MECA IEC 60601, IEC/ISO 80601 Medical Electrical Equipment Standards List [*Rev. 2022-09-06*]

[RED] dates are anticipated regulatory deadlines for meeting specified new Editions/Amendments (~3 years)
[BLUE] are Projects for new Editions/Amendments with anticipated publish dates (Reference Only)

Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance

IEC 60601-1:2005+AMD1:2012+AMD2:2020 (Edition 3.2) (2020-08-20) Ed.4 (Project, no date provided)

IEC 60601-1:2005+AMD1:2012 (Edition 3.1) (2012-07-13) *(In Transition to AMD2 above) (See National Differences below for deadlines)*

IEC 60601-1 Collateral, Particular, TR Standards

IEC 60601-1-xx (Collaterals):

~~IEC~~	~~60601-1-1: Safety Requirements for Medical Electrical Systems.~~ *(Now in base IEC 60601-1 standard)*
IEC	60601-1-2: Electromagnetic Compatibility (EMC). Ed. 4 (2014-02), AMD1 (Ed.4.1) (2020-09) **[~2023]**
IEC	60601-1-3: Radiation Protection in Diagnostic X-ray Equipment. Ed.2 (2008-01), AMD1 (Ed.2.1) (2013-04), AMD2 (Ed.2.2) (2021-01) **[~2024]**
~~IEC~~	~~60601-1-4: Programmable Electrical Medical Systems.~~ *(Now in base IEC 60601-1 standard)*
~~IEC~~	~~60601-1-5: Image quality and dose for X-ray equipment.~~ *(Cancelled)*
IEC	60601-1-6: Usability. Ed.3.1 (2013-10), AMD2 (Ed.3.2) (2020-07) **[~2023]** *-Ref: IEC 62366:2007 (Ed.3.1 of -1-6), IEC 62366-1:2015 (Ed.3.2 of -1-6)*
~~IEC~~	~~60601-1-7: General requirements for multiparameter patient monitoring equipment.~~ *(Moved to IEC 60601-2-49)*
IEC	60601-1-8: Alarms in Medical Electrical Equipment. Ed.2 (2006-10), AMD1 (Ed.2.1) (2012-11), AMD2 (Ed.2.2) (2020-07) **[~2023]**
IEC	60601-1-9: Reduction of environmental impacts. Ed.1 (2007-07), AMD1 (Ed.1.1) (2013-06), AMD2 (Ed.1.2) (2020-07) **[~2023]**
IEC	60601-1-10: Development of therapeutic closed-loop controllers. Ed.1 (2007-11), AMD1 (Ed.1.1) (2013-11), AMD2 (Ed.1.2) (2020-07) **[~2023]**
IEC	60601-1-11: Medical Electrical Equipment for Use in Home Care. Ed.1 (2010-04), Ed.2 (2015-01), AMD1 (Ed.2.1) (2020-07) **[~2023]**
IEC	60601-1-12: ME and MES used in the emergency medical services environment. Ed.1 (2014-06), AMD1 (Ed.1.1) (2020-07) **[~2023]**

