Specifying Transformer for Medical Applications

While military requirements for the design of electronic systems are generally considered the most rigorous, standards for medical electronic devices are just as stringent. Because these standards are especially demanding of products that will be used on or by patients, virtually all components of medical electronic products, as well as the end products themselves, must be designed with safety in mind.

The goal of two of the most widely recognized standards for medical electronic devices -- Underwriters Laboratories (UL) 544 and International Electrotechnical Commission (IEC) 601-1 -- is to ensure that all medical electronic products provide a high level of safety for the operator and the patient. In North America, the primary focus of standards-setting agencies is fire safety, while for the European organizations it is prevention of electric shock. The concern of the latter is not surprising, since in many of the countries where IEC 601-1 has been adopted, line voltages range as high as 260 V, double the U.S. and Canadian standard.

Both the UL 544 and IEC 601-1 standards are end-product, not component, specifications. However, they do contain requirements for the transformer as part of the total system. The designer's main job in accommodating these standards is to isolate the transformer.

The Standards

UL544: Medical and Dental Equipment. The two major standards have been widely adopted by countries throughout the world. UL544 is designed to maintain a satisfactory level of performance for all electrical and electronic medical and dental equipment used in homes and by professionals in hospitals, dental offices, and other healthcare facilities. The standard applies to portable equipment rated at 300 V or less and permanently connected equipment rated at 600 V or less.

Most medical equipment, with the exception of x-ray systems, heating pads, and refrigerated medical equipment, is covered by UL544. The standard specifies different requirements for equipment that is used by or connected to patients and for equipment that is not. UL544 specifically addresses the requirements of transformers, and it is the accepted standard in the United States.

IEC 601-1: Medical Electrical Equipment. Part 1: General Requirements for Safety. Most European countries, as well as a growing number of other countries throughout the world, have adopted IEC 601-1. This standard references transformers as directly as UL544 and also concentrates on the characteristics of the end product. IEC 601-1 is as stringent a standard as UL544 and in some areas more so.

An important difference between the two standards is in the physical separation of the primary and secondary windings. UL544 has a minimum thickness requirement for a copper shield between concentric primary and secondary windings (0.005 in.), and IEC 601-1 has a minimum creepage and clearance requirement from primary to secondary. Figure 1 shows how a transformer manufacturer might comply with these creepage and clearance distances on a dual bobbin.

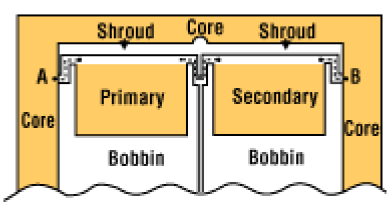

Figure 1. Cross-sectional view of a coil showing the creepage distances between primary and secondary windings And the windings to the core.

IEC 601-1 classifies equipment according to the type of protection it provides against electric shock (Classes I and II are for equipment that uses an external power source and for internally powered equipment), the degree of protection (Types B, BF, and CF), sterilization requirements, environmental protection against water, and mode of operation.

General Guidelines

The overall requirements for transformers used in medical electronic equipment fall into four categories: leakage current, hipot (high potential) requirements, temperature class, and current and thermal fusing. While these are the main considerations, other concerns such as electromagnetic compatibility also affect how a transformer is designed into a system. However, those considerations are addressed in other areas of the standards, and concern the characteristics of the standards, and concern the characteristics of the equipment itself, not the transformer.

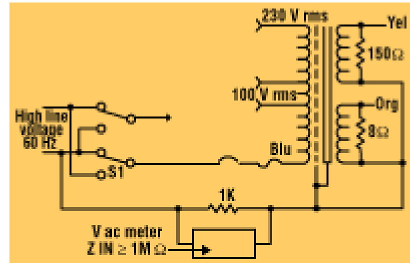

Figure 2. Leakage current test setup.

Leakage Current. Leakage current is mainly due to the capacitance from the primary to ground or secondary circuits. Regardless of the standard, the lower the leakage value, the better. The standards state a maximum acceptable leakage current for the equipment, with a typical requirement being 100 µA. If the equipment, minus the transformer, introduces 50 µA that can be attributed to the transformer. A level of 10 µA is achievable and is often the stated specification in commercially available transformers. A leakage current test system is shown in Figure 2.

The Hipot Test. Both UL544 and IEC 601-1 require the transformer to pass a hipot test. The hipot test generally will be conducted after the transformer has been subjected to an "abnormal" test, in which it has one secondary shorted out and one operating normally at full load, or some other combination of unfavorable operating conditions.

The purpose of the hipot test is to evaluate the quantity, quality, and integrity of the insulation system after subjecting the transformer to the abnormal test. The hipot test requirements of the two standards differ; a typical test voltage for UL544 is 1500 V for a 230-V primary, whereas a typical test voltage for IEC 601-1 is 4000 V for the same primary voltage. However, if patient leads are involved, the UL requirement for input to output is 2500 V.

