Rigel 377

Electrosurgical Analyser

Instruction Manual

367A550 Issue 1.0

November 2010

Issue 1.0

Limited Warranty & Limitation of Liability

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

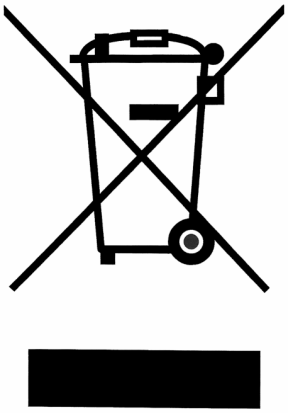
Calibration Statement

The Rigel 377 Electrosurgical Analyser 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 in 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.

Date received into service; ___/___/_____.

Disposal of old product



The Rigel 377 has been designed and manufactured with high quality materials and components, which can be recycled and reused.

When this symbol is attached to a product it means the product is covered by the European Directive 2002/96/EC.

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 dipose 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.

Contents

Declaration of Conformity

Rigel 377 Electrosurgical Analyser

Manufactured by:

Seaward Electronic Ltd, Bracken Hill, South West Industrial Estate
Peterlee, County Durham, SR8 2SW, England

Millennium Statement

This product is Millennium compliant, and conforms fully to the document BSI DISC PD2000-1.

Statement of Conformity

Based on test results using appropriate standards, the product conforms with Electromagnetic Compatibility Directive 89/336/EEC and Low Voltage Directive 73/23/EEC

Standards used:

EN 60601-1 (1990) Medical Electrical Equipment. General Requirements for Safety
EN 61010-1 (1993) Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use
EN 50081-1 (1992) Electromagnetic Compatibility. Generic Emission Standard: EN55022 Class B
EN 50082-1 (1992) Electromagnetic Compatibility. Generic Immunity Standard: IEC1000-4-2, -4-3, -4-4, -4-5

The tests have been performed in a typical configuration.

This Conformity is indicated by the symbol CE, i.e. “Conformité Européenne”

Before you power up

Ensure the mains switch positioned at the base panel of the Rigel 377 is set to the appropriate voltage range i.e. 230VAC +/- 10% or 120 VAC +/- 10%.

Ensure none of the ventilation holes are covered during operation including the ones on the base panel. We strongly recommend positioning the Rigel 377 on its two hinged feet at the front base.

User Notes

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

The following symbols are used in these operating instructions and on the Rigel 377.

⚠ **Warning of electrical danger!**
Indicates instructions must be followed to avoid danger to persons.

⚠ **Important, follow the documentation! This symbol indicates that the operating instructions must be adhered to in order to avoid danger.**

⚠ **Warning, when operating the Rigel 377 at its maximum capability, in ambient temperature of 40˚C and only during certain power tests, the surface temperature of the top cover may exceed temperatures of 50°C but not exceed a surface temperature of 70°C as is permitted under the IEC 61010 design requirements.**

⚠ **Do not connect any active power electrodes to the front panel of the Rigel 377. Failure to comply with this will void the warranty and might lead to internal damage of circuits.**

1. Introduction

The Rigel 377 Electrosurgical Analyser is a versatile bench-mounted yet portable tool, for testing the performance of electrosurgical equipment.

Utilising a large, full colour graphical display, the Rigel 377 is the first fully stand-alone electrosurgical analyser that can offer true intuitive, user friendly operation and operator safety.

1.1. Analyser Functions

The Rigel 377 Electrosurgical Analyser enables biomedical engineers to efficiently analyse the output of electrosurgical diathermy machines. The RF signal input is simultaneously digitally analysed to provide all the characteristics of interest: Watts, current, peak Voltage, crest factor. The Rigel 377 can also produce load/ power curves automatically analysing the load/power performance of an electrosurgical diathermy machine.

The Rigel 377 is able to measure the following parameters manually;

1. Power
2. HF Leakage
3. Plate Security (REM, Remote Electrode Monitoring)

For the power test, an internal array of resistors provide a safe variable load of 10-5100Ω in 10Ω steps; enabling the production of accurate and detailed power distribution curves, with an instant tabular view of test results.

A unique feature of the HF leakage test is on screen graphics illustrating correct test connection configurations, complete with user set pass fail limits.

The plate security (REM) test offers a unique isolated, electronically driven potentiometer, which provides a continuous swept resistance change; enabling accurate and fast testing of alarms, complete with user set pass fail limits.

Any future firmware upgrades can be efficently installed by users, without risk to stored data.

The new Rigel 377 forms part of a comprehensive range of high performance specialist biomedical test equipment supplied by Rigel Medical, part of the Seaward Group.

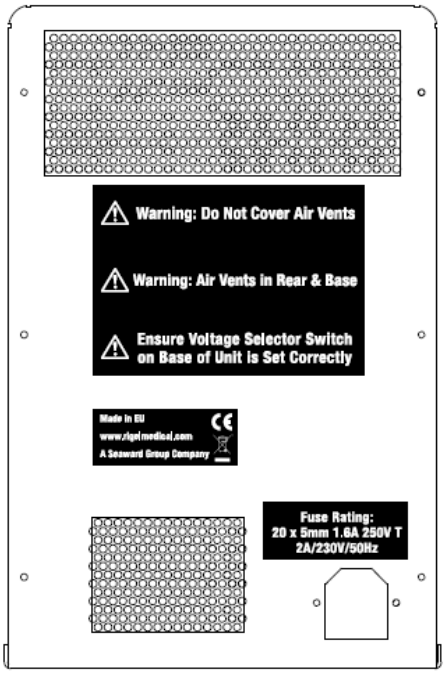
1.2. Key Features

- ✓ **Fully compliant with IEC 60601-2-2** – One instrument for full compliance testing offering peace of mind
- ✓ **Accurate and Safe** – Utilising full 10kV isolation on all measuring systems
- ✓ **Multiple Load Resistors** – For simpler user test configurations, benefiting speed and ease-of-use
- ✓ **High Frequency Leakage –** Easy to connect with on screen help for each configuration
- ✓ **Power distribution curves -** Variable load with full 10kV isolation from 10 to 5100Ω in 10Ω steps – Accurate, fast, and flexible
- ✓ **Plate Security (REM) test** – using electronic potentiometer range up to 500Ω in 1 Ω steps with high and low alarms
- ✓ **Stand-alone** – Not relying on PC or laptop.
- ✓ **Stylish and rugged enclosure** – with small footprint ideal for in-situ testing
- ✓ **Graphic colour user interface** - for fast and easy navigation and connection to DUT
- ✓ **Future upgrade ready** – download future upgrades from the web into your tester

2. Getting started

The Rigel 377 has been designed to ensure that the user is able to test: quickly, easily and safely. The interfaces to the Rigel 377 have been segregated into a high-voltage area (side panel) and a safe low voltage area (front panel). This arrangement also ensures that test leads carrying high frequency power are kept as short as possible, and directly facing the equipment under test.

