Report of Calibration

Taisho Biomed Instruments Co., Ltd.
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Osaka 553-0002 Japan

UNIT UNDER TEST:	Fluke Biomedical ESA612 Electrical Safety Analyzer	TEST_RESULT:	Pass
SERIAL NUMBER:		PERFORMED ON:	
ASSET NUMBER:		DATA TYPE:	Found Left
PROCEDURE NAME:	ESA612B VER2 - Exp Unc WW	TEMPERATURE:	25.8 °C
PROCEDURE_REV:	6	HUMIDITY:	70.3 %
CALIBRATED BY:			
PO NUMBER:			

Taisho Biomed Instruments Co., Ltd. certifies that the above listed instrument meets or exceeds all specifications as stated in the referenced procedure unless otherwise noted). It has been calibrated using measurement standards traceable to the National Institute of Standards and Technology (NIST), or to NIST accepted intrinsic standards of measurement, or derived by the ratio type of self-calibration techniques. This calibration complies with MIL-STD-45662A and ANSI/NCSL Z540.1-1999 (R2002).

Note: Any Test Uncertainty Ratio (TUR) that is less than four to one will appear under the "TUR" heading on the data record. If the TUR meets or exceeds four to one, the field is left blank.

REMARKS:

Standards Used

Asset #	Description	Cal Date	Due Date
001		8/7/2024	8/7/2025
006		9/5/2024	9/5/2025
010		7/22/2024	7/22/2025
014		7/22/2024	7/22/2025
015		7/16/2024	7/16/2025
016		8/26/2024	8/26/2025
017		8/9/2024	8/9/2025
020		7/18/2024	7/18/2025
PRE0000923		8/13/2024	8/13/2025
PRE0000924		7/10/2024	7/10/2025

Test Results

Test Description	True Value	Test Results	Lower Limit	Upper Limit	TUR
OUTLET TENSION TESTS					
Equipment Outlet L1 slot tension is greater than 16 oz (4.45 N)					Pass
Equipment Outlet L2 slot tension is greater than 16 oz (4.45 N)					Pass
Equipment Outlet Ground tension is greater than 8 oz (2.22 N)					Pass
UUT is ESA612B, UI-3.01.03, MTR-3.01.03, VNC-1.01.52, SN-					
As-Found NOMINAL: 100					
Measured line voltage = 100.06 V					
UUT Current Draw: 0.14 A					
FUNCTIONAL TESTS					
Warning LED ON/OFF Test					Pass
UUT Beeper ON/OFF Test					Pass
UUT Keypad Tests					Pass
EQUIPMENT OUTLET POLARITY TESTS					
Normal Polarity, Closed Neutral, Closed Earth					Pass
Normal Polarity, Closed Neutral, Open Earth					Pass

