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JAPANESE INDUSTRIAL STANDARD

General Requirements for Safety of Medical Electrical Equipment

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General Requirements for Safety
of Medical Electrical Equipment

T 1001-1983

1. Scope

This Japanese Industrial Standard specifies the general requirements for safety of medical electrical equipment intended for use in such a way that the safety of medical electrical equipment to be used in the patient environment and of persons in the patient environment is directly affected. However, where there is difference between this standard and the standard for individual equipment, the standard for individual equipment shall be preferred.

2 Definitions

For the purpose of this standard, the following definitions apply:

The voltage value and the current value used in this standard mean the root-mean-square (r.m.s.) values of alternation, direct, or composite voltage and current, unless otherwise specified.

- (1) body of the equipment The enclosure of the equipment including accessible conductive parts, knobs, handles, grips, and the like. For the purpose of tests, metal foil not larger than 10 cm x 20 cm applied in contact with insulating enclosure is included also.
- (2) accessible conductive part Conductive part of equipment which may be touched by user (person to utilize or operate the equipment) or patient without the use of a tool.
- (3) power source primary circuit Circuit in the equipment electrically connected to the commercial power source.
- (4) live The state of a part of the equipment under normal or single fault condition, which, when the part is contacted, can cause a current exceeding the specified allowable leakage current to flow from that part to earth or an accessible part of the same equipment.
- (5) applied part The parts of the equipment including the patient leads which come intentionally into contact with the patient to be examined or treated or are to be inserted.
- (6) F-Type isolated applied part, hereinafter referred to as the "isolated applied part". Applied part isolated from all other parts of the equipment to such a degree that the allowable patient leakage current under single fault conditions is not exceeded when 1.1 times the rated voltage is applied between the applied part and the earth.
- (7) patient All persons to be object for inspection, diagnoses or treatment, not restricting to sick persons.

- (8) patient circuit Electrical circuit of which the patient forms a part.
- (9) Class III equipment input part Part to be connected to medical safety ultra-low voltage by particular plug of Class III equipment.
- (10) Class III equipment output part Part to be connected with outer part excepting applied part and input part of the Class III equipment.
- (11) signal input part Part of equipment, not being an applied part, intended to receive input signal voltages or currents, for example, for display.
- (12) signal output part Part of equipment, not being an applied part, intended to deliver output signal voltages or currents, for example, for display.
- (13) accompanying documents Documents containing information required for the user, installer, etc.
- (14) Class I equipment Equipment in which protection against electric shock does not rely on basic insulation, but which includes protection earth in addition to the basic insulation, and is used with being connected to commercial power source.
- (15) Class II equipment Equipment in which protection against electric shock does not rely on basic insulation only, but in which additional safety precautions such as double insulation or reinforced insulation are provided and which is used with connected to commercial power source, and does not require protective earth.
- (16) commercial power source Power source of 50 Hz or 60 Hz supplied by power supplier or the power source equivalent thereto.
- (17) Class III equipment Equipment in which protection against electric shock relies on supply at medical safety ultra-low voltage in addition to basic insulation, and which is used by connecting with outer power source and does not generate higher voltage than this power source voltage.
- (18) internal power source equipment Equipment which is built-in with battery sufficient to actuate the equipment and has a construction incapable of connection to outer power source.
- (19) Type B equipment Equipment in which the safety for actuation of leakage current and protective earth (if present) is considered. Equipment which is intended for external and internal application to patient, excluding direct cardiac application and equipment having no applied part.

- (20) Type BF equipment Type B equipment with an F-Type isolated applied part.
- (21) Type CF equipment Equipment in which the allowable value of leakage current is particularly severe, and having an F-Type isolated applied part and is intended for direct cardiac application.
- (22) permanent connection Connection that can be loosened or tightened only with the aid of a tool.
- (23) permanently installed equipment Equipment that is electrically connected by means of permanent connection.
- (24) fixed equipment Equipment which is fastened or otherwise secured at a specific location in a building or a vehicle, or equipment which is used at a fixed place.
- (25) portable equipment Equipment able to be moved simply without limitation of range.
- (26) mobile equipment Transportable equipment to be moved by wheels provided to the equipment.
- (27) hand-held equipment Equipment to be supported by the hand during normal use.
- (28) Deadman Type Type which actuates only while the user applies force to controlling device.
- (29) air clearance The shortest distance in air between two conductive parts.
- (30) creepage distance The shortest distance along the surface of insulating material between two conductive parts.
- (31) basic insulation Insulation applied to live parts to provide basic protection against electric shock.
- (32) operational insulation Insulation between live parts which have a potential difference between them and which is necessary for the normal functioning of the equipment.
- (33) supplementary insulation Independent insulation applied in addition to basic insulation in order to provide protection against risk due to a failure of basic insulation.
- (34) double insulation Insulation comprising both basic insulation and supplementary insulation.
- (35) reinforced insulation A single insulation which provides a degree of protection equivalent to double insulation.
- (36) high voltage Any voltage over 1000 V a.c. or over 1500 V d.c. or over 1500 V peak value.



