# Rigel-277

# **Medical Portable Appliance Tester**

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## **Declaration of Conformity**

for the

Seaward Rigel 277 Medical Portable Appliance Tester

#### Manufactured by:

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

### **Millennium Statement**

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

### **Statement of Conformity**

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

### Standards used:

EN 60601-1 (1990) Medical Electrical Equipment. General Requirements for Safety

EN 61010-1 (1993) Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use

EN 50081-1 (1992) Electromagnetic Compatibility. Generic Emission Standard: EN55022 Class B

EN 50082-1 (1992) Electromagnetic Compatibility. Generic Immunity Standard: IEC1000-4-2, -4-3, -4-4, -4-5

The tests have been performed in a typical configuration.

This Conformity is indicated by the symbol **CE**, i.e. "Conformité Européenne"

# **Before Starting**

Upon receipt of your Rigel-277 Tester:-

- 1. Check that all the component parts are present:-
  - Seaward Rigel-277 Tester
  - · Earth Continuity Test Lead
  - Applied Parts Adaptors (11 Off)
  - Instruction Manual
  - MEDIGuard Evaluation Software CD
  - 9 way Computer Lead
  - Thermal Paper Rolls (2 off)
  - Thermal Paper Labels (2 off)
- 2. Read the operating instructions fully before conducting any tests.
- 3. Contact Seaward Electronic if you require training on this Tester or any other Seaward product. Courses can be arranged at Seaward, or at customer premises.
- 4. Seaward Electronic Limited can be contacted at:

Bracken Hill South West Industrial Estate Peterlee Co. Durham SR8 2SW

Tel: +44 (0)191 586 3511 Fax: +44 (0)191 586 0227 sales@seaward.co.uk calibration@seaward.co.uk

# Safety

#### Note

Please read the following Safety Instructions before use!

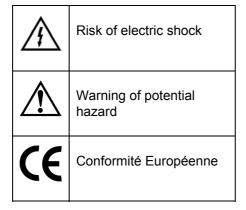
### **Safety Precautions**

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 Tester.

Symbols used within this manual and on the Tester are shown below:



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 Tester performs a number of electrical tests that involve high voltages and high currents. <u>Never</u> 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 Tester 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 Tester behave abnormally do not continue with the testing. Disconnect immediately and contact Seaward Electronic for servicing (see Chapter 6 - Maintaining the Tester).

# Chapter 1 Introducing the Tester

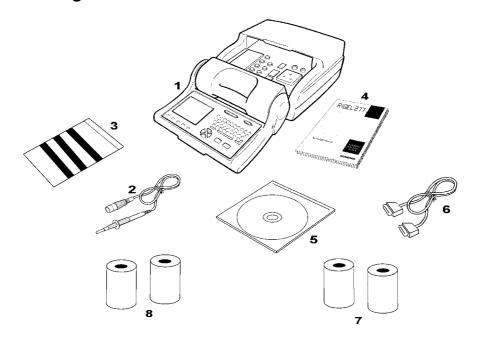
### Introduction

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

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

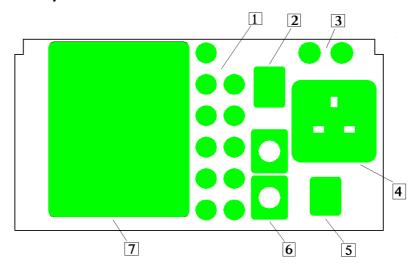
- Stores up to 2,500 results including appliances, location, site, date and time in non-volatile flash memory
- Accurate earth bond measurement even when multiple earth paths exist
- QWERTY keyboard with fast keys.
- Full graphics display, Real-time clock
- Connects to PC, Barcode reader, Brain Cell Scanner and printer
- Compatible with Seaward's MEDIGuard software
- Fast Start-up
- Contains pre-set tests for IEC60601, MDA DB9801, VDE 0751, AAMI, NFPA 99.

# Your Rigel 277 Tester



Item Number	Part
1	Rigel 277 Medical Appliance Tester
2	Earth Continuity Test Lead
3	Applied Part Adaptors and Clip for Earth Bond Lead (11)
4	Instruction Manual
5	MEDIGuard Evaluation Software CD
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 - The EUT is supplied with mains voltage,

with measurements being taken of power

consumption, leakage currents etc.

Tester - The Seaward Rigel-277 Medical Portable

**Appliance Tester** 

Un-powered Tests - The EUT is the subject of electrical tests

using stimuli generated within the Tester. The EUT is not provided with mains power.

User - The test technician/operator using the Tester

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 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 Rigel 277 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 Tester

# Connecting the tester

The Tester 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 Tester will carry out a short self-test procedure (approximately 10 seconds). During this test a boot screen will be displayed.



Configuration Valid and Loading Version: xx.xx PLEASE WAIT... Pxx.xx

#### Note

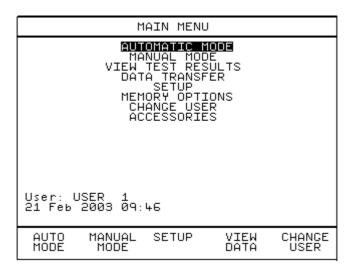
Current version number is shown on this screen.

The Tester will then display the Main Menu

# Chapter 3 Using the Tester

### Introduction

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



Navigation through the menus is by dedicated keys:-

Kev	Function
←	Cursor Left
<b> </b>	Cursor Up
$\rightarrow$	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 Tester 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.

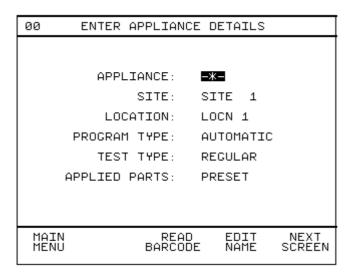
### How to....

The remainder of this chapter has been sub-divided into sections that describe the Tester 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:-



Select EDIT NAME to enter an APPLIANCE number from the keyboard.

