












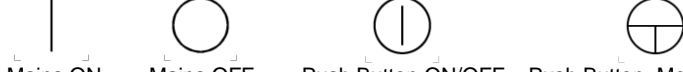




Test Review	P	N	F	Clause	Comment	Requirement
				7		Identification, Marking and Documents
				7.1.1		<u>Usability</u> : Risks associated with the usability of information provided to user (labeling, instructions and technical description) must be evaluated and reduced to acceptable levels. The evaluation must be documented in the RMF using IEC 60601-1-6.
				7.1.2		<u>Legibility of markings</u> : Labeling required in the standard (as well as any safety related labels identified in the RMF) must be legible and clear at 1 meter with normal or corrected vision at between 100 and 1500 lx.
				7.1.2	Note	Position of normal use, and not applicable for ratings labels, etc. (per WG14)
				7.1.3		<u>Durability of Markings</u> : Labeling required in the standard (as well as any safety related labels identified in the RMF) must be legible throughout the useful life of the equipment. Rub tests performed on labels applied to outside surfaces
T3				7.1.3		<u>RUB TEST</u> - Rub 15 sec. each with cloth rag soaked with: - Water, - Methylated Spirits (96% Ethanol), - Isopropyl Alcohol. = Labels legible and do not come loose or curl after tests performed.
				7.2		Marking on the Outside of ME Equipment or parts
				7.2.1		<u>Minimum requirements for marking on ME Equipment and interchangeable parts</u> : If size or the nature of enclosure does not allow affixation of all markings of 7.2.2 to 7.2.20, then at least 7.2.2 (manufacturer, model, software), 7.2.5 (external power supply), 7.2.6 (Class II), 7.2.10 (Applied Parts), 7.2.13 (Physiological effects), as applicable, shall be affixed, and remaining markings provided in the accompanying documents. Where no marking practicable, they may be affixed to the individual packaging.
				7.2.2		<u>Labeling</u> : - Manufacturer/Trademark - Model/Type - Software provides unique identifier (revision level or date of release/issue accessible)
				7.2.3		<u>Accompanying documents</u> (Recommended to consult)  <u>Consult accompanying documents</u> (Required to consult for Safety) 
				7.2.4		<u>Accessories</u> : Manufacturer/Trademark and Model/Type. Where no marking practicable, they may be affixed to the individual packaging.
				7.2.5		<u>Intended to Receive Power from Other Equipment</u> : (Other equipment, AC adapter) Manufacturer/Model identified adjacent to the connection point.
				7.2.6		<u>Connection to Supply Mains</u> : Outside part with Mains connection (adjacent to terminals for permanently installed) - Voltage(s)/range - Number of phases (if not single) and type of current (symbols below) - Rated frequency/range - Input power (see 7.2.7 below) 
				7.2.6		<u>Class II Symbol</u> required for Class II Equipment 
				7.2.7		<u>Input Power</u> : - Given in Amperes or Volt-Amperes - Given in Watts Where power factor exceeds 0.9 If the Input Power range(s) are greater than ± 10 % of the mean value of the given range, the power given for upper and lower voltages. If Input Power rating includes long-time and momentary power ratings, marking include both long-time and most relevant momentary power ratings (plainly identified and indicated in Accompanying Documents). For input terminals used also for outputs, output ratings provided
				7.2.8.1, 2		<u>Mains Power Output</u> : Marked for rated output (voltage, frequency, current or power). Not Applicable for connectors intended only for specified equipment/parts/accessories For Multiple Socket Outlets, see 16.9.2.1b
				7.2.9		<u>IP Classification</u> : Equipment or parts labeled with IPXX, except IPX0/IP0X (see 6.3)

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				7.2.10		<p>Type Applied Parts: Connection points labeled according to the classification (per 6.2). If there are no connection points or multiple connection points, the applied part(s) marked. Type B and B Defib-proof not applied to give impression that it is in a box</p>  <p>B, BF, CF, B Defib-proof, BF Defib-proof, CF Defib-proof</p>
				7.2.10		<p>Applied Part Markings: If part of Defib-proof protection is in patient cable, symbol provided and protection explained in accompanying documents.</p> 
