Chroma Systems Solutions, Inc.

Overview of IEC 60601-1 Medical Electrical Equipment

IEC 60601-1

Keywords: N/A

Title:

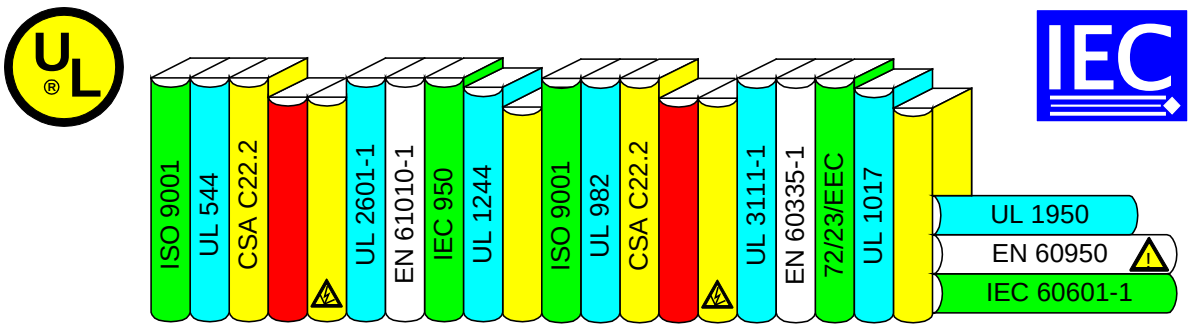
Overview of IEC60601-1 Medical Electrical Equipment

By Leo Eisner, Eisner Safety Consultants for QuadTech *(purchased by Chroma in 2012).*

IEC60601-1, 2nd edition, is an international standard for the safety of medical electrical equipment. The standard was first published in 1977. The second edition was published in 1988 with Amendments to the Second Edition in 1991 (A1) and 1995 (A2).

What are the products that fall under this standard? Medical products that are powered by an electrical energy source and that are used for diagnosis, treatment or monitoring of the patient. The electrical energy source could be AC power, DC battery or other sources. Some examples of medical products include battery operated thermometers, MRI and gamma imaging systems, endoscopic cameras, infusion pumps, and many other medical products. It is also important to realize that accessories used with this equipment can also fall under this standard. To see a more detailed definition of a medical product, refer to sub-clause 2.2.15 of the standard.

This standard has been used as a base for many national standards around the world including UL 2601-1 for the U.S., CSA C22.2 No. 601.1 for Canada, EN60601-1 for Europe, and AS/NZS 3200.1.0 for Australia. Some countries have national deviations that modify some of the requirements of the standard. Some of these deviations cover the differences in National Electrical Codes, labeling differences, among other issues. It is important to be aware of the national deviations and to design your product to meet all deviations that apply for the countries you may be selling to. The IEC60601-1 standard is therefore the base for making a medical product comply with these national regulations. The third edition of IEC60601-1 is currently (Jan 2001) in committee draft and it will be published sometime in the future. This edition will address a very broad set of requirements and incorporate performance requirements in addition to updating the safety requirements.



IEC60601-1 Standards Series Breakdown

How is the IEC60601-1 Standards Series structured? IEC60601-1 is actually a set of standards that is broken up into three distinct areas:

1. IEC60601-1 covers all the general requirements for all electrical medical based products.

2. The collateral standards cover horizontal issues such as system integration, EMC, radiation protection, and programmable electronic medical systems (software, firmware, etc.). The standard numbers are IEC60601-1-1, -1-2, -1-3, and -1-4 respectively. IEC60601-1-1 went to Second Edition in December 2000. This made the system requirements more stringent, including specific requirements when designing with multiple portable socket outlets (i.e. power strips on a portable cart) and also clarifies the requirements for separation devices. Two additional horizontal standards are in the initial stages of development at IEC. These standards are Human Factors Compatibility and alarms in medical electrical equipment. These standards will be identified as IEC60601-1-6 and –1-8 respectively.

3. Particular standards deal with a specific type of medical device. The particular standards are identified as IEC60601-2-XX where XX identifies the particular standard number for the particular type of medical equipment. An example would be IEC60601-2-2 is the particular standard for High Frequency Surgical Devices.

To find out more about IEC60601-1, product safety requirements or the CE mark please contact Eisner Safety Consultants at (503)-244-6151 or visit them on the web at (http://www.eisnersafety.com/). You can view a list of IEC60601-1 based standards (http://www.eisnersafety.com/recent_iec_601-1_standards.htm) or view a list of these standards that are under development (http://www.eisnersafety.com/iec-work-in-progress.htm). Eisner Safety Consultants specializes in assisting clients with obtaining the European CE Mark and meeting US and Canadian regulatory safety standards. Specialties include product evaluation to safety standards, Agency coordination, CE Mark and training.

Leonard (Leo) Eisner is a licensed professional engineer in safety engineering and is an expert in CE marking for the Medical, In-Vitro Diagnostic, Low Voltage and EMC EU Directives. He has over 15 years experience in product safety at Underwriter's Laboratories (UL), TUV Product Service and Karl Storz Imaging, Inc. Leo ran the Compliance Engineering Group at Karl Storz and was a senior Product Safety Engineer at TUV Product Service. Prior to that Leo worked in a cross section of groups at UL for nine years.

