

Le 31 mai 2026

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 29-09-2025)
- Inspection des courants de fuite  
(Analyseur Fluke ESA620 S/N: 2863062 certifiés 29-09-2025)

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



Eric Lavoie  
Coordonnateur Technique GBM  
Service Génie Biomédical

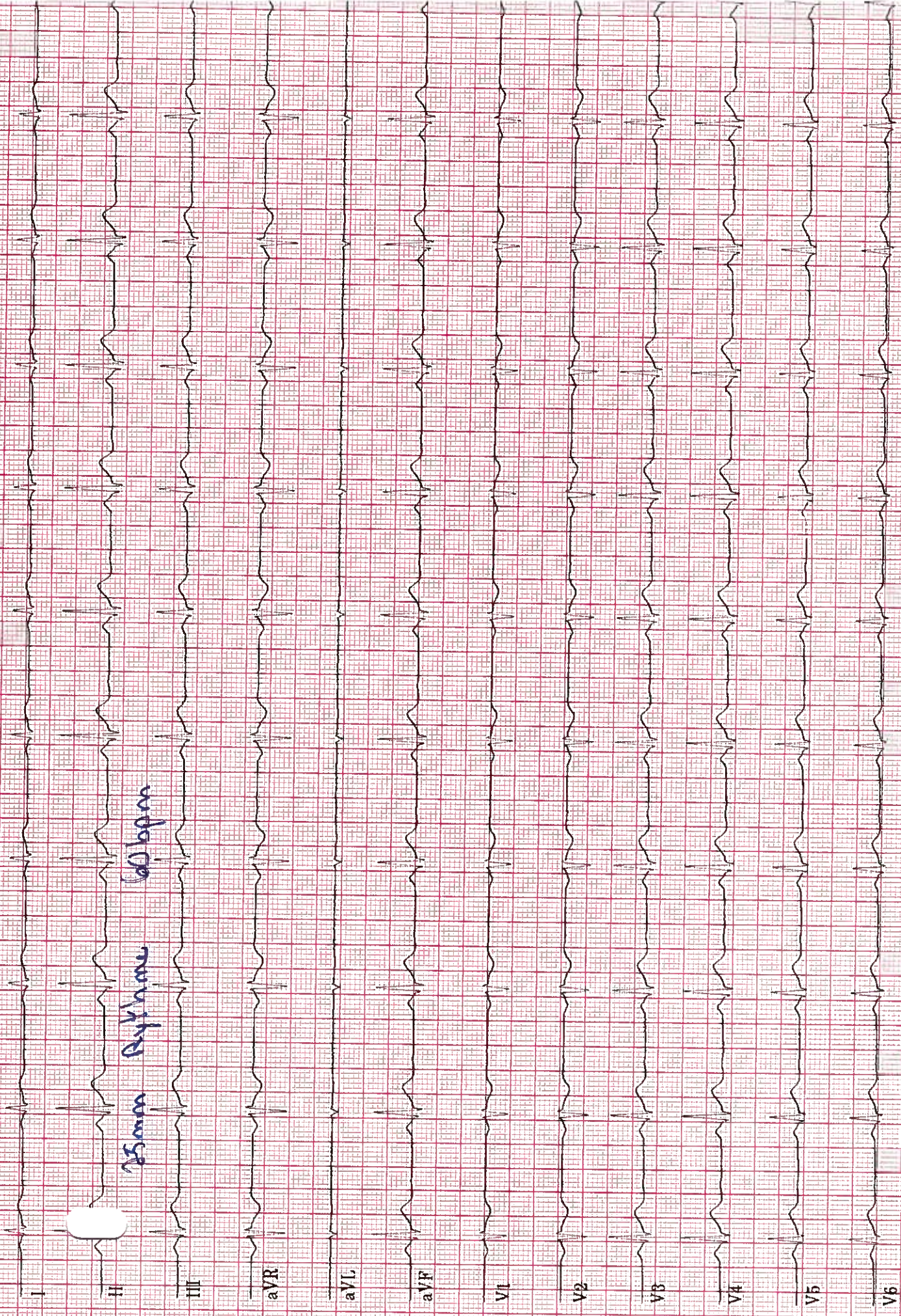


60 bpm

INSTITUT DE Kardiologie  
31-mai-2026 8:21:14

ID: 801055

25mm Rythme 60 bpm





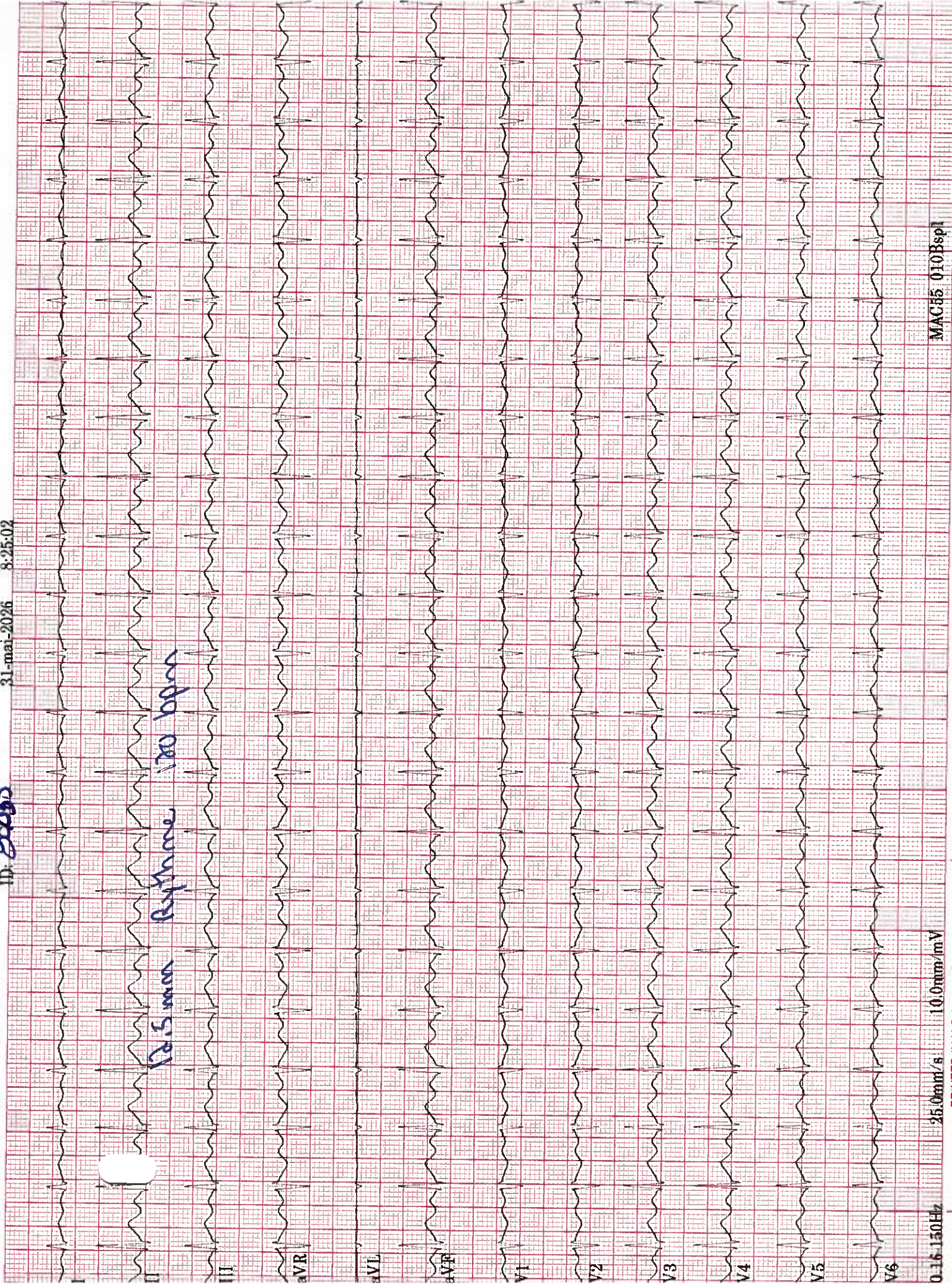
120 bpm

IRADIE DE RYTHME

31-mai-2026 8:25:02

ID: 20455

12.5 mm Rythme 120 bpm



MAC55 010Bspl

0.16 150Hz 25.0mm/s 10.0mm/mV

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# Fluke Biomedical Ansur Test and Inspection Procedure

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## Test Record

### TEST PASSED

**Test Performed**

Date: 31-05-2026  
Record: 801055 2026-05-31.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 | Type  |   |
| Appliance Code | *      | Model | * |
| Manufacturer   | *      |       |   |

### MTI Data

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

## Signatures

31-05-2026

## Test Result

| Test Element                                                                | Test Type                       |             |                   |                  |                 | Fail |
|-----------------------------------------------------------------------------|---------------------------------|-------------|-------------------|------------------|-----------------|------|
| IEC 60601-1 - CL1                                                           | Auto Sequence                   |             |                   |                  |                 |      |
| <b>Procedure:</b>                                                           |                                 |             |                   |                  |                 |      |
| (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 <b>Start Test</b> to perform the safety test.                     |                                 |             |                   |                  |                 |      |
| <b>Applied Part setup</b>                                                   |                                 |             |                   |                  |                 |      |
