

Le 2 juin 2025

Mme Annie Tardif
Coordonnatrice
Recherche Clinique

OBJET : Entretien annuel de l'appareil d'électrophysiologie
Compagnie: GE
Modèle: MAC5500 HD
SN: SKJ19250004PA
ID: 801055

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 certifiés 28-08-2024)
- Inspection des courants de fuite
(Analyseur Fluke ESA620 S/N: 2863062 certifiés 27-08-2024)

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

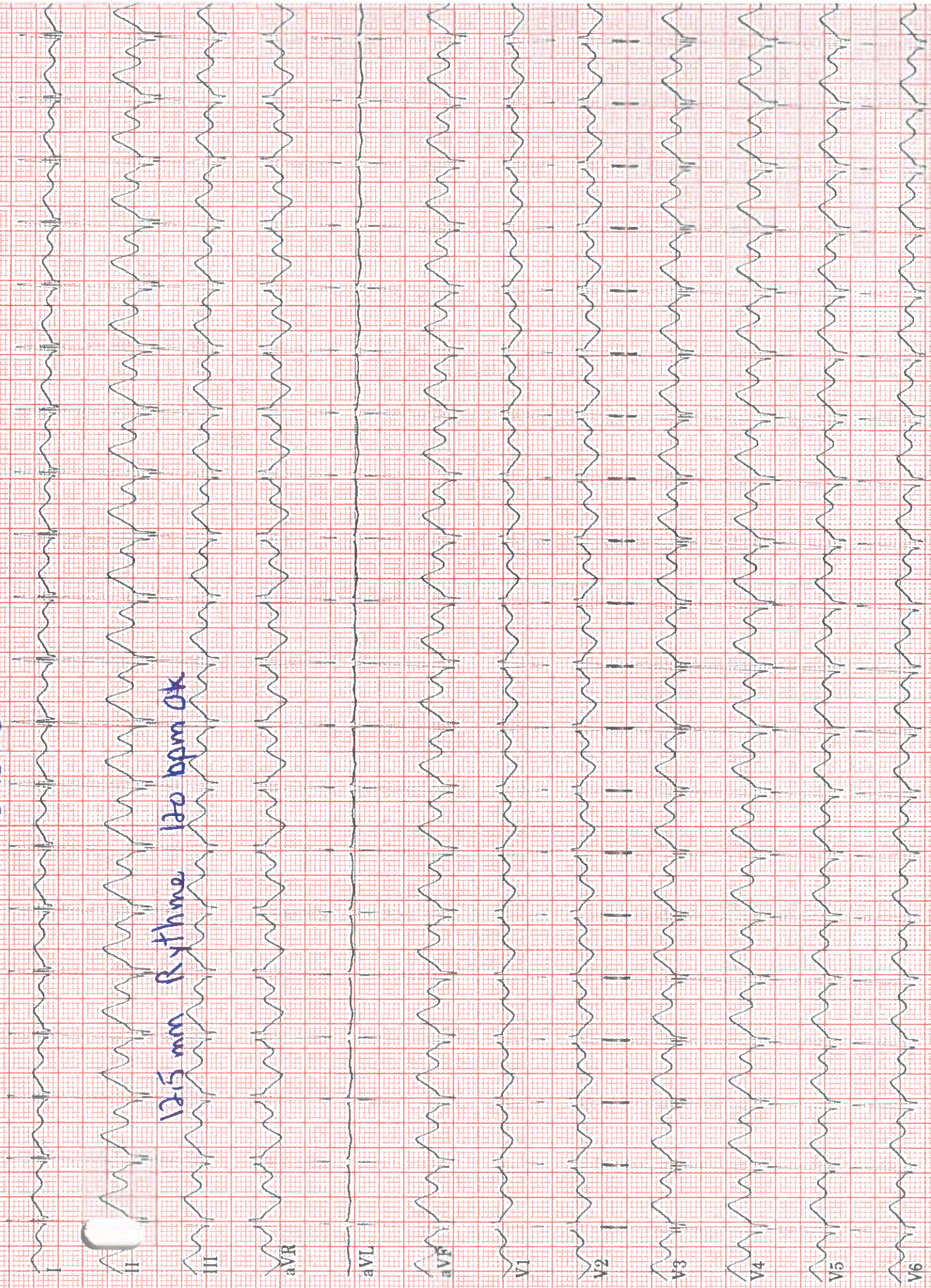


Eric Lavoie
Coordonnateur Technique GBM
Service Génie Biomédical

ID: 001055

2-jun-2025 9:06:41

