

Rigel-277 *PLUS*

Electrical Medical Safety Analyser

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Issue 1.4

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Declaration of Conformity

for the

Rigel 277*PLUS* Medical Safety 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 , i.e. "Conformité Européenne"

Before Starting

Upon receipt of your Rigel-277 PLUS Medical safety analyser: -

1. Check that all the component parts are present: -
 - Rigel-277 PLUS Medical Safety Analyser
 - Calibration Certificate
 - Earth Continuity Test Lead
 - Applied Parts Adaptors (11 Off)
 - Instruction Manual
 - 9 way Computer Lead
 - Thermal Paper Rolls (2 off)
 - Thermal Paper Labels (2 off)
2. The Rigel 277 plus comes fully calibrated. To fully benefit from the instrument's features, we recommend that the unit is calibrated with a 12 months interval.
3. Read the operating instructions fully before conducting any tests.
4. Contact Rigel Medical (part of the Seaward Group) if you require training on this Medical safety analyser or any other Rigel product. Courses can be arranged at Rigel Medical, or at customer premises.
5. Rigel Medical can be contacted at:

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South West Industrial Estate
Peterlee, Co. Durham
SR8 2SW, England

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sales@rigelmedical.com
calibration@rigelmedical.com
www.rigelmedical.com

Safety

Note

Please read the following Safety Instructions before use!

Safety Precautions

The manual contains specific warning and caution statements where they apply.

A Warning will identify the conditions and actions that pose hazard(s) to the user.

A Caution will identify the conditions and actions that may damage the Medical safety analyser.

Symbols used within this manual and on the Medical safety analyser are shown below:

	Risk of electric shock
	Warning of potential hazard
	Conformité Européenne

Use of the instrument in a manner not specified may impair safety. Read the following safety information carefully before attempting to operate the instrument.



Due to the potential hazards associated with any electrical circuit it is important that the user is familiar with the instructions covering the capabilities and operation of this instrument. The user should ensure that all reasonable safety precautions are followed and if any doubt exists should seek advice before proceeding.

This product is designed for use by suitably trained competent personnel and should be operated strictly in accordance with the instructions supplied.

Failure to comply with these instructions may expose the user to electrical hazard

This Medical safety analyser performs a number of electrical tests that involve high voltages and high currents. Never touch the appliance being tested, or the test leads, whilst a test is in progress.

Always check all test leads for signs of damage prior to use. Never use damaged or defective leads.

Always ensure the mains supply to the Medical safety analyser provides an adequate earth.

This manual contains information and warnings that must be heeded to ensure user safety during operation. It is essential that this manual is read fully before proceeding with any tests.

Should the Medical safety analyser behave abnormally do not continue with the testing. Disconnect immediately and contact Seaward Electronic for servicing (see Chapter 6 - Maintaining the Analyser).

Chapter 1 Introducing the Rigel 277 PLUS

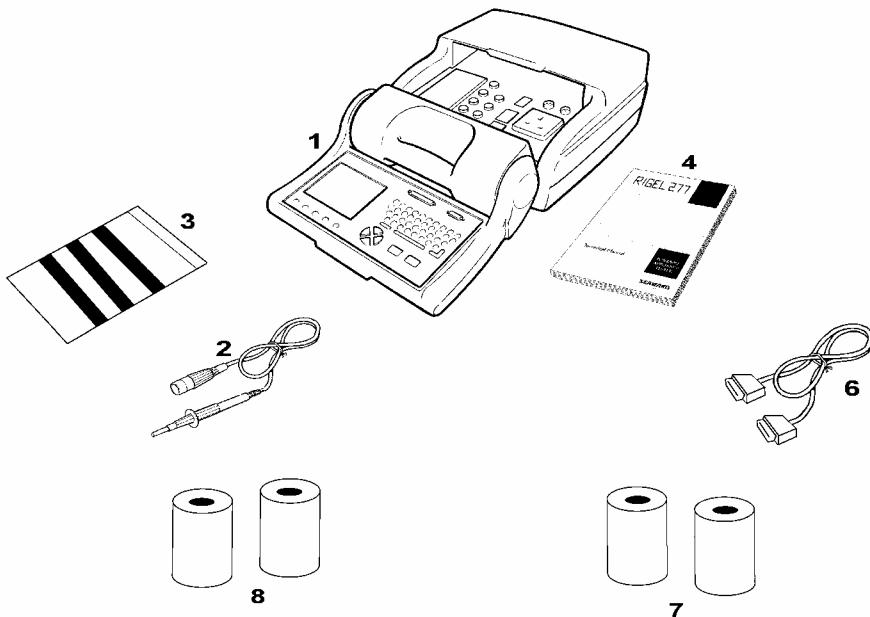
Introduction

The Rigel 277 PLUS Medical Safety Analyser is a powerful tool to assist in the analysis of the safety of medical portable electrical and electronic equipment. A range of tests is provided, with innovative features to aid difficult test situations, which allow testing of a wide variety of equipment.

The Medical safety analyser is designed to be easy to use, and also includes the following innovative features: -

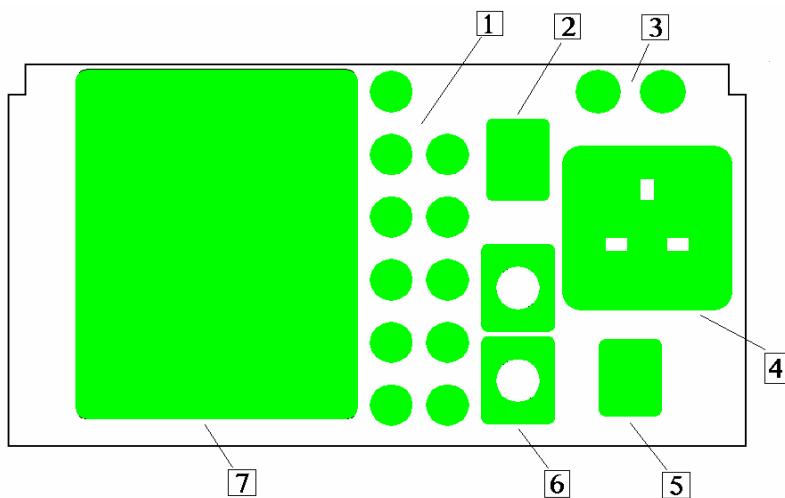
- Stores up to 2,500 results including appliances, location, site, date and time in non-volatile flash memory
- Accurate earth bond measurement even when multiple earth paths exist
- QWERTY keyboard with fast keys.
- Full graphics display, Real-time clock
- Connects to PC, Barcode reader, Brain Cell Scanner and printer
- Compatible with Seaward's MEDIGuard software
- Fast Start-up
- Contains pre-set tests for IEC60601, IEC61010, MDA DB9801, VDE 0751.

Your Rigel 277 Medical safety analyser



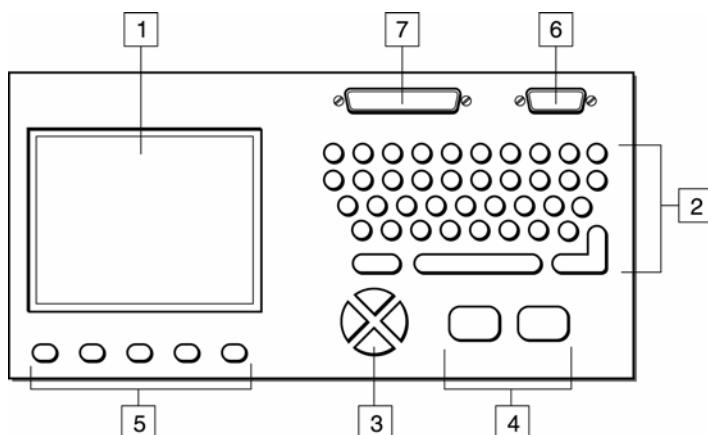
Item Number	Part
1	Rigel 277 <i>PLUS</i> Medical safety analyser
2	Earth Continuity Test Lead
3	Applied Part Adaptors and Clip for Earth Bond Lead (11)
4	Instruction Manual
6	9 Way Computer Lead
7	Thermal Paper Roll (2)
8	Thermal Paper Labels (2)

The Top Panel



Item Number	Part
1	Applied Parts Sockets (11)
2	IEC Test Socket
3	16A or 10A (F) HRC Fuses (2)
4	EUT Test Socket
5	Mains ON / OFF Switch
6	Earth Bond Socket (upper) Aux Earth Socket (lower)
7	On Board Thermal Printer

The Keyboard



Item Number	Part
1	Graphic LCD
2	'QWERTY' keyboard
3	Cursor Keys
4	Go (Green) and Abort (red) keys
5	Fast Keys
6	Serial Port Connector
7	Parallel Port Connector

The user is provided with a 320 x 240 1/4 VGA Graphical Liquid Crystal Display (LCD). The keyboard consists of an alpha-numeric keyboard, together with specific function keys. To the bottom of the keyboard are five function keys, which allow the user fast access to options displayed on the Display

There are four cursor keys used to navigate the menus.

To the bottom of the keyboard are the two main function keys, which perform, execute and cancel function as well as Start and Stop.

Definitions

Equipment Under Test	The electrical / electronic apparatus (EUT) -	which is the subject of testing.
Applied Part -	Part of the EUT (including Patient leads) that comes into contact with a patient.	
Powered Tests - being taken of power	The EUT is supplied with mains voltage, consumption, leakage currents etc.	with measurements
Analyser / Tester-	The Rigel-277 PLUS medical safety analyser	
Un-powered Tests - generated within the analyser.	The EUT is the subject of electrical tests The EUT is not provided with mains power.	using stimuli
User -	The test technician/operator using the Medical safety analyser to perform tests on a EUT.	
F-Type Applied Part -	An Applied Part which is electrically isolated from Earth i.e. floating.	
Type B Applied Part -	Applied part complying with specified requirements for protection against electric shock. Type B applied parts are those parts, which are usually Earth referenced.	
Type BF Applied Part -	F-Type Applied Part complying with a higher degree of protection against electric shock than type B applied parts. Type BF applied parts are those parts not suitable for direct cardiac application.	
Type CF Applied Part -	F-Type Applied Part complying with a higher degree of protection against electric shock than type BF applied parts.	

Quick Reference

Setting the date

On delivery of the Rigel 277 PLUS it is necessary to ensure that the correct time and a date are stored. Once stored the time/date is retained in memory and does not need to be entered again. To edit the date: from the MAIN MENU select SETUP, select, CHANGE DATE TIME. Press EDIT and use the cursor keys to highlight the digit to be changed. To store the changed date and time setting return to the MAIN MENU.

Entering a User Name

On delivery of the Rigel 277 PLUS it is necessary to ensure that a user name(s) is stored. To edit the user list: from the MAIN MENU select SETUP, select EDIT USER LIST, use the cursor keys and select an existing name. Then press the fast key EDIT NAME to change the User name. After entering a new User name, press the Enter key to save the name.

Storing Appliance Test Results in Automatic mode

The Appliance Test Results will not be stored until you hit the SAVE RESULTS fast key, the unit will then display a progress bar until the results are stored.

Storing System Data

System Data consists of everything changed from within the SETUP MENU. To store the System Data select SAVE SETTINGS from the SETUP MENU. A warning message will appear, press SAVE SETTINGS again and the system data will be stored.

Waiting for a Yes/No response

When you are prompted to respond with YES or NO you must use the fast keys under the display.

Chapter 2 Connecting the analyser

Connecting the medical safety analyser

The Medical safety analyser can be powered by either a 230V or 115V supply, which must include an earth connection (e.g. via a 3 pin plug).

When switched on, the Medical safety analyser will carry out a short self-test procedure (approximately 10 seconds). During this test a boot screen will be displayed.



Note

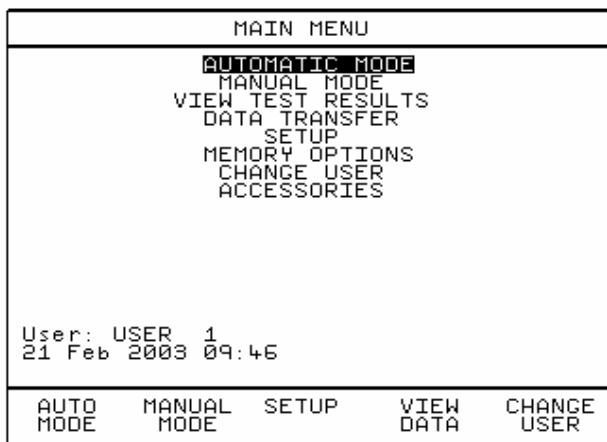
Current version number and unit serial number are shown on this screen.

The Medical safety analyser will then display the Main Menu

Chapter 3 Using the analyser

Introduction

Once the start-up procedure of the analyser has been completed, the following screen will appear: -



Navigation through the menus is by dedicated keys: -

Key	Function
←	Cursor Left
↑	Cursor Up
→	Cursor Right
↓	Cursor Down
'Red' Button	No / Abort / move back thru menu structure
'Green' Button	Yes/Go
Return	Enter/Execute

There are also the five Fast keys under the LCD whose action will change depending on the function of the analyser at any particular point.

To select an option from the Main Menu, use the cursor keys. The selected option will be highlighted in inverse video. The highlighted selection is activated by pressing the Green button.

Fast Key Menus

To facilitate a fast access to commonly used options on the menus, use the 'fast' keys on the keyboard.

How to....

The remainder of this chapter has been sub-divided into sections that describe the Medical safety analyser in terms of the essential functions to be performed. A summary is shown below: -

- How to perform Automatic tests
- How to perform Manual tests
- How to view test results
- How to download test results
- How to upload test results
- How to use Setup
- How to use the memory
- How to change the user
- How to use Help

How to perform Automatic Tests

To perform automatic tests, use the cursor keys to highlight the AUTOMATIC MODE option on the Main Menu and press Green button or press the fast key AUTO MODE to display the following menu: -

ENTER APPLIANCE DETAILS				
APPLIANCE:	ABCDE			
SITE:	SITE 1			
LOCATION:	LOCN 1			
PROGRAM TYPE:	AUTOMATIC			
TEST TYPE:	REGULAR			
MAIN MENU	SITE NAME	LOCN NAME	CHANGE ITEM	SELECT TEST

To manually change any of the fields from the keyboard move the cursor over the required field using the Cursor keys then select CHANGE ITEM. Note: The last appliance name saved will be displayed in this field. If no appliances have been saved the “star” will be displayed.

