– *primary voltage maintained between 90 % to 110 % of RATED voltage*

– *RATED input frequency*

– *loads on other windings between no load and their NORMAL USE load*

Short circuit or resistive load, as appropriate, is applied at the ends of the windings or at the first point that can be short circuited under SINGLE FAULT CONDITION.

Components intended to prevent overheating of the transformer during short circuit and overload conditions are included as part of the tests of 15.5.1.2 and 15.5.1.3 provided that ~~it is unlikely that a short circuit or overload condition could arise for which they would not provide protection. Failure of such circuits to provide protection are considered unlikely to occur where insulation (including spacing) is equal to at least one MEANS OF OPERATOR PROTECTION as defined in Clause 8 and COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS are used.~~:

– *the component is one with high-integrity characteristics, and*

– *two MEANS OF OPERATOR PROTECTION are provided between the output contacts of the transformer up to the COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS.*

During the tests, no winding are to open, no HAZARDOUS SITUATION occurs, and the maximum temperatures of windings are not to exceed the values in Table 31. After the short circuit and overload tests, the transformer is to pass the dielectric strength test (as described in 8.8.3) between primary and secondary windings, between the primary windings and the frame and between the secondary windings and the frame. The tests are performed under the conditions specified in 11.1, either in the ME EQUIPMENT or under simulated conditions on the bench.

Table 31 – Maximum allowable temperatures of transformer windings under overload and short-circuit conditions at 25 °C (± 5 °C) ambient temperature

Parts	Maximum temperature °C
Windings and core laminations in contact therewith, if the winding insulation is:	
– of Class A material	150
– of Class B material	175
– of Class E material	165
– of Class F material	190
– of Class H material	210

15.5.1.2 Short-circuit test

The output winding under test is short circuited. The test is continued until the protective device operates or THERMAL STABILITY is achieved. For transformers not tested according to the 5X frequency and 5X voltage test of 15.5.2 a) or the 2X frequency and 2X voltage test of 15.5.2 b), the short circuit is applied directly across the output windings.

15.5.1.3 Overload test

Windings with more than one protective device could require multiple overload tests in order to fully evaluate worst-case NORMAL USE loading and fusing.

The overload test may be applied after rectification.

If the short-circuit test is completed without operation of a protective device (such as a current limiting circuit), the overload test is not required.

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a) This test (a) is performed if the current at which the protective device operates cannot be determined based on a review of the provided protective devices and their performance data; otherwise test b) is performed.

The winding under test is loaded to its NORMAL USE load until THERMAL STABILITY is reached. The load is then progressively adjusted in appropriate steps to approach the minimum current at which the protective device operates. Each adjustment of the load is followed by a sufficient time to reach THERMAL STABILITY, and the load current and temperature are to be noted.

Following operation of a protective device, b) is performed.

b) If the protective device that operated in a) is external to the transformer, it is shunted. The winding under test is loaded based on the type of protective device as follows.

– *Fuse in accordance with IEC 60127-1:*

30 min at the appropriate test current determined from Table 32.

Table 32 – Test current for transformers

Marked value of RATED current (*I*) of protecting fuse-link A	**Ratio between test current and RATED current of the fuse-link**
$I \leq 4$	2,1
$4 < I \leq 10$	1,9
$10 < I \leq 25$	1,75
$I > 25$	1,6

– *Fuses not in accordance with IEC 60127-1:*

30 min at the current according to the characteristics supplied by the fuse manufacturer, specifically the 30 min clearing-time current. If no 30 min clearing-time current data is available, the test current from Table 32 is used until THERMAL STABILITY is achieved.

– *Other protective device:*

until THERMAL STABILITY at a current just below that which caused the device to operate in a).

This portion of the overload test is concluded at the specified time or when a second protective device opens.

15.5.2 * Dielectric strength

This subclause is not applicable to transformers operating at a frequency above 1 kHz, which are tested in accordance with 8.8.3.

ME EQUIPMENT transformer windings shall have adequate insulation to prevent internal short-circuits that could cause overheating where such overheating could result in a HAZARDOUS SITUATION.

The dielectric strength of the electrical insulation between turns and layers of each winding of a transformer of ME EQUIPMENT where failure of the transformer could result in a HAZARDOUS SITUATION shall be such that after the humidity preconditioning treatment (see 5.7) it passes the following tests.

