000µA | 10000µA | 5000µA | 10000µA | 5000µA | 10000µA |
| Earth Leakage (General) | 500µA | 1000µA | 500µA | 1000µA | 500µA | 1000µA |
| Enclosure Leakage | 100µA | 500µA | 100µA | 500µA | 100µA | 500µA |
| Patient Leakage (dc) | 10µA | 50µA | 10µA | 50µA | 10µA | 50µA |
| Patient Leakage (ac) | 100µA | 500µA | 100µA | 500µA | 10µA | 50µA |
| Patient Leakage (F-Type) | NA | NA | NA | 5000µA | NA | 50µA |
| Patient Leakage (Mains on SIP/SOP) | NA | 5mA | NA | NA | NA | NA |
| Patient Auxiliary Current (dc) | 10µA | 50µA | 10µA | 50µA | 10µA | 50µA |
| Patient Auxiliary Current (ac) | 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 Pass / Fail limits of IEC 62353

| Earthbond test limit at 200mA AC or DC | |
|---|---|
| Excluding Power Cord | < 0.2 Ω |
| Including Power Cord | < 0.3 Ω |

| Current in µA (RMS) | Applied Part | | |
|---|---|---|---|
| | Type B | Type BF | Type CF |
| **Equipment Leakage – Alternative Method** | | | |
| Class I Equipment | 1000µA | 1000µA | 1000µA |
| Class II Equipment | 500µA | 500µA | 500µA |
| **Equipment Leakage – Direct or Differential Method** | | | |
| Class I Equipment | 500µA | 500µA | 500µA |
| Class II Equipment (touch current) | 100µA | 100µA | 100µA |
| **Patient Leakage Current – Alternative Method (a.c.)** | | | |
| Class I & II | | 5000µA | 50µA |
| **Patient Leakage Current – Direct Method (a.c.)** | | | |
| Class I & II | | 5000µA | 50µA |

**Note 1:** This IEC 62353 standard does not provide measuring methods and allowable values for equipment producing d.c. leakage currents. In such a case the manufacturer should give information in accompanying documents.

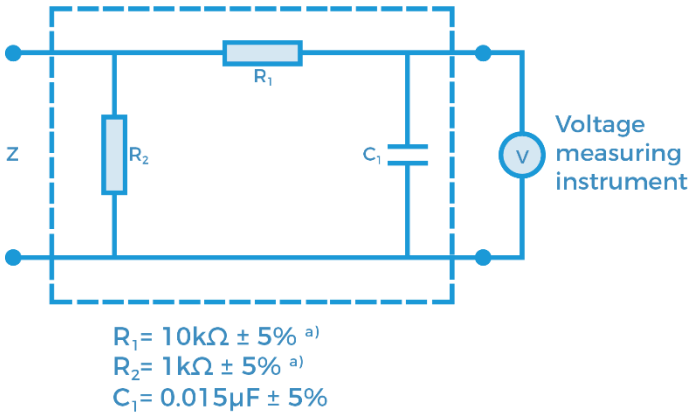
**Note 2:** Particular standards may allow different values of leakage current

# Appendix C Pass / Fail limits of IEC 61010

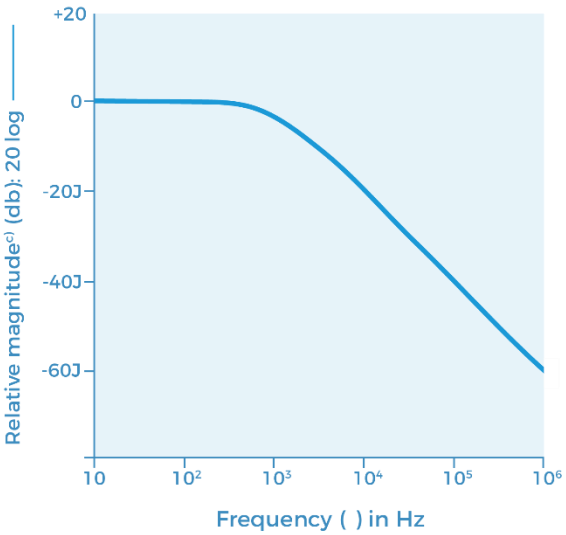
| Earthbond test limit (no current specified in 61010) | |
|---|---|
| Including power cord | < 0.2 Ω |

| Tests | NC | SFC |
|---|---|---|
| Touch Leakage | 500µA | 3500µA |
| Touch Voltage | 33V | 55V |

# Appendix D IEC 60601-1 Measuring Device




a) Measuring device




b) Frequency characteristics

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

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

Example of a measuring device MD according to IEC 60601-1 and its frequency characteristics.

# 16. Support

## 16.1. Contact Us

**Sales and Delivery enquiries**
Tel: +44 (0) 191 586 3511
Fax: +44 (0) 191 586 0227
Email: sales@rigelmedical.com

**Technical enquiries**
Please go to rigelmedical.com/support and raise a support ticket for your enquiry.

**Service, Calibration and Repair**
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