Testing Power Supplies for Medical Electronics Applications

Introduction

The international standard IEC 60601 specifies testing performance for electrical devices used in medical applications. This standard has undergone some significant changes in the last number of years, with the recent adoption of the 3rd edition of the standard in 2012. In fact, IEC recently announced planned introduction of the 4th edition of the IEC60601 standard, slated for adoption in 2018, making it a design consideration for the next generation of medical equipment designs. Since the power supply is considered a component of a medical device, it is the applied part – meaning the medical electronics end-product – that must be evaluated for overall performance to meet standard's requirements. Although a power supply cannot be “certified,” it can be designed and tested to meet the necessary levels of performance according to the applied parts’ intended applications. Testing power supplies to this medical standard can help manufacturers optimize their medical designs to achieve the highest performance and safety levels and thereby enable first-pass success during agency approvals. This paper describes how Excelsys Technologies Xsolo power supplies have been designed and tested to meet both the B and BF type requirements per the IEC 60601 standard.

Safety Classifications for Medical Applied Parts

In July 2014, the IEC updated the medical standard IEC 60601-1-2 as related to “Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests.”

The IEC 60601 standard cites three classifications for meeting these requirements: CF, BF, and B. The requirements for leakage current for these classifications are shown in Tables 1 and 2 on page 2, which are taken from the IEC 60601 specifications.

The CF, or Cardiac Floating, is the most demanding performance level. Applied parts falling under this rating have application in products including, but not limited to, ventricular assist devices (VADs) or dialysis machines. In these applications, electrical connection can be made directly to the patient's heart during the operation of the device.

Type BF or Body Floating is less stringent than CF and is intended for applied parts which have conductive long-term contact with a patient. These products can include incubators, patient heating and cooling equipment, ultrasound monitoring, cardiac monitoring and long term diagnostic equipment and blood pressure monitoring to name a few.

The least stringent requirement is for the type B, or Body, classification and is reserved for applied parts that are not conductive and can be immediately released from the patient. This includes, but is not limited to, LED lighting, medical lasers, medical imaging (i.e., MRI, hospital beds and phototherapy equipment). Another difference
### Table 3—Allowable values of Patient Leakage Currents and Patient Auxiliary Currents under Normal Condition and Single Fault Condition

<table>
<thead>
<tr>
<th>Current Description</th>
<th>Reference</th>
<th>Measuring Circuit</th>
<th>Type B Applied Part NC</th>
<th>Type B Applied Part SFC</th>
<th>Type BF Applied Part NC</th>
<th>Type BF Applied Part SFC</th>
<th>Type CF Applied Part NC</th>
<th>Type CF Applied Part SFC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Auxiliary Current</td>
<td>8.7.4.8</td>
<td>Figure 19</td>
<td>d.c. 10</td>
<td>50</td>
<td>10</td>
<td>50</td>
<td>10</td>
<td>50</td>
</tr>
<tr>
<td>From Patient Connection to earth</td>
<td>8.7.4.7 (a)</td>
<td>Figure 15</td>
<td>d.c. 10</td>
<td>50</td>
<td>10</td>
<td>50</td>
<td>10</td>
<td>50</td>
</tr>
<tr>
<td>From Patient Connection to earth</td>
<td>8.7.4.7 (c)</td>
<td>Figure 17</td>
<td>d.c. 10</td>
<td>50</td>
<td>10</td>
<td>50</td>
<td>10</td>
<td>50</td>
</tr>
<tr>
<td>Total Patient Leakage Current</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>With the same types of Applied Part connected together</td>
<td>8.7.4.7 (a) and 8.7.4.7 (h)</td>
<td>Figure 15 and Figure 20</td>
<td>d.c. 50</td>
<td>100</td>
<td>50</td>
<td>100</td>
<td>50</td>
<td>100</td>
</tr>
<tr>
<td>With the same types of Applied Part connected together</td>
<td>8.7.4.7 (a) and 8.7.4.7 (h)</td>
<td>Figure 15 and Figure 20</td>
<td>a.c. 500</td>
<td>1,000</td>
<td>500</td>
<td>1,000</td>
<td>50</td>
<td>100</td>
</tr>
<tr>
<td>Caused by an external voltage on a sip/sop</td>
<td>8.7.4.7 (c) and 8.7.4.7 (h)</td>
<td>Figure 17 and Figure 20</td>
<td>d.c. 50</td>
<td>100</td>
<td>50</td>
<td>100</td>
<td>50</td>
<td>100</td>
</tr>
<tr>
<td>Caused by an external voltage on a sip/sop</td>
<td>8.7.4.7 (c) and 8.7.4.7 (h)</td>
<td>Figure 17 and Figure 20</td>
<td>a.c. 500</td>
<td>1,000</td>
<td>500</td>
<td>1,000</td>
<td>50</td>
<td>100</td>
</tr>
</tbody>
</table>

Table 1: Leakage current requirements according to specification: IEC 60601-1, Table 3 - Reference: 8.7.4.7 (a).

