

SafeTest 50 USER MANUAL



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 50 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 affected 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; / /	ceived into service; / /	
---------------------------------	--------------------------	--

© Copyright 2021

All rights reserved. Nothing from this edition may be reproduced, or made public in any form, 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.

Due to a policy of continuous development Rigel Medical reserves the right to alter the equipment specification and description outlined in this publication without prior notice and no part of this publication shall be deemed to be part of any contract for the equipment unless specifically referred to as an inclusion within such contract.

Disposal of old product



The Rigel SafeTest 50 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 50 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 50 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 50.

Safety Notes



If the SafeTest 50 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 50.



Do not connect the SafeTest 50 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 50 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 50, no user serviceable parts



Do not operate the SafeTest 50 in an explosive gas or dust environment.



The SafeTest 50 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 50 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.

SafeTest 50 USER MANUAL

1. Introduction	5
1.1. Key Features	5
1.2. Rigel SafeTest 50 Includes:	6
1.3. Interfaces	7
1.4. Optional Accessories	8
1.5. Unique use of ICONS	8
2. Getting Started	10
2.1. Setting your Language and Preferred Test Standard	10
3. Ground Bond Testing	12
4. NFPA-99 Leakage Testing	14
5. AAMI ES 60601 Leakage Testing	16
6. IEC 62353 Leakage Testing	18
7. IEC 61010 Touch Leakage & Voltage Testing	20
8. Displaying Mains Voltage, Frequency and Load Current	22
9. Minimise your Power Breaks in IEC 60601	23
10. Point to Point Testing	24
11. Warning Messages	25
12. About	26
13. Maintaining the Rigel SafeTest 50	27
13.1. Cleaning the Analyzer	27
13.2. User Maintenance	27
13.3. Return Instructions	28
14. Technical Specifications	29
14.1. General Specifications	30
15. Environmental Conditions	30
Appendix A Pass / Fail Limits	31
A.1. NFPA 99	31
A.2. ES 60601	31
A.3. IEC 62353	32
A.4. IEC 61010	32
Appendix B ES 60601-1 Measuring Device	33

1. Introduction

The Rigel SafeTest 50 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 50 can withstand a busy schedule of testing medical equipment that does not require patient lead testing, such as beds, hoists, infusion pumps, CPAP's, centrifuges, etc.

With a large color display and a color coded user interface, it's easy to select the required tests with a single key press, while a fast step-through of the test routine makes the testing process speedy and dependable. Though physically small, the SafeTest 50 includes a range of safety tests to enable compliance with a range of international safety standards, including leakage testing to NFPA-99, AAMI ES 60601, IEC 62353 and 61010, ground bond testing to NFPA-99, IEC 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 ground paths ensures users are made aware when invalid readings are made, thus ensuring correct and accurate test results first time, every time.