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.

To enter an APPLIANCE from a barcode use the fast key READ BARCODE before scanning the barcode.

Once the APPLIANCE number is entered press the Return key to enable other fast key options.

If you need to change the current SITE use the fast key SITE NAME to select from the SITE LIST.

SITE LIST	
\$\frac{1}{2} \tau + 567 \tau \tau \tau \tau \tau \tau \tau \tau	
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.

If you need to change the current LOCATION use the fast key LOC NAME to select from the LOCATION LIST.

LOCATION LIST	
LOC 1 22345678 LOCCCCCCCCCCCCCCCCCCCCCCCCCCCCCCCCCCCC	
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.

The APPLIED PARTS can be set to PRESET in which case the TEST SETTINGS determine the number of applied parts. Or the value can be overridden here for this test.

To choose an Automatic test press the fast key NEXT SCREEN.

### **Test Settings**

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

	SELECT	TEST SETTINGS	S
	TEC TEC TEC TEC TEC		
MAIN MENU	PREVIOUS MENU		SELECT TEST

Use the cursor keys to choose the appropriate test then press the fast key SELECT TEST to display the test sequence.

IEC 60601 1B					
SUB	TEST		MAINS	SFC	STATUS
EART ENC PAT PAT ENC PAT PAT EART	TH CONT LEAK LEAK LEAK AUX LEAK LEAK AUX LEAK AUX LEAK AUX LEAK LEAK LEAK LEAK	Power E	NORM NORM NORM NORM NORM NORM NORM	- - - - - - - - - - - - - - - - - - -	UNTESTED
	To start	the test	t – pres	s S	TART

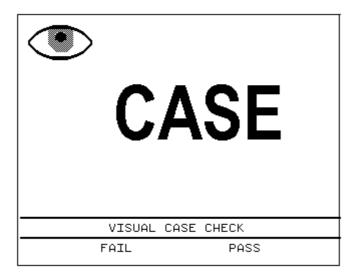
This display shows the first page of the test sequence. The Rigel 277 Automatic tests are carried according to a Unique Test Sequence (UTS). To speed up testing, powered tests are grouped together to reduce the number of power up / down cycles. The Power Breaks shown on this display define the power 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 return to the previous menu.

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 which 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: SITE: SITE: LOCATION: USER: TEST PROGRAM: DATE:	6789 SITE 1 LOC 1 USER 1 REGULAR 27/11/200	12		
ENTER COMMENT:				
PREVIOUS 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.

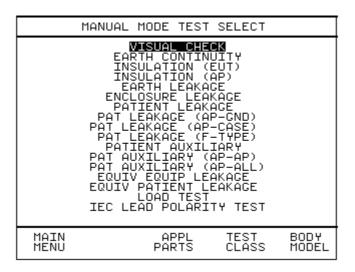
To store a test to a Brain Cell with the scanner connected to the tester's RS232 port point the Brain Cell Scanner close to the Brain Cell which should be located on the EUT and press the fast key WRITE TAG. A Test Summary will be written to the Brain Cell which can be read back when re-testing.

#### Save Results

To store all of the Appliance Test details (Appliance details, Test Results and Comments) press the SAVE RESULTS fast key. The tester will return to the MAIN MENU.

## How to perform Manual Tests

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

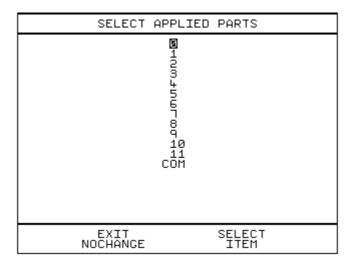


The display lists all possible tests that can be performed with the Rigel-277.

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

## Selecting Applied Parts

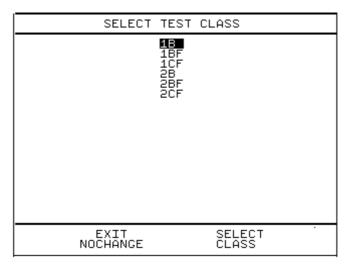
Press the fast key APPL PARTS to display the SELECT APPLIED PARTS screen:-



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

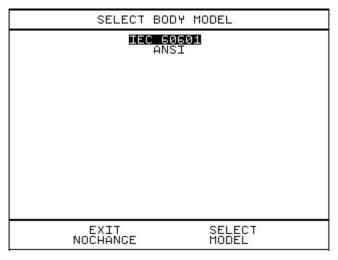
Press the fast key TEST CLASS to display the SELECT TEST CLASS screen:-



Use the cursor keys to select a different setting, 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.

## **Selecting Body Model**

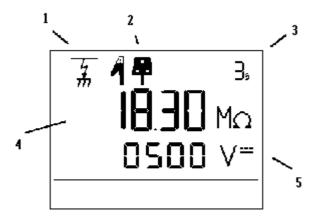
Press the fast key BODY MODEL to display the SELECT BODY MODEL screen:-



Use the cursor keys to select a different setting, then press the fast key SELECT Model 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.

# How to use the Meter Display

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

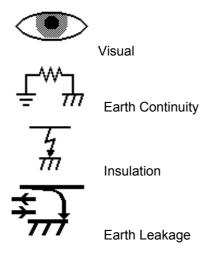


Ref. Number	Function
1	Test Icon
2	Connection Icon
3	Test Duration Counter
4	Primary Display
5	Secondary Display

The display consists of a number of Icons to provide visual indication of the Tester status, a primary 4 digit, 7segment display, along with a 4 digit secondary display, 6 segment display, and a 2 digit duration time display.

### Test Icons

Indicates the test selected as follows:-





## Enclosure Leakage / Load Test



Patient Leakage



Patient Leakage (AP – GND)



Patient Leakage (AP - Case)



Patient Leakage (F – Type) Equivalent Patient Leakage



Patient Auxiliary
Patient Auxiliary (AP – All)



Patient Auxiliary (AP – AP)



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 tester 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.