				7.2.11		<p>Mode of operation: If NOT continuous operation, the mode of operation identified. Duty cycle given as maximum activation (on) time and the minimum deactivation (off) time.</p>
				7.2.12		<p>Fuses: Type and full rating provided adjacent to fuse holder(s). Full ratings = voltage, current, operating speed and breaking capacity</p>
				7.2.13		<p>Physiological effects: Indicate physiological effects not obvious to the user and that can cause harm to the patient or operator by means of an appropriate standard symbol. Where there is no standard symbol, the exclamation point inside of a triangle symbol is used, and explanation of the hazard provided in accompanying documents. Symbol clearly legible in normal use after equipment properly installed.</p> 
				7.2.14		<p>High Voltage Terminal Devices: Outside equipment, accessible without a tool, marked.</p> 
				7.2.15		<p>Cooling conditions: External cooling requirements marked (air, water, etc.).</p>
				7.2.16		<p>Mechanical stability: Limited stability marked (see 9.4)</p>
				7.2.17		<p>Protective Packaging: Labeling on the outside of the equipment shall identify special packaging or handling requirements during transport or storage to assure safety.</p> <ul style="list-style-type: none"> - Permissible environmental conditions for transport and storage marked on packaging (Temperature, Humidity, Pressure) - Where premature unpacking could result in an unacceptable risk, the packaging shall be marked with a suitable safety symbol (Humidity sensitive, hazardous substances) - Sterile equipment marked as sterile
				7.2.18		<p>External Pressure Source: Maximum pressures from external sources adjacent to connector(s).</p>
				7.2.19		<p>Functional Earth Terminals: Identify functional earth terminals with appropriate symbol.</p> 
				7.2.20		<p>Removable Protective Means: Advise when (under which operating conditions) removable protective means (shields, guards, etc.) must be in place - Not required when interlock provided</p>
				7.3		<p>Marking on the inside of ME Equipment or parts</p>
				7.3.1		<p>Heating Elements or Lampholders: Where heating elements or heating lamps are intended for replacement by the user, the maximum power draw/loading shall be clearly marked on the holder or immediately adjacent to it. Where replacement is intended to be performed by a qualified technician (tool is required to access), a label referring to the accompanying documents is sufficient.</p>
				7.3.2		<p>High Voltage Parts: Symbol for high voltages (1 KV AC/1.5 KV dc) within the enclosures.</p> 
				7.3.3		<p>Batteries: Compartments marked with battery type and mode of insertion (as applicable). If replaceable only by the use of a tool, a label referring to the accompanying documents. For <u>Lithium</u> batteries or <u>fuel cells</u>, where incorrect replacement could lead to unacceptable risk, warning label that replacement by inadequately trained personnel could result in excessive temperatures, fire, or explosion shall be given - in ADDITION to the warning required in the accompanying documents.</p>
				7.3.4		<p>Fuses, Thermal Cut-Outs and Over-Current Releases: Where replacement of fuse requires the use of a tool, the type and full rating located near the fuse (or) the symbol for consult accompanying documents with the information provided in the accompanying documents.</p> 

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				7.3.5		<p>Protective earth terminals: Marked with symbol unless it is in an IEC 60320 appliance inlet.</p> 
				7.3.6		<p>Functional Earth terminal(s): Marked with symbol</p> 
				7.3.7		<p>Supply Terminals: Terminals for supply connections marked adjacent to terminals. If equipment so small markings cannot be used, provided in accompanying documents. For permanently installed equipment, Neutral terminal marked per IEC 60445 (below). Three phase marked per IEC 60445 Not marked on parts removed to make connection, visible after connections made.</p> <p>N</p>
				7.3.8		<p>Temperature of Supply Terminals: For permanently installed equipment where terminal compartment temperatures exceed 75 °C, the following marking or equivalent is required: "For supply connections, use wiring materials suitable for at least X °C." X is greater than maximum temperature, adjusted for maximum ambient Not marked on parts removed to make connection, visible after connections made.</p>
