



Evolving Standards Reshape Medical Power Supplies

New medical equipment standards will improve safety and facilitate the process of international compliance.

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The design of medical-grade power supplies or the integration of such supplies into medical equipment has long posed unique challenges to engineers and system designers. The performance of power supplies in such applications can be potentially life saving. With the burgeoning market for medical apparatuses, designers have become more familiar with the particular compliance standards required. However, advances in technology have led to changes in standards that will continue to significantly affect the power-supply designer and system integrator.

New standards are being proposed that would change the medical-device approval process, literally turning the current method upside down. These new standards would change the method of approving medical equipment from simple parameter testing to an involved collaboration of risk declaration and the methods applied to identify and minimize those risks.

Current Standards

Today, global compliance for medical power supplies is based on IEC 60601 “Medical Electrical Equipment, Part 1: General Requirements for Safety.” Most of the medical power-supply compliance standards are based on this, including UL 60601-1, EN 60601-1, JIS T 0601-1 and CSA C22.2 No. 606.1 (Table 1).

The IEC standard has helped define and ensure that the components and systems designed for medical equipment are safe. The IEC 60601 document sets the parameters for the design of medical power supplies such as the unit shown in Fig. 1.

This document and another document, the IEC 60950 for information technology equipment (ITE), use a com-

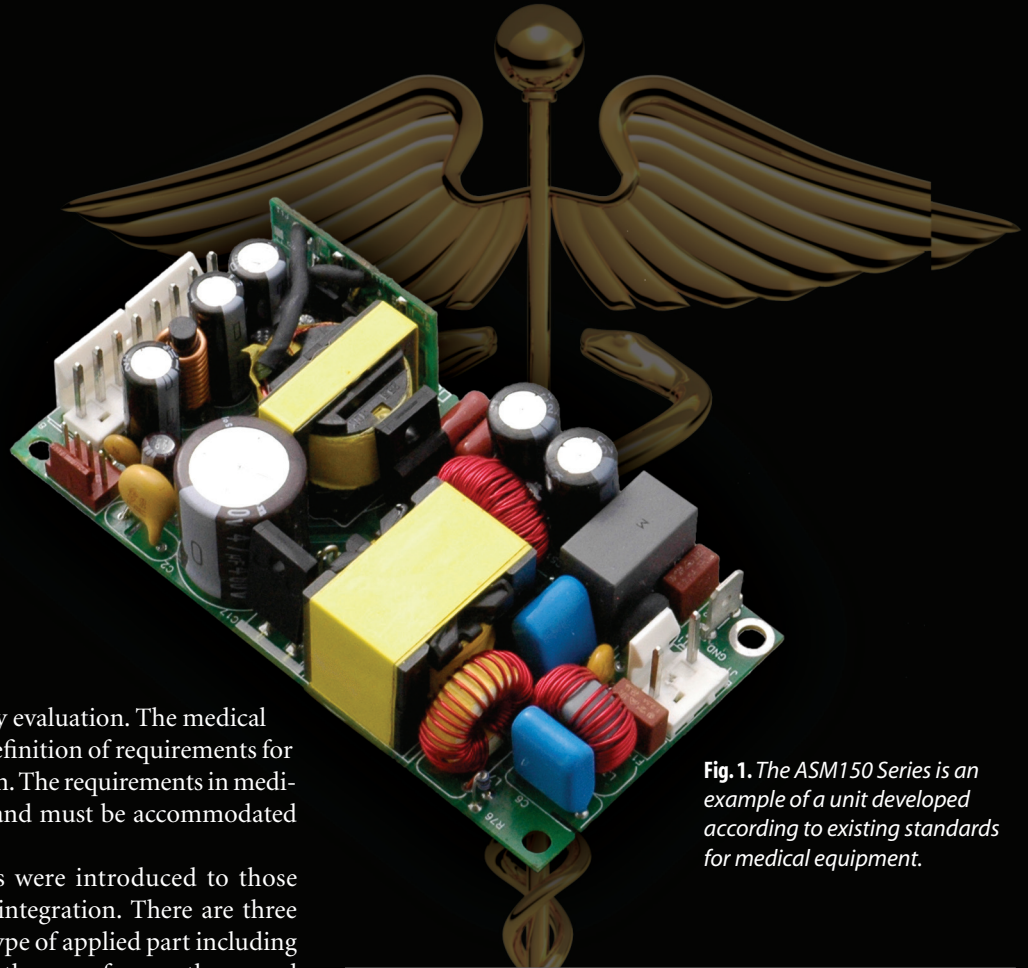


Fig. 1. The ASM150 Series is an example of a unit developed according to existing standards for medical equipment.

mon approach to power-supply evaluation. The medical supply standard includes the definition of requirements for creepage, clearance and isolation. The requirements in medical design are more stringent and must be accommodated in the design.

