Stricter Medical Equipment Certification Standards Improve Protection for Medical Patients and Facilities

— But Call for More Accountability from Equipment Manufacturers —

This paper from Planar Systems, Inc., discusses important new developments in electronic medical equipment certification and its implications for manufacturers and medical customers alike.

Increased concern for patient well-being is resulting in more technical certification standards for electronic medical systems than ever before. Agencies such as the U.S. Food & Drug Administration (FDA) and European Union Medical Device Directive (MDD) have enacted stricter regulations to govern product attributes from the electrical to the ergonomic and beyond.

Driving these tougher standards are advances in the technology itself. Just a few years ago, there was little electronic equipment located near a patient. Today, the patient's bedside bristles with a variety of systems, many of them electromagnetic and generating radiation, others wireless and creating a web of emissions. Systems for monitoring a patient's vital functions, terminals for entering patient data and systems for generating charts — plus an array of portable monitoring, scanning and x-ray equipment — all contribute.

Then there's the issue of electromagnetic immunity. In this sense, immunity is defined by the FDA as "the ability of an electrical or electronic product to operate as intended without performance degradation in the presence of an electromagnetic disturbance." In Europe, the greatly increasing amount of electromagnetic activity in medical equipment has led to issuing a strict new standard – EN 60601-1-2, 2nd Edition – that dramatically increases the level of protection in medical facilities. The standard requires manufacturers to perform extensive analysis to assure that equipment or systems have adequate immunity to electromagnetic disturbances. The new standard has a global reach because its criteria are being adopted in the U.S. as part of new Underwriters Laboratories (UL) standards.

In most cases, electromagnetic interference (EMI) is a minor concern, but EMI can have tragic consequences, too. Clearly documented cases of EMI-related fatalities exist, such as the 1992 death of a patient attached to an ambulance's monitor-defibrillator that stopped working because of interference from the ambulance's radio.[1] In 1992, a patient fitted with a pacemaker went into ventricular fibrillation shortly after being scanned with a metal detector at the entrance to a courtroom. In one of the worst cases, two patients died in 1987 when EMI caused their patient monitoring systems to fail to sound alarms.[2] The U.S. Food & Drug Administration (FDA) reports that there more than 100 reports of EMI-related incidents between 1979 and 1993 affecting a wide range of electronic medical equipment and caused by devices as ubiquitous as electrosurgery, fluorescent lights and radio transmitters[2].

And as part of the growing move to harmonize more standards worldwide, a new U.S. safety standard for medical equipment, UL 2601-1, will become effective January 1, 2003. It is based on Europe's IEC 60601-1 and presents manufacturers with a more complex set of requirements in the areas of product design and documentation.

Protecting the Patient

The basic intent of certification standards – such as the CE mark throughout Europe and the UL mark in the U.S. – is to protect patients against electrical shock hazards, plus to ensure that medical systems satisfy requirements for cleanability, tip/fall avoidance and fire prevention, among others. Additional Electromagnetic Compliance (EMC) standards address the interference problems discussed above, while ergonomic standards set guidelines ranging from ease of use to safety details, such as rounded corners on certain equipment.

Newer standards also address the fact that patients are not the only people subjected to the invisible emissions. Healthcare personnel are experiencing long-term exposure over the course of their careers, such as 20 or 30 years of sustained low-grade radiation that now is subject to regulation.

As a result of new and expanded standards, medical equipment manufacturers face tougher hurdles for certification compliance. Concern has prompted involvement from groups such as the insurance industry and hospital administrators, as examples, in addition to the FDA and MDD. From a global perspective, Europe promulgates the strictest certification standards, taking over that distinction from the FDA in recent years. In addition to stricter rules, Europe also presents the challenge of no single licensing body. European certification compliance is diffused and multi-layered. Key to the standards effort, however, are agencies such as the Geneva-based International Electrotechnical Commission (IEC), International Special Committee on Radio Interference (French acronym CISPR) and the European Committee for Electrotechnical Standards (CENELEC).

And just as certification has become tougher for medical equipment manufacturers, so have penalties for non-compliance. Depending on the type of "incident" resulting from non-certified equipment, penalties for manufacturers can range from a case of bad PR to the financial disasters of banned products and business closure, and even serious legal and financial consequences for senior executives. Of course the very nature of the problems that can occur due to using sub-standard or noncompliant equipment can raise liability issues for medical facilities as well.

Importance of Component Certification

With all of these factors coming into play, equipment manufacturers must ensure that their own medical systems meet all applicable standards, and that any subsystems or components are similarly compliant.

Certified systems – and certified components inside them – not only protect the patient, but also can contribute to the performance, reliability and usability of almost any electronic system in the patient environment. In effect, certification provides quality assurance that makes components and subsystems easier to integrate, with predictable results. And unlike generic components that ship with the disclaimer "Specifications may be changed without notice," certified components carry the assurance of notification about changes that might affect future products.

