

Le 31 mai 2026

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 29-09-2025)
- Inspection des courants de fuite
(Analyseur Fluke ESA620 S/N: 2863062 certifié 29-09-2025)

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



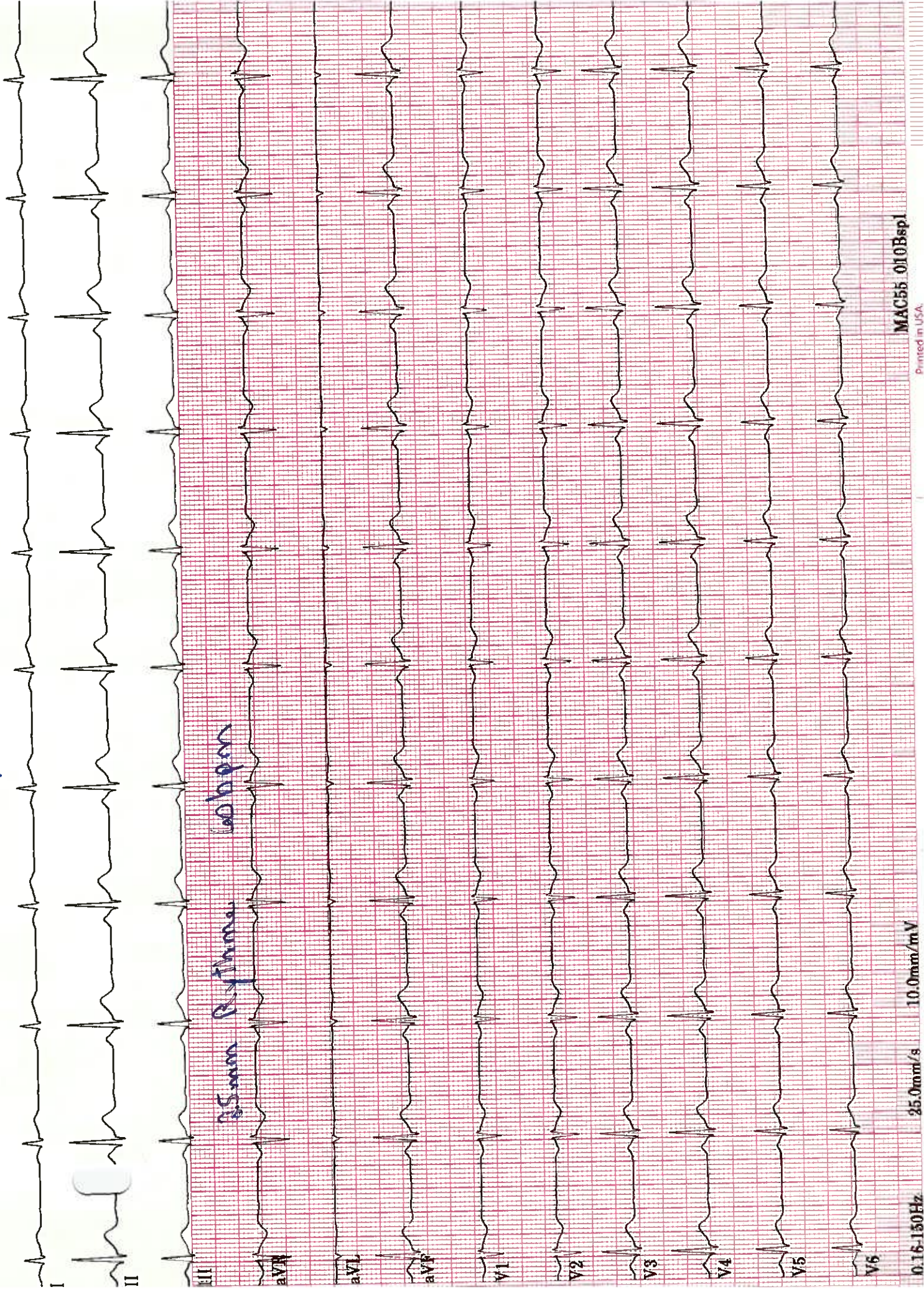
Eric Lavoie
Coordonnateur Technique en GBM
Service Génie Biomédical

