

# Treat Med Company Limited

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## Test record

### TEST PASSED

| Test performed |                                       | Ansur components used |               |
|----------------|---------------------------------------|-----------------------|---------------|
| Date:          | 9/10/2009                             | ansur                 | Version 2.7.1 |
| Record:        | ESA612 - IEC62353<br>CL1 Direct.mtr   | Plug-In: ESA612       | Version 1.0.5 |
| Template:      | IEC 62353 Direct<br>Leakage - CL1.mtt |                       |               |

## Test setup

### Selections

| Service events performed | Standards performed |
|--------------------------|---------------------|
|                          | IEC 62353 (CL1)     |

### 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<br>Serial No.<br>Type | ECG<br>CF | 5     |

### MTI Data

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

## Signatures

# Test result

| Test element                                       | Test type   | Fail                               |
|--|---|------------------------------------|
| IEC 62353 Direct Leakage - Class I                 | Auto Sequence   |                                    |
| Mains Voltage                                      | Mains Voltage   |                                    |
| Live to Neutral                                    | Mains Voltage<br>Live to Neutral                                |                                    |
| <i>Result:</i><br>Live to Neutral                  | <i>Value</i><br>218.4   | <i>Unit</i><br>V                   |
|  | <i>High limit</i>   | <i>Low limit</i>                   |
|  |   | <i>Standard</i><br>IEC 62353 (CL1) |
| Neutral to Earth                                   | Mains Voltage<br>Neutral to Earth                               |                                    |
| <i>Result:</i><br>Neutral to Earth                 | <i>Value</i><br>219.4   | <i>Unit</i><br>V                   |
|  | <i>High limit</i>   | <i>Low limit</i>                   |
|  |   | <i>Standard</i><br>IEC 62353 (CL1) |
| Live to Earth                                      | Mains Voltage<br>Live to Earth                                  |                                    |
| <i>Result:</i><br>Live to Earth                    | <i>Value</i><br>2.5   | <i>Unit</i><br>V                   |
|  | <i>High limit</i>   | <i>Low limit</i>                   |
|  |   | <i>Standard</i><br>IEC 62353 (CL1) |
| Protective Earth Resistance                        | Protective Earth Resistance                                     |                                    |
| <i>Result:</i><br>Protective Earth Resistance      | <i>Value</i><br>.077  | <i>Unit</i><br>Ohm                 |
|  | <i>High limit</i>   | <i>Low limit</i>                   |
|  |   | <i>Standard</i><br>IEC 62353 (CL1) |
| Direct Equipment Leakage                           | Direct Equipment Leakage  |                                    |
| Normal Condition                                   | Direct Equipment Leakage<br>Normal Condition                    |                                    |
| <i>Result:</i><br>Normal Condition                 | <i>Value</i><br>.1  | <i>Unit</i><br>uA                  |
|  | <i>High limit</i>   | <i>Low limit</i>                   |
|  |   | <i>Standard</i><br>IEC 62353 (CL1) |
| Open Earth   | Direct Equipment Leakage<br>Open Earth                          |                                    |
| <i>Result:</i><br>Open Earth                       | <i>Value</i><br>125.5   | <i>Unit</i><br>uA                  |
|  | <i>High limit</i>   | <i>Low limit</i>                   |
|  |   | <i>Standard</i><br>IEC 62353 (CL1) |
| Normal Condition, Reversed mains                   | Direct Equipment Leakage<br>Normal Condition, Reversed mains    |                                    |
| <i>Result:</i><br>Normal Condition, Reversed mains | <i>Value</i><br>.1  | <i>Unit</i><br>uA                  |
|  | <i>High limit</i>   | <i>Low limit</i>                   |
|  |   | <i>Standard</i><br>IEC 62353 (CL1) |
| Open Earth, Reversed Mains                         | Direct Equipment Leakage<br>Open Earth, Reversed Mains          |                                    |
| <i>Result:</i><br>Open Earth, Reversed Mains       | <i>Value</i><br>123.2   | <i>Unit</i><br>uA                  |
|  | <i>High limit</i>   | <i>Low limit</i>                   |
|  |   | <i>Standard</i><br>IEC 62353 (CL1) |
| Direct Applied Part Leakage                        | Direct Applied Part Leakage                                     |                                    |
| Normal Condition                                   | Direct Applied Part Leakage<br>Normal Condition                 |                                    |
| <i>Result:</i><br>ECG                              | <i>Value</i><br>37.1  | <i>Unit</i><br>uA                  |
|  | <i>High limit</i>   | <i>Low limit</i>                   |
|  |   | <i>Standard</i><br>IEC 62353 (CL1) |
| Normal Condition, Reversed mains                   | Direct Applied Part Leakage<br>Normal Condition, Reversed mains |                                    |

| <b>Test element</b>   | <b>Test type</b>     |                   |                         |                                    |                                    | <b>Fail</b> |
|---|----------------------|-------------------|-------------------------|------------------------------------|------------------------------------|-------------|
| <i>Result:</i><br>ECG   | <i>Value</i><br>37.6 | <i>Unit</i><br>uA | <i>High limit</i><br>50 | <i>Low limit</i>                   | <i>Standard</i><br>IEC 62353 (CL1) |             |
| <hr/>   |                      |                   |                         |                                    |                                    |             |
| Insulation Resistance<br><i>Configuration:</i><br>Test Voltage: 500V              |                      |                   |                         |                                    |                                    |             |
| <hr/>   |                      |                   |                         |                                    |                                    |             |
| Mains to Protective Earth<br><i>Result:</i><br>Mains to Protective Earth          |                      |                   |                         |                                    |                                    |             |
| <i>Value</i><br>99999   | <i>Unit</i><br>MOhm  | <i>High limit</i> | <i>Low limit</i><br>2   | <i>Standard</i><br>IEC 62353 (CL1) |                                    |             |
| <hr/>   |                      |                   |                         |                                    |                                    |             |
| Applied Parts to Protective Earth<br><i>Result:</i><br>ECG                        |                      |                   |                         |                                    |                                    |             |
| <i>Value</i><br>99999   | <i>Unit</i><br>MOhm  | <i>High limit</i> | <i>Low limit</i>        | <i>Standard</i>                    |                                    |             |
| <hr/>   |                      |                   |                         |                                    |                                    |             |
| Mains to Applied Parts<br><i>Result:</i><br>ECG                                   |                      |                   |                         |                                    |                                    |             |
| <i>Value</i><br>99999   | <i>Unit</i><br>MOhm  | <i>High limit</i> | <i>Low limit</i>        | <i>Standard</i>                    |                                    |             |
| <hr/>   |                      |                   |                         |                                    |                                    |             |
| Applied Parts to Non-Earth Accessible<br>Conductive Part<br><i>Result:</i><br>ECG |                      |                   |                         |                                    |                                    |             |
| <i>Value</i><br>99999   | <i>Unit</i><br>MOhm  | <i>High limit</i> | <i>Low limit</i>        | <i>Standard</i>                    |                                    |             |