### Table 4—Allowable values of Patient Leakage Currents under the special test conditions identified in 8.7.4.7

<table>
<thead>
<tr>
<th>Current Description</th>
<th>Reference</th>
<th>Measuring Circuit</th>
<th>Type B Applied Part NC</th>
<th>Type B Applied Part SFC</th>
<th>Type BF Applied Part NC</th>
<th>Type BF Applied Part SFC</th>
<th>Type CF Applied Part NC</th>
<th>Type CF Applied Part SFC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Caused by an external voltage on the patient connection of an F-type applied part</td>
<td>8.7.4.7 (b)</td>
<td>Figure 16</td>
<td>Not applicable</td>
<td>5,000</td>
<td>50</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Caused by an external voltage on a metal accessible part not protectively earthed</td>
<td>8.7.4.7 (d)</td>
<td>Figure 18</td>
<td>500</td>
<td>500</td>
<td>-</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Patient Leakage Current</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Caused by an external voltage on the patient connection of an F-type applied part</td>
<td>8.7.4.7 (b) and 8.7.4.7 (h)</td>
<td>Figure 16 and Figure 20</td>
<td>Not applicable</td>
<td>5,000</td>
<td>100</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Caused by an external voltage on a metal accessible part not protectively earthed</td>
<td>8.7.4.7 (d) and 8.7.4.7 (h)</td>
<td>Figure 18 and Figure 20</td>
<td>1,000</td>
<td>1,000</td>
<td>-</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

a This condition referred to in Table IV of the second edition as "maximum mains voltage on applied part." and treated in that edition as a single Table 2: Leakage current requirements according to specification: IEC 60601-1 Table 4 - Reference: 8.7.4.7 (b).

b Total patient leakage current values are only applicable to equipment having multiple applied parts. See 8.7.4.7 (h). The individual applied parts shall comply with the patient leakage current values.

c This condition is not tested with type CF applied parts because it is covered by the test with maximum mains voltage on the applied part. See also the rationale for 8.7.4.7 (d).
between Type B, BF and CF, is that Type B applied parts may be connected to earth ground. Type BF and CF are not connected to earth ground and this is why the specification refers to them as floating.

## Testing Power Supplies to the Medical Standard

Excelsys Technologies developed its XS series of power supplies for medical applications. Testing the power supplies to the 60601 standard was undertaken using both its basic and low-leakage models, the XS1000-48N-000 and XS1000-48N-004, respectively.

The high efficiency XS1000 Power Supply delivers up to 1008W in an enclosed, fan cooled chassis. Nominal output voltages are 24V and 48V with wide adjustment ranges and user defined set-points. Xsolo carries dual safety certification, EN60950 2nd Edition for Industrial Applications and EN60601-1 2nd and 3rd Edition for Medical Applications, meeting the stringent creepage and clearance requirements, 4KVAC isolation and <300uA leakage current. Boasting up to 92% efficiency the XS1000 is ideal for use in acoustic sensitive medical applications, harsh industrial environments, Laboratory equipment and HI-Rel/MIL-COTS applications.

Excelsys used the isolation voltage ratings of each power supply to determine which one would be suitable for a particular application type (Table 3). Power supplies vary widely in terms quality and reliability. There are design differences, depending on the supplier, and many power supplies are not meant for medical applications.

<table>
<thead>
<tr>
<th>Type</th>
<th>Input to Output Isolation</th>
<th>Input to Ground Isolation</th>
<th>Output to Ground Isolation</th>
</tr>
</thead>
<tbody>
<tr>
<td>B rated</td>
<td>4000VAC</td>
<td>1500VAC</td>
<td>500VAC</td>
</tr>
<tr>
<td>BF/CF rated</td>
<td>4000VAC</td>
<td>1500VAC</td>
<td>1500VAC</td>
</tr>
</tbody>
</table>

*Table 3. Isolation voltages necessary for B, BF, or CF rated power supplies.*

## Testing Results

The Excelsys testing procedures were performed in accordance with the IEC 60601 requirements using an AC source providing 264 VAC at 63 Hz, which demonstrates worse-case conditions. The power supplies were tested to Tables 15 and 16 specified by the IEC’s specifications, as shown in Figures 2 and 3 below.[1]

The resulting data from Excelsys is shown Tables 4 and 5 along with the requirements in the specification showing the limits for AC testing. These results indicate that the XS – Xsolo products would be well suited to applications in either type BF or B applied applications.
Test 1: Patient Connection to Earth—Result: PASS

For the first test, Excelsys used the following power supply settings: \( V_{\text{in}} = 264\text{Vrms} \) (maximum rated input voltage), Frequency = 63Hz (maximum rated input frequency)

The test method was to follow the instructions shown in Figure 2 (based on IEC Fig 15.)

