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Text that has been changed in any manner is marked with a vertical line in the margin. Changes in requirements are marked with a vertical line in the margin and are followed by an effective date note indicating the date of publication or the date on which the changed requirement becomes effective.

The revisions dated July 9, 1999 include a reprinted title page (page1) for this Standard.

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New product submittals made prior to a specified future effective date will be judged under all of the requirements in this Standard including those requirements with a specified future effective date, unless the applicant specifically requests that the product be judged under the current requirements. However, if the applicant elects this option, it should be noted that compliance with all the requirements in this Standard will be required as a condition of continued Listing and Follow-Up Services after the effective date, and understanding of this should be signified in writing.

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FOREWORD

A. This Standard contains basic requirements for products covered by Underwriters Laboratories Inc. (UL) under its Follow-Up Service for this category within the limitations given below and in the Scope section of this Standard. These requirements are based upon sound engineering principles, research, records of tests and field experience, and an appreciation of the problems of manufacture, installation, and use derived from consultation with and information obtained from manufacturers, users, inspection authorities, and others having specialized experience. They are subject to revision as further experience and investigation may show is necessary or desirable.

B. The observance of the requirements of this Standard by a manufacturer is one of the conditions of the continued coverage of the manufacturer's product.

C. A product which complies with the text of this Standard will not necessarily be judged to comply with the Standard if, when examined and tested, it is found to have other features which impair the level of safety contemplated by these requirements.

D. A product employing materials or having forms of construction which conflict with specific requirements of the Standard cannot be judged to comply with the Standard. A product employing materials or having forms of construction not addressed by this Standard may be examined and tested according to the intent of the requirements and, if found to meet the intent of this Standard, may be judged to comply with the Standard.

E. UL, in performing its functions in accordance with its objectives, does not assume or undertake to discharge any responsibility of the manufacturer or any other party. The opinions and findings of UL represent its professional judgment given with due consideration to the necessary limitations of practical operation and state of the art at the time the Standard is processed. UL shall not be responsible to anyone for the use of or reliance upon this Standard by anyone. UL shall not incur any obligation or liability for damages, including consequential damages, arising out of or in connection with the use, interpretation of, or reliance upon this Standard.

F. Many tests required by the Standards of UL are inherently hazardous and adequate safeguards for personnel and property shall be employed in conducting such tests.

INTRODUCTION

1 Scope

1.1 These requirements cover electric medical and dental equipment that is intended for professional use by personnel in hospitals, nursing homes, medical care centers, medical and dental offices and similar Health Care Facilities including apparatus intended to be used with oxygen–administering equipment. The equipment covered is for use on interior wiring systems in accordance with the National Electrical Code. These requirements cover portable (cord–connected) equipment rated at 300 V or less and permanently connected equipment rated at 600 V or less.

1.2 The Standard also covers general requirements for equipment batteries, and battery–operated products that are energized by a battery supply having a voltage of 300 V dc or less, or battery power and provisions for connection to branch circuits rated 300 V or less in accordance with the National Electrical Code.

1.3 These requirements do not cover electrically heated pads, refrigerated medical equipment, X–ray equipment, hospital food warming cabinets and carts, nurse call and intercommunication equipment, isolated power systems, nor other equipment or appliances that are covered by separate individual requirements.

1.4 These requirements do not cover equipment for use in hazardous locations (with respect to flammable anesthetics), as defined in the National Electrical Code, ANSI/NFPA No. 70. Equipment intended for hospital operating room use above the hazardous area is judged under the requirements of this standard and in accordance with National Electrical Code, ANSI/NFPA No. 70.

1.5 The requirements in this Standard do not consider the complete spectrum of physiological or therapeutic effects, beneficial or otherwise, except where generally accepted limits for potentially hazardous conditions are defined. Devices which necessitate the utilization of conditions exceeding such accepted limits for patient treatment are intended for use by or under the supervision of licensed medical persons. Such equipment shall be provided with appropriate warnings prominently displayed on the device (see 71.1).

1.6 A product that contains features, characteristics, components, materials, or systems new or different from those covered by the requirements in this Standard, and that involves a risk of fire, electric shock, or injury to persons shall be evaluated using the appropriate additional component and end-product requirements to determine that the level of safety as originally anticipated by the intent of this Standard is maintained. A product whose features, characteristics, components, materials, or systems conflict with specific requirements or provisions of this Standard shall not be judged to comply with this Standard. Where appropriate, revision of requirements shall be proposed and adopted in conformance with the methods employed for development, revision, and implementation of this Standard.

1.6 added December 30, 1998

2 Glossary

2.1 ACCESSIBLE PART – A part located so that it can be contacted by a person, either directly or by means of a probe or tool, or that is not recessed the required distance behind an opening. See 5.2.1 – 5.2.8.

2.2 BASIC INSULATION (FORMERLY FUNCTIONAL INSULATION) – The insulation applied to live parts to provide basic protection against electric shock. Basic insulation does not necessarily include insulation used exclusively for functional purposes.

2.3 CONDUCTIVE CONNECTION – A connection that permits the flow of electric current.

2.4 DOUBLE INSULATION – An insulation system comprised of basic insulation and supplementary insulation with the two insulations physically separated and so arranged that they are not simultaneously subjected to the same deteriorating influences (temperature, contaminants, and the like) to the same degree. See the requirements for double insulation systems for use in electrical equipment, UL 1097.

2.5 ENCLOSURE – That external portion of an appliance that serves to house or support component parts, or both. Enclosures of patient care equipment likely to be contacted by a patient include, for example, bedside monitors, bed frames, dental chairs, and examinations stands.

2.6 FIELD–WIRING TERMINAL – Any terminal to which a supply or other wire is intended to be connected by an installer in the field is a field–wiring terminal unless the wire is provided as part of the unit and a pressure terminal, connector, soldering lug, soldered loop, crimped eyelet, or other means for making the connection is factory–assembled to the wire.

2.7 GAUGE – Wherever the abbreviation AWG appears in this standard it means American Wire Gauge.

2.8 INTERLOCK – A device used to deenergize electrical components or stop moving parts that become exposed so as to cause a risk of electric shock or injury to persons when an enclosure is opened or a cover is removed.

2.9 ISOLATING TRANSFORMER – A transformer in which one or more output windings is electrically separated from the input winding and all other output windings by an insulation at least equivalent to double insulation or reinforced insulation.

2.10 LEAKAGE CURRENT – As employed in this Standard leakage current refers to any current including capacitively–coupled currents which may be conveyed from accessible parts of an appliance to ground or other accessible parts of the appliance and which is not intended to be applied to a patient.

2.11 LIMITED ENERGY (OXYGEN) CIRCUIT – As employed in this standard, a limited energy circuit is one in which the equipment and wiring is incapable of releasing electrical or thermal energy that can cause ignition of cotton in an oxygen–enriched atmosphere. These conditions include unintentional damage to any part of the equipment or wiring, breakdown of insulation or malfunction of electrical components, application of over–voltage, adjustment and maintenance operations and other similar conditions.

2.12 LIVE ENERGIZED PART – A part energized with respect to earth, or energized with respect to some other part other than earth.

2.13 OPERATING CONTROL – A control (usually a knob, pushbutton, or lever) provided to enable the user to cause the appliance to perform its intended function, without the use of tools, when the appliance is in its intended operating condition.

2.14 OPERATOR (USER) SERVICING – Any form of servicing that might be performed by personnel other than qualified service personnel is operator or user servicing. Some examples follow:

a) The attachment of accessories by means of attachment plugs and receptacles or by means of other separable connectors.

b) The replacement of recording paper rolls, tapes, and similar items.

c) Resetting or replacement of circuit breakers, tubes, fuses, and lamps that are accessible without the use of tools; also, replacement of lamps likely to require frequent replacement – such as lamps of the projector type – whether or not the operation requires the use of tools.

d) The making of routine operating adjustments necessary to adapt the appliance for its different intended functions.

e) Routine cleaning, changing of filters, and pens, removal of blockages in tubing, and clearing of jams in data–recording media.

2.15 APPLIED PATIENT CURRENT – Any diagnostic or therapeutic current intended to be administered to a patient. This includes currents applied for measurement purposes.

2.16 PATIENT–CONNECTED CIRCUITS – All patient connections, such as pads, contacts, probes, sensors, or cuffs applied to the patient plus any associated leads, cables, components, or wiring, either within or external to the appliance enclosure. As seen from the patient into the equipment, these circuits extend to the points where the required degree of isolation or protective impedance is reached.

2.17 PATIENT CONNECTIONS – ISOLATED – A direct or indirect patient contact that is deliberately separated from the supply circuit and ground by virtue of spacings, insulation, protective impedance, or a combination thereof (for example, ECG leads, intra–aortic pressure monitor).

2.18 PATIENT CONNECTIONS – ORDINARY – A direct patient contact that does not have the spacings, insulation or protective impedance associated with an isolated patient connection (for example, blood pressure cuff, thermometers, ultrasonic transducer head.)

2.19 PATIENT VICINITY – In areas in which patients are normally cared for, the patient vicinity is the space with surfaces likely to be contacted by the patient or an attendant who can touch the patient. This encloses a space within the room 6 feet (1.83 m) beyond the perimeter of the bed (examination table, dental chair, treatment booth, and the like) in its intended location, and extending vertically 7–1/2 feet (2.29 m) above the floor.

2.20 PRINTED WIRING – A pattern of conductive material formed on the surface or surfaces of an insulating base, and intended to provide point–to–point electrical connections.

2.21 PRINTED WIRING ASSEMBLY – A printed wiring board on which separate components have been added.

2.22 PRINTED WIRING BOARD – The combination of a printed wiring pattern and the insulating base, completely processed as far as the printed portion is concerned.