Once a field has been changed press the Return key or the OK fast key to enable other fast key options.

To enter an APPLIANCE from a barcode firstly ensure the cursor is on the Appliance field (as shown in the example above) then simply plug in the scanner and scan the barcode. Data from the barcode scanner is automatically entered into this field. Follow a similar procedure for entering data into SITE and LOCATION fields.

If you are using the Brain Cell system then Brain cells that had previously been written to after a test can be read just by pointing the Brain Cell Scanner close to the Brain Cell. You will hear beeps as the data is read. The APPLIANCE, SITE and LOCATION details will be displayed as previously written to the Brain Cell.

Another way to change the SITE is to use the fast key SITE NAME to select from the SITE LIST.

SITE LIST	
SITE 1	
SITE 2	
SITE 3	
SITE 4	
SITE 5	
SITE 6	
SITE 7	
SITE 8	
SITE 9	
SITE 10	
SITE 11	
SITE 12	
SITE 13	
SITE 14	
SITE 15	
SITE 16	
SITE 17	
SITE 18	
SELECT ITEM	NEXT PAGE

Use the cursor keys to highlight a Site name and press the fast key SELECT ITEM to select the Site for this Appliance.

Another way to change the LOCATION is to use the fast key LOC NAME to select from the LOCATION LIST.

LOCATION LIST
LOC 1
LOC 2
LOC 3
LOC 4
LOC 5
LOC 6
LOC 7
LOC 8
LOC 9
LOC 10
LOC 11
LOC 12
LOC 13
LOC 14
LOC 15
LOC 16
LOC 17
LOC 18
SELECT ITEM
NEXT PAGE

Use the cursor keys to highlight a Location name and press the fast key SELECT ITEM to select the Location for this Appliance.

Note

Default settings for the SITE LIST, LOCATION LIST and TEST SETTINGS can be changed. To make changes to these lists see 'How to use Setup'.

The PROGRAM TYPE setting enables you to choose to run the test either as an AUTOMATIC or SEMI AUTOMATIC test. A semi automatic test is a user controlled automatic test. The default setting is selected in SYSTEM CONFIGURATION (see Setup in this Manual). It can be changed on this screen but it will revert back to the default setting when next entering this screen.

TEST TYPE can be set to REGULAR or ACCEPTANCE. This is for use by the MEDIGuard program only. A REGULAR test is a routine test whereas an ACCEPTANCE test is linked to an Acceptance Record on MEDIGuard.

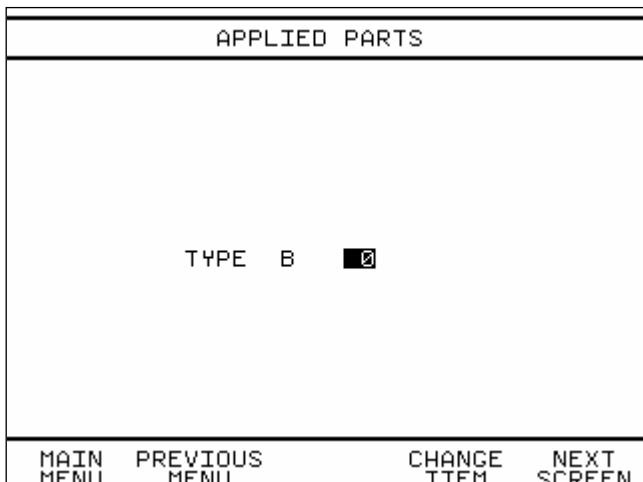
To choose an Automatic test press the fast key SELECT TEST.

Test Settings

Choose from the list of available Automatic test sequences by using the cursor keys to highlight the appropriate test.

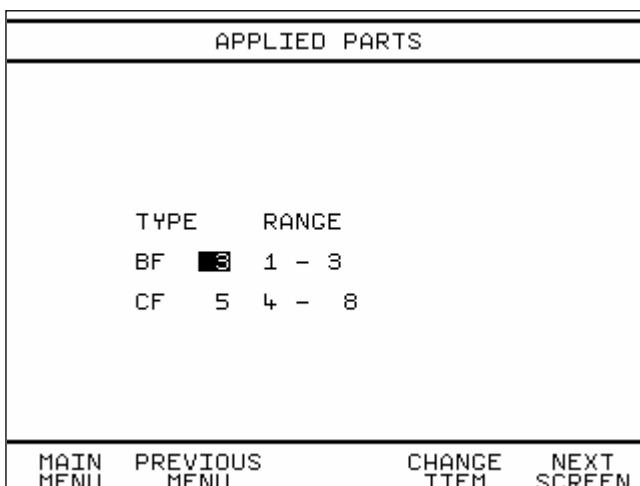
SELECT TEST SETTINGS
IEC60601 1B
IEC60601 2B
IEC60601 1BF/CF
IEC60601 2BF/CF
IEC61010 1
IEC61010 2
MAIN MENU
PREVIOUS MENU
NEXT SCREEN

Use the cursor keys to choose the appropriate test then press the fast key NEXT SCREEN to display Applied Parts Screen.



If a Type B Applied Part test sequence is chosen the screen above will be displayed. Type in the number of applied parts connected followed by the OK fast key.

If a Type BF/CF Applied Part test sequence is chosen the screen below will be displayed.



The Rigel 277 PLUS will allow equipment with different types of applied parts to be tested in a single test routine.

Enter the number of applied parts of each type to be connected, followed by the OK fast key. In the above example there are 3 BF parts assigned to AP1 - 3 connectors and 5 CF applied parts assigned to AP4 - 8 connectors.

Press the fast key NEXT SCREEN to display the test sequence chosen.

Notes on combined BF/CF Testing

If a number of both BF and CF applied parts are selected for an automatic test sequence then during the test these applied parts are dealt with separately. In the above example Patient Leakage tests will be performed on the 3 BF parts followed by the 5 CF parts, Patient Auxiliary tests will be performed on the 3 BF parts followed by the 5 CF parts and finally Patient Leakage (F-Type) tests will be performed on the 3 BF parts followed by the 5 CF parts. Applied parts of different types are NOT tested together.

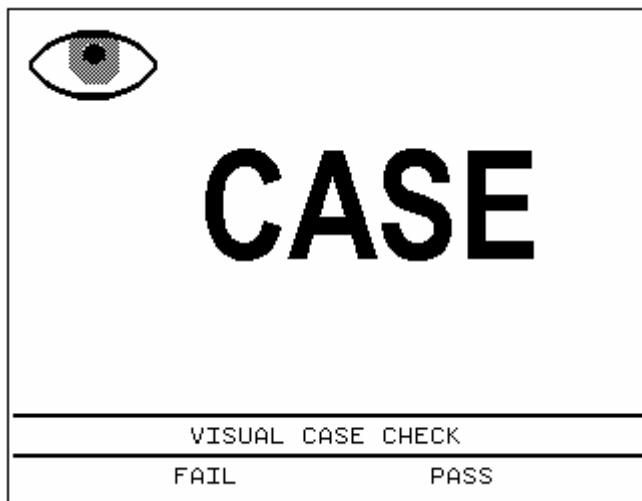
IEC 60601 1B			
SUB TEST	MAINS	SFC	STATUS
VISUAL			UNTESTED
EARTH CONT	NORM	-	UNTESTED
	----- Power Break -----		
EARTH LEAK	NORM	-	UNTESTED
ENC LEAK	NORM	-	UNTESTED
PAT LEAK	NORM	-	UNTESTED
PAT AUX	NORM	-	UNTESTED
ENC LEAK	NORM	E	UNTESTED
PAT LEAK	NORM	E	UNTESTED
PAT AUX	NORM	E	UNTESTED
	----- Power Break -----		
EARTH LEAK	NORM	P	UNTESTED
ENC LEAK	NORM	P	UNTESTED
PAT LEAK	NORM	P	UNTESTED
PAT AUX	NORM	P	UNTESTED
	----- Power Break -----		
To start the test - press START			

This display above shows the first page of a test sequence. The Rigel 277 PLUS automatic tests are carried according to a Unique Test Sequence (UTS). To speed up testing, powered tests are grouped together to reduce the number of power up / down cycles. The Power Breaks shown on this display define the power groups. As the tests proceed the STATUS changes indicating the current position in the test sequence.

Perform Test

Press the Green Start button to perform the test. Pressing the Red Button will assume a test failure.

If a Visual test is included as part of the test sequence, the following screen will be displayed: -



Use the PASS or FAIL fast keys to proceed to the next test. Similar screens will be displayed for LEAD and FUSE checks.

After the VISUAL tests, the test sequence will stop to allow connections to be made for the electrical safety tests. To continue into the first electrical test of the test sequence press the Green Start button on the keyboard. For Automatic Tests the testing will proceed without user intervention.

Semi Automatic Testing

There are some special features incorporated into the Semi Automatic test mode that enable the testing of EUTs with power ramp up / down periods to be easily tested taking full advantage of the faster testing that the UTS system allows.

A Semi Automatic test is simply an Automatic test sequence that requires user action to initiate each test or power group.

To give users control over the power up / down cycle for powered tests pressing the Green Start Key will cause power to be applied the EUT. The power will remain indefinitely.

Once the EUT has stabilized or a power up process is complete the test measurements can be taken. Pressing the fast key TAKE READING will cause all the readings for that power group to be taken. At the end of the power group the power will remain to allow the user to remove the power in a controlled manner from the EUT.

At the appropriate moment pressing the Green Start key (to move on to the next tests in the sequence) will cause the power to be removed from the EUT, the power to be re-configured in terms of mains polarity and Single Fault Condition (SFC) then re-applied to allow the user to ramp up the EUT prior to taking test readings. The whole process is repeated for each power group.

As the tests proceed, the individual test STATUS will be updated. Should any test fail, the remaining tests will be skipped and the test will terminate.

At the end of the test, the SAVE TEST RESULTS screen is displayed allowing you to add comments.

SAVE TEST RESULTS			
APPLIANCE:	SF1		
SITE:	SITE 1		
LOCATION:	LOCN 1		
USER:	USER 1		
TEST TYPE:	REGULAR		
DATE:	28/07/2005		
ENTER COMMENT:			
MAIN MENU	ENTER COMMENT	WRITE TAG	SAVE RESULTS

Add Comments

Press the fast key ENTER COMMENT, then use the keyboard to enter comments. Press the Return key for a new line. After entering Comments, press the Green button on the keyboard to enable the other fast keys.

Storing the Test to a Brain Cell

Brain Cells and Brain Cell Scanners are optional accessories that can be used with the Rigel-277 to store the test with the EUT.

To store a test to a Brain Cell with the scanner connected to the analyser's RS232 port point the Brain Cell Scanner close to the Brain Cell which should be located on the EUT and press the fast key WRITE TAG. A Test Summary will be written to the Brain Cell that can be read back when re-testing.

Save Results

To store all of the Appliance Test details (Appliance details, Test Results and Comments) press the SAVE RESULTS fast key. The analyser will show the memory capacity screen then return to the MAIN MENU.

NOTE: Memory capacity is a maximum of 2500 records or 655KB which ever is reached first.

How to perform Manual Tests

From the MAIN MENU select MANUAL MODE. The following screen is displayed: -

MANUAL MODE TEST SELECT		
VISUAL CHECK EARTH CONTINUITY INSULATION (EUT) INSULATION (AP) EARTH LEAKAGE ENCLOSURE LEAKAGE PATIENT LEAKAGE PAT LEAKAGE (F-TYPE) PATIENT AUXILIARY EQUIV EQUIP LEAKAGE EQUIV PATIENT LEAKAGE LOAD TEST IEC LEAD POLARITY TEST IEC 61010 TOUCH LEAKAGE		
MAIN MENU	APPL PARTS	TEST CLASS

The display lists all possible tests that can be performed with the Rigel-277 PLUS.

Any individual test that is selected will perform the test in accordance with the current selected manual test settings for number of applied parts and test class.

Selecting Applied Parts

Press the fast key APPL PARTS to display the SELECT APPLIED PARTS screen: -

SELECT APPLIED PARTS		
EXIT NOCHANGE	SELECT ITEM	
1	2	3
4	5	6
7	8	9
10	11	COM

Use the cursor keys to select a different setting, then press the fast key SELECT ITEM to confirm your setting. This new setting will remain selected until changed. Press the fast key EXIT NOCHANGE if you were just checking the current setting.

Selecting Test Class

Press the fast key TEST CLASS to display the SELECT TEST CLASS screen: -

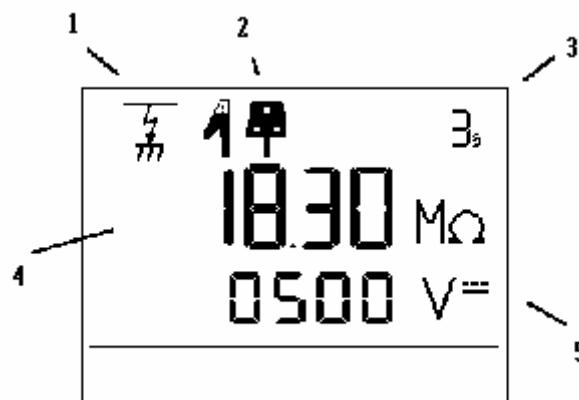
SELECT TEST CLASS	
1B 1BF 1CF 2B 2BF 2CF	
EXIT NOCHANGE	SELECT CLASS

Use the cursor keys to select a different setting, and then press the fast key SELECT CLASS to confirm your setting. This new setting will remain selected until changed. Press the fast key EXIT NOCHANGE if you were just checking the current setting.

Note: The Type (B, BF, CF) of equipment and the number of Applied Parts selected is displayed in the lower right hand corner of the manual test screen for Patient Leakage, Patient Leakage F-Type and Patient Auxiliary tests.

How to use the Meter Display

When selecting a test (other than a VISUAL test) the following screen type is displayed: -



Ref. Number	Function
1	Test Icon
2	Connection Icon
3	Test Duration Counter
4	Primary Display
5	Secondary Display

The display consists of a number of Icons to provide visual indication of the Analyser status, a primary 4 digit,

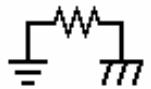
7segment display, along with a 4 digit secondary display, 6 segment display, and a 3 digit duration time display.

