Le 26 juin 2024

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 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

ID: 801055 26-jun-2024 14:30:30

Fréq. ventr.	120	bpm
Intervalle PR	158	ms
Durée QRS	88	ms
QT/QTc	310/438	ms
Axes P-R-T	50 38 47	

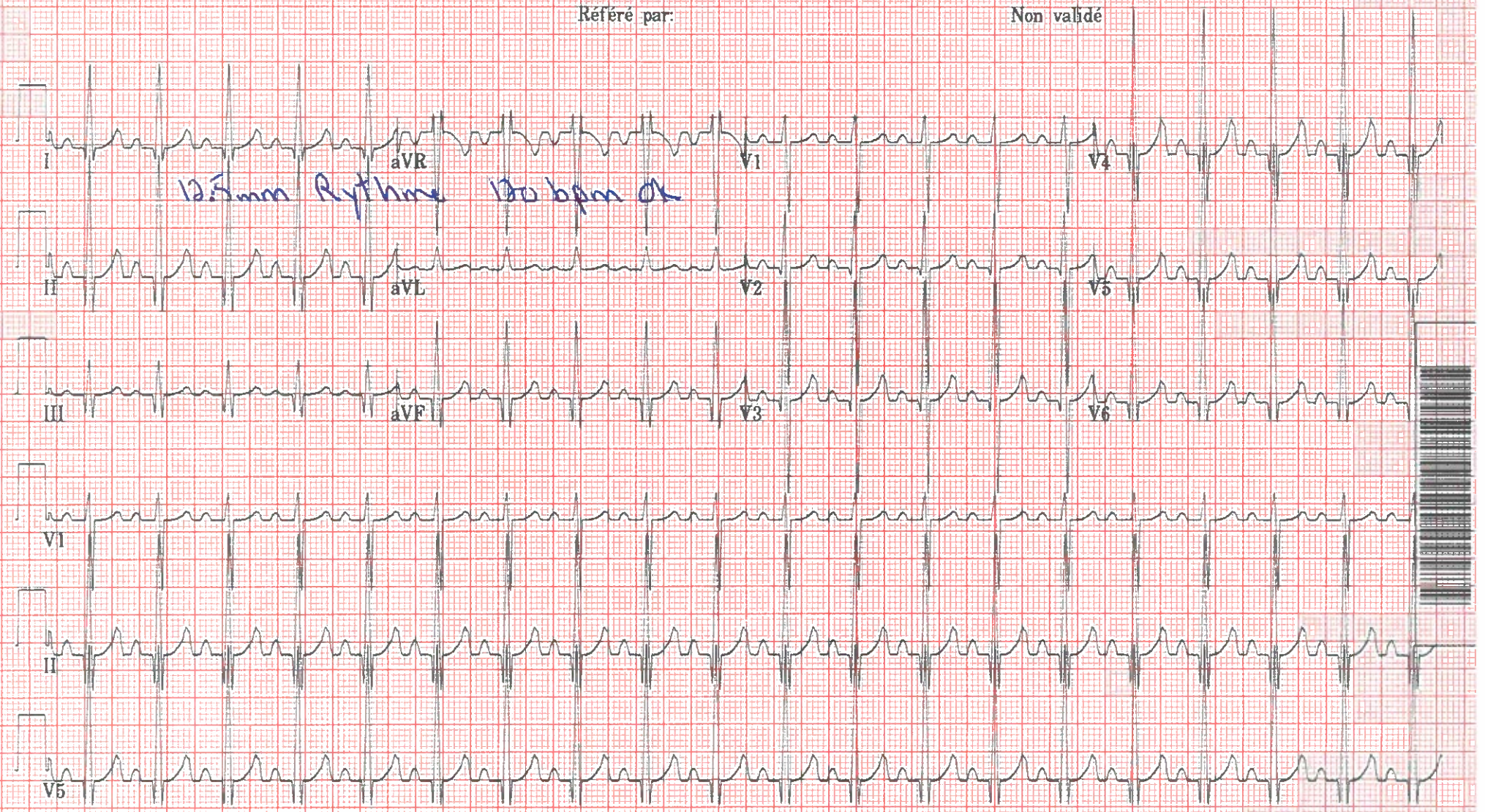
Tachycardie sinusale
Hypertrophie auriculaire droite (HAD)
Les grandes amplitudes des QRS sont soit normales, soit dues à une HVG
Infarctus septal, âge indéterminée
ECG anormal

