ANDOVER 05-03-2024

# Fluke Biomedical Ansur Test and Inspection Procedure

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## **Test Record**

### **TEST PASSED**

Test Performed

05-03-2024 IEC 60601-1 -

Record: CL2.TV019111308.mtr
Template: IEC 60601-1 - CL2.mtt

Template Version: 1.0.0

**Ansur Components Used** 

Ansur Version 3.1.4

Plug-In: ESA612 Version 1.1.3

## **Test Setup**

#### **Selections**

Date:

Service Events Performed	Standards Performed
	IEC 60601

#### **Device under test**

Serial Number	TV019111308	Type	Trilogy
Appliance Code	1040000	Model	202
Group	Ventilador	Location	Andover Alianza Medica S. A.
Status	Reparado	Address 1	Salar de Huasco 795, Pudahuel, Santiago
Manufacturer	Philips Respironic	Address 2	Laboratorio

#### MTI Data

Test Instrument	Serial Number	Firmware Version
ESA612B	6034120	v3.01

## **Signatures**

## **Test Result**

IEC 60601-1 - CL2   Auto Sequence   Procedure: (1) Connect the DUT to the ESA612 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.    Configuration: Polarity Switching Delay:3(s)   Polarity Switching Delay:3(s)	Test Element		Test Ty	уре			Fail
(1) Connect the DUT to the ESA612 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.  Configuration: Polarity Switching Delay;3(s)  Mains Voltage  Live to Neutral Result: Live to Neutral Live to Neutral Clore Leakage Current Configuration: Unused Applied Parts: Floating  Normal Condition Result: Normal Condition Result: Open Neutral  Open Neutral  Normal Condition, Reversed mains Result: Normal Condition, Reversed Mains No			Auto Se	quence			
(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.  Configuration: Polarity Switching Delay:3(s)  Mains Voltage  Live to Neutral  Result: Live to Neutral  Procedure to Neutral  Enclosure Leakage Current  Configuration: Unused Applied Parts:Floating  Normal Condition  Result: Normal Condition  Result: Open Neutral  Open Neutral  Normal Condition, Reversed mains  Result: Normal Condition, Reversed mains  Processor Leakage Current Normal Condition, Reversed mains  Unit High Limit Low Limit  Standard  Unit High Limit Low Limit  Standa		5047	40				
(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.  Configuration: Polarity Switching Delay:3(s)  Mains Voltage  Live to Neutral  Result: Live to Neutral  Live to Neutral  Live to Neutral  Live to Neutral  Enclosure Leakage Current  Configuration: Unused Applied Parts-Floating  Normal Condition  Result: Normal Condition  Result: Normal Condition  Open Neutral  Result: Value Unit High Limit Low Limit Value Unit High Limit Low Limit  Standard IEC 60601  Normal Condition, Reversed mains Result: Normal Condition, Reversed Mains Reversed mains Reversed mains Reversed mains Result: Normal Reversed Mains Result: Normal Condition, Reversed Mains Result: Value Unit High Limit Low Limit Normal Condition, Reversed Mains Normal Condition, Reversed Mains Normal Condition, Reversed Mains Normal Condition, Reversed Mains Result: Value Unit High Limit Low Limit Normal Condition, Reversed Mains Normal Condition, Rever	• •			icated in th	e operators man	ual.	
(4) Connect patient leads as indicated to the right. (5) Click Start Test to perform the safety test.  Configuration: Polarity Switching Delay:3(s)  Mains Voltage  Live to Neutral Result: Live to Neutral Normal Condition Result: Value Unit High Limit Low Limit Value Unit High Limit Low Limit Normal Condition, Reversed mains Result: Value Unit High Limit Low Limit Value Unit High Limit Low Limit Standard Open Neutral, Reversed Mains Live to Neutral Live to Neutral Live to Neutral Low Limit Live Limit Standard Open Neutral, Reversed Mains Live to Neutral Low Limit Live Limit Li							
(5) Click Start Test to perform the safety test.  Configuration: Polarity Switching Delay;3(s)  Mains Voltage  Live to Neutral Result: Live to Neutral Live Limit Live Limit Standard Live to Neutral Live Limit Live Live Limit Live Live Live Live Live Live Live Live	(3) Click module setup	and specif	fy the pat	ient leads t	hat are to be tes	ted.	
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Configuration: Unused Applied Parts:Floating  Normal Condition  Result: Normal Condition  Open Neutral  Result: Open Neutral  Open Neutral  Open Neutral  Normal Condition, Reversed mains  Result: Normal Condition, Reversed Mains  Reversed mains  Perclosure Leakage Current Normal Condition, Reversed mains  Result: Normal Condition  Open Neutral, Reversed Mains  Open Neutral, Pip Limit  Normal Condition  Open Neutral, Reversed Mains  Open Neutral, Standard  Open Neutral, Reversed Mains  Open Neutral, Reversed Mains  Open Neutral, Reversed Mains  Open Neutral, Reversed Mains	Live to Neutral	231,9	V			IEC 00001	
Configuration: Unused Applied Parts:Floating  Normal Condition  Result: Normal Condition  Open Neutral  Result: Open Neutral  Open Neutral  Open Neutral  Normal Condition, Reversed mains  Result: Normal Condition, Reversed Mains  Reversed mains  Perclosure Leakage Current Normal Condition, Reversed mains  Result: Normal Condition  Open Neutral, Reversed Mains  Open Neutral, Pip Limit  Normal Condition  Open Neutral, Reversed Mains  Open Neutral, Standard  Open Neutral, Reversed Mains  Open Neutral, Reversed Mains  Open Neutral, Reversed Mains  Open Neutral, Reversed Mains							
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