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# Rigel 601 CHECKBOX

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*Instruction Manual*

348A551 Issue 2.0

April 2006

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Issue 2.0

## **Limited Warranty & Limitation of Liability**

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

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Due to a policy of continuous development SEAWARD Electronic Limited 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.

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# ***Declaration of Conformity***

## ***The Rigel 601 Electrical Medical Safety Analyser Checker***

### **Manufactured by:**

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

### **Millennium Statement**

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

### **Statement of Conformity**

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

### **Standards used:**


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

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

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

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

The tests have been performed in a typical configuration.

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

## ***Before Starting***

Upon receipt of your Rigel-601 Checkbox:-

1. Check that all the component parts are present:-
  - Rigel 601 Checkbox Unit
  - Instruction manual
  - Function Earth Lead (green) with Crocodile clip
  - Calibration Certificate
2. Read the operating instructions fully before conducting any tests.
3. Contact Rigel Medical if you require training on this Analyser or any other Rigel Medical product. Courses can be arranged at Rigel Medical, or at customer premises.
4. Rigel Medical can be contacted at:

P/A Seaward Electronic Ltd  
Bracken Hill  
South West Industrial Estate  
Peterlee, Co. Durham  
SR8 2SW, England  
Tel : +44 (0)191 587 8730  
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[sales@rigelmedical.com](mailto:sales@rigelmedical.com)  
[calibration@seaward.co.uk](mailto:calibration@seaward.co.uk)

[www.rigelmedical.com](http://www.rigelmedical.com)

## **SAFETY NOTICE**

### **READ INSTRUCTION BEFORE USE**

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.

Check the unit regularly for damage to cable or casing.

## **IMPORTANT!**

NEVER PLUG THE RIGEL 601 CHECKBOX, OR ANY OF ITS CONNECTIONS, DIRECTLY INTO THE MAINS SUPPLY.

DO NOT TOUCH THE RIGEL 601 CHECKBOX WHILE CARRYING OUT TESTS.



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



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

## ***Introduction***

The Rigel 601 Checkbox has been designed to provide an accurate and effective means of checking the accuracy of most IEC 60601-1 Electrical Medical Safety Analysers (from now on referred to as EMSA).

With the ability to generate both AC and DC leakage currents as well offering dedicated F-type circuitry, the Rigel 601 is able to provide traceable values for Earth Leakage, Enclosure Leakage, Patient Leakage and Patient Leakage Mains on Applied Parts.

In addition, the Rigel 601 is able to provide a series of highly accurate resistance values to check the linearity of the Earth Bond and Insulation measuring circuits.

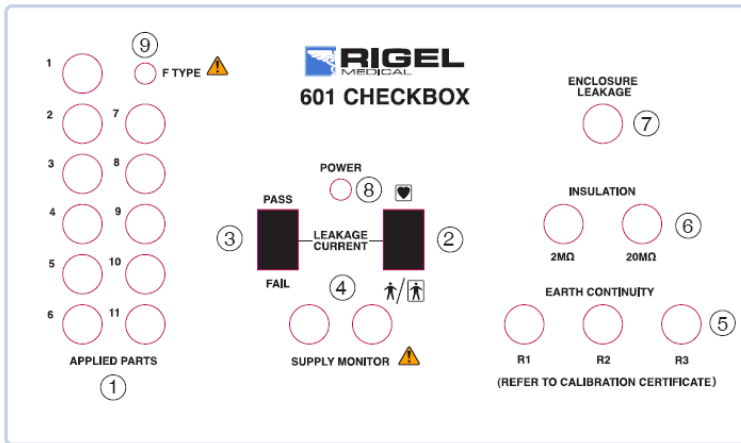
Dedicated switch positions provide individual PASS and FAIL values for B/BF and CF limits as per IEC 60601-1.

With the use of high precision resistors, the Rigel 601 has a recommended calibration interval of 36 months, providing a stable and accurate reference for all IEC 60601-1 safety analysers for years to come.

The Rigel 601 provides separate PASS / FAIL limits for B/BF and CF equipment as per IEC 60601-1 (See tabel T1). A dedicate switch provides either a PASS or FAIL result by generating leakage at 15% under the IEC 60601 limit (PASS) or 15% over the IEC 60601 limit (FAIL)

The Rigel 601 Checkbox is not intended to replace the annual calibration should your quality assurance procedure require it.

