

# Treat Med Company Limited

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## Test record

### TEST PASSED

#### Test performed

Date: 9/10/2009  
 Record: ESA612 - IEC60601  
 CL1.mtr  
 Template: IEC 60601-1 - CL1.mtt

#### Ansur components used

ansur Version 2.7.1  
 Plug-In: ESA612 Version 1.0.5

## Test setup

### Selections

Service events performed	Standards performed
	IEC 60601

### Device under test

Serial number	J2900FI00060	Type	Patient Monitor
Appliance code		Model	Classic 120 Plus
Group		Location	
Status		Address 1	
Manufacturer	Heal Force	Address 2	

### ESA612

#	Module info	Class	Leads
1	Module Code Serial No. Type	ECG CF	5

### MTI Data

Test instrument	Serial number	Firmware version
ESA 612	1051024	v1.01

## Signatures

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# Test result

Test element	Test type					Fail
IEC 60601-1 - CL1 <i>Procedure:</i> (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 <b>Start Test</b> to perform the safety test.	<i>Auto Sequence</i>					
Mains Voltage	<i>Mains Voltage</i>					
Live to Neutral <i>Result:</i> Live to Neutral	<i>Value</i> 221.2	<i>Unit</i> V	<i>High limit</i>	<i>Low limit</i>	<i>Standard</i> IEC 60601	
Neutral to Earth <i>Result:</i> Neutral to Earth	<i>Value</i> 221.4	<i>Unit</i> V	<i>High limit</i>	<i>Low limit</i>	<i>Standard</i> IEC 60601	
Live to Earth <i>Result:</i> Live to Earth	<i>Value</i> 2.1	<i>Unit</i> V	<i>High limit</i>	<i>Low limit</i>	<i>Standard</i> IEC 60601	
Protective Earth Resistance <i>Result:</i> Protective Earth Resistance	<i>Value</i> .077	<i>Unit</i> Ohm	<i>High limit</i> .2	<i>Low limit</i>	<i>Standard</i> 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>Value</i> 99999	<i>Unit</i> MOhm	<i>High limit</i>	<i>Low limit</i> 2	<i>Standard</i> IEC 60601	
Applied Parts to Protective Earth <i>Result:</i> ECG	<i>Value</i> 99999	<i>Unit</i> MOhm	<i>High limit</i>	<i>Low limit</i>	<i>Standard</i>	
Earth Leakage Current <i>Configuration:</i> Applied Parts: Open	<i>Earth Leakage Current</i>					
Normal Condition <i>Result:</i> Normal Condition	<i>Value</i> 124.7	<i>Unit</i> uA	<i>High limit</i> 5000	<i>Low limit</i>	<i>Standard</i> IEC 60601	
Open Neutral <i>Result:</i> Open Neutral	<i>Value</i> 231	<i>Unit</i> uA	<i>High limit</i> 10000	<i>Low limit</i>	<i>Standard</i> IEC 60601	

Test element	Test type					Fail
Normal Condition, Reversed mains	<i>Earth Leakage Current</i> <i>Normal Condition, Reversed mains</i>					
<i>Result:</i> Normal Condition, Reversed mains	<i>Value</i> 123.1	<i>Unit</i> uA	<i>High limit</i> 5000	<i>Low limit</i>	<i>Standard</i> IEC 60601	
Open Neutral, Reversed Mains	<i>Earth Leakage Current</i> <i>Open Neutral, Reversed Mains</i>					
<i>Result:</i> Open Neutral, Reversed Mains	<i>Value</i> 233	<i>Unit</i> uA	<i>High limit</i> 10000	<i>Low limit</i>	<i>Standard</i> IEC 60601	
Enclosure Leakage Current	<i>Enclosure Leakage Current</i>					
<i>Configuration:</i> Applied Parts: Open						
Normal Condition	<i>Enclosure Leakage Current</i> <i>Normal Condition</i>					
<i>Result:</i> Normal Condition	<i>Value</i> .1	<i>Unit</i> uA	<i>High limit</i> 100	<i>Low limit</i>	<i>Standard</i> IEC 60601	
Open Neutral	<i>Enclosure Leakage Current</i> <i>Open Neutral</i>					
<i>Result:</i> Open Neutral	<i>Value</i> .1	<i>Unit</i> uA	<i>High limit</i> 500	<i>Low limit</i>	<i>Standard</i> IEC 60601	
Open Earth	<i>Enclosure Leakage Current</i> <i>Open Earth</i>					
<i>Result:</i> Open Earth	<i>Value</i> 124.8	<i>Unit</i> uA	<i>High limit</i> 500	<i>Low limit</i>	<i>Standard</i> IEC 60601	
Normal Condition, Reversed mains	<i>Enclosure Leakage Current</i> <i>Normal Condition, Reversed mains</i>					
<i>Result:</i> Normal Condition, Reversed mains	<i>Value</i> .1	<i>Unit</i> uA	<i>High limit</i> 100	<i>Low limit</i>	<i>Standard</i> IEC 60601	
Open Neutral, Reversed Mains	<i>Enclosure Leakage Current</i> <i>Open Neutral, Reversed Mains</i>					
<i>Result:</i> Open Neutral, Reversed Mains	<i>Value</i> .1	<i>Unit</i> uA	<i>High limit</i> 500	<i>Low limit</i>	<i>Standard</i> IEC 60601	
Open Earth, Reversed Mains	<i>Enclosure Leakage Current</i> <i>Open Earth, Reversed Mains</i>					
<i>Result:</i> Open Earth, Reversed Mains	<i>Value</i> 123	<i>Unit</i> uA	<i>High limit</i> 500	<i>Low limit</i>	<i>Standard</i> IEC 60601	
Patient Leakage Current	<i>Patient Leakage Current</i>					
Normal Condition	<i>Patient Leakage Current</i> <i>Normal Condition</i>					
<i>Result:</i> ECG	<i>Value</i> 1.9	<i>Unit</i> uA	<i>High limit</i> 10	<i>Low limit</i>	<i>Standard</i> IEC 60601	
Open Neutral	<i>Patient Leakage Current</i> <i>Open Neutral</i>					
<i>Result:</i> ECG	<i>Value</i> 2	<i>Unit</i> uA	<i>High limit</i> 50	<i>Low limit</i>	<i>Standard</i> IEC 60601	