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

IEC	60601-2-1: Medical Electron Accelerators in the Range 1 MeV to 50 MeV. Ed.3 (2009-10), AMD1 (Ed.3.1) (2014-07), Ed.4 (2020-10) **[~2023]**
IEC	60601-2-2: High Frequency Surgical Equipment. Ed.5 (2009-02), Ed.6 (2017-03) , AMD1 (Project 2023-02)
IEC	60601-2-3: Short-Wave Therapy Equipment. Ed.3 (2012-04), AMD1 (Ed.3.1) (2016-04), AMD2 (Project 2022-10)
IEC	60601-2-4: Cardiac Defibrillators, Defibrillator-Monitors. Ed.3 (2010-12), AMD1 (Ed.3.1) (2018-02)
IEC	60601-2-5: Ultrasonic Therapy Equipment. Ed.3 (2009-07)
IEC	60601-2-6: Microwave Therapy Equipment. Ed.2 (2012-04), AMD1 (Ed.2.1) (2016-04), AMD2 (Project 2022-10)
~~IEC~~	~~60601-2-7: High Voltage Generators of Diagnostic X-ray Generators.~~ *(Incorporated into IEC 60601-2-54)*
IEC	60601-2-8: Therapeutic X-ray Equipment in the Range 10 kV to 1 MV. Ed.2 (2010-11), AMD1 (Ed.2.1) (2015-09)
~~IEC~~	~~60601-2-9: Patient Contact Dosimeters used in Radiotherapy with Electrically Connected Radiation Detectors.~~ *(Cancelled)*
IEC	60601-2-10: Nerve and Muscle Stimulators. Ed.2 (2012-06), AMD1 (Ed.2.1) (2016-04), AMD2 (Project 2023-03)
IEC	60601-2-11: Gamma Beam Therapy Equipment. Ed.3 (2013-01)
ISO	80601-2-12: Critical Care Ventilators. Ed.1 (2011-05), Ed.2 (2020-02) **[~2023]**, Ed.3 (Project 2023-07)
ISO	80601-2-13: Anesthetic Workstation. Ed.1 (2011-08), AMD1 (Ed.1.1) (2015-03), AMD2 (Ed.1.2) (2018-07), Ed. 2 (2022-04) **[~2025]**
~~IEC~~	~~60601-2-14: Electroconvulsive Therapy Equipment. (1989-03)~~ *(Withdrawn)*
~~IEC~~	~~60601-2-15: Capacitor Discharge X-ray Generators. (1988-12)~~ *(Withdrawn)*
IEC	60601-2-16: Hemodialysis Equipment. Ed.3 (2008-04), Ed.4. (2012-03), Ed.5 (2018-04), Ed.6 (Project 2023-12)
IEC	60601-2-17: Automatically-controlled brachytherapy afterloading equipment. Ed.3 (2013-11)
IEC	60601-2-18: Endoscopic Equipment. Ed.3 (2009-08), Ed.4 (Project 2023-08)
IEC	60601-2-19: Infant Incubators. Ed.2 (2009-02), AMD1 (Ed.2.1) (2016-04), Ed.3 (2020-09) **[~2023]**
IEC	60601-2-20: Infant transport incubators. Ed.2 (2009-02), AMD1 (Ed.2.1) (2016-04), Ed.3 (2020-09) **[~2023]**, AMD1 (Ed.3.1) (Project 2023-10)
IEC	60601-2-21: Infant Radiant Warmers. Ed.2 (2009-02), AMD1 (Ed.2.1) (2016-04), Ed.3 (2020-09) **[~2023]**, AMD1 (Ed.3.1) (Project 2023-10)
IEC	60601-2-22: Surgical, cosmetic, therapeutic, and diagnostic laser equipment. Ed.3, AMD1 (Ed.3.1) (2012-10), Ed.4 (2019-11) **[~2022]**
IEC	60601-2-23: Transcutaneous Partial Pressure Monitoring Equipment. Ed.3 (2011-02), Ed.4 (Project 2023-08)
IEC	60601-2-24: Infusion Pumps and Controllers. Ed.2 (2012-10), Ed.3 (Project 2023-12)
IEC	60601-2-25: Electrocardiographs. Ed.2 (2011-10)
~~IEC~~	~~60601-2-26: Electroencephalographs. Ed.3 (2012-05)~~ *(Moved to 80601-2-49)*
IEC/ISO	80601-2-26 Electroencephalographs. Ed.1 (2019-05), AMD1 (Ed.1.1) (Project 2023-05)
IEC	60601-2-27: Electrocardiographic Monitoring Equipment. Ed.3 (2011-03), Corr.1 (2012-05)
IEC	60601-2-28: X-ray tube assemblies for medical diagnosis. Ed.2 (2010-03), Ed.3 (2017-06)
IEC	60601-2-29: Radiotherapy Stimulators. Ed.3 (2008-06)
IEC/ISO	80601-2-30: Automated non-invasive sphygmomanometers. Ed.1, AMD1 (Ed.1.1) (2013-07), Ed.2 (2018-03), Ed.3 (Project 2024-02)
IEC	60601-2-31: External Cardiac Pacemakers with Internal Power Source. Ed.2 (2008-03), AMD1 (Ed.2.1) (2011-09), Ed.3 (2020-01) **[~2023]**
~~IEC~~	~~60601-2-32: Associated Equipment of X-ray Equipment.~~ *(Incorporated into IEC 60601-2-54)*
IEC	60601-2-33: Magnetic Resonance Equipment for Med. Diagnosis. Ed.3, AMD2 (Ed.3.2) (2015-06), Cor.2 (2016-02), Ed.4 (2022-08) **[~2025]**
IEC	60601-2-34: Invasive Blood Pressure Monitoring Equipment. Ed.3 (2011-05)
IEC/ISO	80601-2-35: Heating devices using blankets, pads, mattresses. Ed.2 (2009-10), AMD1 (Ed.2.1) (2016-04) *(moved back to IEC 60601 standard)*
IEC	60601-2-35: Heating devices using blankets, pads, mattresses. (to IEC 80601, then back) Ed.2 (2020-09) **[~2023]**, AMD1 (Ed.2.1) (Project 2023-10)
IEC	60601-2-36: Extracorporeally Induced Lithotripsy. Ed.2 (2014-04)
IEC	60601-2-37: Ultrasonic Diagnostic and Monitoring Equipment. Ed.2 (2007-08), AMD1 (Ed.2.1) (2015-06), Ed.3 (Project 2025-07)
~~IEC~~	~~60601-2-38: Electrically Operated Hospital Beds.~~ *(Moved to IEC 60601-2-52)*