# Connections



**Figure 1 Connections**

## Key

- (1) Applied parts connections
- (2) B-BF / CF switch
- (3) PASS / FAIL switch
- (4) Supply monitor outlet
- (5) Earth Bond connections (see calibration certificate for values)
- (6) Insulation Test connections
- (7) Enclosure Leakage connection
- (8) Power input indicator
- (9) F-type Leakage Test indicator



## Using the Rigel 601 Checkbox

The Rigel 601 Checkbox is NOT designed to be directly connected to a mains outlet. Doing so might cause a danger to the operator or damage the Checkbox.

Diagram 1 shows the correct connection of the Rigel 601 Checkbox.

To connect the Rigel 601 Checkbox to your Electrical Medical Safety Analyser, plus the power cable into the EUT / DUT socket of the EMSA. In addition, connect the Function Earth Lead (green cable) to an external earth conductor. By not connecting the Green Earth lead, the simulated leakage values might be incorrect.

Connect the Earthbond test lead to one of the test points R1-R3 (5). Connect your test lead for Enclosure Leakage to terminal (7). In case Patient Connections are required, use up to 11 connections provided under Applied Parts (1).

Note that the Rigel 601 Checkbox uses an internal Isolation Transformer. For this reason, the Checkbox will not produce any correct leakage values when used under Open Neutral single fault condition.

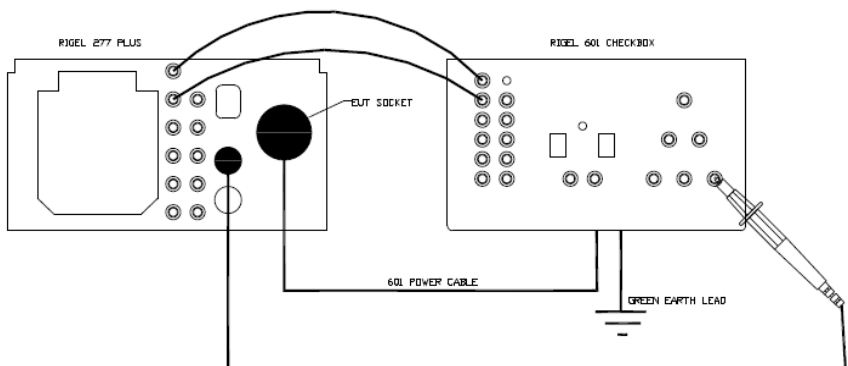


Diagram 1

## **Verifying the Earth Bond Test Measurement**

- a) Connect the Earth Bond Probe to the required Earth Continuity test point (See Fig. 1 (5)).
- b) Carry out the Earth Bond Test. The reading on the EMSA should correspond with the value written beneath the Test Point within the specified limits for the particular EMSA.
- c) Repeat the procedure for each of the Earth Continuity connections, as appropriate, to check for accuracy at each of the critical values.

## **Verifying the Insulation Test Measurement**

- a) Connect the Test Probe (Earth Bond Probe on Rigel EMSA) to the required test point on the Checkbox (See Fig. 1 (6)).
- b) Perform the Insulation Test and confirm that the Insulation reading corresponds with the value of the test point and is within the specified limits for the particular EMSA.
- c) Repeat the procedure for each of the Insulation Test connections, as appropriate, to check for accuracy at each of the critical values.

## **Verifying the Earth Leakage Test Measurement**

- a) Plug the appropriate Test Probe into the Enclosure Leakage test point (Fig. 1 (7)).
- b) Plug a meter into the supply monitor sockets for accurate Line Voltage Indication (Fig. 1 (4)).
- c) Set the PASS / FAIL switch to PASS.
- d) Perform an Earth Leakage Test.
- e) The measured value should correspond to the -15% EARTH value scaled to reflect the actual mains test voltage as described in Table 1 and the equation shown beneath it, or refer to Appendix 1 and cross reference the test data from the column headed with nearest voltage level.
- f) Once complete, set the PASS / FAIL switch to FAIL.
- g) Carry out another Earth Leakage Test.
- h) The measured value should correspond to the +15% EARTH value scaled to reflect the actual mains test voltage as described in Table 1 and the equation shown beneath it, or refer to Appendix 1 and cross reference the test data from the column headed with nearest voltage level.