2.23 REINFORCED INSULATION – An improved basic insulation with such mechanical and electrical properties that it, in itself, provides the same degree of protection against electric shock as double insulation. It may consist of one or more layers of insulating material. Also see requirements for general construction and reinforced insulation in the requirements for double insulation systems for use in electrical equipment, UL 1097.

2.24 SAFETY CIRCUIT – Any circuit (either in the primary or secondary) that is relied upon to reduce the risk of electric shock or fire (an interlock circuit, for example) is considered to be a safety circuit.

2.25 SECONDARY CIRCUITS – Secondary circuits are those circuits supplied from transformer output windings which are electrically separated from the input windings.

2.26 SUPPLEMENTARY (PROTECTING) INSULATION – An independent insulation provided in addition to basic insulation to protect against electric shock in case of mechanical rupture or electric breakdown of the basic insulation. An enclosure of insulating material may form a part or the whole of the supplementary insulation.

2.27 SUPPLY CIRCUIT – The branch circuit supplying electrical energy to the appliance.

2.28 PINCH POINT – The location at which a moving part contacts, crosses or comes in close proximity to another part, moving or fixed, so as to produce a pincer, scissor or crushing affect.

2.29 TYPES OF EQUIPMENT – Recognizing the differences in applications to the patient and in the degree of risk posed by electrical equipment in various areas of a health care facility (for example, professional office, clinic, hospital, and the like), medical and dental equipment covered by this standard is treated as follows:

a) Patient Care Equipment – Equipment that is intended to be used in the patient's vicinity in a health care facility (see 2.19). It includes equipment for use on or with, or likely to be contacted by, a patient in the course of his treatment. It includes equipment used in:

1) Patient rooms.

2) Treatment areas of physicians' offices, clinics, and dental offices.

3) Treatment areas of catheterization laboratories, dialysis rooms, and body scanning laboratories.

4) Paramedical applications where it must be assumed that all emergency equipment would be located in the patient vicinity at the time of use.

b) Non–patient Equipment – Equipment primarily for use in a health care facility that is intended for use in other than the patient vicinity. See 2.19.

2.30 The likely physical separation from the patient vicinity is determined by installation and operating instructions and markings and, in the case of equipment systems, the length and nature of any interconnecting cables or cords.

3 References

3.1 Undated references

3.1.1 Any undated reference to a code or standard appearing in the requirements of this standard shall be interpreted as referring to the latest edition of that code or standard.

CONSTRUCTION

4 General

4.1 An appliance shall employ materials that are acceptable for the particular use, and shall be made and finished with the degree of uniformity and grade of workmanship practicable in a well–equipped factory.

4.2 A component of a product covered by this Standard shall comply with the requirements for that component, and shall be used in accordance with its recognized rating and other limitations of use. A component need not comply with a specific requirement that:

a) Involves a feature or characteristic not needed in the application of the component in the product covered by this Standard, or

b) Is superseded by a requirement in this Standard.

5 Frame and Enclosure

5.1 General

5.1.1 An appliance shall be so formed and assembled that it will have the strength and rigidity necessary to resist the abuse to which it can be subjected, without introducing risk of fire, electric shock, or injury to persons due to total or partial collapse with resulting reduction of spacings, loosening or displacement of parts, or other serious defects.

5.1.2 A risk of fire is considered to exist at a component part or assembly if an investigation shows that the supply for such part or assembly is capable of delivering a power of more than 15 watts into an external resistor connected between the point in question and any return to the power supply.

5.1.3 A risk of electric shock is considered to exist at any accessible conductive part of an appliance or equipment if the available current through an appropriate impedance connected between the part and other accessible conductive parts or between the part and ground, is more than the values specified in 42.3.2 or 42.5.1 as determined by the type of equipment involved (see 2.29). To determine if a risk of electric shock exists at parts accessible only to the user or operator during servicing, the voltage and current criteria in 42.5.1 apply.

5.1.4 For unreinforced, flat surfaces in general, cast metal shall not be less than 1/8 inch thick, except that malleable iron may not be less than 3/32 inch and die–cast metal may not be less than 5/64 inch thick. Corresponding thicknesses of not less than 3/32, 1/16, and 3/64 inch, respectively, may be acceptable if the surface under consideration is curved, ribbed, or otherwise reinforced, or if the shape and/or size of the surface is such that acceptable physical strength is provided.

5.1.5 Unless investigated and found acceptable for the application, the thickness of a sheet–metal enclosure shall not be less than the value indicated in Table 5.1. See 7.1.4 with reference to the minimum acceptable thickness at a point where conduit or armored cable is to be connected.

5.1.6 Among the factors taken into consideration when an enclosure other than that as described in 5.1.4 or 5.1.5 is being judged for acceptability are its relative:

a) physical strength,

b) resistance to impact,

c) moisture–absorptive properties,

d) combustibility,

e) resistance to corrosion, and

f) resistance to distortion at temperatures to which the enclosure may be subjected under conditions of normal or abnormal use.

For a nonmetallic enclosure, all of these factors are also considered with respect to thermal aging.

5.1.7 An appliance shall be so constructed that it can be cleaned or sterilized in accordance with the manufacturer's instructions (64.1) without adversely affecting the proper application and performance of the appliance.

Table 5.1
Thickness of sheet metal for enclosures

Maximum are of any surface in square inches	Maximum dimension in inches	Minimum thickness of sheet metal in inches					
		Steel				Copper, brass, or aluminum	
		Without supporting frame		With supporting frame or equivalent reinforcing		Without supporting frame	With supporting frame or equivalent reinforcing
		Zinc-coated	Uncoated[b]	Zinc-coated	Uncoated[b]		
6[c]	3	0.023	0.020	0.023	0.020	0.023	0.023
36	8	0.029	0.026	0.023	0.020	0.036	0.029
90	12	0.034	0.032	0.023	0.020	0.045	0.029
135	18	0.045	0.042	0.034	0.032	0.058	0.045
360	24	0.056	0.053	0.045	0.042	0.075	0.058
1200	48	0.070	0.067	0.056	0.053	0.095	0.075
1500	60	0.097	0.093	0.056	0.053	0.122	0.075
Over 1500	–	0.126	0.123	0.056	0.053	0.153	0.075

[a] Deleted.
[b] Including stainless steel.
[c] Volume of enclosure not more than 12 cubic inches.

5.1.8 Unless it is obvious that the enclosure construction and the materials involved are acceptable for the cleaning or sterilizing operation called for, one sample of the appliance (or appropriate portion of the sample if it is intended to be only partially cleaned or sterilized) shall be subjected to the tests described in Cleaning and Sterilization, Section 52.

5.1.9 The enclosure of an appliance shall be such as to prevent molten metal, burning insulation, flaming particles, or the like from falling upon combustible materials, including the surface upon which the appliance rests or is otherwise supported.

5.1.10 The requirement in 5.1.9 necessitates the use of a barrier of non combustible material:

a) Under a motor unless:

1) The structural parts of the motor or of the appliance provide the equivalent of such a barrier;

2) The overload (overcurrent) protection provided with the motor is such that no burning insulation or molten material falls to the surface that supports the appliance when the motor is energized under each of the following fault conditions:

i) Open main winding,

ii) Open starting winding,

iii) Starting switch short–circuited, and

iv) Capacitor of a permanent–split–capacitor motor short–circuited, or

3) The motor is provided with a thermal motor protector (a protective device that is sensitive to temperature and current) so that the temperature of the motor windings will not exceed 125°C (257°F) under the maximum load under which the motor will run without causing the protector to cycle and will not exceed 150° C (302°F) with the rotor of the motor locked.

b) Under wire unless it is of the flame–retardant type, for example, polyvinyl chloride– or neoprene–insulated.

5.1.11 The barrier mentioned in 5.1.10 shall be horizontal or designed to provide equivalent protection, shall be located as indicated in Figure 5.1, and shall not be smaller in area than indicated in the figure. Openings for drainage, ventilation, etc., may be employed in the barrier if the openings are protected by a baffle, screen, or the like that molten metal, burning insulation, and the like cannot fall outside the enclosure.

5.1.12 The requirement in 5.1.9 also necessitates that a switch, relay, solenoid, or the like be individually and completely enclosed, except for terminals, unless it can be shown that failure of the component would not result in a fire hazard, or there are no openings in the bottom of the appliance enclosure.