				7.4		<p>Marking of Controls and Instruments</p>
				7.4.1		<p>Power Switches: Switch(es) which control power to the equipment, including mains switches, shall be marked with symbols below (as applicable), or the state of the equipment must be indicated by a power indicator light or other unambiguous means. For push buttons, status indicated by a power indicator light or other unambiguous means.</p>  <p>Mains ON Mains OFF Push Button ON/OFF Push Button Momentary ON</p>
				7.4.2		<p>Control Devices: Positions indicated by symbols, letters, numbers or other visual means. If change of control setting could result in an unacceptable risk to patient, controls provided with indicating device with direction for magnitude indicated.</p>  <p>Part ON Part OFF</p>
				7.4.3		<p>Units of Measure: Indicated in SI units or Base Quantity units listed in Table 1.</p>
				7.5		<p>Safety Signs</p>
				7.5		<p>Safety Signs: Markings used to convey a warning, prohibition or mandatory action that mitigates a risk that is not obvious to the operator provided with safety sign from ISO 7010. Where no sign available, one of the following options available:</p> <ul style="list-style-type: none"> - Construct safety sign, per ISO 3864-1:2002, Clause 7, - General warning sign ISO 7010:2003-W001 with text specifying risk ("Risk of Burns"), - General prohibition sign ISO 7010:2003-P001 with text ("Do not open"), - General mandatory action sign ISO 7010:2003-M001 with text ("Wear eye protection"). <p>If insufficient space for statement with sign, may be placed in the instructions for use. All safety signs specified in the instructions for use. Correct sign colors must be used.</p>  <p>W001 P001 M001</p>
				7.6		<p>Symbols</p>
				7.6.1		<p>Explanation of symbols: Meaning of symbols used explained in the instructions for use.</p>
				7.6.2		<p>Symbols from Annex D:</p>
				7.6.3		<p>Required symbols for compliance shall comply with IEC or ISO standards where possible.</p>
				7.7		<p>Colours of the insulation of conductors</p>
				7.7.1		<p>Protective earth conductor: Identified throughout length by green and yellow insulation.</p>
				7.7.2		<p>Protective earth connections: All wiring that is part of the protective earth circuit (carrying the protective earth connection to protectively earthed parts) identified by green & yellow, at least at their termination points.</p>
				7.7.3		<p>Green and yellow insulation: Only used for:</p> <ul style="list-style-type: none"> - Conductors in the protective earth circuit, - Potential equalization circuit conductors, - Functional earth conductors.
				7.7.4		<p>Neutral conductor: Insulation of neutral conductor(s) of the (mains) power supply cord colored light blue (per IEC 60227 and IEC 60245).</p>

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				7.7.5		Power supply cord conductors: Insulation of conductors in the power supply cord (other than the neutral conductor) in accordance with IEC 60227 or IEC 60245 (1 Ph: Brown).
				7.8		Indicator Lights and Controls
				7.8.1		Colours of indicator lights: - RED: indicating that immediate user intervention is required (dangerous situation) (not applicable for alpha-numeric displays), - YELLOW: Indicating that "prompt" user action or attention required (caution), - GREEN: Normal situation, equipment ready for use. See IEC 60601-1-8 for visual alarm requirements.
				7.8.2		Colours of controls: Color red only used for controls that interrupt a function, in case of a dangerous condition.
				7.9		Accompanying Documents
				7.9.1		General: Documents that accompany the equipment including at least instructions for use and technical description in hard copy or electronic form. Documents are written for education, training, specialized needs of the user.
				7.9.1		Accompanying Document: Each must include at least: - Manufacturer and Address for contact (responsible organization), - Model or Type identification, - Required skills, training and knowledge of operator, - Environmental conditions and restrictions on location, as necessary.