## **Verifying the Enclosure Leakage Test Measurement**

- a) Plug the appropriate Test Probe into the Enclosure Leakage test point.
- b) Plug a meter into the supply monitor sockets.
- c) Set the PASS / FAIL switch to PASS.
- d) Perform an Enclosure Leakage Test.
- e) The measured value should correspond to the -15% ENCLOSURE value scaled to reflect the actual mains test voltage as described in Table 1 and the equation shown beneath it, or refer to Appendix 1 and cross reference the test data from the column headed with nearest voltage level.
- f) Once complete, set the PASS / FAIL switch to FAIL.
- g) Carry out another Enclosure Leakage Test.
- h) The measured value should correspond to the +15% ENCLOSURE value scaled to reflect the actual mains test voltage as described in Table 1 and the equation shown beneath it, or refer to Appendix 1 and cross reference the test data from the column headed with nearest voltage level.

## **Verifying the Patient Leakage Test Measurement**

- a) Plug a meter into the supply monitor sockets.
- b) Set the PASS / FAIL switch to PASS.
- c) Set the CF / B-BF switch to B-BF.
- d) Perform a Patient Leakage Test with the EMSA set to B or BF - if applicable.
- e) The measured value should correspond to the -15% PATIENT LEAKAGE AC (B-BF) and -50% PATIENT LEAKAGE DC values scaled to reflect the actual mains test voltage as described in Table 1 and the equation shown beneath it, or refer to Appendix 1 and cross reference the test data from the column headed with nearest voltage level.
- f) Once complete, set the PASS / FAIL switch to FAIL.
- g) Carry out another Patient Leakage Test with the EMSA set to B or BF - if applicable.
- h) The measured value should correspond to the +15% PATIENT LEAKAGE AC (B-BF) and +50% PATIENT LEAKAGE DC values scaled to reflect the actual mains test voltage as described in Table 1 and the equation shown beneath it, or refer to Appendix 1 and cross reference the test data from the column headed with nearest voltage level.

- i) If necessary, repeat the Patient Leakage Tests for separate measurement of AC and DC readings.
- j) Set the PASS / FAIL switch to PASS.
- k) Set the CF / B-BF switch to CF.
- l) Perform a Patient Leakage Test with the EMSA set to CF - if applicable.
- m) The measured value should correspond to the -15% PATIENT LEAKAGE AC (CF) and -50% PATIENT LEAKAGE DC values scaled to reflect the actual mains test voltage as described in Table 1 and the equation shown beneath it, or refer to Appendix 1 and cross reference the test data from the column headed with nearest voltage level.
- n) Once complete, set the PASS / FAIL switch to FAIL.
- o) Carry out another Patient Leakage Test with the EMSA set to CF - if applicable.
- p) The measured value should correspond to the +15% PATIENT LEAKAGE AC (CF) and +50% PATIENT LEAKAGE DC values scaled to reflect the actual mains test voltage as described in Table 1 and the equation shown beneath it, or refer to Appendix 1 and cross reference the test data from the column headed with nearest voltage level.
- q) If necessary, repeat the Patient Leakage Tests for separate measurement of AC and DC readings.

### **Verifying the F-Type Patient Leakage Test Measurement**

- a) Set the PASS / FAIL switch to PASS.
- b) Set the CF / B-BF switch to B-BF.
- c) Perform an F-type Patient Leakage Test.
- d) The measured value will depend on the specific characteristics of the EMSA under test and as such should be taken as a guide only.
- e) Set the CF / B-BF switch to CF.
- f) Perform an F-type Patient Leakage Test.
- g) The measured value will depend on the specific characteristics of the EMSA under test and as such should be taken as a guide only.

## **Table of Leakage Test Values**

Mains Voltage (V)			210V	220V	<b>230V</b>	240V	250V
Earth Leakage	0.500 mA	-15%	0.388	0.407	<b>0.425</b>	0.443	0.462
		+15%	0.525	0.550	<b>0.575</b>	0.600	0.625
Enclosure Leakage	0.100 mA	-15%	0.078	0.081	<b>0.085</b>	0.089	0.092
		+15%	0.105	0.110	<b>0.115</b>	0.120	0.125
Patient Leakage AC (B/BF)	0.100 mA	-15%	0.078	0.081	<b>0.085</b>	0.089	0.092
		+15%	0.105	0.110	<b>0.115</b>	0.120	0.125
Patient Leakage AC (CF)	0.010 mA	-15%	0.008	0.009	<b>0.009</b>	0.009	0.010
		+15%	0.011	0.011	<b>0.012</b>	0.013	0.013
Patient Leakage DC	0.010 mA	-50%	0.005	0.005	<b>0.005</b>	0.005	0.005
		+50%	0.014	0.014	<b>0.015</b>	0.016	0.016
F-Type Leakage BF (Nominal) CF		-50%			<b>2.500</b>		
		-50%			<b>0.025</b>		

NOTE: The table above only gives mA values corresponding to 10V-steps of Mains voltage and as such are included for guidance only. In order to gain a more accurate value it is necessary to either refer to Appendix 1 or connect a meter to the supply monitor (Fig. 1 (4)) and calculate the actual current using the equation below:-

$$I = \text{nominal current} \times \frac{\text{supply monitor voltage}}{230}$$

Where nominal current is that specified in the table under the 230V column.