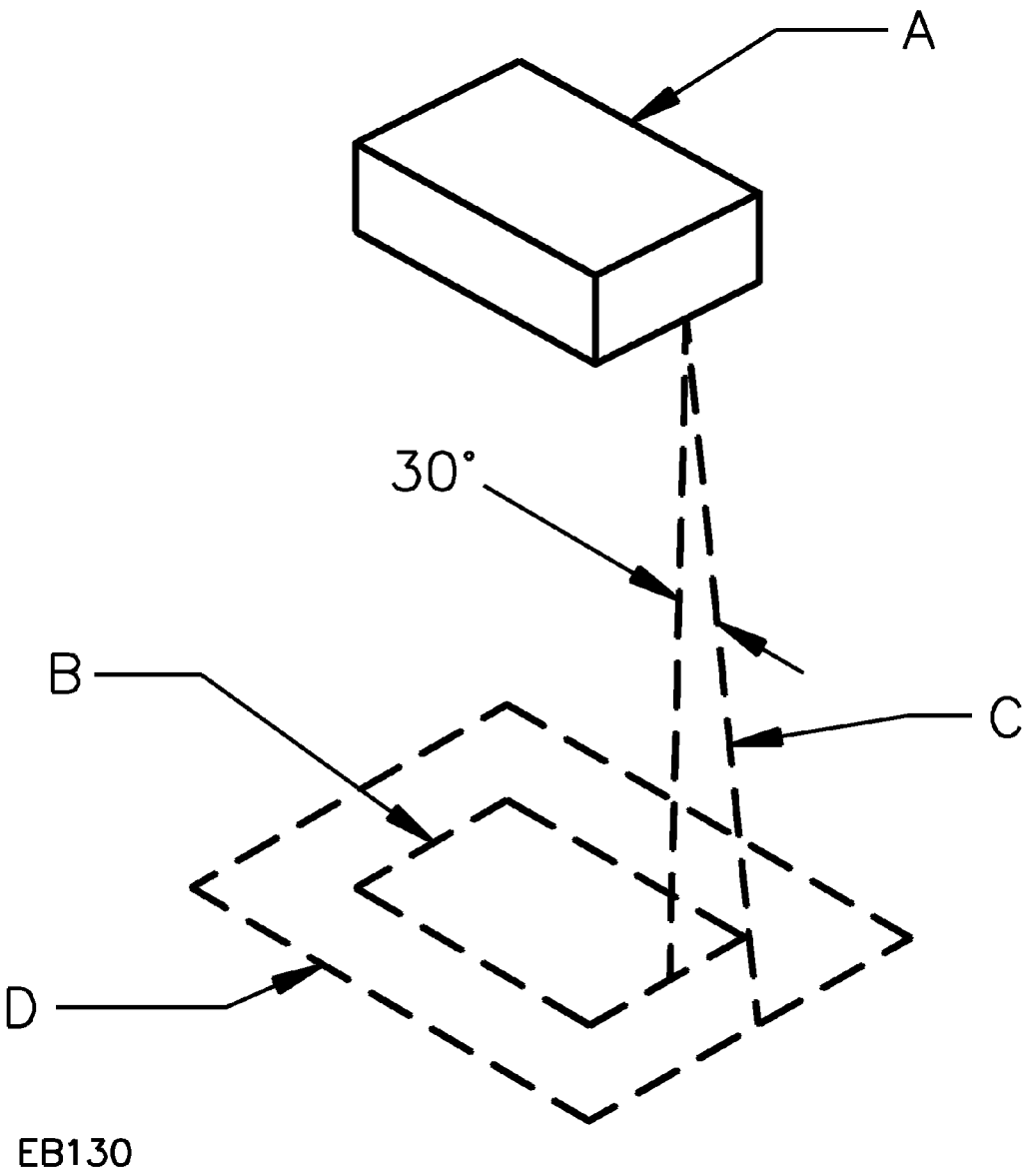
5.1.13 The sheath employed to enclose a heating element of an immersion–type heater shall be of a metal resistant to corrosion by the liquid in which the heater is intended to be immersed.

5.1.14 The enclosure of a graphical display vacuum tube having a diameter of 6 inches (152 mm) or larger, or equivalent face area, shall be constructed so that when the tube is imploded as described in 55.1.1 – 55.1.2.1, the quantity of material expelled does not exceed the limits described in 55.1.2.3 or 55.1.3.3. The tests are performed with the tube in its own enclosure, as described in 55.1.2.1 and 55.1.3.1 and in a manner that does not impair the integrity of the enclosure.

Exception: A product using a graphical display vacuum tube (CRT) that employs integral implosion protection complying with the requirements in Integrally Implosion-Protected Display Vacuum Tubes (CRT), Section 6 need not be subject to the implosion test described in 55.1.1 – 55.1.3.3 when it is mounted in a reliable and conventional manner that is representative of the investigation described in Integrally Implosion-Protected Display Vacuum Tubes (CRT), Section 6.

5.1.15 The requirement in 5.1.14 does not preclude the emission of dust from necessary ventilating openings, seams, and joints.

Figure 5.1
Location and extent of barrier



A– Region to be shielded by barrier. This consists of the entire component if it is not otherwise shielded, and consists of the unshielded portion of the component that is partially shielded by the component enclosure or equivalent. B – Projection of outline of component on horizontal plane. C – Inclined line that traces out minimum area of barrier. When moving, the line is always (1) tangent to the component, (2) thirty degrees from the vertical, and (3) so oriented that the area traced out on a horizontal plane is maximum. D – Location (shown horizontal) and minimum area for barrier. The area is that included inside the line of intersection traced out by the inclined line C and the horizontal plane of the barrier.

5.1.16 The top, sides, and front of the enclosure of a display vacuum tube of any size – including the transparent protective shield or screen that is located in contact with, or in front of, any type of directly viewed tube that does not comply with the requirements of Section 6 (Integrally Implosion–Protected Display Vacuum Tubes), and which is a required part of the implosion protection system for the tube – shall withstand a single impact of 5 ft–lb (6.78 N·m), as described in 55.2.1 without resulting in:

a) Damage that impairs the integrity of the mounting means of an integrally implosion–protected display vacuum tube that complies with the requirements in Section 6 (Integrally Implosion–Protected Display Vacuum Tubes).

b) Damage to the protective shield or screen, or its securing means, – when used on equipment employing a display vacuum tube of a type other than one as described in (a) – so that either cannot perform its intended function.

c) Cracking of a tempered glass protective shield that is used on equipment employing a display vacuum tube of a type other than one as described in (a) above.

5.1.17 In the event that the impact test conducted as described in 5.1.16 results in the implosion of the display vacuum tube, no glass shall be expelled past the first barrier, 3 ft, (0.9 m) described in 55.1.3.1.

5.1.18 Any part that contains, conducts, or otherwise contacts a liquid is to be resistant to the liquid involved under any condition of use, if degradation to the part can result in the risk of electric shock, fire, or injury to persons.

5.1.19 If a liquid, powder, or other material that must be replenished, removed, or replaced is present in an appliance:

a) Parts involving fire or electric shock are to be protected from contact with spilled material, and

b) Protection is to be provided against the risk of fire, electric shock and injury to persons, that could result from filling, emptying, storage, intended movement of the appliance, and the like. See also 51.1.

5.1.20 In patient care equipment, parts operating at an elevated temperature or live parts shall be protected from spilled materials (for example, saline solutions, volatile solutions, and the like) that if contacted by the solution could create a risk of electric shock, fire or injury to persons.

5.1.21 The door or cover of an enclosure shall be hinged or otherwise attached in an equivalent manner if it gives access to any overload protective device whose functioning requires renewal, or if it is necessary to open the cover in connection with the operation of the protective device. Such a door or cover shall be provided with a latch or the equivalent to hold it in a closed position, and shall be tight–fitting or shall overlap the surface of the enclosure around the opening.

5.1.22 A part or component of an appliance that is likely to need inspection, replacement, cleaning or other servicing shall be as accessible as practicable.

5.1.23 A part or component of an appliance that is intended to be manually operated or adjusted by the user, or that definitely requires periodic servicing by the user, shall be readily accessible without the use of special tools.

5.1.24 A component of an appliance or device, for example the bulb and capillary tube of a thermostat, shall be protected from mechanical damage if malfunction of the component can result in the risk of electric shock, fire, or injury to persons.

5.1.25 An appliance intended to be hand–held or hand–guided shall withstand a drop test as described in 56.1.1 without exposing live electrical components or connections or developing a risk of electric shock, fire, or injury to persons.

5.1.26 Carrying handles or grips furnished on a portable appliance shall withstand loading as described in 56.2.1. The handles shall not break loose from the appliance and there shall not be any permanent distortion, cracking or other evidence of damage.

5.1.27 Mounting brackets on an appliance intended to be wall or ceiling mounted, shall be acceptable for the intended purpose and shall withstand loading as described in 56.2.2 without evidence of damage to the brackets or mounting surface.

5.2 Accessibility of live parts

5.2.1 Electrical parts of an appliance shall be so located or enclosed that protection against unintentional contact with uninsulated live parts is provided. Insulated brush caps do not require additional enclosure.

5.2.2 An opening in an enclosure of a product that is grounded (other than a product as described in 5.2.4) is acceptable if the minor dimension is less than 1 inch (25.4 mm) and a probe as illustrated in Figure 5.2, inserted into the opening, cannot be made to touch an uninsulated live part or film–coated wire that may cause a risk of electric shock. The probe shall be applied in all possible articulated positions before, during, and after insertion.

5.2.3 For openings in enclosures of a product that is not connected to a grounding means, including double–insulated products – and other than those openings giving access to uninsulated live parts in a plug, connector, or socket outlet – the probe illustrated in Figure 5.3 shall not be able to contact uninsulated live parts involving risk of electric shock.

5.2.4 For double–insulated products, the probe illustrated in Figure 5.2 shall not be able to be inserted through an opening in an accessible part and contact dead metal parts separated from current–carrying parts by basic insulation.

5.2.5 If the probe illustrated in Figure 5.2 cannot enter the opening, the enclosure shall be mechanically tested by inserting the probe illustrated in Figure 5.4 with a force of 30 N (6.75 lbf). If this probe enters the opening, the probe illustrated in Figure 5.2 is to be used as described in 5.2.2.