Test Icons

Indicates the test selected as follows: -



Visual



Earth Continuity



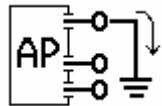
Insulation



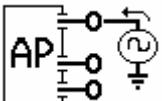
Earth Leakage



Enclosure Leakage / Load Test



Patient Leakage



Patient Leakage (F – Type)
Equivalent Patient Leakage



Equivalent Equipment Leakage



IEC Lead Polarity

Connection Icons

Indicates required external connections as follows: -



Mains socket and Earth Bond lead with crocodile clip



Mains socket only



Mains Socket and Applied Parts



Mains socket, Applied Parts and Earth Bond lead



Mains socket to IEC socket

Class and Type Icons

Indicates currently selected Class and Type



Class I



Class II



Type B



Type BF



Type CF

Test Duration Counter

Indicates the duration of the test. This will count down to zero during the test.

Primary Display

The primary display has two functions; before a test is started, the Pass/Fail limit is displayed, during the test the test measurement is displayed.

Secondary Display

This display indicates test output voltage or current used eg 230V, 25A, 500Vdc etc.

Selecting Test Parameters

After selecting the appropriate test the analyser displays a screen from which you can set test parameters.

Use the left and right cursor keys to highlight a field on the display. Then use the up and down cursor keys to change the variable in the selected field.

Appropriate fast keys are available to set different fault conditions.

Press the Green button to start the test.

Press the Red button to abort the test at any time.

After the test is complete, the result will stay on screen for 10 seconds or until a key is pressed. During this time you can press the PRINT RESULT fastkey, and the measured value will be printed on the internal printer.

Viewing test Results

To view test results stored in memory, use the cursor keys to highlight the VIEW TEST RESULTS option on the MAIN MENU and press Green button to display the following menu: -

VIEW TEST RESULTS	
APPLIANCE:	-*-
SITE:	-*-
LOCATION:	-*-
USER:	-*-
TEST STATUS:	-*-
STORAGE STATUS:	NORMAL
FROM DATE:	01/01/2002 09:00
TO DATE:	01/01/2010 09:00
MAIN MENU	CHANGE ITEM START SEARCH

Use the cursor keys to highlight the required parameters and press the fast key to CHANGE ITEM select an appropriate value. The default selection will display all undeleted (normal) results. Change the search criteria to limit the search to your requirements then press the START SEARCH fast key to display the SEARCH RESULTS screen as follows:-

SEARCH RESULTS						
APPLIANCE NO	I	DATE	I	SITE	I	STATUS
SF1		28/07/2005	SITE	1		F
SF1		28/07/2005	SITE	1		P
EXAMPLE1		29/07/2005	SITE	1		P
MAIN MENU	PREVIOUS MENU	VIEW RECORD	PAGE UP	PAGE DOWN		

This screen contains a one line entry for every Appliance found that met the search criteria. To display further details, select the appropriate Appliance then press the fast key VIEW RECORD to display the following screen:

APPLIANCE: EXAMPLE1	(3BF,5CF)		
SITE: SITE 1			
LOCN: LOCN 1	AUTO		
USER: USER 1			
TEST PROGRAM: IEC60601 2BF/CF			
DATE: 29 Jul 2005 09:30	PASS		
TEST	OUTPUT SFC LIMIT RESULT S		
VISUAL CHECK	P		
L-PE VOLTAGE	238 P		
N-PE VOLTAGE	0 P		
LOAD (kVA)	238V~ 0.00 P		
ENCL LEAK	238V~ - 0.10 0.003 P		
ENCL LEAK	238V~ P 0.50 0.003 P		
ENCL LEAK	238V~R - 0.10 0.003 P		
ENCL LEAK	238V~R P 0.50 0.003 P		
PAT LEAK (COM)	238V~ - 0.10 0.003~P		
PAT LEAK (COM)	238V~ - 0.01 0.000 P		
PAT LEAK (4)	238V~ - 0.01 0.003~P		
PAT LEAK (4)	238V~ - 0.01 0.000 P		
MAIN MENU	PREVIOUS MENU	VIEW COMMENTS	PRINT LIST

Use the PAGE DOWN and PAGE UP fast keys to scroll through the test results. Each Applied Part is tested sequentially and the results are displayed in the same order. Comments associated with the test can be displayed by pressing the fast key VIEW COMMENTS. To return to the results screen press the fast key VIEW RECORD (available when viewing Comments).

The PRINT LIST fast key will cause the record to be printed out onto the internal printer.

The following symbols and abbreviations used when test results are displayed:

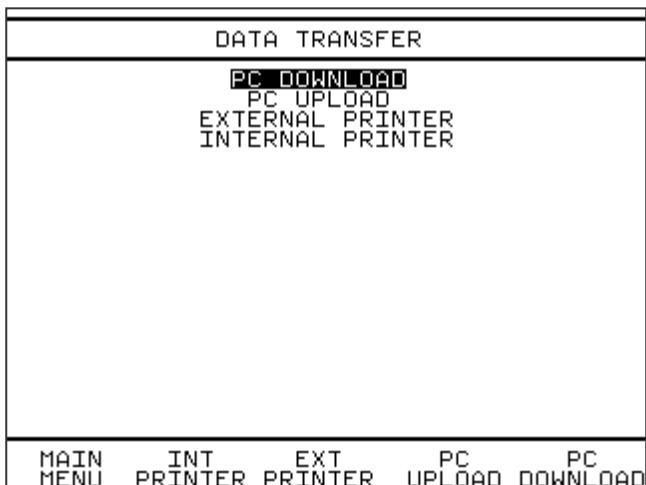
Symbol	Means
<	Less than
>	Greater than
~	AC (if no symbol and a voltage or current is implied then DC)
AP	Applied Part
COM	Common
E	Earth Open
P	PASS (in the Status (S) column)
P	Phase Open (in the SFC column)
R	Mains Reversed
S	Source Normal (Pat Leak (F Type) tests – Mains on Applied Parts)
SFC	Single Fault Condition
SR	Source Reversed (for Pat Leak (F Type) tests – Mains on Applied Parts)

Notes

- 1 In the above example the upper right hand side of the screen shows that this test had 3 BF and 5 CF applied parts connected.
- 2 When a test containing both BF and CF applied parts is viewed it should be noted that the Patient Leakage, Patient Auxiliary and Patient Leakage (F-Type) results will always show the BF results first followed by the CF results.

How to Download Test Results

To download results stored in the memory, use the cursor keys to select DATA TRANSFER from the MAIN MENU. Press the Green key to display the following menu: -

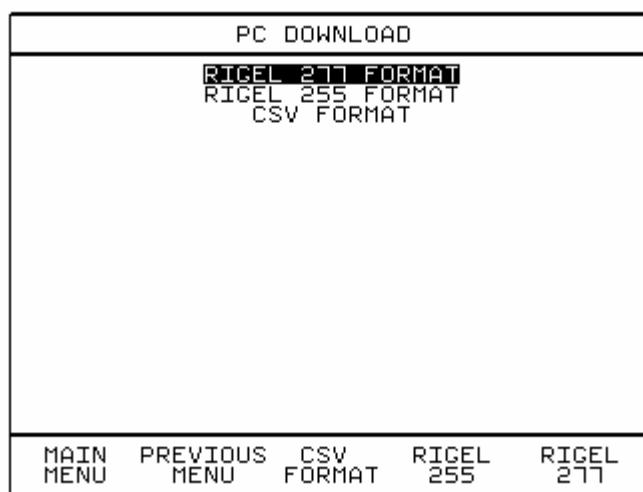


Test Results can be downloaded to a computer or to the on board printer.

Use the fast keys or cursor keys to highlight the required option and press Green button.

PC Download

If PC DOWNLOAD is selected, the following menu is displayed: -



Test Results can be downloaded as a RIGEL 277 FORMAT for Seaward MEDIGuard program, RIGEL 255 FORMAT for compatible software or as a CSV FORMAT for use with Spreadsheet applications (e.g. Microsoft Excel).

Use the fast keys or cursor keys to highlight the required option and press Green button. The following screen will now be displayed: -

DOWNLOAD TEST RESULTS	
APPLIANCE:	-*-
SITE:	-*-
LOCATION:	-*-
USER:	-*-
TEST STATUS:	-*-
STORAGE STATUS:	NORMAL
FROM DATE:	01/01/2002 09:00
TO DATE:	01/01/2010 09:00
MAIN MENU	CHANGE ITEM START SEARCH

Use the cursor keys to highlight the required parameters and press the fast key to CHANGE ITEM select an appropriate value. The default selection will download all undeleted results. Change the search criteria to limit the download to your requirement then press the START SEARCH fast key to commence the download.

Internal Printer

If the INTERNAL PRINTER is selected, the following menu is displayed:-

INTERNAL PRINTER				
PRINT LIST FORMAT	PRINT SUMMARY	PRINT PASS/FAIL LABEL		
MAIN MENU	PREVIOUS MENU	PRINT LIST	PRINT SUMMARY	P/F LABEL

Test Results can be printed as a List of all Results, a Test Summary or as Pass / Fail labels.

Use the fast keys or cursor keys to highlight the required option and press Green button. The following screen will now be displayed: -

VIEW TEST RESULTS	
APPLIANCE:	-*-
SITE:	-*-
LOCATION:	-*-
USER:	-*-
TEST STATUS:	-*-
STORAGE STATUS:	NORMAL
FROM DATE:	01/01/2002 09:00
TO DATE:	01/01/2010 09:00
MAIN MENU	CHANGE ITEM START SEARCH

Use the cursor keys to highlight the required parameters and press the fast key CHANGE ITEM to select an appropriate value. The default selection will print all undeleted results. Change the search criteria to limit the printout to your requirement then press the START SEARCH fast key to commence.

External Printer

If the EXTERNAL PRINTER transfer is selected, the following menu is displayed: -

EXTERNAL PRINTER				
PRINT LIST FORMAT				
PRINT SUMMARY				
PRINT TEST CERTIFICATE				
MAIN MENU	PREVIOUS MENU	PRINT LIST	PRINT SUMMARY	TEST CERT

Test Results can be printed in Certificate form, Test Summary or as List format (as internal printer format but on A4 paper).

Use the fast keys or cursor keys to highlight the required option and press Green button. The following screen will now be displayed:-

Please note that printer must support ASCII-code.

An example of the printed documents can be found at the back of the instruction manual.

VIEW TEST RESULTS	
APPLIANCE:	-*-
SITE:	-*-
LOCATION:	-*-
USER:	-*-
TEST STATUS:	-*-
STORAGE STATUS:	NORMAL
FROM DATE:	01/01/2002 09:00
TO DATE:	01/01/2010 09:00
MAIN MENU	CHANGE ITEM START SEARCH

Use the cursor keys to highlight the required parameters and press the fast key to CHANGE ITEM select an appropriate value. The default selection will download all undeleted results. Change the search criteria to limit the download to your requirement then press the START SEARCH fast key to commence the download.

How to Upload Test Results

To upload results from a PC and store them in the memory, use the cursor keys to select DATA TRANSFER from the MAIN MENU. Then select PC UPLOAD. The following screen will now be displayed: -

PC UPLOAD	
UPLOAD ASSETS FROM PC. YOU MAY WANT TO CLEAR MEMORY BEFORE PROCEEDING.	
MAIN MENU	PREVIOUS MENU CLEAR MEMORY START UPLOAD

If you want to, you can clear out any existing results at this point. It is normal to start upload from a completely empty analyser, however if you are going to more than 1 site for example, you may want to upload the results for one site straight after another site.

Select START UPLOAD and the analyser will go into a mode where it is ready to receive serial data from a PC. You can then start sending data from the PC. As the test data is received, the appliance ID and site name is displayed on the screen.

At the end a summary is displayed: -

PC UPLOAD		
Press ABORT to cancel		
COMPLETE		
APP2	SITE	1
APP3	SITE	1
APP4	SITE	1
APP5	SITE	1
APP6	SITE	1
APP7	SITE	1
TEST RESULTS RECEIVED		
TEST RESULTS SUCCESSFULLY STORED		
PREVIOUS MENU		CONTINUE

Press CONTINUE if you want to upload more results. PREVIOUS MENU takes you back to DATA TRANSFER screen.

Repeating a test

If the analyser has some results in its memory, then the user has the option to repeat any of these tests.

When the user enters an appliance ID, the analyser searches its memory for any test results with the same ID. If the test result was a PASS, then the screen will show a summary of that test, as shown below: -

LAST TEST DETAILS				
APPLIANCE:	EXAMPLE1			
SITE:	SITE 1			
LOCATION:	LOCN 1			
PROGRAM TYPE:	AUTOMATIC			
TEST TYPE:	REGULAR			
APPLIED PARTS:	(3BF,5CF)			
DATE OF LAST TEST:	29 Jul 2005 09:30			
TESTED BY:	USER 1			
LAST TEST SETTING:	IEC60601 2BF/CF			
TYPE & CLASS:	2BF/CF			
LAST TEST RESULT:	PASS			
TEST SCRIPT:				
MAIN MENU	SITE NAME	LOCN NAME	NEW TEST	REPEAT TEST

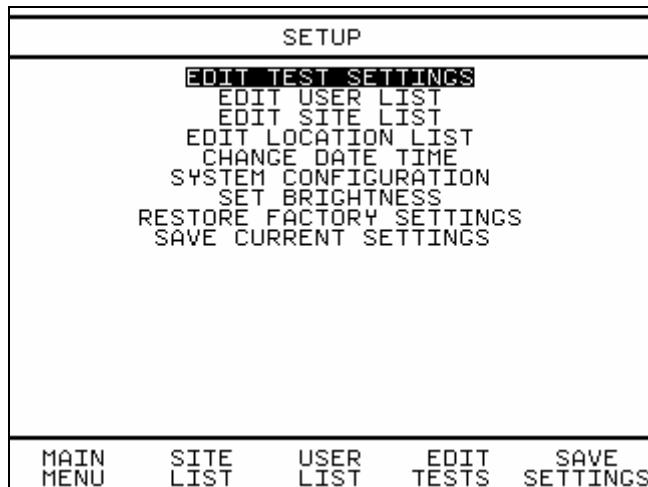
As usual you can alter SITE:, LOCATION:, PROGRAM TYPE: and TEST TYPE:. Simply use the cursor keys to highlight the item and then press CHANGE ITEM.

Note - The number of applied parts cannot be altered from this screen, if a different number of applied parts is required a new test must be performed.

If you press NEW TEST, then you can select a test sequence as normal. If you press REPEAT TEST, then the analyser will recreate the test sequence that was last used.

