

RAPPORTO TECNICO

RAPPORTO TECNICO N° **FN-016-2024** ORDINE N°  
 DATA **12/06/2024**  IN SEDE  FUORI SEDE DATA  
 DIVISIONE  CST  ENT  NEURO  CVG  MITG  ALTRO  
 TIPO DI RAPPORTO  Riparazione  Assistenza Software  Assistenza Applicativa  Manutenzione  Altro  
 TIPO DI INTERVENTO  Fatturare  Garanzia  Contratto  Comodato Uso  Assist. Tecnica  Assist. Vendita  Collaudo

RAGIONE SOCIALE CLIENTE / TEL. **OSPEDALE SANTOBONO - AORN**  
 PRESIDIO OSPEDALIERO **REPARTO NCH** CITTÀ **NAPOLI**  
 STRUMENTO **58** S.N. **N07594579** N.INV. **A0004829**

DESCRIZIONE GUASTO:  
**MANCATO COLLEGAMENTO TRA MAIN CART E CAMERA CART**  
**MANUTENZIONE PREVENTIVA**  
 DESCRIZIONE LAVORI:  
**IL GUASTO SEGNALATO DAL CLIENTE NON È STATO VERIFICATO.**  
**ESEGUITA MANUTENZIONE PERIODICA PREVENTIVA CON ESITO**  
**POSITIVO. SI RILASCIÀ SISTEMA FUNZIONANTE.**

La riparazione/manutenzione è stata eseguita in conformità ai seguenti Manuali Tecnici del Fabbriante:

Q.TÀ	CODICE	DESCRIZIONE	PREZZO TOTALE	TIPOLOGIA INTERVENTO

ATTIVITÀ  
**2** Ore lavoro  
**3** Ore viaggio A/R  
**200** Km A/R  
 Diritto fisso di chiamata  
 Spese di trasporto

TOTALE (Iva esclusa) **0**

NOTE  
 CLIENTE (Nome e Firma) **A.O. OSPEDALE SANTOBONO - PAUSILIPON**  
 TECNICO (Nome e Firma) **F. Liguori**

# Fluke Biomedical Ansur Test and Inspection Procedure

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## Risultati della prova

### PROVA SUPERATA

#### Test effettuato

Data: 12/06/2024  
Record: N07594579.mtr  
Modello: IEC 62353 Dispersione  
diretta - CL1.mtt  
Versione Modello: 1.0.3

#### Componenti Ansur utilizzati

Ansur Versione 3.1.4  
Plug-In: ESA620 Versione 1.2.6

## Setup della prova

### Selezioni

Interventi di manutenzione eseguiti	Norme eseguite
	IEC 62353 (CL1)

### Dispositivo in prova

Numero di serie	N07594579	Nome tecnico	NASTRI FABIO
Tipo	Sistema di navigazione chirurgica	Numero WO	--
Modello	Sealthstation	Produttore	Medtronic Navigation, Inc.
Reparto	NCH	Commenti	Nessuno
Cliente	AORN SANTOBONO - NAPOLI		

### Dati MTI

Strumento per la prova	Numero di serie	Versione del firmware
ESA 620	1061009	v2.14

## Firma

*Fabio Nastri*

## Risultato della prova

Elemento di prova		Tipo di prova			Fallito
IEC 62353 Dispersione Diretta - Classe I		Auto Sequence			
<b>Setup del modulo</b>					
#	Informazioni sulle parti applicate	Classe	Terminali		
1	Codice del modulo Numero di serie Tipo	Moduli	BF	1	
Tensione alimentazione		Tensione alimentazione			
Da Fase a Neutro		Tensione alimentazione Da Fase a Neutro			
<b>Risultato:</b>	<b>Valore</b>	<b>Unità</b>	<b>Limite alto</b>	<b>Limite basso</b>	<b>Standard</b>
Da Fase a Neutro	234,2	V			IEC 62353 (CL1)
Da Neutro a Terra		Tensione alimentazione Da Neutro a Terra			
<b>Risultato:</b>	<b>Valore</b>	<b>Unità</b>	<b>Limite alto</b>	<b>Limite basso</b>	<b>Standard</b>
Da Neutro a Terra	15	V			IEC 62353 (CL1)
Da Fase a Terra		Tensione alimentazione Da Fase a Terra			
<b>Risultato:</b>	<b>Valore</b>	<b>Unità</b>	<b>Limite alto</b>	<b>Limite basso</b>	<b>Standard</b>
Da Fase a Terra	210,3	V			IEC 62353 (CL1)
Resistenza conduttore di terra		Resistenza conduttore di terra			
<b>Risultato:</b>	<b>Valore</b>	<b>Unità</b>	<b>Limite alto</b>	<b>Limite basso</b>	<b>Standard</b>
PE Resistance1	0,069	Ohm	0,3		IEC 62353 (CL1)
Corrente dispersione diretta dispositivo		Corrente dispersione diretta dispositivo			
Polarità diretta		Corrente dispersione diretta dispositivo Terra aperta			
<b>Risultato:</b>	<b>Valore</b>	<b>Unità</b>	<b>Limite alto</b>	<b>Limite basso</b>	<b>Standard</b>
Polarità diretta	157,6	uAAC+DC	500		IEC 62353 (CL1)
Polarità inversa		Corrente dispersione diretta dispositivo Terra aperta, polarità inversa			
<b>Risultato:</b>	<b>Valore</b>	<b>Unità</b>	<b>Limite alto</b>	<b>Limite basso</b>	<b>Standard</b>
Polarità inversa	156	uAAC+DC	500		IEC 62353 (CL1)
Corrente dispersione diretta parti applicate		Corrente dispersione diretta parti applicate			
Condizioni normali		Corrente dispersione diretta parti applicate Condizioni normali			
<b>Risultato:</b>	<b>Valore</b>	<b>Unità</b>	<b>Limite alto</b>	<b>Limite basso</b>	<b>Standard</b>
Moduli	2,2	uAAC+DC	500		IEC 62353 (CL1)
Condizioni normali, polarità inversa		Corrente dispersione diretta parti applicate Condizioni normali, polarità inversa			

