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Advanced Energy

Testing Power Supplies for Medical Electronics Applications

Created by

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Abstract

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 adoption of the 3rd edition of the standard in 2012 and the 4th edition in 2018. Since the power supply is considered a component of a medical device, it is the applied part, meaning the medical electronics end-product must be evaluated for overall performance to meet the standard 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 Advanced Energy's Xsolo power supplies have been designed to meet the requirements of the IEC 60601 standard.

In 2018, IEC 60601-1-2 4th edition was introduced as a collateral standard to IEC 60601-1. IEC 60601-1-2 relates

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to EMC performance for medical equipment and now incorporates risk management requirements.

Testing Power Supplies to the Medical Standard

Advanced Energy's Xsolo series of power supplies is designed for medical applications. Testing the power supplies to the 60601 standard was undertaken using both the basic and low-leakage models, the XS1000-48N-000 and XS1000-48N-004, respectively.

The high efficiency XS1000 power supply delivers up to 1008 W in an enclosed, fan-cooled chassis. Nominal output voltages are 24 V and 48 V with wide adjustment ranges and user defined set-points. Xsolo carries multiple safety certifications including EN60950 2nd Edition for Industrial Applications, EN60601-1 2nd and 3rd Edition for Medical Applications and 4th Edition for EMC. 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.

Power supplies vary widely in terms of quality and reliability. There are design differences, depending on the supplier, and many power supplies are not meant for medical applications.

Testing Results

The Advanced Energy testing procedures were performed in accordance with the IEC 60601 requirements using an AC source providing 264 VAC at 63 Hz, which demonstrates worst-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.The resulting data is shown in Tables 1 and 2 along with the requirements in the specification showing the limits for AC testing.

Figure 1. Advanced Energy's Xsolo power supplies have been designed and tested for medical applications.