Figure 2. (From IEC 60601 Figure 15). Measure circuit for patient leakage current – from patient connection to earth.

Excelsys measured the following parameters shown in Table 4:

<table>
<thead>
<tr>
<th>Measuring Circuit</th>
<th>Test Condition</th>
<th>XS1000-48N-000 (µA)</th>
<th>XS1000-48N-004 (µA)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Vo -</td>
<td>Vo +</td>
</tr>
<tr>
<td>Figure 15</td>
<td>NC (No Fault)</td>
<td>20.1</td>
<td>20.0</td>
</tr>
<tr>
<td>Figure 15</td>
<td>SFC S7 Open (Earth)</td>
<td>150.0</td>
<td>148.0</td>
</tr>
<tr>
<td>Figure 15</td>
<td>SFC S1 Open (Neutral)</td>
<td>30.5</td>
<td>30.7</td>
</tr>
<tr>
<td></td>
<td></td>
<td>21.1</td>
<td>21.2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>96.0</td>
<td>95.0</td>
</tr>
<tr>
<td></td>
<td></td>
<td>32.6</td>
<td>32.6</td>
</tr>
<tr>
<td>S5 Closed Reversed Input Polarity:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Figure 15</td>
<td>NC (No Fault)</td>
<td>19.7</td>
<td>19.7</td>
</tr>
<tr>
<td>Figure 15</td>
<td>SFC S7 Open (Earth)</td>
<td>153.0</td>
<td>151.0</td>
</tr>
<tr>
<td>Figure 15</td>
<td>SFC S1 Open (Live)</td>
<td>30.8</td>
<td>31.0</td>
</tr>
</tbody>
</table>

Table 4. Excelsys power supply test against IEC 60601 Table 15. Result: Pass.
Test 2: Patient Connection of an F-Type Applied Part—Result: Pass

For the second test, Excelsys used the following power supply settings: Vin = 264Vrms (maximum rated input voltage), Frequency = 63Hz (maximum rated input frequency)

The test method was to follow the instructions shown in Figure 3 (based on IEC 60601 Fig 16.)

Excelsys measured the following parameters shown in Table 5:

<table>
<thead>
<tr>
<th>Measuring Circuit</th>
<th>Test Condition</th>
<th>XS1000-48N-000 (µA)</th>
<th></th>
<th>XS1000-48N-004 (µA)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Vo -</td>
<td>Vo +</td>
<td>Vo -</td>
</tr>
<tr>
<td>Figure 16</td>
<td>NC (No Fault)</td>
<td>548.0</td>
<td>547.0</td>
<td>534.0</td>
</tr>
<tr>
<td>Figure 16</td>
<td>SFC S7 Open (Earth)</td>
<td>270.0</td>
<td>269.0</td>
<td>166.0</td>
</tr>
<tr>
<td>Figure 16</td>
<td>SFC S1 Open (Neutral)</td>
<td>545.0</td>
<td>548.0</td>
<td>549.0</td>
</tr>
<tr>
<td></td>
<td>S5 Closed Reversed Input Polarity:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Figure 15</td>
<td>NC (No Fault)</td>
<td>568.0</td>
<td>570.0</td>
<td>585.0</td>
</tr>
<tr>
<td>Figure 15</td>
<td>SFC S7 Open (Earth)</td>
<td>287.0</td>
<td>285.0</td>
<td>186.0</td>
</tr>
<tr>
<td>Figure 15</td>
<td>SFC S1 Open (Live)</td>
<td>570.0</td>
<td>570.0</td>
<td>585.0</td>
</tr>
</tbody>
</table>

Table 5. Excelsys power supply test against IEC Table 16: Result: Pass.
Summary

Excelsys Technologies’ Xsolo power supplies have been designed and tested to demonstrate that they are suitable for use in products intended for medical applications requiring compliance with either B or BF classification.

Moreover, it is not uncommon for applied products needing type CF performance levels to need additional isolation methods such as additional isolated power converters in the system or the addition of medically rated high isolation transformers in the overall system design. Excelsys makes available low leakage power supply versions, which enable incorporation of multiple power supplies into various medical type rated systems depending on the applications. Excelsys has a global applications team available to support and assist customers with their system applications.

References:

http://www.ele.uri.edu/courses/bme484/iee60601-1ed3.0_parts.pdf

Excelsys Technologies Ltd.
www.excelsys.com