| #                                                                           | Applied Part info               |             | Class             | Leads            |                 |      |
| 1                                                                           | A.P. Code<br>Serial No.<br>Type | (new)       | CF                | 10               |                 |      |
| <b>Mains Voltage</b>                                                        |                                 |             |                   |                  |                 |      |
| <i>Mains Voltage</i>                                                        |                                 |             |                   |                  |                 |      |
| <b>Live to Neutral</b>                                                      |                                 |             |                   |                  |                 |      |
| <i>Mains Voltage<br/>Live to Neutral</i>                                    |                                 |             |                   |                  |                 |      |
| <b>Result:</b>                                                              | <b>Value</b>                    | <b>Unit</b> | <b>High Limit</b> | <b>Low Limit</b> | <b>Standard</b> |      |
| Live to Neutral                                                             | 119                             | V           |                   |                  | IEC 60601       |      |
| <b>Neutral to Earth</b>                                                     |                                 |             |                   |                  |                 |      |
| <i>Mains Voltage<br/>Neutral to Earth</i>                                   |                                 |             |                   |                  |                 |      |
| <b>Result:</b>                                                              | <b>Value</b>                    | <b>Unit</b> | <b>High Limit</b> | <b>Low Limit</b> | <b>Standard</b> |      |
| Neutral to Earth                                                            | 0,2                             | V           |                   |                  | IEC 60601       |      |
