

Le 3-juin 2025

Mme Annie Tardif
Coordonnatrice
Recherche Clinique

OBJET : Entretien annuel de l'appareil d'électrophysiologie
Compagnie: GE
Modèle: MAC5500 HD
SN: SKJ19170002PA
ID: 801054

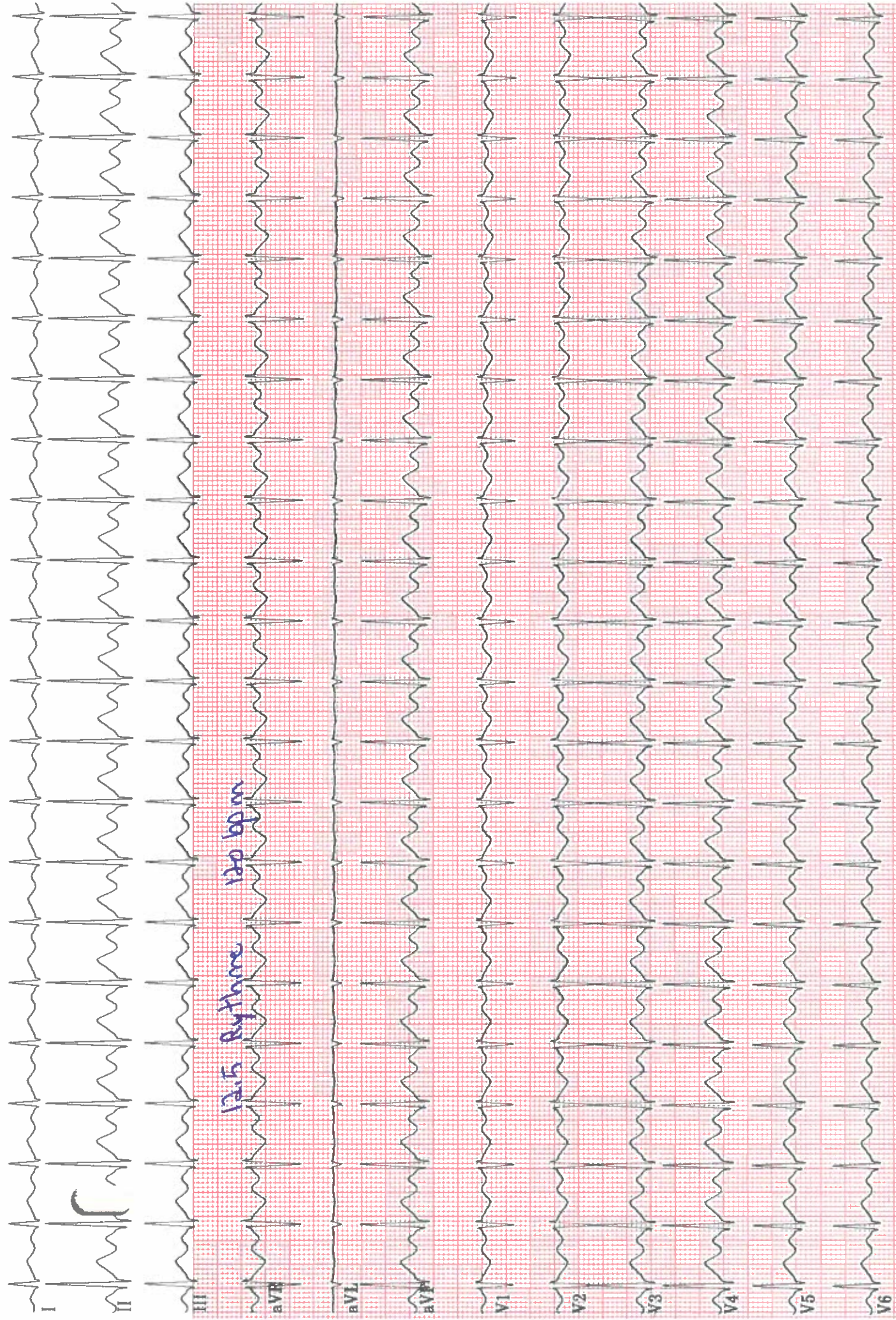
L'entretien suivant a été effectué :

- Vérification de la configuration interne
- Vérification du fonctionnement
- Test de fonctionnement de l'enregistrement ECG avec simulateur
(Simulateur Bio-Tek ECG plus S/N: 91902 certifié 28-08-2024)
- Inspection des courants de fuite
(Analyseur Fluke ESA620 S/N: 2863062 certifié 27-08-2024)

Le tout conforme, seule l'interprétation de l'ECG ne peut être validée.

