

Le 27 juin 2024

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

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



Eric Lavoie
Coordonnateur technique GBM
Service Génie Biomédical

Fréq. ventr. 120 bpm
Intervalle PR 142 ms
Durée QRS 82 ms
QT/QTc 338/477 ms
Axes P-R-T 68 68 68

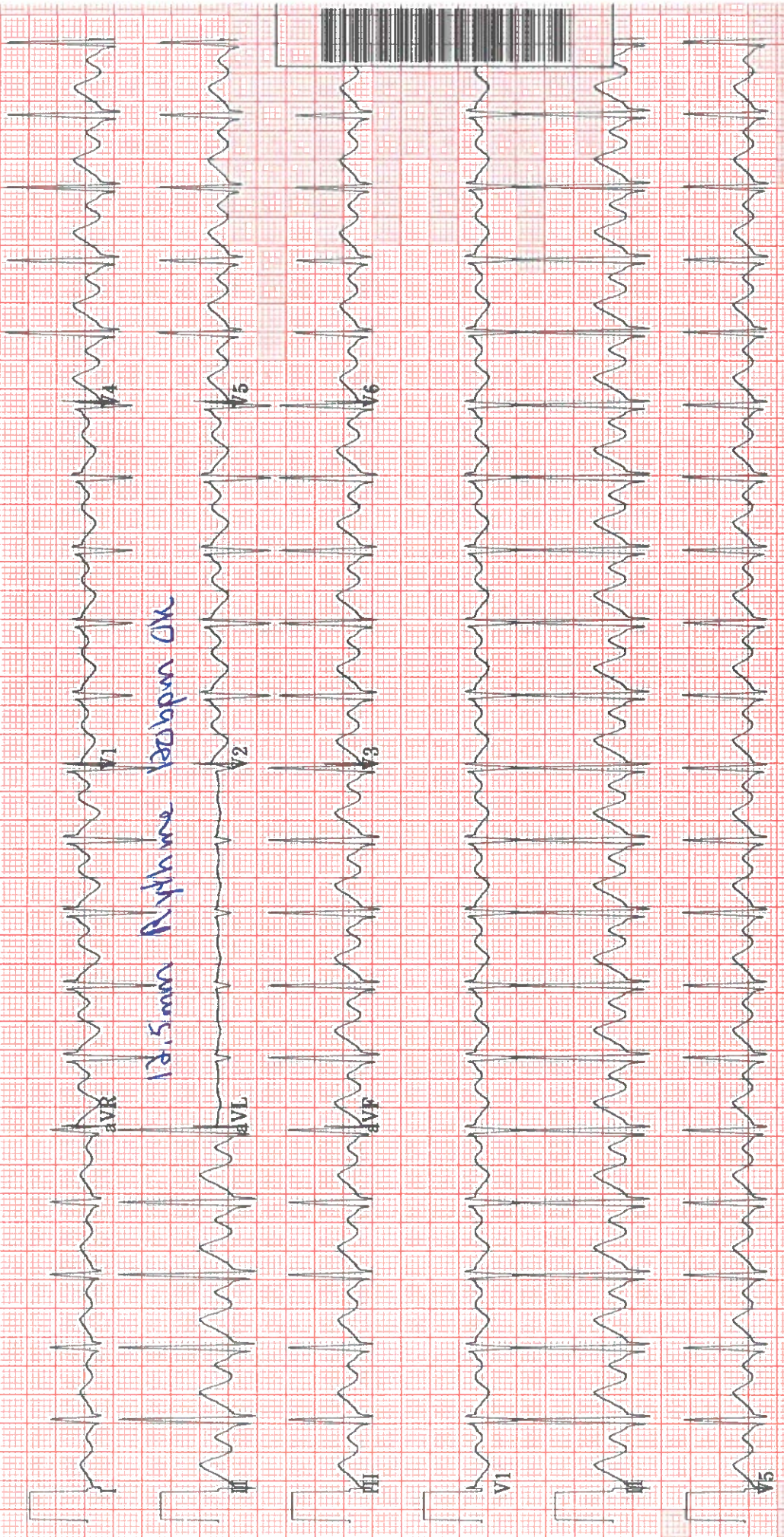
Tachycardie sinusale
Hypertrophie bi-auriculaire
ECG anormal