				7.9.2		Instructions for Use
				7.9.2.1		General: Instructions for use shall document: - Use of the me equipment, as intended by the manufacturer, - Frequently used functions, - Any known contraindication(s) to the use of the me equipment, - All applicable classifications in Clause 6: * Equipment protection (Class I, Class II, Internally powered) * Applied Parts protection (Type B, Type BF, Type CF; Defibrillation-Proof) * Protection against ingress of fluids and particulate matter (IPXX, per IEC 60529) * Sterilization methods (as applicable) * Oxygen Rich Environment (as applicable) * Mode of Operation (if not Continuous) - All applicable markings specified in Clause 7.2 * Manufacturer/Trademark (for Equipment and Accessories) * Model/Type (for Equipment and Accessories) * Software provides unique identifier (revision level or date of release/issue accessible) * Consult accompanying documents (Recommended or Required for Safety) - symbols Need not be in color in the manual (but required in color on equipment) * External power supply Manufacturer and Model (Other equipment, AC adapter) * Input Voltage(s)/range [Matching Label Exactly] * Input - Number of phases (if not single) and type of current [Matching Label Exactly] * Input frequency/range [Matching Label Exactly] * Input power (Amps, Volt-Amps, Watts) [Matching Label Exactly] * Class II symbol where appropriate * For Mains Power Outputs, voltage, frequency, current or power * IP Classification (IPXX) * Applied Parts Ratings (B, BF, CF; Defib-proof) * Specified if Defib-proof protection in patient cables * Fuse Ratings (voltage, current, operating speed and breaking capacity) * Physiological effects not obvious to the user that can harm patient or operator * High Voltage terminals accessible without a tool specified * External cooling requirements * Special packaging or handling requirements * Maximum pressures from external sources * Functional earth terminals specified * Removable protective means (shields, guards, etc.) specified - Explanation of EVERY safety sign and symbol marked on the me equipment
				7.9.2.1		The instructions for use shall be in a language that is acceptable to the intended operator.
				7.9.2.2		Warning and safety notices: General warnings and safety notices placed in a specifically identified section. Warning or safety notices that apply to specific action precede the applicable instruction
				7.9.2.2		Class I Equipment: Instructions for use includes warning statement: "WARNING: To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth."
				7.9.2.2		Reciprocal Interference: Instructions for use provide Warnings regarding any significant Risks of reciprocal interference posed by the presence of equipment during specific investigations or treatments.
				7.9.2.2		Interference: Instructions for use provide potential electromagnetic or other interference between equipment and other devices with advice to avoid or minimize interference.
						Multiple Socket-Outlet: Instructions for use provide warning statement that connecting electrical equipment to the MSO effectively leads to creating an ME System, and the result can be a reduced level of safety. Referred to this standard provided.

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				7.9.2.3		<u>Specification for connection to a separate power supply:</u> If intended for connection to a separate power supply, power supply specified as part of the equipment or the combination specified as an ME System.
				7.9.2 (11.1.2.2)		<u>Applied Part Temperature over 41° C:</u> Any applied part or patient contact surface which can exceed 41 °C specified.
				7.9.2.4		<u>Internal Electrical Power Source:</u> Mains operated equipment with alternate supply (battery backup), not automatically maintained (automatic charging circuit) provides a warning statement indicating the appropriate action (regular checking/replacement of batteries) to assure equipment remains safe and essential performance is maintained. Specified in adequate detail to assure continuing compliance to this standard.
				7.9.2.4		<u>Replaceable Internal Electrical Power Source:</u> Instructions for use provide specification.
				7.9.2.4		<u>Loss of Power:</u> If loss of the power would result in an unacceptable risk, instructions for use contain warning that equipment must be connected to an appropriate power source. Example: Internal or external battery, uninterruptible power supply, stand-by generator.
