

# Rigel 377

**Electrosurgical Analyser** 

Instruction Manual 367A550 Issue 2.0

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#### Limited Warranty & Limitation of Liability

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

#### **Calibration Statement**

The Rigel 377 Electrosurgical Analyser is fully calibrated and found to be within the specified performance and accuracy at the time of production. The Seaward Group provides its products through a variety of channels; therefore it may be possible that the calibration date on the provided certificate may not represent the actual date of first use.

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

Date received into service; / / .

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

## **Disposal of old product**



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

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

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

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

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## **Declaration of Conformity**

#### **Rigel 377 Electrosurgical Analyser**

#### Manufactured by:

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

#### **Millennium Statement**

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

#### **Statement of Conformity**

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

#### Standards used:

EN 60601-1 (1990) Medical Electrical Equipment. General Requirements for Safety EN 61010-1 (1993) Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use

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

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

The tests have been performed in a typical configuration.

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

## Before you power up

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

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

## User Notes

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

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



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



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

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



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

## Introduction

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

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

Tests can be carried out on an individual basis (see chapter 2) and as part of an automatic sequence (see chapter 3).

Data can be stored, viewed and transferred from within the instrument (see chapter 4).

Customisation of the Rigel 377 can be carried out in the setup (see chapter 5).

## Analyser Functions

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

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

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

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

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

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

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

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

## Key Features

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

## Rigel 377 includes:

- Calibration Certificate
- Detachable 2 metre mains cable
- Instruction Manual (p/n 367A550)
- 3 x Jumper Links (p/n 43B759)

### **Optional Accessories**

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

## 1. Getting started

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

## 1.1. Connecting your Analyser

- Elevate the Rigel 377 on its two hinged feet at the front base.
- Ensure none of the large base and rear ventilation inlets are obstructed during operation,

#### Rear panel

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



### Front connection panel



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

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

For REM / plate security test use the black terminals.

### Side panel ESU to ESA connections



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

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

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

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



#### Side panel ESA to Oscilloscope connections

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

### 1.2. Home screen

Upon power-up of the Rigel 377, the display will be showing the HOMESCREEN;



## 2. Manual Mode

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

Available tests are:

- REM test
- HF Leakage
- Power Test

## 2.1. Plate Security (REM) test

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

				RUN RETURN	ELECTR	ODE MONIT	ORINO	G TEST
RIGEL			0 123 AUTO UP	ALARM LI	UP ALARM	0	500 OHMS	
E	ES/	437	7	MANUAL UP	wn	SET OP LIMIT SET DOWN LIMIT DOWN ALARM	90	OHMS   OHMS   OHMS
Menu	REM	HF LEAKAGE	POWER TEST		uto An	CAPTURE ALARM		

Select the REM test from the home screen shown below.

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

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

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

## 2.2. HF Leakage

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

				HF LEAKAGE: TEST SETTING			
				ESA SET	TINGS	ES	UCONTROL
E		GEL A377		START DELAY	200 ms	ON TIME: OFF TIME D/CYCLE:	2 8 2 8 50.0 %
Menu	REM	HF POWER TEST		+			$\checkmark$

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

Use the rotary encoder to navigate the screen

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

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

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

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

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

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

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

HF LEAKAGE TEST SETTING	HF LEAKAGE TEST SETTING		
EP CUT NEUT EARTH ISO ESU	TEST CODE 1111 IEC 601-2-2 part 1 FIGURE 104 MEASUREMENT OF H.F.LEAKAGE CURRENT5 FROM A BIPOLAR ELECTRODE EARTH ISOLATED ESU BIPOLAR ELECTRODE CUT MODE FIRST ELECTRODE		
SET LOAD 200 LEAKAGE LIMIT 150	SET LOAD 200 LEAKAGE LIMIT 150		
SHOW DETAIL RUN	SHOW DIAGRAM		

or the IEC 60601-2-2 reference details (SHOW DETAIL). Press the rotary encoder to activate the SET LOAD and LEAKAGE LIMIT

HF LEAKAGE	HF LEAKAGE TEST SETTING				
TEST CODE 1 1 1 1 IEC 601-2-2 part 1 FIGURE 104 MEASUREMENT OF H.F.LEAKAGE CURRENT5 FROM A BIPOLAR ELECTRODE EARTH ISOLATED ESU BIPOLAR ELECTRODE CUT MODE FIRST ELECTRODE					
SET LOAD 200 LEAKAGE LIMIT 150					
	SHOW DIAGRAM				

Return to the DIAGRAM mode by using the SHOW DIAGRAM fast key.