Elemento di prova	Tipo di prova					Fallito
<b>Risultato:</b>	<b>Valore</b>	<b>Unità</b>	<b>Limite alto</b>	<b>Limite basso</b>	<b>Standard</b>	
Moduli	2,2	uAAC+DC	5000		IEC 62353 (CL1)	

# Outsourced Cal. Certificate

Report Date: 22-Feb-2024

# Medtronic

## EOC Calibration Dept Address

Medtronic EOC  
Calibration, Room 2A216  
Earl Bakkenstraat 10  
6422 PJ Heerlen, Netherlands

## Equipment Information

Property#: 28489  
Serial Number: 1061009  
Manufacturer: FLUKE BIOMEDICAL  
Model: ESA620  
Type:  
Description: TESTER, ELECTRICAL SAFETY

Department: D006 SR FS IT  
Crib: FS IT - FABIO NASTRI  
Bin:

Sub-Type:

## Calibration Information

Cal/Cert. Date: 20-Feb-2024  
Calibration Result: PASS  
Cal. Vendor: FLUKE  
Certificate Ref#: SA01255807 AS-LEFT

Cal. Due Date: 18-Feb-2025  
Cal. Interval: 52 WEEKS  
Spec Type: MAN SPECS

## Comments

## Procedures Used In This Event

Procedure Name	Description	Revision	Revision Date
CAL02510	CALIBRATION OUTSOURCING	C	08-Sep-2021

# Certificate of Calibration

## Fluke Nederland B.V.

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<b>Certificate Number:</b>	SA01255807	<b>Date of Calibration:</b>	20 Feb 2024
<b>Receive Condition:</b>	OUT OF TOLERANCE	<b>Date of Recalibration:</b>	20 Feb 2025
<b>Return Condition:</b>	IN TOLERANCE AFTER REPAIR/ADJUSTMENT	<b>Place of Calibration:</b>	Eindhoven
<b>Manufacturer:</b>	FLUKE BIOMEDICAL	<b>Temperature within:</b>	(23.0 ± 3) °C
<b>Model:</b>	ESA620	<b>Humidity within:</b>	(45 ± 20) %rh
<b>Serial Number:</b>	1061009		
<b>Description:</b>	ELECTRICAL SAFETY ANALYZER		
<b>Procedure:</b>	Fluke_ESA620_Cal_SWB7_230V_CNET_BMS (c5.0F)		

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<b>Customer:</b>	MEDTRONIC B.V. NL-6422 PJ HEERLEN
<b>Customer Asset ID:</b>	28489
<b>RMA Number:</b>	606324354

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All measurements are traceable to national and/or international standards or have been derived by approved ratio techniques. When possible standards used for this calibration are ISO/IEC 17025 accredited calibrated.

This calibration is performed by a DEKRA certified lab for ISO 9001. This certificate may not be reproduced other than in full. Calibration certificates without signatures, either electronic or handwritten, are not valid.

**Comments:** Adjusted  
PCN06629 installed  
FW update to v2.14



**Issue Date:** 20 Feb 2024

Electronically signed

**Authorized By**  
A. Licareti

## Certificate of Calibration

Certificate Number: SA01255807

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### Remarks

- The calibration status found in this certificate on the top of each results page must be interpreted as:
  - As Found : Data collected before the unit was adjusted and / or repaired
  - As Left : Data collected after the unit has been adjusted and / or repaired
  - Found / Left : Data collected without any adjustment and / or repair performed
- The calibration interval (due date) is the responsibility of the end user.
- 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 2013 and the Dutch norm NEN 3140 release 2015 paragraph 5.102.12 through 5.102.16.
- Temperature conversions (if applicable) are performed according to ISO/IEC 60584:2013 for thermocouples, and ISO/IEC 60751:2022 for resistance temperature devices.

### Standards and test-equipment used

Inventory No	Model	Serial No
WP1598	34970A	MY44061803
SL0411	5520A-PQ/6	7200203
WP1726	6221	1386664
WP1217	8846A	9481009
WP1298	ESA620 SHUNT BOX1	WP1298
WP2005	FLUKE-6500	RO2085017
WP1709	TESTBOX 7	30011210

## Calibration Results As Found

Certificate Number: SA01255807

Date of Calibration: 19 Feb 2024

Nominal value	Range	Lower limit	Measurement Result	Upper limit	Unit	% of Tol	TUR <4	Status
Internal fan test								Pass
Warning LED test								Pass
Beeper test								Pass
Keyboard verification								Pass
<b>Test Receptacle verification</b>								
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, Open Gnd.								Pass
230 VAC : Rev Pol, Closed Neut, Closed Gnd.								Pass
<b>Mains Voltage calibration</b>								
<b>L - N</b>								
230.09	V 50 Hz 300	224.5	230.8	235.7	V	13		Pass
<b>L - PE</b>								
230.09	V 50 Hz 300	224.5	230.9	235.7	V	14		Pass
<b>PE - N</b>								
0.03	V 50 Hz 300	0.0	0.1	1.0	V	7		Pass
<b>GFI Tests</b>								
5mA GFI Test limit didn't trip @4.0mA 50Hz								Pass
5mA GFI Test limit tripped @6.0mA 50Hz								Pass
10mA GFI Test limit didn't trip @8mA 50Hz								Pass
10mA GFI Test limit tripped @12mA 50Hz								Pass
25mA GFI Test limit didn't trip @20mA 50Hz								Pass
25mA GFI Test limit tripped @30mA 50Hz								Pass
<b>POINT to POINT Voltage calibration</b>								
0.00	V 47 Hz	-0.2	0.0	0.2	V	9		Pass
4.00	V 47 Hz	3.7	4.0	4.3	V	4		Pass
8.00	V 47 Hz	7.6	8.0	8.4	V	3		Pass
10.00	V 47 Hz	9.6	10.0	10.4	V	1		Pass
25.00	V 47 Hz	24.3	24.9	25.7	V	7		Pass
40.00	V 47 Hz	39.0	40.0	41.0	V	1		Pass
80.00	V 47 Hz	78.2	80.0	81.8	V	1		Pass
130.00	V 47 Hz	127.2	130.0	132.8	V	0		Pass
240.00	V 47 Hz	235.0	240.2	245.0	V	3		Pass
0.00	V 63 Hz	-0.2	0.0	0.2	V	8		Pass
4.00	V 63 Hz	3.7	4.0	4.3	V	4		Pass
8.00	V 63 Hz	7.6	8.0	8.4	V	4		Pass
10.00	V 63 Hz	9.6	10.0	10.4	V	4		Pass
25.00	V 63 Hz	24.3	25.0	25.7	V	4		Pass
40.00	V 63 Hz	39.0	40.0	41.0	V	1		Pass
80.00	V 63 Hz	78.2	80.0	81.8	V	2		Pass
130.00	V 63 Hz	127.2	130.1	132.8	V	3		Pass
240.00	V 63 Hz	235.0	240.3	245.0	V	6		Pass
<b>Ground Resistance calibration</b>								
low test current mode:								
0.1301	Ω 2W	0.113	0.128	0.148	Ω	13		Pass
0.2154	Ω 2W	0.196	0.216	0.235	Ω	3		Pass
0.3089	Ω 2W	0.278	0.310	0.339	Ω	5		Pass
0.5426	Ω 2W	0.500	0.545	0.585	Ω	6		Pass
1.8133	Ω 2W	1.707	1.820	1.919	Ω	6		Pass
0.1624	Ω 4W	0.154	0.175	0.171	Ω	146		FAIL