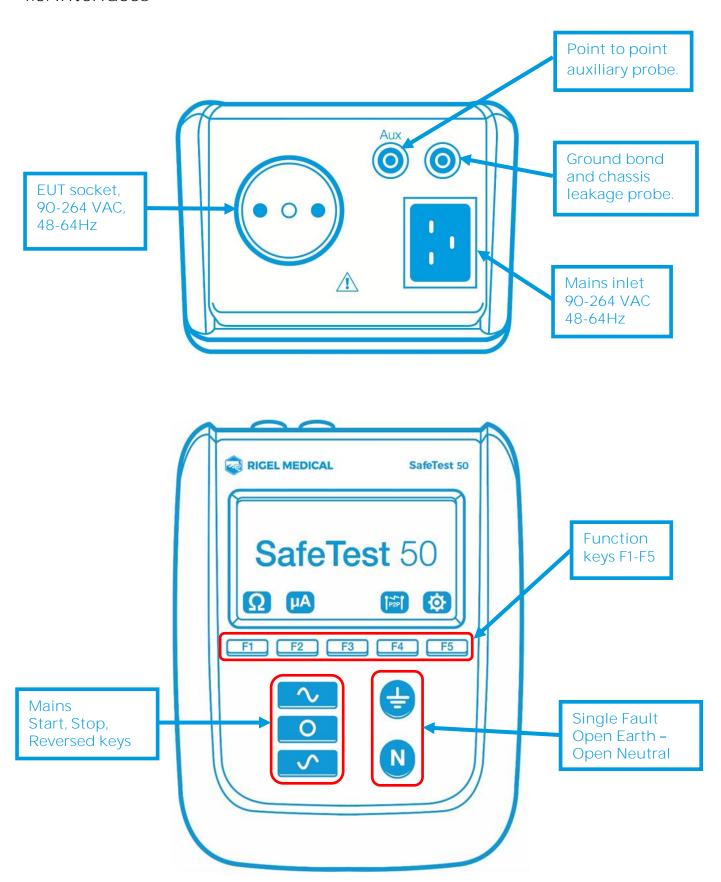
1.1. Key Features

- 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
- Large, highly visible color display
- Secondary earth warnings to ensure valid test setup
- Accurate high current, low energy ground bond testing
- Supplied with free, protective carry case
- Multi voltage operates on any mains supply between 90-264V / 48-64Hz

1.2. Rigel SafeTest 50 Includes:



1.3. Interfaces



1.4. Optional Accessories

Ground bond cable 44B154 Carry case 410A950

1.5. Unique use of ICONS

The Rigel SafeTest 50 features a high resolution color 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 50:



Select Ground Bond Testing



Select Leakage 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



Applies reversed mains to the EUT



Interrupts mains to EUT



Warning, EUT socket live



Select Ground leakage (in IEC60601 setting)



Select Chassis 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



Ground bond test lead compensated



Ground bond test running



Go to Home screen

2. Getting Started

The Rigel SafeTest 50 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 50, please insert the mains cable to the power inlet, the SafeTest 50 will automatically power up in the HOME SCREEN.

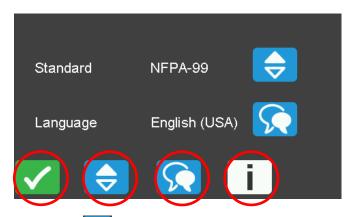
2.1. Setting your Language and Preferred Test Standard

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

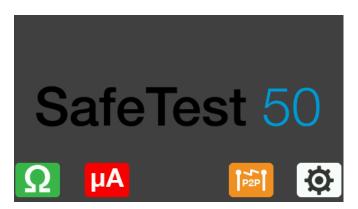
Press the key to change to the required test standard

Press the key to view the firmware and hardware information

Press the key confirm and return to the Home menu

Note: The Rigel SafeTest 50 will store the most recent settings in the Settings menu.

From the Home screen, select the required test;







MΩ To select Insulation Testing

To select Point to Point Testing

To select Settings Menu (change Language and Test Standard)

3. Ground Bond Testing

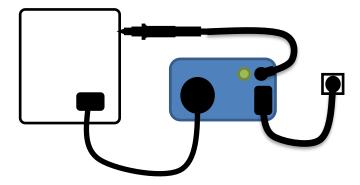
To perform a ground bond test, select the Ω icon from Home screen.



The SafeTest 50 will automatically start the test when it is selected and will automatically stop by pressing the **Leakage**, Point To Point or Home icon.

Connection Between EUT and SafeTest 50;

Ground bond Testing



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

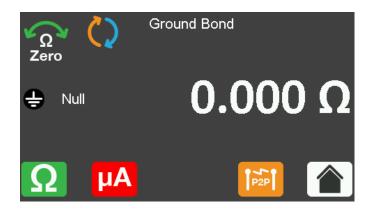


Do not exceed the maximum permitted voltage of 30 V AC/DC with respect to earth potential! Electric Shock danger!

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

Ground 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.

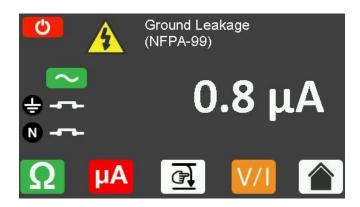


When different ground bond cables are used, the Null function must be repeated for each different cable.