New terms and definitions were introduced to those familiar with ITE design and integration. There are three classifications defined for the type of applied part including B, BF and CF. Type B allowed the use of an earth-ground connection, while type BF is floating. Type CF is floating and the most stringent, designated for cardiac contact.

IEC 60601 also included other related standards of importance to any medical supply design effort. The standards are classified as collateral and particular, and attempt to address unique aspects of given applications. Collateral standards are designated 60601-1-X, also referred to as horizontal standards because they provide additional considerations outside of the base standard. Particular standards are identified by 60601-2-X, also sometimes referred to as vertical standards because they add detailed requirements for specific medical devices, such as X-ray machines and hospital beds.

Perhaps the most important collateral standard for power-supply design is IEC 60601-1-2 for electromagnetic compatibility. This standard impacts all steps of the development process, from power-supply design to integration and product testing.

Proposed Standards

The third edition of the IEC 60601-1 standard will force a philosophical shift in designing for compliance. The proposed medical standard is a response to the rapidly changing medical device market. The market has taken advantage of technology and material science advances to develop more

Country / Region	Standard adapted from IEC 60601-1
United States	UL 60601-1(U.S. national deviations) (Note: UL 60601-1 was previously numbered UL 2601-1)
Canada	CAN/CSA C22.2 No. 606.1 (Canadian national deviations)
European Union	EN 60601-1 (Identical to IEC 60601-1) (Known as BS EN 60601-1 in the United Kingdom)
Japan	JIS T 0601-1 (Japanese national deviations)
Australia/New Zealand	AS/NZ 3200.1.0 (Australian and New Zealand national deviations)

Table 1. IEC 60601 national standards by country.

sophisticated and complex products. Current medical standards are challenged to keep pace with these changes while maintaining the purpose of their existence: providing safe products for use in the medical industry.

To address current and future technology advances, the proposed standard formally introduces several new concepts to the medical approval process. First and foremost is the inclusion of risk management. A second new and important term is that of “essential performance.” To support these

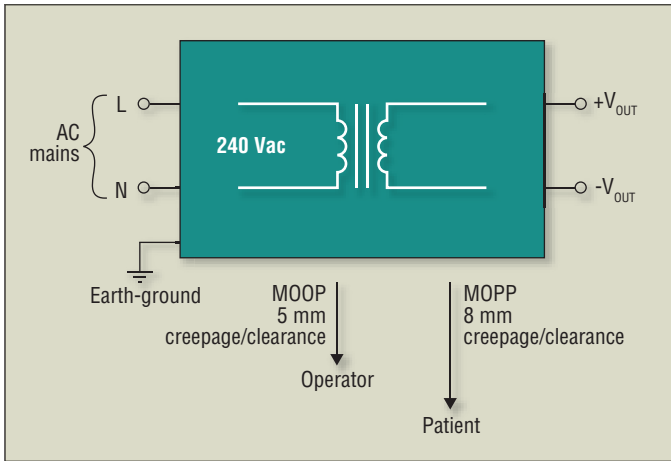


Fig. 2. Two-layer isolation in the third edition IEC 60601 specifications for medical equipment includes provisions for both the operator and the patient.

approaches, new testing and design processes are required. The net result is that the certification process will be less about type tests with defined limits — although these will still be important — and more about the manufacturer identifying potential hazards and documenting how they are addressed.

IEC 60601 Third Edition

The new standard, as mentioned previously, still includes type tests for leakage, isolation and creepage/clearance. The difference is that the determination of the correct category and values is guided by the concept of “essential performance.” Essential performance identifies operating characteristics that can impact the safety of operators or patients. This will tie into the risk analysis performed under the risk-management system employed with the new standard. The purpose is to allow the manufacturer to identify the appropriate levels to ensure safe medical devices. In some cases, this may be a reduction in limit from the current standard, but in many cases it will require additional protection or analysis.

A second concept introduced in the new standard is means of protection (MOP), which describes the isolation protection between the electrically charged circuitry and any equipment that may come in contact with the device (Fig. 2). The isolation protection includes the creepage/clearance distances, insulation and protective earth connections. The means of protection is further separated into two categories: means of operator protection (MOOP) and means of patient protection (MOPP).

As the terms suggest, the classifications provide greater protection for the patient who may be more vulnerable to the medical device in use. MOOP is more closely aligned to the traditional IEC 60950, which is the standard of protection for ITE, while MOPP maintains the more stringent requirements similar to the current IEC 60601 standard (Table 2).

