

ELECTROCHEM
MEDICAL

IEC 60601-1 For
Medical Battery Chargers

Abstract

Understanding, interpreting and implementing standards is a challenge in all industries. Medical standards for electronics can be particularly onerous, and while it is uncommon for regulatory changes to effect products already in production, the third edition of 60601-1 is an exception. IEC 60601-1 applies to all electrical and electronic medical devices and their accessories. The 3rd edition was adopted by global regulatory authorities, and on a national level, regulatory affectivity dates are harmonized across global jurisdictions. Medical OEMs need to carefully manage vendors for their chargers and other accessories as these changes take place. This white paper will provide an outline and update of the standard, as well as compliance guidelines for portable medical devices.

IEC 60601-1 Safety Standard

IEC 60601-1 applies to all electrical and electronic medical devices and their accessories. The 3rd edition was adopted by global regulatory authorities, and on a national level, regulatory affectivity dates are harmonized across global jurisdictions. The requirement for 3rd edition does not apply to products deployed in the field, but it applies to new products going through regulatory approvals, as well as products currently shipping that are approved via the 2nd edition. In the EU, compliance with 3rd edition is required to maintain the CE mark.

Battery chargers affiliated with a medical device and used in a medical environment are classified as an electrical medical device accessory. Examples of medical devices that use standalone battery chargers include surgical tools, ventilators, digital imaging plates and defibrillators. Medical battery chargers destined for sale in Europe must now be certified to EN 60601-1 3rd edition. The EN 60601-1 is based on the standard IEC 60601-1: 2005, which is the general safety standard for Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance. This standard affects medical battery chargers that have embedded power supplies or utilize external AC/DC or DC/DC power adapters.

There are three regional variants: EN 60601-1 in Europe, ANSI/AAMI 60601-1 in the US, and CAN/CSA C22.2 NO. 601.1-M90 (R2005) in Canada.

For the EU, EN 60601-1 is a harmonized standard and is required for Medical Device Directive for all device classes,

and 3rd edition is mandatory.

For Canada, CSA 22.2 is a recognized standard, and is required for submissions for all class of medical devices. 3rd edition is mandatory for this region.

For the US, ANSI/AAMI 60601-1 is a consensus standard and required for 510(k) submissions. 3rd edition is mandatory for this region.

For medical OEMs that offer battery chargers into Europe or Canada, all medical devices - including medical-grade battery chargers - must currently be certified to EN 60601-1 and CSA 22.2. Note that Europe and Canada do not allow the sale of battery chargers that are certified to EN 60601-1 and CSA 22.2 2nd editions.

Relative to the 2nd Edition: IEC 60601-1: 1988, the 3rd Edition: IEC 60601-1: 2005 addresses the general requirements for basic safety and essential performance. The inclusion of "essential performance" is new, and this is performance whose absence or degradation would result in unacceptable risk, or render the equipment no longer capable of performing its intended use.

The major differences between the 2nd and 3rd edition of IEC 60601-1 are highlighted in the following paragraphs;

- Risk Management, Process Risk Analysis
- Insulation Coordination
- Temperature
- Leakage Current
- Mechanical Hazards
- Clarifications on Fire Prevention Requirements
- Clarifications on Component Requirements
- Labeling

Risk Management

Risk Management is an "integral part" of the standard. This requires a formal risk management process complying with ISO 14971. ISO 14971:2007 specifies a process for a manufacturer to identify the hazards associated with

medical devices to estimate and evaluate the associated risks, to control these risks, and to monitor the effectiveness of the controls. Risks analysis must be used to determine acceptable risk levels for failure modes. ISO 14971 does not specify specific technical parameters or risk areas, such as device hazards, acceptable risk levels, risk analysis tools, or risk quantification methodologies. Critical documentation deliverables required for ISO 14971 include risk management files, plans and reports.

Insulation Coordination

Changes are based on new views of Means of Patient Protection (MOPP) and Means of Operator Protection (MOOP). The primary change from 2nd to 3rd edition of IEC 60601-1 is the expansion of two original tables into nine new tables on insulation identification. Despite the more complex table structure in 3rd edition, it does provide for a more liberal view for operator protection. For example, it allows use of non-medical IEC 60950-1 compliant power supplies.

