

Le 2 juin 2025

Mme Annie Tardif
Coordonnatrice
Recherche Clinique

OBJET : Entretien annuel de l'appareil d'électrophysiologie
Compagnie: GE
Modèle: MAC5500 HD
SN: SKJ19290081PA
ID: 801053

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)

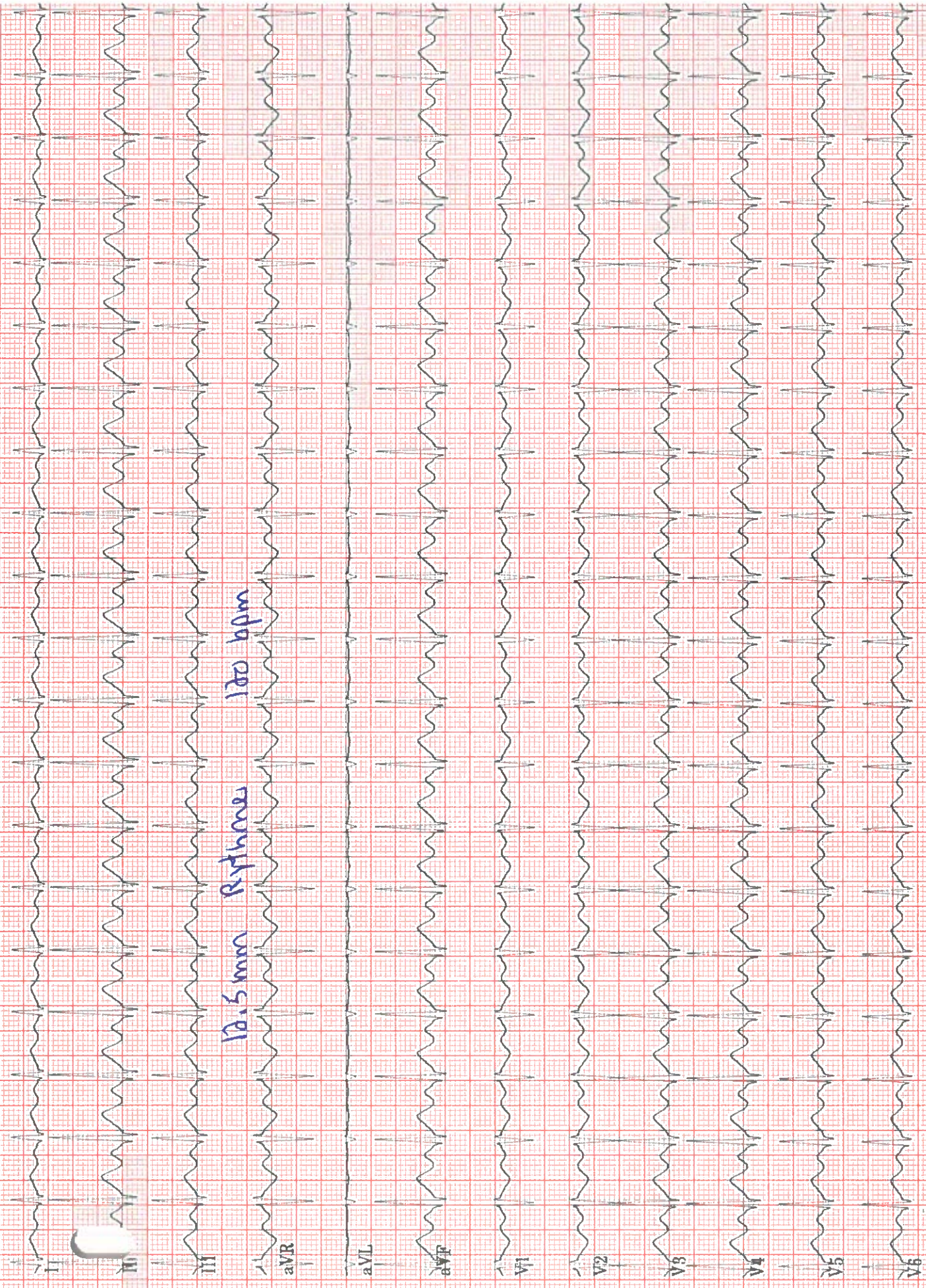
Le tout conforme, seule l'interprétation de l'ECG ne peut être validée.



