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[RED] dates are anticipated regulatory deadlines for specified new Editions/Amendments
[BLUE] are Projects for Editions/Amendment 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 (2020-08-20)
(Also referred to as) **IEC 60601-1, Edition 3.2**
Edition 4 (Project ~2025+)

History of Editions of the IEC Medical Electrical Equipment standards:

2020: IEC 60601-1:2005+AMD1:2012+AMD2:2020 (Ed.3.2)
2012: IEC 60601-1:2005+AMD1:2012/COR1:2012 (Cor)
2012: IEC 60601-1:2005+AMD1:2012 (Ed.3.1)
2005: IEC 60601-1:2005/COR2 (Cor)
2005: IEC 60601-1:2005/COR1 (Cor)
2005: IEC 60601-1:2005 (Ed.3)
1997-xx-xx: IEC 60601-1:1988/AMD2:1995 (IEC added "60" to standards)
1995-06-01: IEC 601-1:1988/AMD2:1995/COR1:1995 (Cor)
1995-03-07: IEC 601-1:1988/AMD2:1995 (Ed.2.2)
1991-11-13: IEC 601-1:1988/AMD1:1991 (Ed.2.1)
1988-12-30: IEC 601-1:1988 (Ed.2)
1984-01-01: IEC 601-1:1977/AMD1:1984 (Ed.1.1)
1977-01-01: IEC 601-1:1977 (Ed.1)

National Standards, based on IEC 60601-1

USA

ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (2012-08-17) **[Required now]**
(Also referred to as) **ANSI/AAMI ES60601-1:2005/(R)2012**
IEC Ed.3.2 equivalent (Project ~2020+)

(IEC 60601-1, Edition 3.1 + US Differences)
FDA Regulatory Submittals: ANSI/AAMI ES60601-1:2005/(R)2012 (IEC Edition 3.1)
NRTL Safety Marks (per OSHA): IEC/AAMI/UL Editions 2, 3, 3.1 (no cessation dates for Edition 2 or 3 yet). *Some NRTLs only accepting Edition 3.1*

USA History - Editions of the Medical Electrical Equipment standards:

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)
1997: UL2601-1, Ed.2 (IEC Ed.2)
1994: UL 2601-1, Ed.1 (IEC Ed.2)
1972: UL 544 (Medical & Dental); UL 187 (X-Ray Equipment)

CANADA

CAN/CSA-C22.2 No. 60601-1:14 (2014-03-01) **[Required now]**
IEC Ed.3.2 equivalent (Project ~2020+)

(IEC 60601-1, Edition 3.1 + Canadian Differences)
Health Canada Regulatory Submittals: 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). Most *SCC labs only accepting Edition 3.1*

Canada History - Editions of the Medical Electrical Equipment standards:

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

EUROPEAN UNION Countries (Including Britain and other countries specified in table on following page)

EN 60601-1:2006/A1:2013 (2013-10-03) + **A.12:2014** (2014-10-02) **[Required now]**
IEC Ed.3.2 equivalent (Project ~2020+)

(IEC 60601-1, Edition 3.1 + European Differences in EN Amendment 12), Required Standards/Editions specified in the EU Official Journal (OJ)
Notified Body Regulatory Submittals for CE Marking:
Medical Device Directive (MDD) [Until May 26, 2021],
Medical Device Regulation (MDR) [Required by May 26, 2021] [Required by May 25, 2024 if already on the market] *(conditional)*

EU History - Editions of the Medical Electrical Equipment standards:

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

JAPAN

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

(IEC 60601-1, Edition 3.1 + Japanese Differences)

REPUBLIC OF KOREA

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

(IEC 60601-1, Edition 3.1 + Korea Differences),
(Notification of MFDS No.2020-12, Annex 1: 110/220/380V, 60Hz, KSC 8305 and 8300 mains plugs, Korean language IFU and markings)

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CHINA

GB 9706.1-2007 (2008-07-01), (IEC Ed.2.2) **[Required or see below, will be withdrawn May 1, 2023]**
(IEC 60601-1, Edition 2.2 + China Differences)

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

China History of Editions of the Medical Electrical Equipment standards:

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)

Additional Countries accepting IEC/EN 60601-1, Edition 3.1, without modification *(not all inclusive)*

Albania: SSH EN 60601-1:2006+A1:2013+AC:2014
*Australia: AS/NZS IEC 60601.1:2015
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
Korea: IEC 60601-1:2012 / MDFS No. 2020-12, Annex 1
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
*Mexico: Equivalency Agreement for Canada and USA (MX-006, 10/2010-10)
Montenegro: MEST EN 60601-1:2010+A1:2015+A12:2015
Netherlands (NO): NEN-EN-IEC 60601-1:2006+A1:2013+A12:2014
*New Zealand: AS/NZS IEC 60601.1:2015
Norway (NO): NEK EN 60601-1:2006+A1:2013
Poland (PL): PN-EN 60601-1:2011+A12:2014+AC1:2015
*Russia: IEC 60601-1:2005+AMD1:2012
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

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. NOTE: 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.

