

Le 27-juin 2024

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 15-08-2023)
- Inspection des courants de fuite
(Analyseur Fluke ESA620 S/N: 2863062 certifié 11-08-2023)

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



Eric Lavoie
Coordonnateur Technique en GBM
Service Génie Biomédical

ID: 801054

26-jun-2024

16:57:23

Fréq. ventr. 120 bpm
Intervalle PR 144 ms
Durée QRS 82 ms
QT/QTc 328/463 ms
Axes P-R-T 67 68 68

Tachycardie sinusale
Hypertrophie bi-auriculaire
ECG anormal

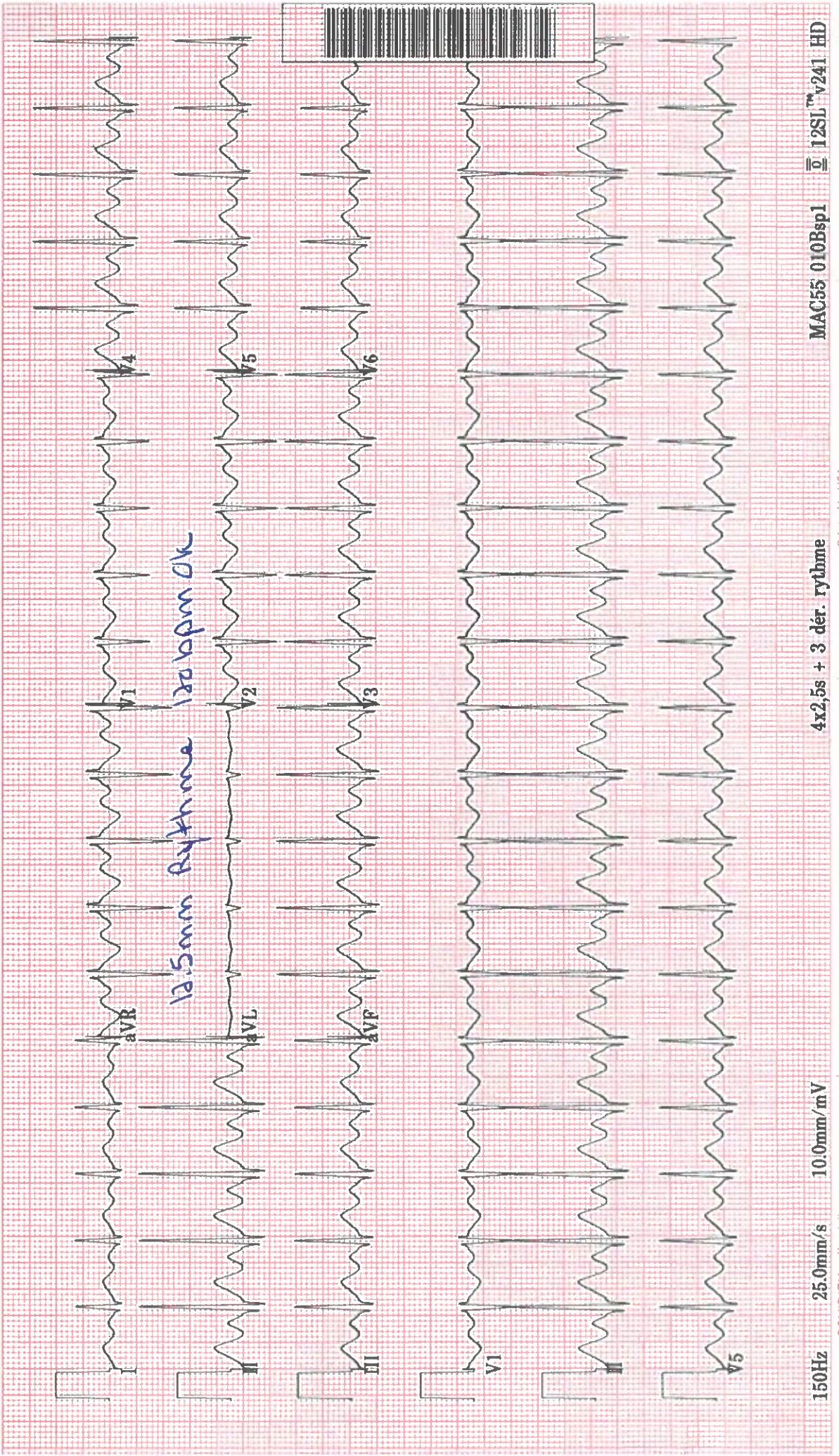


Technicien:
Indications:

Visite:

Référé par:

Non validé





ID: 201054

26-jun-2024 16:58:15

Fréq. ventr. 60 bpm
Intervalle PR 146 ms
Durée QRS 82 ms
QT/QTc 362/362 ms
Axes P-R-T 68 68 68