## Calibration Results As Found

Certificate Number: SA01255807

Date of Calibration: 19 Feb 2024

Nominal value	Range		Lower limit	Measurement Result	Upper limit	Unit	% of Tol	TUR <4	Status
0.2509	Ω	4W	0.241	0.264	0.261	Ω	127		FAIL
0.3437	Ω	4W	0.321	0.357	0.367	Ω	57		Pass
0.5751	Ω	4W	0.541	0.590	0.610	Ω	42		Pass
1.8342	Ω	4W	1.737	1.852	1.932	Ω	18		Pass
high test current mode:									
0.1533	Ω	2W	0.135	0.160	0.172	Ω	38		Pass
0.0398	Ω	4W	0.034	0.046	0.046	Ω	105		FAIL
0.1929	Ω	4W	0.184	0.200	0.202	Ω	75		Pass
high test current mode, open circuit voltage & short circuit current (into 50 mOhm):									
25.00	A	50 Hz	25	22.500	23.286	27.500	A	69	Pass
6.50	V	50 Hz	5.850	6.477	7.150	V	3		Pass
POINT to POINT Resistance calibration									
1.8139	Ω	2W	1.762	1.820	1.865	Ω	13		Pass
1.8370	Ω	4W	1.795	1.842	1.879	Ω	13		Pass
Insulation Resistance Voltage calibration									
250.00	V		250.0	257.0	300.0	V	14		Pass
500.00	V		500.0	511.1	600.0	V	11		Pass
Current limit									
1.5850	mA		1.300	1.442	1.870	mA	50		Pass
Mains-PE Resistance calibration									
9.98	MΩ		9.6	9.9	10.4	MΩ	8		Pass
Insulation Resistance calibration AP-PE									
0.70	MΩ	250 V	20	0.5	0.7	0.9	MΩ	0	Pass
0.70	MΩ	500 V	20	0.5	0.7	0.9	MΩ	1	Pass
1.00	MΩ	250 V	20	0.8	1.0	1.2	MΩ	2	Pass
1.00	MΩ	500 V	20	0.8	1.0	1.2	MΩ	1	Pass
2.00	MΩ	250 V	20	1.8	2.0	2.2	MΩ	5	Pass
2.00	MΩ	500 V	20	1.8	2.0	2.2	MΩ	3	Pass
3.10	MΩ	250 V	20	2.8	3.1	3.4	MΩ	6	Pass
3.10	MΩ	500 V	20	2.8	3.1	3.4	MΩ	4	Pass
6.49	MΩ	250 V	20	6.2	6.5	6.8	MΩ	10	Pass
6.49	MΩ	500 V	20	6.2	6.5	6.8	MΩ	7	Pass
9.98	MΩ	250 V	20	9.6	10.0	10.4	MΩ	13	Pass
9.98	MΩ	500 V	20	9.6	10.0	10.4	MΩ	7	Pass
17.96	MΩ	250 V	20	17.4	18.1	18.5	MΩ	18	Pass
17.96	MΩ	500 V	20	17.4	18.0	18.5	MΩ	8	Pass
21.87	MΩ	250 V	100	20.0	22.0	23.7	MΩ	7	Pass
21.87	MΩ	500 V	100	20.0	21.9	23.7	MΩ	3	Pass
59.61	MΩ	250 V	100	54.9	59.9	64.3	MΩ	6	Pass
59.61	MΩ	500 V	100	54.9	60.5	64.3	MΩ	18	Pass
99.72	MΩ	250 V	100	91.7	104.6	107.8	MΩ	61	Pass
99.72	MΩ	500 V	100	91.9	101.2	107.5	MΩ	19	Pass
Insulation Resistance calibration MAINS-NE									
9.98	MΩ	500 V	20	9.6	10.0	10.4	MΩ	8	Pass
Insulation Resistance calibration MAINS-AP									
RA test point									
9.98	MΩ	500 V	20	9.6	10.0	10.4	MΩ	8	Pass
LL test point									
9.98	MΩ	500 V	20	9.6	10.0	10.4	MΩ	8	Pass
LA test point									

