

Certificate of Calibration

FLUKE

Tektronix

KEITHLEY

Certificate No.: 1418558
Number of pages: 8
Issue date: 10 Feb 2015

Model ESA615
Description ELECTRICAL SAFETY ANALYZER
Manufacturer FLUKE BIOMEDICAL
Serial number 2433026
Inventory number -

Customer VIAMED LTD
KEIGHLEY
Site number 5900954

Date of calibration 10 Feb 2015
Date of recalibration 10 Feb 2016
Calibration location Son
Tested by P. van Duivenbode



G.J.J. Sprik

Head of laboratory

We confirm that, the instrument meets or exceeds the manufacturers published specifications at the points tested. All measurements are traceable to national and/or international standards or have been derived by approved ratio techniques. This certificate may not be reproduced other than in full. Calibration certificates without signature are not valid.

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IDENTIFICATION:

Unit under test ESA615
Serial number 2433026
Inventory number -

CALIBRATION CONDITIONS:

Environmental temperature (23 ± 3) °C
Humidity relative (45 ± 20) %rh

SUMMARY CALIBRATION INFORMATION:

Procedure	Completed		
Failed test(s)	0		
Outgoing status	Conform specifications		
Calibration procedure	Fluke :ESA615 :Cal :SWB	:5520 :BMS	Rev: 3.6F
Remarks			

REMARK:

The following pages contains the calibrations results with two further columns indicating the instrument performance relative to the stated specifications.

The column headed '% of Tol' is the measured error as percentage of the stated limits with no allowance being made for the calibration uncertainty.

The column headed 'Uncertainty' indicates compliance or otherwise with specification taking into account the measurement uncertainty, the four possible conditions are indicated as follows:

Indicator	Explanation
Blank, No indicator	The equipment complies with the stated specification at the measured points, due allowance having been made for the uncertainty of the measurements.
?	The measurement result is within the specification limit by a margin less than the measurement uncertainty; it is therefore not possible to state compliance based on the stated level of confidence. However the results indicate that compliance is more probable than non-compliance with the specification limit.
??	The measurement result is outside the specification limit by a margin less than the measurement uncertainty; it is therefore not possible to state non-compliance based on the stated level of confidence. However the results indicate that non-compliance is more probable than compliance with the specification limit.
Fail	The equipment does not comply with the stated specification at the measured points, due allowance having been made for the uncertainty of the measurements.

The uncertainty values reported in the tables of results have been obtained taking into account all contributing factors to uncertainty affecting the measurement, including those deriving from the resolution and from the short-term stability of the instrument being calibrated. The reported absolute uncertainty is based on the standard uncertainty multiplied by a coverage factor $k = 2$, which provides a confidence level of approximately 95%. The standard uncertainty has been determined in accordance with EA-4/02.

This unit under test is equipped with a line voltage power supply, and a safety test was performed according to the European norm 'Operation of electrical installations' NEN-EN 50110-1 release 2005 and the Dutch norm NEN 3140 release 2011 paragraph 5.102.12 through 5.102.16.

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Standards and test-equipment used for this calibration:

Model:	Serial No:	Inventory No:	Due to:	Certificate No:
5520A/1GHZ	8600003	WP1019	28 Feb 2015	1204041A
8846A	9636020	WP1213	03 Jul 2015	1315207
34970A	MY44061803	WP1598	20 May 2015	WP1598-0514
TESTBOX 7	30011210	WP1709	03 Mar 2015	1224754
6221	1386664	WP1726	11 Sep 2015	1340660