Technicien:
Indications:

Visite:

Référé par:

Non validé



150Hz 25.0mm/s 10.0mm/mV 4x2,5s + 3 dér. rythme MAC55 010Bsp1 12SL™ v241 HD

ID: E01055 20-jun-2024 14:33:16

Freq. ventr.	60	bpm
Intervalle PR	164	ms
Durée QRS	92	ms
QT/QTc	370/370	ms
Axes P-R-T	49 39 49	

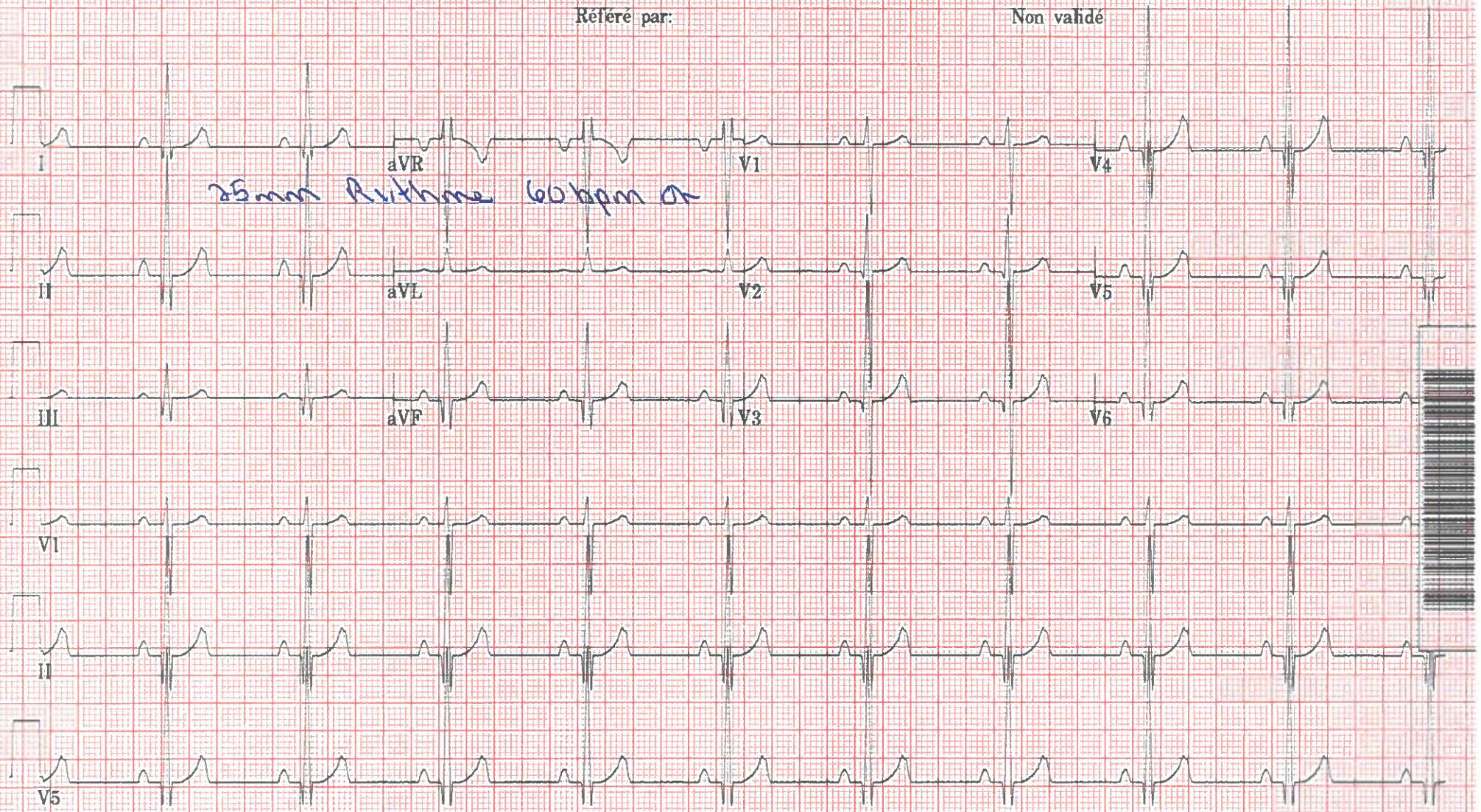
Rythme sinusal normal
Hypertrophie auriculaire droite (HAD)
Les grandes amplitudes des QRS sont soit normales, soit dues à une HVG
Infarctus septal, âge indéterminée
ECG anormal

