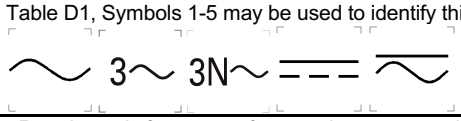
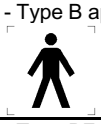
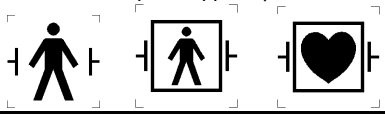
This checklist covers the IEC 60601-1, Edition 3.1 requirements for the labeling and the accompanying documents (IFU) of Medical Electrical Equipment. It also includes information and interpretations for the clause requirements, as applicable.

This is a **FREE download** from **60601-1.com/download** and will be updated often, to provide additional guidance.
Be sure that you have the latest revision.

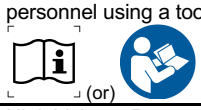
The following is tool for evaluating medical equipment labeling and user manuals to the requirements of the '60601-1 standards. This does not replace the standards, and a purchased copy of the IEC and National standards should also be used.

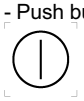
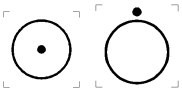
Verdict	Info Verify Doc Test	Clause	Requirement	Comment
	-	**7**	**ME Equipment Identification, Marking, and Documents:**	
	-	7.1	General:	
	-	7.1.1	Usability of the identification, marking and documents: (Removed)	
	Test	7.1.2	Legibility of Markings: Test of markings required in 7.2 - 7.6. Observer: visual acuity of 0 on the log Minimum Angle of Resolution (log MAR) scale or 6/6 (20/20) and is able to read N6 of Jaeger test card in normal room lighting condition (~500lx). Marking read at ambient luminance (100 lx to 1,500 lx), positioned for intended position of the operator, or at any point within the base of a 30° cone (if not defined), at a distance of 1 m.	See Appended Table 7.1.2
	Test	7.1.3	Durability of Markings: Required markings can be removed only with a tool or by appreciable force, are durable, and remain clearly legible during expected service life of me equipment in normal use. Marking rubbed by hand with a cloth rag soaked with each of the following, for 15 sec.: Distilled water, ethanol (96%) C_2H_6O, and Isopropyl alcohol C_3H_8O.	See appended Tables 7.1.3
	-	7.2	**Marking on The Outside of ME Equipment or Parts:**	
	Verify	7.2.1	Minimum Requirements For Marking On ME Equipment: If size or the nature of enclosure does not allow affixation of all required markings, at least - 7.2.2 (manufacturer, model, serial number, date of manufacture, software rev. identifier), - 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.	See attached copy of Markings
	Verify	7.2.1	Remaining markings fully recorded in accompanying documents	Markings only in IFU:
	Verify	7.2.1	Markings applied to individual packaging when impractical to apply to me equipment	
	Verify	7.2.1	- Single use item marked	"Single Use Only" / "Do Not Reuse"/ Symbol 28 of Table D1
	-	7.2.2	Identification: ME Equipment marked with the following.	See attached copy of Markings
	Verify	7.2.2	- Name or trademark - Contact information of the manufacturer	
	Verify	7.2.2	- Model or type reference	
	Verify	7.2.2	- Serial number or lot or batch identifier (readable or identification by technology – RFID, etc.)	
	Verify	7.2.2	- Date of manufacture or use by date (if applicable)	
	-	7.2.2	Unless misidentification does not present unacceptable risk (misidentification could lead to a hazardous situation), detachable components marked with:	
	Verify	7.2.2	- Name or trademark of the manufacturer	
	Verify	7.2.2	- Model or type reference	
	Verify	7.2.2	If not marked, the risk management file includes an assessment of the risks relating to misidentification of all detachable parts	RM reference to specific risks (ISO 14971 Clauses) 4.2: 4.3: 4.4: 5: 6.4:
	Verify	7.2.2	- Software identified with a unique identifier (not required on outside of equipment, can be only available to designated people)	Unique identifier:
	Verify	7.2.3	Consult Accompanying Documents: - Table D1, Symbol 11 MAY be used, to advise operator to consult acompanying documents:  - Table D2, safety sign 10 MUST be used if risk management uses the acompanying documents to reduce risk to an acceptable level, but only when the manufacturer uses the IFU as a risk control measure for a specific risk 	

Verdict	*Info Verify Doc Test*	Clause	Requirement	Comment
	Verify	7.2.4	Accessories: - Marked with name or trademark - Contact information of their manufacturer	Accessories inspected:
	Verify	7.2.4	- Model or type reference	
	Verify	7.2.4	- Serial number or lot or batch identifier	
	Verify	7.2.4	- Date of manufacture or use by date (if applicable)	
	Verify	7.2.4	- Markings applied to individual packaging, when not practical to apply to accessories	
	-	7.2.5	ME Equipment intended to receive power from other equipment: Provided with one of the following:	
	Verify	7.2.5	- Name or trademark of the manufacturer of the other electrical equipment and type reference, marked adjacent to the relevant connection point (or)	
	Verify	7.2.5	- Table D2, safety sign 10, adjacent to the relevant connection point (and) - Listing of the required details in the IFU  (or)	
	Verify	7.2.5	- Special connector style used that is not commonly available on the market (and) - Listing of the required details in the IFU.	
	-	7.2.6	Connection to the Supply Mains: ME Equipment marked with the following information	
	-	7.2.6	The following markings are provided on outside of part containing supply mains connection and, adjacent to the connection point.	
	Verify	7.2.6	Permanently installed me equipment: - Nominal supply voltage or range marked inside or outside of me equipment	
	Verify	7.2.6	All other equipment: - Rated supply voltage(s), or voltage range(s) with a hyphen (-) between min and max voltages	Rated Voltage (V-V):
	Verify	7.2.6	- Rated supply voltages, or multiple rated supply voltage ranges separated by slash (/)	Rated Voltage (V/V):
	Verify	7.2.6	- Nature of supply (number of phases, except for single phase) - Type of current (AC, DC) (or) Use symbols below	Phases AC / DC
	Verify	7.2.6	Table D1, Symbols 1-5 may be used to identify this: 	Symbols provided:
	Verify	7.2.6	- Rated supply frequency, frequencies, or range, in hertz	Hz:
	Verify	7.2.6	- Table D1, Symbol 9 provided for class II ME Equipment 	Symbol provided:
	Verify	7.2.7	Electrical Input Power From The Supply Mains: - Rated input in amps or volt-amps, when power factor is 0.9 or less	A / VA:
	Verify	7.2.7	- Rated input in amps, volt-amps, or watts, when power factor exceeds 0.9	A / VA / W:
	Verify	7.2.7	For equipment with multiple voltage ranges: If the range(s) are greater than ± 10 % of the mean value of given range, - The rated input power is given for the upper and lower limits of the range(s)	A / VA / W:
	Verify	7.2.7	For equipment with multiple voltage ranges: If the range(s) are NOT greater than ± 10 % of the mean value of given range, - The mean input power of the input range is given	A / VA / W:
	Verify	7.2.7	If the ratings include both long-time and momentary current or volt-amp ratings: - Markings and IFU provide both long-time and most relevant momentary volt-amp ratings	Long-time VA: Momentary VA:
	Verify	7.2.7	- Marked input of me equipment provided with means for connection of supply conductors of other electrical equipment, includes rated and marked output of such means.	A / VA / W:

Verdict	*Info Verify Doc Test*	Clause	Requirement	Comment
	-	7.2.8	Output Connectors	
	Info	7.2.8.1	Mains power Output: For integrated MSOs (Multiple Socket-Outlets = *power strips*), see 16.9.2.1 b)	
	-	7.2.8.2	Other Power Sources: Power output connectors marked with the following. (except MSOs or connectors specified for specific parts or accessories)	
	Verify	7.2.8.2	- Rated voltage - Rated current or power (when applicable)	V, A / VA / W:
	Verify	7.2.8.2	- Output frequency (when applicable)	Hz:
	Verify	7.2.9	IP Classification: - ME Equipment or its parts marked with the IP code, per IEC 60529 (marking optional for me equipment or parts rated IPX0)	IPXX:
	-	7.2.10	Applied Parts: Degrees of protection against electric shock marked with relevant symbols for all applied parts	Markings provided:
	Verify	7.2.10	- Type B applied parts with Table D1, symbol 19: 	Applied Part:
	Verify	7.2.10	- Type BF applied parts with Table D1, symbol 20: 	Applied Part:
	Verify	7.2.10	- Type CF applied parts with Table D1, symbol 21: 	Applied Part:
	Verify	7.2.10	- Defibrillation-proof applied parts marked with Table D1, symbols 25-27: 	Applied Part:
	Verify	7.2.10	Proper symbol marked adjacent to or on connector for applied part -If no connector, then marked on applied part -If connector used for multiple applied parts with different ratings, marked on applied part -If isolation for BF or CF is not provided in the equipment, but in the applied part, marked on the applied part	Marking location:
	Verify	7.2.10	- Table D2, Safety sign 2 placed near connector if part of defib-proof protection is in patient cable 	Relevant connector:
	Verify	7.2.10	- IFU indicates that the protection of ME Equipment against effects of a cardiac defibrillator discharge depends on use of proper cables, as applicable.	Explanation in IFU:
	Verify	7.2.11	Mode of operation: ME Equipment suitable for continuous operation	
	Verify	7.2.11	If NOT continuous use, duty cycle appropriately marked to provide maximum “on” and “off” time.	Duty Cycle:
	Verify	7.2.11 (US)	- X-Ray systems marked as “long time operation” or “momentary operation” (NFPA 70)	long time operation / momentary operation
	Verify	7.2.12	Fuses: Markings provided adjacent to accessible fuse-holder	
	Doc	7.2.12	- Fuse type	Type:
	Doc	7.2.12	- Voltage rating - Current rating	V, A:
	Doc	7.2.12	- Operating speed (letter or color code) - Breaking capacity	Fast / Slow, A breaking capacity:

Verdict	*Info Verify Doc Test*	Clause	Requirement	Comment
	Verify	7.2.13	Physiological Effects (Safety Sign And Warning Statements): - ME Equipment producing physiological effects, not obvious to the operator, and can cause harm to the patient or operator provides suitable safety sign in a prominent location. 	Physiological effects:
	Verify	7.2.13	Nature of hazard and precautions for avoiding or minimizing the associated risk described in IFU. (Risk management to address risk of harm)	RM reference to specific risks (ISO 14971 Clauses) 4.2: 4.3: 4.4: 5: 6.3:
	Verify	7.2.14	High Voltage Terminal Devices: When provided on the outside of ME Equipment, accessible without the use of a tool, - Marked with Table D1, symbol 24 	
	Verify	7.2.15	Cooling Conditions: - Requirements for cooling provisions marked, if applicable	Cooling requirements:
	Verify	7.2.17	Protective Packaging: - Packaging marked with special handling instructions for transport and/or storage, if applicable	Special handling instructions:
	Verify	7.2.17	- Permissible environmental conditions marked on outside of packaging	Environmental conditions:
	Verify	7.2.17	When premature unpacking of me equipment could result in an unacceptable risk, - Packaging marked with a suitable safety sign	Safety sign provided:
	Verify	7.2.17	Risk management file includes the assessment to determine risk of premature unpacking of the ME Equipment or its parts , that could result in an unacceptable risk.	RM reference to specific risks (ISO 14971 Clauses) 4.2: 4.3: 4.4: 5: 6.3: 6.4:
	Verify	7.2.17	Packaging of sterile ME Equipment or accessories, - Marked sterile and indication of the method of sterilization	Sterile, Method:
	Verify	7.2.18	External Pressure Source: Marked on me equipment adjacent to each input connector, - Rated maximum supply pressure from an external source	Max supply pressure:
	Verify	7.2.18	- Rated flow rate required to meet basic safety and essential performance	
	Verify	7.2.19	Functional Earth Terminals: - Marked with Table D1, Symbol 7 	Symbol provided:
	Verify	7.2.20	Removable Protective Means: - Marked to indicate the necessity for replacement when the function is no longer needed	Mark provided:
	Verify	7.2.21	Mass of Mobile Equipment: - Marked with its mass, including its safe working load in kilograms (Marked in a way that's obvious that it applies to the entire mobile ME Equipment, with maximum safe working load, and separate from part load ratings)	Equipment mass in kg:
	Info	7.2.22 (US)	Colors of Medical Gas Cylinders: Cylinders containing medical gases and their connection points colored in accordance with NFPA99	