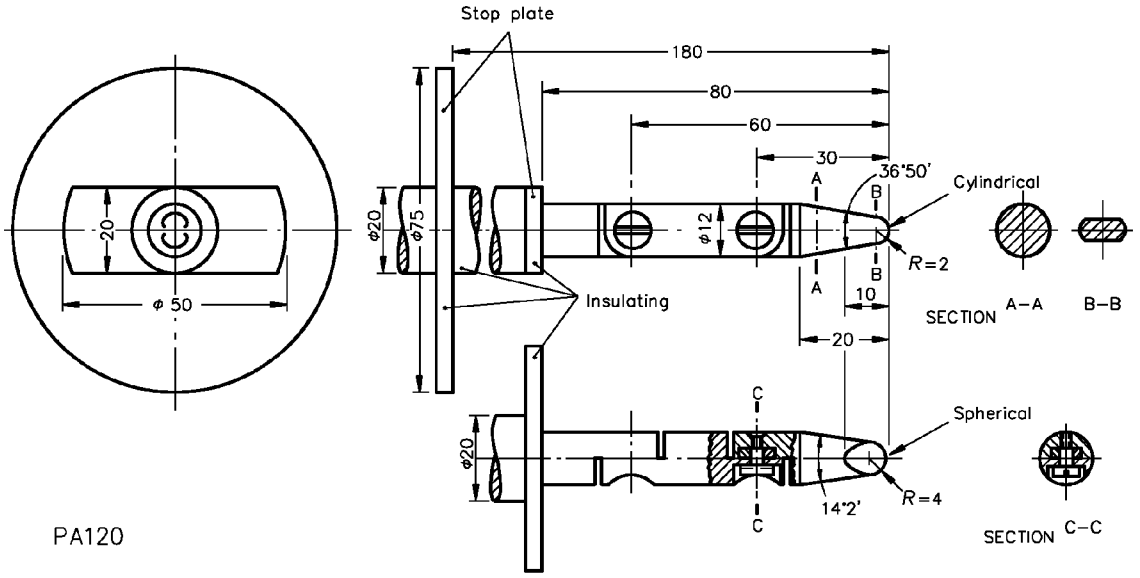
5.2.6 An opening that has a minor dimension of 1 inch (25.4 mm) or more, in an enclosure, as illustrated in Figure 5.5, is acceptable if, within the enclosure, there is no uninsulated live part or film-coated wire that involves a risk of electric shock less than,

a) R distance from the inside edge of the perimeter of the opening, and

b) X distance from the plane of the opening,

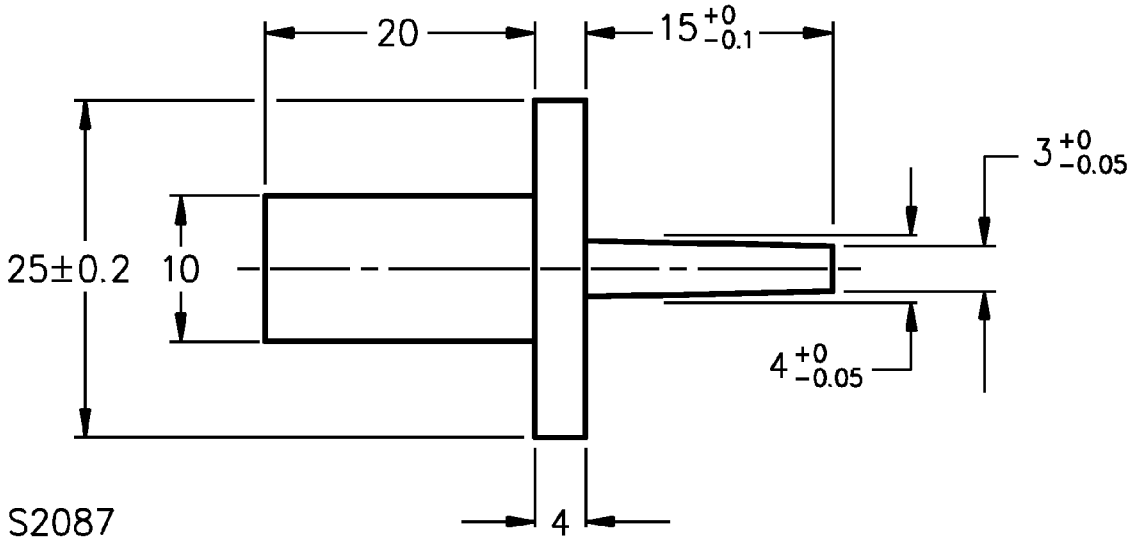
where T equals the enclosure thickness, R equals X minus T, and X equals 5 times the diameter of the largest round rod that can be inserted through the opening but not less than 6–1/16 inches (154 mm). In evaluating an opening, any barrier located within the volume is to be ignored unless it intersects the boundaries of the volume in a continuous, closed line.

Figure 5.2
International Electrotechnical Commission (IEC) "Articulate accessibility probe with stop plate"
All dimensions in millimeters courtesy of IEC



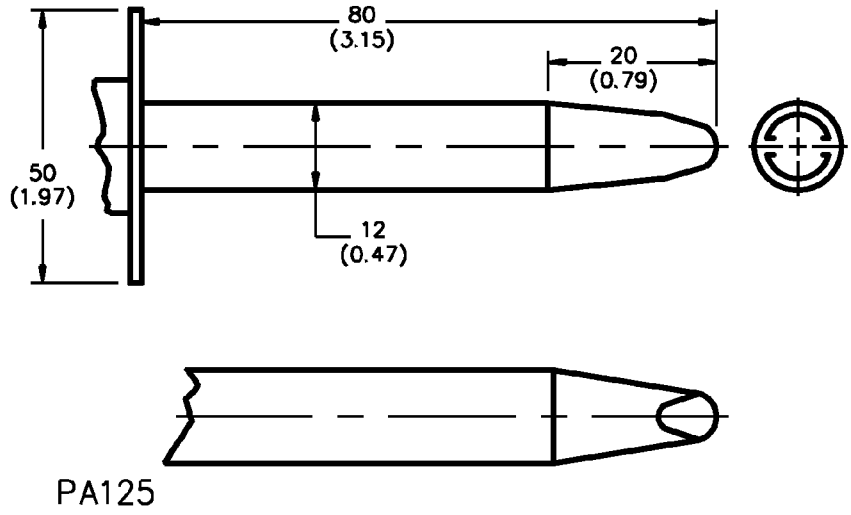
mm	2	4	10	12	20	30	50	60
(inches)	(5/64)	(5/32)	(25/64)	(15/32)	(25/32)	(1-3/16)	(1-31/32)	(2-23/64)
		75		80		180		
		(2-61/64)		(3-5/32)		(7-3/32)		

Figure 5.3
International Electrotechnical Commission (IEC) "Test pin"
Dimensions in millimeters



mm	inches
3	0.118
4	0.157
10	0.394
15	0.591
20	0.787
25	0.984
0.05	0.002
0.1	0.004
0.2	0.008

Figure 5.4
International Electrotechnical Commission (IEC) "Rigid accessibility probe"
All dimensions in millimeters (inches)



Last 20 mm (0.79inch) of probe same as probe Figure 5.2

5.2.7 For double–insulated products, the requirement in 5.2.6 shall also apply to accessibility to dead metal parts separated from current–carrying parts by basic insulation.

5.2.8 During the examination of an appliance in connection with the requirements in 5.2.1, a part of the outer enclosure that may be removed, without the use of tools, or that may be opened or removed by the user (with or without tools) to permit operator servicing (the attachment of accessories, making of adjustments, and the like) is to be disregarded – that is, it will not be assumed that the part in question affords protection against electric shock.

5.3 Mechanical assembly

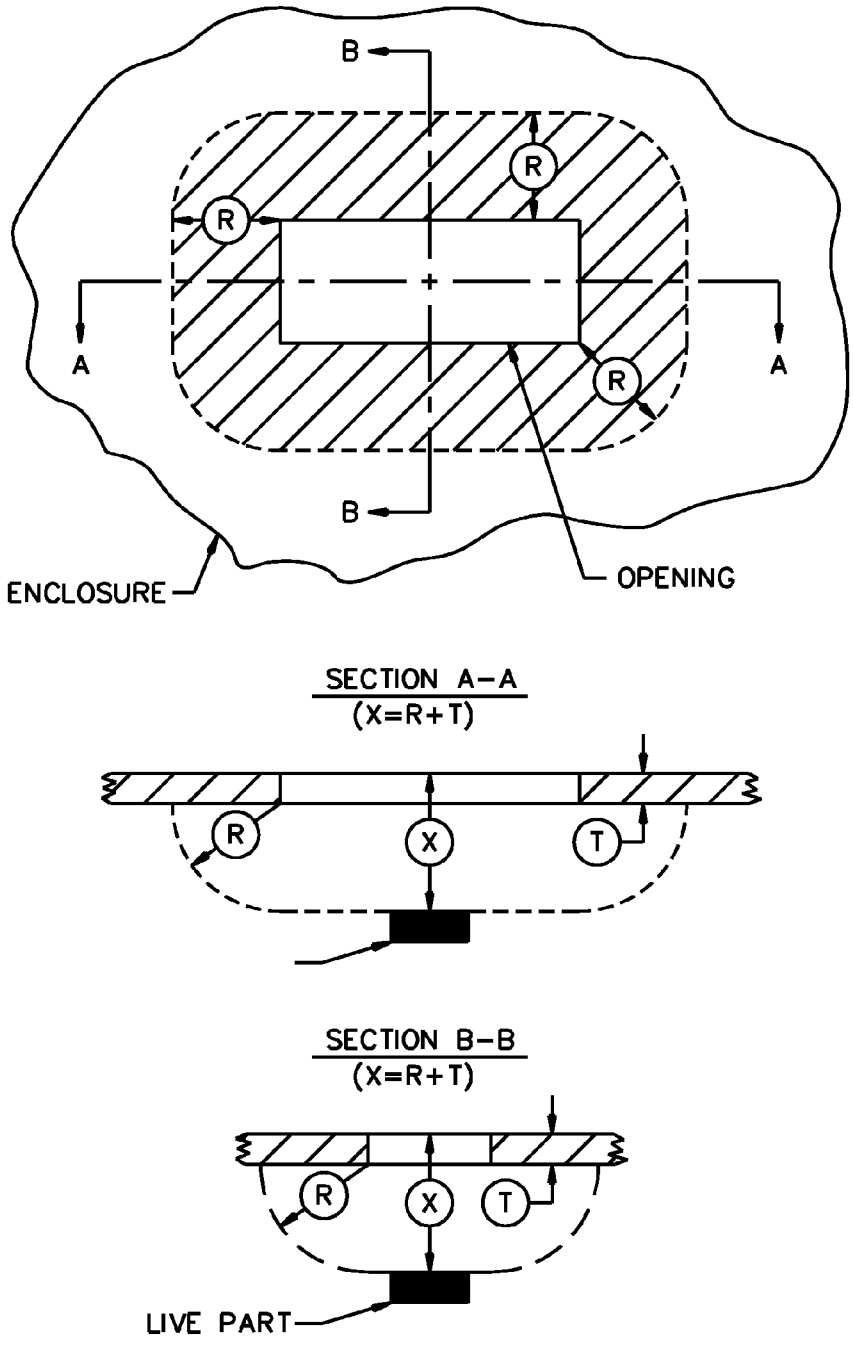
5.3.1 An appliance shall be assembled so that it will not be affected adversely by the vibration of intended operation. Brush caps shall be tightly threaded or otherwise constructed to prevent loosening.