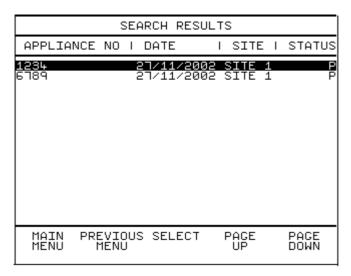
After the test is complete, the result will stay on screen for 10 seconds or until a key is pressed. During this time you can press the PRINT RESULT fastkey, and the measured value will be printed on th internal printer.

# 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:	- <b>*</b> -
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 START ITEM 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 <u>all</u> undeleted 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:-



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 SELECT to display the following screen:-

APPLIANCE: SITE: LOCN: USER:	1234 SITE 1 LOCN 1 USER 1		AUTO
TEST PROGRAM: DATE:	IEC 60601 21/02/2003		PASS
TEST	OUTPUT SFC	LIMIT	RES S
VISUAL CHECK ENCL LEAK PAT LEAK(COM) PAT LEAK(COM) PAT AUX(1) PAT AUX(1) ENCL LEAK PAT LEAK(COM) PAT LEAK(COM) PAT LEAK(COM) PAT AUX(1) ENCL LEAK		00101005050 110101005050 000000000000	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0
MAIN PREVIOU MENU MENU	JS VIEW COMMENTS	PAGE UP	PAGE DOWN

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 following symbols and abbreviations used when test results are displayed:

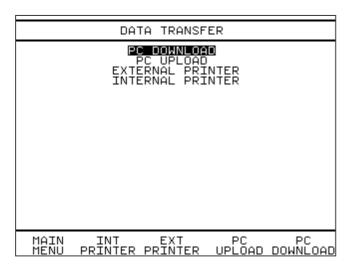
Symbol	<u>Means</u>
<	Less than
>	Greater than
~	AC (if no symbol and a voltage or current is implied
	then DC)
AP	Applied Part
COM	Common
E	Earth Open
Р	PASS (in the Status (S) column)
Р	Phase Open(in the SFC column)
R	Mains Reversed
S	Source Normal (Pat Leak (F Type) tests – Mains on
	Applied Parts)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

#### Note

Two lines are required to display Patient Auxiliary (AP-AP) test results. This shows which 2 applied parts results were stored eg 1-1 1-2 1-3 etc. The same test result reading will appear in both lines.

## 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:-

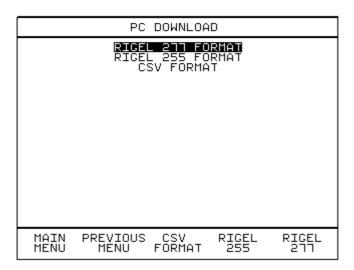


Test Results can be downloaded to a computer or to the on board printer.

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).

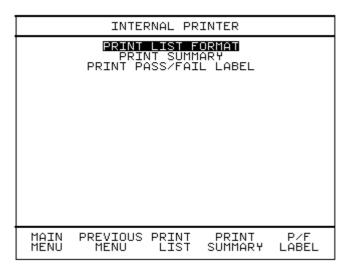
Use the fast keys or cursor keys to highlight the required option and press Green button. The following screen will now be displayed:-

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 START ITEM 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 <u>all</u> 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:-



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:	- <b>*</b> -
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 START ITEM SEARCH

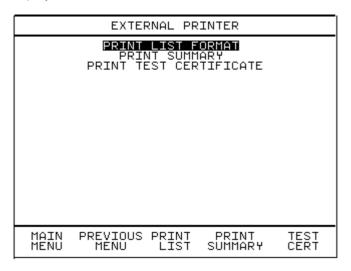
Use the cursor keys to highlight the required parameters and press the fast key CHANGE ITEM to select an appropriate value. The default selection will print <u>all</u> undeleted results. Change the search criteria to limit the printout to your requirement then press the START SEARCH fast key to commence.

#### Note

For List Format two lines are required to display Patient Auxiliary (AP-AP) test results. This shows which 2 applied parts results were stored eg 1-1 1-2 1-3 etc. The same test result reading will appear in both lines.

## **External Printer**

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



Test Results can be downloaded as a Test Summary or as 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:	- <b>*</b> -
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 START ITEM SEARCH

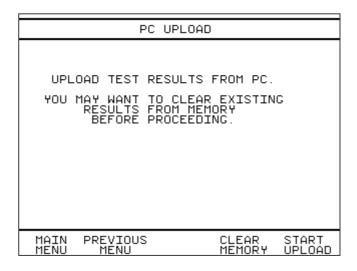
Use the cursor keys to highlight the required parameters and press the fast key to CHANGE ITEM select an appropriate value. The default selection will download <u>all</u> undeleted results. Change the search criteria to limit the download to your requirement then press the START SEARCH fast key to commence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

#### Note

For List Format and Certificate two lines are required to display Patient Auxiliary (AP-AP) test results. This shows which 2 applied parts results were stored eg 1-1 1-2 1-3 etc. The same test result reading will appear in both lines.

# 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:-



If you want to, you can clear out any existing results at this point. It is normal to start upload from a completely empty tester, 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 tester 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:-

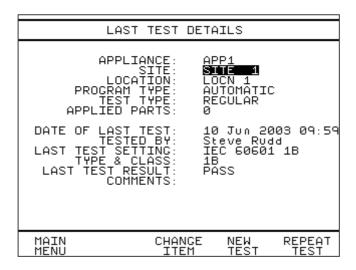
PC UPLOAD		
	Press ABORT to cancel	
	COMPLETE	
APP2 APP3 APP4 APP5 APP6 APP7	SITE 1 SITE 1 SITE 1 SITE 1 SITE 1 SITE 1	00000
7	TEST RESULTS RECEIVED SUCCESSFULLY STORED	
	PREVIOUS MENU	CONTINUE

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

## Repeating a test

If the tester 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 tester 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:-

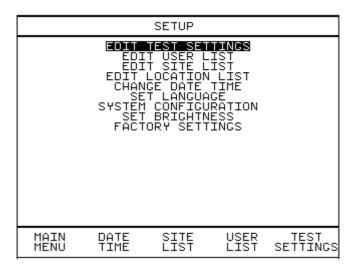


As usual you can alter SITE:, LOCATION:, PROGRAM TYPE:, TEST TYPE: and APPLIED PARTS. Simply user the cursor keys to highlight the item and then press CHANGE ITEM. Also the number of applied parts can be altered using the left and right cursor keys.

