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[RED] dates are anticipated regulatory deadlines for specified new Editions/Amendments
Highlighted Projects for Editions/Amendment are anticipated publish dates (Reference Only)

International Medical Base IEC Standard

2014-07-22: **IEC 60601-1:2005+AMD1:2012/COR1:2012** (Edition 3.1) **Am.2 (Project 2019-12), Ed.4 (Project ~2025)**

1997-01-01: IEC 60601-1:1988/AMD2:1995/COR1:1995
1995-06-01: IEC 601-1:1988/AMD2:1995/COR1:1995
1995-03-07: IEC 601-1:1988/AMD2:1995
1991-11-13: IEC 601-1:1988/AMD1:1991
1988-12-30: IEC 601-1:1988
1984-01-01: IEC 601-1:1977/AMD1:1984
1977-01-01: IEC 601-1:1977

USA

2012-11: **ANSI/AAMI ES60601-1:2005/(R)2012 [Required]**

= *IEC 60601-1, Edition 3.1 + US Differences*
FDA: Only ANSI/AAMI ES60601-1:2005/(R)2012 (Edition 3.1)
NRTL Safety Marks: IEC/AAMI/UL Editions 2, 3, 3.1 (no cessation dates for Edition 2 or 3 yet) – *Note, some NRTLs are not accepting Edition 2*

2003: UL 60601-1
1997: UL2601-1, Ed.2
1994: UL 2601-1, Ed.1
1972: UL544 (Medical & Dental); UL 187 (X-Ray Equipment

CANADA

2014-03: **CAN/CSA-C22.2 No. 60601-1:14 [Required]**

= *IEC 60601-1, Edition 3.1 + Canadian Differences*
Health Canada: Only CAN/CSA-C22.2 NO. 60601-1:14
SCC Safety Marks: IEC/CSA Editions 2, 3, 3.1 (no cessation dates provided for Edition 2 or 3 yet) – *Note, some SCC labs are not accepting Edition 2*

2008: CAN/CSA-C22.2 No. 60601-1:08
1990: CAN/CSA-C22.2 No.601.1-M90
CAN/CSA-C22.2 No.114-M90 (Diagnostic Imaging, Radiation Therapy Eq.)
1984: C22.2 No. 125-M1984 (Electromedical Equipment)

EUROPEAN UNION

2014: **EN 60601-1:2006/A1:2013 + (EU Am.12:2014) [Required]**

= *IEC 60601-1, Edition 3.1 (no declared differences, except Am.12 requirements)*
CE Mark, per Medical Device Directive (MDD) Official Journal: EN 60601-1:2006/A1:2013 (or) IEC 60601-1:2005/A1:2012

1995: EN 60601-1:1990/A2:1995
1993: EN 60601-1:1990/A1:1993

JAPAN

2014: **JIS T 60601-1:2012 + A1:2014 (Edition 3.1) [Required]**

= *IEC 60601-1, Edition 3.1 + Japanese Differences*

REPUBLIC OF KOREA

2011: **KS C IEC 60601-1:2011 [IEC Edition 3 or Edition 3.1 accepted with CB Report]**

= *IEC 60601-1, Edition 3 + Korea Differences*
Korean National Differences: (110/220/380V, 60Hz, KSC 8305 or 8300 plugs, Korean language)

CHINA

1995: **IEC 60601-1:1988/AMD2:1995 (IEC Edition 2 + Am.1 + Am.2) [Required], [No date provided for accepting IEC Edition 3.1]**

= IEC 60601-1:1988/AMD1:1991/AMD2:1995 (Edition 2)

Other Countries accept IEC 60601-1, Edition 3.1, without modification, including below (per the IECEE CB Scheme)