The test also seeks to determine what will happen to the transformer when a combination of secondaries are shorted out. It will either heat up to a certain temperature and catch fire, or, if there is an internal thermal fuse present, it can cease to function when a critical temperature is reached. If the transformer does not perform acceptably, and it either catches fire or surpasses preset temperature limits, it and the equipment in which it is housed will fail the test. Table I lists the temperature rise limits for different classes of insulation.

Temperature Classes. There are several types of insulation system temperature ratings for transformers. A higher temperature rating is usually desired, because the higher the temperature rating of the insulation system, the less likely it is to be damaged during an abnormal test. The higher temperature rating also increases the chance of passing the subsequent hipot test.

Fusing Requirements. The two types of fuses used in electronic equipment are overcurrent and thermal. Overcurrent fusing is a mandatory requirement on every medical electronic product, but the need for thermal fusing is usually determined by a specific agency standard.

Units with primary overcurrent fuses are tested by removing the primary fuse and performing an overload test on each secondary winding. The secondary wining is loaded so that the primary current, with other secondaries loaded normally, is significantly greater than the rated value of the primary fuse. This condition is maintained, usually for 30 minutes, during which time the winding temperature must not exceed a specified limit.

Overcurrent fuses, which are external to the transformer, are placed in series with the primary and secondary windings. The primary fuse is designed to protect against a short circuit in the transformer. It must be of a value high enough to accommodate in-rush current, which can be very high. As an alternative, slow-blow fuses can be used.

The rated current value for the primary overcurrent fuse is generally 1.25 to 1.5 times the maximum full-load current and the secondary overcurrent fuse is usually 2.5 times the full-load current.

It is important to recognize that attempting to predict the steady-state root-mean-square (rms) current present on the primary based on its turns ratio will probably yield incorrect results. This value can be determined by placing a true rms ammeter in series with the primary and measuring worst-case current under low-line and high-line conditions. If the product is rated for 50- or 60- Hz operation, the test should be performed at 50 Hz, at which the transformer's losses will be greatest.

Thermal Fusing. While the overcurrent fuse is standard on every piece of electrical and electronic equipment, a thermal breaker type of fuse also provides options for designers. A transformer can pass UL544 and IEC 601-1 tests without the inclusion of thermal breakers, but they provide an added measure of assurance when complying with standards test requirements because they are tamper proof and will effectively cut off the voltage.

The thermal breaker (also called a thermal cutout) is used in addition to a primary overcurrent fuse. Thermal breakers interrupt current flow and create an open circuit if the transformer gets too hot, which effectively shuts the system down. They also ensure that if a fuse of too great a value is placed in an external fuse holder, the transformer will shut the system down when its critical temperature is reached.

Thermal breakers are available in non-resetting and self-resetting types. Unlike overcurrent fuses, they are located within the transformer (usually under, over, or between primaries) and cannot easily be replaced. The non-resetting type requires the transformer to be replaced for equipment operation to resume, and the self-resetting type restores current flow when the temperature drops to an acceptable level.

While the self-resetting type may seem convenient, if technicians or consumers probe inside the enclosure to see what is wrong, they run the risk of electrical shock if current is suddenly restored as the temperature of the transformer drops to an acceptable level.

Conclusion

The requirements of medical electronic systems are unlike those of any other application, including military, avionics, consumer, or commercial. The detailed requirements of UL544 and IEC 601-1 make it absolutely essential that isolation of the main transformer be carefully conducted. There are various ways of meeting the transformer-related requirements presented in the standards, and working with the transformer manufacturer is recommended. Specifically, designers should provide the transformer manufacturer with the following information: power requirements (input and output voltages, frequency ranges, current rating, total power in VA or W, dielectric strength, and any special requirements), physical constraints, detailed information about the end product or system, likely operating environments (domestic or international, climate, pollution, and facility conditions), and specific safety agency standards that must be met.

Armed with this information, designers can conduct transformer selection and isolation with a high level of accuracy, which will ensure that the end product meets every required standard and provides an exceptional level of safety and performance.

Table 1.
Temperature rise limits for various insulation classes.

Type of Protection	°C Maximum		°C Average	
	Class 105 or A Insulation	Class 130 or B Insulation	Class 105 or A Insulation	Class 130 or B Insulation
Impedance	135	160	---	---
Thermal Cut-Out Automatic Reset				
1. During first hour of operation	175	200	---	---
2. After first hour of operation	150	175	125	150
Manual Reset				
1. During first hour of operation, or during the first 10 cycles of operation mentioned in paragraph 34.17, whichever is the shorter interval.	175	200	---	---
2. After first hour of operation, if the first 10 cycles of operation mentioned in paragraph 34.17 require more than 1 hour for completion.	150	175	---	---
Fusible and Nonresettable Device				
1. Before opening during first hour of operation	175	200	---	---
2. Opening after first hour of operation.	150	200	---	---