Technicien:
Indications:

Visite:

Référé par:

Non validé





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

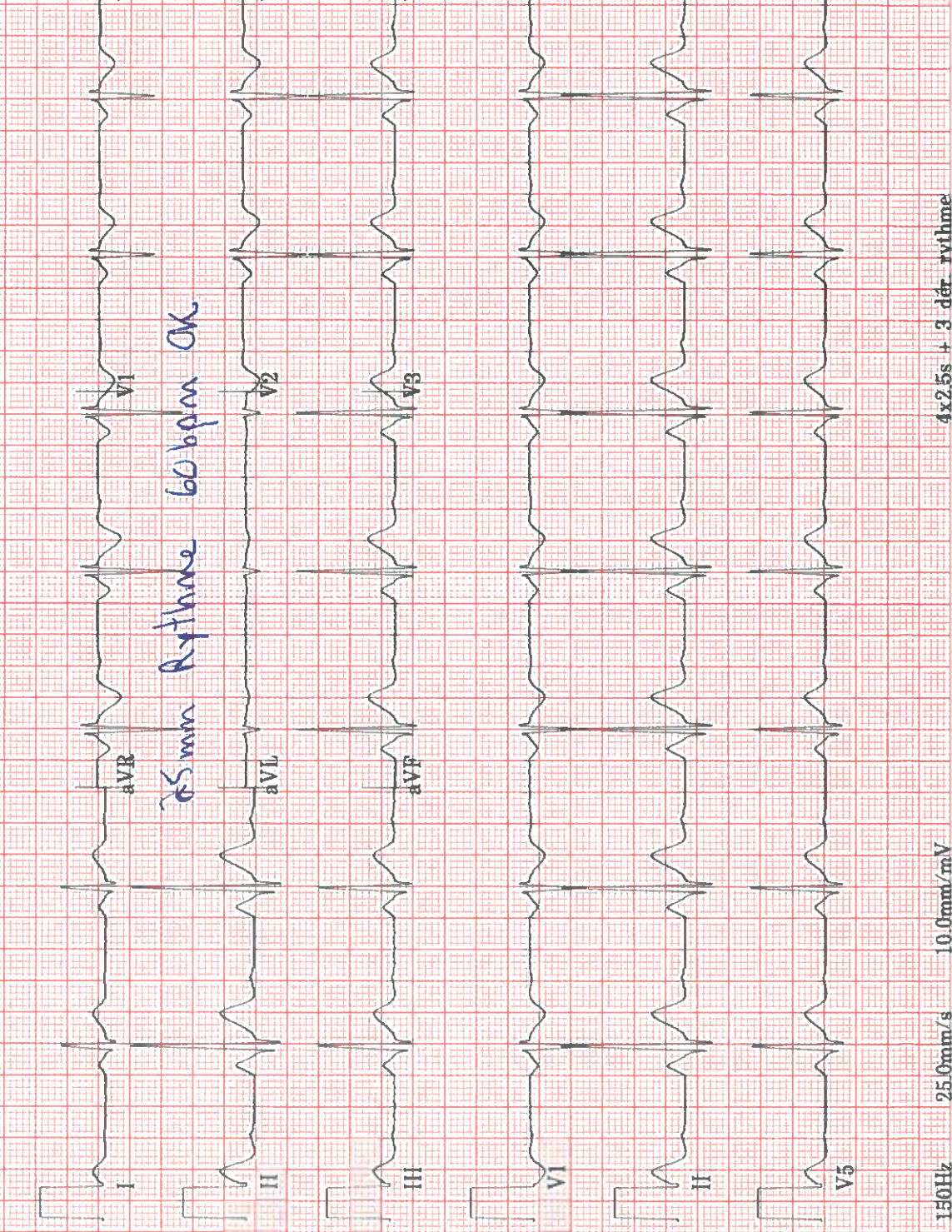
Fréq. ventr. 60 bpm
Intervalle PR 144 ms
Durée QRS 84 ms
QT/QTc 368/368 ms
Axes P-R-T 68 68 68

