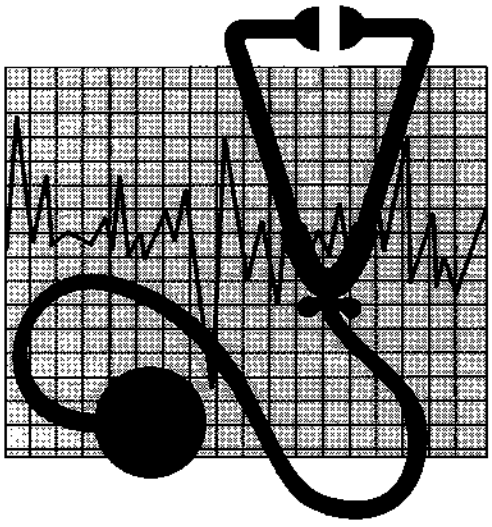

Safe Healthcare Requires Healthy Power

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Healthcare is a subject of substantial discussion. Much of the recent debate has concerned the causes of rising costs for fees and services, and there has been additional concern about the impact of forcing costs to lower levels. Can healthcare services be rendered inexpensively and yet remain safe and of high quality? The healthcare business, like many others today, depends heavily on sophisticated electronic technology to improve the timely, efficient and cost-effective delivery of services. Electrical power is a key consideration in the interface between technology and patient. It must be safe, and it must be high quality. Consider how these two issues, *safe power* and *quality power*, affect modern healthcare, its reliability and its cost.

Safety regulations control the use of electrical power in any application. In addition to normal codes and requirements, the medical industry must observe special patient safety standards. Among these are regulations relating to the presence of leakage currents. UL defines these as; "any current including capacitively coupled currents which may be conveyed from accessible parts of an appliance to ground or other accessible parts of the appliance and which is not intended to be applied to a patient."[1] The applicable UL standard is UL544. It is to be replaced by the year 2005 with UL 2601-1 and it has counterparts throughout the world. In Europe, the standard is known as IEC601.1. Canada, which has used CSA22.2 125, is introducing CSA22.2 601.1. In the United States, the FDA is requiring compliance by instrumentation manufacturers with IEC601.1 equivalent standards.

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All these standards address the limitation of leakage currents in "patient vicinity" and "patient connected" applications. Researchers have studied the physiological effects of electrical currents on the human body. Early studies by electric utilities and later by O.Z. Roy, J.R. Scott, and G.C. Park[2] have helped establish the amount of electrical current needed to cause discomfort, pain or injury. The generally accepted threshold of perception is 500µA. Currents between 10 and 100mA cause pain, fatigue and possible physical injury. Above 100mA, there is a danger of paralysis of the respiratory system, and fibrillation of the ventricular muscle may occur.

UL544, IEC601.1 and their counterparts all specify allowable levels of leakage current, although the regulations may vary in their details. For example, UL544 allows 300µA of leakage current in patient connected applications but 500µA in patient vicinity applications. IEC601.1 limits patient connected leakage currents to 500µA but permits patient vicinity leakage currents of as high as 1000µA. Whatever the limits, these criteria are designed to make sure patients are not endangered by electrical leakage currents. This is an important safety standard to many manufacturers of medical imag-

ing, patient monitoring or other electronic systems located and operated in the vicinity of a patient. In many applications, leakage current requirements are met through the use of an isolation transformer. Power quality is often not even considered in these same applications. This is a serious mistake since patient safety is also affected by power quality issues.

It is noteworthy that there are no clear regulatory guidelines affecting the "qualitative" character of power. Because power quality problems disrupt the reliable performance of electronic systems often used in providing healthcare services, they can have a significant impact on patient safety. Normal-mode disturbances destroy or degrade electronic components. Common-mode disturbances cause lockups, data loss and system reboots. Power outages disrupt or delay the completion of vital clinical procedures.