2.1. Connecting your Analyser



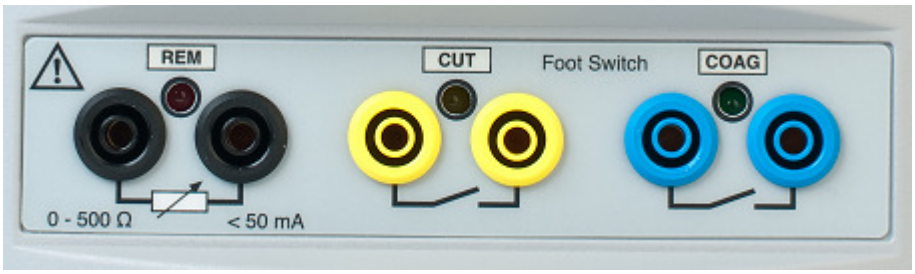
⚠ Elevate the Rigel 377 on its two hinged feet at the front base.

⚠ Ensure none of the large base and rear ventilation inlets are obstructed during operation,

Rear panel

Connect the mains cable to the IEC connector on the rear panel.

Front connection panel

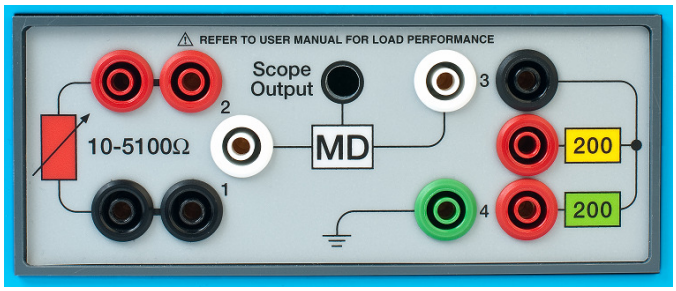


For automatic control during HF leakage and Power tests, connect the ESU footswitch COAG and CUT contacts to the blue and yellow terminals.

⚠ It is strongly advised to always use the Rigel 377's built-in, automatic control rather than manually switching the output of the electrosurgical diathermy machine under test.

For REM / plate security test use the black terminals.

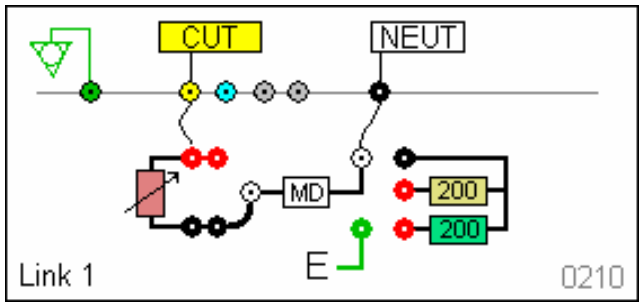
Side panel ESU to ESA connections



Jumper Links

Follow the on-screen instruction diagrams for correct test connection.
See appendices A and B for embedded connection diagrams.

⚠ Do not use **MD** alone, always combine with load resistance.



Connect the ESU active and neutral electrodes to the side panel as indicated, also fit jumper links (positions 1, 2, 3, 4) as required to complete circuits.

NB: each connection diagram has a unique reference code. eg '0210' for identification.

Side panel ESA to Oscilloscope connections

The scope output (SMB connector) provides an isolated* waveform monitoring output. Note: The scope output is not calibrated, * 10kV isolation from HF signal.

2.2. Rigel 377 includes:

- Calibration Certificate
- Detachable 2 metre mains cable
- Removable 'quick start' card
- Instruction Manual (p/n 367a550)
- 3 x Jumper Links (p/n 43b759)

2.3. Optional Accessories

- Finger switch adaptor
- Foot switch adaptor cable set
- Hard carry case
- SMB to BNC Oscilloscope connection lead (p/n 367A950)

3. Test Modes

The test modes provide the user with the features for testing a specific individual test and or test condition; for example to aid fault diagnostic procedures. These tests are available from the home screen.

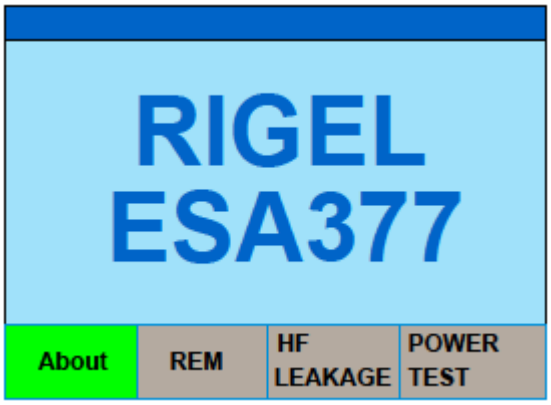
Available tests are:

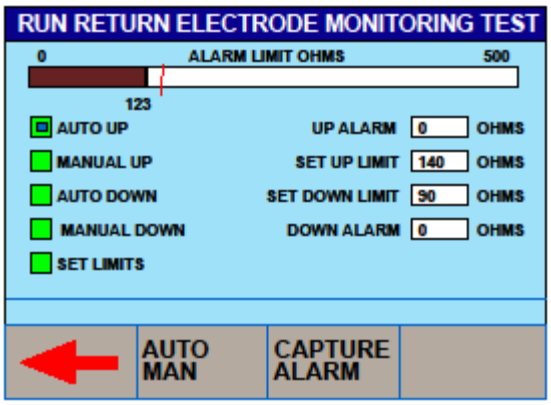
- REM test
- HF Leakage
- Power Test

3.1. Plate Security (REM) test

This test will control a motor driven potentiometer to trigger the neutral (patient plate) alarm on electrosurgical generators by simulating fault conditions (ie resistance too high or too low, a variation in resistance etc). The variable resistance (0 – 500 Ω) is connected to the two black connectors on the front panel.

Select the REM test from the main menu shown below.