Albania: SSH EN 60601-1:2006+A1:2013+AC:2014
Austria (AU): ÖVE/ÖNORM EN 60601-1: 2014 02 01
Brazil (BR); NBR IEC 60601-1:2010+IEC 60601-1:2005/AMD1:2012
Bosna Hercegovina: BAS EN 60601-1:2010+A1:2015+A12:2016
Bulgaria: БДС EN 60601-1:2006+A1:2013+AC:2014
Denmark (DK): DS/EN 60601-1:2006+A1:2013+AC:2014
Finland (FI): SFS-EN 60601-1:2007+A1:2016
France (FR): NF EN 60601-1:2007+A1:2014
Germany (DE): DIN EN 60601-1:2013; VDE 0750-1:2013-12
Hungary (HU): MSZ EN 60601-1:2017
Iceland: IST EN 60601-1:2006+A1:2013+AC:2014
Ireland: I.S. EN 60601-1:2006+AMD1:2013+AMD12:2014
Latvia: LVS EN 60601-1:2007+A1:2014
Lithuania: LST EN 60601-1:2007+A1:2013
Luxembourg: ILNAS-EN 60601-1:2006+A1:2014
Macedonia, Republic of: MCK EN 60601-1:2006+A1:2016+AC:2015
Montenegro: MEST EN 60601-1:2010+A1:2015+A12:2015
Netherlands (NO): NEN-EN-IEC 60601-1:2006+A1:2013+A12:2014
Norway (NO): NEK EN 60601-1:2006+A1:2013
Poland (PL): PN-EN 60601-1:2011+A12:2014+AC1:2015
Serbia: SPRS EN 60601-1:2012+A1:2014+AC:2017
Slovenia (SL): SIST EN 60601-1:2007+A1:2014+AC:2015
Spain: UNE-EN 60601-1:2008+A1:2013+A12:2014
Sweden (SE): SS-EN 60601-1:2006+A1:2013+A11:2014
Switzerland (CH): SN EN 60601-1:2010+A1:2013+Corr:2014
Turkey (TR):
TS EN 60601-1:2007+A12:2015+AC:2017+A12:2017+A1:2017
United Kingdom (UK): BS EN 60601-1:2006+A12:2014

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International Medical Collateral Standards

IEC 60601-1-xx (Collaterals):

60601-1-01: ~~Safety Requirements for Medical Electrical Systems. Ed.2.~~ (Now in base standard)
60601-1-02: Electromagnetic Compatibility (EMC). Ed.3 (2007-03), IS1 (2010-03), Ed. 4 (2014-02) **[2018-12-31]**, Am.1 (Project 2019-12)
60601-1-03: Gen. Requirements for Radiation Protection in Diagnostic X-ray Equipment. Ed.2. (2008-01), Am.1 (2013-04), Ed.2.1 (2013-04)
60601-1-04: ~~Programmable Electrical Medical Systems.~~ (Now in base standard)
60601-1-05: ~~Image quality and dose for X-ray equipment~~ (Cancelled)
60601-1-06: Usability Ed.3.1 (2013-10), Am.2 (Project 2019-12) - Requires IEC 62366 (Usability, Medical Devices) Ed.1 (2007-10)
60601-1-07: ~~General requirements for multiparameter patient monitoring equipment~~ (Moved to IEC 60601-2-49).
60601-1-08: Alarms in Medical Electrical Equipment. Ed.2. (2006-10), Am.1 (2012-11); Ed.2.1 (2012-11), Am.2 (Project 2019-12)
60601-1-09: Reduction of environmental impacts. Ed.1. (2007-07), Ed.1.1 (2013-06)
60601-1-10 Development of therapeutic closed-loop controllers Ed.1. (2007-11), Am.1 (2013), Ed.1.1 (2013-11), Am.2 (Project 2019-12)
60601-1-11: Medical Electrical Equipment for Use in Home Care. Ed.1. (2010-04), Corr.1 (2011), Ed.2 (2015-01), Am.1 (Project 2019-12)
60601-1-12: ME and MES used in the emergency medical services environment. Ed.1. (2014-06)

International Medical Particular Standards

IEC 60601-2-xx, IEC/ISO 80601-2-xx (Particulars):