The only way to ensure that electronic medical systems are safe, reliable, rugged, tamper-proof, and easy to use is to implement clear and consistent guidelines for all systems, plus their subsystems and components.

There is no denying that the certification process can add cost. It means building the component to higher standards and requires ongoing administrative support, including failure analysis,

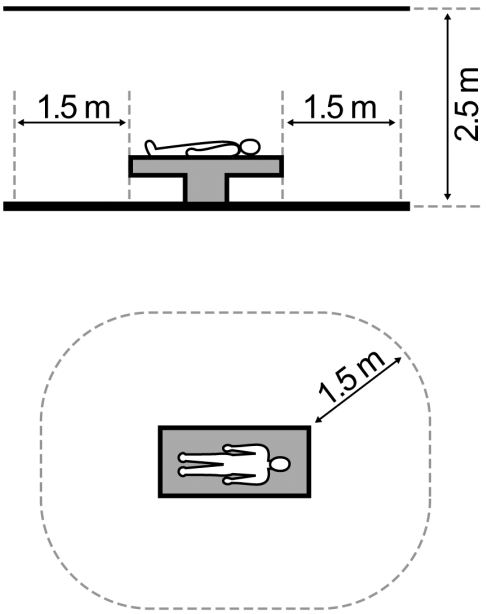
corrective action, recall notification, configuration control and thorough records maintenance. On the other hand, medical system manufacturers have learned that certified components can broaden use of equipment. For example, a piece of equipment manufactured to stricter certification standards can be used anywhere in a medical facility, whereas a equipment meeting only basic standard may be suitable only for clerical or industrial environments and therefore is a less flexible asset for the medical facility. Furthermore, with their designed-in reliability, certified components from service-oriented suppliers such as Planar Systems, Inc., can deliver an overall lower cost of ownership than standard products.

Planar, for example, helps its customers in performing risk analysis by designing products to the new EN 60601-1-2, 2nd Edition Standard with compliance to the more stringent emission levels cited in CISPR 11, the International Special Committee on Radio Interference's standard for industrial, scientific and medical equipment. By meeting the requirements of CISPR 11, suppliers such as Planar achieve a higher level of EMC with its products, qualifying them for an expanded range of operating environments.

Increasing Standards for Increasing Technology

What aspects of medical electrical systems are affected by certification requirements? The answer is, almost everything.

There are two general categories: One, non-critical patient data systems, such as those used for ordering meals or viewing test results; and Two, critical patient care systems, such as anesthesia and cardiac monitors for life support and monitoring vital functions.



This illustration shows the dimensions of the globally accepted "patient environment," within which electrical medical equipment is subject to a growing number of standards.

Proximity to the patient plays a key role in determining which medical systems must be certified and to what level. A frequently cited definition of the patient environment – or patient "envelope" – is a distance of 1.5 meters surrounding the patient's bed, extending 2.5 meters above and 1.5 meters below the patient. Patients are considered electrically sensitive because they often have wounds or incisions that breach the skin's integrity. Moreover, catheters and tubes can under some circumstances conduct current into the patient's body. Therefore any electronic system within the patient's reach must have some degree of protection from electrical hazards.

Any discussion of standards becomes more complex when considering the various regional and regulatory entities that can impact the certification process. But fundamentally, there are six areas of concern common to all of the standards, regardless of their regional origin or enforcing authority:

- Leakage current through ground, the enclosure, and to the patient
- Dielectric withstand (resistance to insulation breakdown)
- Voltages present and accessible by the user or patient
- Current consumption, and power consumption and dissipation
- Liquid ingress (during spillage events and cleaning)
- Electromagnetic interference (EMI), to and from other equipment in the patient vicinity

These are not arbitrary measures. Rather, they present a framework that shows concern for patient and caregiver safety. In turn, these areas are the subjects of a growing list of nomenclated standards.

European Union Medical Device Directive (93/42/EEC)

Medical equipment manufacturers who expect to do business in European Union countries must meet MDD standards. Fundamentally, these provide "conformity routes," articles and annexes defining the qualification process for the required CE mark on medical equipment. Like other standards, there are equipment classifications that pertain to risk and patient proximity.

MDD Technical File

MDD requires construction and maintenance of a Technical File on each product. This is particularly important in the event of an "incident," where MDD requires the manufacturer to submit a Technical File within seven to ten days for review by the surveillance authority. A Technical File includes:

- Description of the product
- Design and production drawings and diagrams
- Detailed technical data for essential aspects of the product
- Risk assessment
- List of standards or solutions applied
- Calculations and tests that have been performed
- Certificates and inspection reports
- Internal safeguards, such as configuration control
- User's manual
- Declaration of Conformity

Failure to comply with MDD's requirement for a Technical File can result in restricting or prohibiting placing the product on the market, or in withdrawing the product from the market altogether.