12.5 mm Rhythm 120 bpm OK

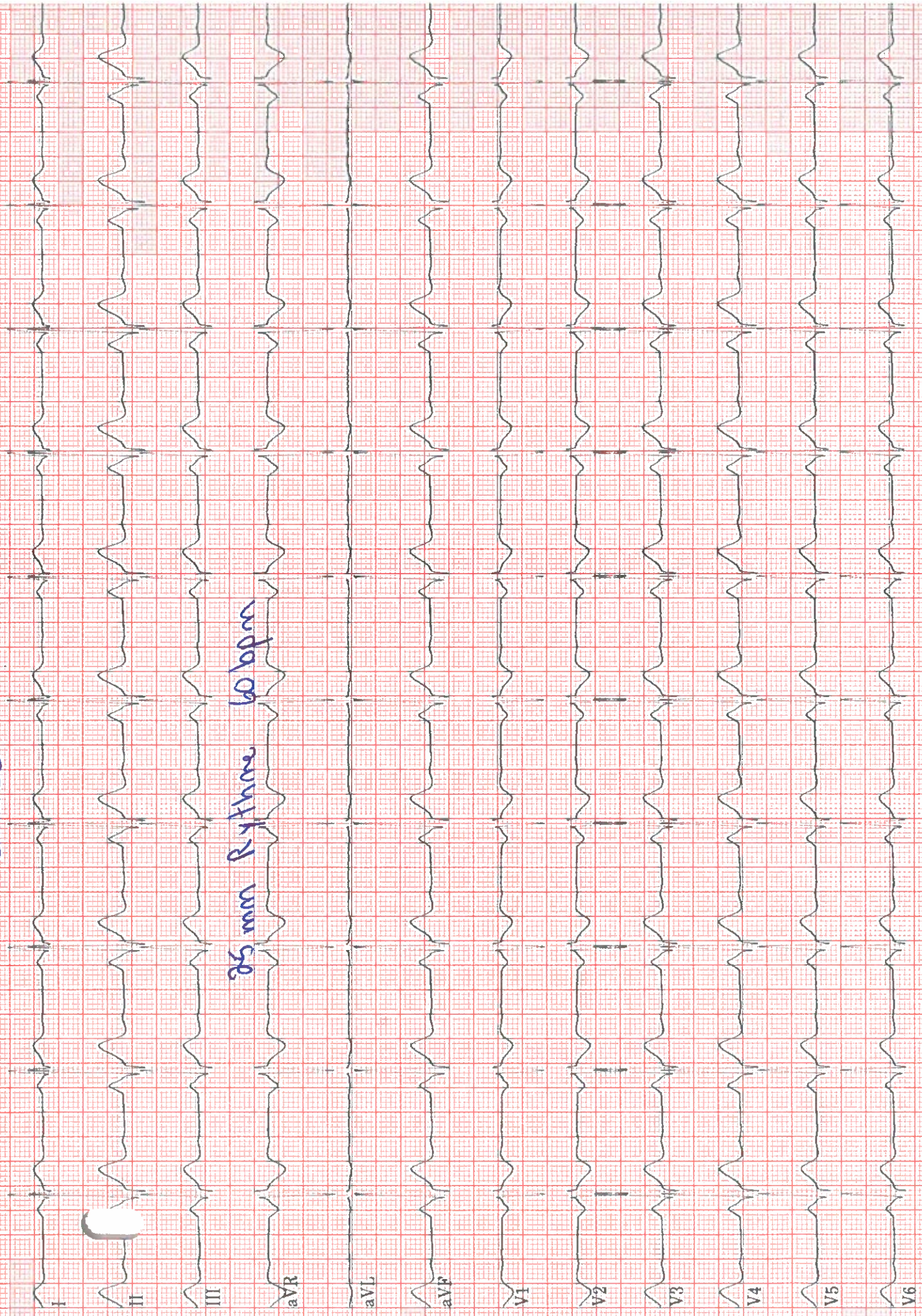


00 bpm

IKALE DE KITHME

2-jun-2025 9:05:35

ID: 801055



0.16-150Hz 25.0mm/s 10.0mm/mV

MAC55 010Bsp1

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Fluke Biomedical Ansur

Test and Inspection Procedure

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Test Record

TEST PASSED**Test Performed**

Date: 02-06-2025
Record: 801055 2025-06-02.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 801055
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