Test 1: Patient Connection to Earth — Result: PASS

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

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

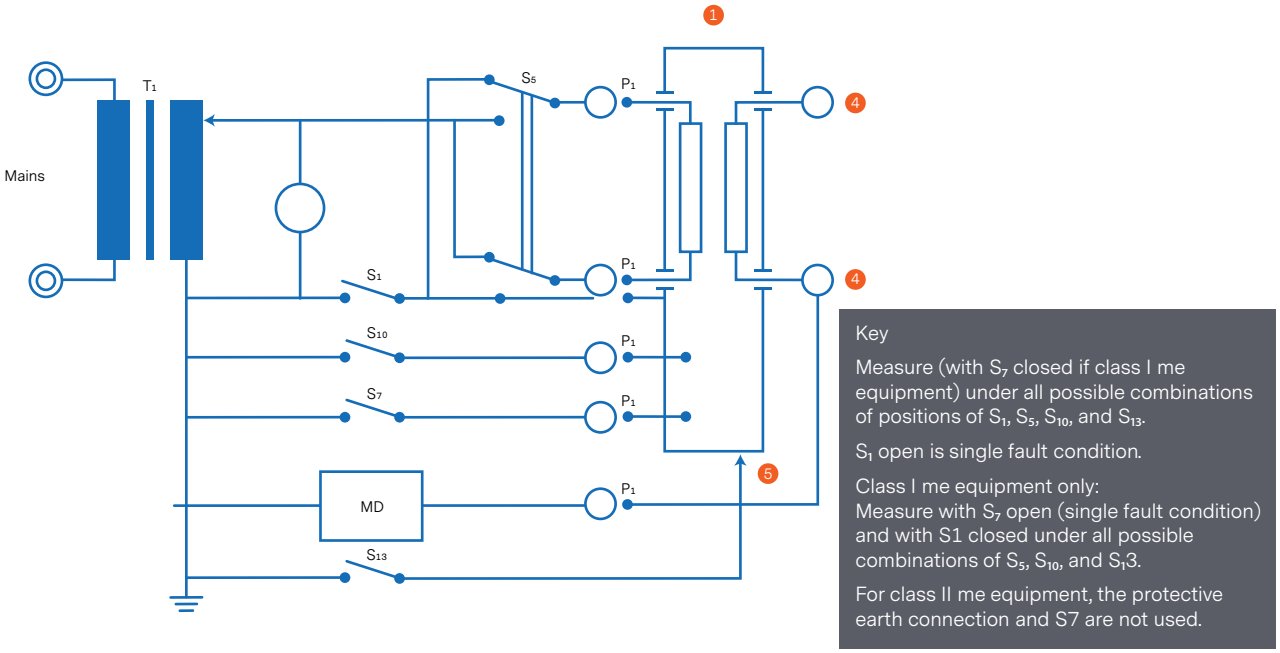


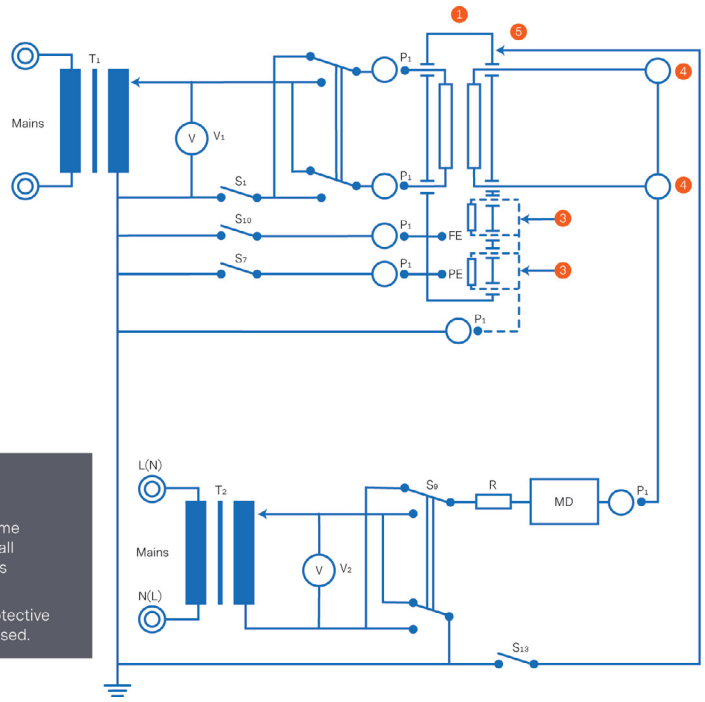
Figure 2. (From IEC 60601 Figure 15). Measure circuit for patient leakage current — from patient connection to earth.

Advanced Energy measured the following parameters shown in Table 1:

Measuring Circuit	Test Condition	XS1000-48N-000 (µA)		XS1000-48N-004 (µA)	
		Vo-	Vo+	Vo-	Vo+
Figure 15	NC (No Fault)	20.1	20.0	21.1	21.2
Figure 15	SFC S7 Open (Earth)	150.0	148.0	96.0	95.0
Figure 15	SFC S1 Open (Neutral)	30.5	30.7	32.6	32.6
S5 Closed Reversed Input Polarity					
Figure 15	NC (No Fault)	19.7	19.7	19.6	19.6
Figure 15	SFC S7 Open (Earth)	153.0	151.0	96.0	95.0
Figure 15	SFC S1 Open (Live)	30.8	31.0	30.4	30.4

Table 1. Advanced Energy power supply test against IEC 60601 Table 15. Result: Pass.

Test 2: Patient Connection of an Applied Part — Result: PASS



For legends, see Table 2.

Key

Measure (with S7 closed if class I me equipment) with S1 closed under all possible combinations of positions of S5, S9, S10, and S13

For class II me equipment, the protective earth connection and S5 are not used.

Figure 3. (From IEC 60601 Figure 16). Measure circuit patient leakage current caused by an external voltage on the patient connection of an applied part.

Advanced Energy measured the following parameters shown in Table 2:

Measured Circuit	Test Condition	XS1000-48N-000 (µA)		XS1000-48N-004 (µA)	
		Vo-	Vo+	Vo-	Vo+
Figure 16	NC (No Fault)	548.0	547.0	534.0	537.0
Figure 16	SFC S7 Open (Earth)	270.0	269.0	166.0	170.0
Figure 16	SFC S1 Open (Neutral)	545.0	548.0	549.0	548.0
S5 Closed Reversed Input Polarity					
Figure 15	NC (No Fault)	568.0	570.0	585.0	588.0
Figure 15	SFC S7 Open (Earth)	287.0	285.0	186.0	186.0
Figure 15	SFC S1 Open (Live)	570.0	570.0	585.0	585.0

Table 2. Advanced Energy power supply test against IEC Table 16: Result: Pass.

Summary

Advanced Energy's Xsolo power supplies have been designed and tested to demonstrate that they are suitable for use in products intended for medical applications. Advanced Energy makes low leakage power supplies, which enables incorporation of multiple power supplies into various medical systems, depending on the application. Advanced Energy has a global applications team available to support and assist customers with their system applications.