| <b>Live to Earth</b>                                                        |                                 |             |                   |                  |                 |      |
| <i>Mains Voltage<br/>Live to Earth</i>                                      |                                 |             |                   |                  |                 |      |
| <b>Result:</b>                                                              | <b>Value</b>                    | <b>Unit</b> | <b>High Limit</b> | <b>Low Limit</b> | <b>Standard</b> |      |
| Live to Earth                                                               | 119,1                           | V           |                   |                  | IEC 60601       |      |
| <b>Protective Earth Resistance</b>                                          |                                 |             |                   |                  |                 |      |
| <i>Earth Resistance</i>                                                     |                                 |             |                   |                  |                 |      |
| <b>Configuration:</b>                                                       |                                 |             |                   |                  |                 |      |
| Test Current: High                                                          |                                 |             |                   |                  |                 |      |
| <b>Result:</b>                                                              | <b>Value</b>                    | <b>Unit</b> | <b>High Limit</b> | <b>Low Limit</b> | <b>Standard</b> |      |
| PE Resistance1                                                              | 0,169                           | Ohm         | 0,2               |                  | IEC 60601       |      |
| <b>Insulation Resistance</b>                                                |                                 |             |                   |                  |                 |      |
| <i>Insulation Resistance</i>                                                |                                 |             |                   |                  |                 |      |