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a) *Transformer windings having a RATED voltage ≤ 500 V or RATED frequency ≤ 60 Hz are tested with a voltage across the winding of five times the RATED voltage or five times the upper limit of the RATED voltage range of that winding and a frequency not less than five times the RATED frequency (where RATED frequency is the normal operating frequency of the transformer input voltage).*

b) *Transformer windings having a RATED voltage exceeding 500 V or RATED frequency exceeding 60 Hz are tested with a voltage across that winding of twice the RATED voltage or twice the upper limit of the RATED voltage range of that winding and a frequency not less than twice the RATED frequency (where RATED frequency is the normal operating frequency of the transformer input voltage).*

In the two cases above, however, the stress on the turn and layer insulation of any winding of the transformer is to be such that the test voltage appearing at the winding with the highest RATED voltage does not exceed the test voltage specified in Table 6, for one MEANS OF PROTECTION, if the RATED voltage of such a winding is considered as the WORKING VOLTAGE. If this should occur, the test voltage on the primary winding is reduced accordingly. The test frequency can be adapted to produce in the core approximately the magnetic induction present in NORMAL USE. Where the core of the transformer is isolated from all external conductive connections (such as in most toroidal transformers), connections to the core described below may be omitted.

– *Three-phase transformers can be tested by means of a three-phase testing device or by three consecutive tests using a single-phase testing device.*

– *The value of the test voltage with respect to the core and to any screen between primary and secondary windings is in accordance with the specification of the relevant transformer. If the primary winding has an identified connection point for the neutral of the SUPPLY MAINS such a point is connected to the core (and screen if present) unless the core (and screen) are specified for connection to an unearthed part of the circuit. To simulate this, the core (and screen) are connected to a source with an appropriate voltage and frequency with respect to the identified connection point.*

  If such a connection point has not been identified, each side of the primary winding in turn is connected to the core (and screen if present) unless the core (and screen) are specified for connection to an unearthed part of the circuit.

  To simulate this, the core (and screen) are connected to a source with an appropriate voltage and frequency with respect to each side of the primary winding in turn.

– *During the test, all windings not intended for connection to the SUPPLY MAINS are left unloaded (open circuit). Windings intended to be earthed at a point or to be operated with a point nearly at earth potential are to have such a point connected to the core, unless the core is specified for connection to an unearthed part of the circuit.*

  To simulate this, the core is connected to a source with an appropriate voltage and frequency with respect to such windings.

– *Initially not more than half the prescribed voltage is applied, then, it is raised over a period of 10 s to the full value, which is then maintained for 1 min, after which the voltage is reduced gradually and switched off.*

– *Tests are not conducted at resonant frequencies.*

Compliance is checked by the following:

During the test, any flashover or breakdown of any part of the insulation constitutes a failure. There is to be no detectable deterioration of the transformer after the test.

Slight corona discharges are neglected, provided that they cease when the test voltage is temporarily dropped to a lower value, that this value is higher than the WORKING VOLTAGE and that the discharges do not provoke a drop in test voltage.

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15.5.3 * Construction of transformers used to provide separation as required by 8.5

Transformers of ME EQUIPMENT that form MEANS OF PROTECTION as required by 8.5 shall comply with ~~IEC 61558-1:1997, Subclause 5.12.~~ the following:

– Means shall be provided to prevent displacement of end turns beyond the interwinding insulation.

– If a protective earthed screen has only one turn, it shall have an insulated overlap of not less than 3 mm. The width of the screen shall be at least equal to the axial winding length of the primary winding.

– The exit of the wires from the internal windings of toroidal transformers shall be provided with double sleeving complying with the requirements for two MEANS OF PROTECTION and having a total wall thickness of at least 0,3 mm, extending at least 20 mm outside the winding.

– The insulation between primary and secondary windings shall comply with 8.8.2.

– CREEPAGE DISTANCES and AIR CLEARANCES shall comply with 8.9.4 with the following exceptions:

- Enamelled or lacquered winding wires are considered as contributing 1 mm each to the CREEPAGE DISTANCES specified in 8.9.4 for MEANS OF PATIENT PROTECTION.
- CREEPAGE DISTANCES are measured through the joint between two parts of an insulation barrier, except when:
  – either the two parts forming the joint are bonded by heat sealing or other similar means at the place where this is of importance;

  or

  – the joint is completely filled with adhesive at the necessary places and the adhesive bonds to the surfaces of the insulating barrier so that humidity cannot be sucked into the joint.
- CREEPAGE DISTANCES within moulded transformers are considered not to exist if it can be shown that no gas bubbles are present and the thickness of the insulation between enamelled or lacquered primary and secondary windings is at least 1 mm for reference voltages *U* not exceeding 250 V and increased proportionally for higher reference voltages.