Eric Lavoie
Coordonnateur technique GBM
Service Génie Biomédical

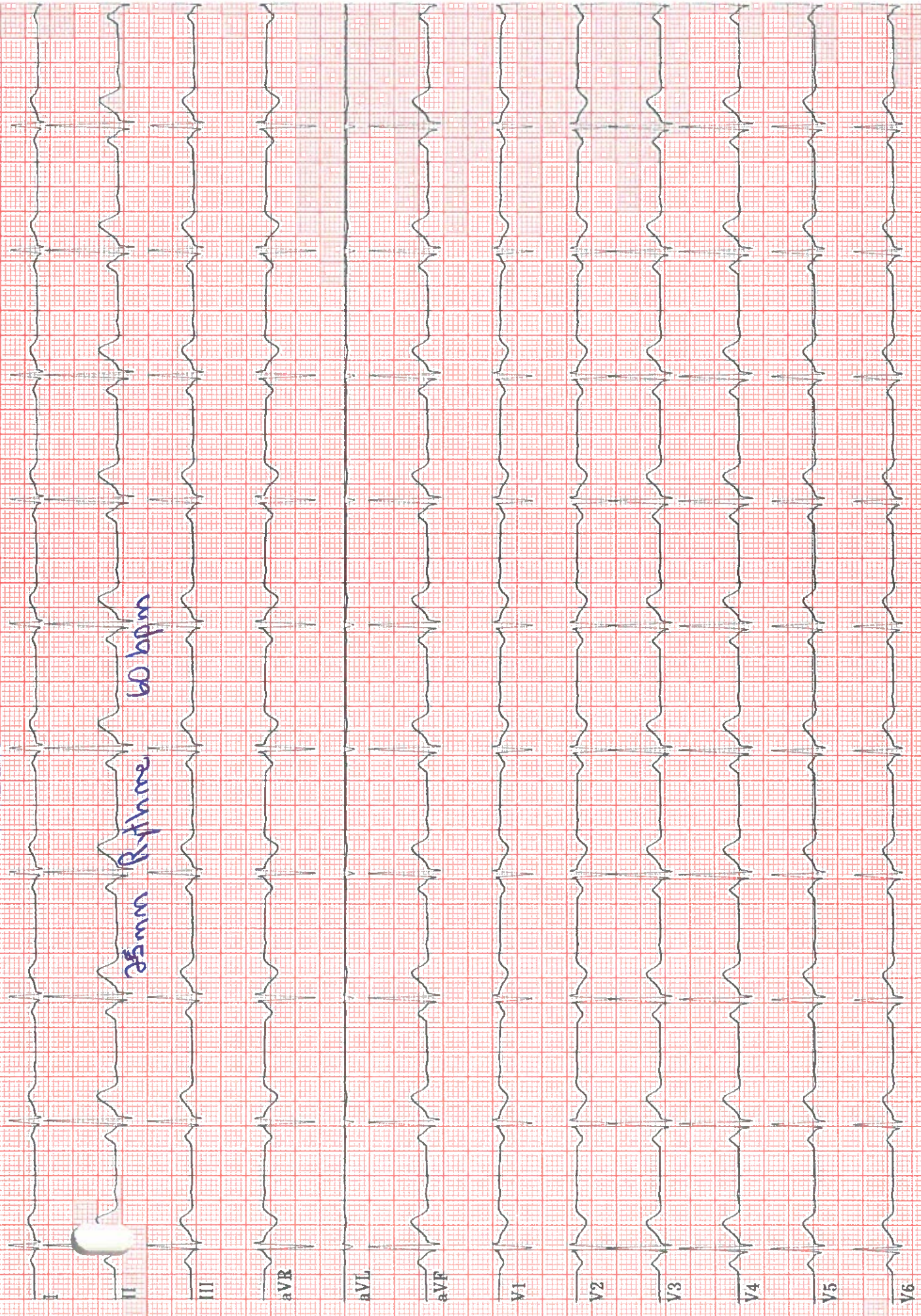
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12.5 mm Rythme 120 bpm