- (37) medical safety ultra-low voltage A voltage which does not exceed 24 V a.c. or 50 V d.c. at rated supply voltage on the transformer or converter, and is isolated from commercial power source and is not earthed.
- (38) leakage current Non-functional current flowing through other than the circuit.
- (39) earth leakage current Current flowing from the power source primary circuit through other than circuit into protective earth conductor.
- (40) enclosure leakage current Current flowing from the enclosure through an external conductor other than the protective earth conductor to earth or to other part of the enclosure.
- (41) patient leakage current Current flowing from the applied part through the patient to earth or flowing from the patient through insulated applied part to earth originating from a voltage appeared on the patient from an external source.
- (42) patient auxiliary current Current flowing in the patient between parts of the applied part and not intended to produce a physiological effect, for example, bias current of amplifier, currents used in impedance plethysmography.
- (43) patient functional current Current flowing in the patient between parts of the applied part and intended to produce a physiological effect, for example, current necessary for nerve and muscle stimulation, pacing, defibrillation, high-frequency surgical procedures.
- (44) functional earth Earth for functional purposes, for example, earth in a measuring power source, earth in a control circuit, or earth of screening part.
- (45) protective earth Earth intended to introduce the leakage current to ground for the purpose of prevention of electric shock.
- (46) additional protective earth Protective earth provided in addition to the normal protective earth.
- (47) additional protective earth conductor Conductor for the purpose of protective earth of internal and external parts of the equipment.
- (48) potential equalization conductor Conductor to connect conductive part to potential equalization busbar independent of each other.
- (49) continuous operation Operation under normal load for an unlimited period, without the specified limits of temperature rise being exceeded.
- (50) short time operation Operation under normal load for a specified period, starting from cold condition without the specified limits of temperature rise being exceeded, the intervals between each period of operation being sufficient to allow the equipment to cool down.

- (51) intermittent operation Operation in a series of specified cycle, each cycle being composed of a period of operation under normal load, without the specified limits of temperature rise being exceeded, followed by a rest period with the equipment running idle.
- (52) normal condition Condition in which all means provided for protection against hazards are complete.
- (53) single fault condition Condition in which a single means for protection against hazards is defective or a single abnormal hazardous condition is present.
- (54) patient environment Any area up to 2.5 m distant from the intended location of the patient.
- (55) preservation environment Environment where the equipment is preserved under the condition with the packing removed for the purpose of next use without the power source being on.
- (56) signal input and output part All parts intended to receive and deliver signal voltage and signal current, for example, for display, or the like, excepting applied part.
- (57) protective earth terminal Terminal for protective earth. In the case of power source cords incapable of attaching and detaching, earth contacts of power source plugs.

3. Using Conditions

The equipment to be applied with this standard shall be able to be used normally and safely under the following using conditions:

- (1) Using Environment The using environment shall be as follows, excepting dew-condensation condition.

- (1.1) Ambient Temperature 10 to 40°C

- (1.2) Relative Humidity 30 to 85 %

- (1.3) Atmospheric Pressure 70 to 106 kPa (700 to 1060 mbar)

- (1.4) Power Source

- (a) Alternating Power Source

Voltage Within ± 10 % of rated voltage, rated voltage of the equipment not more than 250 V

Frequency Within 50 or 60 ± 1 Hz

Waveform Substantially sinusoidal wave, however, in the case of multiphase, substantially symmetrical waveform

- (b) Internal Power Source Within the range of voltage specified by the equipment manufacturer.
- (c) Medical Safety Ultra-low Power Source Power source of not more than d.c. 50 V and a.c. 24 V according to the specification of manufacturer.

(2) Preservation Environment The preservation environment shall be as follows, unless specified by the manufacturer.