60 bpm

TRACE DE RYTHME

31-mai-2026 5:23:53

ID: 801054



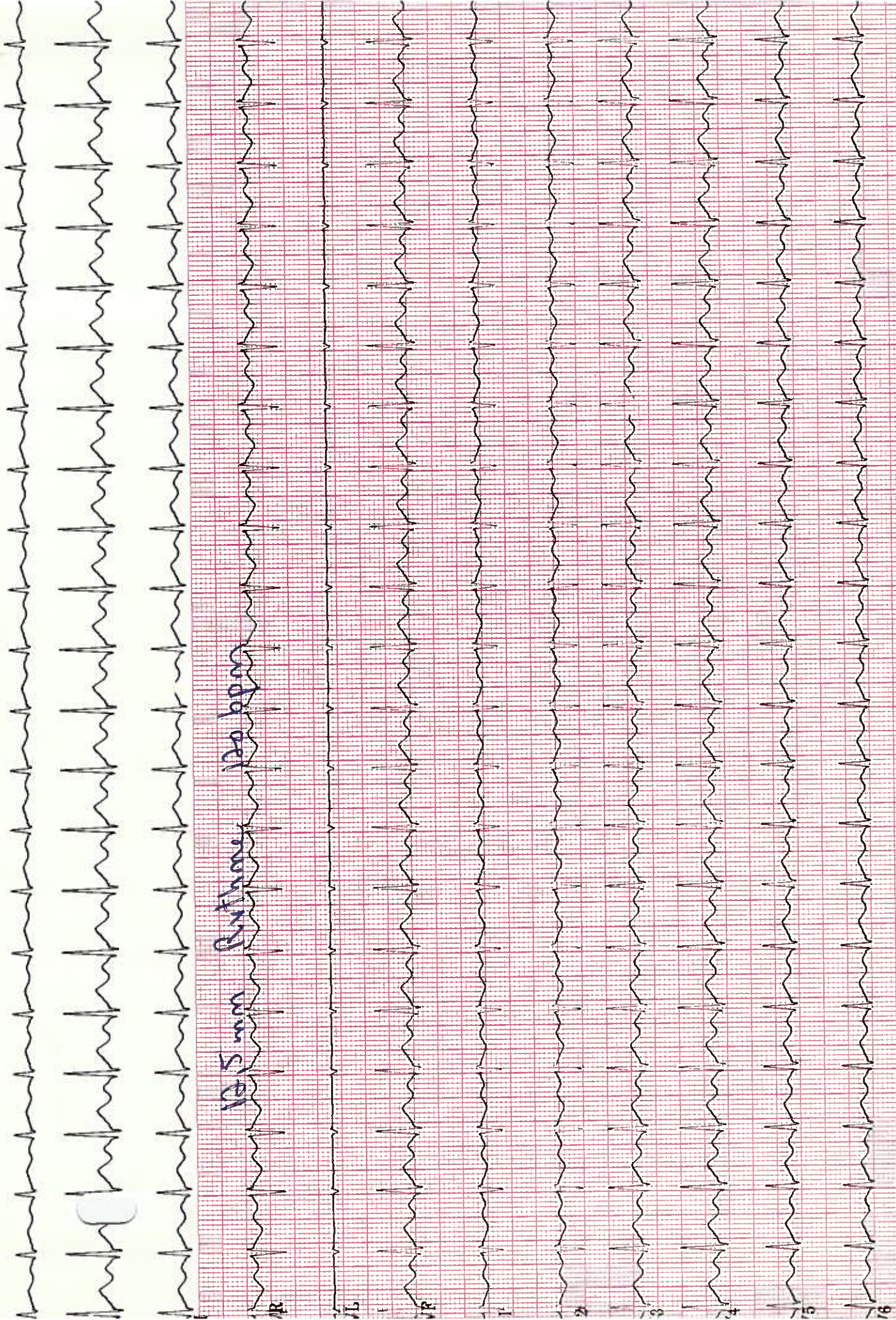
MAC55 010Bsp1

Printed in USA

25.0mm/s 10.0mm/mV

0.15-150Hz

ID: 801054



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TEST PASSED

Ansur Version 3.1.3
 Plug-In: ESA620 Version 1.2.6

31-05-2026

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</i>					
<i>Live to Neutral</i>					
Result: Live to Neutral	Value 120,9	Unit V	High Limit	Low Limit	Standard IEC 60601
Neutral to Earth					
<i>Mains Voltage</i>					
<i>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</i>					
<i>Live to Earth</i>					
Result: Live to Earth	Value 121	Unit V	High Limit	Low Limit	Standard IEC 60601
Protective Earth Resistance					
<i>Earth Resistance</i>					
Configuration: Test Current: High					
Result: PE Resistance1	Value 0,165	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</i>					
<i>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</i>					
<i>Applied Parts to Protective Earth</i>					
Result: Applied Parts to Protective Earth	Value 100,5	Unit MOhm	High Limit	Low Limit	Standard IEC 60601
Earth Leakage Current					
<i>Earth Leakage Current</i>					