Poor quality electrical power prevents medical electronics from performing as they were designed. When this happens, a performance issue becomes a safety issue. How safe is laboratory data when it's not reliable? If common-mode noise halts a computer system used in conducting an invasive patient procedure, is the patient's safety at risk? If spikes and line noise degrade the performance of clinical diagnostic equipment, is the patient's care compromised by not receiving rapid diagnosis and treatment? And there are economic factors to be considered.

Technology has produced quantum advances in medical diagnostics. Tests which once took days are now completed in hours. While cycle times have decreased, the cost per test can be high. From a financial perspective, the investment in improved technology must be fully amortized, and consistent power quality (i.e., electrical power that is free from noise, impulses, outages, etc.) is an integral part of that process. Instrument downtime results in both lost revenue and extra expense. Lost samples, wasted assays and extra maintenance all add cost to the system.

Too often, the burden of defining and providing quality power is carried by the instrument user. A few manufacturers provide an uninterruptible power system with their system if data is volatile or stored in RAM, but since many UPS systems are quite basic and not really power quality tools, the

The Battle for Standards

Regulatory issues are not unique to either the United States or the European Community. In fact, most countries have developed their own electrical and product safety requirements.

Those companies that have manufactured products for export have become familiar over the years with many of the safety agencies. They include UL in the United States, CSA in Canada, and VDE and TUV have been generally accepted throughout Europe. Other countries have their own individual agencies. These include CEB in Austria, DEK in Denmark, France's UT, Finland's SETI, SEK in Sweden, and a long list of others.

For many global exporters whose products are regulated by safety standards, it has often been difficult to achieve simple and universal safety compatibility when the safety requirements themselves have not been in agreement. It has also been difficult to remain current with standards that have been in a state of constant change.

Much of the drive toward a unified Europe has also included "harmonizing" regulatory standards to improve international commerce. Beginning in 1996, IEC standards will be accepted throughout Europe as an alternative to individual national regulations.

Here in the United States, many manufacturers of products destined for export have begun safety agency testing according to IEC standards as a way of simplifying their business in a variety of countries. Underwriters Laboratories is modifying their standards to be compatible with IEC standards (hence the similarity in new code numbers). This change is slated to become effective by the year 2005. IEC standards employ more rigid methodology and some U.S. manufacturers are experiencing delays in safety agency approvals as a result of the extra time required in learning and interpreting these new safety standards.

While some delays may initially be experienced, the standardization will provide international compatibility, improve marketing efficiency, save on safety agency fees and benefit consumer safety.

system may still be at risk. Other manufacturers leave the decision and selection of power quality products entirely up to the user, facility manager or laboratory manager.

Efficient healthcare is a delicate balance between economics and safety. Cost containment strategies recognize the value of doing more with less, spreading instrumentation costs over more patients and reducing cost per exam by extending the useful life cycle of capital equipment. Power quality is an important tool in the achievement of all three.

Improved uptime means more procedures per hour, increased revenue and less expense. Instrumentation that runs on quality power lasts longer, serving more patients during its useful lifetime at a lower per-patient cost. One hospital laboratory calculated its investment in properly specified and installed power conditioning equipment could be paid for in just forty minutes of uptime, an amount it exceeded after only two months. Electronic systems performing faster, more reliably and with greater accuracy improve the quality of medical care. That is an important contribution to patient safety; perhaps as important as meeting regulatory leakage current requirements.

Power quality has an important role in healthcare in the United States. It is equally important in third-world countries and in the emerging Eastern European nations where the electrical distribution system is neither reliable nor high quality. Both here and abroad, power quality is an integral part of quality healthcare. It contributes significantly to the safe, effective, efficient and inexpensive delivery of healthcare services to people worldwide.

References

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2. O.Z Roy, J.R. Scott, G.C. Park, "Ventricular Fibrillation and Pump Failure Thresholds Versus Electrode Area," IEEE Transactions in Biomedical Engineering, 1976, 23, 45-48