| <b>Configuration:</b>                                                       |                                 |             |                   |                  |                 |      |
| Test Voltage: 500V                                                          |                                 |             |                   |                  |                 |      |
| <b>Mains to Protective Earth</b>                                            |                                 |             |                   |                  |                 |      |
| <i>Insulation Resistance<br/>Mains to Protective Earth</i>                  |                                 |             |                   |                  |                 |      |
| <b>Result:</b>                                                              | <b>Value</b>                    | <b>Unit</b> | <b>High Limit</b> | <b>Low Limit</b> | <b>Standard</b> |      |
| Mains to Protective Earth                                                   | 99999                           | MOhm        |                   | 2                | IEC 60601       |      |
| <b>Applied Parts to Protective Earth</b>                                    |                                 |             |                   |                  |                 |      |
| <i>Insulation Resistance<br/>Applied Parts to Protective Earth</i>          |                                 |             |                   |                  |                 |      |
| <b>Result:</b>                                                              | <b>Value</b>                    | <b>Unit</b> | <b>High Limit</b> | <b>Low Limit</b> | <b>Standard</b> |      |
| Applied Parts to Protective Earth                                           | 100,3                           | MOhm        |                   |                  | IEC 60601       |      |
| <b>Earth Leakage Current</b>                                                |                                 |             |                   |                  |                 |      |
| <i>Earth Leakage Current</i>                                                |                                 |             |                   |                  |                 |      |