## ***Specifications (15° to 30°C)***

Earth bond Test current	up to 25A AC or DC
Maximum test duration	10 seconds
Earth Bond Reading	Nominal values
Insulation Reading	+/- 1%
Earth Leakage	+/- 0.5%
Enclosure Leakage	+/- 0.5%
Patient Leakage	+/- 0.5%
Patient F-Type Leakage	Nominal values

## ***Environmental***

Operating	15°C to 30°C (non condensing)
Storage	0°C to 50°C (non condensing)
Maximum RH	90%
Supply Rating	230V +/- 10% 50/60Hz
Fuse Rating	2 x 1A 500V HRC
Protection Rating	IP40

## ***General***

Weight	< 3.2 kg
Size	250 * 140 * 200 mm

## ***Maintenance***

Ensure the unit is clean and dry before use.  
Check the condition of casing and cable regularly.  
Avoid storage in damp conditions and excessive temperature variations.

**Return for Re-calibration every 3 years.**

## ***Warranty & Repair***

**For calibration or repair please return the instrument to:-**

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

Tel : +44 (0)191 586 3511

Fax: +44 (0)191 586 0227

[sales@rigelmedical.com](mailto:sales@rigelmedical.com)

[calibration@seaward.co.uk](mailto:calibration@seaward.co.uk)

[www.rigelmedical.com](http://www.rigelmedical.com)

[www.seaward.co.uk](http://www.seaward.co.uk)

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
- Service request (ie calibration, repair )

Mains Voltage (V)	Limit		207V	208V	209V	210V	211V	212V	213V	214V	215V	216V
Earth Leakage	0.500 mA	-15%	0.383	0.384	0.386	0.388	0.39	0.392	0.394	0.395	0.397	0.399
		15%	0.518	0.52	0.523	0.525	0.528	0.53	0.533	0.535	0.538	0.54
Enclosure Leakage	0.100 mA	-15%	0.077	0.077	0.077	0.078	0.078	0.078	0.079	0.079	0.079	0.08
		15%	0.104	0.104	0.105	0.105	0.106	0.106	0.107	0.107	0.108	0.108
Patient Leakage AC (B/BF)	0.100 mA	-15%	0.077	0.077	0.077	0.078	0.078	0.078	0.079	0.079	0.079	0.08
		15%	0.104	0.104	0.105	0.105	0.106	0.106	0.107	0.107	0.108	0.108
Patient Leakage AC (CF)	0.010 mA	-15%	0.008	0.008	0.008	0.008	0.008	0.008	0.008	0.008	0.008	0.008
		15%	0.01	0.01	0.01	0.011	0.011	0.011	0.011	0.011	0.011	0.011
Patient Leakage DC	0.010 mA	-50%	0.005	0.005	0.005	0.005	0.005	0.005	0.005	0.005	0.005	0.005
		50%	0.014	0.014	0.014	0.014	0.014	0.014	0.014	0.014	0.014	0.014

Mains Voltage (V)	Limit		217	218	219	220	221	222	223	224	225	226
Earth Leakage	0.500 mA	-15%	0.401	0.403	0.405	0.407	0.408	0.410	0.412	0.414	0.416	0.418
		15%	0.543	0.545	0.548	0.550	0.553	0.555	0.558	0.560	0.563	0.565
Enclosure Leakage	0.100 mA	-15%	0.080	0.081	0.081	0.081	0.082	0.082	0.082	0.083	0.083	0.084
		15%	0.109	0.109	0.110	0.110	0.111	0.111	0.112	0.112	0.113	0.113
Patient Leakage AC (B/BF)	0.100 mA	-15%	0.080	0.081	0.081	0.081	0.082	0.082	0.082	0.083	0.083	0.084
		15%	0.109	0.109	0.110	0.110	0.111	0.111	0.112	0.112	0.113	0.113
Patient Leakage AC (CF)	0.010 mA	-15%	0.008	0.008	0.008	0.008	0.008	0.008	0.008	0.008	0.008	0.008
		15%	0.011	0.011	0.011	0.011	0.011	0.011	0.011	0.011	0.011	0.011
Patient Leakage DC	0.010 mA	-50%	0.005	0.005	0.005	0.005	0.005	0.005	0.005	0.005	0.005	0.005
		50%	0.014	0.014	0.014	0.014	0.014	0.014	0.015	0.015	0.015	0.015