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Supplied value	Range	Lower limit	Measured value	Upper limit	Unit	% of Tol	Uncertainty
UI firmware revision: 2.06.07							
MTR firmware revision: 2.06.07							
Functional tests							
Red warning LED test			Pass				
Beeper test			Pass				
Keyboard test			Pass				
Display contrast test			Pass				
Display pixel test			Pass				
Display backlight test			Pass				
Test receptacle verification							
230 VAC : Norm Pol, Closed Neut, Closed Gnd.			Pass				
230 VAC : Norm Pol, Closed Neut, Open Gnd.			Pass				
230 VAC : Norm Pol, Open Neut, Closed Gnd.			Pass				
230 VAC : Rev Pol, Open Neut, Closed Gnd.			Pass				
230 VAC : Rev Pol, Closed Neut, Closed Gnd.			Pass				
230 VAC : Rev Pol, Closed Neut, Open Gnd.			Pass				
Equipment Outlet tests							
EO Ground to NULL Jack: CLOSED			Pass				
EO Ground to NULL Jack: OPEN			Pass				
GFI tests							
5 mA GFI TEST LIMIT @ 4.5 mA AC			Pass				
5 mA GFI TRIPPED @ 5.5 mA AC			Pass				
10 mA GFI TEST LIMIT @ 9 mA AC			Pass				
10 mA GFI TRIPPED @ 11 mA AC			Pass				
25 mA GFI TEST LIMIT @ 22.5 mA AC			Pass				
25 mA GFI TRIPPED @ 27.5 mA AC			Pass				
Voltage calibration							
point to point mode:							
1.00	V	100	Hz	0.8	1.0	1.2	V 0 5.8e-002 V
4.00	V	100	Hz	3.7	4.0	4.3	V 2 5.8e-002 V
8.00	V	100	Hz	7.6	8.0	8.4	V 5 5.8e-002 V
10.00	V	100	Hz	9.6	10.0	10.4	V 5 5.8e-002 V
25.00	V	100	Hz	24.3	25.0	25.7	V 3 5.8e-002 V
40.00	V	100	Hz	39.0	39.9	41.0	V 8 5.8e-002 V
80.00	V	100	Hz	78.2	79.8	81.8	V 12 5.9e-002 V
130.00	V	100	Hz	127.2	129.7	132.8	V 9 6.1e-002 V
240.00	V	100	Hz	235.0	239.6	245.0	V 8 6.9e-002 V
250.00	V	100	Hz	244.8	249.6	255.2	V 7 6.9e-002 V
mains mode:							
L to N							
229.91	V	50	Hz	225.1	229.9	234.7	V 1 2.9e-001 V
L to PE							
229.91	V	50	Hz	225.1	229.9	234.7	V 1 2.9e-001 V

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Supplied value		Range	Lower limit	Measured value	Upper limit	Unit	% of Tol	Uncertainty
Resistance calibration point to point mode								
1.8075	Ω	2	1.756	1.816	1.859	Ω	16	6.0e-004 Ω
ground mode								
0.1472	Ω	2	0.129	0.142	0.165	Ω	28	5.8e-004 Ω
0.2060	Ω	2	0.187	0.208	0.225	Ω	9	5.8e-004 Ω
0.3051	Ω	2	0.284	0.308	0.326	Ω	11	5.8e-004 Ω
0.5099	Ω	2	0.485	0.513	0.535	Ω	13	5.8e-004 Ω
1.8077	Ω	2	1.756	1.816	1.859	Ω	16	6.0e-004 Ω
Insulation resistance calibration output voltage:								
250	V		250.0	263.2	300.0	V	26	5.8e-001 V
500	V		500.0	529.1	600.0	V	29	5.8e-001 V
short circuit current:								
2.00	mA		1.750	1.958	2.250	mA	17	6.2e-006 A
MAINS - PE								
9.97	MΩ	20	9.6	9.9	10.4	MΩ	21	5.8e+004 Ω
AP - PE								
9.97	MΩ	20	9.6	9.9	10.4	MΩ	20	5.8e+004 Ω
AP - NE								
9.97	MΩ	20	9.6	9.9	10.4	MΩ	19	5.8e+004 Ω
MAINS - NE								
9.97	MΩ	20	9.6	9.9	10.4	MΩ	20	5.8e+004 Ω
MAINS - AP								
9.97	MΩ	RA	9.6	9.9	10.4	MΩ	20	5.8e+004 Ω
9.97	MΩ	LL	9.6	9.9	10.4	MΩ	19	5.8e+004 Ω
9.97	MΩ	LA	9.6	9.9	10.4	MΩ	18	5.8e+004 Ω
9.97	MΩ	RL	9.6	9.9	10.4	MΩ	19	5.8e+004 Ω
9.97	MΩ	V1	9.6	9.9	10.4	MΩ	19	5.8e+004 Ω
range calibration:								
0.70	MΩ	250	0.5	0.7	0.9	MΩ	2	5.8e+004 Ω
0.70	MΩ	500	0.5	0.7	0.9	MΩ	2	5.8e+004 Ω
1.00	MΩ	250	0.8	1.0	1.2	MΩ	3	5.8e+004 Ω
1.00	MΩ	500	0.8	1.0	1.2	MΩ	2	5.8e+004 Ω
6.49	MΩ	250	6.2	6.5	6.8	MΩ	5	5.8e+004 Ω
6.49	MΩ	500	6.2	6.4	6.8	MΩ	13	5.8e+004 Ω
17.95	MΩ	250	17.4	17.8	18.5	MΩ	21	6.5e+004 Ω
17.95	MΩ	500	17.4	17.8	18.5	MΩ	18	6.5e+004 Ω
21.86	MΩ	250	20.0	21.7	23.7	MΩ	8	6.5e+004 Ω
21.86	MΩ	500	20.0	21.7	23.7	MΩ	9	6.5e+004 Ω
59.54	MΩ	250	54.9	59.4	64.2	MΩ	4	6.5e+004 Ω