A handwritten signature in blue ink, appearing to read 'Eric Lavoie'.

Eric Lavoie
Coordonnateur Technique en GBM
Service Génie Biomédical

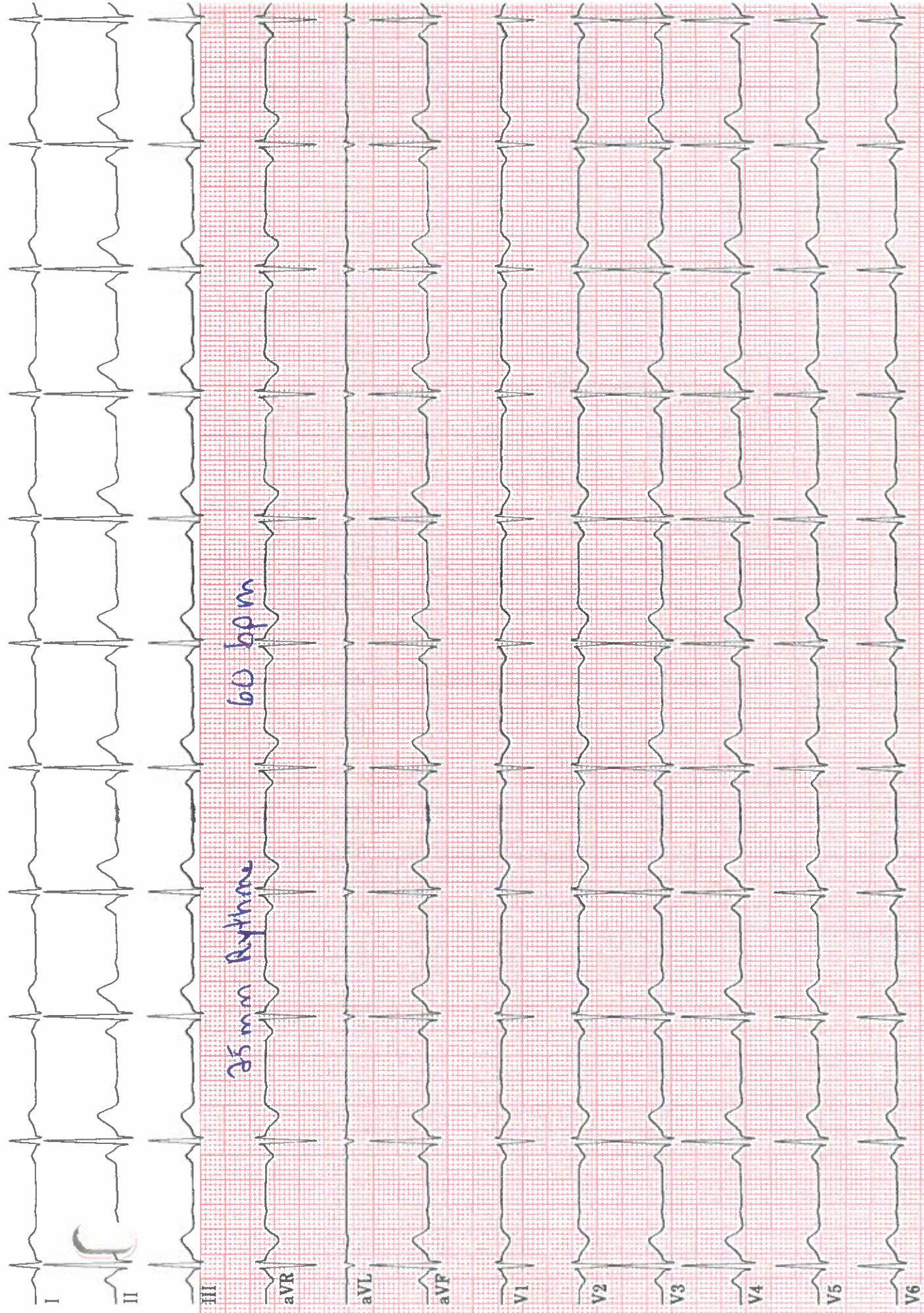


60 bpm

TRACÉ DE RYTHME

3-jun-2025 9:30:43

ID: 801054



MAC55 010Bsp1

10.0mm/mV

25.0mm/s

0.16-150Hz

COVIDIEN Kendali

Printed in USA

23065

Fluke Biomedical Ansur Test and Inspection Procedure

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Test Record

TEST PASSED

Test Performed

Date: 03-06-2025
Record: 801054 2025-06-03.mtr
Template: IEC 60601-1 - CL1.mtt
Template Version: 1.0.0

Ansur Components Used

Ansur Version 3.1.3
Plug-In: ESA620 Version 1.2.6

Test Setup

Selections

Service Events Performed

Standards Performed

IEC 60601

Device under test

Serial Number 801054
Appliance Code .
Group .
Status .
Manufacturer .

