

# Fluke Biomedical Ansur Test and Inspection Procedure

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## Test record

### TEST PASSED

#### Test performed

Date: 05-09-2024  
Record: IEC 60601-1 - CL2.mtr  
Template: IEC 60601-1 - CL2.mtt

#### Components used

Ansur Version 3.1.4  
Plug-In: ESA612 Version 1.1.3

## Test setup

### Selections

#### Service events performed

#### Standards performed

IEC 60601

### Device under test

|                 |                     |              |                               |
|-----------------|---------------------|--------------|-------------------------------|
| Número de serie | TV119042617         | Modelo       | Trilogy 100                   |
| Estado          | Reparado            | Localización | Andover Alianza Medica S. A.  |
| Fabricante      | Philips Respironics | Dirección 1  | Salar de Huasco 795, Pudahuel |
| Tipo            | Ventilador Mecanico | Dirección 2  | Laboratorio                   |

### MTI Data

| Test instrument | Serial number | Firmware version |
|-----------------|---------------|------------------|
| ESA612B         | 4465048       | v3.00            |

## Signatures

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## Test result

| Test element   | Test type             |                   |                          |                  |                              | Fail |
|--|-----------------------|-------------------|--------------------------|------------------|------------------------------|------|
| IEC 60601-1 - CL2  |                       |                   |                          |                  |                              |      |
| Auto Sequence  |                       |                   |                          |                  |                              |      |
| <b>Procedure:</b><br>(1) Connect the DUT to the ESA612 as indicated in the operators manual.<br>(2) Ensure that DUT power is On.<br>(3) Click module setup and specify the patient leads that are to be tested.<br>(4) Connect patient leads as indicated to the right.<br>(5) Click <b>Start Test</b> to perform the safety test. |                       |                   |                          |                  |                              |      |
| <b>Configuration</b><br>Polarity Switching Delay:3(s)  |                       |                   |                          |                  |                              |      |
| Mains Voltage  |                       |                   |                          |                  |                              |      |
| Mains Voltage  |                       |                   |                          |                  |                              |      |
| Live to Neutral  |                       |                   |                          |                  |                              |      |
| Mains Voltage<br>Live to Neutral   |                       |                   |                          |                  |                              |      |
| <b>Result:</b><br>Live to Neutral  | <b>Value</b><br>219,9 | <b>Unit</b><br>V  | <b>High limit</b>        | <b>Low limit</b> | <b>Standard</b><br>IEC 60601 |      |
| Enclosure Leakage Current  |                       |                   |                          |                  |                              |      |
| Enclosure Leakage Current  |                       |                   |                          |                  |                              |      |
| <b>Configuration</b><br>Unused Applied<br>Parts:Floating   |                       |                   |                          |                  |                              |      |
| Normal Condition   |                       |                   |                          |                  |                              |      |
| Enclosure Leakage Current<br>Normal Condition  |                       |                   |                          |                  |                              |      |
| <b>Result:</b><br>Normal Condition   | <b>Value</b><br>0,5   | <b>Unit</b><br>uA | <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>0,6   | <b>Unit</b><br>uA | <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>0,4   | <b>Unit</b><br>uA | <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>0,6   | <b>Unit</b><br>uA | <b>High limit</b><br>500 | <b>Low limit</b> | <b>Standard</b><br>IEC 60601 |      |