ID: 801053

25mm Rhythme 60 bpm



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TEST PASSED

Ansurs	Version 3.1.3
Plug-In: ESA620	Version 1.2.6

206-2025

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 (new) Serial No. Type		CF	10		
Mains Voltage						
Mains Voltage						
Live to Neutral		Mains Voltage Live to Neutral				
Result: Live to Neutral	Value 119,5	Unit V	High Limit	Low Limit	Standard IEC 60601	
Neutral to Earth		Mains Voltage Neutral to Earth				
Result: Neutral to Earth	Value 0,2	Unit V	High Limit	Low Limit	Standard IEC 60601	
Live to Earth		Mains Voltage Live to Earth				
Result: Live to Earth	Value 119,4	Unit V	High Limit	Low Limit	Standard IEC 60601	
Protective Earth Resistance		Earth Resistance				
Configuration: Test Current: High						
Result: PE Resistance1	Value 0,131	Unit Ohm	High Limit 0,2	Low Limit	Standard IEC 60601	
Insulation Resistance		Insulation Resistance				
Configuration: Test Voltage: 500V						
Mains to Protective Earth		Insulation Resistance Mains to Protective Earth				
Result: Mains to Protective Earth	Value 99999	Unit MOhm	High Limit	Low Limit 2	Standard IEC 60601	
Applied Parts to Protective Earth		Insulation Resistance Applied Parts to Protective Earth				
Result: Applied Parts to Protective Earth	Value 100,3	Unit MOhm	High Limit	Low Limit	Standard IEC 60601	
Earth Leakage Current		Earth Leakage Current				

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	21,5	uAAC+DC	5000		IEC 60601	
Open Neutral	Earth Leakage Current Open Neutral					
Result:	Value	Unit	High Limit	Low Limit	Standard	
Open Neutral	42,2	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	21,7	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	42,3	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	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	21,4	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	21,7	uAAC+DC	500		IEC 60601	

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Test Element	Test Type					Fail
Patient Leakage Current Configuration: Total Leakage: No Unused Applied Parts: Floating	Patient Leakage Current					
Normal Condition Result: (new)	Value 0,2	Unit uAAC+DC	High Limit 10	Low Limit	Standard IEC 60601	
Open Neutral Result: (new)	Value 0,3	Unit uAAC+DC	High Limit 50	Low Limit	Standard IEC 60601	
Open Earth Result: (new)	Value 4	Unit uAAC+DC	High Limit 50	Low Limit	Standard IEC 60601	
Normal Condition, Reversed mains Result: (new)	Value 0,3	Unit uAAC+DC	High Limit 10	Low Limit	Standard IEC 60601	
Open Neutral, Reversed Mains Result: (new)	Value 0,3	Unit uAAC+DC	High Limit 50	Low Limit	Standard IEC 60601	
Open Earth, Reversed Mains Result: (new)	Value 4,1	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 Result: (new)	Value 12,8	Unit uA	High Limit 50	Low Limit	Standard IEC 60601	
Single Fault Condition, Reversed Mains Result: (new)	Value 13,2	Unit uA	High Limit 50	Low Limit	Standard IEC 60601	
Patient Auxiliary Current Configuration: Unused Applied Parts: Floating	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					

Fluke 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>					
Result: (new)	Value 2,8	Unit uAAC+DC	High Limit 50	Low Limit	Standard IEC 60601	
Normal Condition, Reversed mains	<i>Patient Auxiliary Current</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>					
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>					
Result: (new)	Value 2,9	Unit uAAC+DC	High Limit 50	Low Limit	Standard IEC 60601	