~~*Compliance is checked as specified in IEC 61558-1.*~~

Compliance is checked by inspection of the transformer construction and measurement of required distances.

16 * ME SYSTEMS

16.1 * General requirements for the ME SYSTEMS

After installation or subsequent modification, an ME SYSTEM shall not result in an unacceptable RISK.

Only HAZARDS arising from combining various equipment to constitute an ME SYSTEM shall be considered.

NOTE RESPONSIBLE ORGANIZATIONS are reminded that the assembly of ME SYSTEMS and modifications during the actual service life require evaluation to the requirements of this standard.

An ME SYSTEM shall provide:

– within the PATIENT ENVIRONMENT, the level of safety equivalent to ME EQUIPMENT complying with this standard; and

– outside the PATIENT ENVIRONMENT, the level of safety equivalent to equipment complying with their respective IEC or ISO safety standards.

Tests shall be performed:

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– in NORMAL CONDITION unless otherwise specified, and

– under the operating conditions specified by the MANUFACTURER of the ME SYSTEM.

Safety tests that have already been performed on individual equipment of the ME SYSTEM according to relevant standards shall not be repeated.

The MANUFACTURER of an ME SYSTEM that is (re)configurable by the RESPONSIBLE ORGANIZATION or OPERATOR may use RISK MANAGEMENT methods to determine which configurations constitute the highest RISKS and which measures are needed to ensure that the ME SYSTEM in any possible configuration does not present an unacceptable RISK.

Non-ME EQUIPMENT, when used in an ME SYSTEM, shall comply with IEC or ISO safety standards that are relevant to that equipment.

Equipment in which protection against electric shock relies only on BASIC INSULATION shall not be used in an ME SYSTEM.

Compliance is checked by inspection of appropriate documents or certificates.

16.2 * ACCOMPANYING DOCUMENTS of an ME SYSTEM

An ME SYSTEM, (including a modified ME SYSTEM), shall be accompanied by documents containing all the data necessary for the ME SYSTEM to be used as intended by the MANUFACTURER, and an address to which the RESPONSIBLE ORGANIZATION can refer. The ACCOMPANYING DOCUMENTS shall be regarded as a part of the ME SYSTEM.

NOTE ACCOMPANYING DOCUMENTS can be provided electronically, e.g. electronic file format or CD-ROM, for an ME SYSTEM capable of displaying or printing those documents.

These documents shall include:

a) the ACCOMPANYING DOCUMENTS for each item of ME EQUIPMENT that is provided by the MANUFACTURER (see 7.8.2);

b) the ACCOMPANYING DOCUMENTS for each item of non-ME EQUIPMENT that is provided by the MANUFACTURER;

c) the following information:

- the specification of the ME SYSTEM, including the use as intended by the MANUFACTURER and a listing of all of the items forming the ME SYSTEM;
- instructions for the installation, assembly and modification of the ME SYSTEM to ensure continued compliance with this standard;
- instructions for cleaning and, when applicable, disinfecting and sterilizing each item of equipment or equipment part forming part of the ME SYSTEM (see 11.6.6 and 11.6.7);
- additional safety measures that should be applied, during installation of the ME SYSTEM;
- which parts of the ME SYSTEM are suitable for use within the PATIENT ENVIRONMENT;
- additional measures that should be applied during preventive maintenance;
- if a MULTIPLE SOCKET-OUTLET is present and it is a separate item, a warning that it shall not be placed on the floor;
- a warning that an additional MULTIPLE SOCKET-OUTLET or extension cord shall not be connected to the ME SYSTEM;
- a warning to connect only items that have been specified as part of the ME SYSTEM or that have been specified as being compatible with the ME SYSTEM;
- the maximum permitted load for any MULTIPLE SOCKET-OUTLET(S) used with the ME SYSTEM;
- an instruction that MULTIPLE SOCKET-OUTLETS provided with the ME SYSTEM shall only be used for supplying power to equipment that is intended to form part of the ME SYSTEM;