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

## How to use Setup

To set up the Tester, 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 six tests are default test sequences for a particular test standard which is set in SYSTEM CONFIGURATION. 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 10 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.

	EDIT T	EST SET	TINGS	
	IEC IEC IEC IEC IEC <b>XIE</b>	60601 1 60601 1 60601 2 60601 2 60601 2	B BF CF B BF CF 118	
MAIN MENU	PREVIOUS MENU	COPY LINE	EDIT	DELETE LINE

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 BODY MODEL CLASS & TYPE	<u>*IEC 50601 18</u> IEC 60601 18	
	OUTPUT LIMIT	DUR NU
APPLIED PARTS VISUAL EARTH CONT INSULATION EUT INSULATION AP EARTH LEAK ENC LEAK PAT LEAK PAT LEAK PAT AUX	YES 25.0A 0.10R 500 V 20.0M 500 V 20.0M 230V~ SEQ 230V~ SEQ 230V~ SEQ 230V~ SEQ 230V~ SEQ	2s 2 2s 0 2s Rui Rui Rui SKIF Rui
MAIN PREVIOUS MENU MENU	CHANGE ITEM	

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

<u>Symbol</u>	Means
~	AC (if no symbol and a voltage or current is implied then DC)
Α	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
Р	PASS (in the Status (S) column)
Р	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.

For BODY MODEL, each action of the CHANGE ITEM fast key will cycle the different body models available

#### Note

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

For APPLIED PARTS, each action of the CHANGE ITEM fast key will cycle the different applied parts options available.

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

For each test, OUTPUT, each action of CHANGE ITEM fast key will cycle the options available.

#### Note

The OUTPUT can only be changed for non-powered tests i.e. EARTH BOND, INSULATION EUT and INSULATION AP.

For each test, LIMIT, each action of CHANGE ITEM fast key will cycle the options available.

#### Note

LIMIT will only be changed as above for non-powered tests i.e. EARTH BOND, INSULATION EUT and INSULATION AP.

For each test, duration, DUR, each action of CHANGE ITEM fast key will cycle the options available.

### Note

DUR will only be changed as above for non-powered tests i.e. EARTH BOND, INSULATION EUT and INSULATION AP.

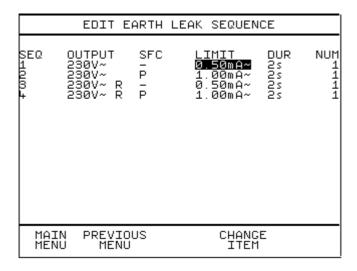
For each test, number of tests, NUM, each action of CHANGE ITEM

fast key will cycle the options available.

#### Note

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:-



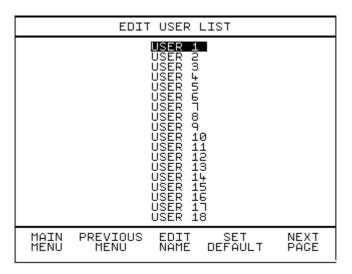
For each Sequence (SEQ), the Pass Limit (LIMIT), Duration (DUR) and Number of tests (NUM) can all be changed by selecting the appropriate value with the cursor keys, then press the CHANGE ITEM fast key. Each action of the CHANGE ITEM fast key will cycle through the available options.

#### Note

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

## **Edit User List**

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



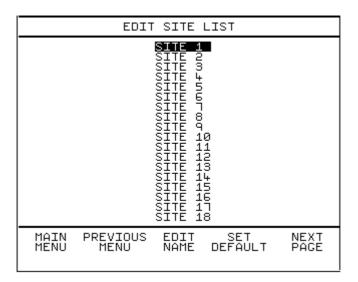
Twenty User names are provided. The fast keys NEXT PAGE and PREV PAGE (displayed after NEXT PAGE action) allow all User names to be selected.

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 tester 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:-



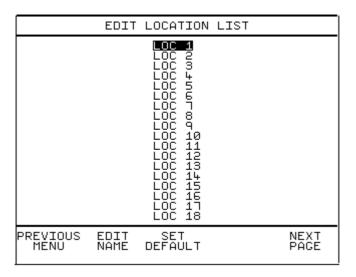
Twenty Site names are provided. The fast keys NEXT PAGE and PREV PAGE (displayed after NEXT PAGE action) allow all Site names to be selected.

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 SITE LIST and the following menu is displayed:-



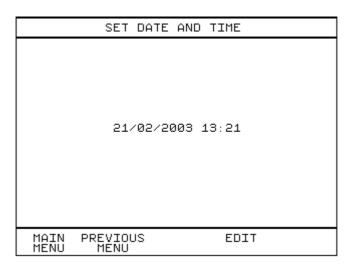
Twenty Location names are provided. The fast keys NEXT PAGE and PREV PAGE (displayed after NEXT PAGE action) allow all Location names to be selected.

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

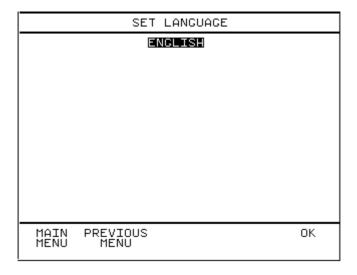
From the SETUP menu select EDIT SITE LIST and the following menu is displayed:-



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.