EN 60601-1

The International Electrotechnical Commission (IEC) sponsors some of the most stringent and comprehensive codes. EN 60601-1 is the basis of most national and European Standards for Electrical Medical Devices, as well as serving as the basis of the U.S. UL 2601-1 standard and the Canadian C22.2 No 601.1 standard.

The EN 60601-1 set is divided into three areas:

- The basic EN 60601-1 standard, which is the general requirement for all electrical medical-based products;
- Collateral standards, covering issues such as combining electromagnetic compliance, radiation protection and programmable medical systems (such as software and firmware) into a system; and,
- Particular standards dealing with specific types of medical equipment.

EN 60601-1 overall applies to equipment used under medical supervision and which makes contact with the patient.

EN 60601-1-2, 2nd Edition

Of intense interest to the medical equipment manufacturer is another layer of collateral standards: EN 60601-1-2. These call out details for specific types of equipment such as defibrillators, anesthetic machines, and similar systems. This layer has significant effect on MDD's compliance specifications, especially in the area of electromagnetic emissions.

The effects of EN 60601-1-2 are far-reaching. There are new requirements and tests for magnetic fields, voltage dips and dropouts, harmonics and flicker, as well as stricter requirements for ESD. The standard's new pass/fail immunity criteria no longer allow component failure, default reset, false alarms or many other incidents previously allowed during testing. The U.S. FDA today recognizes EN 60601-1 and EN 60601-1-2.

UL 1950 and UL 544

The Underwriters' Laboratory UL 1950 standard is a widely accepted safety standard for household electrical equipment but is not considered adequate for the patient environment. For example, UL 1950 does not require a hospital-grade electrical plug, nor does it specify liquid ingress protection. UL 1950 makes a good reference point for comparison of conventional safety standards versus those applied to medical equipment.

UL 544 is a standard devised for hospital equipment and is being phased out. Underwriters' Laboratory will close the books on UL 544 by 2003, when UL 2601-1 will supplant the standard.

UL 2601-1

UL 2601-1 is the prevailing North American standard. It defines safety and testing guidelines for medical electrical equipment, based on input from regulatory agencies like the FDA and the National Fire Protection Agency (NFPA). It also incorporates contributions from cities such as New York and Los Angeles, which have safety entities within their own local governments.

Resulting from the push for harmonized worldwide standards, UL 2601-1 is considered equivalent to, and works in conjunction with, Europe's IEC 60601-1 and most of its collateral requirements.

Some of the important factors facing manufacturers in UL 2601-1 are:

- Requiring manufacturers to replace text-based product markings with universally understood symbols, especially in the areas of shock hazards, volume control, radiation levels and other warnings.
- Stricter regulations on product user manuals, transport and storage instructions, parts lists, and installation procedures.
- Using proper safety factors in design calculations for suspended masses or patient supports, such as x-ray machines or dental chairs, as examples.
- Redefining safety factors addressing contact with the human body and ensuring documentation compliance with ISO requirements.

By producing equipment and systems compliant with UL 2601-1 medical equipment manufacturers can gain access to all countries that have adopted IEC 60601-1 as the national standard.

NFPA 70, NFPA 99, and NFPA 101

The National Fire Protection Association (NFPA) is the primary fire and safety agency recognized by the U.S. government. Its NFPA 70 (National Electrical Code), NFPA 99 (Standard for Health Care facilities), and NFPA 101 (Life Safety Code®) standards are required for medical facilities participating in federal programs such as Medicare. NFPA standards played a substantial role in defining UL2601, so the two sets of standards share many particulars.

Growing Emphasis on EMI/EMC

Through its Center for Device & Radiological Heath section, the FDA is promulgating regulations for a prime area of newer concern, electromagnetic interference. EMI is common to many non-medical devices, but there are special implications for EMI in the medical environment:

- Failure of medical equipment due to EMI can lead to injury or death.
- Some medical equipment is designed intentionally to emit electromagnetic energy, often for therapy.
- Some medical equipment is designed to detect very small electromagnetic signals — such as for physiological diagnosis — and could be located near other electromagnetic-emitting equipment, potentially resulting in EMI.
- Many types of medical equipment are connected directly to patients, which means the manufacturer must prevent electrical shock as well as EMI.

Electromagnetic compliance (EMC) means the equipment is compatible with its electromagnetic environment and not cause interference with other equipment in the vicinity. The wide variation of medical equipment and environments creates vulnerability to interference from conducted, radiated or electrostatic discharge. EMI problems are technically complex, and the immunity level of most medical equipment in use today is unknown. And, it simply is not feasible to perform extensive susceptibility testing on all existing equipment.

On another front, wireless medical telemetry is now seeing widespread use. The wireless link is susceptible to EMI and other intentional or unintentional transmitters, which can result is disruption of other nearby wireless medical equipment. For example, mobile phones are a matter of increasing discussion in the medical environment.