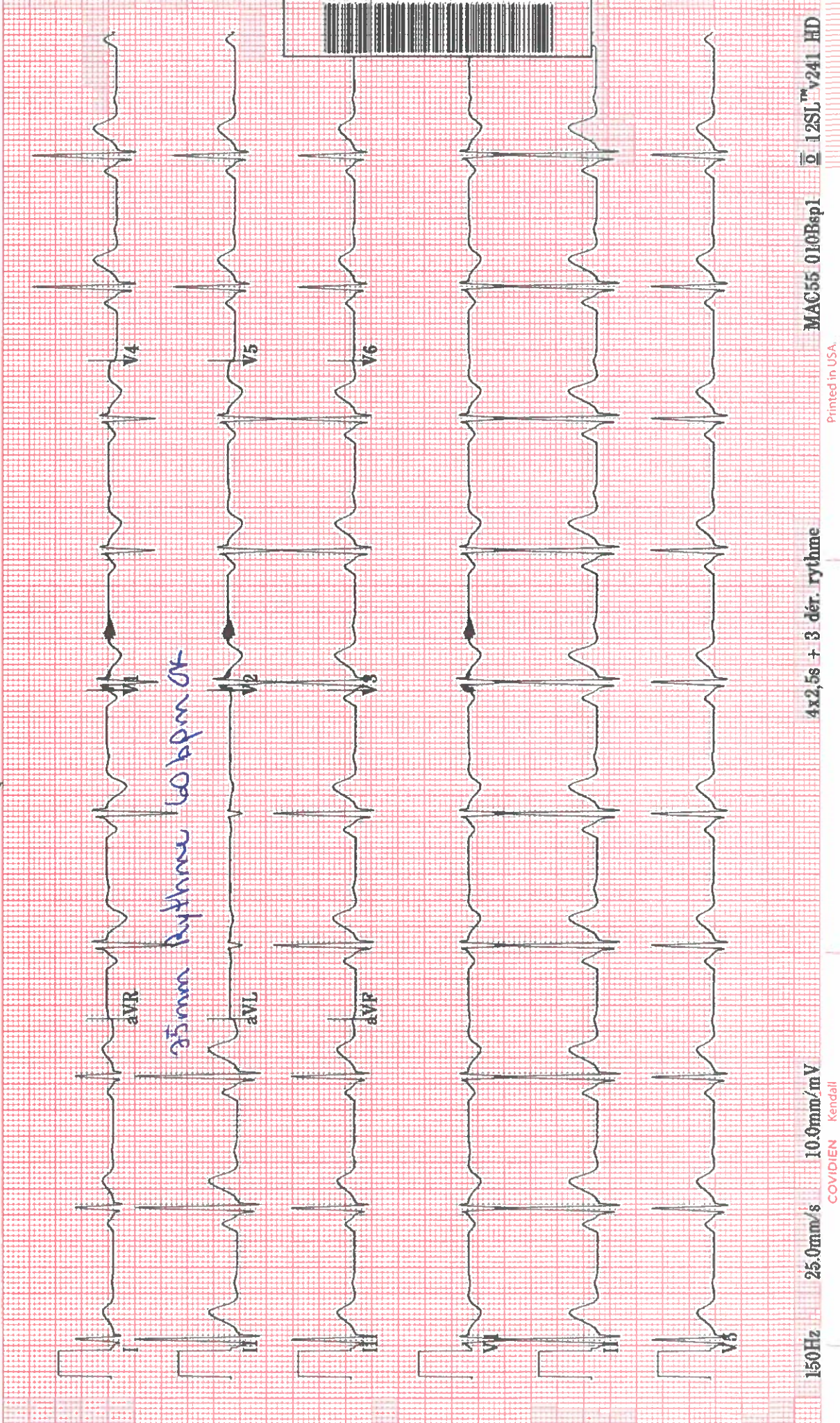
Rythme sinusal normal
Hypertrophie bi-auriculaire
Anomalie non spécifique du segment S-T
ECG anormal

Technicien:
Indications:

Visite:

Référé par:

Non validé





Fluke Biomedical Ansur Test and Inspection Procedure

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Test Record

TEST PASSED

Test Performed

Date: 27-06-2024
Record: 801054 2024-06-27.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	Type	.
Appliance Code	.	Model	.
Group	.	Location	.
Status	.	Address 1	.
Manufacturer	.	Address 2	..