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

Run HF Leakage Test	Run HF Leakage Test		
Load: 200 ohms Leakage: 100 mA Limit: 150 mA Pass 🗸	Load: 200 ohms Leakage: 200 mA Limit: 150 mA Fail X		
HOLD SHOW DIAGRAM	HOLD SHOW DIAGRAM		

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

## 2.3. Power Test

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

					Powe	er Test	
E	RIQ ES/	GEL A377		CONT = GR	= Contin APH = \$	uous Sin Set Of Te	igle Test sts
Menu	REM	HF POWER LEAKAGE TEST		╋	HOLD	SHOW DIAGRAM	

Select Power test from the homescreen and select either the Continuous Single test (CONT) or GRAPH mode using the fast keys;

CONT m	ode	GRAPH mode			
CONTINUOUS MODE	:POWER TEST	GRAPH MODE : POWER TEST SETTING			
ESA SETTINGS	ESU CONTROL	ESA SETTI	NGS	ESU CONTROL	
MONO POLAR	COAG	MONO POLAR	<b>!</b>	COAG	
		BI-POLAR			
LOAD 200 OHMS	ON TIME: 28	START LOAD	100 OHMS	ON TIME: 28	
START DELAY 200 ms	OFF TIME: 28	START DELAY	200 ms	OFF TIME: 28	
	D/CYCLE: 50.0 %	TEST POINTS	7	D/CYCLE: 50.0 %	
TEST TIME 30 8		TEST TIME	28 8		
	HOW	-	DI		

Use the rotary encoder to navigate the screen

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

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

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

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

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

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

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

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

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

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



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

	RUN POWER TEST (DATA VIEW)					
#	Ohms	Wrms	mA rms	V rms	V peak	CF
1	100	50	707	71	99	1.4
2	250	150	775	194	271	1.4
3	400	300	866	346	485	1.4
4	550	180	572	315	440	1.4
5	700	110	396	277	388	1.4
6	850	70	287	244	341	1.4
7	1000	50	224	224	313	1.4
	GOTO GRAPH					

## 3. Automatic Mode

The automatic mode allows the user to select a test sequence which will carry out a pre-determined set of tests against user definable limits. Test results are stored at the end of the test for future reference. To view or transfer stored data, please refer to chapter 4)

To enter the automatic mode, select the MENU key (F1) from the home screen and then AUTOMODE;

	Menu				
RI ES	GEL A377	<mark>Auto</mark> Data Setu	p Mode		
Menu REM	HF POWER LEAKAGE TEST	╋	Auto	Data	Setup

In the following screen, an asset ID number can be entered using the rotary encoder, barcode scanner or a PS2 keyboard.

Auto Mode			
Asset Id Test Sequence	Example 1		
+	$\checkmark$		

When using the barcode scanner, ensure the barcode scanner is paired with the Rigel 377, see chapter 4.3. (The Rigel 377 will only support the Seaward barcode scanner, p/n 339A923). When the barcode is ready to scan, the word "OK" will appear in the asset ID field.

Open the text field by pressing the rotary encoder or ENTER key on the external keyboard.

Auto Mode						
Asset	d	ABCD1	234			
ABCDEF 01234567	GH <b>U</b> KLM 789 ,*	NOPQRST ()+-&í:	UVWXYZ ;			
Delete	Shift	$\checkmark$				

Enter data with the rotary encoder (push to select character) or keyboard (note that the enter key is not required). Use the "tick" mark (F3) to confirm entry.