USA OSHA list of NRTLs (safety marks) with locations for Medical Electrical Equipment

Under standards ANSI/AAMI ES60601-1 (3rd Edition) and UL 60601-1 (2nd Edition) where noted (2020-11-05)

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 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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Collateral and Particular Standards under IEC 60601-1

Latest Editions/Amendments are required, except where noted with **[Year]** for end of transition period.
Specified **[Year]** for new Standards/Editions/Amendments considered typical three year transition, unless full transition date specified **[Year-Month]**.
[BLUE] are Projects for Standards/Editions/Amendment with anticipated publish dates (Reference Only)
IEC publishes the **6**0601-x-x standards. **ISO** or **IEC + ISO** (jointly) publishes the **8**0601-x-x standards.

IEC 60601-1-xx (Collaterals):

~~60601-1-01: Safety Requirements for Medical Electrical Systems. Ed.2~~ (Now in base IEC 60601-1 standard)
60601-1-02: Electromagnetic Compatibility (EMC). Ed.3 (2007-03), IS1 (2010-03), Ed. 4 (2014-02), Am.1Ed.4.1 (2020-09) **[2023]**
60601-1-03: Radiation Protection in Diagnostic X-ray Equipment. Ed.2 (2008-01), Am.1 Ed.2.1 (2013-04), Am.2 (Project 2021-03)
~~60601-1-04: Programmable Electrical Medical Systems.~~ (Now in base IEC 60601-1 standard)
~~60601-1-05: Image quality and dose for X-ray equipment.~~ (Cancelled)
60601-1-06: Usability. Ed.3.1 (2013-10), Am.2 Ed.3.2 (2020-07) **[2023]**
- *Above standard references IEC 62366 Ed.1 (2007-10) for Ed.3.1 of -1-6, IEC 62366-1:2015 Ed.1 (2015-02) for Ed.3.2 of -1-6*
~~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 Ed.2.2 (2020-07) **[2023]**
60601-1-09: Reduction of environmental impacts. Ed.1 (2007-07), Am.1 Ed.1.1 (2013-06), Am.2 Ed.1.2 (2020-07) **[2023]**
60601-1-10: Development of therapeutic closed-loop controllers. Ed.1 (2007-11), Am.1 Ed.1.1 (2013-11), Am.2 Ed.1.2 (2020-07) **[2023]**
60601-1-11: Medical Electrical Equipment for Use in Home Care. Ed.1 (2010-04), Ed.2 (2015-01), Am.1 Ed.2.1 (2020-07) **[2023]**
60601-1-12: ME and MES used in the emergency medical services environment. Ed.1 (2014-06), Am.1 Ed.1.1 (2020-07) **[2023]**