Select automatic (up or down) or manual (up or down) control by using the dedicated AUTO MAN key. This key is also used to set the limits. Once the SET LIMITS field is highlighted in green, use and press the rotary encoder to manipulate the UP and DOWN limits.

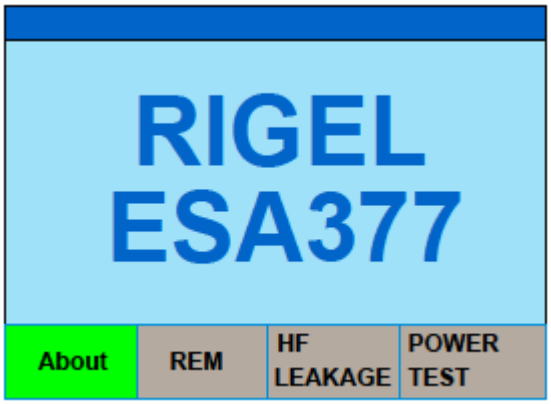
Press the Green button to start the test (for automatic mode only). Then capture the alarm value by pressing the dedicated 'Capture Alarm' key on the screen.

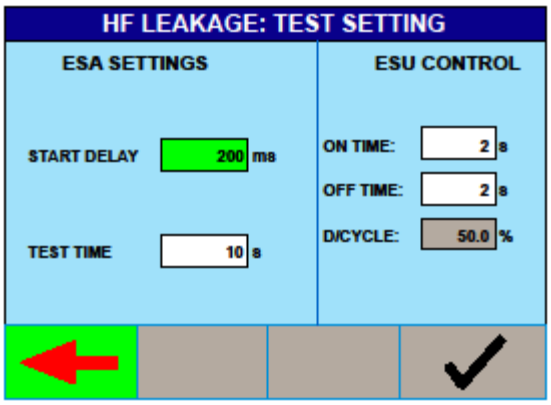
In MANUAL UP and DOWN mode, the rotary encoder is used to directly control the potentiometer. The alarm value is then captured by pressing the dedicated 'Capture Alarm' key on the screen.

3.2. HF Leakage

The HF Leakage test measures the HF leakage current in various test configurations (see appendix A), and compares the result to a user set pass/fail value.

Select the HF LEAKAGE test from the main menu, shown below.





Use the rotary encoder to navigate the screen

Select the required setting and press the rotary encoder to activate the field. Once activated, use the rotary encoder to change the settings. Confirm and de-activate the field by pressing the encoder once again.

START DELAY will allow the user to set a measurement delay for generators operating in a soft start mode.

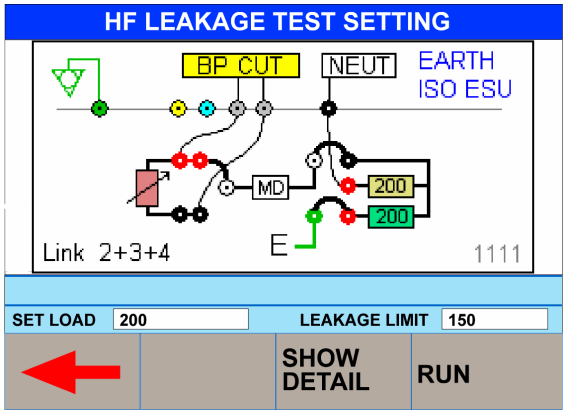
The TEST TIME will display the total test time of the leakage test and dictate the amount of tests done as a result of the selected ON TIME and OFF TIME.

Note: note the D/CYCLE is limited to 50% or less. To increase the ON TIME, the OFF TIME must be increased first in order to remain within the duty cycle limits. This is done to protect the EUT from overheating.

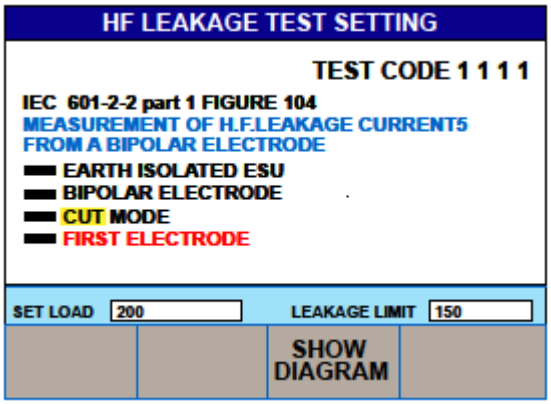
Press the TICK mark to confirm and start selecting the appropriate leakage tests.

Four different measurement scenarios have been described in the particular standard IEC 60601-2-2; See appendix A for all available leakage settings.

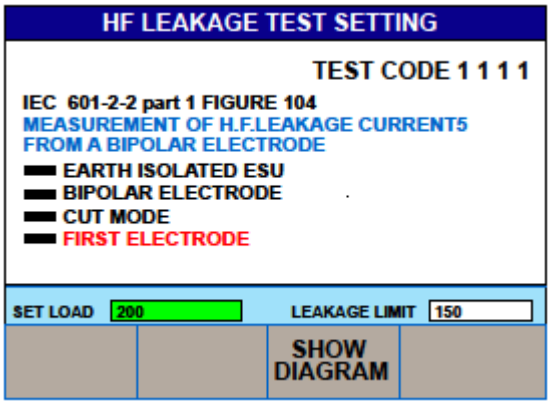
Use the rotary encoder to change between the different leakage configurations. Use either the graph mode, shown below.



or the IEC 60601-2-2 reference details (SHOW DETAIL).

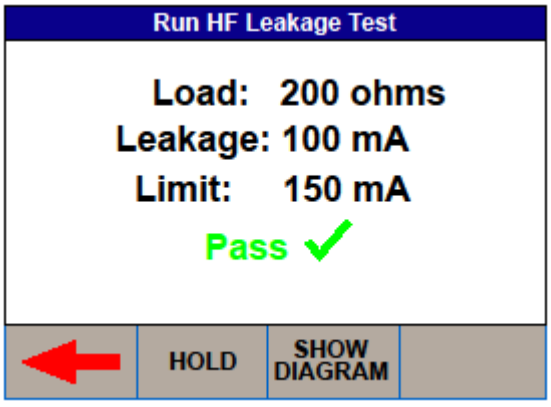


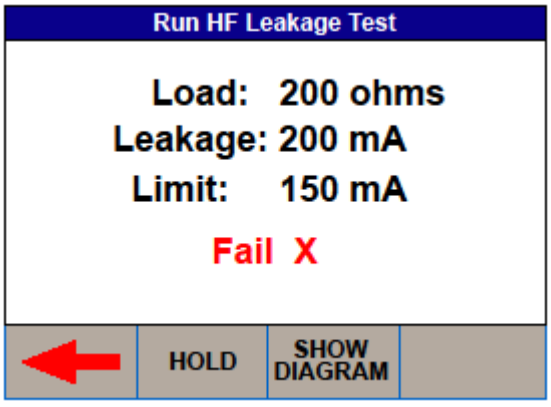
Press the rotary encoder to activate the SET LOAD and LEAKAGE LIMIT



return to the GRAPH mode by using the SHOW DIAGRAM fast key.