Eluke Biomedical Ansur Test Report

Fluke Biomedical Ansur Test Report

31-05-2020

Test Element	Test Type				Fail
Configuration: Unused Applied Parts: Floating					
Normal Condition	Earth Leakage Current Normal Condition				
Result: Normal Condition	Value 22,2	Unit uAAC+DC	High Limit 5000	Low Limit	Standard IEC 60601
Open Neutral	Earth Leakage Current Open Neutral				
Result: Open Neutral	Value 41,4	Unit uAAC+DC	High Limit 10000	Low Limit	Standard IEC 60601
Normal Condition, Reversed mains	Earth Leakage Current Normal Condition, Reversed mains				
Result: Normal Condition, Reversed mains	Value 20,6	Unit uAAC+DC	High Limit 5000	Low Limit	Standard IEC 60601
Open Neutral, Reversed Mains	Earth Leakage Current Open Neutral, Reversed Mains				
Result: Open Neutral, Reversed Mains	Value 41,5	Unit uAAC+DC	High Limit 10000	Low Limit	Standard IEC 60601
Enclosure Leakage Current	Enclosure Leakage Current				
Configuration: Unused Applied Parts: Floating					
Normal Condition	Enclosure Leakage Current Normal Condition				
Result: Normal Condition	Value 0,8	Unit uAAC+DC	High Limit 100	Low Limit	Standard IEC 60601
Open Neutral	Enclosure Leakage Current Open Neutral				
Result: Open Neutral	Value 0,8	Unit uAAC+DC	High Limit 500	Low Limit	Standard IEC 60601
Open Earth	Enclosure Leakage Current Open Earth				
Result: Open Earth	Value 22,1	Unit uAAC+DC	High Limit 500	Low Limit	Standard IEC 60601
Normal Condition, Reversed mains	Enclosure Leakage Current Normal Condition, Reversed mains				
Result: Normal Condition, Reversed mains	Value 0,8	Unit uAAC+DC	High Limit 100	Low Limit	Standard IEC 60601
Open Neutral, Reversed Mains	Enclosure Leakage Current Open Neutral, Reversed Mains				
Result: Open Neutral, Reversed Mains	Value 0,8	Unit uAAC+DC	High Limit 500	Low Limit	Standard IEC 60601
Open Earth, Reversed Mains	Enclosure Leakage Current Open Earth, Reversed Mains				
Result: Open Earth, Reversed Mains	Value 20,7	Unit uAAC+DC	High Limit 500	Low Limit	Standard 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	Patient Leakage Current				
Normal Condition <i>Result:</i> (new)	<i>Value</i> 0,6	<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> 0,6	<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> 4,3	<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> 0,6	<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> 0,6	<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> 4	<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	Mains on Applied Parts				
Single Fault Condition <i>Result:</i> (new)	<i>Value</i> 13,1	<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> 13,1	<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	Patient Auxiliary Current				
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	Patient Auxiliary Current Open Neutral				

Eluke Biomedical Ansur Test Report

Test Element	Test Type					Fail
Result: (new)	Value 0,2	Unit uAAC+DC	High Limit 50	Low Limit	Standard IEC 60601	
Open Earth	<i>Patient Auxiliary Current</i>					
Result: (new)	Value 3	Unit uAAC+DC	High Limit 50	Low Limit	Standard IEC 60601	
Normal Condition, Reversed mains	<i>Patient Auxiliary Current</i>					
Result: (new)	Value 0,2	Unit uAAC+DC	High Limit 10	Low Limit	Standard IEC 60601	
Open Neutral, Reversed Mains	<i>Patient Auxiliary Current</i>					
Result: (new)	Value 0,2	Unit uAAC+DC	High Limit 50	Low Limit	Standard IEC 60601	
Open Earth, Reversed Mains	<i>Patient Auxiliary Current</i>					
Result: (new)	Value 2,8	Unit uAAC+DC	High Limit 50	Low Limit	Standard IEC 60601	