5.3.2 A switch, fuseholder, lampholder, attachment–plug receptacle, motor–attachment plug, or other component that is handled by the user shall be mounted or assembled securely and, except as noted in 5.3.3, shall be prevented from turning in its mounting panel.

5.3.3 The requirement that a switch be prevented from turning may be waived if all four of the following conditions are met:

a) The switch is to be of a plunger, slide, or other type that does not tend to rotate when operated, a toggle switch is considered to be subject to forces that tend to turn the switch during operation of the switch.

Figure 5.5
Opening in enclosure
proportions exaggerated for clarity



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b) The means of mounting the switch is to make it unlikely that operation of the switch will loosen the switch.

c) Spacings are not to be reduced below the minimum acceptable values if the switch rotates.

d) Operation of the switch is to be by mechanical means rather than by direct contact by persons.

5.3.4 The means by which the turning mentioned in 5.3.2 is prevented is to include more than just friction between surfaces – for example, a lock washer, properly applied, is acceptable as a means to prevent turning of a device having a single–hole mounting means.

5.3.5 An appliance may be shipped from the factory unassembled, or disassembled to the degree necessary to facilitate shipment, if all six of the following conditions are met:

a) All of the parts shall be furnished by the manufacturer.

b) Upon assembly electrical continuity shall be provided between the field–assembled components.

c) The equipment shall be constructed so that the field assembly can be accomplished without the necessity of drilling, cutting, threading, or withstand any other alteration other than the attachment of field–installed electrical conduit or raceway.

d) The relationship between separate parts shall be established at the time of manufacture, and shall not be dependent upon installation personnel.

e) Detailed step–by–step installation instructions are packed with the appliance.

f) All protective guards and other safety features shall be factory installed wherever possible.

5.3.6 An adhesive that is required to reduce risk of electric shock, fire, or injury to persons shall comply with the requirements for adhesives in the Standard for Polymeric Materials – Use in Electrical Equipment Evaluations, UL 746C.

5.3.7 The requirement in 5.3.6 applies to an adhesive that is used to bond structural parts or secure a conductive part, including a nameplate, that may, if loosened or dislodged:

a) Energize an accessible dead metal part,

b) Make a live or moving part accessible,

c) Reduce spacings below the minimum acceptable values or,

d) Short–circuit live parts.

5.4 Physical stability

5.4.1 Under all conditions of servicing and intended use, each appliance or combination of appliances (as in the case of cart–mounted equipment, for example) shall not become physically unstable to the degree that it presents a risk of injury to the patient, operator, or service personnel.

5.4.2 The details of tests to determine lack of physical stability cannot be specified as every appliance presents a somewhat different problem. Some of the considerations are the number of doors or drawers that can be extended at any one time, the likelihood of movement of the equipment over obstructions on the floor and the necessity for application of additional weights or moments to the appliance during use or servicing.

5.4.3 If the height of the center of gravity of a cord–connected appliance above the base is more than twice the smallest dimension of the base, the stability of the appliance will generally be made the subject to an appropriate investigation. The ratio mentioned is intended to apply generally to conventional shapes.

5.4.4 Casters, if provided, are to be in their most disadvantageous position during the evaluation of the physical stability.

5.5 Corrosion protection

5.5.1 Iron and steel parts shall be protected against corrosion by enameling, galvanizing, plating, or other equivalent means if the degradation of unprotected parts can result in a risk of electric shock, fire or injury to persons.

Exception: Thermal elements, magnet–pole faces, hardened and polished parts such as latching surfaces, and the like, where such protection is impractical.

5.5.2 Phosphate treatment with an oil or wax coating is acceptable as corrosion protection for magnets and armatures. Oil treatment is acceptable as corrosion protection for steel springs. Stainless steel is acceptable without additional protection if properly polished or treated when necessary.

6 Integrally Implosion–Protected Display Vacuum Tubes (CRT)

6.1 A display vacuum tube (CRT) that has a diameter of 6 inches (152 mm) or larger diameter, or equivalent face area, and employs integral implosion protection, shall comply with the requirements in the Standard for Cathode–Ray Tubes, UL 1418.

7 Supply Connections

7.1 Permanently connected appliances

7.1.1 A permanently connected appliance (an appliance intended for permanent connection to the power supply) shall have provision for connection of the wiring systems that, in accordance with the National Electrical Code, ANSI/NFPA No. 70, would be acceptable for the appliance.

7.1.2 An appliance intended for permanent attachment to the building structure, ducts, water steam, or gas supply, drains, and the like shall be provided with a means for permanent connection to the branch–circuit supply.

Exception: Pipe connected hydromassage equipment is acceptable with a supply–cord connection to facilitate interchange when necessary. The shortest feasible length of Type SJE, SJT, SJO, or heavier cord may be employed.

7.1.3 An appliance that is not actually moved or easily moved in normal use, but which is not obviously intended to be permanently connected, may be acceptable if provided with the shortest feasible length of Type SJE, SJT, SJO, or equivalent cord and an attachment plug for supply connection. The investigation of such feature will include consideration of the utility of the appliance and the necessity of having it readily detachable from its source of supply by means of the plug.

7.1.4 Sheet metal to which a wiring system is to be connected in the field shall have a thickness not less than 0.032 inch (0.81 mm) if of uncoated steel, not less than 0.034 inch (0.86 mm) if of galvanized steel, and not less than 0.045 inch (1.14 mm) if of nonferrous metal.

7.1.5 A terminal or splice compartment shall be complete and shall enclose all field–wiring terminals and all splices to be made in the field unless the appliance enclosure is complete – for example, unless all sides and a complete bottom are provided when the appliance is shipped from the factory.

7.1.6 The location of a terminal or splice compartment in which power supply connections to a permanently connected appliance are to be made shall be such that these connections may be readily inspected after the appliance is installed as intended.

7.1.7 The compartment mentioned in 7.1.6 shall be so located that during conduit connections thereto, internal wiring and electrical components are not exposed to physical abuse or strain.

7.1.8 A terminal compartment intended for connection of a supply raceway shall be attached to the appliance to be prevented from turning with respect thereto.

7.2 Field–wiring terminals

7.2.1 A permanently connected appliance shall be provided with wiring terminals for the connection of conductors having an ampacity (current–carrying capacity in amperes), in accordance with the National Electrical Code, ANSI/NFPA No. 70, suitable for the appliance or the appliance shall be provided with acceptable leads for such connections.

7.2.2 A terminal solely for connection of an equipment–grounding conductor shall be capable of securing a conductor of the size acceptable for the particular application, in accordance with the National Electrical Code, ANSI/NFPA No. 70.

7.2.3 A wiring terminal shall be provided with an acceptable soldering lug or pressure terminal connector securely fastened in place (for example, firmly bolted or held by a screw), except that a wire–binding screw may be employed at a wiring terminal intended to accommodate a No.10 AWG (5.3 mm^2) or smaller conductor if upturned lugs or the equivalent are provided to hold the wire in position.

7.2.4 A wiring terminal shall be prevented from turning.

7.2.5 The free length of a lead inside an outlet box or wiring compartment shall be 6 inches (152.4 mm) or more if the lead is intended for field connection to an external circuit.

Exception: The lead may be less than 6 inches (152.4 mm) long if it is evident that the use of a longer lead might result in risk of fire or electric shock.

7.2.6 A wire–binding screw at a wiring terminal shall not be smaller than No. 10; except that a No. 8 screw may be used at a terminal intended only for the connection of a No. 14 AWG (2.1 mm^2) conductor and a No. 6 screw may be used for connection of a No. 16 AWG (1.3 mm^2) or No. 18 AWG (0.82 mm^2) control–circuit conductor.

7.2.7 A terminal plate tapped for a wire–binding screw shall be of metal not less than 0.050 inch (1.27 mm) thick except that a plate not less than 0.030 inch (0.76 mm) thick is acceptable if the tapped threads have adequate mechanical strength. There shall be two or more full threads in the metal, which may be extruded if necessary to provide the threads.

7.2.8 Upturned lugs or a cupped washer shall be capable of retaining a supply conductor of the size indicated in 7.2.1 under the head of the screw or washer.

7.2.9 An appliance that is intended for permanent connection to a supply circuit that includes a grounded circuit conductor and that employs a lampholder of the screw–shell type, a single–pole switch, or a single–pole automatic control, shall have one terminal or lead identified for connection of the grounded conductor of the supply circuit. This terminal or lead shall be one that is electrically connected to screw shells of lampholders and to which are connected no single–pole switches or single–pole overcurrent protective devices other than automatic controls without a marked off position.

7.2.10 A terminal (for example, plate and screw) intended for the connection of a grounded supply conductor shall be of, or plated with metal that is substantially white in color and shall be readily distinguishable from the other terminals, or proper identification of that terminal shall be clearly shown in some other manner, such as on an attached wiring diagram. A lead intended for the connection of a grounded power–supply conductor shall be finished to show a white or natural grey color and shall be readily distinguishable from the other leads.