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59.54	MΩ	500 V	100	54.9	59.3	MΩ	5	6.5e+004 Ω
99.52	MΩ	250 V	100	91.9	99.1	MΩ	6	6.5e+004 Ω
99.52	MΩ	500 V	100	91.9	98.8	MΩ	10	6.5e+004 Ω
DC Leakage resistance calibration								
1.0000	kΩ		0.98000	0.99972	1.02000	kΩ	1	1.0e-001 Ω
DC Leakage current calibration								
10.00	µA		200	8.9	9.7	µA	31	6.0e-008 A
50.00	µA		200	48.5	49.9	µA	9	6.2e-008 A
100.00	µA		200	98.0	100.2	µA	7	6.4e-008 A
160.00	µA		200	157.4	160.4	µA	17	6.7e-008 A
340.0	µA		2000	336	341	µA	22	5.8e-007 A
500.0	µA		2000	494	502	µA	27	5.8e-007 A
1000.0	µA		2000	989	1004	µA	32	5.9e-007 A
1600.0	µA		2000	1583	1606	µA	34	6.0e-007 A
3.400	mA		10	3.36	3.41	mA	20	5.8e-006 A
5.000	mA		10	4.94	5.01	mA	22	5.8e-006 A
7.000	mA		10	6.92	7.02	mA	25	5.8e-006 A
AC Leakage filter transfer ratio calibration								
0.9980	mA/mA	50 Hz		0.988	1.000	mA/mA	24	2.5e-003 mA/mA
0.6910	mA/mA	1 kHz		0.672	0.693	mA/mA	9	2.5e-003 mA/mA
0.0956	mA/mA	10 kHz		0.089	0.096	mA/mA	4	7.1e-003 mA/mA
?								
Differential leakage current calibration								
76.7	µA	50 Hz	200	47	101	µA	81	5.9e-007 A
160.8	µA	50 Hz	200	122	188	µA	70	7.2e-007 A
240.6	µA	50 Hz	2000	194	270	µA	63	7.6e-007 A
499.7	µA	50 Hz	2000	425	543	µA	58	9.1e-007 A
758.0	µA	50 Hz	2000	656	816	µA	57	1.1e-006 A
1597.7	µA	50 Hz	2000	1408	1700	µA	54	6.5e-006 A
2.394	mA	50 Hz	20	2.12	2.54	mA	52	9.4e-006 A
4.998	mA	50 Hz	20	4.45	5.26	mA	48	1.2e-005 A
7.703	mA	50 Hz	20	6.88	8.08	mA	45	1.5e-005 A
16.410	mA	50 Hz	20	14.68	17.09	mA	40	4.4e-005 A
ECG Leakage current functionality tests								
RA lead:								
100uA level test					Pass			
Opened contact resistance					Pass			
Closed contact resistance					Pass			
LL lead:								
100uA level test					Pass			
Opened contact resistance					Pass			
Closed contact resistance					Pass			
LA lead:								
100uA level test					Pass			
Opened contact resistance					Pass			
Closed contact resistance					Pass			