60601-2-01: Medical Electron Accelerators in the Range 1 MeV to 50 MeV. Ed.3. (2009-10), Am.1/Ed.3.1 (2014-07), Ed.4 (Project 2019-11)
60601-2-02: High Frequency Surgical Equipment. Ed.5. (2009-02), Corr.1 (2014-02), Ed.6 (2017-03)
60601-2-03: Short-Wave Therapy Equipment. Ed.3 (2012-04), Am.1 (2016), Ed.3.1 (2016-04)
60601-2-04: Cardiac Defibrillators, Defibrillator-Monitors. Ed.3. (2010-12), Am.1 (2018-02), Ed.3.1 (2018-02)
60601-2-05: Ultrasonic Therapy Equipment. Ed.3. (2009-07)
60601-2-06: Microwave Therapy Equipment. Ed.2 (2012-04), Am.1 (2016), Ed.2.1 (2016-04)
60601-2-07: ~~High Voltage Generators of Diagnostic X-ray Generators.~~ (Incorporated into IEC 60601-2-54)
60601-2-08: Therapeutic X-ray Equipment in the Range 10 kV to 1 MV. Ed.2. (2010-11), Am.1 (2015), Ed.2.1 (2015-09)
60601-2-09: ~~Patient Contact Dosimeters used in Radiotherapy with Electrically Connected Radiation Detectors.~~ (Cancelled)
60601-2-10: Nerve and Muscle Stimulators. Ed.2. (2012-06), Am.1 (2016), Ed.2.1 (2016-04)
60601-2-11: Gamma Beam Therapy Equipment. Ed.3. (2013-01)
80601-2-12 (ISO): Critical Care Ventilators. Ed.1. (2011-05), Ed.2 (Project 2020-03)
80601-2-13 (ISO): Anesthetic Workstation. Ed.1 (2011-08), Am.1 (2015-03), Am.2 (2018-07), Ed.2 (Project 2021-09)
60601-2-14: ~~Electroconvulsive Therapy Equipment (1989-03)~~ (Withdrawn)
60601-2-15: ~~Capacitor Discharge X-ray Generators (1988-12)~~ (Withdrawn)
60601-2-16: Hemodialysis Equipment. Ed.3. (2008-04), Corr.1. (2008-10); Ed.4. (2012-03), Ed.5 (2018-04)
60601-2-17: Automatically-controlled brachytherapy afterloading equipment. Ed.3. (2013-11)
60601-2-18: Endoscopic Equipment. Ed.3. (2009-08), Ed.4 (Project 2019-12)
60601-2-19: Infant Incubators. Ed.2. (2009-02), Corr.1 (2012-02), Am.1 (2016), Ed.2.1 (2016-04), Ed.3 (Project 2020-02)
60601-2-20: Infant transport incubators. Ed.2. (2009-02), Corr.1 (2012-02), Corr.2 (2013-02), Am.1 (2016), Ed.2.1 (2016-04), Ed.3 (Project 2020-02)
60601-2-21: Infant Radiant Warmers. Ed.2. (2009-02), Corr.1 (2013-02), Am.1 (2016), Ed.2.1 (2016-04), Ed.3 (Project 2020-02)
60601-2-22: Surgical, cosmetic, therapeutic, and diagnostic laser equipment. Ed.3.1 (2012-10), Ed.4 (Project 2019-06)
60601-2-23: Transcutaneous Partial Pressure Monitoring Equipment. Ed.3. (2011-02), Ed.4 (Project 2021-12)
60601-2-24: Infusion Pumps and Controllers. Ed.2 (2012-10)
60601-2-25: Electrocardiographs. Ed.2. (2011-10)
60601-2-26: Electroencephalographs. Ed.3. (2012-05), [Being replaced by 80601]
80601-2-26 (IEC/ISO): Electroencephalographs. Ed.1 (Project 2019-05)