Type .
Model .
Location .
Address 1 .
Address 2 .

MTI Data

Test Instrument

ESA 620

Serial Number

2863062

Firmware Version

v2.12

Signatures

Eric Yarnie

3-06-2024

Test Result

Test Element	Test Type					Fail
IEC 60601-1 - CL1	Auto Sequence					
Procedure: (1) Connect the DUT to the ESA620 as indicated in the operators manual. (2) Ensure that DUT power is On. (3) Click module setup and specify the patient leads that are to be tested. (4) Connect patient leads as indicated to the right. (5) Click Start Test to perform the safety test.						
Applied Part setup						
#	Applied Part info		Class	Leads		
1	A.P. Code Serial No. Type	(new)	CF	10		
Mains Voltage						
<i>Mains Voltage</i>						
Live to Neutral						
<i>Mains Voltage Live to Neutral</i>						
Result: Live to Neutral	Value 120	Unit V	High Limit	Low Limit	Standard IEC 60601	
Neutral to Earth						
<i>Mains Voltage Neutral to Earth</i>						
Result: Neutral to Earth	Value 0,2	Unit V	High Limit	Low Limit	Standard IEC 60601	
Live to Earth						
<i>Mains Voltage Live to Earth</i>						
Result: Live to Earth	Value 119,9	Unit V	High Limit	Low Limit	Standard IEC 60601	
Protective Earth Resistance						
<i>Earth Resistance</i>						
Configuration: Test Current: High						
Result: PE Resistance1	Value 0,144	Unit Ohm	High Limit 0,2	Low Limit	Standard IEC 60601	
Insulation Resistance						
<i>Insulation Resistance</i>						
Configuration: Test Voltage: 500V						
Mains to Protective Earth						
<i>Insulation Resistance Mains to Protective Earth</i>						
Result: Mains to Protective Earth	Value 99999	Unit MOhm	High Limit	Low Limit 2	Standard IEC 60601	
Applied Parts to Protective Earth						
<i>Insulation Resistance Applied Parts to Protective Earth</i>						
Result: Applied Parts to Protective Earth	Value 100,4	Unit MOhm	High Limit	Low Limit	Standard IEC 60601	
Earth Leakage Current						
<i>Earth Leakage Current</i>						

Fluke Biomedical Ansur Test Report

Test Element	Test Type					Fail
Configuration: Unused Applied Parts: Floating						
Normal Condition	Earth Leakage Current Normal Condition					
Result:	Value	Unit	High Limit	Low Limit	Standard	
Normal Condition	21,7	uAAC+DC	5000		IEC 60601	
Open Neutral	Earth Leakage Current Open Neutral					
Result:	Value	Unit	High Limit	Low Limit	Standard	
Open Neutral	41,3	uAAC+DC	10000		IEC 60601	
Normal Condition, Reversed mains	Earth Leakage Current Normal Condition, Reversed mains					
Result:	Value	Unit	High Limit	Low Limit	Standard	
Normal Condition, Reversed mains	20,4	uAAC+DC	5000		IEC 60601	
Open Neutral, Reversed Mains	Earth Leakage Current Open Neutral, Reversed Mains					
Result:	Value	Unit	High Limit	Low Limit	Standard	
Open Neutral, Reversed Mains	41,3	uAAC+DC	10000		IEC 60601	
Enclosure Leakage Current	Enclosure Leakage Current					
Configuration: Unused Applied Parts: Floating						
Normal Condition	Enclosure Leakage Current Normal Condition					
Result:	Value	Unit	High Limit	Low Limit	Standard	
Normal Condition	1,1	uAAC+DC	100		IEC 60601	
Open Neutral	Enclosure Leakage Current Open Neutral					
Result:	Value	Unit	High Limit	Low Limit	Standard	
Open Neutral	1	uAAC+DC	500		IEC 60601	
Open Earth	Enclosure Leakage Current Open Earth					
Result:	Value	Unit	High Limit	Low Limit	Standard	
Open Earth	21,6	uAAC+DC	500		IEC 60601	
Normal Condition, Reversed mains	Enclosure Leakage Current Normal Condition, Reversed mains					
Result:	Value	Unit	High Limit	Low Limit	Standard	
Normal Condition, Reversed mains	1	uAAC+DC	100		IEC 60601	
Open Neutral, Reversed Mains	Enclosure Leakage Current Open Neutral, Reversed Mains					
Result:	Value	Unit	High Limit	Low Limit	Standard	
Open Neutral, Reversed Mains	1	uAAC+DC	500		IEC 60601	
Open Earth, Reversed Mains	Enclosure Leakage Current Open Earth, Reversed Mains					
Result:	Value	Unit	High Limit	Low Limit	Standard	
Open Earth, Reversed Mains	20,4	uAAC+DC	500		IEC 60601	

