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CERTIFICATE OF CALIBRATION

INSTRUMENT: Electrical Safety Analyzer

MODEL: ESA615

CERTIFICATE NO: 48918

SERIAL NO: 2433026

DATE: 07 February 2014

CALIBRATION DUE: 06 February 2015

This notification serves to certify that the unit mentioned above has been inspected and tested in accordance with the manufactures published specifications.

The accuracy and calibration of the test instruments utilised are directly or indirectly traceable to recognised National Standards through calibration at planned intervals.

The calibration will be valid for the period of one year, provided the instrument is used strictly according to the manual.

Quality Management System-ISO 9001:2008 BSI registration number FM40213

AUTHORISED:



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ESA-615 Calibration Data Sheet

Work Order Number: 48918	Serial Number: 2433026
Customer: Viamed	Engineer: S.Rogers

Function check:

Function	Pass/Fail
Firmware	2.05
LED Test	Pass
Beep Test	Pass
Contrast	Pass
Key	Pass
Screen	Pass
Light	Pass

Polarity Test:

Test	Pass/Fail
Live Neutral Reverse	Pass
No Earth	Pass
Neutral Fault	Pass

EO Ground to NULL Jack:

Test Number	Result	Tolerance	Pass/Fail
C.6	Pass	N/A	Pass
C.8	0.300 Ω	0.000 Ω ~ 2.500 Ω	Pass

Mains Voltage:

Test Number	Result	Tolerance	Pass/Fail
D.8	230.10 V	225.6V ~ 234.8V	Pass
D.12	231.50 V	225.6V ~ 234.8V	Pass
D.15	1.00 V	0.0V ~ 2.0V	Pass

GFI Verification:

Test	Pass/Fail
5.0 mA	Pass
10.0 mA	Pass
25.0 mA	Pass

Point to Point Voltage:

Voltage	Result	Tolerance	Pass/Fail
1.00V (100Hz)	1.00 V	0.80 V ~ 1.20 V	Pass
4.00V (50Hz)	4.00 V	3.72 V ~ 4.28 V	Pass
8.00V (50Hz)	8.00 V	7.64 V ~ 8.36 V	Pass
10.00V (50Hz)	10.00 V	9.60 V ~ 10.40 V	Pass

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Point to Point Voltage Continued:

25.00V (50Hz)	25.00 V	24.30 V ~ 25.70 V	Pass
40.00V (50Hz)	40.00 V	39.00 V ~ 40.00 V	Pass
80.00V (50Hz)	80.00 V	78.20 V ~ 81.80 V	Pass
130.00V (50Hz)	130.00 V	127.2 V ~ 132.8 V	Pass
240.00V (50Hz)	240.10 V	235.0 V ~ 245.0 V	Pass
250.00V (50Hz)	250.10 V	244.8 V ~ 255.2 V	Pass

Resistance:

Resistance	Tolerance	Results	Pass/Fail
0.000Ω	0.000Ω ~ 0.015Ω	0.000 Ω	Pass
0.180Ω	0.1764Ω ~ 0.1836Ω	0.180 Ω	Pass
0.000Ω	0.000Ω ~ 0.015Ω	0.000 Ω	Pass
1.800Ω	1.764Ω ~ 1.836Ω	1.807 Ω	Pass

Insulation Resistance:

Test	Tolerance	Results	Pass/Fail
250.0 V	250.00V ~ 287.50V	263.10 V	Pass
500.0 V	500.00V ~ 575.00V	528.90 V	Pass
2.000 mA	1.750 mA ~ 2.250 mA	1.940 mA	Pass

Mains to PE:

Resistance	Tolerance	Result	Pass/Fail
10 MΩ	9.6 MΩ ~ 10.4 MΩ	9.9 MΩ	Pass

AP to PE:

Resistance	Tolerance	Result	Pass/Fail
10 MΩ	9.6 MΩ ~ 10.4 MΩ	9.9 MΩ	Pass

AP to NE

Resistance	Tolerance	Result	Pass/Fail
10 MΩ	9.6 MΩ ~ 10.4 MΩ	9.9 MΩ	Pass

Mains to NE:

Resistance	Tolerance	Result	Pass/Fail
10 MΩ	9.6 MΩ ~ 10.4 MΩ	9.9 MΩ	Pass

Mains to AP:

Applied Part/Voltage	Resistance	Tolerance	Result	Pass/Fail
RA	10 MΩ	9.6 MΩ ~ 10.4 MΩ	9.9 MΩ	Pass
LL	10 MΩ	9.6 MΩ ~ 10.4 MΩ	9.9 MΩ	Pass
LA	10 MΩ	9.6 MΩ ~ 10.4 MΩ	9.9 MΩ	Pass
RL	10 MΩ	9.6 MΩ ~ 10.4 MΩ	9.9 MΩ	Pass
V1	10 MΩ	9.6 MΩ ~ 10.4 MΩ	9.9 MΩ	Pass
250	0.70 MΩ	0.486 to 0.914 MΩ	0.7 MΩ	Pass
500	0.70 MΩ	0.486 to 0.914 MΩ	0.7 MΩ	Pass
250	1.0 MΩ	0.780 to 1.220 MΩ	1.0 MΩ	Pass
500	1.0 MΩ	0.780 to 1.220 MΩ	1.0 MΩ	Pass
250	6.50 MΩ	6.170 to 6.830 MΩ	6.4 MΩ	Pass

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Mains to AP Continued:

500	6.50 MΩ (6.4M)	6.170 to 6.830 MΩ	6.4 MΩ	Pass
250	18.0 MΩ	17.440 to 18.560 MΩ	17.7 MΩ	Pass
500	18.0 MΩ	17.440 to 18.560 MΩ	17.7 MΩ	Pass
250	22.0 MΩ	20.150 to 23.850 MΩ	21.8 MΩ	Pass
500	22.0 MΩ	20.150 to 23.850 MΩ	21.8 MΩ	Pass
250	60.0 MΩ	55.300 to 64.700 MΩ	59.6 MΩ	Pass
500	60.0 MΩ	55.300 to 64.700 MΩ	59.6 MΩ	Pass
250	100.0 MΩ	92.30 to 107.70 MΩ	98.6 MΩ	Pass
500	100.0 MΩ	92.30 to 107.70 MΩ	98.6 MΩ	Pass

DC Leakage:

Test	Tolerance	Result	Pass/Fail
1.000 KΩ	0.980 KΩ ~ 1.020 KΩ	1.000 KΩ	Pass
10.00 μA	8.90 μA ~ 11.10 μA	9.8 μA	Pass
50.00 μA	48.50 μA ~ 51.50 μA	49.9 μA	Pass
100.00 μA	98.00 μA ~ 102.00 μA	100.2 μA	Pass
160.00 μA	157.40 μA ~ 162.60 μA	160.4 μA	Pass
340.00 μA	335.60 μA ~ 344.40 μA	341 μA	Pass
500.00 μA	494.00 μA ~ 506.00 μA	502 μA	Pass
1.00 mA	0.989 mA ~ 1.011 mA	1.003 mA	Pass
1.60 mA	1.583 mA ~ 1.617 mA	1.60 mA	Pass
3.40 mA	3.356 mA ~ 3.444 mA	3.41 mA	Pass
5.00 mA	4.940 mA ~ 5.060 mA	5.01 mA	Pass
8.00 mA	7.910 mA ~ 8.090 mA	8.02 mA	Pass

AC Filter Frequency Response:

Frequency	Measured	Analyzer	Calculated Result	Tolerance	Pass/Fail
50 Hz	1000.00	999.00	0.999	0.988 ~ 1.008	Pass
1000 Hz	1000.00	695.0	0.695	0.672 ~ 0.710	Pass
10000 Hz	1000.00	98.70	0.0987	0.0887 ~ 0.1025	Pass

Differential Leakage:

Current	Tolerance	Results	Pass/Fail
76.00 μA	53.127 μA ~ 109.38 μA	94 μA	Pass
160.00 μA	126.57 μA ~ 199.14 μA	181 μA	Pass
240.00 μA	197.72 μA ~ 286.11 μA	263 μA	Pass
500.00 μA	430.83 μA ~ 571.02 μA	536 μA	Pass
760.00 μA	664.18 μA ~ 856.22 μA	807 μA	Pass
1.60 mA	1422 μA ~ 1782 μA	1688 μA	Pass
2.40 mA	2.140 mA ~ 2.660 mA	2.53 mA	Pass
5.00 mA	4.480 mA ~ 5.520 mA	5.23 mA	Pass
7.60 mA	6.816 mA ~ 8.375 mA	7.91 mA	Pass
16.00 mA	14.38 mA ~ 17.62 mA	16.51 mA	Pass

Leakage Functionality:

Lead Position	Pass/Fail
RA	Pass
LL	Pass
LA	Pass
RL	Pass
V1	Pass

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Direct Applied Part, Alternative Applied Part: Ground ~ RA:

Tolerance	Results	Pass/Fail
990 μ A ~ 1010 μ A	1001 μ A	Pass
990 μ A ~ 1010 μ A	1007 μ A	Pass

Direct Applied Part, Alternative Applied Part: Red ~ RA:

Tolerance	Results	Pass/Fail
990 μ A ~ 1010 μ A	998 μ A	Pass
990 μ A ~ 1010 μ A	1009 μ A	Pass

Alternate Equipment, Red ~ Live:

Tolerance	Results	Pass/Fail
990 μ A ~ 1010 μ A	1006 μ A	Pass

Alternate Equipment Leakage, Alternative Applied Part: RA ~ Live

Tolerance	Results	Pass/Fail
990 μ A ~ 1010 μ A	1004 μ A	Pass
990 μ A ~ 1010 μ A	996 μ A	Pass

Alternative Applied Part Patient: RA ~ Neutral

Tolerance	Results	Pass/Fail
990 μ A ~ 1010 μ A	998 μ A	Pass

Patient Auxiliary : RA ~ RL:

Set Current	Tolerance	Results	Pass/Fail
100.00 μ A	89.00 μ A ~ 111.00 μ A	99.73 μ A	Pass

Direct Equipment, Patient: Ground ~ RA

Set Current	Tolerance	Results	Pass/Fail
100.00 μ A	89.00 μ A ~ 111.00 μ A	99.71 μ A	Pass
100.00 μ A	89.00 μ A ~ 111.00 μ A	99.73 μ A	Pass

Direct Equipment, Enclosure: Ground ~ Red

Set Current	Tolerance	Results	Pass/Fail
100.00 μ A	89.00 μ A ~ 111.00 μ A	99.68 μ A	Pass
100.00 μ A	89.00 μ A ~ 111.00 μ A	99.70 μ A	Pass

Filter Tests:

Tolerance	Results	Pass/Fail
-1.00 μ A ~ 1.00 μ A	0.100 μ A	Pass
-1.00 μ A ~ 1.00 μ A	0.000 μ A	Pass

MAP Voltage and Current Limits:

Voltage/ Current	Tolerance	Results	Pass/Fail
230.0 V	213.90 to 246.10 V	230.0	Pass
3.500 mA	2.625 to 4.375 mA	3.400	Pass
7.500 mA	5.625 to 9.375 mA	7.140	Pass
1.000 mA	0.75 - 1.25 mA	1.15	Pass

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ECG Waveforms:

Set Value	Tolerance	Result	Pass/Fail
2.000 Hz	N/A	Pass	Pass
0.674 mV	0.6403 to 0.7077 mV	0.680	Pass
1.673 mV	1.5893 to 1.7566 mV	1.696	Pass
1.384 mV	1.3148 to 1.4532 mV	1.401	Pass
2.074 mV	1.9703 to 2.1777 mV	2.100	Pass

Current:

Set Value	Applied	Reading	Tolerance	Pass/Fail
≈4.00 A	3.90	3.90	3.51 ~ 4.30	Pass
≈8.00 A	7.90	8.00	7.31 ~ 8.50	Pass

Comments:

Tested unit to specification o.k.

Signature:



Date: 07 Feb. 14



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Calibration And Quality Control Equipment Utilised And Environment Conditions

Product:	ESA615	Serial Number:	2433026
Calibration Date:	07/02/2014	Customer:	Viamed
Work Order Number:	48918	Engineer:	S.Rogers

ISO 9001 Registration Number: 40213

Temperature:	24	°C	Relative Humidity:	34	%
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Calibration And Quality Control Equipment Utilised			
Manufacturer / Model	Equipment Number	Calibration Date	Recalibration Due
QA-90 Mk II	50653	18/11/2013	17/11/2014
Fluke 87 Series V Digital Multimeter	50576	23/08/2013	22/08/2014
Agilent 33220A Arbitrary Waveform Generator	50523	06/02/2014	05/02/2015
Testo 6010 Hygrometer	50529	08/04/2013	07/04/2014
612/620 Resistor Box 50581	50581	22/10/2013	21/10/2014
612/620 Resistor Box 50582	50582	22/10/2013	21/10/2014
Keithly 2000 Multimeter	50590	11/11/2013	10/11/2014

The instrument(s) above were calibrated and inspected against the standards of the laboratory which are traceable, directly or indirectly to National Standards.

Certified by:

Title:

Service Engineer

Date:

07 February 2014