60601-2-27: Electrocardiographic Monitoring Equipment. Ed.3. (2011-03), Corr.1 (2012-05)
60601-2-28: X-ray tube assemblies for medical diagnosis. Ed.2. (2010-03), Ed.3 (2017-06)
60601-2-29: Radiotherapy Stimulators. Ed. 3. (2008-06)
80601-2-30 (IEC/ISO): Automated non-invasive sphygmomanometers. Ed.1.1 (2013-07), Ed.2 (2018-03)
60601-2-31: External Cardiac Pacemakers with Internal Power Source. Ed.2. (2008-03), Am.1. (2011-06), Ed.2.1. (2011-09), Ed.3 (Project 2019-10)
60601-2-32: ~~Associated Equipment of X-ray Equipment.~~ (Incorporated into IEC 60601-2-54)
60601-2-33: Magnetic Resonance Equipment for Medical Diagnosis. Ed. 3.1 (2013), Am.2 (2015), Ed.3.2 (2015-06), Corr.2 (2016-02)
60601-2-34: Invasive Blood Pressure Monitoring Equipment. Ed.3 (2011-05)
80601-2-35 (IEC/ISO): Heating devices using blankets, pads, mattresses. Ed.2. (2009-10), Am.1 (2016-04), Ed.3 (Project 2020-02)
60601-2-36: Extracorporeally Induced Lithotripsy. Ed.2. (2014-04)
60601-2-37: Ultrasonic Diagnostic and Monitoring Equipment. Ed.2. (2007-08), Am.1 (2015), Ed.2.1 (2015-06)
60601-2-38: ~~Electrically Operated Hospital Beds.~~ (Moved to IEC 60601-2-52)
60601-2-39: Peritoneal Dialysis Equipment. Ed.2. (2007-11), Ed.3 (2018-04)
60601-2-40: Electromyographs and Evoked Response Equipment. Ed.2. (2016-08)
60601-2-41: Surgical Luminaires and Luminaires for Diagnosis. Ed.2 (2009-08), Am.1 (2013-10), Ed.2.1 (2013-10), Ed.3 (Project 2020-07)
60601-2-42: ~~Automatic or Advisory External Defibrillators~~ (Incorporated into IEC 60601-2-4).
60601-2-43: X-ray Equipment for Interventional Procedures. Ed.2. (2010-03), Am.1 (2017-05), Am.2 (Project 2019-08)
60601-2-44: X-ray Equipment for Computed Tomography. Ed.3. (2009-02), Am.1. (2012-08), Ed.3.1 (2012-09), Am.2 (2016), Ed.3.2 (2016-03)
60601-2-45: Mammographic X-ray equipment and mammomagraphic stereotactic devices. Ed.3. (2011-02), Am.1 (2015), Ed.3.1 (2015-06)
60601-2-46: Operating Tables. Ed.2. (2010-12), Ed.3 (2016-08)
60601-2-47: Ambulatory Electrocardiographic Monitors [Holter Monitors]. Ed.2. (2012-02)
60601-2-48: ~~Canceled~~
60601-2-49: Multiparameter Patient Monitoring Equipment. Ed.2 (2011-02), [Being replaced by 80601]
80601-2-49 (IEC/ISO): Multiparameter Patient Monitoring Equipment. Ed.1 (2018-03)
60601-2-50: Infant phototherapy equipment. Ed.2. (2009-03), Corr.1. (2010-08), Am.1 (2016), Ed.2.1 (2016-04), Ed.3 (Project 2020-02)
60601-2-51: ~~Recording and analyzing single and Multichannel electrocardiographs.~~ (Incorporated into IEC 60601-2-25)
60601-2-52: Safety of Medical Beds *(replaces IEC 60601-2-38)*. Ed.1. (2009-12), Corr1. (2010), Am.1 (2015), Ed.1.1 (2015-03)