Verdict	*Info Verify Doc Test*	Clause	Requirement	Comment
	Verify	7.3	**Marking on the inside of me equipment or me equipment parts**:	
	Verify	7.3.1	Heating Elements or Lamp Holders (designed for use with heating lamps): - Maximum power loading marked near or in the heater	W:
	Verify	7.3.1	- A marking referring to accompanying documents provided, where they can be changed only by service personnel using a tool  (or)	
	Verify	7.3.2	High Voltage Parts: - Table D1, Symbol 24 (or) Table D2, safety sign 3 used to mark presence of high voltage parts  (or) Risk management could determine that the safety sign is the most appropriate choice if the personnel exposed to the high voltage parts have minimal training or might otherwise be unaware that it is present.	
	Verify	7.3.3	Batteries: - Type of battery and mode of insertion marked	Type, mode of insertion:
	Verify	7.3.3	- An identifying marking provided referring to instructions in IFU for batteries intended to be changed only by service personnel using a tool	Identifying mark:
	Verify	7.3.3	- A warning provided indicating replacement of lithium batteries or fuel cells IF incorrect replacement would result in an unacceptable risk (in addition to reference to IFU)	Warning provided:
	Verify	7.3.3	Risk management file includes an assessment to determine if the replacement of lithium batteries or fuel cells leads to an unacceptable risk if replaced incorrectly. If so, marking above required.	RM reference to specific risks (ISO 14971 Clauses) 4.2: 4.3: 4.4: 5: 6.3:
	Verify	7.3.3	- Accompanying documents contain a warning indicating the replacement of lithium batteries or fuel cells by inadequately trained personnel could result in a hazard, if risk is determined (above)	Warning provided in IFU:
	Verify	7.3.4	Fuses, (Replaceable) Thermal Cut-Outs, and Over-Current Releases: - If ONLY accessible by tool, Identified by specification adjacent to component (Voltage, Current, Operating speed, Size, Breaking capacity) - (or) Reference to IFU, with specifications provided 	Spec. adjacent to component / Reference to IFU
	Verify	7.3.4	- Voltage rating - Current rating	V, A:
	Verify	7.3.4	- Operating speed(s) - Size - Breaking capacity	Fast/Slow, mm, High breaking capacity A:
	Verify	7.3.5	Protective Earth Terminals: - Marked with Table D1, Symbol 6 	
	Verify	7.3.5	-Markings on or next to protective earth terminals -Not applied to parts requiring removal to make the connection -Remain visible after connection made -Not required for internal PE connections, but not precluded	
	Verify	7.3.6	Functional Earth Terminals: Table D1, Symbol 7 marked on functional earth terminals 	

Verdict	*Info Verify Doc Test*	Clause	Requirement	Comment
	Verify	7.3.7	Supply Terminals: - Conductors marked adjacent to terminals	Terminal markings provided:
	Verify	7.3.7	If not marked, the RMF includes an assessment of the risks resulting from misconnections	RM reference to specific risks (ISO 14971 Clauses) 4.3:
	Verify	7.3.7	Terminal markings included in IFU, when equipment too small for markings	
	Verify	7.3.7	- Neutral supply terminal conductor in permanently installed equipment marked with Table D3 , Code 1 **N**	
	Verify	7.3.7	Marking for connection to a 3-phase supply, complies with IEC 60445	
	Verify	7.3.7	Markings on or adjacent to electrical connection points Not applied to parts requiring removal to make connection Markings remain visible after connection made	
	Verify	7.3.8	Temperatures of Supply Terminals: - Marked at the point of supply connections "For supply connections, use wiring materials suitable for at least X °C" (or equivalent)	
	Verify	7.3.8	Statement not applied to parts requiring removal to make the connection Statement clearly legible after connections made	
	-	7.4	**Marking of controls and instruments**:	
	Verify	7.4.1	Power Switches: Switches for "on" & "off" positions to control power to ME Equipment/parts (including mains switches) - Marked with Table D1, Symbols 12 and 13, for Mains on/off  (or)	
	Verify	7.4.1	- Indicated by an adjacent indicator light, (or)	
	Verify	7.4.1	- indicated by other unambiguous means	
	Verify	7.4.1	- Push button "on/off" switches with bi-stable positions marked with Table D1, Symbol 14  (and)	
	Verify	7.4.1	- Status indicated by adjacent indicator light (or)	
	Verify	7.4.1	- Status indicated by other unambiguous means	
	Verify	7.4.1	- Push button "on/off" switches with momentary on positions marked with Table D1, Symbol 15  (or)	
	Verify	7.4.1	- Status indicated by adjacent indicator light (or)	
	Verify	7.4.1	- Status indicated by other unambiguous means	
	Verify	7.4.2	Control Devices: - Different positions of control devices/switches indicated by figures, letters, or other visual means, such as Table D1, Symbols 16 and 17 -Control functionality, but not mains power to the equipment  Part ON Part OFF	
	Verify	7.4.2	Risk management file identifies controls, where a change in setting in normal use results in an unacceptable risk	RM reference to specific risks (ISO 14971 Clauses) 4.2: 4.3: 4.4: 5: 6.2: 6.3:
	Verify	7.4.2	When determined that the change of control settings could result in an unacceptable risk, - Controls provided with an associated indicating device (or)	Indicating device:
	Verify	7.4.2	- An indication of direction in which magnitude of the function changes	