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 (2020-10) **[2023]**
60601-2-02: High Frequency Surgical Equipment. Ed.5 (2009-02), Ed.6 (2017-03)
60601-2-03: Short-Wave Therapy Equipment. Ed.3 (2012-04), Am.1 Ed.3.1 (2016-04)
60601-2-04: Cardiac Defibrillators, Defibrillator-Monitors. Ed.3 (2010-12), Am.1 Ed.3.1 (2018-02) **[2021]**
60601-2-05: Ultrasonic Therapy Equipment. Ed.3 (2009-07)
60601-2-06: Microwave Therapy Equipment. Ed.2 (2012-04), Am.1 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 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 Ed.2.1 (2016-04)
60601-2-11: Gamma Beam Therapy Equipment. Ed.3 (2013-01)
80601-2-12: Critical Care Ventilators. Ed.1 (2011-05), Ed.2 (2020-02) **[2023]**
80601-2-13: Anesthetic Workstation. Ed.1 (2011-08), Am.1 (2015-03), Am.2 (2018-07) **[2021]**, Ed.2 (Project 2021-07)
~~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), Ed.4. (2012-03), Ed.5 (2018-04) **[2021]**
60601-2-17: Automatically-controlled brachytherapy afterloading equipment. Ed.3 (2013-11)
60601-2-18: Endoscopic Equipment. Ed.3 (2009-08), Ed.4 (Project 2021-12)
60601-2-19: Infant Incubators. Ed.2 (2009-02), Corr.1 (2012-02), Am.1 Ed.2.1 (2016-04), Ed.3 (2020-09) **[2023]**
60601-2-20: Infant transport incubators. Ed.2 (2009-02), Corr.1 (2012-02), Corr.2 (2013-02), Am.1 Ed.2.1 (2016-04), Ed.3 (2020-09) **[2023]**
60601-2-21: Infant Radiant Warmers. Ed.2 (2009-02), Corr.1 (2013-02), Am.1 Ed.2.1 (2016-04), Ed.3 (2020-09) **[2023]**
60601-2-22: Surgical, cosmetic, therapeutic, and diagnostic laser equipment. Ed.3.1 (2012-10), Ed.4 (2019-11) **[2022]**
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)~~ (Moved to 80601-2-49)
80601-2-26 Electroencephalographs. Ed.1 (2019-05) **[2022]**
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: Automated non-invasive sphygmomanometers. Ed.1.1 (2013-07), Ed.2 (2018-03) **[2021]**
60601-2-31: External Cardiac Pacemakers with Internal Power Source. Ed.2 (2008-03), Am.1 Ed.2.1 (2011-09), Ed.3 (2020-01) **[2023]**
~~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 Ed.3.2 (2015-06), Corr.2 (2016-02), Ed.4 (Project 2022-01)
60601-2-34: Invasive Blood Pressure Monitoring Equipment. Ed.3 (2011-05)
80601-2-35: Heating devices using blankets, pads, mattresses. Ed.2 (2009-10), Am.1 (2016-04) (moved back to IEC 60601 standard)
60601-2-35: Heating devices using blankets, pads, mattresses. (moved back to IEC 60601 from IEC/ISO 80601) Ed.2 (2020-09) **[2023]**
60601-2-36: Extracorporeally Induced Lithotripsy. Ed.2 (2014-04)
60601-2-37: Ultrasonic Diagnostic and Monitoring Equipment. Ed.2 (2007-08), Am.1 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) **[2021]**
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 Ed.2.1 (2013-10), Ed.3 (Project 2021-08)
~~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 Ed.2.1 (2017-05), Am.2 (2019-10) **[2022]**
60601-2-44: X-ray Equipment for Computed Tomography. Ed.3 (2009-02), Am.1 Ed.3.1 (2012-09), Am.2 Ed.3.2 (2016-03)
60601-2-45: Mammographic X-ray equipment and mammomagraphic stereotactic devices. Ed.3 (2011-02), Am.1 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: Unknown.~~ (Canceled)
~~60601-2-49: Multiparameter Patient Monitoring Equipment.~~ Ed.2 (2011-02) (Moved to 80601-2-49)
80601-2-49: Multiparameter Patient Monitoring Equipment. Ed.1 (2018-03) **[2021]**

Check for the latest revision, FREE to download on MECA's website at https://60601-1.com/information/
Compiled by Brian Biersach, 2020-11-05