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60601-2-53: ~~Computer Assisted Electrocardiography Communication Protocol. Ed.1~~ (Canceled)
60601-2-54: X-ray equipment for radiography and radioscopy. Ed.1. (2009-06), Am.1 (2015), Am.2 (2018-06), Ed.1.2 (2018-06)
80601-2-55 (ISO): Respiratory gas monitors. Ed.1. (2011-12), Ed.2 (2018-02)
80601-2-56 (ISO): Clinical thermometers for body temperature measurement. Ed.1. (2009-012), Ed.2 (2017-03), Am.1 (Project 2018-11)
60601-2-57: Non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use. Ed.1. (2011-01)
80601-2-58 (IEC/ISO): Lens removal devices and vitrectomy devices for ophthalmic surgery. Ed.1 (2008-10), Ed.2 (2014-09), Am.1 (2016-10)
80601-2-59 (IEC/ISO): Screening thermographs for human febrile temperature screening, Ed.1 (2008-10), Corr.1. (2009-04), Ed.2 (2017-09)
80601-2-60 (IEC/ISO): Dental equipment. Ed.1. (2012-02), Ed.2 (Project 2019-06)
80601-2-61 (ISO): Pulse Oximeter equipment. Ed.1. (2011-03), Ed.2 (2017-12)
60601-2-62: High intensity therapeutic ultrasound (HITU) systems. Ed.1. (2013-07)
60601-2-63: Dental X-ray equipment. Ed.1. (2012-09), Am.1 (2017-07)
60601-2-64: Medical light ion accelerators in the range 10 MeV/n to 500 MeV/n. Ed.1 (2014-09)
60601-2-65: Dental intra-oral X-ray equipment. Ed.1. (2012-09), Am.1 (2017-05)
60601-2-66: Hearing Instruments and Hearing Systems. Ed.1. (2012-10), Ed.2 (2015-06), Ed.3 (Project 2019-09)
80601-2-67 (ISO): Oxygen-conserving equipment. Ed.1. (2014-05), Ed.2 (Project 2021-01)
60601-2-68: X-ray Image Guided Radiotherapy Equipment (electron accelerators, ion beam therapy, radionuclide beam). Ed.1. (2014-09)
80601-2-69 (ISO): Oxygen concentrator equipment. Ed.1. (2014-05), Ed.2 (Project 2021-01)
80601-2-70 (ISO): Sleep apnea breathing therapy equipment. Ed.1. (2015-01)
80601-2-71 (IEC/ISO): Functional Oximeter equipment. Ed.1. (2015-06)
80601-2-72 (ISO): Home healthcare environment ventilators for ventilator-dependent patients. (from ISO 10651-2:2004) Ed.1. (2015-09)
80601-2-73 (ISO): Medical supply units (head walls). (Proposal 2017)
80601-2-74 (IEC/ISO): Respiratory humidifying equipment. Ed.1. (2017-05)
60601-2-75: Photodynamic Therapy and Diagnosis equipment. Ed.1 (2017-05)
60601-2-76: Low energy ionized gas haemostasis (Coagulation) equipment. Ed.1 (2018-04)
80601-2-77 (IEC/ISO): Medical Robots for Surgery. Ed.1 (Project 2019-05)
80601-2-78 (IEC/ISO): Medical Robots for Rehabilitation, Compensation, Alleviation of Disease, Injury, Disability. Ed.1 (Project 2019-06)
80601-2-79 (IEC/ISO): Home Health Ventilatory Support Equipment for Respiratory Impairment. Ed.1 (2018-07)
80601-2-80 (IEC/ISO): Home Health Ventilatory Support Equipment for Respiratory Insufficiency. Ed.1 (2018-07)
80601-2-81 (ISO): ~~Electric Radial Pulse Tonometric Devices.~~ (Proposal 2018 not approved)
80601-2-82 (ISO): Electro-Acupuncture Stimulators. (Proposal 2018)
60601-2-83: Ionized Gas Coagulation equipment. Ed.1 (Project 2019-11)
80601-2-84 (ISO/CD) Emergency and transport ventilators Ed.1. (Project 2019-10)
80601-2-85 (ISO/NP): Cerebral tissue oximeter equipment. Ed.1. (Project 2019-12)
80601-2-86 (IEC/ISO): Electrocardiographs - diagnostic, monitoring, ambulatory, electrodes, cables, leadwires. Ed.1 (Project 2020-06)
80601-2-87 (IEC/ISO): High frequency critical care ventilators. Ed.1 (Project 2020-07)