Fluke Biomedical Ansur Test Report

Test Element	Test Type					Fail
Patient Leakage Current <i>Configuration:</i> Total Leakage: No Unused Applied Parts: Floating	<i>Patient Leakage Current</i>					
Normal Condition <i>Result:</i> (new)	<i>Value</i> 0,2	<i>Unit</i> uAAC+DC	<i>High Limit</i> 10	<i>Low Limit</i>	<i>Standard</i> IEC 60601	
Open Neutral <i>Result:</i> (new)	<i>Value</i> 0,2	<i>Unit</i> uAAC+DC	<i>High Limit</i> 50	<i>Low Limit</i>	<i>Standard</i> IEC 60601	
Open Earth <i>Result:</i> (new)	<i>Value</i> 4,1	<i>Unit</i> uAAC+DC	<i>High Limit</i> 50	<i>Low Limit</i>	<i>Standard</i> IEC 60601	
Normal Condition, Reversed mains <i>Result:</i> (new)	<i>Value</i> 0,2	<i>Unit</i> uAAC+DC	<i>High Limit</i> 10	<i>Low Limit</i>	<i>Standard</i> IEC 60601	
Open Neutral, Reversed Mains <i>Result:</i> (new)	<i>Value</i> 0,2	<i>Unit</i> uAAC+DC	<i>High Limit</i> 50	<i>Low Limit</i>	<i>Standard</i> IEC 60601	
Open Earth, Reversed Mains <i>Result:</i> (new)	<i>Value</i> 3,9	<i>Unit</i> uAAC+DC	<i>High Limit</i> 50	<i>Low Limit</i>	<i>Standard</i> IEC 60601	
Mains on Applied Parts <i>Configuration:</i> Total Leakage: No Unused Applied Parts: Floating	<i>Mains on Applied Parts</i>					
Single Fault Condition <i>Result:</i> (new)	<i>Value</i> 12,7	<i>Unit</i> uA	<i>High Limit</i> 50	<i>Low Limit</i>	<i>Standard</i> IEC 60601	
Single Fault Condition, Reversed Mains <i>Result:</i> (new)	<i>Value</i> 12,6	<i>Unit</i> uA	<i>High Limit</i> 50	<i>Low Limit</i>	<i>Standard</i> IEC 60601	
Patient Auxiliary Current <i>Configuration:</i> Unused Applied Parts: Floating	<i>Patient Auxiliary Current</i>					
Normal Condition <i>Result:</i> (new)	<i>Value</i> 0,4	<i>Unit</i> uAAC+DC	<i>High Limit</i> 10	<i>Low Limit</i>	<i>Standard</i> IEC 60601	
Open Neutral	<i>Patient Auxiliary Current</i> <i>Open Neutral</i>					

Eluke Biomedical Ansur Test Report

Test Element	Test Type					Fail
Result: (new)	Value 0,4	Unit uAAC+DC	High Limit 50	Low Limit	Standard IEC 60601	
Open Earth	<i>Patient Auxiliary Current</i> <i>Open Earth</i>					
Result: (new)	Value 2,9	Unit uAAC+DC	High Limit 50	Low Limit	Standard IEC 60601	
Normal Condition, Reversed mains	<i>Patient Auxiliary Current</i> <i>Normal Condition, Reversed mains</i>					
Result: (new)	Value 0,4	Unit uAAC+DC	High Limit 10	Low Limit	Standard IEC 60601	
Open Neutral, Reversed Mains	<i>Patient Auxiliary Current</i> <i>Open Neutral, Reversed Mains</i>					
Result: (new)	Value 0,4	Unit uAAC+DC	High Limit 50	Low Limit	Standard IEC 60601	
Open Earth, Reversed Mains	<i>Patient Auxiliary Current</i> <i>Open Earth, Reversed Mains</i>					
Result: (new)	Value 2,7	Unit uAAC+DC	High Limit 50	Low Limit	Standard IEC 60601	