Test	Sequence
Example 1 TEST 1	
←	$\checkmark$

Next, select the test Sequence box (push to select) and select the required test sequence. (To add new test sequences, see chapter 5.1).

From the auto mode screen, press the "tick" mark (F4) to start the test.

Depending on the test sequence, the individual test screens will appear. As example:

GRAPH MODE : POWER TEST SETTING						
ESA S	ESA SETTINGS			ESU CONTROL		
MONO POLA	R 🔳		COAG	3		
BI-POLAR	MESS/	GE BO	x			
START LOA	START TEST ?					
START DEL						
ENDLOAD	YES		NO	2	8	
TEST DOINT			·	50.0	%	
TEAT TIME	40 0		POWER	300		
TESTTIME	40 8					
		SE	WOF		/	
		DIA	GRAM			

Confirm by pressing the green button on the front panel.

During the test, the sequence can be interrupted or cancelled. Press the red button on the front panel. The following option menu will appear;



- **v** Restart Test will continue the test sequence from where it was interrupted.
- v Restart Test Sequence will start the sequence from the beginning.
- ✓ Next Test will skip the current test and move to the next test (note that a failure will be reported for the skipped test).
- ✓ End Test Sequence will stop the test sequence and store the results (fail).
- ✔ Abort Test Sequence will stop the test sequence. No data is stored.

## 4. Data

Stored data can be viewed and transferred to and from the PC such as test results and power distribution reference curves. To enter the Data menu, select the MENU key (F1) from the home screen and then DATA;

					Mer	nu	
E	RIQ ES/	GEL A37	7	Auto <mark>Data</mark> Setu	p Mode		•
Menu	REM	HF LEAKAGE	POWER TEST	-	Auto	Data	Setup

This leads to 3 options;

- ✓ View data (see Error! Reference source not found.)
- Transfer data (see Error!
  Reference source not found.)
- **v** BT favourites (see 4.3)



### 4.1. View Data

Stored data can be viewed by selecting the VIEW DATA from the DATA screen as shown above.

	View	/ Data	
Asset Id	D 24/8	<b>ate</b> 8/2011	Status FAIL
+	View	Transfer	Date(DES)

Data can be sorted using the F4 key which has the following options:

- **v** Sort by date (ascending)
- ✓ Sort by date (descending)
- ✔ Sort by asset ID (ascending)
- ✔ Sort by asset ID (descending)

DATE (ASC) DATE (DEC) ID (ASC) ID (DEC)

From the view data screen, results and test sequences can be viewed (F2 – VIEW) and transferred to a PC (F3 – TRANSFERRED);

To view data, use the rotary encoder to select the asset ID, press to select or F2. This shows the test results for the selected asset ID;

Test Result					
Asset I	d	AA			
Tested	On	24/8/2011			
Test Se	equence	DDDD			
+	Delete	Setting	View		

Test results can be deleted (F2) and viewed (F4). Test settings can be viewed by pressing F3.

When power distribution graphs are part of the test sequence, the results can be displayed in graph mode and data mode, see below. In graph mode, the reference graph is also shown;



	RUN POWER TEST (DATA VIEW)						
#	Ohms	Wrms	mA rms	V rms	V peak	CF	
1	100	50	707	71	99	1.4	
2	250	150	775	194	271	1.4	
3	400	300	866	346	485	1.4	
4	550	180	572	315	440	1.4	
5	700	110	396	277	388	1.4	
6	850	70	287	244	341	1.4	
7	1000	50	224	224	313	1.4	

## 4.2. Transfer Data

The Rigel 377 is able to transfer data to and from the PC. In addition, power distribution reference curves can be uploaded to the instrument, to allow quick check of power performance against manufacturer curves.

	D	ata				
View	View Data					
Tran	Transfer Data					
BTF	BT Favourites					
+	View	Transfer	BT			

#### 4.2.1. Download data

Stored data can be downloaded to the PC in several formats. To capture data as a text file (CSV), select either CSV full or CSV summary. To download the test results into Med-eBase, select the SSS format.