## Elnke Biomedical Ansur Test Report

| Test Element                                            | Test Type                                                     |                        |                            |                  |                              | Fail |
|---------------------------------------------------------|---------------------------------------------------------------|------------------------|----------------------------|------------------|------------------------------|------|
| <b>Configuration:</b><br>Unused Applied Parts: Floating |                                                               |                        |                            |                  |                              |      |
| Normal Condition                                        | Earth Leakage Current<br>Normal Condition                     |                        |                            |                  |                              |      |
| <b>Result:</b><br>Normal Condition                      | <b>Value</b><br>21,3                                          | <b>Unit</b><br>uAAC+DC | <b>High Limit</b><br>5000  | <b>Low Limit</b> | <b>Standard</b><br>IEC 60601 |      |
| Open Neutral                                            | Earth Leakage Current<br>Open Neutral                         |                        |                            |                  |                              |      |
| <b>Result:</b><br>Open Neutral                          | <b>Value</b><br>40,6                                          | <b>Unit</b><br>uAAC+DC | <b>High Limit</b><br>10000 | <b>Low Limit</b> | <b>Standard</b><br>IEC 60601 |      |
| Normal Condition, Reversed mains                        | Earth Leakage Current<br>Normal Condition, Reversed mains     |                        |                            |                  |                              |      |
| <b>Result:</b><br>Normal Condition,<br>Reversed mains   | <b>Value</b><br>20,3                                          | <b>Unit</b><br>uAAC+DC | <b>High Limit</b><br>5000  | <b>Low Limit</b> | <b>Standard</b><br>IEC 60601 |      |
| Open Neutral, Reversed Mains                            | Earth Leakage Current<br>Open Neutral, Reversed Mains         |                        |                            |                  |                              |      |
| <b>Result:</b><br>Open Neutral,<br>Reversed Mains       | <b>Value</b><br>40,6                                          | <b>Unit</b><br>uAAC+DC | <b>High Limit</b><br>10000 | <b>Low Limit</b> | <b>Standard</b><br>IEC 60601 |      |
| Enclosure Leakage Current                               | Enclosure Leakage Current                                     |                        |                            |                  |                              |      |
| <b>Configuration:</b><br>Unused Applied Parts: Floating |                                                               |                        |                            |                  |                              |      |
| Normal Condition                                        | Enclosure Leakage Current<br>Normal Condition                 |                        |                            |                  |                              |      |
| <b>Result:</b><br>Normal Condition                      | <b>Value</b><br>0,8                                           | <b>Unit</b><br>uAAC+DC | <b>High Limit</b><br>100   | <b>Low Limit</b> | <b>Standard</b><br>IEC 60601 |      |
| Open Neutral                                            | Enclosure Leakage Current<br>Open Neutral                     |                        |                            |                  |                              |      |
| <b>Result:</b><br>Open Neutral                          | <b>Value</b><br>0,8                                           | <b>Unit</b><br>uAAC+DC | <b>High Limit</b><br>500   | <b>Low Limit</b> | <b>Standard</b><br>IEC 60601 |      |
| Open Earth                                              | Enclosure Leakage Current<br>Open Earth                       |                        |                            |                  |                              |      |
| <b>Result:</b><br>Open Earth                            | <b>Value</b><br>21,3                                          | <b>Unit</b><br>uAAC+DC | <b>High Limit</b><br>500   | <b>Low Limit</b> | <b>Standard</b><br>IEC 60601 |      |
| Normal Condition, Reversed mains                        | Enclosure Leakage Current<br>Normal Condition, Reversed mains |                        |                            |                  |                              |      |
| <b>Result:</b><br>Normal Condition,<br>Reversed mains   | <b>Value</b><br>0,8                                           | <b>Unit</b><br>uAAC+DC | <b>High Limit</b><br>100   | <b>Low Limit</b> | <b>Standard</b><br>IEC 60601 |      |
| Open Neutral, Reversed Mains                            | Enclosure Leakage Current<br>Open Neutral, Reversed Mains     |                        |                            |                  |                              |      |
| <b>Result:</b><br>Open Neutral,<br>Reversed Mains       | <b>Value</b><br>0,8                                           | <b>Unit</b><br>uAAC+DC | <b>High Limit</b><br>500   | <b>Low Limit</b> | <b>Standard</b><br>IEC 60601 |      |
| Open Earth, Reversed Mains                              | Enclosure Leakage Current<br>Open Earth, Reversed Mains       |                        |                            |                  |                              |      |
| <b>Result:</b><br>Open Earth, Reversed<br>Mains         | <b>Value</b><br>20,2                                          | <b>Unit</b><br>uAAC+DC | <b>High Limit</b><br>500   | <b>Low Limit</b> | <b>Standard</b><br>IEC 60601 |      |

