

IEC 60601-1-6:2006: Usability
Additional Risk Management Requirements
IEC 60601-1-6:2010: Usability
Additional Risk Management Requirements
IEC 62366
IEC 60601-1-8:2003: Alarms
PEMS/IEC60601-1-4
Additional Manual/Markings Requirements
IEC 60601-1-8:2006: Alarms
PEMS/Clause 14
Additional Manual/Markings Requirements
Additional Risk Management Requirements
IEC 60601-1-8:2012: Alarms
PEMS/(IEC 62304, Ed 3.1 only)
Additional Manual/Markings Requirements
Additional Risk Management Requirements
IEC 60601-1-10:2007: Therapeutic Closed-loop Controllers
PEMS/Clause 14 (Frequently Applicable)
Usability (-1-6)/IEC 62366
Alarms (-1-8) (Frequently Applicable)
IEC 60601-1-10:2013: Therapeutic Closed-loop Controllers
PEMS/(IEC 62304, Ed 3.1 only) (Frequently Applicable)
Usability (-1-6)/IEC 62366
Alarms (-1-8) (Frequently Applicable)
IEC 60601-1-11:2010: Home Care Applications
Shock and Vibration
Usability (-1-6)/IEC 62366
Additional Manual/Markings Requirements
Additional Risk Requirements
IEC 60601-1-11:2015: Home Care Application
Shock and Vibration
Usability (-1-6)/IEC 62366
Additional Manual/Markings Requirements
Additional Risk Requirements
IEC 60601-1-12:2014: Emergency Medical Services Environment
Shock and Vibration
Additional Manual/Markings Requirements
IEC 60601-2-2:1991: High Frequency Surgical Equipment
Additional Manual/Markings Requirements
IEC 60601-2-2:1998: High Frequency Surgical Equipment
Additional Manual/Markings Requirements
IEC 60601-2-2:2006: High Frequency Surgical Equipment
Additional Manual/Markings Requirements
IEC 60601-2-2:2009: High Frequency Surgical Equipment
PEMS/(IEC 62304, Ed 3.1 only)
Alarms (-1-8) (Frequently Applicable)
Additional Manual/Markings Requirements

IEC 60601-2-4:2002: Cardiac Defibrillators, Defibrillator Monitors
PEMS/IEC60601-1-4
Additional Manual/Markings Requirements
IEC 60601-2-4:2010: Cardiac Defibrillators, Defibrillator Monitors
Essential Performance
PEMS/(IEC 62304, Ed 3.1 only)
Additional Manual/Markings Requirements
Additional Risk Requirements
IEC 60601-2-5:2000: Ultrasonic Therapy Equipment
PEMS/IEC60601-1-4 (Frequently Applicable)
Additional Manual/Markings Requirements
IEC 60601-2-5:2009: Ultrasonic Therapy Equipment
Essential Performance
PEMS/(IEC 62304, Ed 3.1 only) (Frequently Applicable)
Additional Manual/Markings Requirements
Additional Risk Requirements
IEC 60601-2-10:1987: Nerve and Muscle Stimulators
PEMS/IEC60601-1-4 (Frequently Applicable)
IEC 60601-2-10:2001: Nerve and Muscle Stimulators
PEMS/IEC60601-1-4 (Frequently Applicable)
IEC 60601-2-10:2012: Nerve and Muscle Stimulators
PEMS/(IEC 62304, Ed 3.1 only) (Frequently Applicable)
Additional Risk Requirements
ISO 80601-2-12:2011: Critical Care Ventilators
Essential Performance
PEMS/(IEC 62304, Ed 3.1 only)
Shock and Vibration
Usability (-1-6)/IEC 62366
Alarms (-1-8)
Additional Manual/Marking Requirements
Additional Risk Requirements
Required Particulars (-2-13, -2-55, -2-2)
ISO 80601-2-13:2011: Anesthetic Workstation
Essential Performance
PEMS/Clause 14
Usability (-1-6)/IEC 62366
Alarms (-1-8)
Additional Manual/Marking Requirements
Additional Risk Requirements
ISO 80601-2-13:2015: Anesthetic Workstation
Essential Performance
PEMS/(IEC 62304, Ed 3.1 only)
Shock and Vibration
Usability (-1-6)/IEC 62366
Alarms (-1-8)
Additional Manual/Marking Requirements
Additional Risk Requirements
IEC 60601-2-16:1998: Hemodialysis Equipment
PEMS/IEC 60601-1-4
Usability (-1-6)
Alarms (-1-8)
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IEC 60601-2-16:2008: Hemodialysis Equipment
Essential Performance
PEMS/Clause 14
Usability (-1-6)/IEC 62366
Alarms (-1-8)
Additional Manual/Marking Requirements
Additional Risk Requirements
IEC 60601-2-16:2012: Hemodialysis Equipment
Essential Performance
PEMS/(IEC 62304, Ed 3.1 only)
Usability (-1-6)/IEC 62366
Alarms (-1-8)
Additional Manual/Marking Requirements
Additional Risk Requirements
IEC 60601-2-18:1996: Endoscopic Equipment
PEMS/IEC 60601-1-4
Additional Manual/Marking Requirements
Additional Risk Requirements
IEC 60601-2-18:2000: Endoscopic Equipment
PEMS/IEC 60601-1-4
Additional Manual/Marking Requirements
Additional Risk Requirements
IEC 60601-2-18:2009: Endoscopic Equipment
Essential Performance
PEMS/(IEC 62304, Ed 3.1 only)
Additional Manual/Marking Requirements
Additional Risk Requirements
IEC 60601-2-24:1998: Infusion Pumps and Controllers
PEMS/IEC 60601-1-4
Shock and Vibration
Additional Manual/Marking Requirements
IEC 60601-2-24:2012: Infusion Pumps and Controllers
Essential Performance
PEMS/(IEC 62304, Ed 3.1 only)
Alarms (-1-8)
Additional Manual/Marking Requirements
IEC 60601-2-25:1999: Electrocardiographs
PEMS/IEC 60601-1-4
Additional Manual/Marking Requirements
IEC 60601-2-49 (Frequently Applicable)
IEC 60601-2-25:2011: Electrocardiographs
Essential Performance
PEMS/(IEC 62304, Ed 3.1 only)
Additional Manual/Marking Requirements
IEC 60601-2-49 (Frequently Applicable)
IEC 60601-2-26:1994: Electroencephalographs
PEMS/IEC 60601-1-4
Additional Manual/Marking Requirements
IEC 60601-2-49 (Frequently Applicable)
IEC 60601-2-26:2002: Electroencephalographs
PEMS/Clause 14
Additional Manual/Marking Requirements
IEC 60601-2-49 (Frequently Applicable)