## Set Language

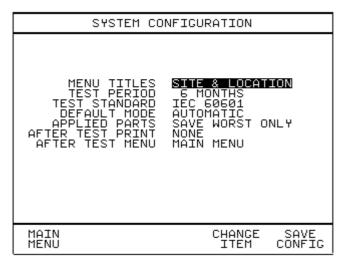
From the SETUP menu select SET LANGUAGE and the following menu is displayed:-



Only ENGLISH is currently available. Press the fast key OK to return to the SETUP menu.

## System Configuration

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



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 tester contains the following standards: IEC 60601, MDA DB9801, AAMI, NFPA 99, 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 tester will SAVE ALL RESULTS or SAVE WORST ONLY for applied part tests.

Default is SAVE WORST ONLY

#### Caution

For long test sequences with many applied parts it is possible the memory capacity for the test sequence may be exceeded when storing results if the option SAVE ALL RESULTS is set. A warning message will be displayed if this has happened during a test.

#### AFTER TEST PRINT

This option determines whether a print-out 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).

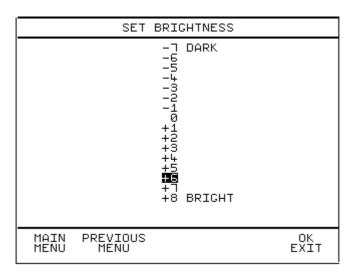
Default is NONE.

#### 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.

## Set Brightness

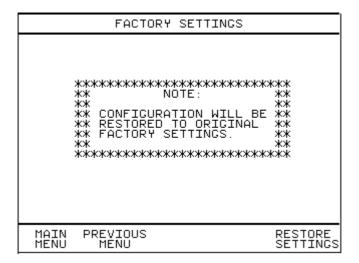
From the SETUP menu select SET BRIGHTNESS and the following menu is displayed:-



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 FACTORY SETTINGS and the following will be displayed:-

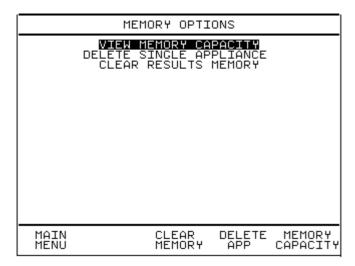


#### Caution

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**

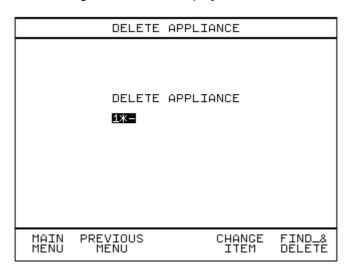
The user can determine the current Memory Capacity. To do this, select VIEW MEMORY CAPACITY with the cursor keys and Green key action or use the fast key MEMORY CAPACITY. The following type of screen is displayed:-

AVAILABLE MEMORY
NUMBER OF RECORDS = 12
CAPACITY = 524288
USED = 18940
FREE = 505348
(Max. Records=2500)
MAIN PREVIOUS MENU MENU

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

## 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.

	DELETE AP	PLIANCE	
	DELETE AP	PLIANCE	
	1234 2 – RECORDS	DELETED	
MAIN		CHANGE	FIND_&
MENU	MENU	ITEM	DELETE

#### Note

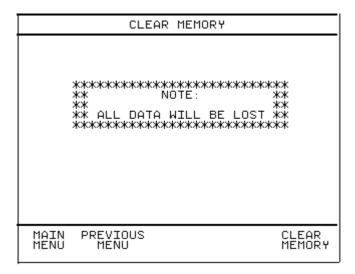
Deleted records are not actually deleted from memory. They are given a STORAGE STATUS as DELETED and can be selected on the SEARCH TEST RESULTS menu prior to viewing or downloading results. They are only lost from memory after a CLEAR RESULTS MEMORY action

## Clear Results Memory

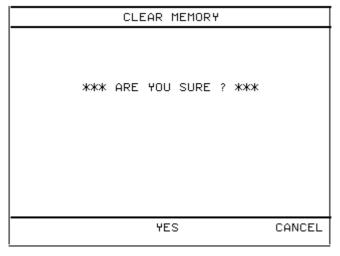
#### Caution

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:-

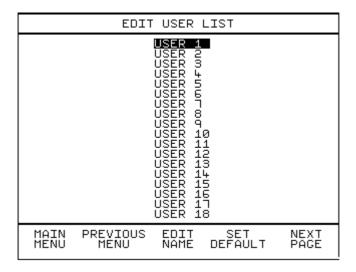


Pressing the fast key YES will clear the results memory of the tester. Pressing the CANCEL fast key will return you to the MEMORY OPTIONS menu.

# 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 tester 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 Tester 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

## Class 1 (earthed) appliances

Plug EUT into Tester 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 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 2 – Because of NOTE 1 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 3 – 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.



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 Tester'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 Tester 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 Tester outlet socket

## Class 2 (unearthed) appliances

Plug EUT into Tester 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 Tester 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 Tester 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

The Tester 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 Tester's fuses may blow.

The Tester also performs an internal safety test to verify that internal relays are properly set before applying full mains supply to the appliance.

#### Load Test



Test Icon Displayed ---

# Warning Mains voltage applied to appliance

#### All Appliances

Plug EUT into Tester outlet socket.

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

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

## Earth Leakage Test



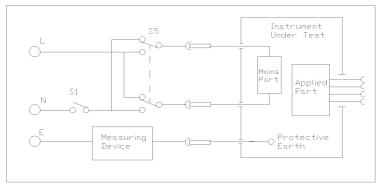
# Warning Mains voltage applied to appliance

All Appliances

Plug EUT into Tester outlet socket.