## Fluke Biomedical Ansur Test Report

| Test Element                                                                                            | Test Type                                 |                        |                         |                  | Fail                         |
|---------------------------------------------------------------------------------------------------------|-------------------------------------------|------------------------|-------------------------|------------------|------------------------------|
| Patient Leakage Current<br><b>Configuration:</b><br>Total Leakage: No<br>Unused Applied Parts: Floating | Patient Leakage Current                   |                        |                         |                  |                              |
| Normal Condition<br><b>Result:</b><br>(new)                                                             | <b>Value</b><br>0,5                       | <b>Unit</b><br>uAAC+DC | <b>High Limit</b><br>10 | <b>Low Limit</b> | <b>Standard</b><br>IEC 60601 |
| Open Neutral<br><b>Result:</b><br>(new)                                                                 | <b>Value</b><br>0,5                       | <b>Unit</b><br>uAAC+DC | <b>High Limit</b><br>50 | <b>Low Limit</b> | <b>Standard</b><br>IEC 60601 |
| Open Earth<br><b>Result:</b><br>(new)                                                                   | <b>Value</b><br>4,1                       | <b>Unit</b><br>uAAC+DC | <b>High Limit</b><br>50 | <b>Low Limit</b> | <b>Standard</b><br>IEC 60601 |
| Normal Condition, Reversed mains<br><b>Result:</b><br>(new)                                             | <b>Value</b><br>0,5                       | <b>Unit</b><br>uAAC+DC | <b>High Limit</b><br>10 | <b>Low Limit</b> | <b>Standard</b><br>IEC 60601 |
| Open Neutral, Reversed Mains<br><b>Result:</b><br>(new)                                                 | <b>Value</b><br>0,5                       | <b>Unit</b><br>uAAC+DC | <b>High Limit</b><br>50 | <b>Low Limit</b> | <b>Standard</b><br>IEC 60601 |
| Open Earth, Reversed Mains<br><b>Result:</b><br>(new)                                                   | <b>Value</b><br>3,9                       | <b>Unit</b><br>uAAC+DC | <b>High Limit</b><br>50 | <b>Low Limit</b> | <b>Standard</b><br>IEC 60601 |
| Mains on Applied Parts<br><b>Configuration:</b><br>Total Leakage: No<br>Unused Applied Parts: Floating  | Mains on Applied Parts                    |                        |                         |                  |                              |
| Single Fault Condition<br><b>Result:</b><br>(new)                                                       | <b>Value</b><br>12,4                      | <b>Unit</b><br>uA      | <b>High Limit</b><br>50 | <b>Low Limit</b> | <b>Standard</b><br>IEC 60601 |
| Single Fault Condition, Reversed Mains<br><b>Result:</b><br>(new)                                       | <b>Value</b><br>12,4                      | <b>Unit</b><br>uA      | <b>High Limit</b><br>50 | <b>Low Limit</b> | <b>Standard</b><br>IEC 60601 |
| Patient Auxiliary Current<br><b>Configuration:</b><br>Unused Applied Parts: Floating                    | Patient Auxiliary Current                 |                        |                         |                  |                              |
| Normal Condition<br><b>Result:</b><br>(new)                                                             | <b>Value</b><br>0,2                       | <b>Unit</b><br>uAAC+DC | <b>High Limit</b><br>10 | <b>Low Limit</b> | <b>Standard</b><br>IEC 60601 |
| Open Neutral                                                                                            | Patient Auxiliary Current<br>Open Neutral |                        |                         |                  |                              |

## Eluke Biomedical Ansur Test Report

| Test Element                     | Test Type                        |                        |                         |                  |                              | Fail |
|----------------------------------|----------------------------------|------------------------|-------------------------|------------------|------------------------------|------|
| <b>Result:</b><br>(new)          | <b>Value</b><br>0,2              | <b>Unit</b><br>uAAC+DC | <b>High Limit</b><br>50 | <b>Low Limit</b> | <b>Standard</b><br>IEC 60601 |      |
| Open Earth                       | <i>Patient Auxiliary Current</i> |                        |                         |                  |                              |      |
| <b>Result:</b><br>(new)          | <b>Value</b><br>3                | <b>Unit</b><br>uAAC+DC | <b>High Limit</b><br>50 | <b>Low Limit</b> | <b>Standard</b><br>IEC 60601 |      |
| Normal Condition, Reversed mains | <i>Patient Auxiliary Current</i> |                        |                         |                  |                              |      |
| <b>Result:</b><br>(new)          | <b>Value</b><br>0,2              | <b>Unit</b><br>uAAC+DC | <b>High Limit</b><br>10 | <b>Low Limit</b> | <b>Standard</b><br>IEC 60601 |      |
| Open Neutral, Reversed Mains     | <i>Patient Auxiliary Current</i> |                        |                         |                  |                              |      |
| <b>Result:</b><br>(new)          | <b>Value</b><br>0,2              | <b>Unit</b><br>uAAC+DC | <b>High Limit</b><br>50 | <b>Low Limit</b> | <b>Standard</b><br>IEC 60601 |      |
| Open Earth, Reversed Mains       | <i>Patient Auxiliary Current</i> |                        |                         |                  |                              |      |
| <b>Result:</b><br>(new)          | <b>Value</b><br>2,8              | <b>Unit</b><br>uAAC+DC | <b>High Limit</b><br>50 | <b>Low Limit</b> | <b>Standard</b><br>IEC 60601 |      |