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IEC	60601-2-39: Peritoneal Dialysis Equipment. Ed.2 (2007-11), Ed.3 (2018-04), Ed.4 (Project 2023-12)
IEC	60601-2-40: Electromyographs and Evoked Response Equipment. Ed.2 (2016-08), Ed.3 (Project 2023-12)
IEC	60601-2-41: Surgical Luminaires and Luminaires for Diagnosis. Ed.2 (2009-08), AMD1 (Ed.2.1) (2013-10), Ed.3 (2021-09) **[~2024]**
~~IEC~~	~~60601-2-42: Automatic or Advisory External Defibrillators.~~ *(Incorporated into IEC 60601-2-4)*
IEC	60601-2-43: X-ray Equipment for Interventional Procedures. Ed.2 (2010-03), AMD1 (Ed.2.1) (2017-05), AMD2 (Ed.2.2) (2019-10) **[~2022]**
IEC	60601-2-44: X-ray Equipment for Computed Tomography. Ed.3 (2009-02), AMD1 (Ed.3.1) (2012-09), AMD2 (Ed.3.2) (2016-03)
IEC	60601-2-45: Mammographic X-ray equipment & stereotactic devices. Ed.3 (2011-02), AMD1 (Ed.3.1) (2015-06), AMD2 (Ed.3.2) (2022-08) **[~2025]**
IEC	60601-2-46: Operating Tables. Ed.2 (2010-12), Ed.3 (2016-08), Ed.4 (Project 2023-05)
IEC	60601-2-47: Ambulatory Electrocardiographic Monitors. [Holter Monitors]. Ed.2 (2012-02)
~~IEC~~	~~60601-2-48: Unknown.~~ *(Canceled)*
~~IEC~~	~~60601-2-49: Multiparameter Patient Monitoring Equipment. Ed.2 (2011-02)~~ *(Moved to 80601-2-49)*
IEC/ISO	80601-2-49: Multiparameter Patient Monitoring Equipment. Ed.1 (2018-03), AMD1 (Ed.1.1) (Project 2023-12)
IEC	60601-2-50: Infant phototherapy equipment. Ed.2 (2009-03), AMD1 Ed.2.1 (2016-04), Ed.3 (2020-09) **[~2023]**, AMD1 (Ed.3.1) (Project 2023-10)
~~IEC~~	~~60601-2-51: Recording and analyzing single and Multichannel electrocardiographs.~~ *(Incorporated into IEC 60601-2-25)*
IEC	60601-2-52: Safety of Medical Beds. *(replaces IEC 60601-2-**38**)*. Ed.1 (2009-12), AMD1 (Ed.1.1) (2015-03)
IEC/AWI	80601-2-52: Safety of Medical Beds. *(IEC/AWI ISO/TC 173: Assistive products, to replace IEC **6**0601-2-52),* Ed.1 (Project Started 2019)
~~IEC~~	~~60601-2-53: Computer Assisted Electrocardiography Communication Protocol.~~ *(Canceled)*
IEC	60601-2-54: X-ray equipment for radiography and radioscopy. Ed.1, AMD1 (Ed.1.1) (2015), AMD2 (Ed.1.2) (2018-06), Ed.2 (Project 2022-09)
ISO	80601-2-55: Respiratory gas monitors. Ed.1 (2011-12), Ed.2 (2018-02)
ISO	80601-2-56: Clinical thermometers for body temperature measurement. Ed.2 (2017-03), AMD1 (Ed.2.1) (2018-12), Ed.3 (Project 2025-01)
IEC	60601-2-57: Non-laser light source equipment - therapeutic, diagnostic, monitoring, cosmetic/aesthetic use. Ed.1 (2011-01), Ed.2 (Project 2023-08)
IEC/ISO	80601-2-58: Lens removal and vitrectomy devices for ophthalmic surgery. Ed.2 (2014-09), AMD1 (Ed.2.1) (2016-10), Ed.3 (Project 2023-10)
IEC/ISO	80601-2-59: Screening thermographs for human febrile temperature screening. Ed.1 (2008-10), Ed.2 (2017-09), AMD1 (Ed.2.1) (Project 2022-12)
IEC/ISO	80601-2-60: Dental equipment. Ed.1 (2012-02), Ed.2 (2019-06)
ISO	80601-2-61: Pulse Oximeter equipment. Ed.1 (2011-03), Ed.2 (2017-12), Ed.3 (Project 2024-02)
IEC	60601-2-62: High intensity therapeutic ultrasound (HITU) systems. Ed.1 (2013-07)