Test Results

Test Description	True Value	Test Results	Lower Limit	Upper Limit		TUR
Normal Polarity, Open Neutral, Closed Earth					Pass	
Reversed Polarity, Closed Neutral, Closed Earth					Pass	
Reversed Polarity, Open Neutral, Closed Earth					Pass	
Reversed Polarity, Closed Neutral, Open Earth					Pass	
EQUIPMENT OUTLET GROUND TO NULL JACK RESISTANCE TEST						
EO Ground to NULL Jack Open (>1 GΩ)					Pass	
0.000 Ω	0.000 Ω	0.5041 Ω	-2.5000 Ω	2.5000 Ω	Pass	
MAINS VOLTAGE ACCURACY						
Measure L1-L2	100.04 V	99.9 V	97.8 V	102.2 V	Pass	
Measure L1-GND	100.06 V	99.9 V	97.9 V	102.3 V	Pass	
GFI VERIFICATION						
5 mA Trip Point						
4.5 mA Test (No Trip)					Pass	
5.5 mA Test (Tripped)					Pass	
GFI Error Test					Pass	
10 mA Trip Point						
9 mA Test (No Trip)					Pass	
11 mA Test (Tripped)					Pass	
25 mA Trip Point						
22.5 mA Test (No Trip)					Pass	
27.5 mA Test (Tripped)					Pass	
POINT-TO-POINT VOLTAGE VERIFICATION						
1.000 V	1.0000 V	1.000 V	0.780 V	1.220 V	Pass	
8.000 V	8.0000 V	8.005 V	7.640 V	8.360 V	Pass	
25.00 V	25.000 V	25.01 V	24.30 V	25.70 V	Pass	
80.00 V	80.000 V	80.02 V	78.20 V	81.80 V	Pass	
240.0 V	240.00 V	240.1 V	235.0 V	245.0 V	Pass	
POINT-TO-POINT RESISTANCE VERIFICATION						
Red/Black Jack Input						
0.000 Ω	0.0000 Ω	0.000 Ω	-0.015 Ω	0.015 Ω	Pass	
0.200 Ω	0.2000 Ω	0.198 Ω	0.181 Ω	0.219 Ω	Pass	
1.800 Ω	1.8000 Ω	1.796 Ω	1.749 Ω	1.851 Ω	Pass	
Red Jack/EO Ground Terminal						
0.000 Ω	0.0000 Ω	0.001 Ω	-0.015 Ω	0.015 Ω	Pass	
1.800 Ω	1.8000 Ω	1.802 Ω	1.749 Ω	1.851 Ω	Pass	
INSULATION RESISTANCE VERIFICATION						
250 V Source	250.0 V	262.67 V	250.00 V	300.00 V	Pass	
500 V Source	500.0 V	524.28 V	500.00 V	600.00 V	Pass	
2 mA Current Limit	2.000 mA	1.9352 mA	1.7500 mA	2.2500 mA	Pass	
Mains-PE (500V)	10.0000 MΩ	9.800 MΩ	9.600 MΩ	10.400 MΩ	Pass	
AP-PE (500V)	10.0000 MΩ	9.992 MΩ	9.600 MΩ	10.400 MΩ	Pass	
AP-NE (500V)	10.0000 MΩ	9.995 MΩ	9.600 MΩ	10.400 MΩ	Pass	
Mains-NE (500V)	10.0000 MΩ	9.994 MΩ	9.600 MΩ	10.400 MΩ	Pass	
Mains-AP (RA) (500V)	10.0000 MΩ	9.995 MΩ	9.600 MΩ	10.400 MΩ	Pass	
Mains-AP (LL) (500V)	10.0000 MΩ	9.995 MΩ	9.600 MΩ	10.400 MΩ	Pass	
Mains-AP (LA) (500V)	10.0000 MΩ	9.992 MΩ	9.600 MΩ	10.400 MΩ	Pass	
Mains-AP (RL) (500V)	10.0000 MΩ	9.992 MΩ	9.600 MΩ	10.400 MΩ	Pass	
Mains-AP (V1) (500V)	10.0000 MΩ	9.992 MΩ	9.600 MΩ	10.400 MΩ	Pass	
INSULATION RESISTANCE RANGE VERIFICATION						
Mains-AP (V1) (250V)	0.70000 MΩ	0.7003 MΩ	0.4860 MΩ	0.9140 MΩ	Pass	
Mains-AP (V1) (500V)	1.00000 MΩ	0.9997 MΩ	0.7800 MΩ	1.2200 MΩ	Pass	
Mains-AP (V1) (250V)	6.50000 MΩ	6.4950 MΩ	6.1700 MΩ	6.8300 MΩ	Pass	
Mains-AP (V1) (500V)	18.0000 MΩ	17.987 MΩ	17.440 MΩ	18.560 MΩ	Pass	