The Rigel 377 could display the following details after the test.

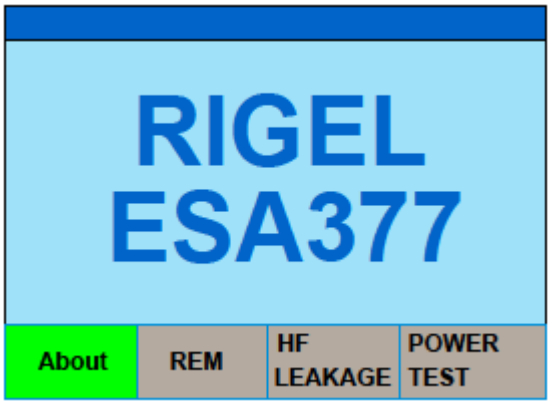




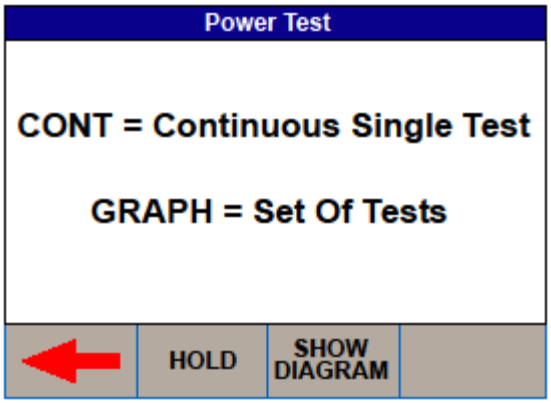
Press the HOLD key to freeze the reading on the screen.

3.3. Power Test

The output power of the Active Electrodes (CUT / COAG and BIPOLAR) is measured, either at a fixed load (Continuous Single Test) or at a range of loads (Power Distribution Graph). The load will vary from a start value to an end value with a number of intervals (resolution). The Rigel 377 will control the EUT by using the internal footswitch controller.

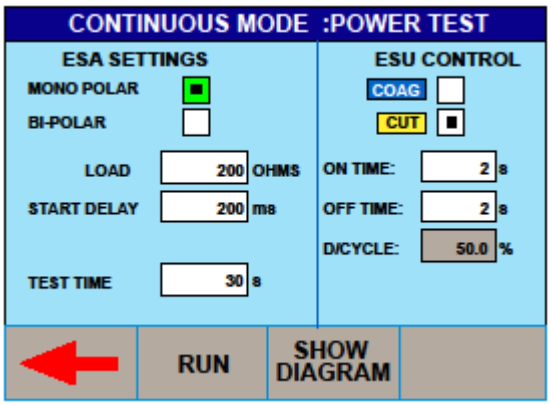


Select Power test from the main menu.

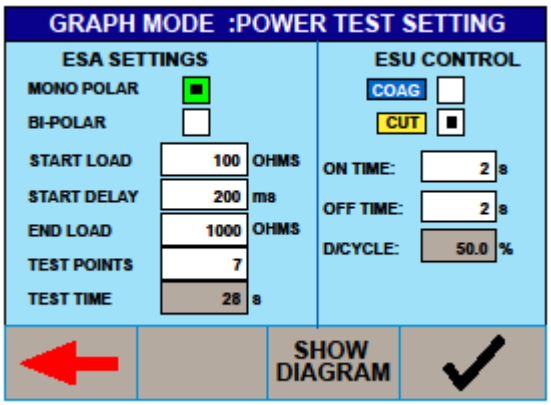


Select either the Continuous Single test (CONT) or GRAPH mode using the fast keys;

CONT mode



GRAPH mode



Use the rotary encoder to navigate the screen

Select the required setting and press the rotary encoder to activate the field. Once activated, use the rotary encoder to change the settings. Confirm and de-activate the field by pressing the encoder once again.

START LOAD is required to determine the resistance at which the power measurement is begun.

START DELAY will allow the user to set a measurement delay for generators operating in a soft start mode.

END LOAD (GRAPH mode only), will set the highest resistance at which power measurements are done.

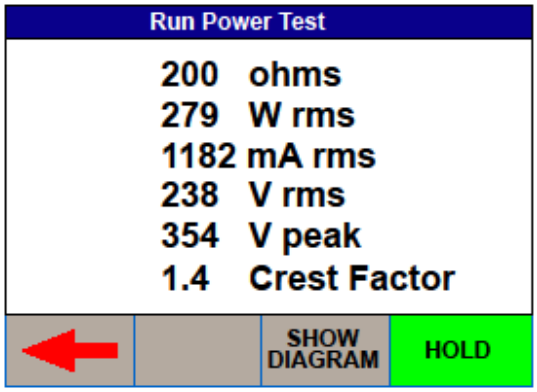
TEST POINTS (GRAPH mode only), determines the number of test points (resolution) of the power distribution graph. The higher the number, the more detailed the power distribution graph.

The TEST TIME will display the total test time of the leakage test and dictate the amount of tests done as a result of the selected ON TIME and OFF TIME.

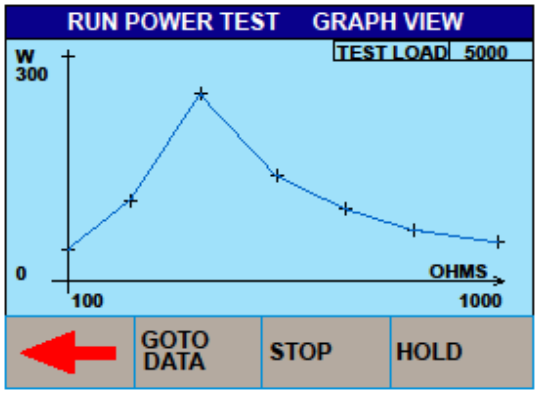
Note: the duty cycle is limited to 50% or less. To increase the ON time, the OFF time must be increased first in order to remain within the duty cycle limits. This is done to protect the EUT from overheating.