IEC	60601-2-63: Dental X-ray equipment. Ed.1 (2012-09), AMD1 (Ed.1.1) (2017-07), AMD2 (Ed.1.2) (2021-05) **[~2025]**
IEC	60601-2-64: Medical light ion accelerators in the range 10 MeV/n to 500 MeV/n. Ed.1 (2014-09), AMD1 (Project 2025-10)
IEC	60601-2-65: Dental intra-oral X-ray equipment. Ed.1 (2012-09), AMD1 (Ed.1.1) (2017-05), AMD2 (Ed.1.2) (2021-05) **[~2025]**
IEC	60601-2-66: Hearing Instruments and Hearing Systems. Ed.1 (2012-10), Ed.2 (2015-06), Ed.3 (2019-10) **[~2022]**
IEC/ISO	80601-2-67: Oxygen-conserving equipment. Ed.1 (2014-05), Ed.2 (2020-10) **[~2023]**
IEC	60601-2-68: X-ray Image Guided Radiotherapy Equip. (electron accelerators, radionuclide beam therapy). Ed.1 (2014-09), AMD1 (Project 2023-11)
ISO	80601-2-69 Oxygen concentrator equipment. Ed.1 (2014-05), Ed.2 (2020-11) **[~2023]**
ISO	80601-2-70: Sleep apnea breathing therapy equipment. Ed.1 (2015-01), Ed.2 (2020-11) **[~2023]**
IEC/ISO	80601-2-71: Functional Oximeter equipment. Ed.1 (2015-06), Ed.2 (Project 2023-12)
ISO	80601-2-72: Home healthcare environment ventilators for ventilator-dependent patients. *(from ISO 10651-2)* Ed.1 (2015-09), Ed.2 (Project 2023-08)
~~IEC~~	~~80601-2-73: Medical supply units (head walls).~~ *(2017 Proposal not approved)*
ISO	80601-2-74: Respiratory humidifying equipment. Ed.1 (2017-05), Ed.2 (2021-07) **[~2024]**
IEC	60601-2-75: Photodynamic Therapy and Diagnosis equipment. Ed.1 (2017-05), AMD1 (Project 2023-03)
IEC	60601-2-76: Low energy ionized gas haemostasis (Coagulation) equipment. Ed.1 (2018-04), AMD1 (Project 2023-07)
IEC/ISO	80601-2-77: Medical Robots for Surgery. Ed.1 (2019-07), AMD1 (Project 2023-03)
IEC/ISO	80601-2-78: Medical Robots for Rehabilitation, Compensation, Alleviation of Disease, Injury, Disability. Ed.1 (2019-07), AMD1 (Project 2023-03)
ISO	80601-2-79: Home Health Ventilatory Support Equipment for Respiratory Impairment. Ed.1 (2018-07), Ed.2 (Project 2024-02)
ISO	80601-2-80: Home Health Ventilatory Support Equipment for Respiratory Insufficiency. Ed.1 (2018-07), Ed.2 (Project 2024-02)
~~IEC/ISO~~	~~80601-2-81: Electric Radial Pulse Tonometric Devices.~~ *(2018 Proposal not approved)*
~~IEC/ISO~~	~~80601-2-82: Electro-Acupuncture Stimulators.~~ *(2018 Proposal not approved)*
IEC	60601-2-83: Ionized Gas Coagulation Equipment. Ed.1 (2019-05), AMD1 (Project 2022-12)
ISO	80601-2-84: Emergency and transport ventilators. Ed.1 (2020-07) **[~2023],** Ed.2 (Project 2023-05)
ISO	80601-2-85: Cerebral tissue oximeter equipment. Ed.1 (2021-03) **[~2025]**
IEC/ISO	80601-2-86: Electrocardiographs, diagnostic, monitoring, ambulatory, electrodes, cables, leadwires. *(replacing -2-25, 27, 47)* (CD-2 on 2022-08)
ISO	80601-2-87: High frequency critical care ventilators. Ed.1 (2021-04) **[~2025]**
~~IEC/ISO~~	~~80601-2-88: Infant Cardiorespiratory Monitors For Home Health.~~ *(Changed to ISO 18778:2007)*
IEC/AWI	80601-2-89: Medical Beds for Children. (New Project Approved 2019-08)
ISO	80601-2-90: Ventilatory High-Flow Therapy Equipment. Ed.1 (2021-08) **[~2025]**

