
















| Pass | N/A | Fail | CLAUSE | COMMENTS | REQUIREMENT | |
|--------------------------|--------------------------|--------------------------|---------------------|----------|---|--------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 6 | | IDENTIFICATION, MARKING AND DOCUMENTS | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 6.1 | | Marking on the Outside of Equipment or Equipment Parts | |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.1c | | Markings of the specific power supply affixed | |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.1d | | If marking is not practicable due to size or nature of enclosure, information is included in accompanying documents [Table DI: 14] | |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.1e | | Name and/or trademark of the manufacturer or supplier | |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.1f | | Model or type reference | |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.1g | | Rated supply voltages or voltage range(s) | |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.1g | | Number of phases (if not single) | |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.1g | | Type of current (AC or DC) [Table DI: 1, 2, 3, 4, 5] | |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.1g (Australia) | | Insert the following between the first and second dashes: For low voltage equipment rated at 200 V or more, a voltage rating (which may be part of a range) of not less than 230 V. Supply frequency ratings which include 60 Hz must also include 50 Hz. | |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.1h | | Rated frequency or rated frequency range(s) (Hz) | |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.1j | | Rated power input (VA, W or A) (Watts: required if power factor > 0.9) | |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.1j (Korea) | | Insert the following sub-clause between the second and third sub-clauses: Equipment for one or several RATED voltage or frequency ranges, the RATED input for 220 V, 60 Hz or if applicable for 110 V, 60 Hz shall be separately marked. | |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.1k | | Power output of auxiliary mains socket - outlets (if provided) | |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.1l | | Class II symbol (if no Protective Earth) [Table DI: 10] | |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.1l | | Symbol for degree of protection against ingress of water provided (Marked "Ordinary Equipment" or IPX0 / IP X X Rating) [or DI: 14 with wording in manual]) | IPX1, IPX2,IPX8 |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.1l | | Symbol for protection against electric shock [Table DII: 1, 2, 3] | |
| | | | | | Symbol for protection of defibrillation-proof applied parts [Table DII: 9, 10, 11] | |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.1l | | Symbol 14 from Table DI for defibrillation-proof with protection partly in patient cable | |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.1l | | If equipment has more than one applied part with different degrees of protection, the relevant symbols are clearly marked on such applied parts, or on or near relevant outlets | |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.1m | | Mode of operation (if no marking, suitable for continuous operation) | |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.1n | | Types and rating of external accessible fuses | |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.1p | | Ratings of external output: | |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.1q | | Symbol for physiological effect(s): | |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.1q | | - attention, consult accompanying documents [Table DI: 14] | |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.1q | | - non-ionizing radiation, or symbols as adopted by ISO or IEC 417 | |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.1r | | Anesthetic-proof symbol: AP or APG [Table DI: 4, 5] | |

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| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.1s | | Dangerous voltage symbol [Table DI: 6]  |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.1s (Korea) | | HIGH VOLTAGE TERMINAL DEVICES on the outside of EQUIPMENT which are accessible without the use of a TOOL shall be marked with the symbol "dangerous voltage" (see Appendix D, Table DI, Symbol 6) and with the Korean language, . |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.1t | | Special cooling requirements |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.1u | | Limited mechanical stability |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.1v | | Protective packing requirement(s) |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.1v | | Marking(s) for unpacking safety hazard(s) |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.1v | | Equipment or accessories supplied sterile, marked as sterile |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.1y | | Potential equalization terminal [Table DI: 7]  |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.1y | | Functional earth terminal [Table DI: 9]  |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.1z | | Removable protective means (marked to indicate necessity for replacement) |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.1 (USA) | | "Grounding Reliability Can Only Be Achieved When The Equipment Is Connected To An Equivalent Receptacle Marked 'Hospital Only' Or 'Hospital Grade'." (located on product or power supply cord) |
| D | D | D | 6.1 (UL) | | <div>  <p>MEDICAL EQUIPMENT WITH RESPECT TO ELECTRIC SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH UL 60601-1, IEC/EN 60601-1, CAN/CSA C22.2 No. 601.1</p> <p>XXXX</p> </div> <p>(OR)</p> <div>  <p>MEDICAL EQUIPMENT</p>  <p>UL 60601-1, IEC/EN 60601-1, CAN/CSA C22.2 No. 601.1</p> <p>XXXX</p> </div> <p>* Additional Collaterals (IEC 60601-1-X) and/or Particulars (IEC 60601-2-XX), as necessary</p> |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6 (Canada) | | Where written safety warnings appear as equipment markings, they should appear in French and English |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6 (USA) | | a) All words in "CAUTION", "WARNING", and "DANGER" markings at least 1.6 mm (1/16") high |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6 (USA) | | b) Signal words "CAUTION", "WARNING", and "DANGER" at least 2.8 mm (7/64") |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6 (USA) | | c) Letters in contrast color to the background |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6 (USA) | | Equipment capable of emitting ionizing radiation provided with warning statement |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6 (USA) | | If equipment produced in more than one factory, factory identification marked on the equipment |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6 (USA) | | Multiple-voltage equipment intended for permanent connection marked with voltage for which it is connected when shipped |