Technicien:
Indications:

Visite:

Référé par:

Non validé



150Hz 25.0mm/s 10.0mm/mV 4x2,5s + 3 dér. rythme MAC55 010Bsp1 12SL™v241 HD

Fluke Biomedical Ansur
Test and Inspection Procedure

Test Record

TEST PASSED

Test Performed		Ansur Components Used	
Date:	26-06-2024	Ansur	Version 3.1.3
Record:	801055 2024-06-26.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	801055	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

Eric Jannie 26-06-2024

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)	CF	10
	Serial No.			
	Type			

Mains Voltage — *Mains Voltage*

Live to Neutral — *Mains Voltage / Live to Neutral*

Result:	Value	Unit	High Limit	Low Limit	Standard
Live to Neutral	121	V			IEC 60601

Neutral to Earth — *Mains Voltage / Neutral to Earth*

Result:	Value	Unit	High Limit	Low Limit	Standard
Neutral to Earth	0,2	V			IEC 60601

Live to Earth — *Mains Voltage / Live to Earth*

Result:	Value	Unit	High Limit	Low Limit	Standard
Live to Earth	121,1	V			IEC 60601

Protective Earth Resistance — *Earth Resistance*

Configuration:
Test Current: High

Result:	Value	Unit	High Limit	Low Limit	Standard
PE Resistance1	0,137	Ohm	0,2		IEC 60601

Insulation Resistance — *Insulation Resistance*

Configuration:
Test Voltage: 500V

Mains to Protective Earth — *Insulation Resistance / Mains to Protective Earth*

Result:	Value	Unit	High Limit	Low Limit	Standard
Mains to Protective Earth	99999	MOhm		2	IEC 60601

Applied Parts to Protective Earth — *Insulation Resistance / Applied Parts to Protective Earth*

Result:	Value	Unit	High Limit	Low Limit	Standard
Applied Parts to Protective Earth	100,2	MOhm			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	21,6	uAAC+DC	5000		IEC 60601	
Open Neutral	*Earth Leakage Current* *Open Neutral*					
Result:	***Value***	***Unit***	***High Limit***	***Low Limit***	***Standard***	
Open Neutral	41,2	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	20,5	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	41,4	uAAC+DC	10000		IEC 60601	
Enclosure Leakage Current ***Configuration:*** Unused Applied Parts: Floating	*Enclosure Leakage Current*					
Normal Condition	*Enclosure Leakage Current* *Normal Condition*					
Result:	***Value***	***Unit***	***High Limit***	***Low Limit***	***Standard***	
Normal Condition	0,9	uAAC+DC	100		IEC 60601	
Open Neutral	*Enclosure Leakage Current* *Open Neutral*					
Result:	***Value***	***Unit***	***High Limit***	***Low Limit***	***Standard***	
Open Neutral	0,8	uAAC+DC	500		IEC 60601	
Open Earth	*Enclosure Leakage Current* *Open Earth*					
Result:	***Value***	***Unit***	***High Limit***	***Low Limit***	***Standard***	
Open Earth	21,6	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	0,8	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	0,8	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	20,5	uAAC+DC	500		IEC 60601	