IEC/TR 60601-4-x (Technical Reports) and Similar for Medical Electrical Equipment (Informative Only):
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 Ed.3, Proposals. Ed.1 (2015-04), Ed.2 (2018-12)
IEC TR 60601-4-4: Guidance for writers of particular standards, Creating alarm system-related requirements. Ed.1 (2017-08)
IEC TR 60601-4-5: Guidance and interpretation – Safety related technical security specifications for medical devices. Ed.1 (2021-01)
IEC TR 62353: Recurrent test and test after repair of medical electrical equipment. Ed.2 (2014-09)
IEC TR 62354: General testing procedures for medical equipment. Ed.3 (2014-09)

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IEC 60601-1 Referenced Standards: *(Below Referenced by IEC 60601-1, where reference specific, Edition 3.1, Edition 3.1 & 3.2, Edition 3.2)*
ISO 10993: (all parts) (**Biocompatibility**) Biological evaluation of medical devices. i.e. ISO 10993-1. Ed.4 (2009), Ed. 5 (2018)
ISO 13857: Safety of **Machinery, Safety Distances** to Prevent Hazard Zones Being Reached… Ed.1 (2008-03), Ed.2 (2019)
ISO 13857: **Safety of Machinery** - Safety Distances to Prevent Hazard Zones Being Reached by Upper and Lower Limbs. Ed.1 (2008-03)
ISO 14971: **Risk Management** for Medical Devices. Ed.2 (2007-03), Ed.3 (2019-12)
ISO 17025: General Requirements for the **Competence of Testing and Calibration Laboratories**. Ed.2 (2005), Ed.2.1 (2006), Ed.3 (2017)
IEC 60086-4: **Primary Lithium Batteries (NON-RECHARGEABLE)**. Ed.4 (2014-09)
IEC 62133: **Secondary Lithium Batteries (RECHARGEABLE)** and batteries other than acidic electrolytes. Ed.2 (2012-12), Ed.3 (2017-02)
IEC 60417: **Graphical symbols** for use on equipment. Ed.1 (2002-10)
IEC 60878: **Graphic Symbols** for Electrical Equipment in Medical Practice. Ed.3 (2015-09)
IEC 60825-1: Safety of **LASER Products** with Wavelength range 180 nm to 1 mm. Ed.3 (2014-05)
IEC 62471: **Photobiological Safety** of Lamps. *(incl. LED, not LASER, wavelength 200 nm to 3,000 nm)* Ed.1 (2006-07)
IEC 62304: **Software** Life Cycle Processes for Medical Equipment. Ed.1 (2006-05), Ed.1.1 (2015-06)
IEC 62366: Application of **Usability** engineering to medical devices. Ed.1 (2007-10), Ed.1.1 (2014-01) No Edition/Date referenced
IEC 62366-1: Application of **Usability** engineering to medical devices. Ed.1 (2015-02), Ed.1.1 (2020-06) No Edition/Date referenced
IEC 60529: **Ingress Protection (IPXX)** Provided by Enclosures. *(IPXX Ratings)* Ed.2 (1989), AMD1 (Ed.2.1) (1999), AMD2 (Ed.2.2) (2013)
IEC 60950-1: **Information Technology Equipment** Safety. Ed.2 (2005-12)
IEC 62368-1: **Audio/video, information, communication technology equipment**. *(combines IEC 60950-1, IEC 60065, UL 62368)* Ed.3 (2018-10)
CSA C22.2 No. 0.4-17: **Bonding and Grounding** of Electrical Equipment *(Canadian Protective Grounding)*. Ed.4 (2017-04)

USA OSHA list of NRTLs (safety marks) with AAMI/UL 60601-1 Accreditation for Medical Electrical Equipment