				7.9.2.5		<u>Equipment description:</u> - Brief description of the me equipment, - How the me equipment functions, - The significant physical and performance characteristics of the equipment. - Indicate any applied part(s), - Information on the materials or ingredients to which the patient or operator is exposed if such exposure can constitute an unacceptable risk. - Specify any restrictions on other equipment or network/data couplings, other than those forming part of an ME System, to which a signal input/output part may be connected. - If applicable, description includes the expected positions of the operator, patient and other persons near the equipment in normal use.
				7.9.2.6		<u>Installation:</u> If installation is required: - Reference to where installation instructions can be found, or - Contact information for persons qualified to perform the installation.
				7.9.2.7		<u>Isolation from Supply Mains:</u> Where an appliance: - Coupler, mains plug or the like used to meet requirement for disconnection from mains, instructions tell the user to avoid positioning the equipment such that access to the coupler, plug, etc. is limited.
				7.9.2.8		<u>Start-up procedure:</u> - Necessary information for operator to bring the equipment into operation, including initial control settings, connection to or positioning of the patient, etc. - Detail treatment or handling needed before equipment, its parts, or accessories used (pre-use checklist).
				7.9.2.9		<u>Operating instructions:</u> - All information necessary to operate the equipment in accordance with its specifications. - Include explanation of functions of controls, displays and signals, the sequence of operation, and connection/disconnection of detachable parts and accessories, and the replacement of material that is consumed during operation. - Meanings of figures, symbols, warning statements, abbreviations, indicator lights.
				7.9.2.10		<u>Messages:</u> - List all system/error/fault messages generated, unless messages are self-explanatory. - List has explanation of messages including important causes, and possible action(s) by the operator, if any, that are necessary to resolve the situation indicated by the message. - List all warning or error messages with indicator signals and alarms, with explanation of the initiating cause of each and any appropriate user action required. (Requirements/guidelines for alarms specified in IEC 60601-1-8)
				7.9.2.11		<u>Shutdown procedure:</u> - Necessary information for operator to safely terminate operation of the equipment.
				7.9.2.12		<u>Cleaning, disinfection and sterilization:</u> - For equipment parts or accessories that can become contaminated through contact with the patient or with body fluids or expired gases during normal use: - Details about cleaning and disinfection or sterilization methods that may be used, - List the applicable parameters such as temperature, pressure, humidity, time limits and number of cycles that such me equipment parts or accessories can tolerate. Not applicable for material, component, accessory or me equipment marked as single use; unless manufacturer specifies to be clean/disinfect/sterilize before use.
				7.9.2.13		<u>Maintenance:</u> - Instruct operator/organization details for preventive inspection, maintenance and calibration to be performed by them, including the frequency. - Information for safe performance of routine maintenance necessary to ensure the continued safe use of the equipment. - Identify parts on which preventive inspection and maintenance shall be performed by service personnel and periods to be applied (details about this maintenance not required). - Adequate maintenance for rechargeable batteries intended to be maintained by anyone other than service personnel (as applicable).

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				7.9.2.14		<p>Accessories, Supplementary Equipment, Used Material:</p> <ul style="list-style-type: none"> - List of accessories, detachable parts and materials manufacturer has determined are intended for use with the equipment. - Specifications of the external power supply or other equipment if equipment receives power from external power supply or other equipment.
				7.9.2.15		<p>Environmental protection:</p> <ul style="list-style-type: none"> - Identify any risks associated with the disposal of waste products, residues, accessories. - Provide advice on minimizing these risks.
				7.9.2.16		<p>Reference to the technical description:</p> <ul style="list-style-type: none"> - Information in 0 or a reference to where material specified in 0 is to be found.