Fluke 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:	***Value*** ***Unit*** ***High Limit*** ***Low Limit*** ***Standard***	
(new)	0,3 uAAC+DC 10 IEC 60601	
Open Neutral	*Patient Leakage Current* *Open Neutral*	
Result:	***Value*** ***Unit*** ***High Limit*** ***Low Limit*** ***Standard***	
(new)	0,3 uAAC+DC 50 IEC 60601	
Open Earth	*Patient Leakage Current* *Open Earth*	
Result:	***Value*** ***Unit*** ***High Limit*** ***Low Limit*** ***Standard***	
(new)	4,1 uAAC+DC 50 IEC 60601	
Normal Condition, Reversed mains	*Patient Leakage Current* *Normal Condition, Reversed mains*	
Result:	***Value*** ***Unit*** ***High Limit*** ***Low Limit*** ***Standard***	
(new)	0,3 uAAC+DC 10 IEC 60601	
Open Neutral, Reversed Mains	*Patient Leakage Current* *Open Neutral, Reversed Mains*	
Result:	***Value*** ***Unit*** ***High Limit*** ***Low Limit*** ***Standard***	
(new)	0,3 uAAC+DC 50 IEC 60601	
Open Earth, Reversed Mains	*Patient Leakage Current* *Open Earth, Reversed Mains*	
Result:	***Value*** ***Unit*** ***High Limit*** ***Low Limit*** ***Standard***	
(new)	3,9 uAAC+DC 50 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:	***Value*** ***Unit*** ***High Limit*** ***Low Limit*** ***Standard***	
(new)	12,7 uA 50 IEC 60601	
Single Fault Condition, Reversed Mains	*Mains on Applied Parts* *Single Fault Condition, Reversed Mains*	
Result:	***Value*** ***Unit*** ***High Limit*** ***Low Limit*** ***Standard***	
(new)	12,7 uA 50 IEC 60601	
Patient Auxiliary Current ***Configuration:*** Unused Applied Parts: Floating	*Patient Auxiliary Current*	
Normal Condition	*Patient Auxiliary Current* *Normal Condition*	
Result:	***Value*** ***Unit*** ***High Limit*** ***Low Limit*** ***Standard***	
(new)	0,4 uAAC+DC 10 IEC 60601	
Open Neutral	*Patient Auxiliary Current* *Open Neutral*	

Fluke Biomedical Ansur Test Report

Test Element	Test Type					Fail
Result:	*Value*	*Unit*	*High Limit*	*Low Limit*	*Standard*	
(new)	0,4	uAAC+DC	50		IEC 60601	
Open Earth	*Patient Auxiliary Current* *Open Earth*					
Result:	*Value*	*Unit*	*High Limit*	*Low Limit*	*Standard*	
(new)	2,9	uAAC+DC	50		IEC 60601	
Normal Condition, Reversed mains	*Patient Auxiliary Current* *Normal Condition, Reversed mains*					
Result:	*Value*	*Unit*	*High Limit*	*Low Limit*	*Standard*	
(new)	0,4	uAAC+DC	10		IEC 60601	
Open Neutral, Reversed Mains	*Patient Auxiliary Current* *Open Neutral, Reversed Mains*					
Result:	*Value*	*Unit*	*High Limit*	*Low Limit*	*Standard*	
(new)	0,4	uAAC+DC	50		IEC 60601	
Open Earth, Reversed Mains	*Patient Auxiliary Current* *Open Earth, Reversed Mains*					
Result:	*Value*	*Unit*	*High Limit*	*Low Limit*	*Standard*	
(new)	2,7	uAAC+DC	50		IEC 60601	