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60601-2-50: Infant phototherapy equipment. Ed.2 (2009-03), Corr.1 (2010-08), Am.1 Ed.2.1 (2016-04), Ed.3 (2020-09) **[2023]**
~~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 Ed.1.1 (2015-03)
80601-2-52: Safety of Medical Beds. *(replaces IEC **6**0601-2-52)*. Ed.1 (Project 2022-04)
~~60601-2-53: Computer Assisted Electrocardiography Communication Protocol.~~ (Canceled)
60601-2-54: X-ray equipment for radiography and radioscopy. Ed.1 (2009-06), Am.1 Ed.1.1 (2015), Am.2 Ed.1.2 (2018-06) **[2021]**
80601-2-55: Respiratory gas monitors. Ed.1 (2011-12), Ed.2 (2018-02) **[2021]**
80601-2-56: Clinical thermometers for body temperature measurement. Ed.1 (2009-012), Ed.2 (2017-03), Am.1 Ed.2.1 (2018-12) **[2021]**
60601-2-57: Non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use. Ed.1 (2011-01)
80601-2-58: Lens removal devices and vitrectomy devices for ophthalmic surgery. Ed.1 (2008-10), Ed.2 (2014-09), Am.1 Ed.2.1 (2016-10)
80601-2-59: Screening thermographs for human febrile temperature screening. Ed.1 (2008-10), Ed.2 (2017-09)
80601-2-60: Dental equipment. Ed.1 (2012-02), Ed.2 (2019-06) **[2022]**
80601-2-61: 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 Ed.1.1 (2017-07), Am.2 (Project 2021-04)
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 Ed.1.1 (2017-05), Am.2 (Project 2021-04)
60601-2-66: Hearing Instruments and Hearing Systems. Ed.1 (2012-10), Ed.2 (2015-06), Ed.3 (2019-10) **[2022]**
80601-2-67: Oxygen-conserving equipment. Ed.1 (2014-05), Ed.2 (2020-10) **[2023]**
60601-2-68: X-ray Image Guided Radiotherapy Equip. (electron accelerators, ion, radionuclide beam therapy). Ed.1 (2014-09), Am.1 (Project 2022-12)
80601-2-69 Oxygen concentrator equipment. Ed.1 (2014-05), Ed.2 (2020-11) **[2023]**
80601-2-70: Sleep apnea breathing therapy equipment. Ed.1 (2015-01), Ed.2 (Project 2021-04)
80601-2-71: Functional Oximeter equipment. Ed.1 (2015-06)
80601-2-72: Home healthcare environment ventilators for ventilator-dependent patients. *(from ISO 10651-2:2004)* Ed.1 (2015-09)
~~80601-2-73: Medical supply units (head walls).~~ (2017 Proposal not approved)
80601-2-74: Respiratory humidifying equipment. Ed.1 (2017-05), Ed.2 (Project 2021-11)
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) **[2021]**
80601-2-77: Medical Robots for Surgery. Ed.1 (2019-07) **[2022]**
80601-2-78: Medical Robots for Rehabilitation, Compensation, Alleviation of Disease, Injury, Disability. Ed.1 (2019-07) **[2022]**
80601-2-79: Home Health Ventilatory Support Equipment for Respiratory Impairment. Ed.1 (2018-07) **[2021]**
80601-2-80: Home Health Ventilatory Support Equipment for Respiratory Insufficiency. Ed.1 (2018-07) **[2021]**
~~80601-2-81: Electric Radial Pulse Tonometric Devices.~~ (2018 Proposal not approved)
~~80601-2-82: Electro-Acupuncture Stimulators.~~ (2018 Proposal not approved)
60601-2-83: Ionized Gas Coagulation Equipment. Ed.1 (2019-05) **[2022]**
80601-2-84: Emergency and transport ventilators. Ed.1 (2020-07) **[2023]**
80601-2-85: Cerebral tissue oximeter equipment. Ed.1 (Project 2021-02)
80601-2-86: Electrocardiographs - diagnostic, monitoring, ambulatory, electrodes, cables, leadwires. (to replace -2-25, 27, 47) Ed.1 (Project 2021-10)
80601-2-87: High frequency critical care ventilators. Ed.1 (Project 2021-08)
80601-2-88: Infant Cardiorespiratory Monitors *(for Home Health). (to replace ISO 18778:2007)* Ed.1 (Project ???)
80601-2-89: Medical Beds for Children. Ed.1 (Project 2022-03)
80601-2-90: Ventilatory High-Flow Therapy Equipment. Ed.1 (Project 2021-11)

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, new requirements. 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 (Project 2021-02)

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:

ISO 17025: General Requirements for the Competence of **Testing and Calibration Laboratories**. Ed.2 (2005), Ed.2.1 (2006), Ed.3 (2017)
ISO 14971: **Risk Management** for Medical Devices. Ed.2 (2007-03) *60601-1 Ed.3.1 ref.*, Ed.3 (2019-12) *60601-1 Ed.3.2 ref.*
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 by Limbs. Ed.1 (2008-03) *60601-1 Ed.3.1, 3.2 ref.*, Ed.2 (2019)
IEC 62304: **Software** Life Cycle Processes for Medical Equipment. Ed.1 (2006-05) *60601-1 Ed.3.1 ref.*, Ed.1.1 (2015-06) *IEC 60601-1 Ed.3.2 ref.*
IEC 62366: Application of **Usability** engineering to medical devices. Ed.1 (2007-10) *60601-1 Ed.3.1 ref.*, Ed.1.1 (2014-01) Not referenced
IEC 62366-1: Application of **Usability** engineering to medical devices. Ed.1 (2015-02) *60601-1 Ed.3.2 ref.*, Ed.1.1 (2020-06) Not referenced
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