The compliance measures for leakage current have been altered to ensure patient and operator protection in contact

New classifications	Third Edition IEC 60601-1
One MOOP Basic, or one layer of insulation (at 240 Vac)	Test voltage: 1500 Vac, Creepage: 2.5 mm
Two MOOP Double, or two layers of insulation (at 240 Vac)	Test voltage: 3000 Vac, Creepage: 5 mm
One MOPP Basic, or one layer of insulation (at 240 Vac)	Test voltage: 1500 Vac, Creepage: 4 mm
Two MOPP Double, or two layers of insulation (at 240 Vac)	Test voltage: 4000 Vac, Creepage: 8 mm

Table 2. The third edition IEC 60601-1 classifications.

Step 1: Risk analysis
Step 2: Risk evaluation
Step 3: Risk control
Step 4: Overall residual risk
Step 5: Risk-management report
Step 6: Post-production information

Table 3. Risk-management process complying with ISO 14971.

with medical devices. First, the present standard definition of “enclosure leakage current” is now described as “touch current.” Touch currents are the leakage paths from an enclosure that may be in contact with a patient or operator. The levels within the third edition of IEC 60601 are 100 µA for normal operation and 500 µA for a single fault condition, which is the same as the enclosure leakage limits for the current IEC 60601 standards.

In addition to the terminology change, a new leakage test has been added called total patient leakage current. The basis for the total patient leakage current test is to measure the leakage current when all applied parts required for the operation of the medical device are in contact with the patient (Fig. 3). This new test further protects the patient in light of devices that may have multiple connections and leakage paths.

ISO 14971

ISO 14971:2000 “Medical Devices – Application of Risk Management to Medical Devices” was developed in a joint ISO/IEC committee along with the third edition 60601 standards. As such, they are tied closely together in defining the procedure and requirements for the certification of medical devices. Specifically, Clause 4.2 in the third edition standard states: “A risk-management process complying with ISO 14971 shall be performed.” The goal and major shift in this approach, summarized in Table 3, is to guide the development engineer through a process that ensures hazards are identified and mitigated. In this way, the standard can last over time and include current and future advancements in medical technology.