Test element	Test type	Fail
Open Earth <i>Result:</i> ECG	<i>Patient Leakage Current</i> <i>Open Earth</i> <i>Unit High limit Low limit</i> uA 50	<i>Standard</i> IEC 60601
Normal Condition, Reversed mains <i>Result:</i> ECG	<i>Patient Leakage Current</i> <i>Normal Condition, Reversed mains</i> <i>Unit High limit Low limit</i> uA 10	<i>Standard</i> IEC 60601
Open Neutral, Reversed Mains <i>Result:</i> ECG	<i>Patient Leakage Current</i> <i>Open Neutral, Reversed Mains</i> <i>Unit High limit Low limit</i> uA 50	<i>Standard</i> IEC 60601
Open Earth, Reversed Mains <i>Result:</i> ECG	<i>Patient Leakage Current</i> <i>Open Earth, Reversed Mains</i> <i>Unit High limit Low limit</i> uA 50	<i>Standard</i> IEC 60601
Mains on Applied Parts	<i>Mains on Applied Parts</i>	
Normal Condition <i>Result:</i> ECG	<i>Mains on Applied Parts</i> <i>Normal Condition</i> <i>Unit High limit Low limit</i> uA 50	<i>Standard</i> IEC 60601
Reversed Mains <i>Result:</i> ECG	<i>Mains on Applied Parts</i> <i>Reversed Mains</i> <i>Unit High limit Low limit</i> uA 50	<i>Standard</i> IEC 60601
Patient Auxiliary Current	<i>Patient Auxiliary Current</i>	
Normal Condition <i>Result:</i> ECG	<i>Patient Auxiliary Current</i> <i>Normal Condition</i> <i>Unit High limit Low limit</i> uA 10	<i>Standard</i> IEC 60601
Open Neutral <i>Result:</i> ECG	<i>Patient Auxiliary Current</i> <i>Open Neutral</i> <i>Unit High limit Low limit</i> uA 50	<i>Standard</i> IEC 60601
Open Earth <i>Result:</i> ECG	<i>Patient Auxiliary Current</i> <i>Open Earth</i> <i>Unit High limit Low limit</i> uA 50	<i>Standard</i> IEC 60601
Normal Condition, Reversed mains <i>Result:</i> ECG	<i>Patient Auxiliary Current</i> <i>Normal Condition, Reversed mains</i> <i>Unit High limit Low limit</i> uA 10	<i>Standard</i> IEC 60601
Open Neutral, Reversed Mains <i>Result:</i> ECG	<i>Patient Auxiliary Current</i> <i>Open Neutral, Reversed Mains</i> <i>Unit High limit Low limit</i> uA 50	<i>Standard</i> IEC 60601
Open Earth, Reversed Mains	<i>Patient Auxiliary Current</i> <i>Open Earth, Reversed Mains</i>	

Test element	Test type				Fail
<i>Result:</i>	<i>Value</i>	<i>Unit</i>	<i>High limit</i>	<i>Low limit</i>	<i>Standard</i>
ECG	2.4	uA	50		IEC 60601