

Report of Calibration

Taisho Biomed Instruments Co., Ltd.
2-2-22 Sangenya-Higashi, Taisho-ku
Osaka 551-0002 Japan

FLUKE
Biomedical

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 VER - Exp Unc WW	TEMPERATURE:	25.2 °C
PROCEDURE_REV:	11	HUMIDITY:	36.0 %
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).

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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

<u>Asset #</u>	<u>Description</u>	<u>Cal Date</u>	<u>Due Date</u>
056		9/17/2021	9/17/2022
061		9/7/2021	9/7/2022
064		9/2/2021	9/2/2022
1		9/6/2021	9/6/2022
11		9/15/2021	9/15/2022
12		8/23/2021	8/23/2022
4		8/25/2021	8/25/2022
PRE0001929		9/3/2021	9/3/2022
PRE0001930		8/23/2021	8/23/2022

Test Results

<u>Test Description</u>	<u>True Value</u>	<u>Test Results</u>	<u>Lower Limit</u>	<u>Upper Limit</u>	<u>TUR</u>
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-1.00.15, SN-					
As-Found NOMINAL: 100					
Measured line voltage = 100.04 V					
UUT Current Draw: 0.09 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
Normal Polarity, Open Neutral, Closed Earth					Pass

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Print Date:

Test Results

Test Description	True Value	Test Results	Lower Limit	Upper Limit	TUR
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	0.7477 Ω	-2.5000 Ω	2.5000 Ω	Pass
MAINS VOLTAGE ACCURACY					
Measure L1-L2	100.04 V	100.2 V	97.8 V	102.2 V	Pass
Measure L1-GND	100.05 V	100.2 V	97.8 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	0.998 V	0.780 V	1.220 V	Pass
8.000 V	8.0000 V	7.980 V	7.640 V	8.360 V	Pass
25.00 V	25.0000 V	24.95 V	24.30 V	25.70 V	Pass
80.00 V	80.0000 V	79.85 V	78.20 V	81.80 V	Pass
240.0 V	240.00 V	239.5 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	0.199 Ω	0.181 Ω	0.219 Ω	Pass
1.800 Ω	1.8000 Ω	1.800 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	1.789 Ω	1.749 Ω	1.851 Ω	Pass
INSULATION RESISTANCE VERIFICATION					
250 V Source	250.0 V	261.90 V	250.00 V	300.00 V	Pass
500 V Source	500.0 V	525.15 V	500.00 V	600.00 V	Pass
2 mA Current Limit	2.000 mA	1.9381 mA	1.7500 mA	2.2500 mA	Pass
Mains-PE (500V)	10.0000 MΩ	9.960 MΩ	9.600 MΩ	10.400 MΩ	Pass
AP-PE (500V)	10.0000 MΩ	9.961 MΩ	9.600 MΩ	10.400 MΩ	Pass
AP-NE (500V)	10.0000 MΩ	9.961 MΩ	9.600 MΩ	10.400 MΩ	Pass
Mains-NE (500V)	10.0000 MΩ	9.960 MΩ	9.600 MΩ	10.400 MΩ	Pass
Mains-AP (RA) (500V)	10.0000 MΩ	9.966 MΩ	9.600 MΩ	10.400 MΩ	Pass
Mains-AP (LL) (500V)	10.0000 MΩ	9.961 MΩ	9.600 MΩ	10.400 MΩ	Pass
Mains-AP (***) (500V)	10.0000 MΩ	9.957 MΩ	9.600 MΩ	10.400 MΩ	Pass
Mains-AP (RL) (500V)	10.0000 MΩ	9.959 MΩ	9.600 MΩ	10.400 MΩ	Pass
Mains-AP (V1) (500V)	10.0000 MΩ	9.961 MΩ	9.600 MΩ	10.400 MΩ	Pass
INSULATION RESISTANCE RANGE VERIFICATION					
Mains-AP (V1) (250V)	0.70000 MΩ	0.6980 MΩ	0.4860 MΩ	0.9140 MΩ	Pass
Mains-AP (V1) (500V)	1.00000 MΩ	0.9963 MΩ	0.7800 MΩ	1.2200 MΩ	Pass
Mains-AP (V1) (250V)	6.50000 MΩ	6.4750 MΩ	6.1700 MΩ	6.8300 MΩ	Pass
Mains-AP (V1) (500V)	18.0000 MΩ	17.926 MΩ	17.440 MΩ	18.560 MΩ	Pass
Mains-AP (V1) (250V)	22.0000 MΩ	21.898 MΩ	20.150 MΩ	23.850 MΩ	Pass