| Pass | N/A | Fail | CLAUSE | COMMENTS | REQUIREMENT | |
|--------------------------|--------------------------|--------------------------|---------------------|----------|---|---|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 6.2 | | Marking on the Inside of Equipment or Equipment Parts | |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.2a | | Nominal voltage of permanently installed equipment | |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.2b | | Maximum power loading for heating elements or holders for heating lamps | |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.2c | | Dangerous voltage symbol [Table DI: 6] |  |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.2c (Korea) | | Replace the existing subclause wit the following: The presence of HIGH VOLTAGE PARTS shall be marked with the symbol "dangerous voltage" (see Appendix D, Table DII, Symbol 6) and in the Korean language. [Table DI: 6] |  |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.2d | | Type of battery and mode of insertion | |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.2d | | - Marking referring to accompanying documents used for battery not intended to be changed by the operator |  |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.2e | | Fuses accessible with a tool identified either by type and rating or by a reference to diagram | |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.2f | | Protective earth terminal [Table DI: 6] |  |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.2g | | Functional earth terminal [Table DI: 7] |  |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.2h | | Supply neutral conductor in permanently installed equipment marked (N) | |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.2j | | Markings required in 6.2 f), h), k), and l) remain visible after connection and are not affixed to parts which have to be removed | |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.2j | | - Markings comply with IEC 445 | |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.2k | | For permanently connected devices the supply connections are clearly marked adjacent to the terminals (or in accompanying documents for small equipment) | |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.2l | | Statement for suitable wiring materials at temperatures over 75°C | |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.2l (USA) | | Statement for suitable wiring materials at temperatures over 60 °C | |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.2n | | Capacitors and/or circuit parts marked as required in Sub-clause 15c | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 6.3 | | Marking of Controls and Instruments | |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.3a | | Mains switch clearly identified | |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.3a | | - ON and OFF positions marked according to Symbols 15 and 16 of table D1 or indicated by an adjacent indicator light [Table DI: 15, 16, IEC Symbol, IEC Symbol] |  |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.3b | | Indication of different positions of control devices and switches [Table DI: 17, 18] |  |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.3c | | Indication of the direction in which the magnitude of the function changes, or an indicating device (if change of settings could cause a hazard) | |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.3f | | The functions of operator controls and indicators are identified | |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.3g | | Numeric indications of parameters are in SI units except for units listed in Am. 2 | |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.3 (SI) (UL) | | Ethernet Connectors marked "not for phone connection" or pass 1 kV Dielectric test between connectors and enclosure, other secondary circuits | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 6.4 | | Symbols | |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.4 | | Used symbols comply with Appendix D or IEC 417 and/or IEC 878 or ISO publications (if applicable) | |