The solution for these situations as backed by the FDA and MDD is enforcing compliance with EMC standards such as EN 60601-1-2 that address immunity and emissions. With the enactment of the EN 60601-1-2 standard, responsibility is shared between manufacturers and medical personnel to ensure that equipment and systems are designed and operate as intended. The manufacturer must meet the applicable standards requirements, with disclosure to the customer of any information needed to maintain a compatible electromagnetic environment:

Medical equipment manufacturers should design equipment to meet appropriate levels of emissions and immunity.
Hospital administrators, planners and architects should keep sources and potential victims of EMI apart.
Users should be aware of the threat of EMI and should report serious incidents.[3]

Global Trends and Regional Standards

There is no single, worldwide standard pertaining to electronic medical equipment. In general, the more rigorous safety standards exert the most influence on emerging standards and specifications, and on the design of new medical equipment.

Like other markets, the medical equipment field is becoming more global, and no manufacturer wants to be left out of fast-growing markets in Europe or Asia simply because a small safety feature was omitted. Although designing to the tougher European codes might be regarded as over-engineering for other markets, it has the benefits of yielding a product that is marketable anywhere and is fundamentally safer and more reliable.

However, harmonized standards are not the same as a single, universal standard. Harmonized standards will have a common core and common terminology, presumably based on EU directives. But cities, states, provinces and nations will create their own local requirements beyond the global standards. To market a defibrillator in New York City, for example, it may be necessary to comply with guidelines very different from those enforced in Singapore. Consequently, it is essential to research local requirements –or to work with component vendors who have already done so.

Certification Compliance Has Realistic Benefits

To paraphrase an old adage, the certified whole is the sum of its certified parts. The components manufacturers select for their new products — whether a cardiac monitor or an X-ray system — can determine the ease with which the finished product achieves certification. Selecting pre-

certified components from a proven vendor can reduce significantly your time-to-market for the manufacturer and can greatly expand the number of medical environments in which the equipment can operate.

Configuration management also can have a major impact on any certified product. It means that any changes to a product after its initial certification can push it out of compliance. If a display supplier — in a quest to reduce production costs, for example — changes a connector or a resistor value in the original design, the display may no longer be certified and could, should an incident develop, lead the manufacturer and medical facility to unwanted consequences.

Manufacturing certified equipment is not a "low-bid" business, and the conscientious supplier will not make changes just to save a few cents on every unit. The supplier also will have a tightly controlled process for managing necessary configuration changes and notifying its user base, especially in regard to "form, fit, and function" changes, such as EMI signatures.

In today's intensely competitive medical equipment market, time-to-market is more critical than ever before. Many manufacturers find it more effective in terms of medical customer purchasing requirements to design-in a certified component with proven specifications instead of qualifying a generic component to the same level.

Not surprisingly, certified components, such as displays, prove beneficial even when full certification is not absolutely required. Many products are enhanced by the durability, improved display viewing quality, and EMI integrity of the medically certified display. A monitor display on a system in the hospital cafeteria, for example, can be susceptible to the same impacts and cleaning procedures as the one at the patient's bedside. Because the certified display meets more stringent ruggedness standards, it better resists the hardships of frequent handling and cleaning.

In the case of Planar Systems, a host of products are designed to the strictest certification standards so that OEMs and other end-product integrators are assured of long-term compliance as well as product quality.

Aside from the obvious durability benefit – that the unit will work when you need it – there is also the issue of cost of ownership. The more resilient, certified device tends to have less downtime, which translates to lower maintenance costs and less need for expensive redundant systems.

Service-oriented Suppliers Key to Certification Success

Medical equipment manufacturers can choose among many sources when selecting a medically certified component, such as a display. Once the field has been narrowed to a few models with appropriate technical credentials, the final choice usually is driven by the service levels available from the supplier.

Some system builders prefer to assemble products from certified components and pursue system-level certification on their own. This is an effective approach if the system builder commits appropriate resources to standards research and administration. However, it requires a costly infrastructure and can leave the system builder's product vulnerable to unannounced configuration changes from its suppliers.

Today, most equipment manufacturers seek out suppliers with proven history and expertise in the certification field. System builders have learned to ask the hard questions about past performance, certification infrastructure, configuration management, global support, and quality control.

Planar Systems, as an example, certifies products to appropriate standards, such as CE mark, UL 2601 standards, and Canadian standards and all applicable compatibility requirements. With suppliers such as Planar, medical equipment manufacturers and medical customers are assured that components will be compliant anywhere in the world.

[1] UK EMC Journal, vol. 15, p.8, February 1998.

[2] Compliance Engineering, vol. 10, p. 25, 1993.

[3] York EMC Services, EMC of Medical Equipment, p.2, 2002