- (2.1) Ambient Temperature -10 to 60°C
- (2.2) Relative Humidity 30 to 95 %
- (2.3) Atmospheric Pressure 70 to 106 kPa (700 to 1060 mbar)

4. Classification of Equipments

The medical electrical equipments to be applied with this standard shall be classified as follows according to the type and degree of protection against electric shock.

(1) Classification according to type of protection against electric shock

- (a) Class I equipment
- (b) Class II equipment
- (c) Class III equipment
- (d) Internal power source equipment

(2) Classification according to degree of protection against electric shock

- (a) Type B equipment
- (b) Type BF equipment
- (c) Type CF equipment

5. Safety Requirements

5.1 Basic Safety Countermeasures The safety countermeasures for the patient, users and environment should preferably be carried out in the order given in the following:

- (1) Unconditional Safety All means required for hazard prevention shall be incorporated in the equipment.
- (2) Conditional Safety Special external protective means shall be provided.
- (3) Descriptive Safety The conditions required for safe operation of the equipment shall be marked.

5.2 Countermeasures with Respect to Single Fault The countermeasures with respect to single fault shall be as follows:

- (1) Single fault of the equipment shall be able to be detected according to either of the following methods:
 - (a) At the time of fault, simultaneously the alarm is displayed.
 - (b) It is detected easily by checking.
- (2) The equipment shall comply with the specifications of 6.2 even under the single fault condition as shown in the following:
 - (a) The interruption of one protective earth conductor
 - (b) The appearance of an external voltage in an applied part or in an input part and output one
 - (c) The interruption of one power source conductor
 - (d) Loss of insulation effect of either of the parts of a double insulation
 - (e) Loss of insulation effect between the applied part and the live part (in case where the insulation between these does not comply with the specified air clearance or creepage distance)
 - (f) Faults of components the failure of which may result in a safety hazard

6. Protection against Electric Shock

6.1 Requirements Related to Classification

6.1.1 Class I Equipment, Class II Equipment, and Class III Equipment
The protection of Class I equipment, Class II equipment and Class III equipment shall be in accordance with the following:

- (1) For the power source primary circuit of the equipment, protective measures required for constructions of Class I, Class II and Class III equipments, other than basic insulation, shall be applied.
- (2) The earth of Class I equipment shall be carried out according to the permanent connection or the "Hospital Grade" outlets-socket and plugs specified in JIS T 1021.
- (3) The Class II equipment shall be of either type of the following:
 - (a) Insulation-enclosed Class II equipment Equipment having an enclosure of insulating material which envelops the metallic parts with the exception of small parts, such as screws, rivets and name-plate which are isolated from live parts by insulation at least equivalent to reinforced insulation.

Further, this enclosure may form the supplementary insulation.



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- (b) Metal-enclosed Class II equipment Equipment having a metal inclosure in which double insulation is used throughout the power supply primary circuit at least.
- (c) Equipment which is a combination of (a) and (b).
- (4) Class II equipment shall not be connected with a capacitor between the power source primary circuit and the accessible conductive part. Further, the capacitor with enclosure of only basic insulation shall not be attached on the accessible conductive part.

6.1.2 Equipment with an Internal Power Source The equipment shall be built-in with battery sufficient to actuate the equipment and be of such construction that cannot be connected with external power source.

6.1.3 Protection against Electric Shock The Protection against electric shock shall be as follows:

- (1) The equipment without applied part shall comply with Type B equipment.
- (2) The equipment to be connected directly with the heart shall be of Type CF equipment.
- (3) Type BF or Type CF equipment may have applied part of Type B or Type BF equipment together.

6.2 Limits of Leakage Currents and Patient Auxiliary Currents The leakage current and patient auxiliary current, when measured by using a 1 k Ω non-inductive resistor, shall be as follows:

- (1) The leakage current of each part of the equipment shall not exceed the value given in Table 1, excepting the temporary leakage current.

Further, the patient leakage current shall be the current flowing from the part where all applied parts are combined for Type B equipment, the current following from individual parts after the applied parts relating to one function are connected to each other of Type BF equipment, and the current flowing from and to each electrically isolated part of applied parts for Type CF equipment.

- (2) The allowable value where the frequency exceeds 1 kHz shall be the value given in Table 1 multiplied by the number of its frequency expressed by the unit of kHz, provided that 10 mA shall be the limit.