Verdict	*Info Verify Doc Test*	Clause	Requirement	Comment
	Verify	7.4.2	Control device or switch that brings the ME Equipment into the "stand-by" condition, - Marked with Table D1, Symbol 29 -Control functionality, but not mains power to the equipment 	
	Verify	7.4.3	Units of Measurement: Numeric indications of parameters on ME Equipment expressed in SI units, according to ISO 80000-1 (Base quantities listed in Table 1 expressed in the indicated units)	
	Verify	7.4.3	Application of SI units, their multiples, and certain other units, ISO 80000-1 applied	
	Verify	7.4.3	All Markings in 7.4 comply with 7.1.2 (legibility of markings) and 7.1.3 (durability of markings)	See Appended Tables 7.1.2 and 7.1.3
	-	7.5	Safety signs:	
	Verify	7.5	Safety sign with established meaning used (per ISO 7010)(see Table D2)	
	Verify	7.5	Risk management process identifies markings used to convey a warning, prohibition or mandatory action that mitigate a risk not obvious to the operator	RM reference to specific risks (ISO 14971 Clauses) 4.2: 4.3: 4.4: 5: 6.3:
	Verify	7.5	If insufficient space on ME Equipment for sign and statement, it may be placed in the IFU	
	Verify	7.5	Specified colors in ISO 3864-1 used for safety signs (see Table D2)  D2, #2 General warning  D2, #4 General prohibition  D2, #9 General mandatory action	Safety signs used:
	Verify	7.5	Safety notices include appropriate precautions or instructions on how to reduce risk(s)	
	Verify	7.5	Safety signs including any supplementary text or symbols described in instructions for use	
	Verify	7.5	Language acceptable to the intended operator	
	Verify	7.6	Symbols:	
	Verify	7.6.1	Explanation of Symbols: Meanings of symbols used for marking described in IFU	See instructions for use
	Info	7.6.2	Symbols from Annex D: Required symbols shall meet the referenced IEC and ISO standards in Annex D	
	Verify	7.6.3	Symbols For Controls and Performance: Conform to IEC or ISO publications, as applicable	
	-	7.8	Indicator Lights and controls: Color alone should not be used to convey important information. Redundant means recommended.	

Verdict	*Info Verify Doc Test*	Clause	Requirement	Comment
	-	7.9	**Accompanying documents**:	
	-	7.9.1	General:	
	Verify	7.9.1	ME Equipment provided with documents containing instructions for use, and a technical description	
	Verify	7.9.1	Accompanying documents identify ME Equipment by the following, as applicable:	-
	Verify	7.9.1	- Name or trade-name of manufacturer - Contact information for the responsible organization -Intended environments of use	Name / Contact Info.:
	Verify	7.9.1	- Model or type reference	Model/Type:
	Verify	7.9.1	If accompanying documents provided electronically, Usability engineering process determines what's required in hard copy or markings on the equipment	
	Verify	7.9.1	- Specify special skills, training, and knowledge required by operator or responsible organization - Environmental restrictions on locations of use	
	Verify	7.9.1	- Written at a level consistent with education, training, and other needs of those they are intended for	
	-	7.9.2	Instructions For Use:	
	-	7.9.2.1	General:	
	Verify	7.9.2.1	- Intended use of me equipment, as intended by the manufacturer	Intended use:
	Verify	7.9.2.1	- Frequently used functions	
	Verify	7.9.2.1	- Any known contraindication(s) of the equipment	
	Verify	7.9.2.1	- Parts of the ME Equipment that are not to be serviced or maintained while in use with the patient	
	Verify	7.9.2.1	- Name or trademark of the manufacturer - Address of the manufacturer	
	Verify	7.9.2.1	- Model or type reference	
	-	7.9.2.1	When the patient is an intended operator, instructions for use indicate:	
	Verify	7.9.2.1	- That the patient is an intended operator	
	Verify	7.9.2.1	- Warning against servicing and maintenance while the me equipment is in use	
	Verify	7.9.2.1	- Which functions the patient can safely use (and) - Where applicable, which functions the patient cannot safely use (and)	
	Verify	7.9.2.1	- What maintenance the patient can perform (change batteries, etc.)	
	-	7.9.2.1	Classifications as in Clause 6:	
	Verify	7.9.2.1-6	- Classification (Class I, Class II, Internally Powered Equipment)	
	Verify	7.9.2.1-6	- Type Applied Parts (B, BF, CF, Defib-proof)	
	Verify	7.9.2.1-6	- IPXX (protection against the ingress of water, particulate matter)	
	Verify	7.9.2.1-6	- Method(s) of sterilization (if applicable)	
	Verify	7.9.2.1-6	- Suitability for use in an Oxygen rich environment (if applicable)	
	Verify	7.9.2.1-6	- Mode of operation	
	-	7.9.2.1	All markings per Clause 7.2:	
	Verify	7.9.2.1-7.2	- Single use items specified	
	Verify	7.9.2.1-7.2	- Name or trademark	
	Verify	7.9.2.1-7.2	- Contact information of the manufacturer	
	Verify	7.9.2.1-7.2	- Model or type reference	
	Verify	7.9.2.1-7.2	- Serial number or lot or batch identifier (description)	
	Verify	7.9.2.1-7.2	- Date of manufacture or use by date (description)	
	Verify	7.9.2.1-7.2	- Nominal supply voltage or range	
	Verify	7.9.2.1-7.2	- Nature of supply (number of phases, except for single phase)	
	Verify	7.9.2.1-7.2	- Type of current (AC, DC)	
	Verify	7.9.2.1-7.2	- Rated supply frequency, frequencies, or range, in hertz	
	Verify	7.9.2.1-7.2	- Rated input in amps, volt-amps, or watts	
	Verify	7.9.2.1-7.2	- MSO output Mains voltage, current or power, frequency	
	Verify	7.9.2.1-7.2	- IPXX (protection against the ingress of water, particulate matter)	
	Verify	7.9.2.1-7.2	- Type Applied Parts (B, BF, CF, Defib-proof)	
	Verify	7.9.2.1-7.2	- Mode of operation (if not continuous) - duty cycle on/off times	
	Verify	7.9.2.1-7.2	- Fuse type, voltage, current rating, operating speed, breaking capacity	
	Verify	7.9.2.1-7.2	- Physiological effects (if applicable)	
	Verify	7.9.2.1-7.2	- Requirements for cooling provisions (if applicable)	