Note: Switching off the Rigel SafeTest 50 will not cancel the 'probe zero'.

4. NFPA-99 Leakage Testing

To perform an NFPA-99 leakage test, press from Home screen to enter Leakage test. If the required test standard needs to change, please press Home and see 2.1.



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.

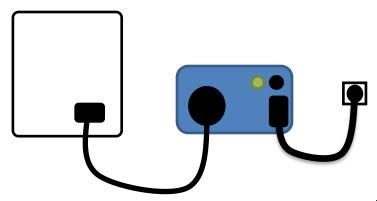
To apply mains in Reversed Polarity and START the test, press the button on the front panel. The test will run until the button is pressed.

To minimise the power breaks during your tests, please see 8.

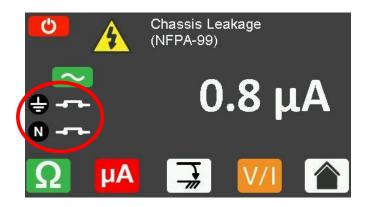
will appear on the screen when the DUT socket is activated.

Connection Between EUT and SafeTest 50;

Ground Leakage NFPA-99



When the Safetest 50 is set to test to NFPA-99, the will go to Chassis leakage and to Ground leakage.

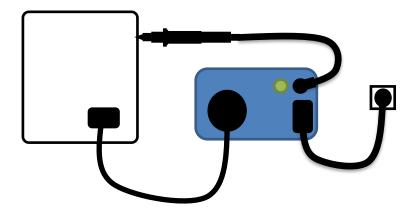


To activate single fault conditions, use the and buttons on the front panel. opens the Earth fault condition relay whilst the opens the Neutral fault condition relay.

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

Connection Between EUT and SafeTest 50;

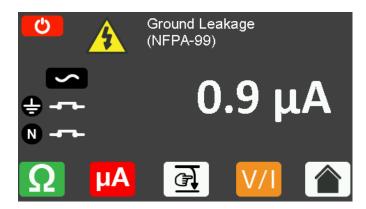
Chassis Leakage NFPA-99



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

5. AAMI ES 60601 Leakage Testing

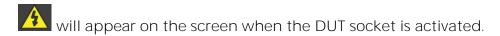
To perform an ES 60601 leakage test, press from Home screen to enter Leakage test. If the required test standard needs to change, please press Home and see 2.1.



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.

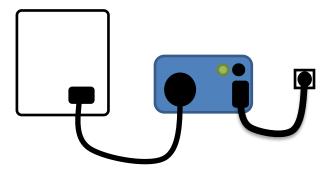
To apply mains in Reversed Polarity and Start the test, press the button on the front panel. The test will run until the button is pressed.

To minimise the power breaks during your tests, please see Error! Reference source not found.8.

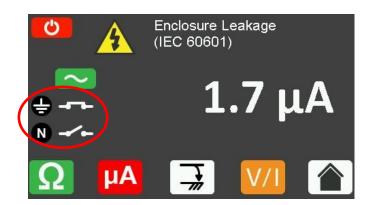


Connection Between EUT and SafeTest 50;

Ground Leakage



When the Safetest 50 is set to test to IEC 60601, the will go to Enclosure Leakage and to Ground Leakage.

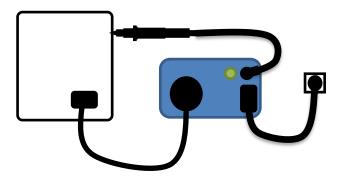


To activate single fault conditions, use the and buttons on the front panel. opens the Earth fault condition relay whilst the opens the Neutral fault condition relay.

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

Connection Between EUT and SafeTest 50;

Enclosure Leakage



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

 $^{^*}$ The pass-fail limit for Ground Leakage in the 3rd edition of IEC 60601 has been increased from $500\mu A$ under normal condition to $5000\mu A$ for class I equipment with NO exposed metal parts that may become live when a fault appears.