The Earth Leakage Test shows the current flowing down the protective earth conductor of the mains inlet lead. The tester 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

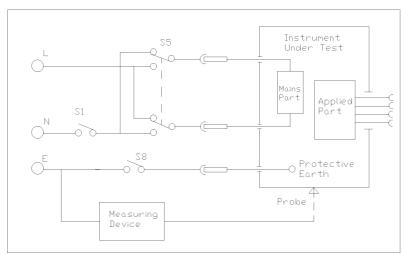
#### Mains voltage applied to appliance

#### All Appliances

Plug EUT into Tester 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. Both the IEC60601 'body model' or the ANSI 'body model' can be selected. The Tester 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 Tester displays the 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, 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

For enclosure leakage tests the earth bond probe is used to make contact with all conductive non-protectively 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 and S8 closed and S5 normal and reversed.

#### Enclosure Leakage, single fault, supply open

This test measures the enclosure leakage current with a single fault condition (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 ---



Mains voltage applied to appliance.

#### All Appliances

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

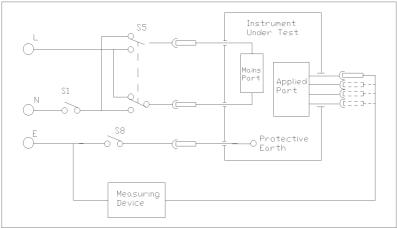
The Patient Leakage Test displays the current that would flow if an Applied Part was attached to a person. The Tester detects any current

flowing in the Applied Parts Lead. The Tester 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 Tester will stop the automatic test sequence.

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



Test Circuit For Patient Leakage Current

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 (AP - GND)

Test Icon Displayed ---



#### Mains voltage applied to appliance.

#### General

This test is specific to the AAMI and NFPA 99 standards (USA). It is similar to Patient Leakage described above.

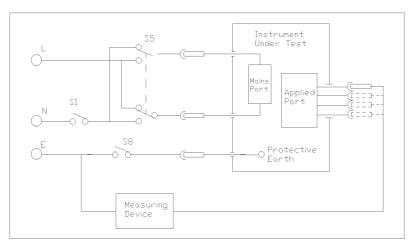
#### All Appliances

Plug EUT into Tester outlet socket, and attach the applied parts from the EUT to the Tester (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 Tester detects any current flowing in the Applied Parts Lead. The Tester displays a combined AC/DC result in milliamps (mA).

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

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



Test Circuit For Patient Leakage Current

# Applied Parts Connections

As far as AAMI and NFPA 99 are concerned there are 2 types of equipment those with applied parts floating and non-floating. The Rigel 277 uses the terms B, BF and CF(as per IEC60601). For this test type B is Non-floating while types BF and CF are Floating. Selecting BF or CF will give the same test sequence & pass/fail limit.

In manual mode the applied parts are connected as per the AAMI standard. In automatic mode the applied parts are connected as described below.

AAMI - for all types of equipment (B, BF or CF) the patient leakage current is measured first with all applied parts connected together, and then individually.

NFPA 99 – for type B equipment the patient leakage current is measured with all applied parts connected together. For type BF & CF equipment the patient leakage current is measured from each applied part separately.

#### Patient Leakage(AP-GND), 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(AP-GND), 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 (AP - Case)



**Warning** 

#### Mains voltage applied to appliance.

#### General

This test is specific to the AAMI standard (USA). It is similar to Patient Leakage described above except that the leakage current path is from the applied parts, through the patient, to the case of the EUT.

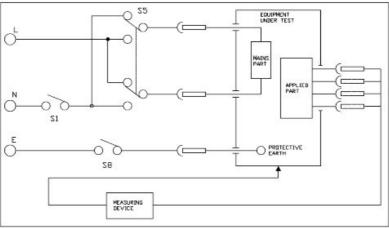
#### All Appliances

Plug EUT into Tester outlet socket, and attach the applied parts from the EUT to the Tester (Use Applied Parts adaptors, where necessary). Connect the Earth bond probe to the case of the EUT

The Patient Leakage Test displays the current that would flow if an Applied Part was attached to a person and that person was to touch the case of the EUT . The Tester detects any current flowing in the Applied Parts Lead. The Tester displays a combined AC/DC result in milliamps (mA).

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

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



TEST CIRCUIT FOR PATIENT LEAKAGE AP-CASE

#### Applied Parts Connections

As far as AAMI and NFPA 99 are concerned there are 2 types of equipment those with applied parts floating and non-floating. The Rigel 277 uses the terms B, BF and CF(as per IEC60601). For this test type B is Non-floating while types BF and CF are Floating. Selecting BF or CF will give the same test sequence & pass/fail limit.

In manual mode the applied parts are connected as per the AAMI standard. In automatic mode the applied parts are connected as described below.

AAMI - for all types of equipment (B, BF or CF) the patient leakage current is measured first with all applied parts connected together, and then individually.

NFPA 99 - for type B equipment the patient leakage current is measured with all applied parts connected together. For type BF & CF equipment the patient leakage current is measured from each applied part separately.

#### Patient Leakage(AP-Case), 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(AP-Case), 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 ---



This test involves applying a current limited mains potential (110% of mains input voltage) to the Applied Parts connections. Due to the requirements for EN60601 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.

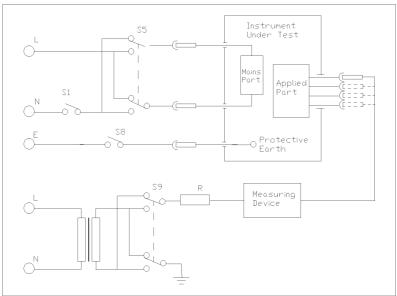
#### All Appliances

Plug EUT into Tester 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 Tester 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 Tester will stop the automatic test sequence.



Test Circuit For Patient Leakage Current, Mains 🛭 Applied Part

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

AAMI - for Floating applied parts equipment the patient leakage current is measured with all parts of the applied part connected together. If using manual mode select the equipment type to BF

NFPA 99 - for Floating applied parts equipment the patient leakage current is measured with all parts of the applied part connected together. If using manual mode select the equipment type to BF

Note – for this test 'body model' selection will also change the current limiting resistance to that specified by IEC60601 or AAMI

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

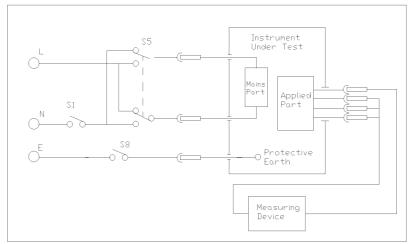
Plug EUT into Tester outlet socket, and attach the applied parts from the EUT to the Tester (use the supplied adaptors where necessary).