Verdict	*Info Verify Doc Test*	Clause	Requirement	Comment
	Verify	7.9.2.1-7.2	- Packaging with special handling (if applicable)	
	Verify	7.9.2.1-7.2	- Permissible environmental conditions	
	Verify	7.9.2.1-7.2	- Information for when premature unpacking of me equipment could result in an unacceptable risk	
	Verify	7.9.2.1-7.2	- Information on equipment or accessories provided sterile (if applicable)	
	Verify	7.9.2.1-7.2	- Rated maximum supply pressure from an external source (if applicable)	
	Verify	7.9.2.1-7.2	- Specification of removable protective means (if applicable)	
	Verify	7.9.2.1-7.2	- Mass of mobile equipment, including its safe working load (parts serving for support or suspension of patient/operators is the mass of the patients/operators plus the mass of accessories intended to be supported/suspended by the equipment or equipment parts) in kilograms	
	-	7.9.2.1-7.2	Detachable components:	
	Verify	7.9.2.1-7.2	- Name or trademark of the manufacturer	
	Verify	7.9.2.1-7.2	- Model or type reference	
	Verify	7.9.2.1-7.2	- Software identified with a unique identifier (description)	
	Verify	7.9.2.1-7.2	- Consult accompanying documents	
	Verify	7.9.2.1-7.2	Accessories:	
	Verify	7.9.2.1-7.2	- Name or trademark	
	Verify	7.9.2.1-7.2	- Manufacturer contact information	
	Verify	7.9.2.1-7.2	- Model or type reference	
	Verify	7.9.2.1-7.2	- Serial number or lot or batch identifier (description)	
	Verify	7.9.2.1-7.2	- Date of manufacture or use by date (description)	
	Verify	7.9.2.1-7.2	Power from other equipment:	
	Verify	7.9.2.1-7.2	- Name/trademark of manufacturer and type reference of other electrical equipment (supplying power)	
	Verify	7.9.2.1	- Explanation of safety signs and symbols marked on ME Equipment	
	Verify	7.9.2.1	Instructions for use are in a language acceptable to the intended operator	
	Verify	7.9.2.2	Warning and Safety Notices: - All warning and safety notices defined in IFU	
	Verify	7.9.2.2	- Warning statement for class I me equipment included: “WARNING: To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth”	
	Verify	7.9.2.2	- Warnings of significant risks of reciprocal interference posed by me equipment during specific investigations or treatments	
	Verify	7.9.2.2	- Information on potential electromagnetic or other interference and advice on how to avoid or minimize such interference	
	Verify	7.9.2.2	-Class I equipment with and internal electrical power source shall state that the internal electrical power source is to be used if the integrity of the PE conductor or the protective earthing system in the installation is in doubt.	
	Verify	7.9.2.2	- Warning statement for ME Equipment/Systems supplied with an integral MSO (multiple socket-outlet)	
	Verify	7.9.2.2	- Responsible organization referred to this standard, for the requirements applicable to ME Systems	
	Verify	7.9.2.3	ME Equipment Specified For Connection to a Separate Power Supply: For Equipment with separate power supply - Power supply specified as part of the ME Equipment (or) - Combination of Equipment and power supply specified as an ME System	
	Verify	7.9.2.4	Electrical Power Source: - Warning statement for mains powered ME Equipment with additional power source, not automatically maintained in a fully usable condition (indicating necessity for periodic checking or replacement of power source)	
	Verify	7.9.2.4	Risk management file assesses risk from leakage of batteries	RM reference to specific risks (ISO 14971 Clauses) 4.2: 4.3: 4.4: 5: 6.3:
	Verify	7.9.2.4	- Warning to remove the battery if the me equipment is not likely to be used for some time, where there is an unacceptable risk	“Remove the battery if the ME Equipment is not likely to be used for some time”
	Verify	7.9.2.4	- Specifications of any replaceable internal electrical power source	Battery specifications:
	Verify	7.9.2.4	- Warning that ME Equipment must be connected to an appropriate power source, when loss of power would result in an unacceptable risk	Specified power source:

Verdict	*Info Verify Doc Test*	Clause	Requirement	Comment
	Verify	7.9.2.5	ME Equipment Description: - Description of ME Equipment - Functions - Significant physical and performance characteristics - (If applicable) Expected positions of operator, patient, other persons near ME Equipment, normal use	
	Verify	7.9.2.5	- Information provided on materials and ingredients that the patient or operator is exposed to , if exposure can constitute an unacceptable risk	
	Verify	7.9.2.5	- Specified restrictions on what other equipment or network/data couplings (other than those forming ME System) the SIP/SOPs may be connected to	
	Verify	7.9.2.5	- Indication of all applied parts	
	Verify	7.9.2.6	Installation: ME Equipment or its parts requiring installation require the following - Reference to where the installation instructions may be found (or) - Contact information for qualified personnel to perform the installation -Statement that manufacturer/installer/assembler is responsible for the effect on basic safety/reliability/performance only if -appropriately trained personnel are used, electrical installation of the room complies with requirements, and ME Equipment or System is used in accordance with the IFU	
	Verify	7.9.2.7	Isolation From The Supply Mains: - Indication not to position equipment to make it difficult to operate the disconnection device, when appliance coupler/mains plug used for mains disconnection	
	Verify	7.9.2.8	Start-Up Procedure: - Necessary information provided for operator to bring me equipment into operation (initial control settings, connection to or positioning of patient, etc.)	
	Verify	7.9.2.9	Operating Instructions: - Information provided to operate ME Equipment in accordance with specifications - Functions of controls, displays, signals - Sequence of operation - Connection and disconnection of detachable parts and accessories - Replacement of materials consumed in operation	
	Verify	7.9.2.9	- Meanings of figures, symbols, warning statements, abbreviations, indicator lights	
	Verify	7.9.2.10	Messages: - All system, error, and fault messages, unless they are self-explanatory - Explanation of messages including important causes and possible action(s) to resolve the problem	
	Verify	7.9.2.11	Shutdown Procedure: - Information to safely terminate operation of ME Equipment	
	Verify	7.9.2.12	Cleaning, Disinfection, and Sterilization: - For parts or accessories that can be contaminated through contact with patient, body fluids, or expired gasses in normal use, - Cleaning, disinfection, sterilization methods that may be used - Applicable parameters that can be tolerated by me equipment parts or accessories specified (eg. temperature, pressure, humidity, time limits, number of cycles)	
	Verify	7.9.2.12	Not required if marked for single use, except when manufacturer specifies it to be cleaned, disinfected, or sterilized before use	
	Verify	7.9.2.13	Maintenance: - Preventive inspection, maintenance, calibration along with its frequency (if applicable)	
	Verify	7.9.2.13	- Information provided for safe performance of such routine maintenance necessary to ensure continued safe use of me equipment	
	Verify	7.9.2.13	- Identify parts requiring preventive inspection and maintenance to be performed by service personnel including periods of application (details of actual performance not necessary)	
	Verify	7.9.2.13	- Instructions provided to ensure adequate maintenance of rechargeable batteries, maintained by anyone other than service personnel	
	Verify	7.9.2.14	Accessories, Supplementary Equipment, Used Material: - List of accessories, detachable parts, and materials intended for use with the ME Equipment	
	Verify	7.9.2.14	Other equipment providing power to ME System sufficiently specified (e.g. part number, rated voltage, max/min power, protection class, continuous/duty cycle)	
	Verify	7.9.2.15	Environmental Protection: - Advice on proper disposal of waste products, residues, etc. - Advice on proper disposal of ME Equipment and accessories at the end of their expected service life	Advice:
	Verify	7.9.2.16	Reference to Technical Description: - Information specified in 7.9.3 (see below) or identify where it can be found (such as service manual)	

Verdict	*Info Verify Doc Test*	Clause	Requirement	Comment
	Verify	7.9.2.17	ME Equipment Emitting Radiation: ME Equipment emitting radiation for medical purposes - Indication of the nature, type, intensity and distribution of the radiation (as appropriate)	
	Verify	7.9.2.18	ME Equipment and Accessories Supplied Sterile: - Indicate that they have been sterilized - Indicate the method of sterilization	
	Verify		- Indicate the necessary instructions in the event of damage to the sterile packaging - Details of the appropriate methods of re-sterilization (if applicable)	
	Verify	7.9.2.19	Unique Version Identifier: - IFU contains a unique version identifier	IFU Identifier (revision):
	-	7.9.3	Technical description:	
	Verify	7.9.3.1	General: Provide all essential data for safe operation (see below)	
	Verify	7.9.3.1	- Permissible environmental conditions for use, transport, and storage (from 7.2.17)	
	Verify	7.9.3.1	All characteristics of ME Equipment - Range(s), accuracy, precision of displayed values (or where they can be found)	
	Verify	7.9.3.1	- Any special installation requirements	
	Verify	7.9.3.1	- Cooling liquids, range of inlet pressure, flow, chemical composition	
	Verify	7.9.3.1	- Means of isolating ME Equipment from supply mains, if not incorporated in ME Equipment	
	Verify	7.9.3.1	- Describe means for checking oil level, for partially sealed oil filled ME Equipment or parts	
	Verify	7.9.3.1	- Warning statement to address hazards from unauthorized modification of ME Equipment: “WARNING: No modification of this equipment is allowed” (or) “WARNING: Do not modify this equipment without authorization of the manufacturer” (or) “WARNING: If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment”	Warning statement provided:
	Verify	7.9.3.1	- Information about any essential performance - Any necessary recurrent essential performance and basic safety testing, with details on means, methods, and recommended frequency	

Verdict	*Info Verify Doc Test*	Clause	Requirement	Comment
	Verify	7.9.3.1	**If technical description separable from IFU**, technical description provides the following information	
	Verify	7.9.3.1	- All applicable information in Clause 7.2 (see 7.9.2.1 requirements above)	
	Verify	7.9.3.1	- All applicable classifications in Clause 6 (see 7.9.2.1 requirements above) - Any warning and safety notices - Explanation of safety signs on ME Equipment	
	Verify	7.9.3.1	- Brief description of the ME Equipment - How the ME Equipment functions - Significant physical and performance characteristics	
	Verify	7.9.3.1	- Unique version identifier	Technical description Identifier (revision):
	Verify	7.9.3.1	- Manufacturer's requirements for minimum qualifications of service personnel (optional)	
	-	7.9.3.1	-Permissible environmental conditions for which a hazard is not induced - humidity, temperature, atmospheric pressure, shock and vibration, UV radiations, water temperature used for cooling, pollution, transport and storage conditions	
			-Accuracy and precision addressed in particular standards	
	Verify	7.9.3.2	Replacement of Fuses, Power Supply Cords, and Other Parts: Technical description contains the following applicable information	
	Verify	7.9.3.2	- Type and full rating of fuses used in supply mains external to permanently installed ME Equipment (if not apparent from rated current and mode of operation)	Fuse type and ratings:
	Verify	7.9.3.2	- Statement if power supply cord is replaceable by service personnel (for non-detachable cord)	
	Verify	7.9.3.2	- instructions for correct replacement of interchangeable or detachable parts (specified by manufacturer as replaceable by service personnel)	
	Verify	7.9.3.2	Risk management file includes an assessment to determine if replacement of components results in any unacceptable risks, when replacement is specified	RM reference to specific risks (ISO 14971 Clauses) 4.2: 4.3: 4.4: 5: 6.2: 6.3: 6.4: 6.5:
	Verify	7.9.3.2	- Warnings identifying nature of hazard, when replacement of a component could result in an unacceptable risk, when replaceable by service personnel - All information necessary to replace the component safely	
	Verify	7.9.3.3	Circuit Diagrams, Component Part List, etc.: - Indication that manufacturer will provide the following information to assist service personnel in the repair of parts that are designated by the manufacturer as replaceable service personnel: (circuit diagrams, component part lists, descriptions, calibration instructions)	
	Verify	7.9.3.4	Mains Isolation: - Identify means used to comply with requirements of 8.11.1 (method equipment uses to isolate itself from the supply mains: switch, power cord plug, etc.)	