## Calibration Results As Found

Certificate Number: SA01255807

Date of Calibration: 19 Feb 2024

Nominal value	Range	Lower limit	Measurement Result	Upper limit	Unit	% of Tol	TUR <4	Status
9.98 MΩ 500 V 20		9.6	10.0	10.4	MΩ	7		Pass
RL test point								
9.98 MΩ 500 V 20		9.6	10.0	10.4	MΩ	8		Pass
V1 test point								
9.98 MΩ 500 V 20		9.6	10.0	10.4	MΩ	8		Pass
V2 test point								
9.98 MΩ 500 V 20		9.6	10.0	10.4	MΩ	7		Pass
V3 test point								
9.98 MΩ 500 V 20		9.6	10.0	10.4	MΩ	8		Pass
V4 test point								
9.98 MΩ 500 V 20		9.6	10.0	10.4	MΩ	8		Pass
V5 test point								
9.98 MΩ 500 V 20		9.6	10.0	10.4	MΩ	7		Pass
V6 test point								
9.98 MΩ 500 V 20		9.6	10.0	10.4	MΩ	7		Pass
<b>Insulation Resistance calibration AP-NE</b>								
V6 test point								
9.98 MΩ 500 V 20		9.6	10.0	10.4	MΩ	8		Pass
V5 test point								
9.98 MΩ 500 V 20		9.6	10.0	10.4	MΩ	8		Pass
V4 test point								
9.98 MΩ 500 V 20		9.6	10.0	10.4	MΩ	8		Pass
V3 test point								
9.98 MΩ 500 V 20		9.6	10.0	10.4	MΩ	9		Pass
V2 test point								
9.98 MΩ 500 V 20		9.6	10.0	10.4	MΩ	8		Pass
V1 test point								
9.98 MΩ 500 V 20		9.6	10.0	10.4	MΩ	8		Pass
RL test point								
9.98 MΩ 500 V 20		9.6	10.0	10.4	MΩ	9		Pass
LA test point								
9.98 MΩ 500 V 20		9.6	10.0	10.4	MΩ	8		Pass
LL test point								
9.98 MΩ 500 V 20		9.6	10.0	10.4	MΩ	8		Pass
RA test point								
9.98 MΩ 500 V 20		9.6	10.0	10.4	MΩ	8		Pass
<b>DC Leakage Resistance calibration</b>								
AAMI								
1.0000 kΩ		0.980	1.002	1.020	kΩ	9		Pass
IEC60601								
1.0000 kΩ		0.980	1.002	1.020	kΩ	9		Pass
IEC61010								
2.0000 kΩ		1.960	2.002	2.040	kΩ	5		Pass
<b>DC Leakage Current calibration</b>								
10.00 μA	200	8.9	9.8	11.1	μA	16		Pass
50.00 μA	200	48.5	49.7	51.5	μA	21		Pass
100.00 μA	200	98.0	99.5	102.0	μA	25		Pass
160.00 μA	200	157.4	159.4	162.6	μA	22		Pass
340.0 μA	2000	336	339	344	μA	22		Pass
500.0 μA	2000	494	499	506	μA	20		Pass
1.0000 mA	2	0.989	0.999	1.011	mA	11		Pass
1.6000 mA	2	1.583	1.599	1.617	mA	6		Pass
3.400 mA	10	3.36	3.40	3.44	mA	9		Pass
5.000 mA	10	4.94	4.99	5.06	mA	10		Pass
7.000 mA	10	6.92	6.98	7.08	mA	24		Pass

Differential Leakage calibration

## Calibration Results As Found

Certificate Number: SA01255807

Date of Calibration: 19 Feb 2024

Nominal value	Range	Lower limit	Measurement Result	Upper limit	Unit	% of Tol	TUR <4	Status
75.7 $\mu$ A	50 Hz	200	47	89	105	$\mu$ A	46	Pass
161.3 $\mu$ A	50 Hz	200	125	167	198	$\mu$ A	16	Pass
240.4 $\mu$ A	50 Hz	2000	196	244	285	$\mu$ A	8	Pass
500.4 $\mu$ A	50 Hz	2000	430	503	571	$\mu$ A	4	Pass
759.3 $\mu$ A	50 Hz	2000	663	761	855	$\mu$ A	2	Pass
1.6000 mA	50 Hz	2	1.420	1.600	1.780	mA	0	Pass
2.398 mA	50 Hz	20	2.14	2.40	2.66	mA	1	Pass
5.004 mA	50 Hz	20	4.48	5.01	5.52	mA	1	Pass
7.703 mA	50 Hz	20	6.91	7.71	8.49	mA	1	Pass
16.410 mA	50 Hz	20	14.75	16.39	18.07	mA	1	Pass
<b>Leakage functionality tests</b>								
Apply DC current, attempt to measure with AC mode								
0.0000 $\mu$ A		0.000	0.280	1.000	$\mu$ A	28		Pass
Apply AC current, attempt to measure with DC mode								
0.0000 $\mu$ A	50 Hz	-1.000	0.107	1.000	$\mu$ A	11		Pass
<b>RA Leakage calibration</b>								
UUT detected 100.823 $\mu$ A from 8846A								
RA shorted to GND								
0.0000 $\Omega$		0.000	0.982	5.000	$\Omega$	20		Pass
RA open								
RA > 1 M Ohms.								
<b>LL Leakage calibration</b>								
UUT detected 100.824 $\mu$ A from 8846A								
LL shorted to GND								
0.0000 $\Omega$		0.000	0.987	5.000	$\Omega$	20		Pass
LL open								
LL > 1 M Ohms.								
<b>LA Leakage calibration</b>								
UUT detected 100.818 $\mu$ A from 8846A								
LA shorted to GND								
0.0000 $\Omega$		0.000	0.674	5.000	$\Omega$	14		Pass
LA open								
LA > 1 M Ohms.								
<b>RL Leakage calibration</b>								
UUT detected 100.815 $\mu$ A from 8846A								
RL shorted to GND								
0.0000 $\Omega$		0.000	0.561	5.000	$\Omega$	11		Pass
RL open								
RL > 1 M Ohms.								
<b>V1 Leakage calibration</b>								
UUT detected 100.827 $\mu$ A from 8846A								
V1 shorted to GND								
0.0000 $\Omega$		0.000	0.999	5.000	$\Omega$	20		Pass
V1 open								
V1 > 1 M Ohms.								
<b>V2 Leakage calibration</b>								
UUT detected 100.815 $\mu$ A from 8846A								
V2 shorted to GND								
0.0000 $\Omega$		0.000	0.897	5.000	$\Omega$	18		Pass
V2 open								