IEC60601-1 Based Standards*

Included here is a partial listing of the individual standards that comprise the IEC 60601-1 Medical Electrical Equipment Standard. For a complete listing visit the Eisner Safety Consultant's (http://www.eisnersafety.com/recent_iec_601-1standards.htm) page.

IEC60601 - X - XX	Published Date	Title
-1, 2ND Edition	DEC 1988	Medical Electrical Equipment – Part 1: General Requirements for Safety
-1, A1 to 2ND Edition	NOV 1991	Amendment 1 to Medical Electrical Equipment – Part 1: General Requirements for Safety
-1, A2 to 2ND Edition	MAR 1995	Amendment 2 to Medical Electrical Equipment – Part 1: General Requirements for Safety
1-1, 2ND Edition	DEC 2000	Medical Electrical Systems
1-2, 1ST Edition	APR 1993	Electromagnetic Compatibility
1-3, 1ST Edition	JUL 1994	Radiation Protection in Diagnostic X-Ray Equipment
2-1, 2ND Edition	JUN 1998	Electron Accelerators
2-2, 3RD Edition	SEP 1998	High Frequency Surgical
2-3, 2ND Edition	JUN 1991	Short Wave Therapy
2-3, A1 to 2ND Edition	SEP 1998	Amendment 1 to Short Wave Therapy
2-4, 2ND Edition	JAN 1983	Cardiac Defibrillators and Cardiac Defibrillator Monitors
2-5, 2ND Edition	JUL 2000	Ultrasonic Physiotherapy
2-6, 1ST Edition	JAN 1984	Microwave Therapy
2-7, 2ND Edition	FEB 1998	High Voltage Generators of Diagnostic Ray Generators
2-20, 1ST Edition	DEC 1990	Transport Incubators
2-20, A1 to 1ST Edition	OCT 1996	Amendment 1 to Transport Incubators
2-21 1ST Edition	FEB 1994	Infant Radiant Warmers
2-21, A1 to 1ST Edition	OCT 1996	Amendment 1 to Infant Radiant Warmers
2-22, 2ND Edition	NOV 1995	Diagnostic and Therapeutic Laser Equipment

2-23, 2ND Edition	DEC 1999	Transcutaneous Partial Pressure Monitoring
2-24, 1ST Edition	FEB 1998	Infusion Pumps and Controllers
2-25, 1ST Edition	MAR 1993	Electrocardiographs
2-43, 1ST Edition	JUN 2000	X-Ray Equipment for Interventional Procedures
2-44, 1ST Edition	FEB 1999	X-Ray Equipment for Computed Tomography
2-45, 1ST Edition	SEP 1998	Mammographic X-Ray Equipment & Stereotactic Devices
2-46, 1ST Edition	JUN 1998	Operating Tables
2-50, 1ST Edition	JUN 1998	Infant Phototherapy Equipment

* As of 1-26-2001. For most current information go to (http://www.iec.ch)

Standards Organizations & NRTL'S (Partial Listing)

ACRONYM	NAME	URL (http://)	Address	Telephone
AAMI	Association for the Advancement of Medical Instrumentation	www.aami.org	3330 Washington Blvd Suite 400 Arlington, VA 22201	703-525-4890
ANSI	American National Standards Institute	www.ansi.org	1 West 42ND Street New York, NY 10036	212-642-4900
BSI	British Standards Institute	www.bsi-global.com	389 Chiswick High Road London, UK W4 4AL	44 181 996 9001
CENELEC	European Committee for Electrotechnical Standardization	www.cenelec.org	rue de Stassart 35B Brussels, Belgium 1050	+32 2 519 68 71
CSA	Canadian Standards Institute	www.csa.ca	178 Rexdale Blvd Etobicoke, Ontario M9W1R3	416-747-4000 1-800-463-6727
IEC	International Electrotechnical Commission	www.iec.ch	3 rue de Varembe P.O. Box 131 1211 Geneva, Switzerland	+41 22 919 02 11

IEEE	Institute of Electrical and Electronic Engineers	www.ieee.org	345 East 47TH Street New York, NY 10017	1-800-678-IEEE
ISO	International Standards Organization	www.iso.ch	1 rue de Varembe Case Postale 56 CH-1211 Geneva, Switzerland	+41 22 749 01 11
NEMA	National Electrical Manufacturers Association	www.nema.org	2101 L Street, NW Suite 300 Washington DC 20037	202-457-8400
NFPA	National Fire Protection Association	www.nfpa.org	1 Batterymarch Park P.O. Box 9101 Quincy, MA 02269	617-770-3000
NIST	National Institute of Standards & Technology	www.nist.gov	Bldg. 820, Room 232 Gaithersburg, MD 20899	301-975-NIST
OSHA	Occupational Safety & Health Administration	www.osha.gov	JFK Federal Bldg. Rm E340 Boston, MA 02203	617-565-9860
TUV	TUV Rheinland of North America	www.us.tuv.com	12 Commerce Road Newton, CT 06470	203-426-0888
TUV	TUV Product Service	www.tuvps.com	5 Cherry Hill Drive Danvers, MA 01923	978-739-7000
UL	Underwriter's Laboratory	www.ul.com	333 Pfingsten Road Northbrook, IL 60062	847-272-8800

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