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- an explanation of the RISKS of connecting non-ME EQUIPMENT that has been supplied as a part of the ME SYSTEM directly to the wall outlet when the non-ME EQUIPMENT is intended to be supplied via a MULTIPLE SOCKET-OUTLET with a separating transformer;
- an explanation of the RISKS of connecting any equipment that has not been supplied as a part of the ME SYSTEM to the MULTIPLE SOCKET-OUTLET;
- the permissible environmental conditions of use of the ME SYSTEM including conditions for transport and storage; and
- instructions to the OPERATOR not to touch parts referred to in 16.4 and the PATIENT simultaneously.

d) advice to the RESPONSIBLE ORGANIZATION:

- to carry out all adjustment cleaning, sterilization and disinfection PROCEDURES specified therein; and
- that the assembly of ME SYSTEMS and modifications during the actual service life require evaluation to the requirements of this standard.

Compliance is checked by inspection.

16.3 * Power supply

If ME EQUIPMENT is intended to receive its power from other equipment in an ME SYSTEM, the instructions for use shall specify the other equipment sufficiently to ensure compliance with the requirements of this standard (see 4.10.1, 5.5 f) and 7.9.2.3). See also Figure F.5.

If an ME SYSTEM:

- is intended to receive its power from an isolated power supply (IPS) or an uninterruptible power supply (UPS), and
- the ME SYSTEM can draw large transient currents when being switching on or off or when operating,

the MANUFACTURER shall restrict such transient currents to the allowed level according to the specification of the IPS or the UPS from which the ME SYSTEM is intended to be supplied.

If an IPS or UPS is not specified, the actual transient current level shall be disclosed in the technical description and any installation instructions.

Compliance is checked by inspection.

16.4 ENCLOSURES

Parts of non-ME EQUIPMENT in the PATIENT ENVIRONMENT that can be contacted by the OPERATOR during routine maintenance, calibration, etc. after removal of covers, connectors, etc., without the use of a TOOL shall operate at a voltage not exceeding the voltage specified in 8.4.2 c) supplied from a source that is separated from the SUPPLY MAINS by two MEANS OF OPERATOR PROTECTION (see 8.5.1).

Compliance is checked by inspection.

16.5 * SEPARATION DEVICES

When FUNCTIONAL CONNECTION between ME EQUIPMENT and other items of equipment of an ME SYSTEM or other systems can cause the allowable values of LEAKAGE CURRENT to be exceeded, then safety measures incorporating a SEPARATION DEVICE shall be applied.

The SEPARATION DEVICE shall have the dielectric strength, CREEPAGE DISTANCES and AIR CLEARANCES required for one MEANS OF OPERATOR PROTECTION appropriate for the highest voltage occurring across the SEPARATION DEVICE during a fault condition.

The WORKING VOLTAGE shall be the highest voltage across the SEPARATION DEVICE during a fault condition, but not less than the MAXIMUM MAINS VOLTAGE.

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NOTE 1 For CLASS I equipment, potential differences can occur between the protective earth of the ME EQUIPMENT and the protective earth of other parts of the ME SYSTEM in the absence of a common protective earth.

NOTE 2 Situations that can require a SEPARATION DEVICE include FUNCTIONAL CONNECTIONS to an emergency calling system or a data processing system.

Compliance is checked by the tests in 8.8 and 8.9.

16.6 * LEAKAGE CURRENTS

16.6.1 TOUCH CURRENT

In NORMAL CONDITION, the TOUCH CURRENT from or between parts of the ME SYSTEM within the PATIENT ENVIRONMENT shall not exceed 100 μA.

In the event of the interruption of any non-PERMANENTLY INSTALLED PROTECTIVE EARTH CONDUCTOR, the TOUCH CURRENT from or between parts of an ME SYSTEM within the PATIENT ENVIRONMENT shall not exceed 500 μA.

NOTE For the purposes of this clause, the LEAKAGE CURRENT from accessible outer surfaces of equipment is also considered to be TOUCH CURRENT.

16.6.2 EARTH LEAKAGE CURRENT of MULTIPLE SOCKET-OUTLET

If the ME SYSTEM or part of the ME SYSTEM is supplied from a MULTIPLE SOCKET-OUTLET, then the current in the PROTECTIVE EARTH CONDUCTOR of the MULTIPLE SOCKET-OUTLET shall not exceed 5 mA.