Press RUN / TICK to confirm the settings and start the test.

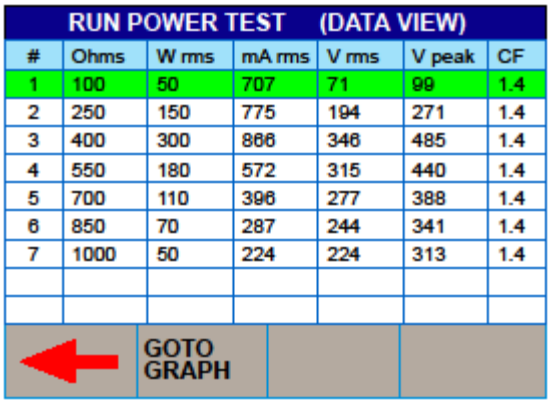
During the Continuous power test, the Rigel 377 will display continuously updated readings.



During the Graph power test, the Rigel 377 will display the power distribution graph.

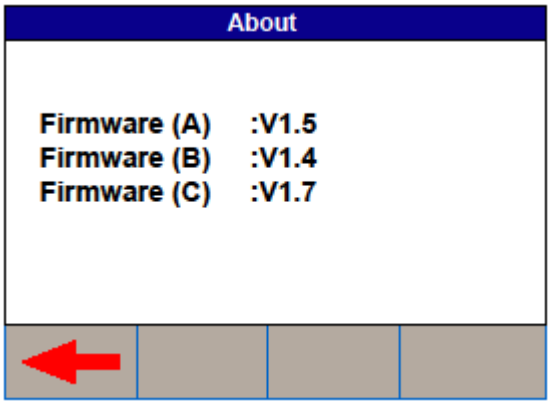


At the end of the test, toggle between GRAPH MODE and DATA by pressing the GOTO DATA fast key.



4. About

This screen provides details on the Rigel 377's firmware version



Ensure you have this information available when contacting Rigel Medical for Technical Support or Service. See section 5.3 for more information on Service and Calibration.

5. Maintaining the Rigel 377

5.1. Cleaning the Analyser

The Rigel 377 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 377 or near the sockets. Do not use: abrasives, solvents, or alcohol.

If any liquid is spilt into the Rigel 377 case, the analyser should be returned for repair, stating the cause of the defect.

5.2. User Maintenance

The Rigel 377 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 377 is subject to condensation, allow the Analyser to completely dry before use.

- Always check the Rigel 377 and all test leads for signs of damage and wear before use.
- Do not open the Rigel 377 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 377.
- The unit should be regularly calibrated.

5.3. Firmware Upgrade

The Rigel 377 is designed to allow service agents and users to easily upgrade the firmware by using the internet to download: the latest firmware, a loading application, and instructions.

The firmware is installed using a PC via the USB port.

To obtain the latest firmware, the Rigel 377 will need to be registered; this will also provide automatic upgrade alerts to the user.

5.4. Return Instructions.

For repair or calibration return the instrument to:-

Rigel Medical
Service Dept.,
p.a. Seaward Electronic Limited.
Bracken Hill
South West Industrial Estate
Peterlee, Co. Durham
SR8 2SW, England