Test Results

Test Description	True Value	Test Results	Lower Limit	Upper Limit		TUR
Mains-AP (V1) (250V)	22.0000 MΩ	22.004 MΩ	20.150 MΩ	23.850 MΩ	Pass	
Mains-AP (V1) (500V)	60.0000 MΩ	59.923 MΩ	55.300 MΩ	64.700 MΩ	Pass	
Mains-AP (V1) (250V)	100.000 MΩ	100.19 MΩ	92.30 MΩ	107.70 MΩ	Pass	
DC LEAKAGE VERIFICATION						
AAMI Load Resistance Test						
1.000 kΩ	1.000 kΩ	1.0007 kΩ	0.9800 kΩ	1.0200 kΩ	Pass	
DC Leakage Current Tests						
10.0 uA	10.00 µA	9.9 µA	8.9 µA	11.1 µA	Pass	
50.0 uA	50.00 µA	49.9 µA	48.5 µA	51.5 µA	Pass	
100.0 uA	100.00 µA	99.9 µA	98.0 µA	102.0 µA	Pass	
500 uA	500.0 µA	500 µA	494 µA	506 µA	Pass	
1600 uA	1600.0 µA	1600 µA	1583 µA	1617 µA	Pass	
7.000 mA	7.000 mA	7.00 mA	6.92 mA	7.08 mA	Pass	
AC LEAKAGE FILTER FREQUENCY RESPONSE (AAMI Load)						
1000 uA, 60 Hz	998.00 µA	999.7 µA	987.0 µA	1009.0 µA	Pass	
1000 uA, 1 kHz	691.00 µA	688.0 µA	683.1 µA	698.9 µA	Pass	
1000 uA, 10 kHz	95.60 µA	94.7 µA	92.7 µA	98.5 µA	Pass	2.19
1000 uA, 30 kHz	33.10 µA	32.8 µA	31.4 µA	34.8 µA	Pass	2.32
DIFFERENTIAL LEAKAGE VERIFICATION - NORMAL POLARITY						
(75 to 199)uA Range						
76 uA @ 60 Hz	76.1 µA	76 µA	48 µA	104 µA	Pass	
160 uA @ 60 Hz	160.2 µA	162 µA	124 µA	196 µA	Pass	
(200 to 1999)uA Range						
500 uA @ 60 Hz	499.4 µA	509 µA	429 µA	569 µA	Pass	
1600 uA @ 60 Hz	1600.3 µA	1634 µA	1420 µA	1780 µA	Pass	
(2 to 20)mA Range						
5.00 mA @ 60 Hz	5.007 mA	5.07 mA	4.49 mA	5.53 mA	Pass	
16.00 mA @ 60 Hz	15.995 mA	16.04 mA	14.38 mA	17.61 mA	Pass	
DIFFERENTIAL LEAKAGE VERIFICATION - REVERSE POLARITY						
(2 to 20)mA Range						
16.00 mA @ 60 Hz	15.997 mA	16.05 mA	14.38 mA	17.62 mA	Pass	
ECG LEAKAGE FUNCTIONALITY VERIFICATION						
Applied Part (RA), 101 uA Detected					Pass	
Applied Part (RA) Open Measures > 1 GigaΩ					Pass	
Applied Part (LL), 101 uA Detected					Pass	
Applied Part (LL) Open Measures > 1 GigaΩ					Pass	
Applied Part (LA), 101 uA Detected					Pass	
Applied Part (LA) Open Measures > 1 GigaΩ					Pass	
Applied Part (RL), 101 uA Detected					Pass	
Applied Part (RL) Open Measures > 1 GigaΩ					Pass	
Applied Part (V1), 101 uA Detected					Pass	
Applied Part (V1) Open Measures > 1 GigaΩ					Pass	
DIRECT APPLIED PART LEAKAGE - STD 353 VERIFICATION						
GND to RA						
1.000 mA @ 60 Hz	0.8637 mA	0.861 mA	0.854 mA	0.873 mA	Pass	
RED to RA						
1.000 mA @ 60 Hz	0.8629 mA	0.860 mA	0.853 mA	0.873 mA	Pass	
ALTERNATIVE EQUIPMENT LEAKAGE						
RED to HOT						
1.000 mA @ 60 Hz	0.8685 mA	0.868 mA	0.859 mA	0.878 mA	Pass	
ALTERNATIVE EQUIPMENT, APPLIED PART LEAKAGE						
RA to HOT (SAF)						