How to use Setup

To set up the Analyser, use the cursor keys to highlight the Setup option on the Main Menu and press the Green Start key to display the following menu: -



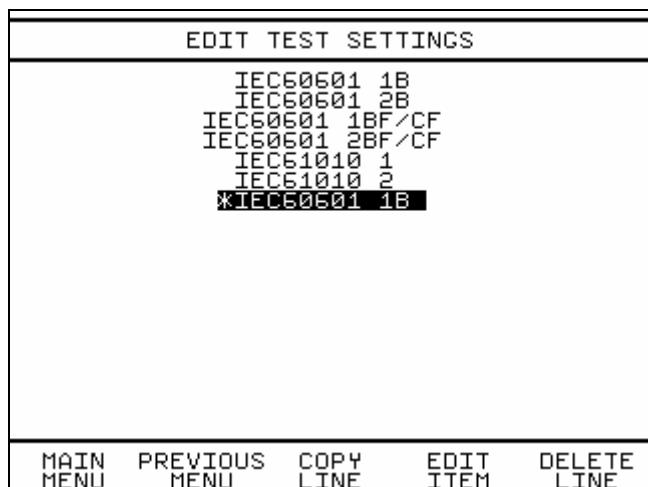
Edit Test Settings

This allows the user to view test sequence details or copy test sequences. These test sequences are selected when running AUTOMATIC or SEMI AUTOMATIC tests

The first four tests are default test sequences for a particular test standard which is set in SYSTEM CONFIGURATION. The next two tests are IEC61010 sequences. These default tests cannot be edited. A copy of a default test sequence can be pasted into the list. Copied test sequences can be edited. Up to 12 user defined Tests can be created.

Use the fast key TEST SETTINGS to display the following menu: -

Use the cursor keys to select a test sequence, then use the fast key COPY LINE to copy the test sequence.



The display above shows the IEC 60601 1B test has been copied. The copied test has automatically been renamed *IEC 60601 1B.

Use the EDIT ITEM fast key to change the settings (including the Test name). See EDIT TEST SETTINGS below on how to make changes settings.

Note

Choosing EDIT ITEM for a default test (the first six IEC tests) will allow you to view the settings but will not allow

any changes to be made.

The DELETE LINE fast key will enable you to delete a user created test, but not a default test (the first six tests).

On selecting EDIT ITEM the follow menu is displayed: -

EDIT TEST SETTINGS				
TEST NAME	*IEC60601 1B			
CLASS & TYPE	1B			
	OUTPUT	LIMIT	DUR	NUM
VISUAL		YES		
EARTH CONT	25.0A	0.10R	2s	1
INSULATION EUT	500V	20.0M	2s	0
INSULATION AP	500V	20.0M	2s	0
EARTH LEAK	230V~	SEQ		RUN
ENC LEAK	230V~	SEQ		RUN
TOUCH LEAK	230V~	SEQ		SKIP
PAT LEAK	230V~	SEQ		RUN
PAT LEAK (F)	230V~	SEQ		SKIP
PAT AUX	230V~	SEQ		RUN
MAIN MENU	PREVIOUS MENU		CHANGE ITEM	

The following symbols and abbreviations used when the EDIT TEST SETTINGS are displayed:

Symbol	Means
~	AC (if no symbol and a voltage or current is implied then DC)
A	Amps
AP	Applied Part
DUR	Duration
COM	Common
E	Earth open
F	F Type test – Mains on Applied Parts
M	Mega-ohms
mA	milliamps
NUM	Number of tests
P	PASS (in the Status (S) column)
P	Phase open (in the SFC column)
R	Reversed (in the SFC column)
R	Ohms (in the LIMIT column)
S	Seconds
S	Source normal (for F Type tests)
SEQ	Sequence
SFC	Single Fault Condition
SR	Source Reversed (for F Type tests)
V	Volts

Use the cursor keys to select the item to be changed, then press the fast key CHANGE ITEM.

For TEST NAME use the keyboard and fast keys to change the TEST NAME. Press the Return key when editing of the TEST NAME is complete to enable other items to be edited.

Note

CLASS & TYPE cannot be changed and do not interact with test settings

For the VISUAL test, each action of the CHANGE ITEM fast key will toggle between YES and NO.

To change the Earth Bond Test Current, Insulation Test Voltage, subsequent PASS/FAIL limits and Test Duration (OUTPUT / LIMIT / DUR / NUM – column), highlight the field using the up and down arrow keys and use the CHANGE ITEM fast key to change the setting.

Note

The OUTPUT – LIMIT – DUR columns can only be changed for non-powered tests i.e. EARTH BOND, INSULATION EUT and INSULATION AP. For a Test with NUM set to 0 or SKIP, the test will be disabled.

For powered tests which contain a test sequence selecting SEQ with the cursor keys then CHANGE ITEM will cause the following type of menu to be displayed: -

EDIT PATIENT LEAK SEQUENCE							
SEQ	OUTPUT	SFC	BF LIMIT	CF LIMIT	DUR	NUM	
1	230V~	-	0.10mA~ 0.01mA=	0.01mA~ 0.01mA=	2s	1	
2	230V~	E	0.50mA~ 0.05mA=	0.05mA~ 0.05mA=	2s	1	
3	230V~	P	0.50mA~ 0.05mA=	0.05mA~ 0.05mA=	2s	1	
4	230V~ R	-	0.10mA~ 0.01mA=	0.01mA~ 0.01mA=	2s	1	
5	230V~ R	E	0.50mA~ 0.05mA=	0.05mA~ 0.05mA=	2s	1	
6	230V~ R	P	0.50mA~ 0.05mA=	0.05mA~ 0.05mA=	2s	1	

MAIN	PREVIOUS	CHANGE	CHANGE
MENU	MENU	-	+

For each Sequence (SEQ), the Pass Limit (LIMIT), Duration (DUR) and Number of tests (NUM) can all be changed by selecting the appropriate value with the cursor keys, then press the CHANGE + or CHANGE - fast key. Press CHANGE + to increase the value, CHANGE – to decrease the value.

Note

To disable a test within a Sequence (SEQ) set the Number of tests (NUM) to 0.

The example above shows a Patient Leakage sequence for a BF/CF test. The individual pass/fail limits can be adjusted here.

Edit User List

From the SETUP menu select EDIT USER LIST and the following menu is displayed: -

EDIT USER LIST				
USER 1				
MAIN	PREVIOUS	EDIT	SET	NEXT
MENU	MENU	NAME	DEFAULT	PAGE

Twenty User names are provided. The fast keys NEXT PAGE and PREV PAGE (displayed after NEXT PAGE action) allow all User names to be selected.

Use the cursor keys to highlight the User name you wish to edit, then press the fast key EDIT NAME. Use the keyboard and fast keys to change the User name. Press the Return key when editing of the User name is complete to return to the above menu

The fast key SET DEFAULT will change the current User displayed on the MAIN MENU. This User is the current User of the analyser and all tests stored will have this User name stored with them.

Edit Site List

From the SETUP menu select EDIT SITE LIST and the following menu is displayed: -

EDIT SITE LIST				
SITE 1				
MAIN	PREVIOUS	EDIT	SET	NEXT
MENU	MENU	NAME	DEFAULT	PAGE

Twenty Site names are provided. The fast keys NEXT PAGE and PREV PAGE (displayed after NEXT PAGE action) allow all Site names to be selected.

Use the cursor keys to highlight the Site name you wish to edit, then press the fast key EDIT NAME. Use the keyboard and fast keys to change the Site name. Press the Return key when editing of the User name is complete to return to the above menu

The fast key SET DEFAULT will change the current Site displayed on the ENTER APPLIANCE DETAILS screen.

Edit Location List

From the SETUP menu select EDIT LOCATION LIST and the following menu is displayed: -

EDIT LOCATION LIST			
LOC 1 LOC 2 LOC 3 LOC 4 LOC 5 LOC 6 LOC 7 LOC 8 LOC 9 LOC 10 LOC 11 LOC 12 LOC 13 LOC 14 LOC 15 LOC 16 LOC 17 LOC 18			
PREVIOUS MENU	EDIT NAME	SET DEFAULT	NEXT PAGE

Twenty Location names are provided. The fast keys NEXT PAGE and PREV PAGE (displayed after NEXT PAGE action) allow all Location names to be selected.

Use the cursor keys to highlight the Location name you wish to edit, then press the fast key EDIT NAME. Use the keyboard and fast keys to change the Location name. Press the Return key when editing of the User name is complete to return to the above menu.

The fast key SET DEFAULT will change the current Location displayed on the ENTER APPLIANCE DETAILS screen.

Change Date Time

From the SETUP menu select SET DATE & TIME and the following menu is displayed: -

SET DATE AND TIME			
21/02/2003 13:21			
MAIN MENU	PREVIOUS MENU	EDIT	

Use the EDIT fast key to enable you to change the current settings. Use the keyboard to change the values, then press the Return key to save the new settings.

System Configuration

From the SETUP menu select SYSTEM CONFIGURATION and the following menu is displayed: -

SYSTEM CONFIGURATION	
MENU TITLES	SITE & LOCATION
TEST PERIOD	6 MONTHS
TEST STANDARD	IEC 60601
DEFAULT MODE	AUTOMATIC
APPLIED PARTS	SAVE WORST ONLY
AFTER TEST PRINT	SUMMARY
AFTER TEST MENU	NEW TEST
CSV FORMAT	1
INC. ASSET ID	YES
REPEAT FAILED TEST	YES
PREVIOUS MENU	CHANGE ITEM

SYSTEM CONFIGURATION is where overall options are set.

To change a setting use the cursor keys to select the option then press the fast key CHANGE ITEM.

The options available are as follows: -

MENU TITLES

Determines the menu titles for the location of the appliance options are: SITE & LOCATION or HOSPITAL & WARD.

Default is SITE & LOCATION.

TEST PERIOD

The INTERNAL PRINTER option (see DATA TRANSFER) has an option to PRINT PASS / FAIL LABEL. The label requires a re-test date. This date is calculated from the TEST PERIOD set here. A re-test period up to 60 months can be set.

Default is 6 Months.

TEST STANDARD

The analyser contains the following standards: IEC 60601, MDA DB9801, VDE0751. The standard that is selected here will enable the appropriate tests for that standard in the TEST SETTINGS menu.

Default is IEC60601.

DEFAULT MODE

This sets the default PROGRAM TYPE on the ENTER APPLIANCE DETAILS screen to either AUTOMATIC or SEMI AUTOMATIC.

Default is AUTOMATIC.

APPLIED PARTS

This option determines whether at the end of a test sequence the analyser will SAVE ALL RESULTS or SAVE WORST ONLY for applied part tests.

Default is SAVE WORST ONLY.

AFTER TEST PRINT

This option determines whether a printout is automatically to be provided at the end of the test sequence. The options are: to disable print at the end of test: NONE, for the internal printer: LABEL, LIST, SUMMARY, for the external printer: CERTIFICATE (EXT), LIST (EXT), SUMMARY (EXT), CSV (SERIAL)

Default is NONE.

AFTER TEST MENU

This option determines the action after completion of a test sequence. Options are return to the MAIN MENU or commence a NEW TEST.

Default is MAIN MENU.

CSV FORMAT

This option determines the type of CSV format output.

Default is type 1.

Detailed descriptions of both CSV type 1 and CSV type 2 are available upon request.

INC. ASSET ID

This option determines whether the appliance id will be incremented after a test has been completed. This feature is very useful when testing lots of equipment for the first time, as it will create sequential serial numbers from any given start value.

Default is NO.

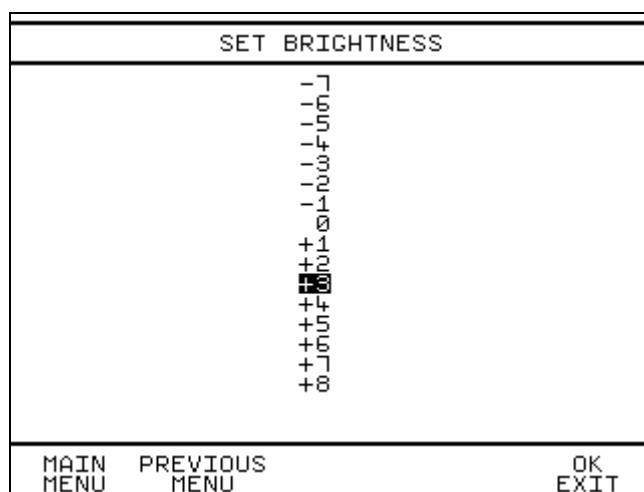
REPEAT FAILED TEST

This option determines whether the user will be allowed to repeat a failed earth bond test. If set to YES and the earth bond test fails in auto mode, the user will be prompted to repeat the test. This gives the user an opportunity to fix the probe to a different point for example and try again.

Default is NO

Set Brightness

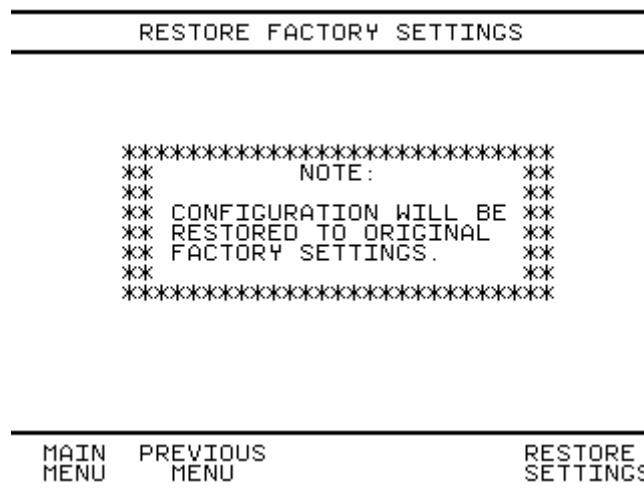
From the SETUP menu select SET BRIGHTNESS and the following menu is displayed: -



Use the cursor keys to highlight the required brightness level required then press the fast key to save the setting.

Factory Settings

From the SETUP menu select RESTORE FACTORY SETTINGS and the following will be displayed: -



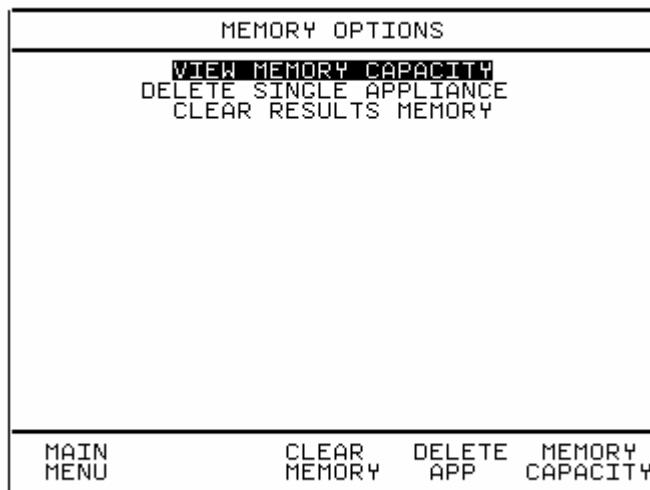
Caution

Selecting RESTORE SETTINGS will restore the default Factory Settings for SITE LIST, LOCATION LIST,

USER LIST, TEST SETTINGS and SYSTEM CONFIGURATION.