6. IEC 62353 Leakage Testing

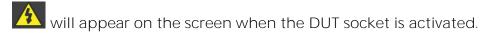
To perform an IEC 62353 leakage test, press from Home screen to enter Leakage test. If the required test standard needs to change, please press home and see 2.1.



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.

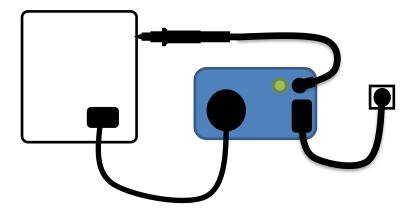
To minimise the power breaks during your tests, please see chapter 9.



When the Safetest 50 is set to test to IEC 62353, the Single Fault buttons and are deactivated in order to perform the test as per IEC 62353 requirements.

Connection Between EUT and SafeTest 50:

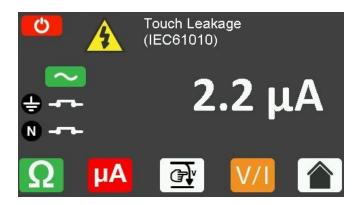
Equipment Leakage IEC 62353



Current in µA (RMS)	All Applied Parts
Equipment leakage - direct method.	
Class I Equipment	0.5mA
Class II Equipment (touch current)	0.1mA

7. IEC 61010 Touch Leakage & Voltage Testing

To perform an IEC 61010 touch leakage test, press From Home screen to enter Leakage test. If the required test standard needs to change, please press Home and see 2.1.



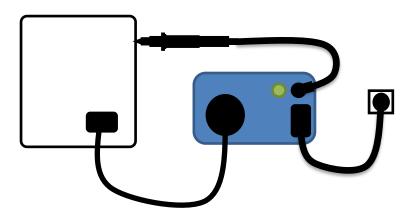
To apply mains voltage in Normal Polarity and START the test, press the button on the front panel. The test will run until the button is pressed.

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.

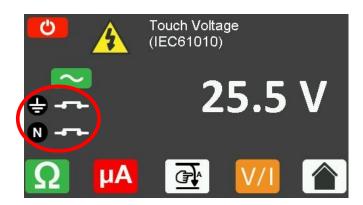
will appear on the screen when the DUT socket is activated.

Connection Between EUT and SafeTest 50:

Touch Leakage and Touch Voltage IEC 61010



When the SafeTest 50 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. Displaying Mains Voltage, Frequency and Load Current

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



9. 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 50 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. Ground Leakage Normal Supply
- 2. Chassis Leakage Normal Supply, Earth CLOSED
- 3. Chassis Leakage Normal Supply, Earth OPEN

Normal Polarity Testing - Power Down

- 4. Chassis Leakage Normal Supply, Neutral OPEN
- 5. Ground Leakage Normal Supply, Neutral OPEN

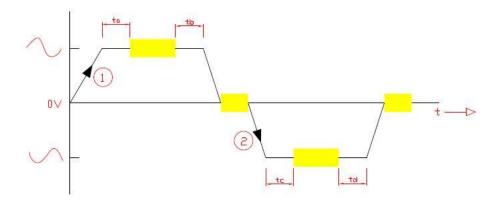
Reversed Polarity Testing - Power Up

- 6. Ground Leakage Reversed Supply
- 7. Chassis Leakage Reversed Supply, Earth CLOSED
- 8. Chassis Leakage Reversed Supply, Earth OPEN

Reversed Polarity Testing - Power Down

- 9. Chassis 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.



10. Point to Point Testing

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



Select Ω to perform a point to point ground bond test

Select to perform a point to point leakage test

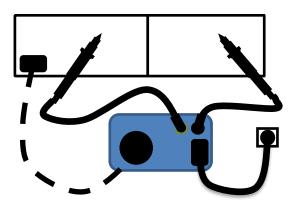
Select to exit the point to point function and return to the Home screen

Select $\overline{^{\text{M}\Omega}}$ 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 ground bond testing on larger and or fix installed installations.