The Patient Auxiliary Current displays the leakage current that would flow between Applied Parts under normal and fault conditions. The Tester detects any current flowing between one Applied Part and the remaining Applied parts connected together. The Tester 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 Tester will stop the automatic test sequence.

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



Test Circuit For Patient Auxilary 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.

#### Patient Auxiliary (AP - AP)



Test Icon Displayed--

Warning

Mains voltage applied to appliance

#### General

This test is specific to the AAMI standard (USA). It is similar to Patient Auxiliary current described above.

#### All Appliances

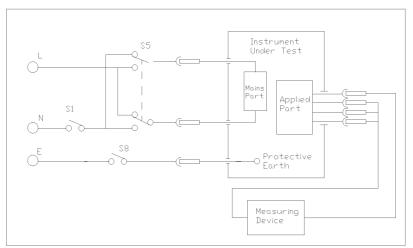
Plug EUT into Tester outlet socket, and attach the applied parts from the EUT to the Tester (use the supplied adaptors where necessary).

The Patient Auxiliary Current displays the leakage current that would flow between Applied Parts under normal and fault conditions. The Tester detects any current flowing between any 2 Applied Parts. The tester displays a combined AC/DC current result in milliamps (mA).

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

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

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



Test Circuit For Patient Auxilary Current

#### Applied Parts Connections

As far as AAMI and NFPA 99 are concerned there are 2 types of equipment those with applied parts floating and non-floating. The Rigel 277 uses the terms B, BF and CF(as per IEC60601). For this test type B is Non-floating while types BF and CF are Floating. Selecting BF or CF will give the same test sequence & pass/fail limit.

For this test, current is measured between a single applied part and each of the other applied parts in turn. This test should be repeated until all combinations have been tested.

## Patient Auxiliary(AP-AP), 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(AP-AP), 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.

#### Patient Auxiliary (AP - All)



Test Icon Displayed ---

#### Warning

#### Mains voltage applied to appliance

This test is specific to the AAMI standard (USA). It is similar to Patient Auxilliary current described above.

#### All Appliances

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

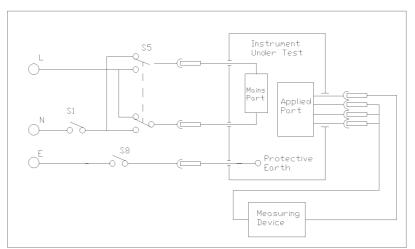
The Patient Auxiliary Current displays the leakage current that would flow between Applied Parts under normal and fault conditions. The Tester detects any current flowing between one Applied Part and the remaining Applied parts connected together. The Tester displays a combined AC/DC current result in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

The selection of normal or reverse operation and single fault condition (earth open circuit) is done automatically during an Automatic test, but

requires user action for Manual tests.

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

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



Test Circuit For Patient Auxilary Current

#### Applied Parts Connections

As far as AAMI and NFPA 99 are concerned there are 2 types of equipment those with applied parts floating and non-floating. The Rigel 277 uses the terms B, BF and CF(as per IEC60601). For this test type B

is Non-floating while types BF and CF are Floating. Selecting BF or CF will give the same test sequence & pass/fail limit.

For this test, current is measured between a single applied part and each of the other applied parts in turn. This test should be repeated until all combinations have been tested.

#### Patient Auxiliary(AP-All), 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(AP-All), 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.

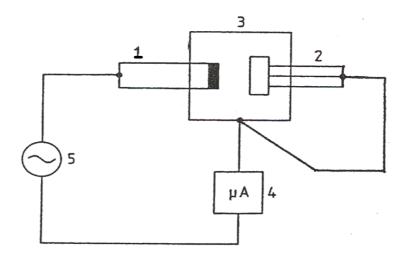
#### Equivalent Equipment Leakage Current



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**



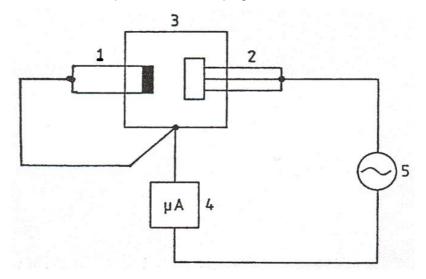
Test Icon Displayed ---

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

#### 40Va.c. test voltage applied to lead

Plug the lead into the Tester outlet socket, and also into the Tester 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.

# Chapter 5 Tips & Troubleshooting

#### Power On Self tests

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

#### **Power Polarity Test**

The tester 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:-

-----POWER POLARITY IS REVERSED!

SELECT AUTO CORRECT OR RESOLVE
POWER POLARITY REVERSAL.

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

#### Caution

AUTO CORRECT should <u>only</u> 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 the following message is displayed:-

#### **EARTH FAULT**

**TESTS CANNOT PROCEED!** 

NO INCOMING EARTH TO THE TESTER

PLEASE HAVE THE POWER OUTLET CHECKED

MAIN MENU

Have the building earth to socket checked as the tester is indicating the power source has no earth.

Note – This message will also appear if the unit is powered from a floating supply, such as an isolation transformer.

#### Internal Relay Test

The tester checks the internal relays for correct operation. Should a relay associated with safe use of the tester fail this test the following message is displayed:-

INTERNAL RELAY FAULT

**TESTS CANNOT PROCEED!** 

PLEASE ARRANGE TO RETURN TO SERVICE AGENT

MAIN MENU

This message can also be displayed during tests as the relays are also

checked prior to powered tests.