Data Transfer					
Number Of Records	1				
Pc Status	Connected				
Port Option	USB				
Operation	CSV Full				
Form	at Port Start				

Change the data format between CSV full, CSV summary and SSS by pressing the F2 (Format) key.

Change between USB and Bluetooth, using the F3 (port) key.

Start download by pressing F4 (Start)

### 4.2.2. Upload data

Using Med-eBase software, work and assets can be scheduled (see Med-eBase user manual) These assets can be uploaded to the tester for easy retest. Change to upload by pressing the F2 (Format) key.

Data Transfer						
Number Of Records	1					
Pc Status	Connected					
Port Option	USB					
Operation	Upload					
Form	at Port	Start				

Change between USB and Bluetooth, using the F3 (port) key.

Start upload by pressing F4 (Start) (refer to Med-eBase user manual for procedures on Med-eBase)

#### 4.2.3. Upload reference curves

To assist with the power distribution graph tests, expected or reference curves can be uploaded to the instrument for quick comparison. A upper and lower limit graph can be uploaded by selecting "reference graph" on the data transfer screen. Use F2 (Format) to change.

Data Transfer				
Number Of Records	1			
Pc Status	Connected			
Port Option	USB			
Operation	Reference Graph			
Form	at Port Start			

Change between USB and Bluetooth, using the F3 (port) key.

Start upload by pressing F4 (Start) (refer to Med-eBase user manual for procedures on Med-eBase)

#### 4.2.4. Transfer test sequences

Test sequences can be created on the Med-eBase software and uploaded to the Rigel 377 (see Med-eBase user manual on how to create these test sequences). Use F2 (Format) to change to uploading of test sequences.

Data Transfer					
Number Of Records		1			
Pc Status	Connected	I			
Port Option	USB				
Operation	Test Seque	ence			
Form	at Port	Start			

Change between USB and Bluetooth, using the F3 (port) key.

Start upload by pressing F4 (Start) (refer to Med-eBase user manual for procedures on Med-eBase)

### 4.3. Bluetooth Favourites

In order for the Rigel 377 to automatically connect to the correct Bluetooth accessory, details of that accessory must be stored into the Bluetooth Favourites list (pairing).

The Bluetooth Favourites list comprises of two device types, each of which can store up to 3 devices of the same type. The sub-lists are shown below:

- Barcode (Scanner)
- Computer

To start the pairing process, select DATA from the home screen, followed by BT FAVOURITES.



From the BT Favourites screen, select the device type you'd like to pair.

BT Favourites				
Compu	ter			
Bar Coo	Bar Code			
BT Status Searching : 1 Found				
+	Select	Search	Clear	

Note that the Bluetooth module needs to finish initializing (a ready message will appear in bottom of screen) before a search can commence.

Press F3 (Search) to start searching. The found devices will not show on the screen instead, the number of found devices will show (in this example 1)

Select COMPUTER using the rotary encoder and push to select. Now scroll with the rotary encoder until the device is selected. Push the rotary encoder to select or press F2 (Select)

Repeat this for the barcode scanner;

BT Favourites					
Computer SELLT047					
Bar Code 0PL-2724_3150					
BT Status Ready					
	Salact	Search	Cloar		
	Select	Search	Ciedi		

- Note If the required device is not shown, check that it is powered on with the Bluetooth function active then repeat the search.
- Note Some Bluetooth devices do not report a recognisable name and may cause confusion when setting up Favourites. Turn off or disable unused Bluetooth devices when configuring Favourites.
- Note Seaward and Rigel accessories do not require a PIN. When the PC requires an authorisation (some Windows version might ask), enter 0000 (four zero's)

When all your favourite devices have been set up, press F1 and they will be saved.