Tel : +44 (0)191 587 8739
Fax: +44 (0)191 586 0227

sales@rigelmedical.com

calibration@seaward.co.uk

www.seaward.co.uk

www.rigelmedical.com

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
- Firmware version

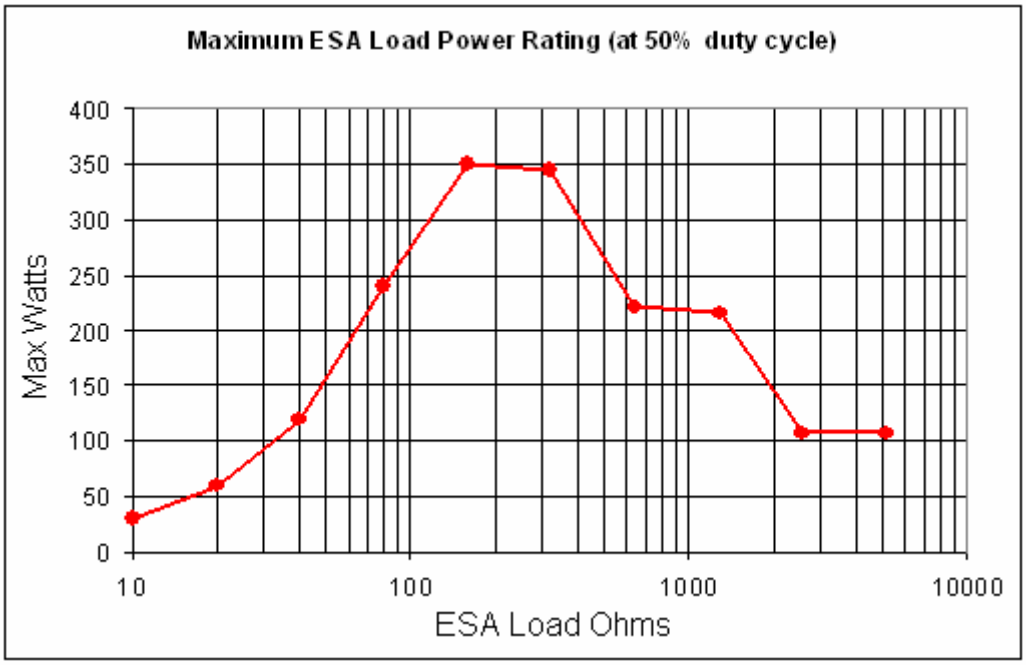
6. Specifications

6.1. Technical Specification

HF Power Watt (RMS)	True RMS Watts (0 -500W) Refer to load/power graph)
Accuracy	±5%,±1W of value
HF Current (RMS)	0 – 2200mA
Accuracy	±2%,±10mA of value
Voltage (RMS)	0 - 700V
Accuracy	±3%, ± 5V of value
Voltage (peak)	0 – 10KV (Peak) – Closed load only
Accuracy	±10% ± 50V of value.
Crest Factor	1.4 – 20 (± Vpeak / V RMS)
RMS Bandwidth	30 Hz to 2.5 MHz (-3 dB)
Interference Frequency Filter	100 Hz high pass filter
Isolation (earth to measurement device)	10kV
Measurement delay adjustment	200 – 2000ms (10ms resolution)
Variable Load	10 – 5100Ω, steps @ 10Ω
Load Resistor Type	Ceramic Resistors (Non inductive)
Accuracy	±1%, + 0.5, -0.0 Ω of set load
Power rating	(Refer to load/power graph)
Duty cycle * (see load rating graph below)	50%
Fixed Loads	2 x 200Ω
Accuracy	±1%, + 0.5,-0.0 Ω
Power rating	150 Watt (50% duty cycle)
Plate Security (REM) resistor	0 - 500Ω, 1Ω step Motor driven potentiometer
Accuracy	±5% ± 2 Ω
Alarm register	High and low, manual confirmation
Ranging	Manual or automatic
Oscilloscope output	5V/A, un-calibrated , indication only
Connections	
Variable load 10 – 5100Ω	2 x 4mm Red = Active, Black = Plate
Fixed Load x 200Ω	1 x 4 mm - black (common), 2 x 4 mm - red
Measuring device (MD)	2 x 4mm White
Oscilloscope output	SMB coaxial connector
REM test 0-500 ohm	2 x 4 mm - black
Remote foot switch control (CUT)	2 x 4 mm - yellow, Single relay contact
Remote foot switch control (COAG)	2 x 4 mm - blue, Single relay contact
USB port	PC interface

Load Power rating Rigel 377

The graph below states the worst case power rating at a 50% duty cycle. The maximum power may be exceeded at duty cycles below 50%.

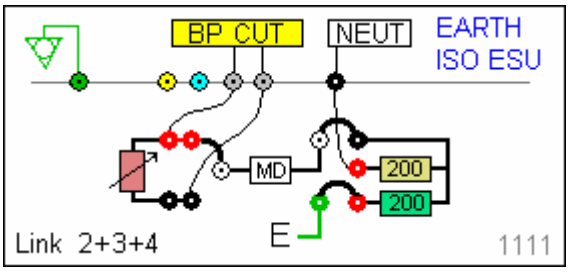


6.2. General Specification

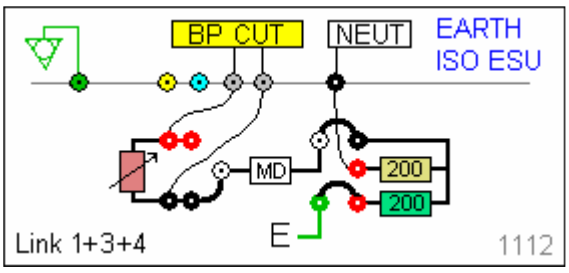
Dimensions	370 X 300 X 204mm
Weight	11 Kg
Operating Temperature	15 ˚C to 35 ˚C
Storage Temperature	0˚C to 50 ˚C
Mains power	115/230 ±10% VAC; 48 to 66 Hz, 35 VA
Fuses	2 x 1.6 A (T) ceramic

Appendix A IEC 60601-2-2 Leakage Tests

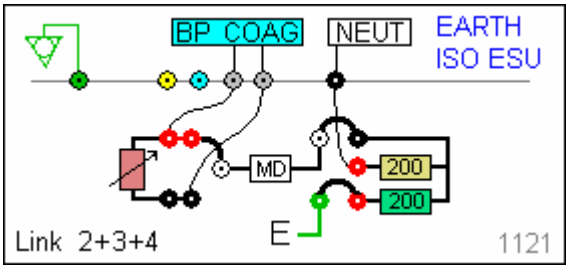
TEST CODE 1111
IEC 601-2-2 part 1, FIGURE 104
MEASUREMENT OF H.F. LEAKAGE CURRENT FROM A BIPOLAR ELECTRODE
EARTH ISOLATED ESU
BIPOLAR ELECTRODE
CUT MODE
FIRST ELECTRODE



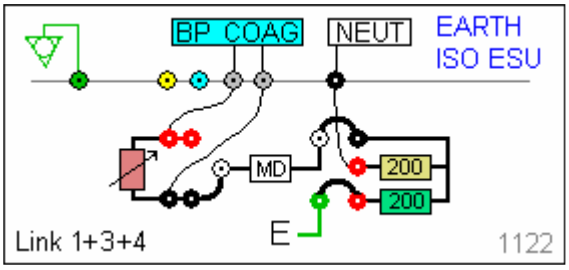
TEST CODE 1112
IEC 601-2-2 part 1, FIGURE 104
MEASUREMENT OF H.F. LEAKAGE CURRENT FROM A BIPOLAR ELECTRODE
EARTH ISOLATED ESU
BIPOLAR ELECTRODE
CUT MODE
SECOND ELECTRODE



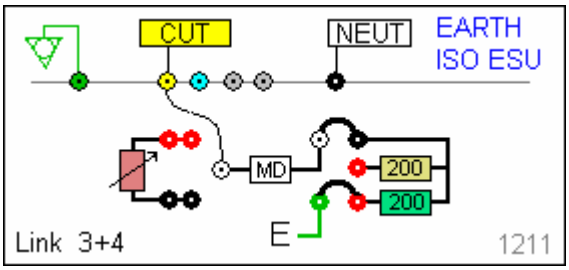
TEST CODE 1121
IEC 601-2-2 part 1, FIGURE 104
MEASUREMENT OF H.F. LEAKAGE CURRENT FROM A BIPOLAR ELECTRODE
EARTH ISOLATED ESU
BIPOLAR ELECTRODE
COAG MODE
FIRST ELECTRODE



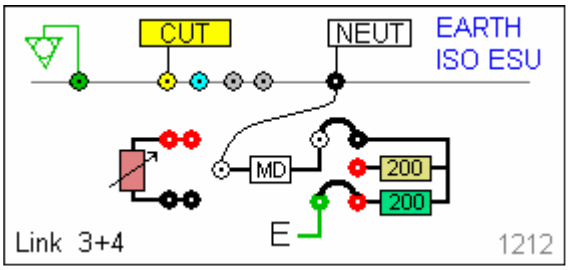
TEST CODE 1122
IEC 601-2-2 part 1, FIGURE 104
MEASUREMENT OF H.F. LEAKAGE CURRENT FROM A BIPOLAR ELECTRODE
EARTH ISOLATED ESU
BIPOLAR ELECTRODE
COAG MODE
SECOND ELECTRODE



