

**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 Started ~2025)**

Countries with Specified Transition Dates to new Edition 3.2:

- United States: **[2023-12-17]**
- 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 above)*

**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) **[~2024-01]**
- ~~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 (Project 2024-03)**
- 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 2024-04)**
- IEC 60601-2-17: Automatically-controlled brachytherapy afterloading equipment. Ed.3:2013
- IEC 60601-2-18: Endoscopic Equipment. Ed.3:2009, **Ed.4 (Project 2023-08?, Reference of project Removed)**
- 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, **Ed.4 (Project 2024-12)**
- IEC 60601-2-24: Infusion Pumps and Controllers. Ed.2:2012, **Ed.3 (Project 2024-12)**
- 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 (Project 2024-04)**
- 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 2024-09)**
- 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. (Replacing IEC 60601-2-31) Ed.1 (Project 2024-12)**
- ~~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.3:2010, AMD1:2013, AMD2:2015, Ed.4:2022 **[~2025-08]**



**MECA IEC 60601, IEC/ISO 80601 Medical Electrical Equipment Standards List [Rev. 2024-01-30]**

IEC 60601-2-34: Invasive Blood Pressure Monitoring Equipment. Ed.3:2011, <a href="#">Ed.4 (Project 2024-04)</a>
<del>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)</del>
IEC 60601-2-35: Heating devices using blankets, pads, mattresses. Ed.2:2020, AMD1:2023 <b>[~2026-12]</b>
IEC 60601-2-36: Extracorporeally Induced Lithotripsy. Ed.2:2014
IEC 60601-2-37: Ultrasonic Diagnostic and Monitoring Equipment. Ed.2:2007, AMD1:2015, <a href="#">Ed.3 (Project 2024-08)</a>
<del>IEC 60601-2-38: Electrically Operated Hospital Beds. (Moved to IEC 60601-2-52)</del>
IEC 60601-2-39: Peritoneal Dialysis Equipment. Ed.2:2007, Ed.3:2018, <a href="#">Ed.4 (Project 2024-04)</a>
IEC 60601-2-40: Electromyographs and Evoked Response Equipment. Ed.2:2016, <a href="#">Ed.3 (Project 2024-11)</a>
IEC 60601-2-41: Surgical Luminaires and Luminaires for Diagnosis. Ed.2:2009, AMD1:2013, Ed.3:2021 <b>[~2024-09]</b>
<del>IEC 60601-2-42: Automatic or Advisory External Defibrillators. (Incorporated into IEC 60601-2-4)</del>
IEC 60601-2-43: X-ray Equipment for Interventional Procedures. Ed.2:2010, AMD1:2017, AMD2:2019, Ed.3:2022 <b>[~2025-12]</b>
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 <b>[~2025-08]</b>
IEC 60601-2-46: Operating Tables. Ed.2:2010, Ed.3:2016, Ed.4:2023 <b>[~2026-05]</b>
IEC 60601-2-47: Ambulatory Electrocardiographic Monitors. [Holter Monitors]. Ed.2:2012
<del>IEC 60601-2-48: Unknown. (Canceled)</del>
<del>IEC 60601-2-49: Multiparameter Patient Monitoring Equipment. Ed.2 (2011-02) (Moved to 80601-2-49)</del>
IEC/ISO 80601-2-49: Multiparameter Patient Monitoring Equipment. Ed.1:2018, <a href="#">AMD1 (Project 2024-04)</a>
IEC 60601-2-50: Infant phototherapy equipment. Ed.2:2009, AMD1:2016, Ed.3:2020, AMD1:2023 <b>[~2026-10]</b>
<del>IEC 60601-2-51: Recording and analyzing single and Multichannel electrocardiographs. (Incorporated into IEC 60601-2-25)</del>
IEC 60601-2-52: Safety of Medical Beds. (Replaced IEC 60601-2-38) Ed.1:2009, AMD1:2015
<a href="#">IEC 80601-2-52: Safety of Medical Beds. (Replacing IEC 60601-2-52) Ed.1 (Project 2024-12)</a>
<del>IEC 60601-2-53: Computer Assisted Electrocardiography Communication Protocol. (Canceled)</del>
IEC 60601-2-54: X-ray equipment for radiography and radioscopy. Ed.1:2009, AMD1:2015, AMD2:2018, Ed.2:2022 <b>[~2025-09]</b>
ISO 80601-2-55: Respiratory gas monitors. Ed.1:2011, Ed.2:2018, <a href="#">AMD1 (Project 2024-08)</a>
ISO 80601-2-56: Clinical thermometers for body temperature measurement. Ed.2:2017, AMD1:2018, <a href="#">Ed.3 (Project 2025-01)</a>
IEC 60601-2-57: Non-laser light source equipment - therapeutic, diagnostic, monitoring, cosmetic/aesthetic use. Ed.1:2011, Ed.2:2023 <b>[~2026-07]</b>
IEC/ISO 80601-2-58: Lens removal and vitrectomy devices for ophthalmic surgery. Ed.2:2014, AMD1:2016, <a href="#">Ed.3 (Project 2024-03)</a>
IEC/ISO 80601-2-59: Screening thermographs for human febrile temperature screening. Ed.2:2017, AMD1:2023 <b>[~2026-01]</b>
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, <a href="#">Ed.3 (Project 2024-09)</a>