## 5. Setup

To enter the setup mode, select the MENU key (F1) from the home screen and then SETUP;

					Mer	าน	
E	RIQ ES/	GEL A37	7	Auto Data <mark>Setu</mark>	Mode P		•
Menu	REM	HF P LEAKAGE T	OWER	+	Auto	Data	Setup

## 5.1. Test Sequences

The Rigel 377 can be set-up to perform automatic test sequences. These can be created by the user and can be specific to for example; manufacturers recommendations. The total number of possible test sequences is 100.

From SETUP menu, select the test sequence option;

Setup				
Test S Time Langu Facto Memo Abour	Sequence / Date uage ry Restore ory Option t	9		
╉	Test Seq	Time	About	

This brings up an overview of all the stored test sequences. (the factory default is only one). From the test sequence menu, the following options are available:

le 1		
1		•
New	Edit	Options
	New	New Edit

F2 (NEW)	Create a new test sequence
F3 (EDIT	Edit an existing test sequence
F4 (OPTIONS)	Options menu (delete, copy, rename a test sequence)

Use the RTE to select the required test sequence and the function keys (F2-F4) for the required action.

#### 5.1.1. Create a new test sequence

To create a new Test Sequence, press F2 (NEW), in the test sequence menu.

At first, the test sequence must be given a unique name. Open the text field by pressing the rotary encoder or ENTER key on the external keyboard;

	New Test Sequence				
Name NEW SEQUENCE					
BCDEFGHIJKLMNOPQRSTUVWXYZ 0123456789 ,*()+-&í:;					
Delete	Shift	$\checkmark$	×		

Enter data with the rotary encoder (push to select character) or keyboard (note that the enter key is not required). Use the "tick" mark (F3) to confirm entry.

The newly created test sequence is now appearing in the test sequence menu:

Test Sequence			
Example 1			
TEST	1		
NEW	SEQUENC	CE	
-	New	Edit	Options

The test sequence can now be built by opening the sequence using F3 (EDIT);

Edit Test Sequence			
NEW SE			
Add	Edit	Delete	
	Edit Tes	Edit Test Sequence	

Press F2 (ADD) to insert, F3 (EDIT) to edit or F4 (DELETE) to delete an individual test. Use the rotary encoder to navigate.

In the following example, a test sequence is built by inserting a selection of tests such as REM test followed by a number of HF leakage tests (on CUT and COAG) and a power distribution graph from 50-1250 OHM (example)

Press F2 to add a test:



Configure the REM test requirements as per chapter 2.1. Repeat this action for the individual HF leakage (refer to chapter 2.2) and power distribution (refer to chapter 2.3) tests;

	Edit Test Sequence				
Name	Name NEW SEQUENCE				
Rem Test					
HF Test -	1211				
HF Test -	1212				
HF Test -	1221				
HF Test -	1222				
Graph po	wer Test				
╋	Add	Edit	Delete		

Save the test sequence by pressing F1 (back);

Test Sequence			
Exam	ple 1		
TEST	1		
NEW	NEW SEQUENCE		
-	New	Edit	Options

and confirm the changes by pressing F1 (back) again followed by save (F4) see below;

	Save Changes?	
	Save Changes?	
No		Yes

Saving the changes might take up to 10 seconds, please wait until the screen returns to the setup menu.

#### 5.1.2. Edit an existing test sequence

Test Sequence						
Exam	Example 1					
TEST	TEST 1					
NEW	SEQUEN	E	1.0			
-	New	Edit	Options			

Use the RTE to select the required test sequence and press F3 (EDIT)

Use the RTE to select the individual test and press F3 (EDIT).

If an individual test needs adding to the sequence, use the RTE to highlight a position within the sequence and press F2 (ADD). Note that the new test will be added after the highlighted position. See chapter 5.1.1 for details on changing individual test settings.

Edit Test Sequence					
Name NEW SEQUENCE					
Rem Test	Rem Test				
HF Test -	HF Test - 1211				
HF Test -	1212				
HF Test -	1221				
HF Test -	1222				
Graph power Test					
+	Add	Edit	Delete		

Repeat the action above until the required result has been achieved.