Temperature

Third edition of IEC 60601-1 requires no functional changes to equipment meeting 2nd edition. Improvements to definitions used in tables of 2nd edition, as well as addition of some new parameters such as allowable maximum temperature (Table 22), external surfaces that are likely to be touched over time (Table 23), maximum applied part temperatures (Table 24). Plus, the 3rd edition allows a more liberal view on surface temperatures in brief contact with patient.

Leakage Current

Touch current replaces enclosure leakage current. Leakage current is measured to ensure that direct contact with the medical equipment is highly unlikely to result in electrical shock. Leakage tests are designed to simulate a human body coming in contact with different parts of the equipment. The measured leakage current values are compared with acceptable limits.

The leakage test is conducted before and after humidity conditioning at 93% +/- 3% RH. Components shall be kept in the humidity cabinet for 2 days for ordinary components with IPX0 rating and 7 days for components rated IPX1 to IPX7. Improvements in the 3rd edition of IEC 60601-1 include the definition of touch current replacing enclosure leakage (but measured parameters have not changed), earth leakage

verbiage has been simplified with 5 mA in normal conditions and 10 mA in single fault conditions.

The specifications define several different kinds of leakage current, but the most important with respect to medical battery charger design are:

- Earth leakage current - Current flowing along the earth conductor
- Touch leakage current - Current flowing from the enclosure to earth via the patient

Maximum leakage current is defined for three main types of applications with respect to IEC 60601-1;

- Type B - Equipment where there is no physical contact with the patient e.g. medical battery chargers, ear examination equipment
- Type BF - Equipment where there is intentional physical contact with the patient, e.g. ultrasound, monitors and ventilators.
- Type CF - Equipment where there is intentional cardiac physical contact with the patient e.g. defibrillators, heart monitors

A common misunderstanding is that leakage current specifications vary within these types of applications. In fact, in all of these classes of application, the allowable leakage current is the same. But note that there are differences in the permissible leakage current levels between EN 60601-1 and ANSI/AAMI 60601-1. For example, EN 60601-1 limits leakage current to 0.5mA in Europe, while ANSI/AAMI 60601-1 specifies 0.3mA is permissible in the US. Therefore, medical equipment designers need to appreciate where their systems may be sold.

Mechanical Hazards

The 3rd edition of IEC 60601-1 has many changes to the parameters defining mechanical hazards. Examples of the parameters that have changed include crushing, shearing, cutting, punctures, entanglement, instability. Additionally, the 3rd edition includes new parameters for vibration and noise that were not covered in the 2nd edition.

Clarifications On Fire Prevention Requirements

The 2nd edition of IEC 60601-1 had no requirements for fire enclosure, although they were addressed in ANSI/AAMI 60601-1. The ANSI requirements have been incorporated into the 3rd edition of IEC 60601-1. For enclosures, insulated wires shall have flammability FV-1, or better, in accordance with IEC

60695. For connectors, printed circuit board, and insulating material on which components are mounted shall have flammability FV-2, or better, in accordance with IEC 60695.

Clarifications on Component Requirements

If a component is used as means for protection, that component must meet the requirements via references to the affiliated IEC component standards. If a component is critical to reliability or protection, then that component requires reliability assessment.

Labeling

New symbols and signs have been added to the labeling specification. "Caution" used to be "Consult accompanying documents". Symbols have been standardized. Additionally, more emphasis is applied to operating instructions to eliminate user error during operation.

Electrochem Solutions has developed many medical battery chargers that have received approval for both 2nd and 3rd edition IEC 60601-1 standard. Applicable skillsets utilized in these developments include electrical engineering, mechanical engineering, risk management processes, and regulatory agency management. Additionally, we have enabled medical OEMs to upgrade their medical battery chargers, with approval to 2nd generation IEC 60601-1, to the 3rd edition of this standard.

About Electrochem Solutions, Inc.

Electrochem, founded in 1979, is a world leader in the design and manufacture of customized battery and wireless sensing technology solutions. A subsidiary of Greatbatch, Inc., Electrochem was born from the lithium battery invented for the implantable pacemaker by founder, Wilson Greatbatch. Today, Electrochem is known for providing reliable products which are used across a range of critical applications in the portable medical, energy, military, aerospace and environmental industries.

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