(2020-11-05) [Updating]

Under standards ANSI/AAMI ES60601-1, Edition 3 (includes Amendments) and UL 60601-1 (IEC Edition 2.2) where noted

Mark	*NRTL Name*	*Standard*	*NRTL Specified Location(s)*
	Bureau Veritas Consumer Products Services, Inc.	*Ed. 3*	*USA (MA)*
	CSA Group Testing and Certification Inc.	*Ed. 2, 3*	*USA (OH, CA), Canada*
DEKRA	*DEKRA Certification, Inc.*	*Ed. 3*	*USA (VA), The Netherlands*
Intertek	*Intertek Testing Services NA, Inc.*	*Ed. 2, 3*	*USA (WI, MN, IL, NY, NJ, TX, GA, CA, MA, CA), Sweden, Canada, Hong Kong*
	MET Laboratories, Inc.	*Ed. 2, 3*	*USA (MD)*
	Nemko North America, Inc.	*Ed. 2, 3*	*USA (UT, CA), Canada*
	QAI Laboratories, LTD	*Ed. 3*	*USA (CA), Canada*
	QPS Evaluation Services Inc.	*Ed. 2, 3*	*Canada*
	SGS North America, Inc.	*Ed. 2, 3*	*USA (GA), China, Spain, UK, France, Finland*
	TUV Rheinland of North America, Inc.	*Ed. 2, 3*	*USA (CT, CA), Germany, Japan, China, Taiwan*
	TÜV SÜD America Inc.	*Ed. 2, 3*	*USA (MA, CA, MN), Germany, Canada*
	TÜV SÜD Product Services GmbH	*Ed. 2*	*Germany*
	UL Underwriters Laboratories Inc.	*Ed. 2, 3*	*USA (IL, NY, NC), Canada, Japan, Korea, Hong Kong, Taiwan, Germany, Denmark, UK, Italy, The Netherlands*

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IEC 60601-1 Base Standard & National Differences, With History & Information

IEC 60601-1:2005+AMD1:2012+AMD2:2020 (Edition 3.2) (2020-08-20) Ed.4 (Project, no date provided)
IEC 60601-1:2005+AMD1:2012 (Edition 3.1) (2012-07-13) *(In Transition to AMD2 above) (See National Differences below for deadlines)*

History of Editions: *(COR: Corrigendum, which is a non-technical correction)*

2020: IEC 60601-1:2005+AMD1:2012+AMD2:2020 (Ed.3.2)
2012: IEC 60601-1:2005+AMD1:2012/COR1:2012 (Ed.3.1)
2012: IEC 60601-1:2005+AMD1:2012 (Ed.3.1)
2005: IEC 60601-1:2005/COR2 (Ed.3)
2005: IEC 60601-1:2005/COR1 (Ed.3)
2005: IEC 60601-1:2005 (Ed.3)
1997: IEC 60601-1:1988/AMD2:1995 (Ed.2.2) (IEC added "60" to front)
1995: IEC 601-1:1988/AMD2:1995/COR1:1995 (Cor) (Ed.2.2)
1995: IEC 601-1:1988/AMD2:1995 (Ed.2.2)
1991: IEC 601-1:1988/AMD1:1991 (Ed.2.1)
1988: IEC 601-1:1988 (Ed.2)
1984: IEC 601-1:1977/AMD1:1984 (Ed.1.1)
1977: IEC 601-1:1977 (Ed.1)

Countries officially accepting IEC 60601-1, Edition 3.1, with* and without modification (not all inclusive)

Edition 3.2 National Standards provided in BLUE, being added as information available (TBD: To Be Determined)

Countries with no differences are considered covered based on compliance with IEC 60601-1:2005+A1:2012.
Identification of differences is based either on the referenced National/Regional Standard or on the IECEE CB Scheme list of declared differences.
(Where the publisher of a National/Regional Standard identifies their standard as identical (idt) or equivalent (eqv), it is assumed to be identical to IEC 60601-1:2005+A1:2012).