7.2.11 The surface of an insulated lead intended solely for the connection of an equipment–grounding conductor shall be green with or without one or more yellow stripes, and no other lead shall be so identified.

7.2.12 A wire–binding screw intended for the connection of an equipment–grounding conductor shall have a green–colored head that is hexagonal shaped, slotted, or both.

7.2.13 A pressure wire connector intended for connection of such a conductor shall be plainly identified, such as being marked "G", "Gr", "Ground", "Grounding", or the like, or by a similar marking on a wiring diagram provided on the appliance. The grounding symbol in a circle, ⏚

(IEC Publication 417, Symbol No. 5019) may be used for this purpose. When used alone, the symbol shall be defined in the installation instructions provided with the equipment.

7.2.14 The wire–binding screw or pressure wire connector shall be so located that it is unlikely to be removed during normal servicing of the appliance.

7.3 Cord–connected appliances

7.3.1 Input voltage selector

7.3.1.1 A portable appliance employing an input–voltage selector shall not create a risk of fire or electric shock when tested in accordance with 49.5.1. The appliance shall be marked in accordance with 61.4.

7.3.1.2 The construction shall be such that the voltage setting cannot be changed without the use of a tool.

7.3.2 Cords and plugs

7.3.2.1 A cord and plug connected appliance (an appliance intended to be connected to the power–supply circuit by means of a flexible cord) shall be provided with either an acceptable length of flexible cord and an attachment plug, or with a detachable power–supply cord.

7.3.2.2 In general, the attachment plugs are to conform with the configurations as covered in the American National Standard, C73 Series.

7.3.2.3 A grounded–type patient care appliance shall employ either the nonhazardous location locking type attachment plug designated "Hospital Only" or a conventional 2–blade with grounding pin attachment plug designated "Hospital Grade", and shall be marked in accordance with 62.1.

7.3.2.4 The flexible cord shall be of a type that is acceptable for the particular application. It shall be acceptable for use at a voltage not less than the rated voltage of the appliance and shall have an ampacity, as given in the National Electrical Code, ANSI/NFPA No. 70, not less than the current rating of the appliance.

7.3.2.5 The flexible cord shall be Type SJE, SJO, SJT, SJTO, or other jacketed cord at least as serviceable. An oil–resistant cord is required if the equipment is likely to be subjected to grease or oil.

Exception: Types SVE, SVO, SVT, and SVTO may be considered for light–duty appliances where extreme flexibility or weight is a factor. Appliances weighing 1–1/4 pounds (567 g) or less would qualify for consideration.

7.3.2.6 The attachment plug shall be acceptable for use with a current not less than 125 percent of the rated current, and at a voltage equal to the rated voltage of the appliance. If the appliance is intended for being adapted for use on two or more different values of voltage by field alteration of internal connections, the attachment plug provided with the appliance shall be acceptable for the voltage for which the appliance is connected when shipped from the factory. See 61.3.

7.3.2.7 The supply cord shall be attached permanently to the appliance.

Exception: A separate cord set with means for connection to the appliance may be employed if it can be shown that accidental disconnection is unlikely or that a) accidental disconnection or b) the additional impedance of the ground circuit contacts will not increase the risk of electric shock to the patient or operator.

7.3.2.8 If a polarized attachment plug is used, the circuit conductors in the flexible cord shall be connected to the plug and to the wiring in the appliance so that any of the following devices used in the primary circuit shall be connected in an undergrounded side of the line: the center contact of anedison–base lampholder, a single-pole switch, an automatic control with a marked off position, a solitary fuseholder, and any other single–pole overcurrent protective device.

Exception: If a second fuseholder or other overcurrent protective device is provided in the appliance, it may be placed in the grounded side of the line. See 17.1.9

7.3.3 Strain relief

7.3.3.1 Strain relief shall be provided to prevent a mechanical stress on a flexible cord, such as a pull or a twist, from being transmitted to terminals, splices, or interior wiring.

7.3.3.2 A clamp may be employed to accomplish strain relief. In such cases, auxiliary insulation may be required if the clamp can damage the cord insulation.

7.3.3.3 Means shall be provided to prevent the flexible cord from being pushed into the appliance through the cord–entry hole if such displacement can subject the cord to mechanical damage or to exposure to a temperature higher than that for which the cord is considered acceptable, or can reduce spacings below the acceptable minimum values.

7.3.3.4 When tested in accordance with 7.3.3.5, the strain–relief means provided on the flexible cord shall be capable of withstanding for one minute, without displacement, a pull of 35 pounds applied to the cord with the connections within the appliance disconnected.

7.3.3.5 A 35–pound weight is to be suspended on the cord and so supported by the appliance that the strain–relief means will be stressed from any angle which the construction of the appliance permits. The strain relief is not acceptable if, at the point of disconnection of the conductors, there is such movement of the cord as to indicate that stress would have resulted on the connections.

7.3.4 Bushings

7.3.4.1 At a point where a flexible cord passes through an opening in a wall, barrier, or enclosing case, there shall be a bushing or the equivalent which shall be substantial, reliably secured in place, and shall have a smooth, well–rounded surface against which the cord may bear.

8 Current–Carrying Parts

8.1 A current–carrying part shall be of silver, copper, a copper alloy, stainless steel, aluminum, or other metal that is acceptable for the particular application.

Exception No. 1: Other than for a terminal rod and a terminal plate of a heating element, unplated iron or steel shall not be used for a current–carrying part of an appliance.

Exception No. 2: Plated iron or steel may be used for a current–carrying part:

a) If the temperature of such part is more than 100°C (212°F) under any condition of normal operation of the appliance,

b) If in accordance with 4.2, or

c) Within a motor or associated governor, but not elsewhere.

8.2 Uninsulated live parts shall be secured to the base or mounting surface so that they will not turn or shift in position, if such motion may result in a reduction of spacings below the minimum acceptable values.

8.3 Friction between surfaces is not acceptable as a means to prevent shifting or turning of live parts, but a properly applied lockwasher is acceptable.

9 Internal Wiring

9.1 General

9.1.1 The wiring and connections between parts of an appliance shall be protected or enclosed, except that a length of flexible cord may be employed for external connections if flexibility is essential (see 9.1.2, 14.1 and 14.3.)

9.1.2 With reference to exposure of insulated wiring through an opening in the enclosure of an appliance, the protection of such wiring required in 7.1.1 is considered to exist if, when evaluated as though it were enamel–insulated wire, the wiring would be acceptable according to 5.2.2 and 5.2.6.

9.1.3 A hole by means of which insulated wires pass through a sheet–metal wall within the overall enclosure of an appliance shall be provided with a smooth, well–rounded bushing or shall have smooth, well–rounded surfaces upon which the wires may bear, to prevent abrasion of the insulation. A flexible cord used for external interconnection as mentioned in 7.1.1 shall be provided with bushings and strain relief in accordance with 7.3.3.1 – 7.3.3.3 unless the construction is such that the cord will be protected from stress or motion.

9.1.4 Insulated wires may be bunched and passed through a single opening in a metal wall within the enclosure of the appliance. See also 10.1.1 – 10.1.3.

9.1.5 Metal clamps and guides used for routing stationary internal wiring shall be provided with smooth, well–rounded edges. Auxiliary nonconducting mechanical protection shall be provided under a clamp at which pressure is exerted on a conductor having thermoplastic insulation less than 1/32 inch thick and no overall braid.

9.1.6 Wiring which is subject to flexing shall be provided with supplementary insulation at any point where it is flexed, unless the wiring is standard flexible cord that is acceptable for the purpose or unless an appropriate flexing test shows that the wiring without supplementary insulation is acceptable for the particular application.

9.1.7 Supplementary insulation may be a short length of acceptable insulating sleeving, tubing, or a wrap of not less than two layers of insulating tape.

9.1.8 Wires shall be reliably routed away from sharp edges, screw threads, burrs, fins, moving parts, drawers, and the like, that can abrade the wires.

9.1.9 The internal wiring of an appliance shall consist of wires of a type or types which are acceptable for the particular application, when considered with respect to the temperature and voltage to which the wiring can be subjected, with respect to its exposure to oil or grease, and with respect to other conditions of service to which it is likely to be subjected.

9.1.10 If rubber or thermoplastic insulation is employed on internal wiring which involves fire or electric shock, the thickness of the insulation shall not be less than 0.028 inch unless the wire is provided with an outer braid or jacket, in which case the thickness of the rubber or thermoplastic insulation may be less than 0.028 inch but not less than 0.013 inch.

Exception: Internal wiring employing thermoplastic insulation having a wall thickness less than 0.028 inch, but not less than 0.007 inch, and otherwise determined as being acceptable for the application, is not required to have an outer braid if the wire is entirely within a chassis or is protected against mechanical damage.

9.1.11 Asbestos or cotton insulated wire shall not be employed in an appliance if the wire is likely to be exposed to moisture.

9.1.12 Internal wiring smaller than No. 24 AWG shall be protected against mechanical damage (within an enclosure or chassis and not accessible during user or operator servicing) and particular care shall be taken to consider the effects of vibration and impact.

9.1.13 If color–coded insulation is used for internal wiring, grounding and bonding conductors shall be identified by the color green with or without one or more yellow stripes.

9.2 Splices and connections

9.2.1 All splices and connections shall be mechanically secure and shall provide reliable electrical continuity. A soldered connection shall be made mechanically secure before being soldered if breaking or loosening of the connection can result in any hazardous condition. Consideration shall be given to vibration, and the like, when determining the acceptability of electrical connections.