Technicien:
Indicatifs:

Visite:
Référé par:

Non validé

65mm Rythme 60 bpm OK





Fluke Biomedical Ansur Test and Inspection Procedure

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Test Record

TEST PASSED

Test Performed		Ansur Components Used	
Date:	27-06-2024	Ansur	Version 3.1.3
Record:	801053 2024-06-27.mtr	Plug-In: ESA620	Version 1.2.6
Template:	IEC 60601-1 - CL1.mtt		
Template Version:	1.0.0		

Test Setup

Selections

Service Events Performed	Standards Performed
	IEC 60601

Device under test

Serial Number	801053	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>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.	Auto Sequence									
Applied Part setup										
<table border="1"> <thead> <tr> <th>#</th> <th>Applied Part info</th> <th>Class</th> <th>Leads</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>A.P. Code (new) Serial No. Type</td> <td>CF</td> <td>10</td> </tr> </tbody> </table>	#	Applied Part info	Class	Leads	1	A.P. Code (new) Serial No. Type	CF	10		
#	Applied Part info	Class	Leads							
1	A.P. Code (new) Serial No. Type	CF	10							
Mains Voltage	Mains Voltage									
Live to Neutral <i>Result:</i> Live to Neutral	<i>Mains Voltage</i> <i>Live to Neutral</i> Value 119,9	Unit V High Limit Low Limit	Standard IEC 60601							
Neutral to Earth <i>Result:</i> Neutral to Earth	<i>Mains Voltage</i> <i>Neutral to Earth</i> Value 0,2	Unit V High Limit Low Limit	Standard IEC 60601							
Live to Earth <i>Result:</i> Live to Earth	<i>Mains Voltage</i> <i>Live to Earth</i> Value 119,5	Unit V High Limit Low Limit	Standard IEC 60601							
Protective Earth Resistance <i>Configuration:</i> Test Current: High <i>Result:</i> PE Resistance1	<i>Earth Resistance</i> Value 0,103	Unit Ohm High Limit 0,2 Low Limit	Standard IEC 60601							
Insulation Resistance <i>Configuration:</i> Test Voltage: 500V	<i>Insulation Resistance</i>									
Mains to Protective Earth <i>Result:</i> Mains to Protective Earth	<i>Insulation Resistance</i> <i>Mains to Protective Earth</i> Value 99999	Unit MOhm High Limit Low Limit 2	Standard IEC 60601							
Applied Parts to Protective Earth <i>Result:</i> Applied Parts to Protective Earth	<i>Insulation Resistance</i> <i>Applied Parts to Protective Earth</i> Value 100,2	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
<i>Configuration:</i> Unused Applied Parts: Floating					
Normal Condition	<i>Earth Leakage Current</i> <i>Normal Condition</i>				
Result: Normal Condition	Value 21,2	Unit uAAC+DC	High Limit 5000	Low Limit	Standard IEC 60601
Open Neutral	<i>Earth Leakage Current</i> <i>Open Neutral</i>				
Result: Open Neutral	Value 41,7	Unit uAAC+DC	High Limit 10000	Low Limit	Standard IEC 60601
Normal Condition, Reversed mains	<i>Earth Leakage Current</i> <i>Normal Condition, Reversed mains</i>				
Result: Normal Condition, Reversed mains	Value 21,6	Unit uAAC+DC	High Limit 5000	Low Limit	Standard IEC 60601
Open Neutral, Reversed Mains	<i>Earth Leakage Current</i> <i>Open Neutral, Reversed Mains</i>				
