

Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1:2005+AMD1:2012+AMD2:2020 (Edition 3.2) (Published 2020-08-20) **Ed.4 (Project Just Started ~2026)**

Countries with Specified Transition Dates to new Edition 3.2:

- United States: **[Required Now]**
- European Union: **[2024-10-08]**
- Canada: **[2025-03-01]**

 Replaces **IEC 60601-1:2005+AMD1:2012 (Edition 3.1)** (Published 2012-07-13) *(In Transition to Ed.3.2, as noted above).*

See Document "MECA IEC 60601-1 National Standards List - US NRTL List" for details on National Versions and date requirements.

IEC 60601-1-xx Collateral Standards
~~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, AMD1:2020 (Ed.4.1)

IEC 60601-1-3: Radiation Protection in Diagnostic X-ray Equipment. Ed.2:2008, AMD1:2013, AMD2:2021(Ed.2.2)

~~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.3:2010, AMD1:2013, AMD2:2020

 References: (for Ed.3.1 of -1-6: [IEC 62366:2007](#)), (for Ed.3.2 of -1-6: [IEC 62366-1:2015](#))

~~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, AMD1:2012, AMD2:2020

IEC 60601-1-9: Reduction of environmental impacts. Ed.1:2007, AMD1:2013, AMD2:2020

IEC 60601-1-10: Development of therapeutic closed-loop controllers. Ed.1:2007, AMD1:2013, AMD2:2020

IEC 60601-1-11: Medical Electrical Equipment for Use in Home Care. Ed.1:2010, Ed.2:2015, AMD1:2020

IEC 60601-1-12: ME and MES used in the emergency medical services environment. Ed.1:2014, AMD1:2020

IEC 60601-2-xx Particular, TR Standards
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, AMD1:2014, Ed.4:2020

 IEC 60601-2-2: High Frequency Surgical Equipment. Ed.5:2009, Ed.6:2017, AMD1:2023 **[~2026-02]**

 IEC 60601-2-3: Short-Wave Therapy Equipment. Ed.3:2012, AMD1:2016, AMD2:2022 **[~2025-09]**

IEC 60601-2-4: Cardiac Defibrillators, Defibrillator-Monitors. Ed.3:2010, AMD1:2018

IEC 60601-2-5: Ultrasonic Therapy Equipment. Ed.3:2009

 IEC 60601-2-6: Microwave Therapy Equipment. Ed.2:2012, AMD1:2016, AMD2:2022 **[~2025-09]**
~~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, AMD1:2015

~~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, AMD1:2016, AMD2:2023 **[~2026-01]**

IEC 60601-2-11: Gamma Beam Therapy Equipment. Ed.3:2013

 ISO 80601-2-12: Critical Care Ventilators. Ed.1:2011, Ed.2:2020, Ed.3:2023 **[~2026-11]**

 ISO 80601-2-13: Anesthetic Workstation. Ed.1:2011, AMD1:2015, AMD2:2018, Ed. 2:2022 **[~2025-04]**
~~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.4:2012, Ed.5:2018, **Ed.6 (Project 2024-09)**

IEC 60601-2-17: Automatically-controlled brachytherapy afterloading equipment. Ed.3:2013

 IEC 60601-2-18: Endoscopic Equipment. Ed.3:2009, **Ed.4 (IEC cancelled Project, being re-started)**

 IEC 60601-2-19: Infant Incubators. Ed.2:2009, AMD1:2016, Ed.3:2020, AMD1:2023 **[~2026-11]**

 IEC 60601-2-20: Infant transport incubators. Ed.2:2009, AMD1:2016, Ed.3:2020, AMD1:2023 **[~2026-11]**

 IEC 60601-2-21: Infant Radiant Warmers. Ed.2:2009, AMD1:2016, Ed.3:2020, AMD1:2023 **[~2026-11]**

IEC 60601-2-22: Surgical, cosmetic, therapeutic, and diagnostic laser equipment. Ed.3:2012, Ed.4:2019