## Calibration Results As Found

Certificate Number: SA01255807

Date of Calibration: 19 Feb 2024

Nominal value	Range	Lower limit	Measurement Result	Upper limit	Unit	% of Tol	TUR <4	Status
V2 > 1 M Ohms.								Pass
<b>V3 Leakage calibration</b>								
UUT detected 100.811 uA from 8846A								Pass
V3 shorted to GND								
0.0000	Ω	0.000	1.029	5.000	Ω	21		Pass
V3 open								
V3 > 1 M Ohms.								Pass
<b>V4 Leakage calibration</b>								
UUT detected 100.811 uA from 8846A								Pass
V4 shorted to GND								
0.0000	Ω	0.000	1.226	5.000	Ω	25		Pass
V4 open								
V4 > 1 M Ohms.								Pass
<b>V5 Leakage calibration</b>								
UUT detected 100.827 uA from 8846A								Pass
V5 shorted to GND								
0.0000	Ω	0.000	1.290	5.000	Ω	26		Pass
V5 open								
V5 > 1 M Ohms.								Pass
<b>V6 Leakage calibration</b>								
UUT detected 100.814 uA from 8846A								Pass
V6 shorted to GND								
0.0000	Ω	0.000	1.779	5.000	Ω	36		Pass
V6 open								
V6 > 1 M Ohms.								Pass
<b>Leakage calibration</b>								
HOT-NE, Direct Equipment, STD 353, OPEN EARTH								
1.04500	mA 50 Hz	1.0335	1.0440	1.0565	mA	9		Pass
HOT-NE; Accessible Part Leakage: STD 1010, CLOSED EARTH								
1.03980	mA 50 Hz	1.0283	1.0380	1.0513	mA	16		Pass
HOT-AP; Direct Equipment Leakage: STD 353, OPEN EARTH								
1.04930	mA 50 Hz	1.0378	1.0440	1.0608	mA	46		Pass
Direct Applied Part: Ground-RA								
0.97350	mA 50 Hz	0.9620	0.9756	0.9850	mA	18		Pass
Alternate Equipment Leakage: Ground-Neutral								
0.97430	mA 50 Hz	0.9628	0.9694	0.9858	mA	42		Pass
Alternative Applied Part Patient Leakage: Ground-RA								
0.97530	mA 50 Hz	0.9638	0.9738	0.9868	mA	13		Pass
Alternative Applied Part Patient Leakage: Hot-RA								
0.97520	mA 50 Hz	0.9637	0.9754	0.9867	mA	2		Pass
Alternative Applied Part Patient Leakage: NE-RA								
0.97530	mA 50 Hz	0.9628	0.9755	0.9878	mA	2		Pass
<b>ECG Waveform calibration</b>								
10	Hz	9.8	10.0	10.2	Hz	2		Pass
RA-RL Amplitude								
0.6740	mV 2 Hz	0.640	0.679	0.708	mV	16		Pass

## Calibration Results As Found

Certificate Number: SA01255807

Date of Calibration: 19 Feb 2024

Nominal value	Range		Lower limit	Measurement Result	Upper limit	Unit	% of Tol	TUR <4	Status
LL-RL Amplitude 1.6730	mV	2 Hz	1.589	1.682	1.757	mV	11		Pass
LA-RL Amplitude 1.3840	mV	2 Hz	1.315	1.395	1.453	mV	16		Pass
V1-RL Amplitude 2.0740	mV	2 Hz	1.970	2.095	2.178	mV	20		Pass
V2-RL Amplitude 2.5710	mV	2 Hz	2.442	2.595	2.700	mV	19		Pass
V3-RL Amplitude 3.1850	mV	2 Hz	3.026	3.202	3.344	mV	10		Pass
V4-RL Amplitude 3.5040	mV	2 Hz	3.329	3.530	3.679	mV	15		Pass
V5-RL Amplitude 2.8940	mV	2 Hz	2.749	2.914	3.039	mV	14		Pass
V6-RL Amplitude 2.5710	mV	2 Hz	2.442	2.588	2.700	mV	13		Pass
<b>Equipment current calibration</b>									
Normal mains polarity:									
1.19	A	50 Hz	20	0.9	1.2	1.4	A	4	Pass
2.08	A	50 Hz	20	1.8	2.1	2.4	A	7	Pass
3.98	A	50 Hz	20	3.6	4.1	4.4	A	29	Pass
7.92	A	50 Hz	20	7.3	8.0	8.5	A	13	Pass
Reversed mains polarity:									
1.18	A	50 Hz	20	0.9	1.2	1.4	A	6	Pass
2.08	A	50 Hz	20	1.8	2.1	2.4	A	7	Pass
3.99	A	50 Hz	20	3.6	4.1	4.4	A	27	Pass
7.93	A	50 Hz	20	7.3	8.0	8.5	A	12	Pass
Safety test									