Connection Between EUT and SafeTest 50;

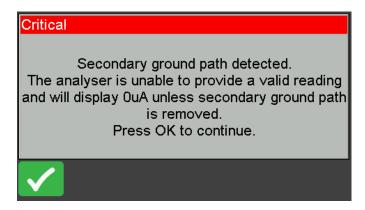
Point to Point Testing



11. Warning Messages

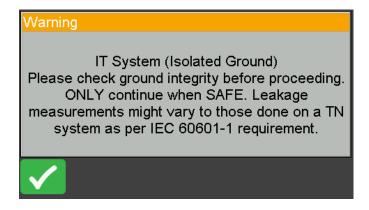
The Rigel SafeTest 50 will automatically warn the user of possible incorrect test setups such as secondary grounding and isolated mains supply (mains voltage isolated from ground).

Secondary Ground Warning:



To perform a valid test, the secondary ground must be removed. Testing with a secondary ground will lead to invalid readings as the leakage current will flow through the low resistance secondary ground rather than the high resistance (1k Ω) body model in the SafeTest 50.

Isolated Ground Error:

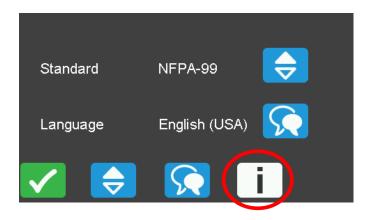


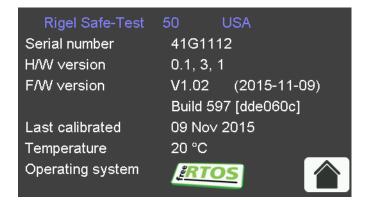
Please note that leakage values can appear at half the value as would be expected under a normal mains configuration.

12. About

From the Home screen, select Settings, then the 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 50

13.1. Cleaning the Analyzer

The Rigel SafeTest 50 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 50 or near the sockets. Do not use abrasives, solvents, or alcohol.

If any liquid is spilt into the Rigel SafeTest 50 case, the Analyzer should be returned for repair, stating the cause of the defect.

13.2. User Maintenance

The Rigel SafeTest 50 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 50 is subject to condensation, allow the Analyzer to completely dry before use.

- Always check the Rigel SafeTest 50 and all test leads for signs of damage and wear before use.
- Do not open the Rigel SafeTest 50 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 50.
- The unit should be regularly calibrated (at least annually).

13.3. Return Instructions

For repair or calibration return the instrument to:

Contact Details

Service, Calibration and Repair

Tel: 813 886 2775 Fax: 813 886 2754

Email: service@seaward-groupusa.com

Address details

Seaward Group USA 6304 Benjamin Road Suite 506 Tampa, FL 33634 United States

Prior to returning your unit for service, please contact our service department to obtain a Return Material Authorization (RMA) number.

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

When asking for a RMA, please provide:

- Instruments name and model
- Serial number (see section 12)
- Firmware version (see section 12)

14. Technical Specifications

Ground Continuity

Pre-pulse 65-25A peak current, (0.1 to 0.8Ω respectively)

Pulse Shape Exponential Decay

Decay Time 200 – 550µs to 5% of peak current,

(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) $0.001 - 0.999\Omega$ Resolution 0.001Ω

Measuring Range (Mid Range) 1.00 – 9.99 Ω

Resolution 0.01Ω Measuring Range (High Range) $10.0 - 19.9\Omega$

Resolution 0.1 Ω Accuracy \pm 1% of value, \pm 5m Ω \pm 1% of value, \pm 5m Ω

Circuit Protection Test inhibited if ≥ 30VAC or DC at

4mm inputs

Powered Leakage Measurements

IEC 62353 Equipment Leakage (Direct)

IEC / AAMI 60601 Ground + Enclosure Leakage
NFPA-99 Ground + Chassis Leakage
IEC 61010 Touch Leakage, Touch Voltage

Test Voltage Mains Supply Voltage

Measuring Range 0.1 - 9999µA

(0.1 - 8000µA typical for IEC61010)