2-06-2025

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:	Value	Unit	High Limit	Low Limit	Standard	
Live to Neutral	119,5	V			IEC 60601	
Neutral to Earth						
<i>Mains Voltage Neutral to Earth</i>						
Result:	Value	Unit	High Limit	Low Limit	Standard	
Neutral to Earth	0,2	V			IEC 60601	
Live to Earth						
<i>Mains Voltage Live to Earth</i>						
Result:	Value	Unit	High Limit	Low Limit	Standard	
Live to Earth	119,5	V			IEC 60601	
Protective Earth Resistance						
<i>Earth Resistance</i>						
Configuration: Test Current: High						
Result:	Value	Unit	High Limit	Low Limit	Standard	
PE Resistance1	0,141	Ohm	0,2		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:	Value	Unit	High Limit	Low Limit	Standard	
Mains to Protective Earth	99999	MOhm		2	IEC 60601	
Applied Parts to Protective Earth						
<i>Insulation Resistance Applied Parts to Protective Earth</i>						
Result:	Value	Unit	High Limit	Low Limit	Standard	
Applied Parts to Protective Earth	100,5	MOhm			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					
Result: Normal Condition	Value 21,2	Unit uAAC+DC	High Limit 5000	Low Limit	Standard IEC 60601
Open Neutral					
Result: Open Neutral	Value 40,2	Unit uAAC+DC	High Limit 10000	Low Limit	Standard IEC 60601
Normal Condition, Reversed mains					
Result: Normal Condition, Reversed mains	Value 19,9	Unit uAAC+DC	High Limit 5000	Low Limit	Standard IEC 60601
Open Neutral, Reversed Mains					
Result: Open Neutral, Reversed Mains	Value 40,4	Unit uAAC+DC	High Limit 10000	Low Limit	Standard IEC 60601
Enclosure Leakage Current					
Configuration: Unused Applied Parts: Floating					
Normal Condition					
Result: Normal Condition	Value 1	Unit uAAC+DC	High Limit 100	Low Limit	Standard IEC 60601
Open Neutral					
Result: Open Neutral	Value 1	Unit uAAC+DC	High Limit 500	Low Limit	Standard IEC 60601
Open Earth					
Result: Open Earth	Value 21,1	Unit uAAC+DC	High Limit 500	Low Limit	Standard IEC 60601
Normal Condition, Reversed mains					
Result: Normal Condition, Reversed mains	Value 1	Unit uAAC+DC	High Limit 100	Low Limit	Standard IEC 60601
Open Neutral, Reversed Mains					
Result: Open Neutral, Reversed Mains	Value 1	Unit uAAC+DC	High Limit 500	Low Limit	Standard IEC 60601
Open Earth, Reversed Mains					
Result: Open Earth, Reversed Mains	Value 20	Unit uAAC+DC	High Limit 500	Low Limit	Standard IEC 60601

Eduke Biomedical Ansur Test Report

Test Element	Test Type				Fail
Patient Leakage Current Configuration: Total Leakage: No Unused Applied Parts: Floating	Patient Leakage Current				
Normal Condition	Patient Leakage Current Normal Condition				
Result: (new)	Value 0,3	Unit uAAC+DC	High Limit 10	Low Limit	Standard IEC 60601
Open Neutral	Patient Leakage Current Open Neutral				
Result: (new)	Value 0,3	Unit uAAC+DC	High Limit 50	Low Limit	Standard IEC 60601
Open Earth	Patient Leakage Current Open Earth				
Result: (new)	Value 4	Unit uAAC+DC	High Limit 50	Low Limit	Standard IEC 60601
Normal Condition, Reversed mains	Patient Leakage Current Normal Condition, Reversed mains				
Result: (new)	Value 0,3	Unit uAAC+DC	High Limit 10	Low Limit	Standard IEC 60601
Open Neutral, Reversed Mains	Patient Leakage Current Open Neutral, Reversed Mains				
Result: (new)	Value 0,3	Unit uAAC+DC	High Limit 50	Low Limit	Standard IEC 60601
Open Earth, Reversed Mains	Patient Leakage Current Open Earth, Reversed Mains				
Result: (new)	Value 3,8	Unit uAAC+DC	High Limit 50	Low Limit	Standard IEC 60601
Mains on Applied Parts Configuration: Total Leakage: No Unused Applied Parts: Floating	Mains on Applied Parts				
Single Fault Condition	Mains on Applied Parts Single Fault Condition				
Result: (new)	Value 12,6	Unit uA	High Limit 50	Low Limit	Standard IEC 60601
Single Fault Condition, Reversed Mains	Mains on Applied Parts Single Fault Condition, Reversed Mains				
Result: (new)	Value 12,9	Unit uA	High Limit 50	Low Limit	Standard IEC 60601
Patient Auxiliary Current Configuration: Unused Applied Parts: Floating	Patient Auxiliary Current				
Normal Condition	Patient Auxiliary Current Normal Condition				
Result: (new)	Value 0,4	Unit uAAC+DC	High Limit 10	Low Limit	Standard IEC 60601
Open Neutral	Patient Auxiliary Current Open Neutral				

Eluke Biomedical Ansur Test Report

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