9.2.2 A splice shall be provided with insulation equivalent to that of the wires involved.

9.2.3 In determining if splice insulation consisting of coated–fabric, thermoplastic, or other type of tubing is acceptable, consideration is to be given to such factors as its dielectric properties, heat–resistant and moisture–resistant characteristics, and the like. Thermoplastic tape wrapped over a sharp edge is not acceptable.

9.2.4 Where stranded internal wiring is connected to a wire–binding screw, the construction shall be such that loose strands of wire will not contact other uninsulated live parts not always of the same polarity as the wire, and will not contact dead metal parts. This can be accomplished by use of pressure terminal connectors, soldering lugs, crimped eyelets, soldering all strands of the wire together, or any other reliable means.

9.2.5 Manually applied pressure cable connectors used for splicing internal wiring shall be located within the overall enclosure and taped to the conductors.

9.2.6 A printed–wiring board used in a primary circuit, in a secondary circuit that represents a risk of electric shock, a risk of fire, or a risk of injury to persons, and in secondary circuits where separation of the bond between the conductor and the base material might result in contact with uninsulated parts that represent a risk of electric shock, a risk of fire or a risk of injury to persons, shall comply with the Standard for Printed Wiring–Boards, UL 796.

9.2.7 The securing of components, such as resistors, capacitors, inductors, transformers, and the like, to a printed–wiring board to form a printed–wiring assembly, and the mounting of the printed–wiring assembly itself, shall be such that any forces that might be exerted on the components or board during assembly, shipping or handling of the equipment, or during use or servicing, will not displace the components or deflect the board so as to produce an electric shock or fire.

9.2.8 When required for compliance with 54.2.3, a printed circuit board shall be evaluated for the applicable classification in accordance with the requirements for tests for flammability of plastic materials for parts in devices and appliances, UL 94.

10 Separation of Circuits

10.1 Patient care equipment

10.1.1 If the shorting together of two adjacent conductive parts (wires, terminals, structural metal, and the like) of an appliance will result in available leakage current in patient–connected circuits in excess of the limits outlined in 42.3.2, the construction shall comply with at least one of the following:

a) For insulated conductive parts, each insulation employed shall be acceptable for the maximum voltage possible (for example, the highest voltage on a part with respect to ground or with respect to any exposed conductive part, either with or without the introduction of any random malfunction of one insulation involved). A spacing between parts that is not less than that required to Table 23.1 may be used in place of a single insulation.

b) For two uninsulated conductive parts, a spacing between parts that is not less than twice that required in Table 23.1 may be used.

c) If not insulated or spaced apart as in item a) or b), the parts shall be separated by means of a solid (unpierced) barrier, permanently secured in place, of one of the types noted below:

1) An insulating barrier, so located and of such integrity that the barrier is acceptable as a supplement to conductor insulation, or in the case of a barrier between two uninsulated part, will satisfy the requirements for reinforced insulation thereby affording a degree of protection against electric shock equivalent to that afforded by double insulation.

2) A conductive barrier so located and electrically connected that any likely breakdown will not result in any increase in available leakage current above the specified limits.

10.1.2 In evaluating the required separation of the patient–connected circuits from adjacent circuits derived from different sources in accordance with 10.1.1, consideration should be given to the effects, including deterioration of insulation, of abnormal operation involving overload, short–circuit, or component failure conditions.

10.1.3 For nonpatient–connected accessible parts (enclosures, chassis, remote low voltage circuitry, and the like) of patient care equipment, the construction of the appliance shall comply with the requirements for nonpatient equipment in 10.2.1.

10.2 Nonpatient equipment

10.2.1 The construction of an appliance shall comply with 10.2.2 when the shorting together of two adjacent conductive parts (wires, terminals, structural metal, and the like) of the appliance will result in either of the following:

a) A difference of potential greater than 212 V peak (150 V rms if the waveform is sinusoidal) between any accessible parts of an appliance or between any accessible parts of an appliance and ground which would cause more than 7.07 mA peak (5.0 mA rms if the waveform is sinusoidal) to flow through a 500 ohm resistor connected between the parts in question.

b) A difference of potential greater than 42.4 V peak (30 V rms if the waveform is sinusoidal) between any accessible parts associated with circuitry routed to remote locations not within the confines of the appliance enclosure, between the terminals intended for the connection for such circuits, or between such parts or terminals and ground which would cause more than 7.07 mA peak (5.0 mA if the waveform is sinusoidal) to flow through a 500 ohm resistor connected between the parts in question.

10.2.2 An appliance mentioned in 10.2.1 shall comply with at least one of the following:

a) For insulated conductive parts, each insulation employed shall be acceptable for the maximum voltage possible (for example, the highest voltage on a part with respect to ground or with respect to any exposed conductive part, either with or without the introduction of any random failure of one insulation involved). A spacing between parts that is not less than that required in Table 23.1 may be used in place of a single insulation.

b) For two uninsulated conductive parts, a spacing between parts that is not less than twice that required in Table 23.1 may be used.

c) If not insulated or spaced apart as in (a) or (b), the parts shall be separated by means of a solid (unpierced) barrier, permanently secured in place, of one of the types noted below:

1) An insulating barrier, so located and of such integrity that the barrier is acceptable as a supplement to conductor insulation, or, in the case of a barrier between two uninsulated parts, will satisfy the requirements for reinforced insulation thereby affording a degree of protection against electric shock equivalent to that afforded by double insulation.

2) A conductive barrier so located and electrically connected that any likely electrical breakdown will not cause voltages in excess of the limits in 10.2.1, to appear on exposed conductive parts or on circuitry to remote locations.

11 Heating Elements

11.1 A heating element shall be supported in a substantial and reliable manner. It shall be protected against mechanical damage and accidental contact with outside objects.

11.2 Among the factors to be considered in determining the acceptability of a heating element with respect to mechanical damage and accidental contact with outside objects are the conditions of normal operation (including cleaning) of the appliance, and the utensils and implements likely to be used with it.

11.3 In determining whether or not the support of a heating element is acceptable, consideration is to be given to sagging, loosening, and other adverse conditions of the element resulting from continuous heating.

12 Thermal Insulation

12.1 Thermal insulation, if employed, shall be of such a nature and so located and mounted or supported that it will not be adversely affected by any normal operation of the appliance.

12.2 Combustible or electrically conductive thermal insulation shall not make contact with uninsulated live parts of the appliance.

12.3 Some types of mineral–wool thermal insulation contain conductive impurities in the form of slag, which make their use unacceptable if in contact with uninsulated live parts.

13 Insulation Material

13.1 Uninsulated live parts shall be mounted on porcelain, phenolic composition, or other material that is acceptable for the particular application.

13.2 Ordinary vulcanized fiber may be used for insulating bushings, washers, separators, and barriers, but not as the sole support for uninsulated live parts if shrinkage, current leakage, or warpage can introduce risk of fire or electric shock. Thermoplastic materials generally are not considered to be acceptable for the sole support of uninsulated live parts, but they can be employed if found to have the mechanical strength and rigidity, resistance to heat, resistance to flame propagation, dielectric strength, and other properties needed for the application. These properties will also be considered with respect to thermal aging of the materials involved.

13.3 Molded parts shall have the mechanical strength and rigidity needed to withstand the stresses of actual service.

14 Interconnecting Cords and Cables

14.1 Flexible–cord or –cable assemblies used for external interconnection between sections of an appliance or between appliances shall be provided with bushings and strain relief in accordance with 7.3.3.1 – 7.3.4.1.

14.2 Cord and cable assemblies that are used for external interconnection – such as between units of a system – shall be of a type that is acceptable for the voltage and temperature to which they are subjected in normal use and shall be provided with an outer jacket acceptable for such use.

Exception: Cords and cable assemblies employed in secondary, low energy circuits that do not involve the risk of electric shock or fire, need not be provided with an outer jacket.

14.3 Inserting a male connector in a female connector other than the one intended to receive it, misalignment of male and female connectors and other manipulations of parts that are accessible to the operator shall not result in a fire, electric shock, or injury to persons.

15 Patient–Connected Leads

15.1 A connector, plug, pin, or the like that is attached to a patient–connected lead or contact shall be constructed so that it cannot engage any part on the equipment – including a separable cord set – that can introduce a risk of electric shock, fire, or injury to persons.

15.2 In addition to the requirement in 15.1, a connector, plug, pin or the like that is attached to a patient–connected lead or contact, and that is used with a product that may be used without professional supervision, shall be constructed so that it cannot be inserted or otherwise manipulated so as to make contact with the live parts of a power receptacle outlet or separable cord set.

16 Motors

16.1 A motor shall be capable of handling its maximum normal load during operation of the appliance (see 45.2.1) without introducing risk of fire, electric shock, or injury to persons.

16.2 A motor winding shall be such as to resist the absorption of moisture and shall be formed and assembled in a workmanlike manner.

16.3 With reference to the requirement in 16.2 enameled wire is not required to be additionally treated to resist absorption of moisture, but fiber slot liners, cloth coil wrap, and similar moisture–absorptive materials should be provided with impregnation or otherwise treated to resist moisture absorption.

16.4 The tables in the National Electrical Code, ANSI/NFPA No. 70, that give the relationships between horsepower and full–loaded currents for motors are to be used when applying requirements based on horsepower for motors having current ratings.

17 Overcurrent (Overload) Protection

17.1 General

17.1.1 An overcurrent or thermal protective device shall be of a type that is acceptable for the particular application.

17.1.2 If an appliance includes one or more medium–base or smaller lampholders or one or more attachment–plug receptacles, and if the rating of the overcurrent protection of a branch circuit to which the appliance can properly be connected in accordance with the National Electrical Code, ANSI/NFPA No. 70, exceeds that which is acceptable for the lampholder or lampholders, receptacle or receptacles, each lampholder or receptacle circuit shall have overcurrent protection rated at not more than 20 A provided as part of the appliance.