Result: Open Neutral, Reversed Mains	Value 41,8	Unit uAAC+DC	High Limit 10000	Low Limit	Standard IEC 60601
<i>Enclosure Leakage Current</i> <i>Configuration:</i> Unused Applied Parts: Floating					
Normal Condition	<i>Enclosure Leakage Current</i> <i>Normal Condition</i>				
Result: Normal Condition	Value 0,9	Unit uAAC+DC	High Limit 100	Low Limit	Standard IEC 60601
Open Neutral	<i>Enclosure Leakage Current</i> <i>Open Neutral</i>				
Result: Open Neutral	Value 0,9	Unit uAAC+DC	High Limit 500	Low Limit	Standard IEC 60601
Open Earth	<i>Enclosure Leakage Current</i> <i>Open Earth</i>				
Result: Open Earth	Value 21,2	Unit uAAC+DC	High Limit 500	Low Limit	Standard IEC 60601
Normal Condition, Reversed mains	<i>Enclosure Leakage Current</i> <i>Normal Condition, Reversed mains</i>				
Result: Normal Condition, Reversed mains	Value 0,9	Unit uAAC+DC	High Limit 100	Low Limit	Standard IEC 60601
Open Neutral, Reversed Mains	<i>Enclosure Leakage Current</i> <i>Open Neutral, Reversed Mains</i>				
Result: Open Neutral, Reversed Mains	Value 0,9	Unit uAAC+DC	High Limit 500	Low Limit	Standard IEC 60601
Open Earth, Reversed Mains	<i>Enclosure Leakage Current</i> <i>Open Earth, Reversed Mains</i>				
Result: Open Earth, Reversed Mains	Value 21,6	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	<i>Patient Leakage Current</i>	
Normal Condition <i>Result:</i> (new)	<i>Patient Leakage Current</i> Normal Condition Value Unit High Limit Low Limit 0,4 uAAC+DC 10	Standard IEC 60601
Open Neutral <i>Result:</i> (new)	<i>Patient Leakage Current</i> Open Neutral Value Unit High Limit Low Limit 0,5 uAAC+DC 50	Standard IEC 60601
Open Earth <i>Result:</i> (new)	<i>Patient Leakage Current</i> Open Earth Value Unit High Limit Low Limit 4,1 uAAC+DC 50	Standard IEC 60601
Normal Condition, Reversed mains <i>Result:</i> (new)	<i>Patient Leakage Current</i> Normal Condition, Reversed mains Value Unit High Limit Low Limit 0,4 uAAC+DC 10	Standard IEC 60601
Open Neutral, Reversed Mains <i>Result:</i> (new)	<i>Patient Leakage Current</i> Open Neutral, Reversed Mains Value Unit High Limit Low Limit 0,5 uAAC+DC 50	Standard IEC 60601
Open Earth, Reversed Mains <i>Result:</i> (new)	<i>Patient Leakage Current</i> Open Earth, Reversed Mains Value Unit High Limit Low Limit 4,2 uAAC+DC 50	Standard 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>Mains on Applied Parts</i> Single Fault Condition Value Unit High Limit Low Limit 13,4 uA 50	Standard IEC 60601
Single Fault Condition, Reversed Mains <i>Result:</i> (new)	<i>Mains on Applied Parts</i> Single Fault Condition, Reversed Mains Value Unit High Limit Low Limit 13,5 uA 50	Standard IEC 60601
Patient Auxiliary Current <i>Configuration:</i> Unused Applied Parts: Floating	<i>Patient Auxiliary Current</i>	
Normal Condition <i>Result:</i> (new)	<i>Patient Auxiliary Current</i> Normal Condition Value Unit High Limit Low Limit 0,3 uAAC+DC 10	Standard IEC 60601
Open Neutral	<i>Patient Auxiliary Current</i> 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)	2,9	uAAC+DC	50		IEC 60601