Save the test sequence by exiting the screens using F1 (back) and confirm by pressing SAVE (F4) or exit without changes by pressing F1 (NO)

#### 5.1.3. Options menu

In the options menu, the test sequence can be copied, deleted or remaned. Use the function keys or rotary encoder to navigate.



## 5.2. Time Date

To modify the time or date including time format (12 / 24h clock), select the Time / Date option in the setup menu (see below;

Setup		Time / Datep			
Test Sequence		Time		12 · 20 · 4	51
Time / Date		- Think			<u>,</u>
Language		Date		24:08:1	11
Factory Restore					
About					
Test Seq Tin	e About	+	12		Save

Use the rotary encoder to navigate, push to activate field and change values using the rotary encoder. Press the Save (F4) button to confirm.

## 5.3. Language

To change the language, select the language option in the setup menu, see below;

Setup	Language
Test Sequence Time / Date <mark>Language</mark> Factory Restore Memory Option About	<mark>English</mark> French Spanish Italian
Test Seq Time About	-

Use the rotary encoder to navigate, push to select the language. Press the back button (F1) to confirm or return to previous menu.

## 5.4. Factory reset

Restore instrument to factory default settings will delete all user created test sequences. Test result memory will not be affected. To clear results see chapter **Error! Reference source not found.** 

To restore factory default, select the factory restore option in the setup menu, see below;

Setup	Factory Restore	
Test Sequence Time / Date	Are You Sure?	
Factory Restore Memory Option About	Factory Restore Will Delete All Test Sequences	
Test Seq Time About	No Yes	

Confirm by pressing F4 (yes) or F1 (NO).

### 5.5. Memory options

The memory options menu provides an overview of the number of stored records, the % of free memory and allows the user to clear the memory.

Individual assets can be delete from the view data menu, see chapter **Error! Reference** source not found.

To view or clear the memory status, press memory options from the setup menu, see below;

Setup			Memory Option			
Test Sequence			Total As	set		1
Time / Date Language Factory Restore			Total Memory Free 100.0%		100.0%	
Memory Option	Memory Option		Are You Sure?			
About		Erase Memory				
Test Seq	Time	About	No			Yes

To return to the previous menu, press F1 (NO). To clear the memory, press F4 (YES)

## 5.6. About

The about screen shows the firmware versions, serial number and contact information. Ensure you have this information available when contacting Rigel Medical for Technical Support or Service. See section 5.3 for more information on Service and Calibration.

Setup					
Test Sequence Time / Date Language Factory Restore Memory Option <mark>About</mark>					
╋	Test Seq	Time	About		
	About				
Displa	Display Version 4.06				
IO Co	ntrol	4.03			
Measu	irement	4.02			
Support: (+44) 191 587 8701					
Support@rigeImedical.com					
Serial Number: 19c-0444					
<b>-</b>					

## 6. Maintaining the Rigel 377

## 6.1. Cleaning the Analyser

The Rigel 377 case can be cleaned with a damp cloth with, if necessary, a small amount of mild detergent. Prevent excessive moisture around the socket panel.

Do not allow liquid inside the Rigel 377 or near the sockets. Do not use: abrasives, solvents, or alcohol.

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

## 6.2. User Maintenance

The Rigel 377 is a rugged quality instrument. However, care should always be taken when using, transporting and storing this type of equipment. Failure to treat the product with care will reduce both the life of the instrument and its reliability.

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

- Always check the Rigel 377 and all test leads for signs of damage and wear before use.
- Do not open the Rigel 377 under any circumstances.
- Keep the instrument clean and dry.
- Avoid testing in conditions of high electrostatic or electromagnetic fields.
- Maintenance should only be performed by authorised personnel.
- Apart from the mains cable and fuses, there are no user replaceable parts in the Rigel 377.
- The unit should be regularly calibrated.