				7.9.2.16		<p>Compliance of 0: Checked by inspection of the instructions for use in a language of an intended operator.</p>
				7.9.3		<p>Technical description</p>
				7.9.3.1		<p>General: Provide all data that is essential for safe operation, transport and storage, and measures or conditions necessary for installing the me equipment, and preparing it for use:</p> <ul style="list-style-type: none"> * Permissible environmental conditions of use (conditions for transport and storage), * Characteristics of equipment, including range(s), accuracy, and precision of the displayed values or an indication where they can be found, * Any special installation requirements, * If liquid used for cooling, range of inlet pressures and flow, liquid chemical composition, * Means of isolating equipment from the supply mains, if not incorporated in equipment, * Means for checking the oil level in partially sealed oil-filled parts (as applicable), * Warning that addresses hazards from unauthorized modification of the me equipment: <ul style="list-style-type: none"> * "WARNING: No modification of this equipment is allowed." * "WARNING: Do not modify this equipment without authorization of the manufacturer." * "WARNING: If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment."
				7.9.3.1		<p>Technical description, if separable from the instructions for use:</p> <ul style="list-style-type: none"> - All applicable classifications in Clause 6: <ul style="list-style-type: none"> * Equipment protection (Class I, Class II, Internally powered) * Applied Parts protection (Type B, Type BF, Type CF; Defibrillation-Proof) * Protection against ingress of fluids and particulate matter (IPXX, per IEC 60529) * Sterilization methods (as applicable) * Oxygen Rich Environment (as applicable) * Mode of Operation (if not Continuous) - All applicable information in Clause 7.2 <ul style="list-style-type: none"> * Manufacturer/Trademark (for Equipment and Accessories) * Model/Type (for Equipment and Accessories) * Software provides unique identifier (revision level or date of release/issue accessible) * Consult accompanying documents (Recommended or Required for Safety) * External power supply Manufacturer and Model (Other equipment, AC adapter) * Input Voltage(s)/range [Matching Label Exactly] * Input - Number of phases (if not single) and type of current [Matching Label Exactly] * Input frequency/range [Matching Label Exactly] * Input power (Amps, Volt-Amps, Watts) [Matching Label Exactly] * Class II symbol where appropriate * For Mains Power Outputs, voltage, frequency, current or power * IP Classification (IPXX) * Applied Parts Ratings (B, BF, CF; Defib-proof) * Specified if Defib-proof protection in patient cables * Fuse Ratings (voltage, current, operating speed and breaking capacity) * Physiological effects not obvious to the user that can harm patient or operator * High Voltage terminals accessible without a tool specified * External cooling requirements * Special packaging or handling requirements * Maximum pressures from external sources * Functional earth terminals specified * Removable protective means (shields, guards, etc.) specified - Warning and safety notices and the explanation of safety signs marked on equipment, - Description of the equipment, - How the me equipment functions and its significant physical/performance characteristics. The manufacturer may designate the minimum qualifications for service personnel. If designated, requirements documented in the technical description.

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				7.9.3.2		<p><u>Replacement of Fuses, Power Supply Cords and Other Parts:</u></p> <ul style="list-style-type: none"> - Fuse type and rating, used in the supply external to permanently installed equipment (if the type and rating not apparent from the information on rated current and operation) - Non-detachable power supply cord: <ul style="list-style-type: none"> * Statement as to whether the power supply cord is replaceable by service personnel. * If replaceable, instructions for correct connection and anchoring. - Correct replacement of interchangeable or detachable parts (by service personnel), - Where replacement of a component could result in an unacceptable risk: <ul style="list-style-type: none"> * Appropriate warnings that identify the nature of the hazard and * If manufacturer specifies component as replaceable by service personnel, all information necessary to safely replace the component.
				7.9.3.3		<p><u>Circuit Diagrams, Component part lists, etc.:</u></p> <ul style="list-style-type: none"> - statement that the manufacturer will make available on request: <ul style="list-style-type: none"> * Circuit diagrams, Component part lists, Descriptions, Calibration instructions, Other information to assist service personnel to repair those parts of equipment that are designated by the manufacturer as repairable by service personnel.
				7.9.3.3		<p><u>Compliance of 0:</u> Checked by inspection of the technical description.</p>
				7.9.3.4		<p><u>Mains Isolation:</u> The technical description shall clearly identify any means used to comply with the requirements of 0 (Isolation from the supply mains).</p>