COUNTRY	STANDARD
Albania	SSH EN 60601-1:2006 + A1:2013 + AC:2014
	TBD
Austria (AU)	ÖVE/ÖNORM EN 60601-1: 2014 02 01
	TBD
Brazil (BR)	NBR IEC 60601-1:2010 + IEC 60601-1:2005/AMD1:2012
	TBD
Bosna Hercegovina	BAS EN 60601-1:2010 + A1:2015 + A12:2016
	TBD
Bulgaria	БДС EN 60601-1:2006 + A1:2013 + AC:2014
	TBD
Canada (CA) *	CAN/CSA C22.2 No. 60601-1:2014
	CAN/CSA-C22.2 NO. 60601-1:14/A2:22
China (CN)	GB 9706.1:2020
	TBD
Denmark (DK)	DS/EN 60601-1:2006 + A1:2013 + AC:2014
	TBD
European Union (EU)	EN 60601-1:2006 + A1:2013 + A12:2014 + AC:2014
	EN 60601-1:2006/A2:2021
Finland (FI)	SFS-EN 60601-1:2007 + A1:2016
	TBD
Former Yugoslav Republic of Macedonia	MCK EN 60601-1:2006 + A1:2016 + AC:2015
	TBD
France (FR)	NF EN 60601-1:2007 + A1:2014
	TBD
Germany (DE)	DIN EN 60601-1:2013; VDE 0750-1:2013-12
	TBD
Hungary (HU)	MSZ EN 60601-1:2017
	TBD
Iceland	IST EN 60601-1:2006 + A1:2013 + AC:2014
	TBD
Ireland	I.S. EN 60601-1:2006 + AMD1:2013 + AMD12:2014
	TBD
Israel *	SI 60601-1 Part 1
	TBD
Japan (JP) *	JIS T 60601-1:2017
	TBD
Korea *	IEC 60601-1:2012 / MDFS No. 2020-12, Annex 1
	TBD
Latvia	LVS EN 60601-1:2007 + A1:2014
	TBD
Lithuania	LST EN 60601-1:2007 + A1:2013
	TBD
Luxembourg	ILNAS-EN 60601-1:2006 + A1:2014
	TBD
Montenegro	MEST EN 60601-1:2010 + A1:2015 + A12:2015
	TBD
Netherlands (NO)	NEN-EN-IEC 60601-1:2006 + A1:2013 + A12:2014

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	TBD
Norway (NO)	NEK EN 60601-1:2006 + A1:2013
	TBD
Poland (PL)	PN-EN 60601-1:2011 + +A12:2014 AC1:2015
	TBD
Serbia	SPRS EN 60601-1:2012 + A1:2014 + AC:2017
	TBD
Slovenia (SL)	SIST EN 60601-1:2007 + A1:2014 + AC:2015
	TBD
Spain	UNE-EN 60601-1:2008 + A1:2013 + A12:2014
	TBD
Sweden (SE)	SS-EN 60601-1:2006 + A1:2013 + A11:2014
	TBD
Switzerland (CH)	SN EN 60601-1:2010 + A1:2013 + Corr:2014
	TBD
Turkey (TR)	TS EN 60601-1:2007 + A12:2015 + AC:2017 + A12:2017 + A1:2017
	TBD
United States of America (US) *	ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (ANSI/AAMI ES60601-1:2005/A1:2012)
	ANSI/AAMI ES60601-1:2005/A2:2021
United Kingdom (UK) *	BS EN 60601-1:2006 + A12:2014
	TBD

USA National Standard & History

ANSI/AAMI ES60601-1:2005/A2:2021 (2022-02-01) *(IEC Ed.3.2)* **[2023-12-17]**

ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (2012-08-17) *(IEC Ed.3.1)* **[Transition Period]**

- Also referred to as ANSI/AAMI ES60601-1:2005/A1:2012

US FDA Regulatory Submittals:

ANSI/AAMI ES60601-1:2005/A2:2021 (IEC Edition 3.2) **[2023-12-17]** *(Same date for all updated Collaterals & Particulars for Ed.3.2)*

ANSI/AAMI ES60601-1:2005/A1:2012 (IEC Edition 3.1) **[Transition until 2023-12-17]**

NRTL Safety Marks: IEC/AAMI/UL Editions 2, 3, 3.1, 3.2 *(No cessation dates for Ed.2 or later)* (per OSHA)
(Most NRTLs currently allow only Editions 3.1 or 3.2, some allow Editions 2.2, 3.1, 3.2)

History of Editions:

2022: ANSI/AAMI ES60601-1:2005/A2:2021 (IEC Ed.3.2)

2012: ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (IEC Ed.3.1) = ANSI/AAMI ES60601-1:2005/A1:2012

2012: ANSI/AAMI ES60601-1:2005/(R)2012 (IEC Ed.3.1)

2005: ANSI/AAMI ES60601-1:2005 (IEC Ed.3)

2003: UL 60601-1 (IEC Ed.2.2)