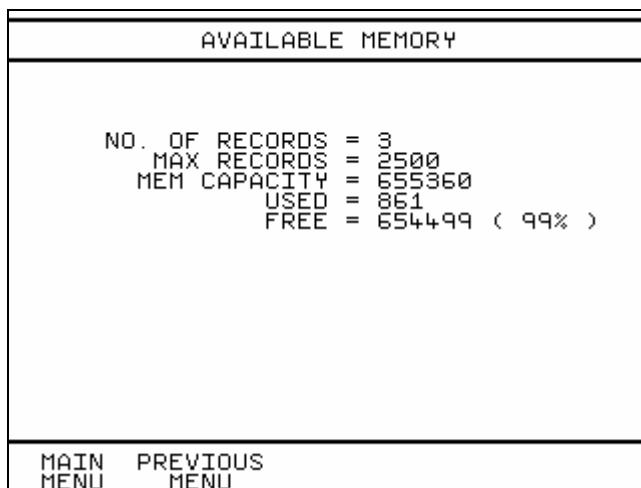
How to use the Memory

To use the memory tests and functions, use the cursor keys to highlight the MEMORY OPTIONS on the MAIN MENU and press the Green key to display the following menu: -



View Memory Capacity

The user can determine the current Memory Capacity. To do this, select VIEW MEMORY CAPACITY with the cursor keys and Green key action or use the fast key MEMORY CAPACITY. The following type of screen is displayed: -

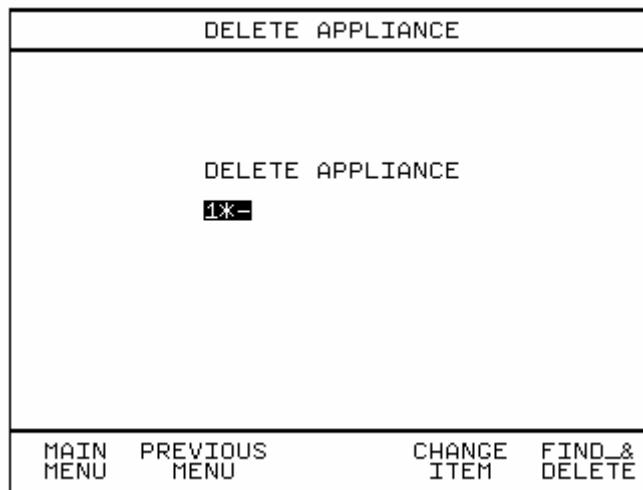


This screen shows the NUMBER OF RECORDS stored in memory, the total memory CAPACITY, memory USED and FREE memory available.

NOTE: Memory capacity is a maximum of 2500 records or 655KB which ever is reached first.

Delete Single Appliance

To delete individual Appliances in the memory use the cursor keys to select DELETE SINGLE APPLIANCE from the MEMORY OPTIONS menu then press the Green key or press the fast key DELETE APP. The following screen will be displayed: -

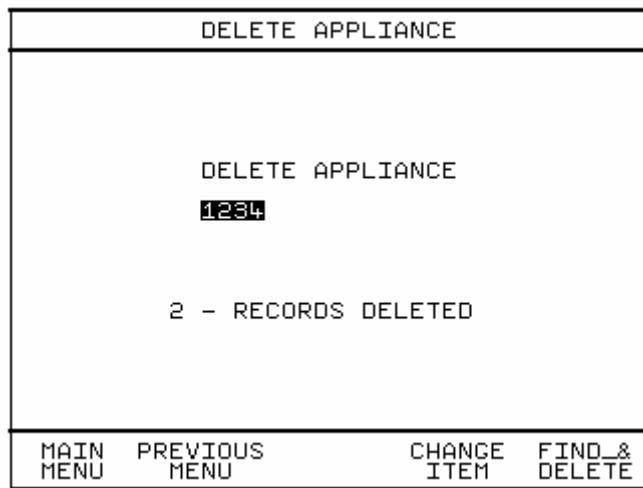


Press the CHANGE ITEM fast key to enable you to enter an Appliance number then use the keyboard and fast keys to enter the Appliance you wish to delete. Press the Return key to return to the menu above.

Note

All Appliance records will be deleted for the specified Appliance.

Press the FIND_& DELETE key to search for the Appliance in memory and delete it. The following type of screen will be displayed depending on the number of records found.



Note

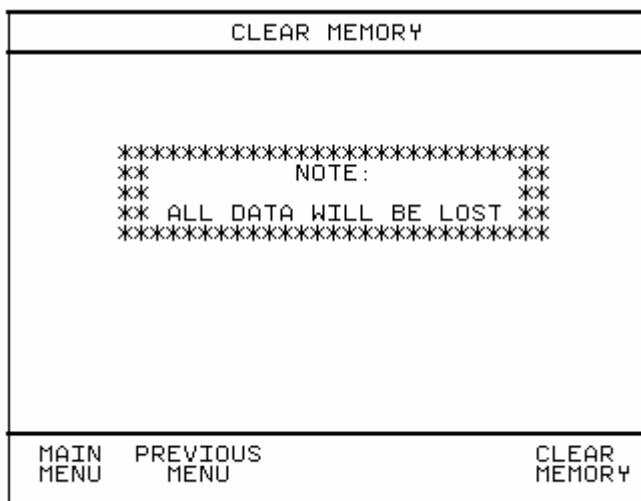
Deleted records are not actually deleted from memory. They are given a STORAGE STATUS as DELETED and can be selected on the SEARCH TEST RESULTS (assuming STORAGE STATUS field is set to DELETED) menu prior to viewing or downloading results. They are only lost from memory after a CLEAR RESULTS MEMORY action

Clear Results Memory

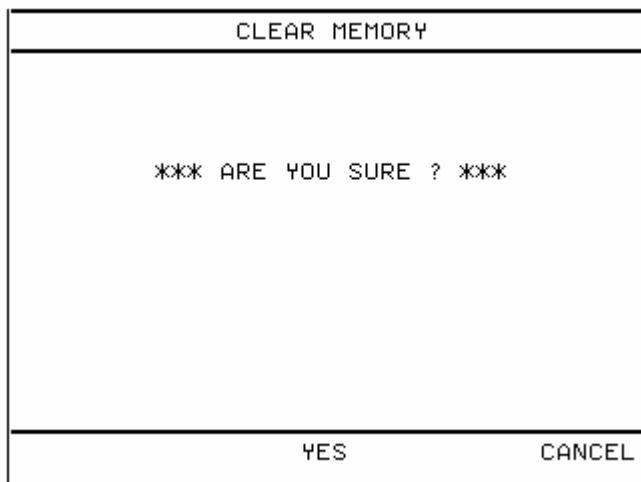
Caution

This action will lead to a complete and unrecoverable loss of all test results from memory and should only be done after the test results have been successfully downloaded to PC or printer or are no longer required.

To free up the memory for testing it is necessary to clear the results memory between each download. Use the cursor keys to select CLEAR RESULTS MEMORY from the MEMORY OPTIONS menu then press the Green key or press the fast key CLEAR MEMORY. The following screen will be displayed: -



Pressing the fast key CLEAR MEMORY will lead to the following confirmation screen: -

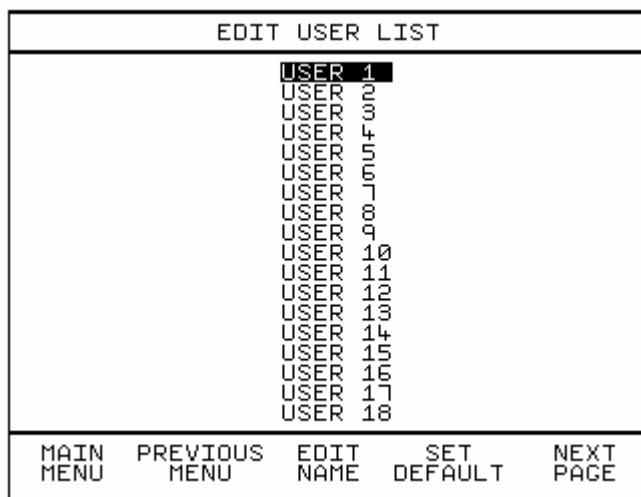


Pressing the fast key YES will clear the results memory of the analyser. Pressing the CANCEL fast key will return you to the MEMORY OPTIONS menu.

How to Change User

There is always a current User set on the MAIN MENU. This is User that recorded with Test Results. When another person is to use the analyser it is important that the current User is changed so that all tests carried out are recorded as having been carried out by the new user.

To change User, from the MAIN MENU select CHANGE USER with the cursor keys then press the Green key or press the fast key CHANGE USER. The following menu will be displayed: -



This is the same menu that is accessible from the SETUP menu. All the EDIT USER LIST functions are available here. See Edit User List in the Setup section of this manual on how to use these functions.

To change the current User use the cursor keys to select the new User. Then press the SET DEFAULT fast key. Return to the MAIN MENU by pressing the fast key MAIN MENU. The new User should now be set in the lower left corner of the screen.

How to use Help

The Analyser is provided with an on-line help function which can be displayed prior to a Manual test by pressing the Help fast key.

The Help information provided for each test will have three or four pages describing the test, the sequences of the test and any warning information.

Chapter 4 Description of Tests

Earth Continuity Tests

Test Icon Displayed ---



Class 1 (earthing) appliances

Plug EUT into Analyser outlet socket, connect the Earth Bond lead to the appliance metal part.

Class 2 (unearthed) appliances

This test cannot be performed as there is no earth connection to exposed conductive parts of the EUT.

This test is to ensure that the connection between the earth pin in the mains plug of the appliance and the metal casing of the appliance is satisfactory and of sufficiently low resistance.

The test current is applied between the earth pin of the mains supply plug and the earth bond test lead clip/probe.

A high current is normally used to stress the connection under fault conditions. The length of the test should be limited to prevent overheating. Tests currents of 100mA, 1A, 10A and 25A AC are available.

For fixed installations a Point-to-Point continuity measurement can be made by fitting a second lead into the Aux Earth socket (2). The resistance is then measured between the 2 leads.

NOTE 1 – the standard Earth Continuity test (ie not point-point) uses a 4 wire measurement technique therefore no null procedure is required.

NOTE 2 – the resistance of the lead in the Aux Earth socket is included in the measurement taken therefore an initial test should be performed with the 2 leads connected together. This value can then be subtracted from the actual point-to-point measurement taken.

NOTE 3 – Because of NOTE 2 above it is **not** recommended that a Point-to-Point continuity measurement be performed as part of an Automatic or Semi-automatic test sequence as an incorrectly high value will be stored.

NOTE 4 – The 25 Amp earth bond test will only produce the specified current when performing standard test (not point to point) using the earth bond lead provided (part no. 286A925). Use of longer leads may result in reduced test current.



Caution

Prolonged use of the earth bond probe at high currents can lead to a high probe temperature. Care should be taken to avoid touching the probe tip under these conditions. The Analyser's internal over temperature switch may operate with prolonged repetitive use of high test currents. If the temperature is sufficiently high a thermal cut out will activate. In order to proceed with further tests the Analyser must be allowed to cool down.

Insulation Tests

Test Icon Displayed ---



Warning**350V or 500V d.c. test voltage****Class 1 (earthed) appliances**

Plug EUT into Analyser outlet socket

Class 2 (unearthed) appliances

Plug EUT into Analyser outlet socket, connect Earth Bond lead socket to the appliance.

Insulation (EUT)

This test is used to verify that the mains supply lines (live & neutral) are adequately insulated from earth.

During the insulation test, a 350V or 500V DC voltage is applied between the earth pin and both live and neutral pins of the appliance mains supply plug. The Analyser displays the insulation resistance measured.

For Class 2 appliances, the Earth Bond lead can be used for an earth return lead.

Insulation (AP)

This test is used to verify that the applied parts are adequately insulated from earth.

During the insulation test, a 350V or 500V DC voltage is applied between all Applied Parts (connected together) and Earth. The Analyser displays the insulation resistance measured.

NOTE – this test is only valid for appliances with F-Type applied parts.

For Class 2 appliances, the Earth Bond lead can be used for an earth return lead.

Powered Tests**Warning****Mains voltage applied to appliance**

The following powered tests differ from the previous tests in that they apply mains supply voltage to the appliance to perform their functions: -

- Load (Operation) Test
- Earth Leakage Test
- Enclosure Leakage Test
- All Patient Leakage Tests
- Patient Auxiliary Current Test
- IEC61010 Touch Leakage

The Analyser performs an initial low voltage test to establish that the appliance can be safely powered.

Warning

It is important that the user verifies that an appliance with moving parts (e.g. an electric drill or motor) is safely mounted to allow movement without causing damage to equipment or personnel.

If the potential load current is too high, a warning message appears preventing the user from continuing. This message will be displayed if a Live to Neutral short exists or the EUT mains current consumption is too high, and if tests are continued the Analyser's fuses may blow.

The Analyser also performs an internal safety test to verify that internal relays are properly set before applying full mains supply to the appliance. This includes checking for unwanted secondary earth paths.

Note - if a secondary earth path is detected the unit will NOT allow mains power to be applied to the EUT

Load Test

Test Icon Displayed ---

A large, bold, black 'KVA' icon representing the power measurement unit.

Warning

Mains voltage applied to appliance

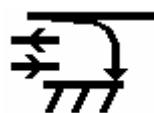
All Appliances

Plug EUT into Analyser outlet socket.

The Load test supplies the equipment under test with incoming mains (230V/115V).

The Analyser measures the power used by the appliance and displays the reading in kVA. The analyser also measures and displays the mains voltage.