Test Results

<u>Test Description</u>	<u>True Value</u>	<u>Test Results</u>	<u>Lower Limit</u>	<u>Upper Limit</u>	<u>TUR</u>
Mains-AP (V1) (500V)	60.0000 MΩ	59.945 MΩ	55.300 MΩ	64.700 MΩ	Pass
Mains-AP (V1) (250V)	100.000 MΩ	99.21 MΩ	92.30 MΩ	107.70 MΩ	Pass
DC LEAKAGE VERIFICATION					
AAMI Load Resistance Test					
1.000 kΩ	1.000 kΩ	1.0003 kΩ	0.9800 kΩ	1.0200 kΩ	Pass
DC Leakage Current Tests					
10.0 uA	10.00 uA	10.2 uA	8.9 uA	11.1 uA	Pass
50.0 uA	50.00 uA	50.3 uA	48.5 uA	51.5 uA	Pass
100.0 uA	100.00 uA	100.4 uA	98.0 uA	102.0 uA	Pass
500 uA	500.0 uA	501 uA	494 uA	506 uA	Pass
1600 uA	1600.0 uA	1602 uA	1583 uA	1617 uA	Pass
7.000 mA	7.000 mA	7.02 mA	6.92 mA	7.08 mA	Pass
AC LEAKAGE FILTER FREQUENCY RESPONSE (AAMI Load)					
1000 uA, 60 Hz	998.00 uA	1001.3 uA	987.0 uA	1009.0 uA	Pass
1000 uA, 1 kHz	691.00 uA	694.0 uA	683.1 uA	698.9 uA	Pass
1000 uA, 10 kHz	95.60 uA	96.0 uA	92.7 uA	98.5 uA	Pass 2.19
1000 uA, 30 kHz	33.10 uA	33.3 uA	31.4 uA	34.8 uA	Pass 2.32
DIFFERENTIAL LEAKAGE VERIFICATION - NORMAL POLARITY					
(75 to 199)uA Range					
76 uA @ 60 Hz	76.0 uA	73 uA	48 uA	104 uA	Pass
160 uA @ 60 Hz	160.1 uA	161 uA	124 uA	196 uA	Pass
(200 to 1999)uA Range					
500 uA @ 60 Hz	500.2 uA	515 uA	430 uA	570 uA	Pass
1600 uA @ 60 Hz	1600.8 uA	1661 uA	1421 uA	1781 uA	Pass
(2 to 20)mA Range					
5.00 mA @ 60 Hz	4.999 mA	5.17 mA	4.48 mA	5.52 mA	Pass
16.00 mA @ 60 Hz	16.005 mA	16.47 mA	14.38 mA	17.63 mA	Pass
DIFFERENTIAL LEAKAGE VERIFICATION - REVERSE POLARITY					
(2 to 20)mA Range					
16.00 mA @ 60 Hz	16.007 mA	16.48 mA	14.39 mA	17.63 mA	Pass
ECG LEAKAGE FUNCTIONALITY VERIFICATION					
Applied Part (RA), 98 uA Detected					Pass
Applied Part (RA) Open Measures > 1 GigaΩ					Pass
Applied Part (LL), 98 uA Detected					Pass
Applied Part (LL) Open Measures > 1 GigaΩ					Pass
Applied Part (LA), 98 uA Detected					Pass
Applied Part (LA) Open Measures > 1 GigaΩ					Pass
Applied Part (RL), 98 uA Detected					Pass
Applied Part (RL) Open Measures > 1 GigaΩ					Pass
Applied Part (V1), 98 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	0.8674 mA	0.866 mA	0.856 mA	0.879 mA	Pass
RED to RA					
1.000 mA @ 60 Hz	0.8665 mA	0.866 mA	0.855 mA	0.878 mA	Pass
ALTERNATIVE EQUIPMENT LEAKAGE					
RED to HOT					
1.000 mA @ 60 Hz	0.8721 mA	0.872 mA	0.860 mA	0.884 mA	Pass
ALTERNATIVE EQUIPMENT, APPLIED PART LEAKAGE					
RA to HOT (SAF)					
1.000 mA @ 60 Hz	0.8735 mA	0.872 mA	0.862 mA	0.885 mA	Pass