Verdict	*Info Verify Doc Test*	Clause	Requirement	Comment
Additional Accompanying Documents and Marking Requirements Throughout IEC 60601-1 (Other Than Section 7):				
	Verify	5.4a	Working conditions: - Specified in the **accompanying documents** (used for determining and testing to worst-case)	
	Verify	8.4.2c	Accessible parts: limits of enclosure (touch) leakage current are not applied to the following parts if the operator is instructed (in **accompanying documents**) to not touch the parts and the patient simultaneously and the probability is negligible: -accessible contacts of connectors -contacts of fuse holders -parts inside access covers (without a tool or with a tool and instructed by the documentation)	
	Verify	8.4.4	Non-automatic discharging of internal capacitive circuits: If circuits are not automatically discharged and an access cover can be removed with a tool, the capacitor or connected circuitry is marked with symbol 24 of Table D.1 and the non-automatic discharges device is specified in the **accompanying documents** 	Manual discharging instructions:
	Verify	8.5.5.1.1b	Defibrillation Recovery Time: - Disclose the necessary recovery time following exposure to a defibrillation in the **accompanying documents**	Recovery time:
	Verify	8.6.7	Potential Equalization Terminal: Marked with symbol 8 of Table D.1  - Specify the function/use of PE conductor, reference to requirements of IEC 60601 for ME systems in the **accompanying documents**	
	Verify	8.6.9	Class II Equipment with Isolated internal screens: Functional earth connections to isolated internal screens via the 3rd conductor of the power supply - State that third conductor in power supply cord is only functional earth in the **accompanying documents**	
	Verify	8.11.1 i	Isolation from Mains: Parts above 42.4Vpeak or 60Vdc that cannot be disconnected externally protected against being touched even after opening of the ENCLOSURE by an additional covering or - marked with symbol 10 of Table D.1 with warning notice **marked on outside of the equipment**  + Warning	
	Verify	8.11.4.1	Mains Terminal Devices: Marking of terminals other than terminal blocks: Terminals of components other than terminal blocks may be used as terminals intended for external conductors if they comply with the requirements of 8.11.4 and are - Properly **marked** according to 7.3.7	
	Verify	9.2.1	Mechanical hazards associated with moving parts: Residual risk of moving parts is acceptable if necessary for the equipment's intended function and - Warnings implemented as risk control measures in the **labeling** and **instructions for use**	
	Verify	9.2.4i	Emergency stops: -Colored red If emergency stop interrupts/opens mechanical movement either - **Marked** with "STOP" or - **Marked** with Symbol 18 of Table D.1 	

Verdict	*Info Verify Doc Test*	Clause	Requirement	Comment
	Verify	9.4.2.2	Instability in transport conditions: - Equipment is prepared as indicated in the **accompanying documents** for transportation or any normal use configuration and must not overbalance at 10º.	
	Verify	9.4.2.2	Instability in non-transport conditions: If the equipment overbalances (any normal use configuration) at 10º, - a **warning marking** is provided, stating transport should only be done in a certain configuration. Any residual risk is: - Specified in the **accompanying documents** or - **Marked on the equipment** (including loading/unloading or opening/closing doors, shelves, and drawers) - See also clause 7.9.2.2	
	Verify	9.4.2.3a	Instability from pushing, leaning, and resting: Equipment with a mass >25 kg, intended to be used on the floor and not fixed shall not - Overbalance due to pushing, leaning or resting or - Be **marked** with Safety Sign 5 of Table D.2 - Marking visible during normal use, but not applied to area associated with pushing (ie handles) - See test for determination of overbalance 	
	Verify	9.4.2.3b	Instability from sitting or stepping: Equipment intended to be used on the floor or table and not fixed shall not - Overbalance due to sitting or stepping, or - Be **marked** with Safety Sign 6 and 7 (as applicable) of Table D.2 - Symbol must be visible during potential sitting or stepping - See test for determination of overbalance 	
	Verify	9.4.2.4.2	Force for Propulsion: If the mobile equipment requires more than 200N to move, - **Instructions for use** shall state that more than one person is required to move the equipment	Statement, if >200 N required:
	Verify	9.4.2.4.3	Movement over a Threshold: Method of mobile equipment passing over a threshold - Shall be specified in the **accompanying documents** and tested as such or - The default method will be used for testing	
	Verify	9.4.4	Grips and Handling Devices: - Equipment is provided with grip or handling devices (handles, lifting eyes, etc) or - The **accompanying documents** indicate points where the equipment can be safely lifted	
	Verify	9.6.2.1b	Audible Acoustic Energy: Measurements of the acoustic energy - Made with any auditory protective means called out in the **accompanying documents**	
	Verify	9.7.2	Pneumatic and hydraulic parts: - Pressure elements that can remain under pressure after isolation of the equipment from power and - That could result in an unacceptable risk clearly identify exhaust devices - **Warning label** provided about need to depressurize the elements	
	Verify	9.8.1	Fixing of structures to floors, walls, ceilings, etc - **Accompanying documents** disclose: - Instructions on attachment of structures, - Quality of the materials to be used for the attachment, - Required materials, and - Adequacy of the surface of the structures	
	Verify	9.8.3.1	Patient or Operator Support or Suspension systems: Where the maximum value of the patient is less than 135 kg: - Value is **marked** on the equipment and described in the **accompanying documents** Where the maximum value of the patient is more than 135 kg: - Value is described in the **accompanying documents**	
	Verify	9.8.4.3	Mechanical Protective Device for Single Activation: - **Marked** adjacent to protective device with safety sign 2 of Table D.2 - **Accompanying documents** instruct user to contact service personnel once the protective device has been activated 	