The process begins by analyzing potential hazards the

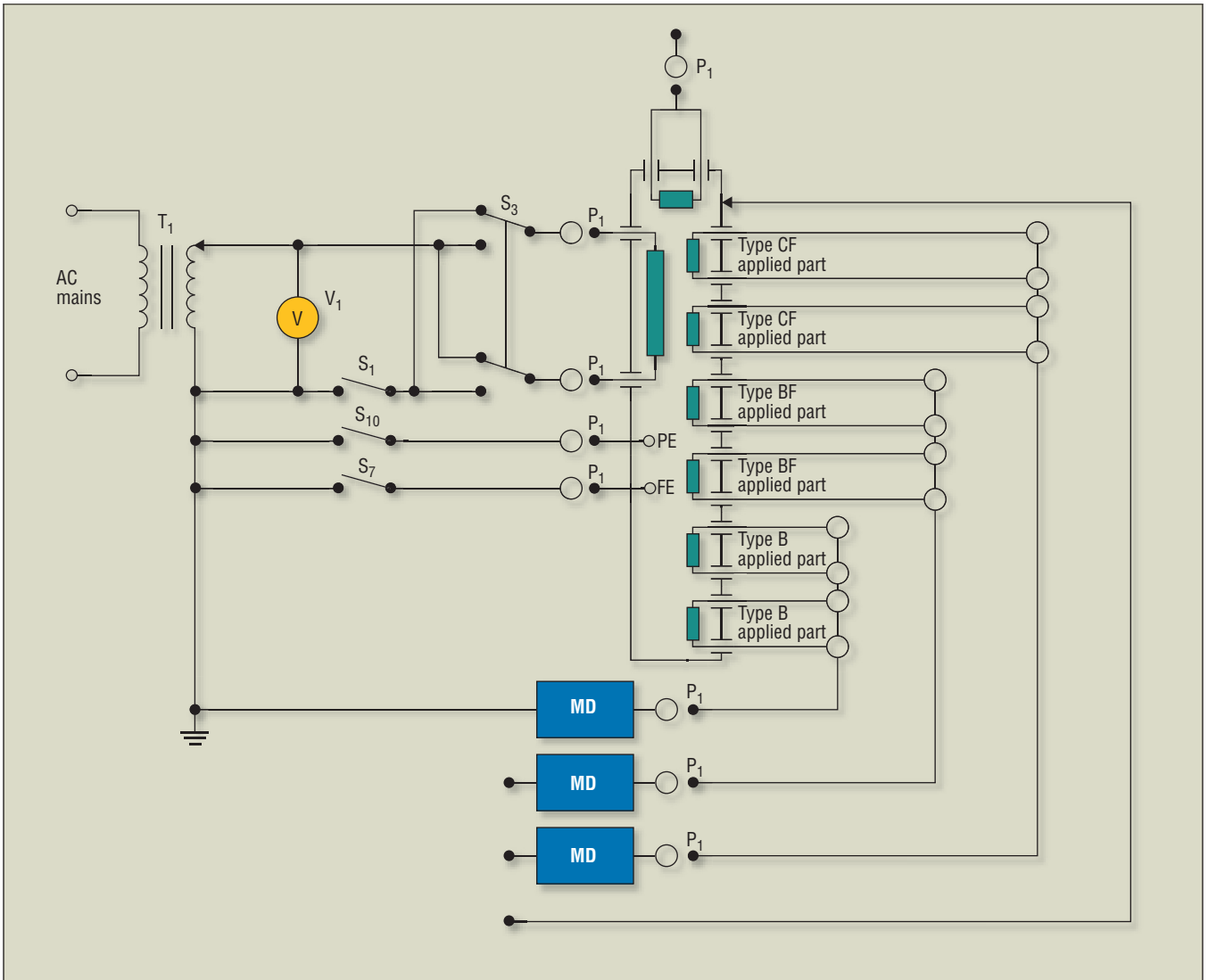


Fig. 3. In this IEC 60601-1 test setup for measuring total patient leakage current, the different types of patient-applied parts are electrically connected within separate groups.^[7]

medical device may cause in its application. It also considers possible misuse and fault conditions to account for all potential dangers. Once presumed risks are identified, an evaluation is made to determine the level of each risk. During the risk-control phase, the manufacturer must consider methods to mitigate or identify the potential hazards. This includes design considerations (design-in safety and/or protection and alarms), system considerations (design-in safety in application) and notification (markings, notes and instructions). Following the risk-control phase, the potential dangers are reevaluated with the identified measures taken. If the residual risk is deemed acceptable, the process continues to the report, which documents the steps taken and considerations made. The concluding step completes the loop by evaluating the medical device data in production.

The importance of ISO 14971 cannot be understated in the application of the third edition IEC 60601-1 standard. The role of risk management is mentioned more than 100 times in the standard. To support device compliance, the

third edition describes a risk-management file, which is the supporting body of work that the risk-management process was applied to the device under evaluation. Documented evidence, including the analysis of hazards, steps taken to mitigate hazards and identification of unavoidable hazards, would be found in the file.

U.S. Adoption

For the United States, there is a more subtle change that would occur with the adoption of the new medical standard. The decision was made that the American Advancement for Medical Instrumentation (AAMI) would publish the standard as opposed to Underwriters Laboratory, who had published the previous editions based on the IEC 60601 medical standards. This is a minor shift, as the prior UL standards were based on the IEC standard and included input from the AAMI ES 1 standard and both AAMI and UL have long histories with the common goal of promoting the development of safe devices for the market.

However, the AAMI has attempted to publish a document more in line with the harmonized standard published by the IEC. The AAMI 60601 standard has reduced the U.S. country deviations to two pages. This is a significant change as the current UL 60601-1 has 32 pages of deviations for the United States. The deviations primarily include requirements outlined by the National Fire Protection Association (NFPA) and the National Electrical Code (NEC). Although it is likely the deviation list may grow slightly to resolve a few outstanding issues, it will maintain its goal of minimizing the differences for global compliance. The standard has been published as American National Standards Institute (ANSI)/AAMI ES 60601-1:2005 and is available through a variety of outlets including the AAMI website, www.aami.org.

Meeting New Challenges

The environment for electrical designers in the medical arena is challenging. Understanding, interpreting and applying the wide variety of global standards for the product requires extensive knowledge of the standards. This knowledge must include general requirements, collateral standards, type specifications and an understanding of the regulatory differences between individual countries, which can disrupt the development and marketing process. This is a difficult challenge and now designers must begin to

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Keeping the Acronyms Straight

Organizations that provide medical-device approval standards.

- Canadian Standards Association (CSA), www.csa.ca
- Underwriters Laboratories (UL), www.ul.com
- International Organization for Standards (ISO), www.iso.org
- International Electrotechnical Commission (IEC), www.iec.ch
- American National Standards Institute (ANSI), www.ansi.org
- ASTM International Standards Worldwide, www.astm.org
- Association for the Advancement of Medical Instrumentation (AAMI), www.aami.org

understand the new requirements being proposed.

These new challenges require design engineers, system engineers and manufacturers to be aware of the changes. It also requires significant changes to the certification of medical power supplies. The product compliance test, which starts at the product, is now inverted to start with compliant processes. To comply with the proposed standards, managers would have to institute risk-management processes from which compliant products could be spawned.

The timing of the transition to the new standards has not been set. In fact, most industry experts believe we are still one to three years away from the third edition becoming required for medical devices including power supplies. Despite the new standards not being required today, power-supply manufacturers and system integrators should pay careful attention to the changes in anticipation of modifying current practices for future compliance.

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