MTI Data

Test Instrument	Serial Number	Firmware Version
ESA 620	2863062	v2.12

Signatures





Test Result

Test Element	Test Type				Fail
IEC 60601-1 - CLI	<i>Auto Sequence</i>				
<i>Procedure:</i>					
(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:	Value	Unit	High Limit	Low Limit	Standard
Live to Neutral	122.2	V			IEC 60601
Neutral to Earth					
<i>Mains Voltage</i>					
<i>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</i>					
<i>Live to Earth</i>					
Result:	Value	Unit	High Limit	Low Limit	Standard
Live to Earth	122.1	V			IEC 60601
Protective Earth Resistance					
<i>Earth Resistance</i>					
<i>Configuration:</i>					
Test Current: High					
Result:	Value	Unit	High Limit	Low Limit	Standard
PE Resistance1	0.11	Ohm	0.2		IEC 60601
Insulation Resistance					
<i>Insulation Resistance</i>					
<i>Configuration:</i>					
Test Voltage: 500V					
Mains to Protective Earth					
<i>Insulation Resistance</i>					
<i>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</i>					
<i>Applied Parts to Protective Earth</i>					
Result:	Value	Unit	High Limit	Low Limit	Standard
Applied Parts to Protective Earth	100.4	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	<i>Earth Leakage Current</i> Normal Condition Value Unit High Limit Low Limit 22,3 uAAC+DC 5000	Standard IEC 60601
Open Neutral Result: Open Neutral	<i>Earth Leakage Current</i> Open Neutral Value Unit High Limit Low Limit 42,2 uAAC+DC 10000	Standard IEC 60601
Normal Condition, Reversed mains Result: Normal Condition, Reversed mains	<i>Earth Leakage Current</i> Normal Condition, Reversed mains Value Unit High Limit Low Limit 20,9 uAAC+DC 5000	Standard IEC 60601
Open Neutral, Reversed Mains Result: Open Neutral, Reversed Mains	<i>Earth Leakage Current</i> Open Neutral, Reversed Mains Value Unit High Limit Low Limit 42,3 uAAC+DC 10000	Standard IEC 60601
Enclosure Leakage Current Configuration: Unused Applied Parts: Floating		
Normal Condition Result: Normal Condition	<i>Enclosure Leakage Current</i> Normal Condition Value Unit High Limit Low Limit 0,9 uAAC+DC 100	Standard IEC 60601
Open Neutral Result: Open Neutral	<i>Enclosure Leakage Current</i> Open Neutral Value Unit High Limit Low Limit 0,9 uAAC+DC 500	Standard IEC 60601
Open Earth Result: Open Earth	<i>Enclosure Leakage Current</i> Open Earth Value Unit High Limit Low Limit 22,2 uAAC+DC 500	Standard IEC 60601
Normal Condition, Reversed mains Result: Normal Condition, Reversed mains	<i>Enclosure Leakage Current</i> Normal Condition, Reversed mains Value Unit High Limit Low Limit 0,9 uAAC+DC 100	Standard IEC 60601
Open Neutral, Reversed Mains Result: Open Neutral, Reversed Mains	<i>Enclosure Leakage Current</i> Open Neutral, Reversed Mains Value Unit High Limit Low Limit 0,9 uAAC+DC 500	Standard IEC 60601
Open Earth, Reversed Mains Result: Open Earth, Reversed Mains	<i>Enclosure Leakage Current</i> Open Earth, Reversed Mains Value Unit High Limit Low Limit 20,8 uAAC+DC 500	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)	Value 0,4	Unit uAAC+DC	High Limit 10	Low Limit	Standard IEC 60601
Open Neutral <i>Result:</i> (new)	Value 0,4	Unit uAAC+DC	High Limit 50	Low Limit	Standard IEC 60601
Open Earth <i>Result:</i> (new)	Value 4,1	Unit uAAC+DC	High Limit 50	Low Limit	Standard IEC 60601
Normal Condition, Reversed mains <i>Result:</i> (new)	Value 0,4	Unit uAAC+DC	High Limit 10	Low Limit	Standard IEC 60601
Open Neutral, Reversed Mains <i>Result:</i> (new)	Value 0,4	Unit uAAC+DC	High Limit 50	Low Limit	Standard IEC 60601
Open Earth, Reversed Mains <i>Result:</i> (new)	Value 3,9	Unit uAAC+DC	High Limit 50	Low Limit	Standard 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)	Value 13,2	Unit uA	High Limit 50	Low Limit	Standard IEC 60601
Single Fault Condition, Reversed Mains <i>Result:</i> (new)	Value 13,2	Unit uA	High Limit 50	Low Limit	Standard IEC 60601
Patient Auxiliary Current <i>Configuration:</i> Unused Applied Parts: Floating	Patient Auxiliary Current				
Normal Condition <i>Result:</i> (new)	Value 0,3	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	Test Type				Fail
Result:	Value	Unit	High Limit	Low Limit	Standard
(new)	0,3	uAAC+DC	50		IEC 60601
<hr/>					
Open Earth	<i>Patient Auxiliary Current</i>				
	<i>Open Earth</i>				
Result:	Value	Unit	High Limit	Low Limit	Standard
(new)	2,9	uAAC+DC	50		IEC 60601
<hr/>					
Normal Condition, Reversed mains	<i>Patient Auxiliary Current</i>				
	<i>Normal Condition, Reversed mains</i>				
Result:	Value	Unit	High Limit	Low Limit	Standard
(new)	0,3	uAAC+DC	10		IEC 60601
<hr/>					
Open Neutral, Reversed Mains	<i>Patient Auxiliary Current</i>				
	<i>Open Neutral, Reversed Mains</i>				
Result:	Value	Unit	High Limit	Low Limit	Standard
(new)	0,3	uAAC+DC	50		IEC 60601
<hr/>					
Open Earth, Reversed Mains	<i>Patient Auxiliary Current</i>				
	<i>Open Earth, Reversed Mains</i>				
Result:	Value	Unit	High Limit	Low Limit	Standard
(new)	2,7	uAAC+DC	50		IEC 60601