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 <b>[~2024-05]</b>
IEC 60601-2-64: Medical light ion accelerators in the range 10 MeV/n to 500 MeV/n. Ed.1:2014, <a href="#">AMD1 (Project 2025-10)</a>
IEC 60601-2-65: Dental intra-oral X-ray equipment. Ed.1:2012, AMD1:2017, AMD2:2021 <b>[~2024-05]</b>
IEC 60601-2-66: Hearing Instruments and Hearing Systems. Ed.1:2012, Ed.2:2015, Ed.3:2019, <a href="#">Ed.4 (Project 2026-05)</a>
IEC/ISO 80601-2-67: Oxygen-conserving equipment. Ed.1:2014, Ed.2:2020, <a href="#">Ed.3 (Project 2026-05)</a>
IEC 60601-2-68: X-ray Image Guided Radiotherapy Equip. (electron accelerators, radionuclide beam therapy). Ed.1:2014, <a href="#">AMD1 (Project 2024-09)</a>
ISO 80601-2-69: Oxygen concentrator equipment. Ed.1:2014, Ed.2:2020 <b>[~2023-11]</b> , <a href="#">Ed.3 (Project 2026-05)</a>
ISO 80601-2-70: Sleep apnea breathing therapy equipment. Ed.1:2015, Ed.2:2020 <b>[~2023-11]</b>
IEC/ISO 80601-2-71: Near-Infrared Spectroscopy (NIRS) Equipment. Ed.1:2015, <a href="#">Ed.2 (Project 2024-10)</a>
ISO 80601-2-72: Home healthcare environment ventilators for ventilator-dependent patients. (from ISO 10651-2) Ed.1:2015, Ed.2023 <b>[~2026-06]</b>
<del>IEC 80601-2-73: Medical supply units (head walls). (2017 Proposal not approved)</del>
ISO 80601-2-74: Respiratory humidifying equipment. Ed.1:2017, Ed.2:2021 <b>[~2024-07]</b> , <a href="#">Ed.3 (Project 2026-05)</a>
IEC 60601-2-75: Photodynamic Therapy and Diagnosis equipment. Ed.1:2017, AMD1:2023 <b>[~2026-01]</b>
IEC 60601-2-76: Low energy ionized gas haemostasis (Coagulation) equipment. Ed.1:2018, AMD1:2023 <b>[~2026-08]</b>
IEC/ISO 80601-2-77: Medical Robots for Surgery. Ed.1:2019, AMD1:2023 <b>[~2026-11]</b>
IEC/ISO 80601-2-78: Medical Robots for Rehabilitation, Compensation, Alleviation of Disease, Injury, Disability. Ed.1:2019, <a href="#">AMD1 (Project 2024-03)</a>
ISO 80601-2-79: Home Health Ventilatory Support Equipment for Respiratory Impairment. Ed.1:2018, <a href="#">Ed.2 (Project 2024-11)</a>
ISO 80601-2-80: Home Health Ventilatory Support Equipment for Respiratory Insufficiency. Ed.1:2018, <a href="#">Ed.2 (Project 2024-11)</a>
<del>IEC/ISO 80601-2-81: Electric Radial Pulse Tonometric Devices. (2018 Proposal not approved)</del>
<del>IEC/ISO 80601-2-82: Electro-Acupuncture Stimulators. (2018 Proposal not approved)</del>
IEC 60601-2-83: Home light therapy equipment. Ed.1:2019, AMD1:2022 <b>[~2025-12]</b>
ISO 80601-2-84: Emergency and transport ventilators. Ed.1:2020, <a href="#">Ed.2 (Project 2024-03)</a>
ISO 80601-2-85: Cerebral tissue oximeter equipment. Ed.1:2021 <b>[~2024-03]</b>
<a href="#">ISO/IEC 80601-2-86: Electrocardiographs, diagnostic, monitoring, ambulatory, electrodes, cables, leadwires. (replace -2-25, 27, 47) (Project)</a>
ISO 80601-2-87: High frequency critical care ventilators. Ed.1:2021 <b>[~2024-03]</b>
<del>IEC/ISO 80601-2-88: Infant Cardiorespiratory Monitors For Home Health. (Changed to ISO 18778:2007)</del>
<a href="#">IEC 80601-2-89: Medical Beds for Children. Ed.1 (Project 2024-11)</a>
ISO 80601-2-90: Ventilatory High-Flow Therapy Equipment. Ed.1:2021 <b>[~2024-08]</b> , <a href="#">Ed.2 (Project 2026-05)</a>
<a href="#">IEC 60601-2-91: Non-thermal plasma wound treatment equipment. Ed.1 (Project 2025-01)</a>
<a href="#">IEC 60601-2-92: MRI based image guided radiotherapy equipment for use with electron accelerators. Ed.1 (Project 2025-07)</a>
<a href="#">IEC 60601-2-93: Neutron capture therapy equipment. Ed.1 (Project 2025-07)</a>
<a href="#">ISO 80601-2-94: Inhalational therapy nebulizer equipment. Ed.1 (Project 2026-10)</a>

**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 TR 60601-4-2: Guidance and interpretation; Electromagnetic immunity, performance. Ed.1:2016
<a href="#">IEC TS 60601-4-2: Electromagnetic immunity: Performance of medical electrical equipment and medical electrical systems. Ed.1 (Project 2024-02)</a>
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
<a href="#">IEC TS 60601-4-6: Guidance to help achieve basic safety, essential performance - possible effects of EM disturbances. Ed.1 (Project 2024-02)</a>
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)

**IEC 60601-1 Referenced Standards:**

Below Referenced by IEC 60601-1. Where reference Edition specific, IEC 60601-1, [Edition 3.1](#), [Edition 3.1 & 3.2](#), [Edition 3.2](#)

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