The fault reported by this message requires 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:-

#### **EARTH HOT FAULT**

**TESTS CANNOT PROCEED!** 

AN AUTO RESET THERMAL CUT OUT WAS DETECTED ON POWER ON

PLEASE WAIT FOR THE CUT OUT TO RESET...

MAIN MENU

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 Tests

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

#### EARTH BOND TEST WARNING

AN EARTH BOND TEST FAILURE HAS BEEN DETECTED CAUSED BY AN AUTO RESET THERMAL CUT OUT

TESTS CAN BE RESUMED WHEN CONDITIONS ALLOW...

MAIN MENU

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 tester's display.

#### Internal Relay Test

The tester checks the internal relays for correct operation. Should a relay associated with safe use of the tester fail this test the following message is displayed:-

#### INTERNAL RELAY FAULT

**TESTS CANNOT PROCEED!** 

PLEASE ARRANGE TO RETURN TO SERVICE AGENT

MAIN MENU

The fault reported by this message requires 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 access of 15A a warning will be displayed as follows:-

# EXCESSIVE POWER FAULT THE APPLIANCE IS DRAWING EXCESSIVE CURRENT! TEST ABORTED! MAIN

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

## Memory

**MENU** 

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 tester 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 Tester 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 Tester provides two interfacing ports:-

Parallel – for connection to parallel printer.

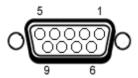
Serial Port - for connection to a PC, Barcode Scanner, Brain Cell Scanner

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

The Connector pin outs for Serial port are:-

Interfacing

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 Tester

#### Cleaning the Tester

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

If any liquid is spilt into the Tester case, the Tester 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 Tester 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 Tester is subject to condensation, allow the Tester to completely dry before use.

- Always check the Tester and all test leads for signs of damage and wear before use.
- On powering up the tester 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 Tester 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 Tester.
- The unit should be regularly calibrated (at least annually).
- For repair or calibration return the instrument to:-

Service Dept., Seaward Electronic Limited. Bracken Hill South West Industrial Estate Peterlee Co. Durham SR8 2SW

Tel: +44 (0)191 586 3511 Fax: +44 (0)191 586 0227

sales@seaward.co.uk calibration@seaward.co.uk www.seaward.co.uk

# Chapter 7 Accessories

A series of standard and optional accessories are available for the Seaward Rigel-277 Tester. The standard accessories are supplied with the Tester.

#### Standard Accessories

Accessory	Part Number
Earth Bond Test Lead	286A925
Applied Part Adaptors (11)	298A678
Instruction Manual	298A552
MEDIGuard Evaluation Software	301A912
9 Way Computer Lead	194A919
Thermal Paper Roll (2)	
Thermal Printer Labels (2)	

# **Optional Accessories**

Accessory	Part Number
MEDIGuard Software	301A910
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

# Chapter 8 Specifications

#### AC Earth Bond Test

Test Voltage	6V rms nominal (no load)
Test Current100mA, 1A, 1	0A, 25A (0 - $0.2\Omega$ range as per IEC60601)
Range1A, 10A, 25	Α0.00Ω - 19.99Ω
100mA	$$ $0.00\Omega$ - $4.99\Omega$
Resolution	
<b>Accuracy</b> 1A, 1	0A, 25A+/- 5% of reading, +/- 2 digits
0.10	A+/- 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 (0.35M $\Omega$  load), 500V (0.5M $\Omega$  load) d.c. nominalShort Circuit Current2mA d.c. maximumRange... 100k $\Omega$  - 100 M $\Omega$ Resolution0.01 M $\Omega$  (<100 M $\Omega$ )Accuracy+/- 10% of reading, +/- 2 digits (100k $\Omega$  - 100M $\Omega$ )NOTE – The accuracy of this test is correct after an initial warm up of 3-5 minutes.

## Earth Leakage Test

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Body Model	IEC60601 or ANSI
Input Impedance (measuring instrument)	>1Mohm
Frequency Response (measuring instrument	)dc to 1MHz (-3dB)
Range	0.000mA – 9.999mA
Accuracy+/- 5%	of reading, +/- 4 digits
Frales and Lastra va Tast	
Enclosure Leakage Test	
Body Model	IEC60601 or ANSI
Input Impedance (measuring instrument)	>1Mohm
Frequency Response (measuring instrument	)dc to 1MHz (-3dB)
Range	0.000mA – 9.999mA
Accuracy+/- 5%	of reading, +/- 4 digits
Patient Leakage Test	
Body Model	IEC60601 or ANSI
Input Impedance (measuring instrument)	>1Mohm
Frequency Response (measuring instrument	)dc to 1MHz (-3dB)
Range	0.000mA – 9.999mA
Accuracy AC. & DC+/- 5%	of reading, +/- 4 digits

# Patient Auxiliary Test

Body Model	IEC60601 or ANSI
Input Impedance (measuring instrument)	>1Mohm
Frequency Response (measuring instrumen	<b>it)</b> dc to 1MHz (-3dB)
Range	0.000mA – 9.999mA
Accuracy AC.& DC+/- 5%	% of reading, +/- 4 digits

# Patient F-Type Test

Body Model	IEC60601 or ANSI
Input Impedance (measuring instrument)>1Mohm	
Frequency Response (measuring instrument) dc to 1MHz (-3dB)	
Range	0.000mA – 9.999mA
Accuracy	+/- 5% of reading, +/- 4 digits
F-type Short Circuit Current	Nominal 5mA ac minimum
Current Limiting Resistance	48K for IEC60601 body model
	120K for ANSI 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 Le	eakage
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
DetectsGood, Op	oen Live, Open Neutral, Short, Reverse
Mechanical	
Size	450mm x 410mm x 155mm
Weight	9.5kg
Environmental	
Operating	0°C to 40°C (non condensing)
Storage	10°C to 50°C (non condensing)
Maximum R.H	90%
Supply Rating	
	115v +/-10% / 230V +/- 10%, 50/60Hz 30VA
Max EUT Output Current	16A (10A for certain country variants)