IEC 60601-2-23: Transcutaneous Partial Pressure Monitoring Equipment. Ed.3:2011

IEC/ISO 80601-2-23: Transcutaneous Partial Pressure Monitoring Equipment. Ed.1 (Replacing IEC 60601-2-23 (Project 2025-07))

 IEC 60601-2-24: Infusion Pumps and Controllers. Ed.2:2012, **Ed.3 (Project 2025-05)**

IEC 60601-2-25: Electrocardiographs. Ed.2:2011

~~IEC 60601-2-26: Electroencephalographs. Ed.3 (2012-05) (Moved to 80601-2-26)~~
IEC/ISO 80601-2-26: Electroencephalographs. Ed.1:2019, COR1:2021, AMD1:2024 [~2027-02]

IEC 60601-2-27: Electrocardiographic Monitoring Equipment. Ed.3:2011, Corr.1:2012

IEC 60601-2-28: X-ray tube assemblies for medical diagnosis. Ed.2:2010, Ed.3:2017

IEC 60601-2-29: Radiotherapy Stimulators. Ed.3:2008

IEC/ISO 80601-2-30: Automated non-invasive sphygmomanometers. Ed.1:2013, Ed.2:2018, Ed.3 (Project 2025-05)

IEC 60601-2-31: External Cardiac Pacemakers with Internal Power Source. Ed.2:2008, AMD1:2011, Ed.3:2020

IEC/ISO 80601-2-31: External Cardiac Pacemakers with Internal Power Source. Ed.1 (Replacing IEC 60601-2-31) (Project 2024-12)
~~IEC 60601-2-32: Associated Equipment of X-ray Equipment. (Incorporated into IEC 60601-2-54)~~


MECA IEC 60601, IEC/ISO 80601 Medical Electrical Equipment Standards List [Rev. 2024-04-16]