Verdict	*Info Verify Doc Test*	Clause	Requirement	Comment
	Verify	11.1.2.1	Applied Part Temperatures Intended to Supply Heat: The temperatures and clinical effects of Applied Parts intended to supply heat (or cold) to patients - Disclosed in the **instructions for use**.	
	Verify	11.1.2.2	Applied Part Temperatures Not Intended to Supply Heat: Maximum temperature, conditions for safe contact (duration or condition of patient) - Disclosed in the **instructions for use**, if greater than 41°C	
	Info	11.6.2	Overflow of a reservoir or liquid storage container: - **Marking** of the maximum fill level and a **safety notice** given: changes parameters of overflow test. With markings: Maximum fill, tilted at 10º (non-mobile) or rolled over a 10 mm threshold (mobile) Without markings: Filled to 115%, tilted at 10º (non-mobile) or rolled over a 10 mm threshold (mobile)	
	Verify	11.6.6	Cleaning and disinfection: - Agents and process specified in the **instructions for use**	Cleaning/disinfections agents specified:
	Verify	14.13	PEMS (software) intended to be connection to an IT-Network **Instructions** for implementing the connection includes: - Purpose - Characteristics of the IT-Network - Required configuration of the IT-Network - Technical specifications (including security) of the IT-Network - Intended information flow between the PEMS, IT-Netword and other devices on the network - Hazardous situations resulting from failure of the IT-Network to provide the necessary characteristics **Instructions** state that: - Connection of the PEMs to IT-Networks with other equipment could result in unidentified risks - The responsible organization should identify, analyze and control risks - Changes to the IT-Network could introduce new risks, where changes include configuration, the connection of additional items, disconnection of items, update/upgrade of the equipment connected	Connections specified:
	Verify	15.4.2.2	Temperature Settings: Where temperature settings of thermostats can be varied - Temperature setting is clearly indicated by **marking(s)**	
	Verify	15.4.6.1b	Actuating controls: - Controls secured so the indication of the scale **markings** correspond to the position of the control	
	Verify	15.4.7.3b	Footswitches: **- Accompanying documents** include/exclude areas of use where liquids are likely to be present at floor level	
	Verify	16.2 a, b	ME Systems: - **Accompanying documents** for all system elements provided with system (medical/non-medical)	
	Verify	16.2 c	- **Specification** for the system that identifies the intended use and identifies all elements of the system	
	Verify	16.2 c	- **Instruction** for installation, assembly, modification of the system (such that it meets the 60601-1 standard and any applicable collateral and particular standards)	
	Verify	16.2 c	- **Instructions** for proper cleaning and disinfection of the system	
	Verify	16.2 c	- **Instructions** for safety measures during installation/assembly of the system	
	Verify	16.2 c	- **Identification** of those parts that may be used within the patient environment.	
	Verify	16.2 c	- **Instruction** of steps required during maintenance of the system	
	Verify	16.2 c	- A **warning in the instructions** that multiple socket outlets not attached to system elements should not be placed on the floor.	
	Verify	16.2 c	- A **warning in the instructions** not to connect additional multiple socket outlets to the system	
	Verify	16.2 c	- A **warning in the instructions** not to attach other pieces (other than those specified) to the system	
	Verify	16.2 c	- **Instructions** specify the maximum (total) electrical load for multiple socket outlets	
	Verify	16.2 c	- A **warning in the instructions** that multiple socket outlets are only to be used to supply power to elements of the system	
	Verify	16.2 c	- **Instructions** provide an explanation of risks associated with connecting non-medical pieces of equipment (supplied as part of the system) to wall outlets if it is intended to be supplied from the system	
	Verify	16.2 c	- **Instructions** provide an explanation of risks associated with connecting equipment other than that intended to be part of the system to multiple socket outlets	
	Verify	16.2 c	- **Instructions** provide environmental restrictions necessary for safe operation of the system (including shipping and storage)	
	Verify	16.2 c	- A **warning in the instructions** to the operator not to touch parts that could result in excessive leakage currents and the patient at the same time	

Verdict	*Info Verify Doc Test*	Clause	Requirement	Comment
	Verify	16.2 d	- **Instructions** that all specified cleaning and disinfection procedures must be performed	
	Verify	16.2 d	- **Instructions** that specific tests must be carried out after assembly or modifications to the system during its life	
	Verify	16.3	If some elements of the system are intended to receive power from other elements: - **Instructions for use** specify such interconnections in adequate detail to assure correct assembly of the system such that the requirements of this standard will be met	
	Verify	16.3	If ME System is intended to receive power from an IPS or UPS and can draw large transient currents: - **Accompanying documents with installation instructions** disclose actual transients current levels (or restrict currents to allowed levels specified for the IPS/UPS)	Transient currents:
	Verify	16.9.2.1b	Accessible Multiple Socket-Outlets **marked** with safety sign 2 of Table D.2 (visible during normal use)  - **Marked** with maximum allowable continuous output in A or VA (individually or in combinations), or - **Marked** with the equipment or parts that may be attached	
	Verify	16.9.2.1d	Multiple Socket-Outlets with a Separating transformer - Separate assembly **marked** according to 7.2 and 7.3 (see Clauses 7.2 and 7.3 above)	
	Verify	G.3.1	Category APG Equipment (use with flammable anesthetic mixtures with Oxygen or Nitrous Oxide): - **Marked** with symbol 23 of Table D.1 (Green colored band at least 2 cm wide by 4 cm in length) - If **marking** is not possible, information given in the **accompanying documents** - **Marking** is present on major part of the equipment - **Marking** clearly indicates parts that are not category APG, if they exist 	
	Verify	G.3.2	Category AP Equipment (use with flammable anesthetic mixtures with Air): - **Marked** with symbol 22 of Table D.1 (Green colored circle at least 2 cm in diameter) - If **marking** is not possible, information given in the **accompanying documents** - **Marking** is present on major part of the equipment - **Marking** clearly indicates parts that are not category AP, if they exist 	
	Verify	G.3.4	APG and AP Category Equipment Disclosure: - **Accompanying documents** indicate which parts of the equipment are category AP and APG and which are not	