Earth Leakage Test



Test Icon Displayed ---

Warning

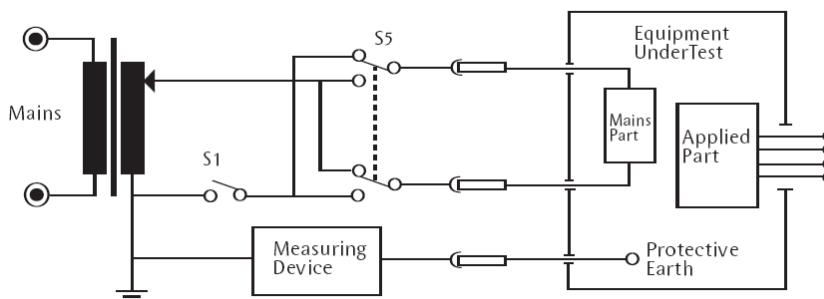
Mains voltage applied to appliance

All Appliances

Plug EUT into Analyser outlet socket.

The Earth Leakage Test shows the current flowing down the protective earth conductor of the mains inlet lead. The analyser displays the result in milliamps (mA).

The selection of normal and reverse operation and single fault conditions (neutral open circuit) is done automatically during an Automatic test but requires user action for Manual tests via the fast keys.



Test Circuit for Earth Leakage

The above diagram shows the test circuit used to measure the Earth leakage current.

The earth leakage tests are valid for Class I equipment with Types B, BF and CF applied parts.

Earth Leakage, normal conditions

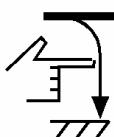
This test measures the earth leakage current under normal conditions. The current is measured through the Measuring Device with S1 closed and S5 normal and then S5 reversed.

Earth Leakage, single fault, supply open

This test measures the earth leakage current with a single fault condition (supply open). The current is measured through the Measuring Device with S1 open and S5 normal and then S5 reversed.

Enclosure Leakage Test

Test Icon Displayed ---



Warning

Mains voltage applied to appliance

All Appliances

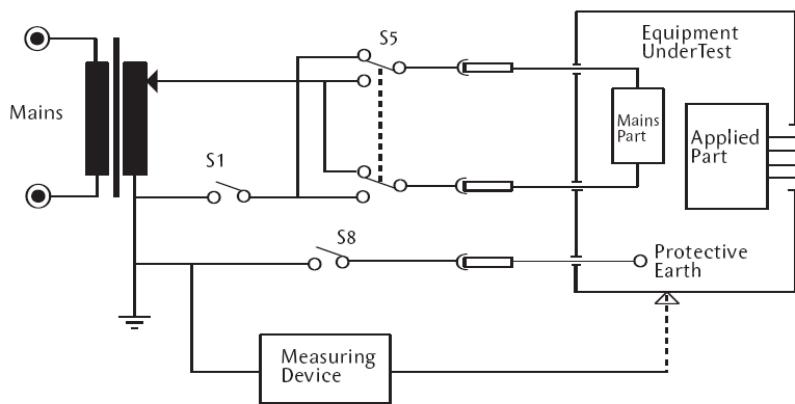
Plug EUT into Analyser outlet socket and connect the earth bond probe to touch appliance metal part. For Class

II equipment use the Earth Bond probe as a return path.

The Enclosure Leakage Test displays the current that would flow if a person touched the appliance. The IEC60601 'body model' is used. The Analyser uses the earth bond probe to detect any current flowing on the appliance metalwork (attached to an appropriate point on the appliance) and indicates the potential leakage through a metal panel. The Analyser displays the result in millamps (mA).

The selection of normal or reverse operation and single fault conditions (neutral or earth open circuit) is done automatically during an Automatic test, for a Manual test user action is required. Note - for Class II equipment, the Single Fault Earth Open tests are not required.

Test Circuit for Enclosure Leakage



S1 and S8 closed and S5 normal and reversed.

enclosure leakage tests the earth bond probe is used to make contact with all conductive non-electively earthed parts of the equipment.

Enclosure Leakage, normal condition

This test measures the enclosure leakage current under normal conditions. The current is measured through the Measuring Device with S1 closed, S8 open and S5 in normal and then S5 reversed.

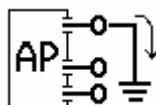
Enclosure Leakage, single fault, supply open

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

Enclosure Leakage, single fault, earth open

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

Patient Leakage



Test Icon Displayed ---



Warning

Mains voltage applied to appliance.

All Appliances

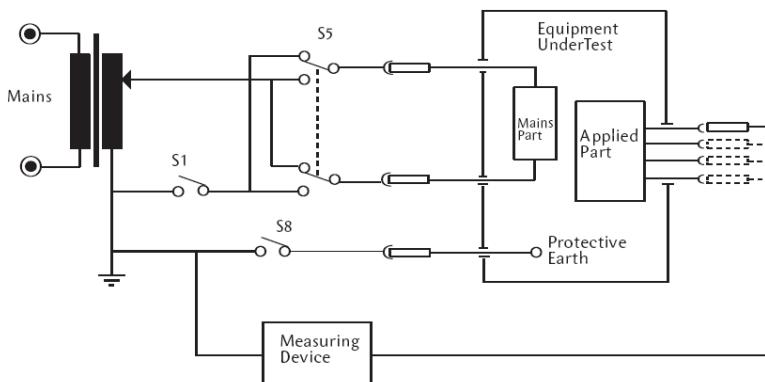
Plug EUT into Analyser outlet socket, and attach the applied parts from the EUT to the Analyser (Use Applied Parts adaptors, where necessary).

The Patient Leakage Test displays the current that would flow if an Applied Part was attached to a person. The Analyser detects any current flowing in the Applied Parts Lead. The Analyser displays both the AC and DC current components of the test result in millamps (mA).

The selection of normal or reverse operation and single fault conditions (neutral or earth open circuit) is done automatically during an Automatic test, but requires user action for Manual tests.

Should a test fail, the Analyser will stop the automatic test sequence.

For Class II equipment, the Single Fault Earth Open tests are not required.



Test Circuit for Patient Leakage

For type B and BF equipment, the patient leakage current is measured with all applied parts connected together, shown dotted above. For type CF equipment the patient leakage current is measured from each applied part separately.

Patient Leakage, normal condition

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

Patient Leakage, single fault, supply open

This test measures the patient leakage current with a single fault condition (supply open).

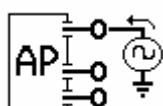
The current is measured through the Measuring Device with S1 open, S8 closed and S5 normal and then S5 reversed.

Patient Leakage, single fault, earth open

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

Note – this test is not performed on class II equipment.

Patient Leakage – F-Type



Test Icon Displayed ---



Warning

This test involves applying a current limited mains potential (110% of mains input voltage) to the Applied Parts connections. Due to the requirements for IEC60601 this test current can be in

excess of 5mA under short circuit conditions and as such is hazardous to the user. Caution should be taken when conducting this test. Current limiting is via a limiting resistor in series with the measurement circuit.

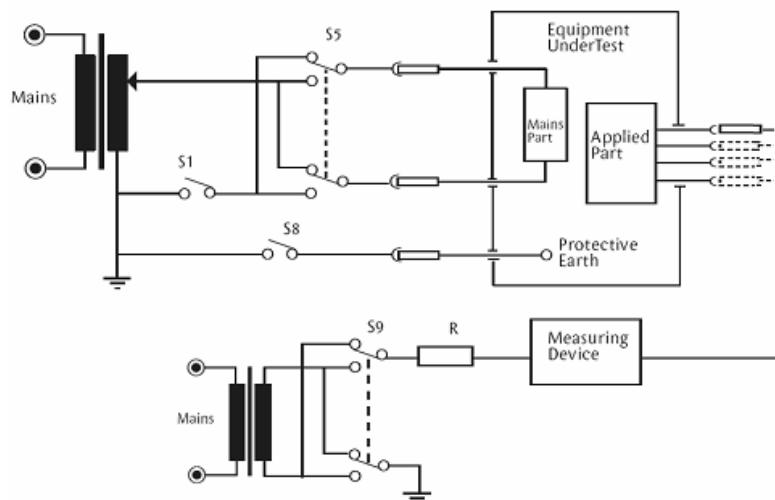
All Appliances

Plug EUT into Analyser outlet socket, and attach the applied parts from the EUT to the lead (use supplied adaptors where necessary).

The Patient Leakage F-Type Test (also known as mains on Applied Parts test) displays the current that would flow if a mains potential was applied to the Applied Part which was attached to a patient (i.e. a single fault condition). This test is applied only to type BF and CF equipment. The Analyser displays the result in milliamps (mA).

The selection of mains normal or reverse and source voltage normal or reverse is done automatically during an Automatic test but requires user action for Manual tests.

Should a test fail, the Analyser will stop the automatic test sequence.



Test Circuit for Patient Leakage
Mains on Applied Parts

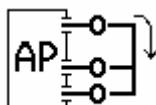
IEC60601-for type BF equipment the leakage current is measured with all parts of the applied part connected together, shown dotted above. For type CF equipment the leakage current is measured from each of the applied parts separately

Note – for this test 'body model' selection will be IEC60601.

The current is measured through the

Measuring Device with S1 and S8 closed. S5 and S9 are switched between normal and reversed.

Patient Auxiliary Current



Test Icon Displayed ---

Warning

Mains voltage applied to appliance

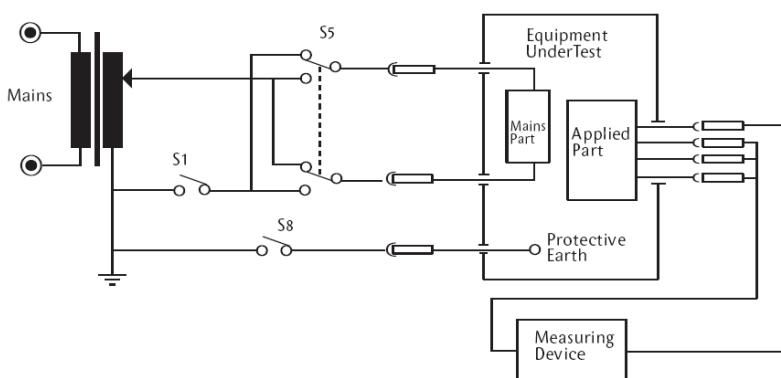
All Appliances

Plug EUT into Analyser outlet socket, and attach the applied parts from the EUT to the Analyser (use the supplied adaptors where necessary).

The Patient Auxiliary Current displays the leakage current that would flow between Applied Parts under normal and fault conditions. The Analyser detects any current flowing between one Applied Part and the remaining Applied parts connected together. The Analyser displays both the AC and DC current components of the test result in milliamps (mA).

The selection of normal or reverse operation and single fault conditions (neutral or earth open circuit) is done automatically during an Automatic test, but requires user action for Manual tests. Should a test fail, the Analyser will stop the automatic test sequence.

For Class II equipment, the Single Fault Earth Open tests are not required.



Test Circuit for Patient Auxiliary Current

For these tests, current is measured between a single part of the applied part and all other applied parts connected together. This test should be repeated until all combinations have been tested.

Patient Auxiliary, normal condition

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

Patient Auxiliary, single fault, supply open

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

Patient Auxiliary, single fault, earth open

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

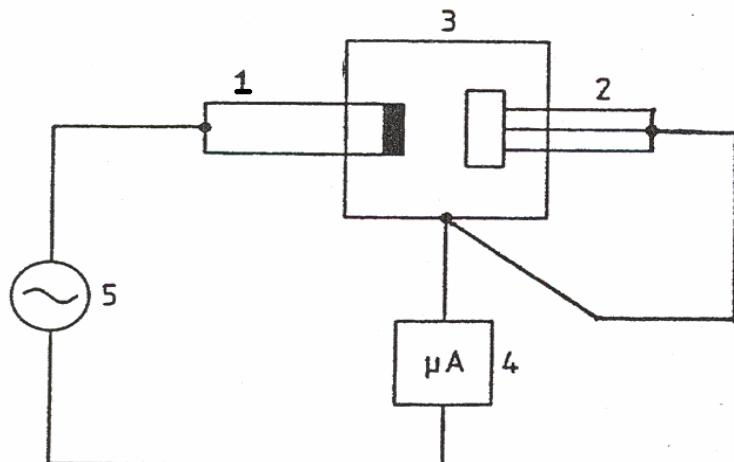
Equivalent Equipment Leakage Current



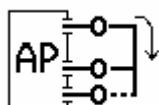
Test Icon Displayed ---

This test is a requirement of VDE0751

The temporarily conductively connected mains plug pins (excluding the protective earth contacts) and exposed conductive parts of the enclosure are connected to the measuring device according to the diagram below.



Equivalent Patient Leakage Current

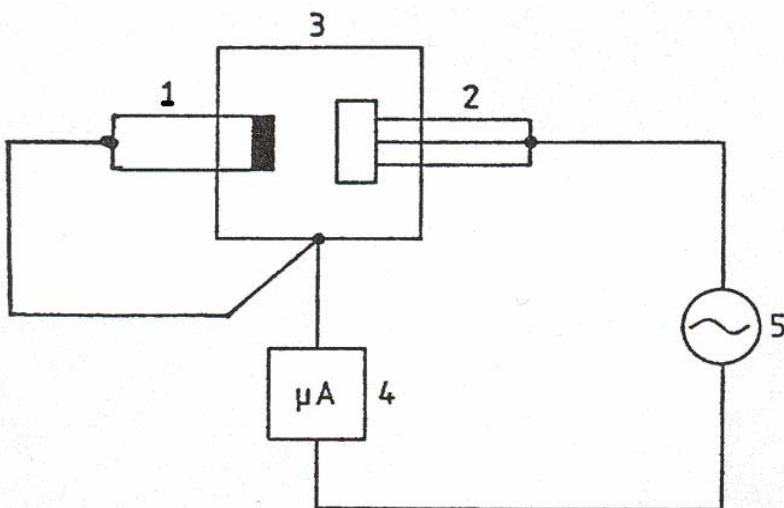


Test Icon Displayed ---

This test is a requirement of VDE0751

This measurement can only be carried out to insulated applied parts.

All patient connections leading to the insulated applied parts are temporarily connected together. These connections and the exposed conductive parts of the equipment are connected to the measuring device. In addition the exposed conductive parts of the equipment are connected to the pins on the mains plug as shown below.



IEC Lead Polarity Test

Test Icon Displayed ---



Warning

40V a.c. test voltage applied to lead

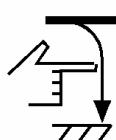
Plug the lead into the Analyser outlet socket, and also into the Analyser IEC socket.

The IEC test performs a continuity and polarity check on the **Live** and **Neutral** conductors and confirms that there are no breaks or cross wiring in these conductors.