IEC 60601-2-26:2012: Electroencephalographs
Essential Performance
PEMS/(IEC 62304, Ed 3.1 only)
Additional Manual/Marking Requirements
Additional Risk Requirements
IEC 60601-2-49 (Frequently Applicable)

IEC 60601-2-27:1994: Electrocardiographic Monitoring Equipment
PEMS/(IEC 62304, Ed 3.1 only)
Additional Manual/Marking Requirements
IEC 60601-2-49 (Frequently Applicable)

IEC 60601-2-27:2005: Electrocardiographic Monitoring Equipment
Essential Performance
PEMS/Clause 14
Additional Manual/Marking Requirements
IEC 60601-2-49 (Frequently Applicable)

IEC 60601-2-27:2011: Electrocardiographic Monitoring Equipment
Essential Performance
PEMS/(IEC 62304, Ed 3.1 only)
Alarms (-1-8)
Additional Manual/Marking Requirements
Additional Risk Requirements
IEC 60601-2-49 (Frequently Applicable)

IEC 60601-2-30:1995: Automated Non-invasive Sphygmomanometers
PEMS/IEC 60601-1-4
Additional Manual/Marking Requirements
IEC 60601-2-49 (Frequently Applicable)

IEC 60601-2-30:1999: Automated Non-invasive Sphygmomanometers
PEMS/IEC 60601-1-4
Additional Manual/Marking Requirements
IEC 60601-2-49 (Frequently Applicable)

IEC 60601-2-30:2009: Automated Non-invasive Sphygmomanometers
Essential Performance
PEMS/(IEC 62304, Ed 3.1 only)
Shock and Vibration
Alarms (-1-8) (Frequently Applicable)
Additional Manual/Marking Requirements
Additional Risk Requirements
IEC 60601-2-49 (Frequently Applicable)

IEC 60601-2-30:2013: Automated Non-invasive Sphygmomanometers
Essential Performance
PEMS/(IEC 62304, Ed 3.1 only)
Shock and Vibration
Alarms (-1-8) (Frequently Applicable)
Additional Manual/Marking Requirements
Additional Risk Requirements
IEC 60601-2-49 (Frequently Applicable)

IEC 60601-2-33:2002: Magnetic Resonance Equipment for Medical Diagnosis
PEMS/IEC 60601-1-4 (Frequently Applicable)
Additional Manual/Marking Requirements

IEC 60601-2-33:2008: Magnetic Resonance Equipment for Medical Diagnosis
PEMS/Clause 14 (Frequently Applicable)
Additional Manual/Marking Requirements

IEC 60601-2-33:2012: Magnetic Resonance Equipment for Medical Diagnosis
PEMS/(IEC 62304, Ed 3.1 only) (Frequently Applicable)
Additional Manual/Marking Requirements