16.6.3 * PATIENT LEAKAGE CURRENT

The PATIENT LEAKAGE CURRENT and total PATIENT LEAKAGE CURRENT of an ME SYSTEM in NORMAL CONDITION shall not exceed the values specified for ME EQUIPMENT, as given in Table 3 and Table 4 (see also 8.7.3 and 16.1).

The total PATIENT LEAKAGE CURRENT may be measured at installation.

Compliance with the requirements of 16.6.1, 16.6.2 and 16.6.3 is checked by inspection and measurement using a measuring device as specified in 8.7.4.4.

16.6.4 Measurements

16.6.4.1 General conditions for ME SYSTEMS

a) *The TOUCH CURRENT, the PATIENT LEAKAGE CURRENT, the total PATIENT LEAKAGE CURRENT and the total EARTH LEAKAGE CURRENT ~~of any MULTIPLE SOCKET-OUTLET~~ are measured after the ME SYSTEM has been brought up to operating temperature as follows:*

The ME SYSTEM is operated:

– *For ME SYSTEMS intended for non-CONTINUOUS OPERATION;*

After operating in standby/quiescent mode until THERMAL STABILITY is reached, the ME SYSTEM is operated in NORMAL USE over consecutive cycles until THERMAL STABILITY is again achieved, or for seven hours, whichever is shorter. The "on" and "off" periods for each cycle are the RATED "on" and "off" periods;

– *For ME SYSTEMS intended for CONTINUOUS OPERATION;*

The ME SYSTEM is operated until THERMAL STABILITY is reached.

b) *The ME SYSTEM is connected to a supply with a voltage equal to the highest RATED MAINS VOLTAGE. When the characteristics of an ME SYSTEM can only be measured properly after it has been installed at the site of the RESPONSIBLE ORGANIZATION, prior to its clinical use, the ME SYSTEM is connected to the local SUPPLY MAINS.*

NOTE Where examination of the circuit arrangement and the arrangement of components and material of the ME SYSTEM shows no possibility of any HAZARD, the number of tests could be reduced.

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16.6.4.2 Connection of the ME SYSTEM to the measuring supply circuit

a) The ME SYSTEM is tested after being assembled according to its ACCOMPANYING DOCUMENTS.

b) Measuring arrangement

If an isolating transformer is not used for LEAKAGE CURRENT measurements (e.g. when measuring LEAKAGE CURRENT for very high input power ME SYSTEMS), the reference earth of the measuring circuits is connected to the protective earth of the SUPPLY MAINS.

NOTE 1 It is recommended to position the measuring circuit as far as possible away from unscreened power supply leads and (unless specified otherwise in the following subclauses) to avoid placing the ME SYSTEM on or near a large earthed metal surface.

NOTE 2 However, APPLIED PARTS, including PATIENT cables (when present), should be placed on an insulating surface with a dielectric constant of approximately 1 (for example, expanded polystyrene) and approximately 200 mm above an earthed metal surface.

16.7 * Protection against MECHANICAL HAZARDS

If a MECHANICAL HAZARD exists, the ME SYSTEM shall comply with the applicable requirements of Clause 9.

Compliance is checked by inspection or applicable tests.

16.8 Interruption of the power supply to parts of an ME SYSTEM

An ME SYSTEM shall be so designed that an interruption and restoration of the power to the ME SYSTEM as a whole, or any part of the ME SYSTEM, shall not result in ~~a HAZARDOUS SITUATION other than interruption of its intended function~~ the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE.

Compliance is checked by interruption and restoration of relevant power connections one at a time and all connections simultaneously.

16.9 ME SYSTEM connections and wiring

16.9.1 Connection terminals and connectors

Design and construction of electrical, hydraulic, pneumatic and gas connection terminals and connectors shall be such that incorrect connection of accessible connectors, removable without the use of a TOOL, shall be prevented ~~where a HAZARDOUS SITUATION could otherwise exist.~~ unless it can be proven that no unacceptable RISK can result. In particular:

~~– Connectors shall comply with 15.4.1.~~

– Plugs for connection of PATIENT leads or PATIENT cables shall be so designed that they cannot be connected to other outlets of the same ME SYSTEM that are likely to be located in the PATIENT ENVIRONMENT unless it can be proved that no ~~HAZARDOUS SITUATION~~ unacceptable RISK can result.