IEC 60601-2-33: Magnetic Resonance Equipment for Med. Diagnosis. Ed.3:2010, AMD1:2013, AMD2:2015, Ed.4:2022 [-2025-08]
IEC 60601-2-34: Invasive Blood Pressure Monitoring Equipment. Ed.3:2011, Ed.4 (Project 2024-06)
IEC 60601-2-35: Heating devices using blankets, pads, mattresses. Ed.2:2020, AMD1:2023 [-2026-12]
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 60601-2-36: Extracorporeally Induced Lithotripsy. Ed.2:2014
IEC 60601-2-37: Ultrasonic Diagnostic and Monitoring Equipment. Ed.2:2007, AMD1:2015, Ed.3 (Project 2024-06)
IEC 60601-2-38: Electrically Operated Hospital Beds. (Moved to IEC 60601-2-52)
IEC 60601-2-39: Peritoneal Dialysis Equipment. Ed.2:2007, Ed.3:2018, Ed.4 (Project 2024-06)
IEC 60601-2-40: Electromyographs and Evoked Response Equipment. Ed.2:2016, Ed.3 (Project 2024-11)
IEC 60601-2-41: Surgical Luminaires and Luminaires for Diagnosis. Ed.2:2009, AMD1:2013, Ed.3:2021 [-2024-09]
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, AMD1:2017, AMD2:2019, Ed.3:2022 [-2025-12]
IEC 60601-2-44: X-ray Equipment for Computed Tomography. Ed.3:2009, AMD1:2012, AMD2:2016
IEC 60601-2-45: Mammographic X-ray equipment & stereotactic devices. Ed.3:2011, AMD1:2015, AMD2:2022 [-2025-08]
IEC 60601-2-46: Operating Tables. Ed.2:2010, Ed.3:2016, Ed.4:2023 [-2026-05]
IEC 60601-2-47: Ambulatory Electrocardiographic Monitors. [Holter Monitors]. Ed.2:2012
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: Multifunction Patient Monitoring Equipment. Ed.1:2018, AMD1 (Project 2024-06)
IEC 60601-2-50: Infant phototherapy equipment. Ed.2:2009, AMD1:2016, Ed.3:2020, AMD1:2023 [-2026-10]
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. (Replaced IEC 60601-2-38) Ed.1:2009, AMD1:2015
IEC 80601-2-52: Safety of Medical Beds. Ed.1 (Replacing IEC 60601-2-52) (Project 2025-04)
IEC 60601-2-53: Computer Assisted Electrocardiography Communication Protocol. (Canceled)
IEC 60601-2-54: X-ray equipment for radiography and radioscopy. Ed.1:2009, AMD1:2015, AMD2:2018, Ed.2:2022 [-2025-09]
ISO 80601-2-55: Respiratory gas monitors. Ed.1:2011, Ed.2:2018, AMD1:2023 [-2026-12]
ISO 80601-2-56: Clinical thermometers for body temperature measurement. Ed.2:2017, AMD1:2018, Ed.3 (Project 2025-01)
IEC 60601-2-57: Non-laser light source equipment - therapeutic, diagnostic, monitoring, cosmetic/aesthetic use. Ed.1:2011, Ed.2:2023 [-2026-07]
IEC/ISO 80601-2-58: Lens removal and vitrectomy devices for ophthalmic surgery. Ed.2:2014, AMD1:2016, Ed.3:2024 [-2027-03]
IEC/ISO 80601-2-59: Screening thermographs for human febrile temperature screening. Ed.2:2017, AMD1:2023 [-2026-01]
IEC/ISO 80601-2-60: Dental equipment. Ed.1:2012, Ed.2:2019
ISO 80601-2-61: Pulse Oximeter equipment. Ed.1:2011, Ed.2:2017, Ed.3 (Project 2025-05)
IEC 60601-2-62: High intensity therapeutic ultrasound (HITU) systems. Ed.1:2013
IEC 60601-2-63: Dental X-ray equipment. Ed.1:2012, AMD1:2017, AMD2:2021 [-2024-05]
IEC 60601-2-64: Medical light ion accelerators in the range 10 MeV/n to 500 MeV/n. Ed.1:2014, AMD1 (Project 2025-10)
IEC 60601-2-65: Dental intra-oral X-ray equipment. Ed.1:2012, AMD1:2017, AMD2:2021 [-2024-05]
IEC 60601-2-66: Hearing Instruments and Hearing Systems. Ed.1:2012, Ed.2:2015, Ed.3:2019, Ed.4 (Project 2026-05)
IEC/ISO 80601-2-67: Oxygen-conserving equipment. Ed.1:2014, Ed.2:2020, Ed.3 (Project 2026-05)
IEC 60601-2-68: X-ray Image Guided Radiotherapy Equip. (electron accelerators, radionuclide beam therapy). Ed.1:2014, AMD1 (Project 2024-12)
ISO 80601-2-69: Oxygen concentrator equipment. Ed.1:2014, Ed.2:2020, Ed.3 (Project 2026-05)
ISO 80601-2-70: Sleep apnea breathing therapy equipment. Ed.1:2015, Ed.2:2020, Ed.3 (Project 2026-05)
IEC/ISO 80601-2-71: Near-Infrared Spectroscopy (NIRS) Equipment. Ed.1:2015, Ed.2 (Project 2024-10)
ISO 80601-2-72: Home healthcare environment ventilators for ventilator-dependent patients. (from ISO 10651-2) Ed.1:2015, Ed.2:2023 [-2026-06]
IEC 80601-2-73: Medical supply units (head walls). (2017 Proposal not approved)
ISO 80601-2-74: Respiratory humidifying equipment. Ed.1:2017, Ed.2:2021 [-2024-07], Ed.3 (Project 2026-05)
IEC 60601-2-75: Photodynamic Therapy and Diagnosis equipment. Ed.1:2017, AMD1:2023 [-2026-01]
IEC 60601-2-76: Low energy ionized gas haemostasis (Coagulation) equipment. Ed.1:2018, AMD1:2023 [-2026-08]
IEC/ISO 80601-2-77: Medical Robots for Surgery. Ed.1:2019, AMD1:2023 [-2026-11]
IEC/ISO 80601-2-78: Medical Robots for Rehabilitation, Compensation, Alleviation of Disease, Injury, Disability. Ed.1:2019, AMD1:2024 [-2027-03]
ISO 80601-2-79: Home Health Ventilatory Support Equipment for Respiratory Impairment. Ed.1:2018, Ed.2 (Project 2024-12)
ISO 80601-2-80: Home Health Ventilatory Support Equipment for Respiratory Insufficiency. Ed.1:2018, Ed.2 (Project 2024-12)
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: Home light therapy equipment. Ed.1:2019, AMD1:2022 [-2025-12]
ISO 80601-2-84: Emergency and transport ventilators. Ed.1:2020, Ed.2:2023 [-2026-11]
ISO 80601-2-85: Cerebral tissue oximeter equipment. Ed.1:2021 [-2024-03]
ISO/IEC 80601-2-86: Electrocardiographs, diagnostic, monitoring, ambulatory, electrodes, cables, leadwires. (replace -2-25, 27, 47) (Cancelled, Restarting)
ISO 80601-2-87: High frequency critical care ventilators. Ed.1:2021
IEC/ISO 80601-2-88: Infant Cardiorespiratory Monitors For Home Health. (Changed to ISO 18778:2007)
IEC 80601-2-89: Medical Beds for Children. Ed.1 (Project 2025-04)
ISO 80601-2-90: Ventilatory High-Flow Therapy Equipment. Ed.1:2021 [-2024-08], Ed.2 (Project 2026-05)
IEC 60601-2-91: Non-thermal plasma wound treatment equipment. Ed.1 (Project 2025-05)
IEC 60601-2-92: MRI based image guided radiotherapy equipment for use with electron accelerators. Ed.1 (Project 2025-07)
IEC 60601-2-93: Neutron capture therapy equipment. Ed.1 (Project 2025-07)
ISO 80601-2-94: Inhalational therapy nebulizer equipment. Ed.1 (Project 2026-10)