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RL lead:							
100uA level test					Pass		
Opened contact resistance					Pass		
Closed contact resistance					Pass		
V1 lead:							
100uA level test					Pass		
Opened contact resistance					Pass		
Closed contact resistance					Pass		
Direct/Alternative AP leakage current calibration							
RA-LL to GROUND							
957.9 μA	50 Hz	2000	917	957	999 μA	2	1.3e-006 A
ALL to GROUND							
968.5 μA	50 Hz	2000	928	959	1009 μA	23	1.3e-006 A
RA-LL to RED							
957.6 μA	50 Hz	2000	917	958	998 μA	1	1.3e-006 A
ALL to RED							
968.3 μA	50 Hz	2000	927	959	1009 μA	23	1.3e-006 A
Alternative Equipment leakage current calibration							
RED to HOT							
971.4 μA	50 Hz	2000	930	970	1013 μA	3	1.3e-006 A
RA to HOT							
971.2 μA	50 Hz	2000	930	969	1012 μA	5	1.3e-006 A
968.2 μA	50 Hz	2000	927	957	1009 μA	28	1.3e-006 A
Alternative AP Patient leakage current calibration							
RA to NEUTRAL							
968.2 μA	50 Hz	2000	927	957	1009 μA	28	1.3e-006 A
Patient Auxiliary leakage current calibration							
RA to RL							
100.22 μA	100 Hz	200	96.7	99.9	103.7 μA	10	1.7e-007 A
Direct Equipment/Patient leakage current calibration							
RA to GROUND							
100.12 μA	100 Hz	200	96.6	99.9	103.6 μA	5	1.7e-007 A
100.14 μA	100 Hz	200	96.6	99.9	103.6 μA	7	1.7e-007 A
Direct Equipment/Enclosure leakage current calibration							
RED to GROUND							
100.12 μA	100 Hz	200	96.6	99.9	103.6 μA	6	1.7e-007 A
100.14 μA	100 Hz	200	96.6	99.9	103.6 μA	6	1.7e-007 A
DC Filter test					Pass		
AC Filter test					Pass		
MAP Voltage and current limit calibration							
230.0 V	50 Hz		213.90	233.30	246.10 V	21	2.9e-001 V

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3.5 mA	50 Hz	2.63	3.50	4.38	mA	1	5.8e-005 A
7.5 mA	50 Hz	5.63	7.17	9.38	mA	18	5.9e-005 A
1.0 mA	50 Hz	0.75	1.16	1.25	mA	65	5.8e-005 A
ECG Waveform calibration							
ECG frequency:							
10.00 Hz		9.800	10.000	10.200	Hz	0	6.2e-003 Hz
ECG amplitudes:							
RA to RL							
0.6740 mV		0.640	0.684	0.708	mV	28	3.6e-006 V
LL to RL							
1.6730 mV		1.588	1.700	1.758	mV	31	3.6e-006 V
LA to RL							
1.3840 mV		1.314	1.404	1.454	mV	28	3.6e-006 V
V1 to RL							
2.0740 mV		1.969	2.103	2.179	mV	27	3.6e-006 V
Equipment current calibration							
Normal mains polarity:							
1.18 A	50 Hz	20	0.9	1.2	A	7	5.8e-002 A
2.12 A	50 Hz	20	1.8	2.1	A	6	5.8e-002 A
4.01 A	50 Hz	20	3.6	4.0	A	5	5.8e-002 A
7.99 A	50 Hz	20	7.4	8.0	A	1	6.0e-002 A
Reversed mains polarity:							
1.18 A	50 Hz	20	0.9	1.2	A	5	5.8e-002 A
2.12 A	50 Hz	20	1.8	2.1	A	5	5.8e-002 A
4.00 A	50 Hz	20	3.6	4.0	A	4	5.8e-002 A
7.99 A	50 Hz	20	7.4	8.0	A	3	6.0e-002 A