

(2011-11-15)

IEC 60601-1, Edition 3 Harmonized Medical Standards

European Official Journal Due Dates for Transition to the 3rd Ed. Standards in **[RED]**

IEC 60601-1 (2005-12) Ed.3, Corr.1 (2006-12), Corr.2 (2007-12), IS1 (2008-04), Am.1 (Project)

National Deviations:

USA: AAMI/ANSI ES60601-1 (02/05) **[US FDA New/Resubmitted Products: 2013-06-01]**

EU: EN 60601-1 (7/2007) **[European MDD: 2012-06-01]**

CANADA: CSA-C22.2 No.60601-1:2008 **[Health Canada: New/Resubmitted Products: 2012-06-01]**

IEC 60601-1-xx

- 1: Safety Requirements for Medical Electrical Systems. Ed.2. (In Base Standard)
- 2: Electromagnetic Compatibility - Requirements and Tests. Ed.3 (2007-03), Ed. 4 (Project) **[2012-06-01]**
- 3: Gen. Requirements for Radiation Protection in Diagnostic X-ray Equipment. Ed.2. (2008-01) **[2012-06-01]**
- 4: Programmable Electrical-Medical Systems. (In Base Standard)
- 5: Image quality and dose for X-ray equipment (Cancelled)
- 6: Usability Ed.3. (2010-01) - Used with IEC 62366: Application of usability engineering to medical devices. (2007) **[2012-06-01]**
- 7: General requirements for multiparameter patient monitoring equipment (Moved to IEC 60601-2-49).
- 8: Requirements/guidelines for alarms in Medical Electrical Equipment. Ed.2. (2006-10), Am.1 (Project)
- 9: Requirements for the reduction of environmental impacts. Ed.1. (2007-07) – (Not yet required by any nations)
- 10: Process requirements for the development of therapeutic closed-loop controllers Ed.1. (2007-11) **[2012-06-01]**
- 11: Medical Electrical Equipment for Use in Home Care Applications. Ed.1. (2010-04), Corr.1 (2011-04) **[2012-06-01]**
- 12: ME and MES used in the emergency medical services environment. Ed.1. (Project)

IEC 60601-2-xx

- 1: Medical Electron Accelerators in the Range 1 MeV to 50 MeV. Ed.3. (2009-10), Am.1. (Project)
- 2: High Frequency Surgical Equipment. Ed.5. (2009-02) **[2012-04-01]**
- 3: Short-Wave Therapy Equipment. Ed.3 (Project)
- 4: Cardiac Defibrillators, Defibrillator-Monitors. Ed.3. (2010-12)
- 5: Ultrasonic Therapy Equipment. Ed.3. (2009-07)
- 6: Microwave Therapy Equipment.. Ed.2 (Project)
- 7: High Voltage Generators of Diagnostic X-ray Generators. (Incorporated into IEC 60601-2-54)
- 8: Therapeutic X-ray Equipment in the Range 10 kV to 1 MV. Ed.2. (2010-11)
- 9: Patient Contact Dosimeters used in Radiotherapy with Electrically Connected Radiation Detectors. (Cancelled).
- 10: Nerve and Muscle Stimulators. Ed.2. (Project)
- 11: Gamma Beam Therapy Equipment. Ed.3. (Project)
- 13: Anesthetic Machines. Ed. 3.1 (2009-08). (Also moved to IEC/ISO 80601-2-13 on 2011-08).
- 14: Electroconvulsive Therapy Equipment (1989-03) (Withdrawn).
- 15: Capacitor Discharge X-ray Generators (1988-12) (Withdrawn).
- 16: Hemodialysis Equipment. Ed.3. (2008-04), Corr.1. (2008-10), Ed.4. (Project)
- 17: Automatically-controlled brachytherapy afterloading equipment. Ed.3. (Project)
- 18: Endoscopic Equipment. Ed.18. (2009-08)
- 19: Infant Incubators. Ed.2. (2009-02) **[2012-04-01]**
- 20: Infant transport incubators. Ed.2. (2009-02) **[2012-09-01]**
- 21: Infant Radiant Warmers. Ed.2. (2009-02) **[2012-06-01]**
- 22: Surgical, cosmetic, therapeutic, and diagnostic laser equipment. Ed.3. (2007-05), Am.1. (Project)
- 23: Transcutaneous Partial Pressure Monitoring Equipment. Ed.3. (2011-02)
- 24: Infusion Pumps and Controllers. Ed.2 (Project)
- 25: Electrocardiographs. Ed.2. (2011-10)
- 26: Electroencephalographs. Ed.3. (Project)
- 27: Electrocardiographic Monitoring Equipment. Ed.3. (2011-03)
- 28: X-ray tube assemblies for medical diagnosis. Ed.2. (2010-03) **[2013-04-01]**
- 29: Radiotherapy Stimulators. Ed. 3. (2008-06) **[2011-11-01]**
- 31: External Cardiac Pacemakers with Internal Power Source. Ed.2. (2008-03), Am.1. (2011-06), Consolidated Ed.2.1. (2011-09)
- 32: Associated Equipment of X-ray Equipment. (Incorporated into IEC 60601-2-54)
- 33: Magnetic Resonance Equipment for Medical Diagnosis. Ed.3 (2010-03)
- 34: Invasive Blood Pressure Monitoring Equipment. Ed.3 (2011-05)
- 36: Extracorporeally Induced Lithotripsy. Ed.2. (Project)
- 37: Ultrasonic Diagnostic and Monitoring Equipment. Ed.2. (2007-08), Am.1. (Project)
- 38: Electrically Operated Hospital Beds. (Moved to IEC 60601-2-52)
- 39: Peritoneal Dialysis Equipment. Ed.2. (2007-11)
- 40: Electromyographs and Evoked Response Equipment. Ed.2. (Project???)
- 41: Surgical Luminaires and Luminaires for Diagnosis. Ed.2. (2009-08), Am.1. (Project) **[2012-11-01]**
- 42: Automatic or Advisory External Defibrillators (Incorporated into IEC 60601-2-4).
- 43: X-ray Equipment for Interventional Procedures. Ed.2. (2010-03) **[2013-06-01]**
- 44: X-ray Equipment for Computed Tomography. Ed.3. (2009-02), Corr.1. (2010-05), Am.1. (Project) **[2012-05-01]**
- 45: Mammographic X-ray equipment and mammographic stereotactic devices. Ed.3. (2011-02)
- 46: Operating Tables. Ed.2. (2010-12)
- 47: Ambulatory Electrocardiographic Monitors [Holter Monitors]. Ed.2. (Project)
- 48: Canceled
- 49: Multiparameter Patient Monitoring Equipment. Ed.2. (2011-02)
- 50: Infant phototherapy equipment. Ed.2. (2009-03), Corr.1. (2010-08) **[2012-05-01]**
- 51: Recording and analyzing single and Multichannel electrocardiographs. (Incorporated into IEC 60601-2-25)
- 52: Safety of Medical Beds (replaces IEC 60601-2-38). Ed.1. (2009-12), Corr1. (2010-09)
- 53: Computer Assisted Electrocardiography Communication Protocol. Ed.1. (Project?)