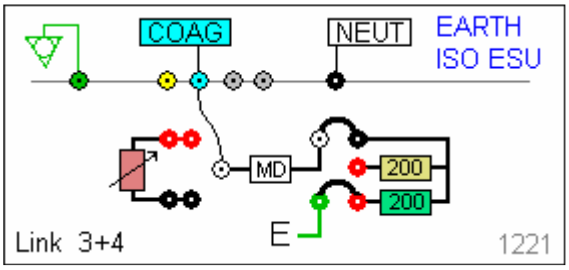
TEST CODE 1211
IEC 601-2-2 part 1 FIGURE 103
MEASUREMENT OF H.F. LEAKAGE CURRENT WITH NEUTRAL ELECTRODE ISOLATED FROM EARTH AT HIGH FREQUENCY
EARTH ISOLATED ESU
MONO-POLAR ELECTRODE
CUT MODE
ACTIVE ELECTRODE



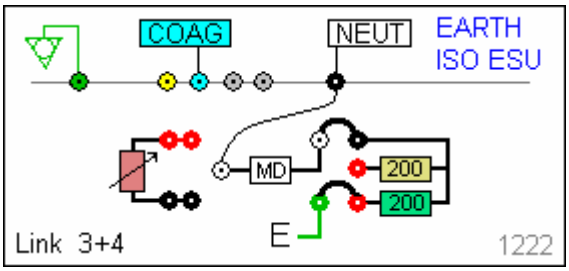
TEST CODE 1212
IEC 601-2-2 part 1 FIGURE 103
MEASUREMENT OF H.F. LEAKAGE CURRENT WITH NEUTRAL ELECTRODE ISOLATED FROM EARTH AT HIGH FREQUENCY
EARTH ISOLATED ESU
MONO-POLAR ELECTRODE
CUT MODE
NEUTRAL ELECTRODE



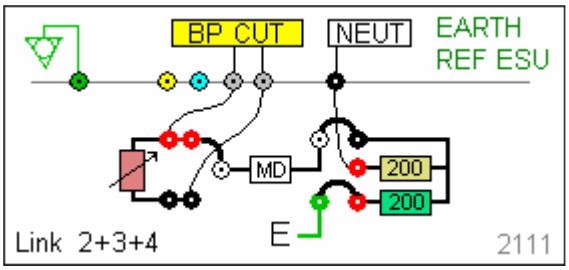
TEST CODE 1221
IEC 601-2-2 part 1 FIGURE 103
MEASUREMENT OF H.F. LEAKAGE CURRENT WITH NEUTRAL ELECTRODE ISOLATED FROM EARTH AT HIGH FREQUENCY
EARTH ISOLATED ESU
MONO-POLAR ELECTRODE
COAG MODE
ACTIVE ELECTRODE



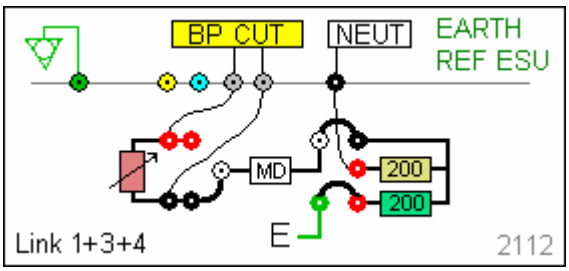
TEST CODE 1222
IEC 601-2-2 part 1 FIGURE 103
MEASUREMENT OF H.F. LEAKAGE CURRENT WITH NEUTRAL ELECTRODE ISOLATED FROM EARTH AT HIGH FREQUENCY
EARTH ISOLATED ESU
MONO-POLAR ELECTRODE
COAG MODE
NEUTRAL ELECTRODE



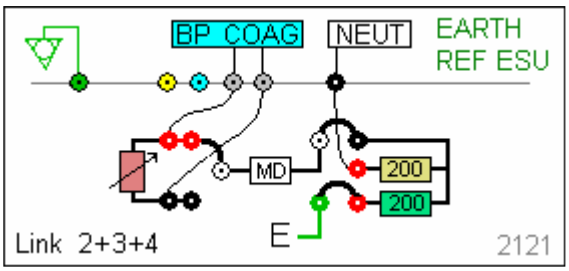
TEST CODE 2111
IEC 601-2-2 part 1, FIGURE 104
MEASUREMENT OF H.F. LEAKAGE CURRENT FROM A BIPOLAR ELECTRODE
EARTH `REFERENCED ESU
BIPOLAR ELECTRODE
CUT MODE
FIRST ELECTRODE



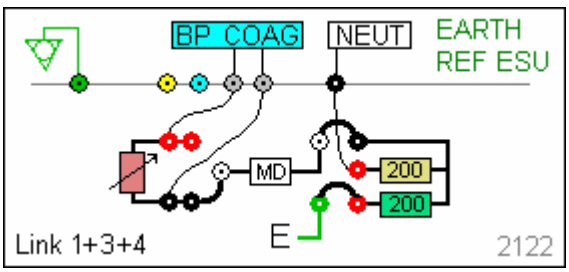
TEST CODE 2112
IEC 601-2-2 part 1, FIGURE 104
MEASUREMENT OF H.F. LEAKAGE CURRENT FROM A BIPOLAR ELECTRODE
EARTH REFERENCED ESU
BIPOLAR ELECTRODE
CUT MODE
SECOND ELECTRODE



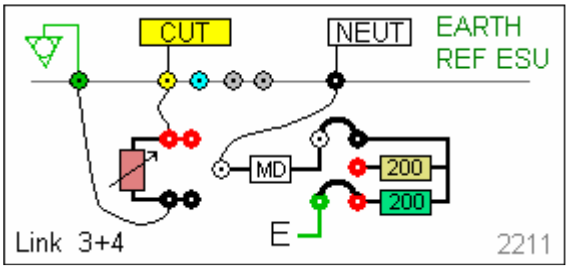
TEST CODE 2121
IEC 601-2-2 part 1, FIGURE 104
MEASUREMENT OF H.F. LEAKAGE CURRENT FROM A BIPOLAR ELECTRODE
EARTH REFERENCED ESU
BIPOLAR ELECTRODE
COAG MODE
FIRST ELECTRODE