Test Results

<u>Test Description</u>	<u>True Value</u>	<u>Test Results</u>	<u>Lower Limit</u>	<u>Upper Limit</u>	<u>TUR</u>
ALTERNATIVE APPLIED PART PATIENT LEAKAGE					
RA to NEUTRAL (SPAT)					
1.000 mA @ 60 Hz	0.8708 mA	0.869 mA	0.859 mA	0.883 mA	Pass
PATIENT AUXILIARY LEAKAGE - STD 601					
RA to RL					
0.1000 mA @ 100 Hz	0.10002 mA	0.0998 mA	0.0980 mA	0.1020 mA	Pass
DIRECT EQUIPMENT, PATIENT LEAKAGE - STD 353					
GND to RA					
0.1000 mA @ 100 Hz	0.10002 mA	0.0999 mA	0.0980 mA	0.1020 mA	Pass
DIRECT EQUIPMENT, PATIENT LEAKAGE - STD 601					
GND to RA					
0.1000 mA @ 100 Hz	0.10001 mA	0.0999 mA	0.0980 mA	0.1020 mA	Pass
DIRECT EQUIPMENT, ENCLOSURE LEAKAGE - STD 353					
GND to RED					
0.1000 mA @ 100 Hz	0.10002 mA	0.0999 mA	0.0980 mA	0.1020 mA	Pass
DIRECT EQUIPMENT, ENCLOSURE LEAKAGE - STD 601					
GND to RED					
0.1000 mA @ 100 Hz	0.10002 mA	0.0999 mA	0.0980 mA	0.1020 mA	Pass
FILTER TESTS					
Apply 100Hz, Measure DC					
0.00 uA @ 100 Hz	0.000 uA	0.00 uA	0.00 uA	1.00 uA	Pass
Apply DC, Measure AC					
0.00 uA	0.000 uA	0.00 uA	0.00 uA	1.00 uA	Pass
MAP VOLTAGE AND CURRENT LIMIT TESTS					
120.0 V @ 60 Hz	120.11 V	120.5 V	111.7 V	128.5 V	Pass
230.0 V @ 50 Hz	230.17 V	232.2 V	214.1 V	246.3 V	Pass
3.50 mA @ 50 Hz	3.507 mA	3.51 mA	2.63 mA	4.38 mA	Pass
7.50 mA @ 50 Hz	7.300 mA	7.31 mA	5.48 mA	9.13 mA	Pass
1.00 mA @ 60 Hz	1.056 mA	1.05 mA	0.79 mA	1.32 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	0.6831 mV	0.6403 mV	0.7077 mV	Pass 2.28
LL-RL Amplitude	1.673 mV	1.6620 mV	1.5894 mV	1.7567 mV	Pass
** -RL Amplitude	1.384 mV	1.3933 mV	1.3148 mV	1.4532 mV	Pass
VI-RL Amplitude	2.074 mV	2.0927 mV	1.9703 mV	2.1777 mV	Pass
EQUIPMENT CURRENT VERIFICATION					
Test 1	1.0436 A	1.000 A	0.791 A	1.296 A	Pass 3.41
Test 2	2.8469 A	2.800 A	2.505 A	3.189 A	Pass

Cal Info , CAL DATE:

*** End of Procedure ***

**** End of Certificate ****