- End of As Found data ~

Summary Report	Total	Pass	Fail	n/a
Number of Tests	182	179	3	0

## Calibration Results As Left

Certificate Number: SA01255807

Date of Calibration: 20 Feb 2024

Nominal value	Range	Lower limit	Measurement Result	Upper limit	Unit	% of Tol	TUR <4	Status
Internal fan test								Pass
Warning LED test								Pass
Beeper test								Pass
Keyboard verification								Pass
<b>Test Receptacle verification</b>								
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, Open Gnd.								Pass
230 VAC : Rev Pol, Closed Neut, Closed Gnd.								Pass
<b>Mains Voltage calibration</b>								
<b>L - N</b>								
230.05	V 50 Hz 300	224.4	230.8	235.7	V	13		Pass
<b>L - PE</b>								
230.08	V 50 Hz 300	224.5	230.9	235.7	V	15		Pass
<b>PE - N</b>								
0.03	V 50 Hz 300	0.0	0.1	1.0	V	7		Pass
<b>GFI Tests</b>								
5mA GFI Test limit didn't trip @4.0mA 50Hz								Pass
5mA GFI Test limit tripped @6.0mA 50Hz								Pass
10mA GFI Test limit didn't trip @8mA 50Hz								Pass
10mA GFI Test limit tripped @12mA 50Hz								Pass
25mA GFI Test limit didn't trip @20mA 50Hz								Pass
25mA GFI Test limit tripped @30mA 50Hz								Pass
<b>POINT to POINT Voltage calibration</b>								
0.00	V 47 Hz	-0.2	0.0	0.2	V	9		Pass
4.00	V 47 Hz	3.7	4.0	4.3	V	4		Pass
8.00	V 47 Hz	7.6	8.0	8.4	V	8		Pass
10.00	V 47 Hz	9.6	10.0	10.4	V	5		Pass
25.00	V 47 Hz	24.3	25.0	25.7	V	5		Pass
40.00	V 47 Hz	39.0	40.0	41.0	V	5		Pass
80.00	V 47 Hz	78.2	79.9	81.8	V	4		Pass
130.00	V 47 Hz	127.2	130.0	132.8	V	2		Pass
240.00	V 47 Hz	235.0	240.1	245.0	V	2		Pass
0.00	V 63 Hz	-0.2	0.0	0.2	V	9		Pass
4.00	V 63 Hz	3.7	4.0	4.3	V	0		Pass
8.00	V 63 Hz	7.6	8.0	8.4	V	5		Pass
10.00	V 63 Hz	9.6	10.0	10.4	V	4		Pass
25.00	V 63 Hz	24.3	25.0	25.7	V	3		Pass
40.00	V 63 Hz	39.0	40.0	41.0	V	0		Pass
80.00	V 63 Hz	78.2	80.0	81.8	V	0		Pass
130.00	V 63 Hz	127.2	130.0	132.8	V	2		Pass
240.00	V 63 Hz	235.0	240.2	245.0	V	5		Pass
<b>Ground Resistance calibration</b>								
low test current mode:								
0.1265	Ω 2W	0.109	0.124	0.144	Ω	13		Pass
0.2153	Ω 2W	0.196	0.216	0.235	Ω	4		Pass
0.3087	Ω 2W	0.278	0.310	0.339	Ω	4		Pass
0.5419	Ω 2W	0.500	0.544	0.584	Ω	6		Pass
1.8143	Ω 2W	1.708	1.822	1.920	Ω	7		Pass
0.1704	Ω 4W	0.162	0.171	0.179	Ω	4		Pass

## Calibration Results As Left

Certificate Number: SA01255807

Date of Calibration: 20 Feb 2024

Nominal value	Range	Lower limit	Measurement Result	Upper limit	Unit	% of Tol	TUR <4	Status
0.2501	Ω 4W	0.240	0.253	0.260	Ω	26		Pass
0.3430	Ω 4W	0.321	0.346	0.365	Ω	14		Pass
0.5739	Ω 4W	0.540	0.578	0.608	Ω	13		Pass
1.8335	Ω 4W	1.736	1.843	1.931	Ω	10		Pass
high test current mode:								
0.1527	Ω 2W	0.135	0.155	0.171	Ω	14		Pass
0.0386	Ω 4W	0.033	0.042	0.044	Ω	63		Pass
0.1917	Ω 4W	0.183	0.195	0.201	Ω	42		Pass
high test current mode, open circuit voltage & short circuit current (into 50 mOhm):								
25.00	A 50 Hz	22.500	24.116	27.500	A	35		Pass
6.50	V 50 Hz	5.850	6.477	7.150	V	4		Pass
POINT to POINT Resistance calibration								
1.8133	Ω 2W	1.762	1.822	1.865	Ω	17		Pass
1.8369	Ω 4W	1.795	1.843	1.879	Ω	15		Pass
Insulation Resistance Voltage calibration								
250.00	V	250.0	257.0	300.0	V	14		Pass
500.00	V	500.0	511.1	600.0	V	11		Pass
Current limit								
1.5850	mA	1.300	1.442	1.870	mA	50		Pass
Mains-PE Resistance calibration								
9.98	MΩ	9.6	10.0	10.4	MΩ	5		Pass
Insulation Resistance calibration AP-PE								
0.70	MΩ 250 V	0.5	0.7	0.9	MΩ	0		Pass
0.70	MΩ 500 V	0.5	0.7	0.9	MΩ	0		Pass
1.00	MΩ 250 V	0.8	1.0	1.2	MΩ	1		Pass
1.00	MΩ 500 V	0.8	1.0	1.2	MΩ	1		Pass
2.00	MΩ 250 V	1.8	2.0	2.2	MΩ	1		Pass
2.00	MΩ 500 V	1.8	2.0	2.2	MΩ	3		Pass
3.10	MΩ 250 V	2.8	3.1	3.4	MΩ	0		Pass
3.10	MΩ 500 V	2.8	3.1	3.4	MΩ	4		Pass
6.49	MΩ 250 V	6.2	6.5	6.8	MΩ	14		Pass
6.49	MΩ 500 V	6.2	6.6	6.8	MΩ	19		Pass
9.98	MΩ 250 V	9.6	10.0	10.4	MΩ	1		Pass
9.98	MΩ 500 V	9.6	10.0	10.4	MΩ	8		Pass
17.96	MΩ 250 V	17.4	18.0	18.5	MΩ	4		Pass
17.96	MΩ 500 V	17.4	18.0	18.5	MΩ	7		Pass
21.87	MΩ 250 V	20.0	21.9	23.7	MΩ	1		Pass
21.87	MΩ 500 V	20.0	21.9	23.7	MΩ	2		Pass
59.61	MΩ 250 V	54.9	59.6	64.3	MΩ	0		Pass
59.61	MΩ 500 V	54.9	59.8	64.3	MΩ	4		Pass
99.72	MΩ 250 V	92.1	99.4	107.4	MΩ	4		Pass
99.72	MΩ 500 V	92.1	99.5	107.4	MΩ	3		Pass
Insulation Resistance calibration MAINS-NE								
9.98	MΩ 500 V	9.6	10.0	10.4	MΩ	7		Pass
Insulation Resistance calibration MAINS-AP								
RA test point								
9.98	MΩ 500 V	9.6	10.0	10.4	MΩ	8		Pass
LL test point								
9.98	MΩ 500 V	9.6	10.0	10.4	MΩ	7		Pass
LA test point								