### 6.3. Firmware Upgrade

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

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

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

## 6.4. Return Instructions.

#### For repair or calibration return the instrument to:-

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

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

sales@rigeImedical.com

calibration@seaward.co.uk

#### www.seaward.co.uk

#### www.rigelmedical.com

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

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

When asking for a Returns Number, please quote:

- Instruments name and model
- Serial number
- Firmware version

## 7. Specifications

### 7.1. Technical Specification

#### HF Power Watt (RMS)

Accuracy

HF Current (RMS) Accuracy

Voltage (RMS) Accuracy

Voltage (peak) Accuracy

**Crest Factor** 

RMS Bandwidth Interference Frequency Filter Isolation (earth to measurement device)

#### Measurement delay adjustment

Variable Load

Load Resistor Type Accuracy Power rating Duty cycle \* (see load rating graph below)

Fixed Loads Accuracy Power rating

#### Plate Security (REM) resistor

Accuracy Alarm register Ranging

#### Oscilloscope output

Connections Variable load  $10 - 5100\Omega$ Fixed Load x 200 $\Omega$ Measuring device (MD) Oscilloscope output

REM test 0-500 ohm Remote foot switch control (CUT) Remote foot switch control (COAG)

#### **USB** port

True RMS Watts (0 -500W) Refer to load/power graph) ±5%,±1W of value

0 – 2200mA ±2%,±10mA of value

0 - 700V ±3%, ± 5V of value

0 - 10KV (Peak) – Closed load only  $\pm 10\% \pm 50$ V of value.

1.4 - 20 (± Vpeak / V RMS)

30 Hz to 2.5 MHz (-3 dB) 100 Hz high pass filter 10kV

200 - 2000ms (10ms resolution)

 $10 - 5100\Omega$ , steps @  $10\Omega$ Ceramic Resistors (Non inductive)  $\pm 1\%$ , + 0.5, -0.0  $\Omega$  of set load (Refer to load/power graph) 50%

2 x 200Ω ±1%, + 0.5,-0.0 Ω 150 Watt (50% duty cycle)

0 - 500 $\Omega$ , 1 $\Omega$  step Motor driven potentiometer ±5% ± 2  $\Omega$ High and low, manual confirmation Manual or automatic

5V/A, un-calibrated , indication only

2 x 4mm Red = Active, Black = Plate 1 x 4 mm - black (common), 2 x 4 mm - red 2 x 4mm White SMB coaxial connector

2 x 4 mm - black 2 x 4 mm - yellow, Single relay contact 2 x 4 mm - blue, Single relay contact

PC interface

### Load Power rating Rigel 377

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



## 7.2. General Specification

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

## Appendix A IEC 60601-2-2 Leakage Tests

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



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



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



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

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

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







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

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

MEASUREMENT OF H.F. LEAKAGE CURRENT FROM

IEC 601-2-2 part 1, FIGURE 104

A BIPOLAR ELECTRODE EARTH `REFERENCED ESU BIPOLAR ELECTRODE

CUT MODE

**FIRST ELECTRODE** 

**TEST CODE 2111** 









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

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







#### TEST CODE 2211

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

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









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

TEST CODE 2222

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

## Appendix B IEC 60601-2-2 Power Tests

TEST CODE 0110

TEST CODE 0210

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



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

IEC 601-2-2 part 1 FIGURE 105

MONO-POLAR OUTPUT USER SET LOAD RESISTANCE MONO-POLAR ELECTRODE

CUT MODE

MEASUREMENT OF OUTPUT POWER

ACTIVE AND NEUTRAL ELECTRODE







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

# Appendix C Firmware Route Map

#### Menu

Auto Mode

Data		
	View Data	
	Transfer	Download data Upload data Upload reference curves Transfer test sequences
Setup	Bluetooth Favourites	
octup	Test Sequences	View, create and edit test sequences
	Time Date	Change time and date settings
	Language	Change language settings
	Factory reset	Restore instrument to factory default
	Memory options	View memory capacity, clear all
	About	View firmware revision and serial number.
REM test		Manual testing of the REM function
HF Leakage		Manual testing of the HF leakage
Power		Manual testing of the Power output