(2011-11-15)

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54: X-ray equipment for radiography and radioscopy. Ed.1. (2009-06), Corr.1. (2010-03), Corr.2. (2011-06)
57: Non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use. Ed.1. (2011-01)
62: High intensity therapeutic ultrasound (HITU) systems. Ed.1. (Project)
63: Dental X-ray equipment. Ed.1. (Project)
64: Medical light ion accelerators in the range 10 MeV/n to 500 MeV/n. Ed.1. (Project)
65: Dental intra-oral X-ray equipment. Ed.1. (Project)
66: Hearing Instruments and Hearing Systems. Ed.1. (Project)
68: X-ray based Image Guided Radiotherapy Equipment (For: electron accelerators, light ion beam therapy, radionuclide beam). Ed.1. (Project)
XX: Treadmill and Crank Ergometers. Ed.

IEC/ISO 80601-2-xx

12: Gamma beam therapy equipment. Ed.1. (2011-04), Corr.1. (2011-10)
13: Anesthetic systems. Ed.1. (2011-08)
30: Automated non-invasive sphygmomanometers. Ed.1 (2009-01), Corr.1. (2010-01), Am.1. (Project)
35: Heating devices using blankets, pads and mattresses and intended for heating in medical use. Ed.2. (2009-10) [2012-11-01]
55: Respiratory gas monitors. Ed.1. (2009-09)
56: Clinical thermometers for body temperature measurement. Ed.1. (2009-09)
58: Lens removal devices and vitrectomy devices for ophthalmic surgery. Ed.1 (2008-10)
59: Screening thermographs for human febrile temperature screening, Ed.1 (2008-10), Corr.1. (2009-04)
60: Dental equipment. Ed.1. (Project)
61: Pulse Oximeter equipment. Ed.1. (2011-03)
67: Oxygen-conserving equipment. Ed.1. (Project)
69: Oxygen concentrator equipment. Ed.1. (Project)
70: Sleep apnea breathing therapy equipment. Ed.1. (Project)

Other Related Standards:

ISO 14971: Medical Devices - Application of Risk Management to Medical Devices. Ed.1. (2000), Am.1 (2003), Ed.2. (2007).
IEC 60529: Protection provided by Enclosures - IPXX Rating Ed.2.1 (2001)
ISO 13857: Safety of machinery - Safety distances to prevent hazard zones being reached by upper and lower limbs. (2008)
IEC 60825-1: Safety of LASER Products - Part 1. Ed.2. (2007).
IEC 60878: Graphic Symbols for Electrical Equipment in Medical Practice Ed.2 (2003).
IEC 62353: Recurrent test and test after repair of medical electrical equipment. Ed.2. (2007)
IEC 62354 TR: General testing procedures for medical equipment. Ed.2. (2009)
ISO 10993-1: Biological Evaluation of Medical Devices [Biocompatibility]. Ed.4. (2010)
CSA C22.2 No. 0.4-04: Bonding and Grounding of Electrical Equipment (Protective Grounding). Update No.2. (2006)