IEC 60601-2-33:2012: Medical Resonance Equipment for Medical Diagnosis
PEMS/(IEC 62304, Ed 3.1 only) (Frequently Applicable)
Additional Manual/Marking Requirements
IEC 60601-2-34:1994: Invasive Blood Pressure Monitoring Equipment
PEMS/IEC 60601-1-4
Additional Manual/Marking Requirements
IEC 60601-2-49 (Frequently Applicable)
IEC 60601-2-34:2000: Invasive Blood Pressure Monitoring Equipment
PEMS/IEC 60601-1-4
Alarms (-1-8) (Frequently Applicable)
Additional Manual/Marking Requirements
IEC 60601-2-49 (Frequently Applicable)
IEC 60601-2-34:2011: Invasive Blood Pressure Monitoring Equipment
Essential Performance
PEMS/(IEC 62304, Ed 3.1 only)
Alarms (-1-8) (Frequently Applicable)
Additional Manual/Marking Requirements
Additional Risk Requirements
IEC 60601-2-49 (Frequently Applicable)
IEC 60601-2-35:1996: Heating Devices using Blankets, Pads, and Mattresses...
PEMS/IEC 60601-1-4 (Frequently Applicable)
Additional Manual/Marking Requirements
IEC 60601-2-35:2009: Heating Devices using Blankets, Pads, and Mattresses...
Essential Performance
PEMS/(IEC 62304, Ed 3.1 only) (Frequently Applicable)
Alarms (-1-8) (Frequently Applicable)
Additional Manual/Marking Requirements
Additional Risk Requirements
IEC 60601-2-36:1997: Extracorporeal Induced Lithotripsy
Additional Manual/Marking Requirements
IEC 60601-2-36:2014: Extracorporeal Induced Lithotripsy
Essential Performance
Additional Manual/Marking Requirements
IEC 60601-2-38:1996: Electrically Operated Hospital Beds
Additional Manual/Marking Requirements
Additional Risk Requirements
IEC 60601-2-38:1999: Electrically Operated Hospital Beds
Additional Manual/Marking Requirements
Additional Risk Requirements
IEC 60601-2-39:1999: Peritoneal Dialysis Equipment
Additional Manual/Marking Requirements
IEC 60601-2-39:2007: Peritoneal Dialysis Equipment
Essential Performance
PEMS/(IEC 62304, Ed 3.1 only)
Usability (-1-6)/IEC 62366
Additional Manual/Marking Requirements
IEC 60601-2-40:1998: Electromyographs and Evoked Response Equipment
Additional Manual/Marking Requirements
IEC 60601-2-49 (Frequently Applicable)
IEC 60601-2-46:1998: Operating Tables
Additional Manual/Marking Requirements

IEC 60601-2-46:2010: Operating Tables
Additional Manual/Marking Requirements
IEC 60601-2-47:2001: Ambulatory Electrocardiographic Monitors
Additional Manual/Marking Requirements
IEC 60601-2-49 (Frequently Applicable)
IEC 60601-2-47:2012: Ambulatory Electrocardiographic Monitors
Essential Performance
PEMS/(IEC 62304, Ed 3.1 only) (Frequently Applicable)
Additional Manual/Marking Requirements
IEC 60601-2-49 (Frequently Applicable)
IEC 60601-2-49:2001: Multi-parameter Patient Monitoring Equipment
PEMS/IEC 60601-1-4
Additional Manual/Marking Requirements
IEC 60601-2-49:2011: Multi-parameter Patient Monitoring Equipment
Essential Performance
PEMS/(IEC 62304, Ed 3.1 only)
Alarms (-1-8)
Additional Manual/Marking Requirements
Additional Risk Requirements
IEC 60601-2-51:2003: Recording and Analyzing Single and Multi-channel Electrocardiographs
Additional Manual/Marking Requirements
IEC 60601-2-52:2009: Medical Beds (Replaces IEC 60601-2-38)
PEMS/Clause 14 (Frequently Applicable)
Additional Manual/Marking Requirements
Additional Risk Requirements
Cycling Testing Required
IEC 60601-2-52:2015: Medical Beds (Replaces IEC 60601-2-38)
PEMS/(IEC 62304, Ed 3.1 only) (Frequently Applicable)
Additional Manual/Marking Requirements
Additional Risk Requirements
Cycling Testing Required
IEC 60601-2-55:2011: Respiratory Gas Monitors
Essential Performance
PEMS/(IEC 62304, Ed 3.1 only)
Usability (-1-6)/IEC 62366
Alarms (-1-8)
Additional Manual/Marking Requirements
Additional Risk Requirements
IEC 60601-2-49 (Frequently Applicable)
IEC 60601-2-56:2009: Clinical Thermometers for Body Temperature Measurement
Essential Performance
PEMS/(IEC 62304, Ed 3.1 only)
Alarms (-1-8) (Frequently Applicable)
Additional Manual/Marking Requirements
Additional Risk Requirements
IEC 60601-2-49 (Frequently Applicable)
IEC 60601-2-60:2012: Dental Equipment
Additional Manual/Marking Requirements
Additional Risk Requirements

IEC 60601-2-61:2011: Pulse Oximeter Equipment
Essential Performance
PEMS/(IEC 62304, Ed 3.1 only)
Shock and Vibration
Alarms (-1-8) (Frequently Applicable)
Additional Manual/Marking Requirements
Additional Risk Requirements
IEC 60601-2-49 (Frequently Applicable)