1997: UL2601-1, Ed.2 (IEC Ed.2.2)

1994: UL 2601-1, Ed.1 (IEC Ed.2)

1972: UL 544 (Medical & Dental); UL 187 (X-Ray Equipment)

CANADA National Standard & History

CAN/CSA-C22.2 NO. 60601-1:14/A2:22 (2022-03-01) *(IEC Ed.3.2)* **[~2025-03-01]**

CAN/CSA-C22.2 No. 60601-1:14 (2014-03-01) *(IEC Ed.3.1)* **[Transition Period]**

Health Canada Regulatory Submittals:

CAN/CSA-C22.2 NO. 60601-1:14/A2:22 & CAN/CSA-C22.2 NO. 60601-1:14

SCC Safety Marks: IEC/CSA Editions 3.2, 3.1, 2.2 *(no cessation dates provided for Edition 2.2 or later)*
(Most SCC labs accepting only Editions 3.2 & 3.1)

History of Editions:

2022: CAN/CSA-C22.2 NO. 60601-1:14/A2:22 (IEC Ed.3.2)

2014: CAN/CSA-C22.2 No. 60601-1:14 (IEC Ed.3.1)

2008: CAN/CSA C22.2 No. 60601-1:08 (IEC Ed.3)

1990: CAN/CSA C22.2 No.601.1-M90 (IEC Ed.2)

1990: CAN/CSA-C22.2 No.114-M90 (Diagnostic Imaging & Radiation Therapy Equip.)

1984: CAN/CSA C22.2 No. 125-M1984 (Electromedical Equipment)

EUROPEAN UNION National Standard & History

EN 60601-1:2006/A2:2021 (2021-10-08) *(IEC Ed.3.2)* **[2024-10-08]**

EN 60601-1:2006/A1:2013 (2013-10-03) *(IEC Ed.3.1)* + **A.12:2014** (2014-10-02) **[Transition Period]**

CE Marking Medical Devices, EU Notified Body Regulatory Submittals:

Medical Device Regulation (MDR): **[Required for new devices, May 25, 2024 for devices already on market]** *(conditional)*

Medical Device Directive (MDD): **[Expired for new devices, until May 25, 2024 for devices already on market]** *(conditional)*

History of Editions:

2022: EN 60601-1:2006/A2:2021 (IEC Ed.3.2)

2014: EN 60601-1:2006/A1:2013 + EU AMD12:2014 (IEC Ed.3.1)

2013: EN 60601-1:2006/A1:2013 (IEC Ed.3.1)

2006: EN 60601-1:2006 (IEC Ed.3)

1995: EN 60601-1:1990/A2:1995 (IEC Ed.2)

1993: EN 60601-1:1990/A1:1993 (IEC Ed.2)

MECA IEC 60601, IEC/ISO 80601 Medical Electrical Equipment Standards List

JAPAN National Standard & History

JIS T 60601-1:2012 + A1:2014 (2014-11-02) *(IEC Ed.3.1)* **[Required]**

History of Editions:

2014: JIS T 60601-1:2012 + AMD1:2014 (IEC Ed.3.2)

2012: JIS T 60601-1:2012 (IEC Ed.3.1)

REPUBLIC OF KOREA National Standard & History

KS C IEC 60601-1:2011 (2011-12-08) (*IEC 60601-1, Edition 3.1 + Korea Differences)* **[Required + CB Report/Certificate]**

(Requires In-Country Testing or a CB Report/Certificate to get In-Country Report for ALL Devices)

(Notification of MFDS No.2020-12, Annex 1: 110/220/380V, 60Hz, KSC 8305 and 8300 mains plugs, Korean language IFU and markings)

History of Editions:

2011: KS C IEC 60601-1:2011 (IEC Ed.3.1)

CHINA National Standard & History

GB 9706.1-2020 (2020-04-09), (IEC Ed.3.1) *(IEC 60601-1, Edition 3.1 + China Differences)* **[May 1, 2023]**

GB 9706.1-2007 (2008-07-01), (IEC Ed.2.2) **[Transition Period, to be withdrawn May 1, 2023]**

(Requires In-Country Testing of ALL Devices, even with CB Report/Certificate)

History of Editions:

2020: GB 9706.1-2020 (IEC Ed.3.1)

2008: GB 9706.1-2007 (IEC Ed. 2.2)

1996: GB 9706.1-1995 (IEC Ed. 2.1)

1985: GB 9706.1-88 (IEC Ed1.1)