Note: Earth Bond and Insulation tests also need to be made to confirm the electrical safety of IEC leads.

IEC 61010 Touch Leakage Test

Test Icon Displayed ---



Warning

Mains voltage applied to appliance

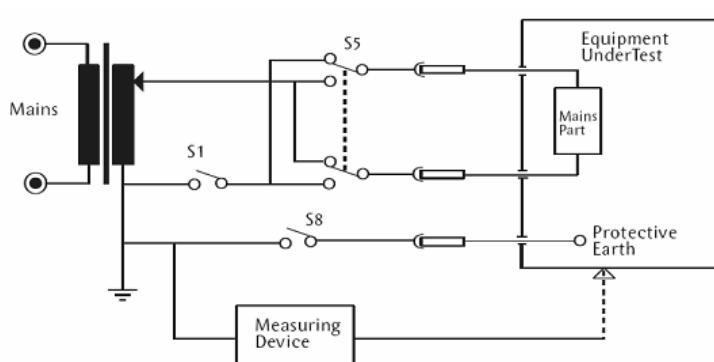
All Appliances

Plug EUT into Analyser outlet socket and connect the earth bond probe to EUT metal part.

The IEC61010 Touch Leakage test is a 2 stage test. Firstly the voltage on the metal part of the EUT is measured. At this stage the impedance of the Earth Bond probe is high. This is a fixed 2 second test. Next the IEC61010 'body model' is switched in and the current flowing from the EUT metal part to earth is measured. The duration of the current measurement can be adjusted.

During the Touch Leakage Test the analyser displays the voltage on the probe and the current that flows.

The selection of normal or reverse operation and single fault conditions (neutral or earth open circuit) is done automatically during an Automatic test, for a Manual test user action is required. Note - for Class II equipment, the Single Fault Earth Open tests are not required.



Test Circuit for Touch Leakage

For touch leakage tests the earth bond probe is used to make contact with all conductive non-protectively earthed parts of the equipment.

IEC61010 Touch Leakage, normal condition

This test measures the touch leakage current under normal conditions. The current is measured through the Measuring Device with S1 and S8 closed and S5 normal and reversed.

current is measured through the Measuring Device with S1 and S8 closed and S5 normal and reversed.

IEC61010 Touch Leakage, single fault, supply open

This test measures the touch leakage current with a single fault condition (supply open). The current is measured through the Measuring Device with S1 open, S8 closed and S5 in normal and then S5 reversed

IEC61010 Touch Leakage, single fault, earth open

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

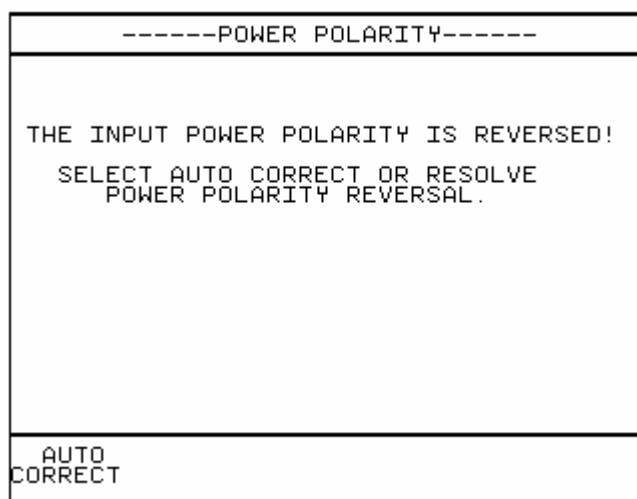
Chapter 5 Tips & Troubleshooting

Power On Self tests

When the analyser is powered on, a number of messages can possibly appear as the analyser performs safety tests on itself and the mains power supply.

Power Polarity Test

The analyser requires correct polarity of its incoming mains supply. This test checks that the polarity is correct. If the polarity is incorrect the following message is displayed:-



To continue the power polarity will need to be corrected. This can be done automatically by selecting AUTO CORRECT.

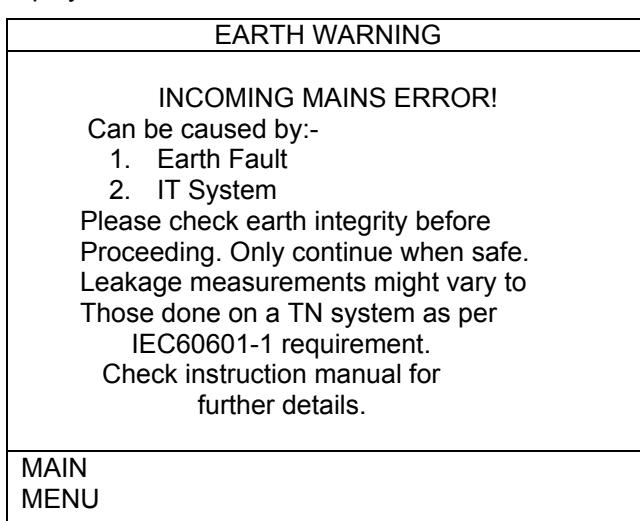
Caution

AUTO CORRECT should only be used for non-polarised input power eg European Schuko sockets.

Note – The Auto Correction feature will, on a Schuko unit, connect the pin on the right hand side of the EUT outlet to LIVE.

Earth Test

If the tester is not earthed to the building earth or it is running from an IT mains distribution system the following message is displayed:-



In order to comply with IEC60601-1 the incoming mains supply should be a TN system ie the Neutral line is connected to Protective Earth.

The tester will run from an IT system however the user is warned about this. Typical IT systems include:

- 1 Mains isolated via an isolation transformer
- 2 Split rail supply (120V - 0 - 120V) as used in USA

With all IT mains systems there will be a measurable voltage between the Neutral and Earth lines. This is detected within the tester. It is also true that if there is a fault with the Protective Earth of the building this too can look like an IT system.

If the tester is powered from a known TN system and the above message appears **then tests should NOT continue** until the building Earth has been checked.

Note 1: Any leakage measurements taken with the tester powered from an IT mains system will only be valid for that condition and will vary when powered from a TN system.

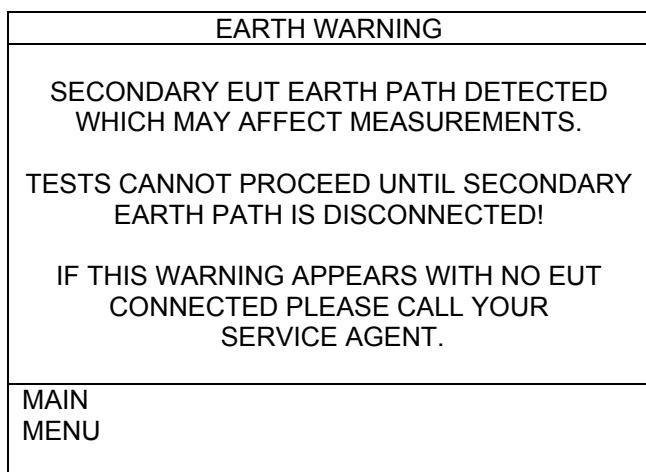
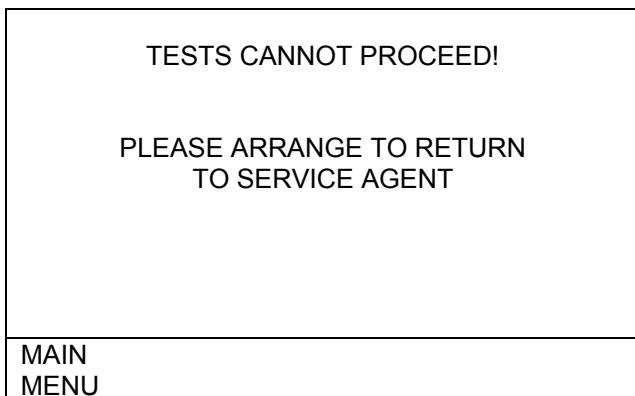
Note2: At all times when performing a manual LOAD test the displayed voltage is the measured Live potential with respect to protective earth (L-PE) not Live with respect to Neutral as may be expected. When the tester is powered from an IT system this displayed voltage may, at first, appear confusing.

Note 3: If an Automatic test sequence is run whilst the tester is powered from an IT mains system a comment is automatically added into the SAVE TEST RESULTS screen. This comment states "**IT Supply – Confirm Correct Measurements**". This comment may be deleted if required.

Internal Relay Test

The analyser checks the internal relays for correct operation. Should a relay associated with safe use of the analyser fail one of the following messages is displayed: -

INTERNAL RELAY FAULT

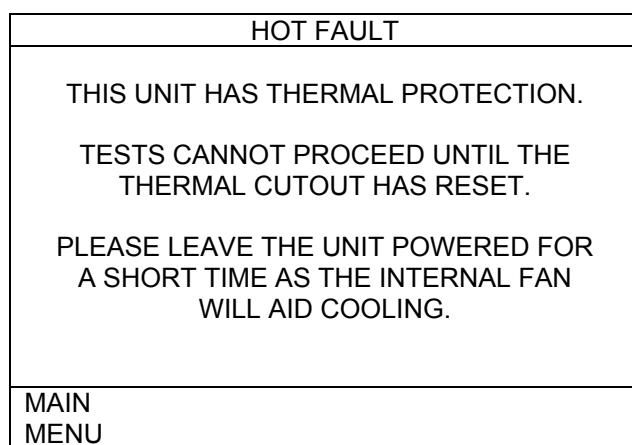


These messages can also be displayed during tests as the relays are also checked prior to powered tests.

The faults reported by these messages may require a service action by an approved Service Agent to resolve the problem.

Earth Hot Fault

There is an internal thermal cut-out which monitors the Earth Bond circuit, if on power on this was found to have tripped the following message is displayed:-



The cut-out will auto reset once the circuit has cooled down sufficiently.

Ensure the ventilating fan on the left hand side of the test bay, under the outer cover, is working properly and is not obstructed. Also ensure the vent on the right hand side is not obstructed.

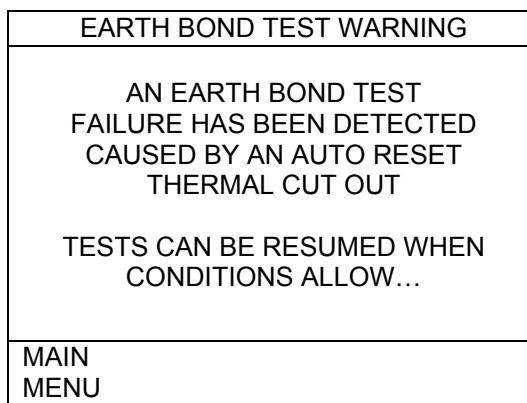
If this message is present when the unit is clearly cold then a fault has probably occurred which requires a service action by an approved Service Agent to resolve the problem.

Safety Checks during Tests

Before and during tests the Rigel-277 carries out safety checks. If these checks fail then messages will appear on the analyser's display.

Earth Bond Test

The temperature of the Earth Bond circuit is constantly monitored. Repeated Earth Bond tests at high current can cause the Earth Bond circuit to overheat. If this happens the test will be inhibited and the following message will be displayed: -



The cut-out will auto reset once the circuit has cooled down sufficiently.

Ensure the ventilating fan on the left hand side of the test bay, under the outer cover, is working properly and is not obstructed. Also ensure the vent on the right hand side is not obstructed.

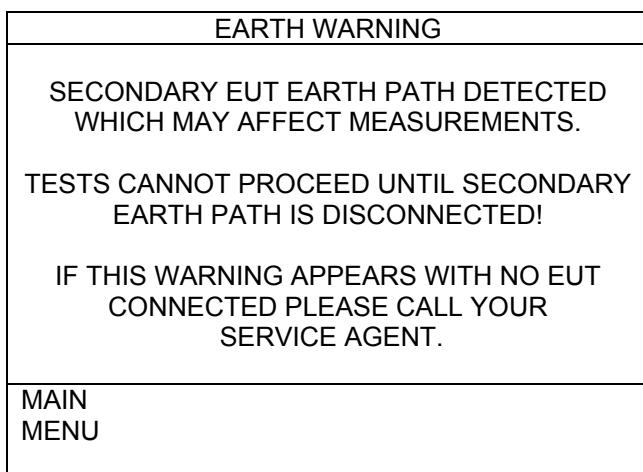
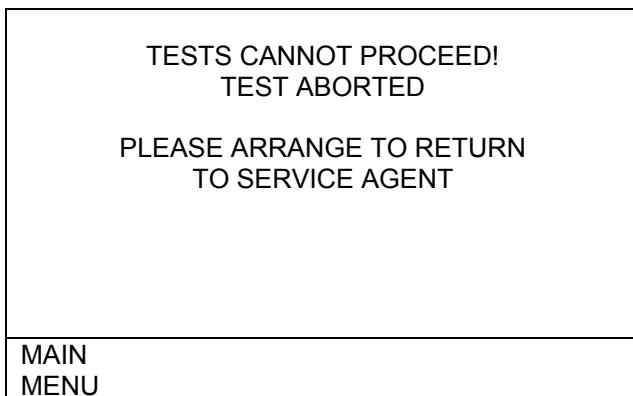
Safety Checks during Powered Tests

For each test during the first powered test, of a possible sequence of powered tests a safety check is carried out. If these checks fail then messages will appear on the analyser's display.

Internal Relay Test

The analyser checks the internal relays for correct operation. Should a relay associated with safe use of the analyser fail one of the following messages is displayed: -

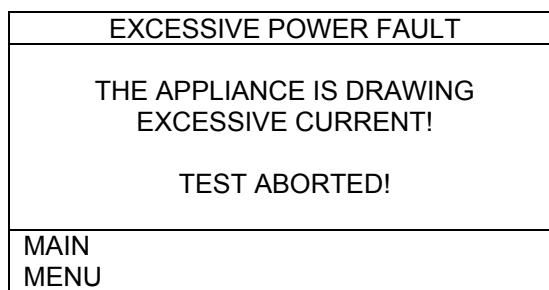
INTERNAL RELAY FAULT



The faults reported by these messages may require a service action by an approved Service Agent to resolve the problem.

Excessive Power Fault

When power is first applied a monitor circuit will measure current drawn if the current drawn is in excess of 15A a warning will be displayed as follows: -



Aborted tests are not stored in the memory. Storage of test results proceeds from the Comments screen only.

Memory

There is a limit to the memory available for storing Test Results. This is calculated to be 2,500 Appliances depending on tests performed and SYSTEM CONFIGURATION settings. If the memory is not Cleared periodically, then eventually the analyser will run out of memory. If this happens then the warning message "Results Memory Full" is displayed each time an attempt is made to store a Test Result and the Test Result will not be saved.