Compliance is checked by inspection ~~and, if possible, by interchanging connectors~~ of PATIENT leads, PATIENT cables, connectors and outlets and, if interchange of the leads, cables, connectors or outlets is possible, by inspection of the RISK MANAGEMENT FILE.

– Medical gas connections on the ME SYSTEM for different gases to be operated in NORMAL USE shall not be interchangeable. See also ISO 407 [27].

Compliance is checked by inspection of all medical gas connections.

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16.9.2 MAINS PARTS, components and layout

16.9.2.1 * MULTIPLE SOCKET-OUTLET

a) A MULTIPLE SOCKET-OUTLET shall:

- only allow connection by using a TOOL (see Figure I.1), or
- be of a type that cannot accept MAINS PLUGS of any of the kinds specified in IEC/TR 60083, or
- be supplied via a separating transformer (see 16.9.2.1 d) and Annex I).

Compliance is checked by inspection.

b) A MULTIPLE SOCKET-OUTLET:

- shall be marked with safety sign ISO 7010-W001 (see Table D.2, safety sign 2) such that it is visible in NORMAL USE; and:
  - shall be marked either individually or in combinations, with the maximum allowed continuous output in amperes or volt-amperes, or
  - shall be marked to indicate which equipment or equipment parts may be safely attached.
- may be a separate item or an integral part of ME EQUIPMENT or non-ME EQUIPMENT.

NOTE Each outlet does not have to be marked.

Compliance is checked by inspection.

c) The MULTIPLE SOCKET-OUTLET shall comply with IEC 60884-1 and the following requirements.

- CREEPAGE DISTANCES and AIR CLEARANCES shall comply with 8.9.
- It shall be of CLASS I construction and the PROTECTIVE EARTH CONDUCTOR shall be connected to the earthing contacts in the socket-outlets.
- ~~*~~ PROTECTIVE EARTH TERMINALS and PROTECTIVE EARTH CONNECTIONS shall comply with 8.6~~, except that the total impedance of the protective earth path for an ME SYSTEM may be up to 400 mΩ, or higher if the conditions of 8.6.4 b) are satisfied~~.
- ENCLOSURES shall comply with 8.4.2 d).
- MAINS TERMINAL DEVICES and wiring shall comply with 8.11.4, if applicable.
- RATINGS of components shall not conflict with the conditions of use (see 4.8).
- Design and construction of electrical connection terminals and connectors of MULTIPLE SOCKET-OUTLETS shall prevent the incorrect connection of accessible connectors that are removable without the use of a TOOL.
- Requirements for the POWER SUPPLY CORD as described in 8.11.3 shall be fulfilled.

d) * If the MULTIPLE SOCKET-OUTLET is combined with a separating transformer, the following additional requirements apply.

- The separating transformer shall comply with ~~the requirements of IEC 61558-2-1,~~ this standard. Alternatively the separating transformer may comply with the requirements of IEC 61558-2-1, except that the requirements of maximum RATED output power of 1 kVA and degree of protection IPX4 do not apply.

NOTE 1 As a separating transformer is not a MAINS SUPPLY TRANSFORMER, it does not require more than BASIC INSULATION.

NOTE 2 Limitation of output power is not explained in IEC 61558-2-1 and the RATED output power is defined by the fuse in the installation and by the allowable power supply cable used. However, the characteristics of the separating transformer need to be carefully selected, taking into account the variations in the load current of the ME SYSTEM to ensure that the voltage supplied to the various items of the ME SYSTEM remains within the limits specified for the equipment.

~~NOTE 3 IEC 61558-2-1 should be used with the general standard IEC 61558-1.~~

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- The separating transformer assembly shall be of CLASS I construction.
- The degree of protection against ingress of water as given in IEC 60529 shall be specified.
- The separating transformer assembly shall be marked according to the requirements of 7.2 and 7.3.
- The MULTIPLE SOCKET-OUTLET shall be permanently connected to the separating transformer or the socket-outlet of the separating transformer assembly shall be of a type that cannot accept MAINS PLUGS of any of the kinds identified in IEC/TR 60083 (see Figure I.1 and Figure I.2).

Compliance is checked by inspection and as described in the relevant subclauses of this standard.