## Calibration Results As Left

Date of Calibration: 20 Feb 2024

Certificate Number: SA01255807

Nominal value	Range	Lower limit	Measurement Result	Upper limit	Unit	% of Tol	TUR <4	Status
9.98 MΩ	500 V 20	9.6	10.0	10.4	MΩ	8		Pass
RL test point	9.98 MΩ 500 V 20	9.6	10.0	10.4	MΩ	8		Pass
V1 test point	9.98 MΩ 500 V 20	9.6	10.0	10.4	MΩ	7		Pass
V2 test point	9.98 MΩ 500 V 20	9.6	10.0	10.4	MΩ	8		Pass
V3 test point	9.98 MΩ 500 V 20	9.6	10.0	10.4	MΩ	7		Pass
V4 test point	9.98 MΩ 500 V 20	9.6	10.0	10.4	MΩ	8		Pass
V5 test point	9.98 MΩ 500 V 20	9.6	10.0	10.4	MΩ	8		Pass
V6 test point	9.98 MΩ 500 V 20	9.6	10.0	10.4	MΩ	7		Pass
<b>Insulation Resistance calibration AP-NE</b>								
V6 test point	9.98 MΩ 500 V 20	9.6	10.0	10.4	MΩ	8		Pass
V5 test point	9.98 MΩ 500 V 20	9.6	10.0	10.4	MΩ	8		Pass
V4 test point	9.98 MΩ 500 V 20	9.6	10.0	10.4	MΩ	8		Pass
V3 test point	9.98 MΩ 500 V 20	9.6	10.0	10.4	MΩ	8		Pass
V2 test point	9.98 MΩ 500 V 20	9.6	10.0	10.4	MΩ	8		Pass
V1 test point	9.98 MΩ 500 V 20	9.6	10.0	10.4	MΩ	8		Pass
RL test point	9.98 MΩ 500 V 20	9.6	10.0	10.4	MΩ	8		Pass
LA test point	9.98 MΩ 500 V 20	9.6	10.0	10.4	MΩ	9		Pass
LL test point	9.98 MΩ 500 V 20	9.6	10.0	10.4	MΩ	8		Pass
RA test point	9.98 MΩ 500 V 20	9.6	10.0	10.4	MΩ	8		Pass
<b>DC Leakage Resistance calibration</b>								
AAMI	1.0000 kΩ	0.980	1.002	1.020	kΩ	9		Pass
IEC60601	1.0000 kΩ	0.980	1.002	1.020	kΩ	9		Pass
IEC61010	2.0000 kΩ	1.960	2.002	2.040	kΩ	6		Pass
<b>DC Leakage Current calibration</b>								
10.00 μA	200	8.9	9.7	11.1	μA	25		Pass
50.00 μA	200	48.5	49.6	51.5	μA	26		Pass
100.00 μA	200	98.0	99.5	102.0	μA	26		Pass
160.00 μA	200	157.4	159.1	162.6	μA	36		Pass
340.0 μA	2000	336	339	344	μA	27		Pass
500.0 μA	2000	494	499	506	μA	23		Pass
1.0000 mA	2	0.989	0.998	1.011	mA	20		Pass
1.6000 mA	2	1.583	1.598	1.617	mA	12		Pass
3.400 mA	10	3.36	3.39	3.44	mA	16		Pass
5.000 mA	10	4.94	4.99	5.06	mA	13		Pass
7.000 mA	10	6.92	6.97	7.08	mA	40		Pass

Differential Leakage calibration



## Calibration Results As Left

Certificate Number: SA01255807

Date of Calibration: 20 Feb 2024

Nominal value	Range	Lower limit	Measurement Result	Upper limit	Unit	% of Tol	TUR <4	Status
75.7	µA 50 Hz 200	47	91	105	µA	53		Pass
181.2	µA 50 Hz 200	124	168	198	µA	19		Pass
240.3	µA 50 Hz 2000	196	245	285	µA	11		Pass
500.4	µA 50 Hz 2000	430	502	571	µA	2		Pass
759.2	µA 50 Hz 2000	663	759	855	µA	0		Pass
1,600.0	mA 50 Hz 2	1,420	1,600	1,780	mA	0		Pass
2,398	mA 50 Hz 20	2,14	2,39	2,66	mA	3		Pass
5,003	mA 50 Hz 20	4,48	4,99	5,52	mA	3		Pass
7,702	mA 50 Hz 20	6,91	7,69	8,49	mA	2		Pass
16,410	mA 50 Hz 20	14,75	16,37	18,07	mA	2		Pass
<b>Leakage functionality tests</b>								
Apply DC current, attempt to measure with AC mode								
0.0000	µA	0.000	0.279	1.000	µA	28		Pass
Apply AC current, attempt to measure with DC mode								
0.0000	µA 50 Hz	-1.000	0.194	1.000	µA	19		Pass
<b>RA Leakage calibration</b>								
UUT detected 100.811 uA from 8846A								
RA shorted to GND								
0.0000	Ω	0.000	1.221	5.000	Ω	24		Pass
RA open								
RA > 1 M Ohms.								
<b>LL Leakage calibration</b>								
UUT detected 100.806 uA from 8846A								
LL shorted to GND								
0.0000	Ω	0.000	1.022	5.000	Ω	20		Pass
LL open								
LL > 1 M Ohms.								
<b>LA Leakage calibration</b>								
UUT detected 100.811 uA from 8846A								
LA shorted to GND								
0.0000	Ω	0.000	0.706	5.000	Ω	14		Pass
LA open								
LA > 1 M Ohms.								
<b>RL Leakage calibration</b>								
UUT detected 100.801 uA from 8846A								
RL shorted to GND								
0.0000	Ω	0.000	0.592	5.000	Ω	12		Pass
RL open								
RL > 1 M Ohms.								
<b>V1 Leakage calibration</b>								
UUT detected 100.804 uA from 8846A								
V1 shorted to GND								
0.0000	Ω	0.000	1.051	5.000	Ω	21		Pass
V1 open								
V1 > 1 M Ohms.								
<b>V2 Leakage calibration</b>								
UUT detected 100.809 uA from 8846A								
V2 shorted to GND								
0.0000	Ω	0.000	0.929	5.000	Ω	19		Pass
V2 open								