Once the memory is cleared then storing Test Results can proceed normally.

Barcodes

Barcode Scanner Specification

The Rigel 277 PLUS Analyser can be used with compatible barcodes and barcode scanners (see Accessories). These connect to the serial (RS232) connector. The required configuration is as follows: -

Baud Rate:	9600
Start Bits:	1
Data Bits	8
Stop Bits:	2
Parity:	None

When to use a Barcode Scanner

Barcodes can be scanned when entering an Appliance number

Interfacing

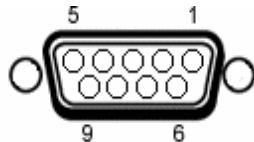
The Analyser provides two interfacing ports: -

Parallel – for connection to parallel printer.

Serial Port - for connection to a PC, Barcode Scanner, Brain Cell Scanner

To avoid any problems during download, ensure that leads are undamaged and correctly wired.

The serial port is a standard 9-way D-type connector



Pin	Description
1.	N.C.
2.	RX
3.	TX
4.	DTR
5.	0V
6.	N.C.
7.	0V
8.	N.C.
9.	+5V

Baud Rate: 9600

Start Bits: 1

Data Bits 8

Stop Bits: 2

Parity: None

Chapter 6 Maintaining the Analyser

Cleaning the Analyser

The Analyser 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 Analyser or near the sockets. Do not use abrasives, solvents or alcohol.

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

Changing printer paper rolls

To remove a paper roll, open the printer lids. Note a small lever on the right hand side of the printer mechanism. Lift this up to release the paper. The paper roll can now be pulled back out of the mechanism and the entire roll can be removed.

To insert a new roll, make sure the lever is in the upright position. Put the fresh roll including its spindle, into the holder. Feed the free end of the paper roll into the mechanism and rotate the thumb wheel. The mechanism should start to engage and the printer will automatically drive the paper forward for a short distance. Move the lever back down to ensure the mechanism has a good grip on the paper.

User Maintenance

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

- Always check the Analyser and all test leads for signs of damage and wear before use.
- On powering up the analyser ensure the ventilating fan on the left hand side of the test bay, under the outer cover, is working properly and is not obstructed. Also ensure the vent on the right hand side is not obstructed.
- Do not open the Analyser 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 Analyser.
- It is recommended that the unit be regularly checked for calibration (at least annually).
- 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@rigelmedical.com
 www.seaward.co.uk
 www.rigelmedical.com

Chapter 7 Accessories

A series of standard and optional accessories are available for the Seaward Rigel-277 Medical safety analyser. The standard accessories are supplied with the Analyser.

Standard Accessories

Accessory	Part Number
Earth Bond Test Lead	286A925
Applied Part Adaptors (11)	298A678
Instruction Manual	340A552
9 Way Computer Lead	194A919
Thermal Paper Roll (2)	-----
Thermal Printer Labels (2)	-----

Optional Accessories

Accessory	Part Number
MEDIGuard Additional Licences	301A913
Bar Code Scanner	194A922
Thermal Printer Rolls (5)	283A964
Thermal Printer Labels (5)	283A304
Brain Cell Scanner	288A910
Self Adhesive Brain Cells (50)	288A953
Cable Tie Brain Cells (50)	288A954
Carry case	298A950

Chapter 8 Specifications

AC Earth Bond Test

Test Voltage.....6V rms nominal (no load)

Test Current....100mA, 1A, 10A, 25A (0 - 0.2Ω range as per IEC60601)

Range1A, 10A, 25A0.00Ω - 19.99Ω

100mA.....0.00Ω - 4.99Ω

Resolution 0.01Ω

Accuracy 1A, 10A, 25A ...+/- 5% of reading, +/- 2 digits
0.10A+/- 5% of reading, +/- 4 digits

Misc floating earth

NOTE – The 25 Amp earth bond test will only produce the specified current when performing standard test (not point to point) using the earth bond lead provided (part no. 286A925). Use of longer leads may result in reduced test current.

Insulation Test

Test Voltage ... 350V (0.35MΩ load), 500V (0.5MΩ load) d.c. nominal

Short Circuit Current 2mA d.c. maximum

Range 100kΩ - 100 MΩ

Resolution 0.01 MΩ (<100 MΩ)

Accuracy +/- 10% of reading, +/- 2 digits (100kΩ - 100MΩ)

NOTE – The accuracy of this test is correct after an initial warm up of 3-5 minutes.

Earth Leakage Test

Body Model..... IEC60601
Input Impedance (measuring instrument).....>1Mohm
Frequency Response (measuring instrument)... dc to 1MHz (-3dB)
Range 0.000mA – 9.999mA
Accuracy..... +/- 3% of reading, +/- 4 digits

Enclosure Leakage Test

Body Model..... IEC60601
Input Impedance (measuring instrument).....>1Mohm
Frequency Response (measuring instrument)... dc to 1MHz (-3dB)
Range 0.000mA – 9.999mA
Accuracy..... +/- 3% of reading, +/- 4 digits

Patient Leakage Test

Body Model..... IEC60601
Input Impedance (measuring instrument)>1Mohm
Frequency Response (measuring instrument)... dc to 1MHz (-3dB)
Range 0.000mA – 9.999mA
Accuracy AC. & DC..... +/- 3% of reading, +/- 4 digits

Patient Auxiliary Test

Body Model..... IEC60601
Input Impedance (measuring instrument)>1Mohm
Frequency Response (measuring instrument)... dc to 1MHz (-3dB)
Range 0.000mA – 9.999mA
Accuracy AC.& DC..... +/- 3% of reading, +/- 4 digits

Patient F-Type Test

Body Model..... IEC60601
Input Impedance (measuring instrument).....>1Mohm
Frequency Response (measuring instrument)... dc to 1MHz (-3dB)
Range 0.000mA – 9.999mA
Accuracy..... +/- 3% of reading, +/- 4 digits
F-type Short Circuit CurrentNominal 5mA ac minimum
Current Limiting Resistance48K for IEC60601 body model
F-Type Open Circuit Voltage 110% +/-10% of Mains Input Voltage

Equivalent Equipment Leakage

Test Voltage.....40V AC Nominal
Test Current (into s/c).....~ 7mA

Range 0.02mA – 19.99mA
Resolution 0.01mA
Accuracy +/- 5% of reading, +/- 2 digits

Equivalent Patient Leakage

Test Voltage 40V AC Nominal
Test Current (into s/c) ~ 7mA
Range 0.02mA – 19.99mA
Resolution 0.01mA
Accuracy +/- 5% of reading, +/- 2 digits

Load Test

Measured Load 0.00 - 4kVA (+/-10%)
Measured Voltage Mains Supply +/-10%

IEC Lead Test

Test 40V a.c., 1mA nominal
Detects Good, Open Live, Open Neutral, Short, Reverse

IEC 61010 Touch Leakage Test

Body Model IEC 61010
Touch Voltage Measurement Impedance >900K
Range Voltage 0 – 300V
Range Current 0.000mA – 9.999mA
Accuracy. Voltage +/- 10% of reading, +/- 4 digits
Accuracy. Current +/- 10% of reading, +/- 4 digits

Mechanical

Size 450mm x 410mm x 155mm
Weight 9.5kg

Environmental

Operating 0°C to 40°C (non condensing) (see note)
Storage -10°C to 50°C (non condensing)
Maximum R.H 90%

Note For Insulation tests only this range is reduced to 16°C to 26°C (non condensing)

Supply Rating

Mains supply 115v +/-10% / 230V +/- 10%, 50/60Hz
Power Rating 30VA
Max EUT Output Current 16A (10A for certain country variants)

Sample of Certificate on External Printer

RIGEL 277 PLUS TEST CERTIFICATE			(SERIAL NUMBER: U44-0315)		
APPLIANCE:	12345	DATE:	29 Dec 2005		
SITE:	RIGEL MEDICAL	USR:	USER 1		
LOCATION:	RBMR DEPARTMENT	TEST TYPE:	REGULAR		
TEST PROGRAM:	IEC60601 1BF/CF	PROGRAM TYPE:	AUTOMATIC		
APPLIED PARTS:	(1BF,1CF)				
TEST	OUTPUT	SFC	LIMIT	RESULT	STATUS
VISUAL CHECK					
EARTH CONT	25A	0.20	0.00ohm	PASS	
L-PE VOLTAGE			238V	PASS	
N-PE VOLTAGE			0V	PASS	
LOAD (kVA)	NORMAL		0.00kVA	PASS	
EARTH LEAK	NORMAL	-	0.50	0.004mA	PASS
EARTH LEAK	NORMAL	PHASE O/C	1.00	0.004mA	PASS
EARTH LEAK	REVERSED	PHASE O/C	1.00	0.004mA	PASS
EARTH LEAK	REVERSED	PHASE O/C	1.00	0.004mA	PASS
ENCL. LEAK	NORMAL	-	0.10	0.003mA	PASS
ENCL. LEAK	NORMAL	EARTH O/C	0.50	0.003mA	PASS
ENCL. LEAK	NORMAL	PHASE O/C	0.50	0.003mA	PASS
ENCL. LEAK	REVERSED	EARTH O/C	0.50	0.004mA	PASS
ENCL. LEAK	REVERSED	PHASE O/C	0.50	0.003mA	PASS
PAT LEAK (COM) BF	NORMAL	-	0.10	0.003mA	PASS
PAT LEAK (COM) BF	NORMAL	-	0.01	0.000mA	PASS
PAT LEAK (2) CF	NORMAL	-	0.01	0.003mA	PASS
PAT LEAK (2) CF	NORMAL	-	0.01	0.000mA	PASS
PAT LEAK (COM) BF	NORMAL	EARTH O/C	0.50	0.003mA	PASS
PAT LEAK (COM) BF	NORMAL	EARTH O/C	0.05	0.000mA	PASS
PAT LEAK (2) CF	NORMAL	EARTH O/C	0.05	0.003mA	PASS
PAT LEAK (2) CF	NORMAL	EARTH O/C	0.05	0.000mA	PASS
PAT LEAK (COM) BF	NORMAL	PHASE O/C	0.50	0.003mA	PASS
PAT LEAK (COM) BF	NORMAL	PHASE O/C	0.05	0.000mA	PASS
PAT LEAK (2) CF	NORMAL	PHASE O/C	0.05	0.003mA	PASS
PAT LEAK (2) CF	NORMAL	PHASE O/C	0.05	0.000mA	PASS
PAT LEAK (COM) BF	REVERSED	-	0.10	0.003mA	PASS
PAT LEAK (COM) BF	REVERSED	-	0.01	0.000mA	PASS
PAT LEAK (2) CF	REVERSED	-	0.01	0.003mA	PASS
PAT LEAK (2) CF	REVERSED	-	0.01	0.000mA	PASS
PAT LEAK (COM) BF	REVERSED	EARTH O/C	0.50	0.003mA	PASS
PAT LEAK (COM) BF	REVERSED	EARTH O/C	0.05	0.000mA	PASS
PAT LEAK (2) CF	REVERSED	EARTH O/C	0.05	0.003mA	PASS
PAT LEAK (2) CF	REVERSED	EARTH O/C	0.05	0.000mA	PASS
PAT LEAK (COM) BF	REVERSED	PHASE O/C	0.50	0.003mA	PASS
PAT LEAK (COM) BF	REVERSED	PHASE O/C	0.05	0.000mA	PASS
PAT LEAK (2) CF	REVERSED	PHASE O/C	0.05	0.003mA	PASS
PAT LEAK (2) CF	REVERSED	PHASE O/C	0.05	0.000mA	PASS
PAT LK (F) (COM) BF	NORMAL	SOURCE	5.00	0.004mA	PASS
PAT LK (F) (2) CF	NORMAL	SOURCE	0.05	0.004mA	PASS
PAT LK (F) (COM) BF	NORMAL	SOURCE REV	5.00	0.004mA	PASS
PAT LK (F) (2) CF	NORMAL	SOURCE REV	0.05	0.004mA	PASS
PAT LK (F) (COM) BF	REVERSED	SOURCE	5.00	0.004mA	PASS
PAT LK (F) (2) CF	REVERSED	SOURCE	0.05	0.004mA	PASS
PAT LK (F) (COM) BF	REVERSED	SOURCE REV	5.00	0.004mA	PASS
PAT LK (F) (2) CF	REVERSED	SOURCE REV	0.05	0.004mA	PASS
COMMENTS: DEFIB MONITOR EASY LIFE DM2000		OVERALL TEST STATUS:	PASS		
		SIGNATURE:			
123 JB92837364534113					

Sample of List on External Printer

RIGEL 277 PLUS
 SERIAL NUMBER: U44-0315
 LIST OF TEST RESULTS

DATE: 29/12/2005

APPLIANCE:	12345
APPLIED PARTS:	(1BF, 1CF)
SITE:	RIGEL MEDICAL
LOCATION:	EBME DEPARTMENT
USER:	USER 1
TEST PROGRAM:	IEC60601 1BF/CF
VISUAL CHECK	
EARTH CONT	0.00
L-PE VOLTAGE	238
N-PE VOLTAGE	0
LOAD (kVA)	0.00
EARTH LEAK	- 0.004
EARTH LEAK	P - 0.004
EARTH LEAK	R - 0.004
EARTH LEAK	R P - 0.004
ENCL LEAK	- 0.003
ENCL LEAK	E - 0.003
ENCL LEAK	P - 0.003
ENCL LEAK	R - 0.003
ENCL LEAK	R E - 0.004
ENCL LEAK	R P - 0.003
PAT LEAK (COM) BF	- 0.003 [~]
PAT LEAK (COM) BF	- 0.000
PAT LEAK (2) CF	- 0.003 [~]
PAT LEAK (2) CF	- 0.000
PAT LEAK (COM) BF	E - 0.003 [~]
PAT LEAK (COM) BF	E - 0.000
PAT LEAK (2) CF	E - 0.003 [~]

Sample of Summary on External Printer

RIGEL 277 PLUS
SERIAL NUMBER: U44-0315
SUMMARY OF TEST RESULTS

DATE: 29/12/2005
APPLIANCE: 12345
APPLIED PARTS: (1BF, 1CF)
SITE: RIGEL MEDICAL
LOCATION: EBME DEPARTMENT
USER: USER 1
TEST PROGRAM: IEC60601 1BF/CF
OVERALL TEST STATUS: PASS