16.9.2.2 * PROTECTIVE EARTH CONNECTIONS in ME SYSTEMS

For each part of an ME SYSTEM that shares a MAINS CONNECTION, the impedance and current carrying capability of the total protective earth path of an ME SYSTEM when tested as a unit shall comply with 8.6.4. The impedance between the protective earth pin in the MAINS PLUG and any part that is PROTECTIVELY EARTHED shall not exceed 200 mΩ.

PROTECTIVE EARTH CONNECTIONS shall be made so that the removal of any single item of equipment in the ME SYSTEM will not interrupt the protective earthing of any other part of the ME SYSTEM, without at the same time disconnecting the electrical supply to that part.

Additional PROTECTIVE EARTH CONDUCTORS shall only be detachable by use of a TOOL.

Compliance is checked by inspection.

16.9.2.3 Protection of conductors

Conductors that connect different items of equipment within an ME SYSTEM shall be protected against mechanical damage.

Compliance is checked by inspection.

17 * Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

The MANUFACTURER shall address In the RISK MANAGEMENT PROCESS the RISKS associated with:

- the electromagnetic phenomena existing at the locations where the ME EQUIPMENT or ME SYSTEM is intended to be used as indicated in the ACCOMPANYING DOCUMENTS; and
- the introduction by the ME EQUIPMENT or ME SYSTEM of electromagnetic phenomena into the environment that might degrade the performance of other devices, electrical equipment and systems.

See IEC 60601-1-2 and also see 1.3.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

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Annex A
(informative)

General guidance and rationale

A.1 General guidance

The requirements for ME EQUIPMENT and ME SYSTEMS differ from those for other kinds of electrical equipment because of the particular relationship of ME EQUIPMENT or ME SYSTEM to the PATIENT, the OPERATOR and the surroundings. The following aspects play an important role in this relationship:

a) the inability of the PATIENT or OPERATOR to detect the presence of certain HAZARDS, such as ionizing and non-ionizing radiation;

b) absence of normal reactions of the PATIENT who can be ill, unconscious, anaesthetized, immobilized, etc.;

c) absence of normal protection to currents provided by the PATIENT'S skin, if this is penetrated or treated to obtain a low skin-resistance;

d) support or replacement of vital body functions, which depends on the reliability of ME EQUIPMENT or ME SYSTEM;

e) the simultaneous connection to the PATIENT of more than one piece of ME EQUIPMENT;

f) combination of high-power ME EQUIPMENT and sensitive low-signal ME EQUIPMENT often in ad hoc combinations;

g) the application of electrical circuits directly to the human body, either through contacts to the skin or through the insertion of probes into internal organs;

h) conditions, particularly in operating theatres, that can present a combination of humidity, moisture or HAZARDS of fire or explosion ~~HAZARDS~~ caused by air, oxygen or nitrous oxide.

When ME EQUIPMENT is combined with another electrical equipment to form an ME SYSTEM, additional requirements apply. These are given in Clause 16. In some instances, reference to other parts of this standard is made. If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause could be applicable to ME SYSTEMS as well as to ME EQUIPMENT.

A.2 Safety of ME EQUIPMENT and ME SYSTEMS

BASIC SAFETY and ESSENTIAL PERFORMANCE of ME EQUIPMENT and ME SYSTEMS, as described in IEC/TR 60513 [12], are part of the total safety situation, comprising safety of ME EQUIPMENT, safety of the installation to which the ME EQUIPMENT or ME SYSTEM is connected and safety of application.

BASIC SAFETY and ESSENTIAL PERFORMANCE of ME EQUIPMENT and ME SYSTEMS are required for NORMAL USE and for reasonably foreseeable misuse and in NORMAL CONDITION and SINGLE FAULT CONDITIONS. Reliability of functioning is regarded as a safety aspect for life-supporting ME EQUIPMENT and where interruption of an examination or treatment is considered as a ~~HAZARD~~ HAZARDOUS SITUATION for the PATIENT.

Adequate construction, lay-out and ACCOMPANYING DOCUMENTS that serve to prevent use errors are regarded as safety aspects.

Safety precautions are considered acceptable if they provide adequate protection without an undesirable restriction of normal function.

Generally, it is presumed that ME EQUIPMENT and ME SYSTEMS are operated under the jurisdiction of qualified or licensed persons and that the OPERATOR has the skill required for a particular medical application and acts according to the instructions for use.

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