Test Results

Test Description	True Value	Test Results	Lower Limit	Upper Limit		TUR
1.000 mA @ 60 Hz	0.8697 mA	0.868 mA	0.860 mA	0.879 mA	Pass	
ALTERNATIVE APPLIED PART PATIENT LEAKAGE						
RA to NEUTRAL (SPAT)						
1.000 mA @ 60 Hz	0.8666 mA	0.864 mA	0.857 mA	0.876 mA	Pass	
PATIENT AUXILIARY LEAKAGE - STD 601						
RA to RL						
0.1000 mA @ 100 Hz	0.10004 mA	0.0997 mA	0.0980 mA	0.1020 mA	Pass	
DIRECT EQUIPMENT, PATIENT LEAKAGE - STD 353						
GND to RA						
0.1000 mA @ 100 Hz	0.10004 mA	0.0997 mA	0.0980 mA	0.1020 mA	Pass	
DIRECT EQUIPMENT, PATIENT LEAKAGE - STD 601						
GND to RA						
0.1000 mA @ 100 Hz	0.10004 mA	0.0997 mA	0.0980 mA	0.1020 mA	Pass	
DIRECT EQUIPMENT, ENCLOSURE LEAKAGE - STD 353						
GND to RED						
0.1000 mA @ 100 Hz	0.10004 mA	0.0997 mA	0.0980 mA	0.1020 mA	Pass	
DIRECT EQUIPMENT, ENCLOSURE LEAKAGE - STD 601						
GND to RED						
0.1000 mA @ 100 Hz	0.10004 mA	0.0997 mA	0.0980 mA	0.1020 mA	Pass	
FILTER TESTS						
Apply 100Hz, Measure DC						
0.00 uA @ 100 Hz	0.000 μA	0.00 μA	0.00 μA	1.00 μA	Pass	
Apply DC, Measure AC						
0.00 uA	0.000 μA	0.00 μA	0.00 μA	1.00 μA	Pass	
MAP VOLTAGE AND CURRENT LIMIT TESTS						
120.0 V @ 60 Hz	120.10 V	120.0 V	111.7 V	128.5 V	Pass	
230.0 V @ 50 Hz	230.10 V	230.1 V	214.0 V	246.2 V	Pass	
3.50 mA @ 50 Hz	3.472 mA	3.47 mA	2.60 mA	4.34 mA	Pass	
7.50 mA @ 50 Hz	7.183 mA	7.17 mA	5.39 mA	8.98 mA	Pass	
1.00 mA @ 60 Hz	1.040 mA	1.03 mA	0.78 mA	1.30 mA	Pass	
ECG WAVEFORM TESTS - 2 Hz SQUAREWAVE						
2.000 Hz	2.000 Hz	2.0000 Hz	1.9600 Hz	2.0400 Hz	Pass	
RA-RL Amplitude	0.674 mV	0.6879 mV	0.6403 mV	0.7077 mV	Pass	2.29
LL-RL Amplitude	1.673 mV	1.7123 mV	1.5894 mV	1.7567 mV	Pass	
LA-RL Amplitude	1.384 mV	1.4128 mV	1.3148 mV	1.4532 mV	Pass	
V1-RL Amplitude	2.074 mV	2.1208 mV	1.9703 mV	2.1777 mV	Pass	
EQUIPMENT CURRENT VERIFICATION						
Test 1	1.0060 A	1.000 A	0.756 A	1.256 A	Pass	3.38
Test 2	3.0094 A	3.000 A	2.659 A	3.360 A	Pass	

Cal Info SN: CAL DATE:

*** End of Procedure ***

**** End of Certificate *****