IEC/TR 60601-4-x Technical Reports, Interpretations, 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
IEC TS 60601-4-2:	Guidance and interpretation; Electromagnetic immunity, performance. Ed.1:2016, Ed.2:2024
IEC TR 60601-4-3:	Considerations of unclear/unaddressed safety aspects of IEC 60601-1 Ed.3, Proposals. Ed.1:2015, Ed.2:2018
IEC TR 60601-4-4:	Guidance for writers of particular standards, creating alarm system-related requirements. Ed.1:2017
IEC TR 60601-4-5:	Guidance and interpretation – Safety related technical security specifications for medical devices. Ed.1:2021
IEC TS 60601-4-6:	<i>Guidance to help achieve basic safety, essential performance - possible effects of EM disturbances. Ed.1 (Project 2024-05)</i>
IEC TS 60601-4-7:	<i>Physiological and Anthropometric Characteristics for human and animal patients. Ed.1 (Project 2027-09)</i>
IEC TR 62353:	Recurrent test and test after repair of medical electrical equipment. Ed.2:2014
IEC TR 62354:	General testing procedures for medical equipment. Ed.3:2014

IEC 60601-1 Referenced Standards:

Below Referenced by IEC 60601-1. Where reference Edition specified: Edition 3.1, Edition 3.1 & 3.2, Edition 3.2 (No Edition/Date references: not highlighted)

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 TR 62471-4:	Photobiological safety of lamps and lamp systems - Measuring methods,
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)
IEC 62366-1:	Application of Usability engineering to medical devices. Ed.1 (2015-02), Ed.1.1 (2020-06)
IEC 60529:	Degrees of Protection Provided by Enclosures. (IPXX Ratings) Ed.2 (1989), AMD1 (Ed.2.1) (1999), AMD2 (Ed.2.2) (2013), COR:2019
IEC 60950-1:	Information Technology Equipment Safety. Ed.2 (2005-12) (replaced by IEC 62368 below)
IEC 62368-1:	Audio/video, information, communication technology equipment. Ed.3 (2018-10) (combines IEC 60950-1, IEC 60065, UL 62368)
CSA C22.2 No. 0.4-17:	Bonding of Electrical Equipment (Canadian Protective Earthing). Ed.4 (2017-04), R2022