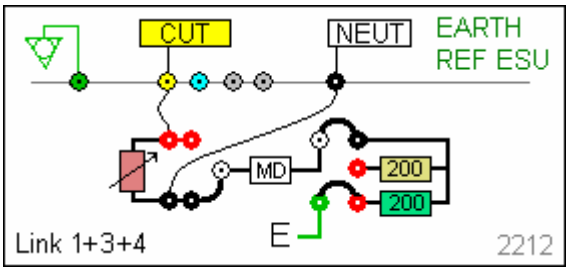
TEST CODE 2122
IEC 601-2-2 part 1, FIGURE 104
MEASUREMENT OF H.F. LEAKAGE CURRENT FROM A BIPOLAR ELECTRODE
EARTH REFERENCED ESU
BIPOLAR ELECTRODE
COAG MODE
SECOND ELECTRODE



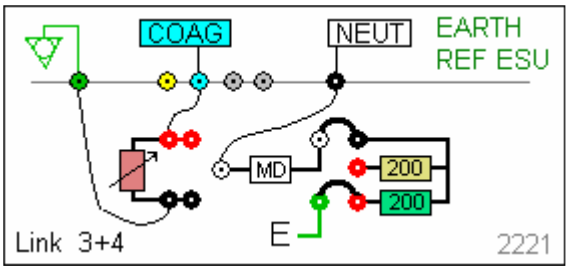
TEST CODE 2211
IEC 601-2-2 part 1 FIGURE 102
MEASUREMENT OF H.F. LEAKAGE CURRENT WITH NEUTRAL ELECTRODE REFERENCED TO EARTH AND LOAD FROM ACTIVE ELECTRODE TO EARTH
EARTH REFERENCED ESU
MONO-POLAR ELECTRODE
CUT MODE
ACTIVE ELECTRODE



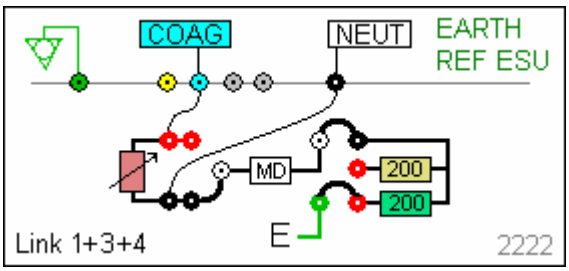
TEST CODE 2212
IEC 601-2-2 part 1 FIGURE 101
MEASUREMENT OF H.F. LEAKAGE CURRENT WITH NEUTRAL ELECTRODE REFERENCED TO EARTH AND LOAD BETWEEN ELECTRODES
EARTH REFERENCED ESU
MONO-POLAR ELECTRODE
CUT MODE
NEUTRAL ELECTRODE



TEST CODE 2221
IEC 601-2-2 part 1 FIGURE 102
MEASUREMENT OF H.F. LEAKAGE CURRENT WITH NEUTRAL ELECTRODE REFERENCED TO EARTH AND LOAD FROM ACTIVE ELECTRODE TO EARTH
EARTH REFERENCED ESU
MONO-POLAR ELECTRODE
COAG MODE
ACTIVE ELECTRODE

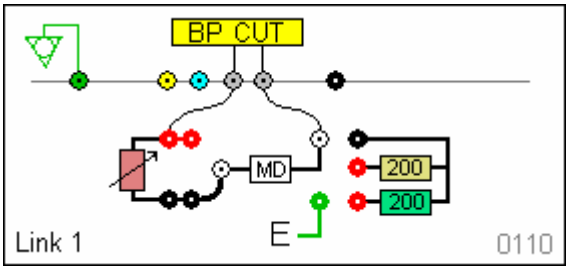


TEST CODE 2222
IEC 601-2-2 part 1 FIGURE 101
MEASUREMENT OF H.F. LEAKAGE CURRENT WITH NEUTRAL ELECTRODE REFERENCED TO EARTH AND LOAD BETWEEN ELECTRODES
EARTH REFERENCED ESU
MONO-POLAR ELECTRODE
COAG MODE
NEUTRAL ELECTRODE

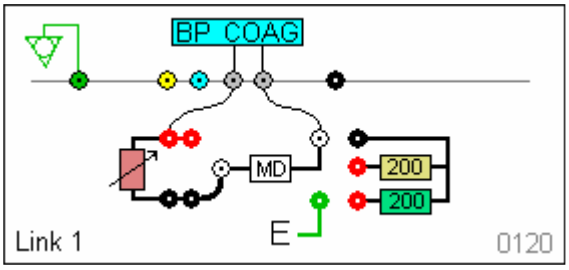


Appendix B IEC 60601-2-2 Power Tests

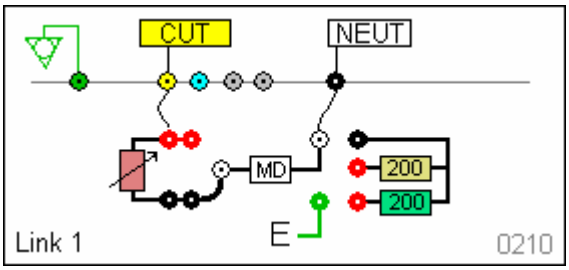
TEST CODE 0110
IEC 601-2-2 part 1 FIGURE 106
MEASUREMENT OF OUTPUT POWER
BI-POLAR OUTPUT
USER SET LOAD RESISTANCE
BI-POLAR ELECTRODE
CUT MODE
BOTH ELECTRODES



TEST CODE 0120
IEC 601-2-2 part 1 FIGURE 106
MEASUREMENT OF OUTPUT POWER
BI-POLAR OUTPUT
USER SET LOAD RESISTANCE
BI-POLAR ELECTRODE
COAG MODE
BOTH ELECTRODES



TEST CODE 0210
IEC 601-2-2 part 1 FIGURE 105
MEASUREMENT OF OUTPUT POWER
MONO-POLAR OUTPUT
USER SET LOAD RESISTANCE
MONO-POLAR ELECTRODE
CUT MODE
ACTIVE AND NEUTRAL ELECTRODE



TEST CODE 0220
IEC 601-2-2 part 1 FIGURE 105
MEASUREMENT OF OUTPUT POWER
MONO-POLAR OUTPUT
USER SET LOAD RESISTANCE
MONO-POLAR ELECTRODE
COAG MODE
ACTIVE AND NEUTRAL ELECTRODE