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| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 6.8 | | ACCOMPANYING DOCUMENTS |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.8 (USA) | | Cord-connected equipment provided with instructions to indicate type of attachment plug for alternate voltage |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.8 (USA) (SI) | | To avoid spacing requirements in mains power switch, include the following wording in manual: "The power cord is to be used for mains disconnection" |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.8.1 | | Equipment accompanied by documents containing at least instructions for use |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.8.1 | | Equipment accompanied by documents containing at least a technical description |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.8.1 | | Equipment accompanied by documents containing at least an address to which the user can refer |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.8.1 | | Classifications specified in Clause 5 included in both the instructions for use and the technical description |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.8.1 | | * Type of protection against electric shock: (Class I) / (Class II) / (Internally Powered) Equipment |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.8.1 | | * Degree of protection against electric shock: Type (B) / (BF) / (CF) Applied Parts |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.8.1 | | * Degree of protection against the ingress of water: (IP__) / (Ordinary) |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.8.1 | | * Methods of sterilization or disinfection: |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.8.1 | | * Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide. Or: Category (AP) / (APG) Equipment |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.8.1 | | * Mode of operation if not continuous: (Specified Period, loading, cycling...) |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.8.1 | | Markings specified in Sub-clause 6.1 included in the accompanying documents if they <u>have not</u> been permanently affixed to equipment (See also 6.8.3) |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.8.1 | | Warning statements and the explanation of warning symbols provided in the accompanying documents |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.8.1 (Korea) | | Insert the following sub-clause after the last paragraph: Language of accompanying documents shall be included in Korean. |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 6.8.2 | | Instructions for Use |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.8.2a | | General information provided in instructions for use |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.8.2a | | - <u>state the function and intended application of the equipment</u> |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.8.2a | | - include an explanation of: the function of controls, displays and signals |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.8.2a | | - the sequence of operation |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.8.2a | | - the connection and disconnection of detachable parts and accessories |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.8.2a | | - the replacement of material which is consumed during operation |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.8.2a | | - information regarding potential electromagnetic or other interference and advice regarding avoidance (See IEC 60601-1-2 Standard for EMC) |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.8.2a | | - include: indications of recognized accessories, detachable parts and materials, if the use of other parts or materials can degrade minimum safety |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.8.2a | | - instructions concerning cleaning, preventive inspection and maintenance to be performed including the frequency of such maintenance |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.8.2a | | General information provided in instructions: |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.8.2a | | - information for the safe performance or routine maintenance |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.8.2a | | - parts on which preventive inspection and maintenance shall be performed by other persons including the periods to be applied |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.8.2a | | - <u>explanation of figures, symbols, warning statements and abbreviations on the equipment</u> |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.8.2c | | Signal output or signal input parts intended only for connection to specified equipment described |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.8.2d | | Details about acceptable cleaning, disinfection or sterilization methods included |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.8.2e | | Warning statement for mains operated equipment with additional power source |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.8.2f | | A warning to remove primary batteries if equipment is not likely to be used for some time |

| Pass | N/A | Fail | CLAUSe | COMMENTS | REQUIREMENT |
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| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.8.2g | | Instructions to ensure safe use and adequate maintenance of rechargeable batteries |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.8.2h | | Identification of specified external power supplies or battery chargers necessary to ensure compliance with the requirements of IEC 601-1 |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.8.2j | | Identification of any risks associated with the disposal of waste products, residues, etc. |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.8.2j | | - Advice in minimizing these risks |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.8.3 | | Technical description |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.8.3a | | All characteristics essential for safe operation provided (Markings used from Clause 6.1) |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.8.3a | | * Manufacturer Name/Model |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.8.3a | | * Voltage Range/Type of Current- AC/DC /Frequency |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.8.3a | | * Power Input- Watts, Amps, VA |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.8.3a | | * Aux. Mains Output Power- if provided |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.8.3a | | * Mode of operation- if not continuous |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.8.3a | | * Type & Ratings of External Fuses |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.8.3a | | * Ratings of External Outputs |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.8.3a | | * Special cooling requirements |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.8.3a | | * Limited Mechanical Stability |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.8.3a | | * Protective Packing Requirements / Unpacking Safety Hazards |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.8.3a | | * Sterile Equipment & Accessories Marked Sterile |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.8.3b | | Required type and rating of fuses utilized in the mains supply circuit external to permanently installed equipment |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.8.3b | | - Instructions for replacement of interchangeable and/or detachable parts which are subject to deterioration during normal use |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.8.3c | | Instructions or reference information for repair of equipment parts designated by the manufacturer as repairable provided |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.8.3d | | Environmental conditions for transport and storage specified in accompanying documents and marked on packaging Ranges must stay within the following to avoid additional testing: [Temperature range within -40°C to +70°C]. [Relative humidity range within 10% to 100%]. [atmospheric pressure range within 500 to 1060 hPa]. |
| D | D | D | 6.8 (UL) | |  <p>MEDICAL EQUIPMENT WITH RESPECT TO ELECTRIC SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH UL 60601-1, IEC/EN 60601-1, CAN/CSA C22.2 No. 601.1</p> <p>XXXX</p> <p>* Additional Collaterals (IEC 60601-1-X) and/or Particulars (IEC 60601-2-XX), as necessary</p> |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.61 (Canada) | | Point of connection of gas cylinders: |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.61 (Canada) | | - is gas specific |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.61 (Canada) | | - is non-interchangeable |
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | 6.61 (Canada) | | - is identified |