## Calibration Results As Left

Certificate Number: SA01255807

Date of Calibration: 20 Feb 2024

Nominal value	Range	Lower limit	Measurement Result	Upper limit	Unit	% of Tol	TUR <4	Status	
V2 > 1 M Ohms.								Pass	
<b>V3 Leakage calibration</b>									
UUT detected 100.812 uA from 8846A									
V3 shorted to GND		0.000	1.060	5.000	Ω	21		Pass	
0.0000	Ω								
V3 open								Pass	
V3 > 1 M Ohms.									
<b>V4 Leakage calibration</b>									
UUT detected 100.804 uA from 8846A									
V4 shorted to GND		0.000	1.256	5.000	Ω	25		Pass	
0.0000	Ω								
V4 open								Pass	
V4 > 1 M Ohms.									
<b>V5 Leakage calibration</b>									
UUT detected 100.803 uA from 8846A									
V5 shorted to GND		0.000	1.323	5.000	Ω	27		Pass	
0.0000	Ω								
V5 open								Pass	
V5 > 1 M Ohms.									
<b>V6 Leakage calibration</b>									
UUT detected 100.794 uA from 8846A									
V6 shorted to GND		0.000	1.814	5.000	Ω	36		Pass	
0.0000	Ω								
V6 open								Pass	
V6 > 1 M Ohms.									
<b>Leakage calibration</b>									
HOT-NE, Direct Equipment, STD 353, OPEN EARTH									
1.04740	mA	50	Hz	1.0359	1.0440	1.0589	mA	30	Pass
HOT-NE; Accessible Part Leakage: STD 1010, CLOSED EARTH									
1.04000	mA	50	Hz	1.0285	1.0380	1.0515	mA	17	Pass
HOT-AP; Direct Equipment Leakage: STD 353, OPEN EARTH									
1.04630	mA	50	Hz	1.0348	1.0440	1.0578	mA	20	Pass
Direct Applied Part: Ground-RA									
0.97310	mA	50	Hz	0.9616	0.9772	0.9846	mA	36	Pass
Alternate Equipment Leakage: Ground-Neutral									
0.97390	mA	50	Hz	0.9624	0.9683	0.9854	mA	49	Pass
Alternative Applied Part Patient Leakage: Ground-RA									
0.97510	mA	50	Hz	0.9636	0.9745	0.9866	mA	5	Pass
Alternative Applied Part Patient Leakage: Hot-RA									
0.97490	mA	50	Hz	0.9634	0.9756	0.9864	mA	6	Pass
Alternative Applied Part Patient Leakage: NE-RA									
0.97500	mA	50	Hz	0.9625	0.9743	0.9875	mA	6	Pass
<b>ECG Waveform calibration</b>									
10	Hz		9.8	10.0	10.2	Hz	0	Pass	
RA-RL Amplitude									
0.6740	mV	2	Hz	0.640	0.679	0.708	mV	15	Pass

## Calibration Results As Left

Certificate Number: SA01255807

Date of Calibration: 20 Feb 2024

Nominal value			Range	Lower limit	Measurement Result	Upper limit	Unit	% of Tol	TUR <4	Status
LL-RL Amplitude	1.6730	mV	2 Hz	1.589	1.682	1.757	mV	11		Pass
LA-RL Amplitude	1.3840	mV	2 Hz	1.315	1.394	1.453	mV	15		Pass
V1-RL Amplitude	2.0740	mV	2 Hz	1.970	2.095	2.178	mV	20		Pass
V2-RL Amplitude	2.5710	mV	2 Hz	2.442	2.595	2.700	mV	19		Pass
V3-RL Amplitude	3.1850	mV	2 Hz	3.026	3.201	3.344	mV	10		Pass
V4-RL Amplitude	3.5040	mV	2 Hz	3.329	3.530	3.679	mV	15		Pass
V5-RL Amplitude	2.8940	mV	2 Hz	2.749	2.914	3.039	mV	14		Pass
V6-RL Amplitude	2.5710	mV	2 Hz	2.442	2.588	2.700	mV	14		Pass
<b>Equipment current calibration</b>										
Normal mains polarity:										
	1.19	A	50 Hz	20	0.9	1.2	1.5	A	3	Pass
	2.10	A	50 Hz	20	1.8	2.1	2.4	A	2	Pass
	3.99	A	50 Hz	20	3.6	4.0	4.4	A	3	Pass
	7.92	A	50 Hz	20	7.3	7.9	8.5	A	4	Pass
Reversed mains polarity:										
	1.18	A	50 Hz	20	0.9	1.2	1.4	A	9	Pass
	2.08	A	50 Hz	20	1.8	2.1	2.4	A	7	Pass
	4.01	A	50 Hz	20	3.6	4.1	4.4	A	22	Pass
	7.93	A	50 Hz	20	7.3	8.0	8.5	A	12	Pass
Safety test										Pass

~ End of As Left data ~

Summary Report	Total	Pass	Fail	n/a
Number of Tests	182	182	0	0

[ End of Certificate ]

# REPAIR REPORT



No.: 3727912  
RMA: 606324354 Line: 7

## REPAIR INFORMATION

Model: ESA620  
Serial number: 1061009  
Inventory number: 28489  
Receive date: 15/Feb/24  
Report date: 20/Feb/24

### REPAIR DESCRIPTION:

Pcn installed

### COMMENTS (OPTIONAL):

PCN06629 installed. FW update to v2.14

**TECHNICIAN:** A. Licareti

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