Mains Voltage (V)	Limit		227V	228V	229V	230V	231V	232V	233V	234V	235V	236V
Earth Leakage	0.500 mA	-15%	0.419	0.421	0.423	0.425	0.427	0.429	0.431	0.432	0.434	0.436
		15%	0.568	0.570	0.573	0.575	0.578	0.580	0.583	0.585	0.588	0.590
Enclosure Leakage	0.100 mA	-15%	0.084	0.084	0.085	0.085	0.085	0.086	0.086	0.086	0.087	0.087
		15%	0.114	0.114	0.115	0.115	0.116	0.116	0.117	0.117	0.118	0.118
Patient Leakage AC (B/BF)	0.100 mA	-15%	0.084	0.084	0.085	0.085	0.085	0.086	0.086	0.086	0.087	0.087
		15%	0.114	0.114	0.115	0.115	0.116	0.116	0.117	0.117	0.118	0.118
Patient Leakage AC (CF)	0.010 mA	-15%	0.008	0.008	0.008	0.009	0.009	0.009	0.009	0.009	0.009	0.009
		15%	0.011	0.011	0.011	0.012	0.012	0.012	0.012	0.012	0.012	0.012
Patient Leakage DC	0.010 mA	-50%	0.005	0.005	0.005	0.005	0.005	0.005	0.005	0.005	0.005	0.005
		50%	0.015	0.015	0.015	0.015	0.015	0.015	0.015	0.015	0.015	0.015

Mains Voltage (V)	Limit		237V	238V	239V	240V	241V	242V	243V	244V	245V	246V
Earth Leakage	0.500 mA	-15%	0.438	0.440	0.442	0.443	0.445	0.447	0.449	0.451	0.453	0.455
		15%	0.593	0.595	0.598	0.600	0.603	0.605	0.608	0.610	0.613	0.615
Enclosure Leakage	0.100 mA	-15%	0.088	0.088	0.088	0.089	0.089	0.089	0.090	0.090	0.091	0.091
		15%	0.119	0.119	0.120	0.120	0.121	0.121	0.122	0.122	0.123	0.123
Patient Leakage AC (B/BF)	0.100 mA	-15%	0.088	0.088	0.088	0.089	0.089	0.089	0.090	0.090	0.091	0.091
		15%	0.119	0.119	0.120	0.120	0.121	0.121	0.122	0.122	0.123	0.123
Patient Leakage AC (CF)	0.010 mA	-15%	0.009	0.009	0.009	0.009	0.009	0.009	0.009	0.009	0.009	0.009
		15%	0.012	0.012	0.012	0.012	0.012	0.012	0.012	0.012	0.012	0.012
Patient Leakage DC	0.010 mA	-50%	0.005	0.005	0.005	0.005	0.005	0.005	0.005	0.005	0.005	0.005
		50%	0.015	0.016	0.016	0.016	0.016	0.016	0.016	0.016	0.016	0.016

Mains Voltage (V)	Limit		247V	248V	249V	250V	251V	252V	253V			
Earth Leakage	0.500 mA	-15%	0.456	0.458	0.460	0.462	0.464	0.466	0.468			
		15%	0.618	0.620	0.623	0.625	0.628	0.630	0.633			
Enclosure Leakage	0.100 mA	-15%	0.091	0.092	0.092	0.092	0.093	0.093	0.094			
		15%	0.124	0.124	0.125	0.125	0.126	0.126	0.127			
Patient Leakage AC (B/BF)	0.100 mA	-15%	0.091	0.092	0.092	0.092	0.093	0.093	0.094			
		15%	0.124	0.124	0.125	0.125	0.126	0.126	0.127			
Patient Leakage AC (CF)	0.010 mA	-15%	0.009	0.009	0.009	0.009	0.009	0.009	0.009			
		15%	0.012	0.012	0.012	0.013	0.013	0.013	0.013			
Patient Leakage DC	0.010 mA	-50%	0.005	0.005	0.005	0.005	0.005	0.005	0.006			
		50%	0.016	0.016	0.016	0.016	0.016	0.016	0.017			