Measurement/Display Resolution 0.1 μ A Accuracy \pm 2%, \pm 5 μ A Mains Reversal Soft Key

Single Fault Conditions Open Neutral and Open Ground Via

Soft Key

IEC 60601 – 62353, NFPA-99, and IEC

Frequency Response 61010 selectable

Voltage Measurement

Application H-N, H-G, N-G and touch voltage (IEC

61010)

Range O.OV – 300VAC

Resolution 0.1V

Accuracy ± 2% ± 5 digits (between 10V - 270VAC)

Mains frequency 45.0 – 66.0Hz

Resolution 0.1Hz

Accuracy Unspecified Overvoltage category CAT II 300V

RIGEL MEDICAL

EUT Load Current Measurement

Range

Resolution

Accuracy

0.0A - 20.0A

0.1A

 $\pm 5\% \pm 2$ digits

Power Source

Maximum Current Rating

Duty cycle (@21°C ambient)

16A to 20A, 3 min. on/10 min. off 10A to 15A, 3 min. on/ 5 min. off

20A @ 120V / 16A @ 230V

OA to 10A, continuous

Mains Power

90-264V 48-64Hz

14.1. General Specifications

Weight

Size (L x W x D)

2lbs (unit)

5lbs (complete with accessories)

9 x 6 x 4"

15. Environmental Conditions

Operating Temperature

Humidity

Storage Temperature

Altitude

Ingress Protection

Operating Pollution Degree

0 to 40°C

0 -98% Relative humidity,

non-condensating

-10 to 50°C

0 - 2000m

IP 40

2, according to IEC 60529

Appendix A Pass / Fail Limits

A.1. NFPA 99

Leakage Current Type	NC	SFC
Ground Leakage	0.3mA	1mA
Chassis Leakage	0.1mA	0.5mA

A.2. ES 60601

Ground bond test limit at 25A, 50Hz	
Excluding power cord	< 0.1 Ω
Including power cord	< 0.2 Ω

Leakage Current Type	NC	SFC
Ground Leakage (3rd edition) *	5000μΑ	10000μΑ
Ground Leakage (General)	500μΑ	1000μΑ
Enclosure (Chassis) Leakage	100μΑ	500μΑ

 $^{^*}$ The pass-fail limit for Ground Leakage in the 3rd edition of ES 60601 has been increased from 500μ A under normal condition to 5000μ A for class I equipment with NO exposed metal parts that may become live when a fault appears.

A.3. IEC 62353

Ground bond test limit at 200mA AC or DC	
Excluding Power Cord	< 0.2 Ω
Including Power Cord	< 0.3 Ω

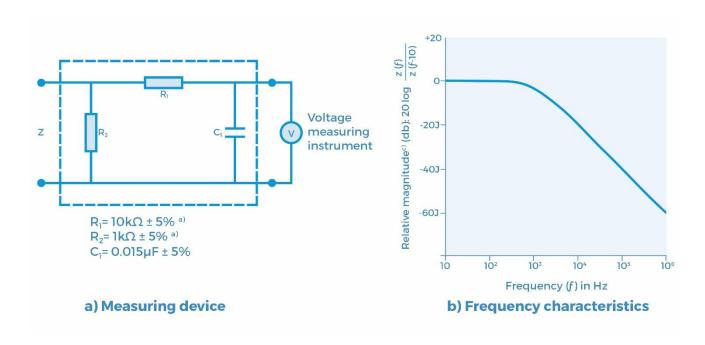
Equipment leakage - direct method	μA (RMS)
Class I equipment	500μΑ
Class II equipment	100μΑ

A.4. IEC 61010

Ground bond test limit (no current specified in 61010)		
Including power cord	< 0.2 Ω	

Tests	NC	SFC
Touch Leakage	500μΑ	3500μΑ
Touch Voltage	33V	55V

Appendix B ES 60601-1 Measuring Device



Note: The network and voltage measuring instrument above are replaced by the symbol 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. $V_{out/ln}$, for a current frequency f

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



Rev 2