IEC TR (Technical Reports):

IEC/TR 60601-4-1: Medical electrical equipment and medical electrical systems employing a degree of autonomy Ed.1 (2017-05)
IEC/TR 60601-4-2: Guidance and interpretation; Electromagnetic immunity, performance Ed.1 (2016-05)
IEC/TR 60601-4-3: Considerations of unclear/unaddressed safety aspects of IEC 60601-1, new requirements, Ed.1 (2015-04), Ed.2 (Project 2018-12)
IEC/TR 60601-4-4: Guidance for writers of particular standards - Creating alarm system-related requirements Ed.1 (2017-08)
IEC/TR 62353:2014: Recurrent test and test after repair of medical electrical equipment. Ed.2 (2014-09)
IEC/TR 62354:2014: General testing procedures for medical equipment. Ed.3 (2014-09)

Related Medical Device Evaluation Standards:

ISO 17025:2017: General Requirements for the Competence of Testing and Calibration Laboratories. Ed.2 (2005), Ed.2.1 (2006), Ed.3 (2017)
ISO 14971:2007: Risk Management for Medical Devices. Ed.2 (2007) [*IEC 60601-1 Ed.3.1 references 2007 Ed., not EN 2012 Ed.*]
EN/ISO 14971:2012: Risk Management for Medical Devices, (2012-07) Adds Annex Z to ISO 2007 Edition, for EU MDD only.
IEC 62304:2006: Software Life Cycle Processes for Medical Equipment. Ed.1 (2006-05), Ed.1.1 (2014-06) [*IEC 60601-1 Ed.3.1 references 2006 Ed.*]
IEC 62366:2007: Usability for Medical Devices. Ed.1 (2007-10), Ed.1.1 (2014-01) [*IEC 60601-1 Ed.3.1 references 2007 Ed.*]
ISO 10993-1:2018: Biological Evaluation of Medical Devices [Biocompatibility] - Ed.4. (2009) [*IEC 60601-1 Ed.3.1 references "ISO 10993 (all parts)"*]
IEC 60878:2015: Graphic Symbols for Electrical Equipment in Medical Practice. Ed.3 (2015-09)

IEC 60086-4:2014: Primary Lithium Batteries (NON-RECHARGEABLE). Ed.4 (2014-09)
IEC 62133:2017: Secondary Lithium Batteries (RECHARGEABLE) and batteries other than acidic electrolytes. Ed.2 (2012-12), Ed.3 (2017-02)
IEC 62471:2006: Photobiological Safety of Lamp Radiation (including LED), with wavelength range 3,000 nm to 200 nm. Ed.1 (2006-07)
IEC 60825-1:2014: Safety of LASER Products with Wavelength range 180 nm to 1 mm. Ed.3 (2014-05)
IEC 60529:1989+AMD1:1999+AMD2:2013: Ingress Protection Provided by Enclosures (IPXX Ratings). Ed.2.2 (2013)
CSA C22.2 No. 0.4-17: Bonding and Grounding of Electrical Equipment (Protective Grounding). Ed.3 (2004-06), Ed.4 (2017-04)
ISO 13857:2008: Safety of Machinery - Safety Distances to Prevent Hazard Zones Being Reached by Upper and Lower Limbs. Ed.1 (2008-03)

IEC 60950-1: Information Technology Equipment Safety. Ed.2 (2005-12)
IEC 62368-1: Audio/video, information, communication technology equipment. (combines IEC 60950-1 and IEC 60065 and UL 62368)