17.1.3 A fuseholder provided in accordance with 17.1.2 shall be of Type S construction or shall be of the Edison–base type with a factory–installed nonremovable adapter of Type S construction or other noninterchangeable type.

17.1.4 A protective device shall be wholly inaccessible from outside the appliance without opening a door or cover, except that the operating handle of a circuit breaker, the operating button of a manually–operable motor protector, the cap of an extractor–type fuseholder, and similar parts may project outside the appliance enclosure.

17.1.5 A thermal or overcurrent (overload) protective device shall not open the circuit during normal use of the appliance.

17.1.6 The functioning of an overcurrent (overload) protective device provided as part of an appliance (whether or not such a device is required) shall not result in a fire, electric shock, or injury to persons.

17.1.7 A fuse mounted in a fuseholder that is marked as such, (see 66.1) and a fuse that is accessible without the use of a tool, shall be mounted or guarded so that live parts will not be exposed to accidental contact. The arrangement shall be such that the fuse will not be positively gripped or held by any part of the fuseholder while live parts are exposed at any time during replacement.

17.1.8 Clips for cartridge fuses shall be mounted securely and shall not turn.

17.1.9 The screw shell of a plug fuseholder and the accessible contact of an extractor fuseholder shall be connected toward the load.

Exception: For fuseholders located in grounded side of the line as determined by the use of a polarized attachment plug, an accessible contact shall be located toward the grounded supply line.

17.2 Motors

17.2.1 An inherently thermally protected motor provided on an appliance shall be marked "Thermally protected" except that if the inherent protection is for locked rotor only, the marking shall be "Thermally Protected L". An impedance protected motor provided on an appliance shall be marked "Impedance protected".

17.2.2 All motors in circuits involving a risk of fire or electric shock shall be protected from overheating due to any condition of load up to and including stalled rotor. Refer to 45.1.1 for operating requirements.

Exception No. 1: A motor that is protected against locked–rotor conditions and used for:

a) Air–handling only, such as direct–drive blower motors or ventilating fans, or

b) Specific short–term operations under attended conditions such as positioning operating tables, dental chairs for operating or exiting purposes, and the like.

Exception No. 2: A shaded–pole motor having a difference of 1 ampere or less between no–load and locked–rotor currents and having a 2 to 1 or smaller ration between locked–rotor and no–load currents, if it is protected against locked–rotor conditions.

Exception No. 3: A motor in equipment that is:

a) Controlled by a momentary contact switch not likely to be actuated by the patient, or

b) Continuously loaded by hand by the user.

17.2.3 The overheating protection required in 17.2.2 may be accomplished by one of the following:

a) Thermal protection complying with requirements in the Standard for Thermal Protectors for Motors, UL 547.

b) Impedance protection complying with appropriate requirements in the Standard for Impedance Protected Motors, UL 519.

c) Other protection that tests show is equivalent to the protection mention in (a) or (b).

18 Switches and Controllers

18.1 A switch or other control device shall be acceptable for the application, with a rating per circuit, or in the case of a multiple position device, a rating per position not less than that of the load that it controls and where applicable shall be marked in accordance with 64.3.

18.2 If a switch is employed as the on–off device for the appliance, it shall open all supply circuit conductors. The equipment grounding conductor shall not be interrupted. The on–off positions of the switch shall be clearly indicated by the words "on" and "off" or the symbol "I" and "O". The word "on" or the symbol "I" need not be provided if the switch is marked to indicate its in an energized position. See 64.1.

Exception: A switch that appears to be in the same position when on or off may employ an illumination device as the indicating means provided the means is rated for a minimum of 20,000 hours of life at the normal operating voltage and if there is no risk of electric shock or injury to persons if the appliance is connected to the supply while the switch is in the on position.

18.3 A switch shall not be marked "off" only, if it does not disconnect all parts of an appliance from the branch circuit supply.

Exception: An overcurrent device or an electromagnetic interference filter need not be disconnected.

18.4 If a switch in the equipment does not disconnect the supply as indicated in 18.3, the status of its condition shall be indicated, such as, "Off/Recharge – On" or "Off/Standby – On."

18.5 With reference to the requirement in 18.1, the current–carrying capacity of a switch that controls an inductive load, such as a transformer or an electric–discharge lamp ballast, is required to not be less than twice the rated full–load current of the transformer or ballast unless the switch is rated for the particular application.

18.6 In addition to complying with the requirements of 18.1, a switch or other device that controls a solenoid, relay coil, or the like and has not been tested and shown to be acceptable for this purpose shall perform acceptably when subjected to an overload test consisting of 50 cycles of operation as described in 18.7. The switch shall be electrically and mechanically operable at the conclusion of the test; at which time, the switch shall be capable of performing its intended function and shall show no wear, loosening of parts, or defects of any other description that will appreciably diminish the usefulness and reliability of the switch.

18.7 In a test to determine whether a switch or other control device complies with the requirements in 18.6, the appliance is to be connected to a grounded supply circuit of rated frequency and 110–percent of maximum rated voltage. The load on the device under test is to be the same as that which it is intended to control in intended service. During the test, exposed metal parts of the appliance are to be connected to ground through a 3–ampere fuse, and the connection is to be such that any single–pole, current–rupturing device will be located in the ungrounded conductor of the supply circuit. If the appliance is intended for use on direct current, or on direct current as well as alternating current, the exposed dead metal parts of the appliance are to be connected to be positive with respect to a single–pole, current–rupturing, control device. The device is to be operated at a rate of not more than 10 cycles per minute, except that a faster rate of operation may be employed if agreeable to all concerned. The performance is unacceptable if the fuse in the grounding connection opens during the test.

18.8 In addition to complying with the requirements of 18.1, a switch or other device that controls a motor of an appliance, unless tested and shown to be acceptable for this application or unless so interlocked that it will not break the locked–rotor motor current, shall be capable of performing acceptably when subjected to an overload test consisting of 50 cycles of operation, making and breaking the locked–rotor current of the motor. The switch shall be electrically and mechanically operable at the conclusion of the test; at which time the switch shall be capable of performing its intended function and shall show no wear, loosening of parts, or defects of any other descriptions that will appreciably diminish the usefulness and reliability of the switch.

18.9 In a test to determine whether the switch or other control device is capable of performing acceptably in the overload test mentioned in 18.8, the appliance is to be connected to a grounded supply circuit of rated frequency and maximum rated voltage (see 39.3) with the rotor of the motor locked in position. During the test, exposed dead metal parts of the appliance are to be connected to ground through a 3–ampere fuse, and the connection is to be such that any single–pole, current–rupturing device will be located in the ungrounded conductor of the supply circuit. If the appliance is intended for use on direct current, or on direct current as well as alternating current, the exposed dead metal parts of the appliance are to be so connected as to be positive with respect to a single–pole, current–rupturing, control device. The device is to be operated at a rate of not more than 10 cycles per minute, except that a faster rate of operation may be employed if agreeable to all concerned. The performance is unacceptable if the fuse in the grounding connection opens during the test.

18.10 A switch that controls a lampholder for an incandescent lamp other than a 15 W or smaller pilot or indicating lamp shall be of a type that is acceptable for use with tungsten–filament lamps.

18.11 If an appliance that is intended for connection to the branch–circuit supply by means of a flexible cord and an attachment plug contains a motor rated at more than 1/3 horsepower, a manually–operated motor–control device shall be provided in the appliance.

19 Capacitors

19.1 A capacitor provided as a part of a capacitor–run motor, and a capacitor connected across the line (such as a capacitor for radio–interference elimination or power–factor correction), shall be housed within a suitable enclosure or container that protects the plates against mechanical damage and that prevents the emission of flame or molten material resulting from failure of the capacitor. The container shall be of metal providing strength and protection not less than that of sheet steel having a minimum thickness of 0.020 inch (No. 24 MSG) if measured uncoated, or equivalent.

Exception: The individual container of a capacitor may be of sheet metal less in thickness or may be of suitable material other than metal if a) it can be shown that the material is equivalent and is provided with additional supporting material which is otherwise acceptable for live parts, or b) the capacitor is mounted in an enclosure which houses other parts of the appliance and provided that such a box, case, etc., is acceptable for the enclosure of live parts.

19.2 If a capacitor which is not a part of a capacitor motor or a capacitor–start motor is so connected in an appliance that capacitor failure could result in any hazardous condition, adequate protection shall be provided in the appliance to prevent the establishment of such a condition (see also 49.4.1 – 49.4.4).

19.3 The materials and construction of a capacitor or its enclosure within an appliance (including a means for venting) shall be such that no hazardous pressures can develop in the capacitor in the event of failure of the capacitor or the circuit in which it is connected.

19.4 The voltage rating of a capacitor other than a motor–starting or motor–running capacitor shall equal or exceed the maximum steady–state potential to which the capacitor is subjected during operation or user servicing of the appliance at rated voltage.

20 Lampholders and Lamps

20.1 A lampholder shall be designed and installed that uninsulated live parts other than the screwshell are not exposed to contact by persons removing or replacing lamps during user servicing.

Exception: The requirement does not apply if, in order to remove or replace a lamp, it is necessary to dismantle the appliance by means of tools. However, common Edison–base or fluorescent lamps used for illumination, or pilot lamps are to be user serviceable without such dismantling of the appliance. [Also see 2.14(c)].

20.2 A lampholder shall not employ a paper liner if the lampholder is likely to be exposed to moist vapors during the operation of the appliance.

20.3 Wherever necessary to prevent injury or shock hazard to persons during the operation of the appliance, a suitable guard or equivalent shall be provided to adequately contain lamp fragments and prevent contact with live parts in the event of lamp breakage.

20.4 The guard indicated in 20.3 is to be formed and assembled so that it has the strength and rigidity necessary to resist the abuse to which it may be subjected.

21 Accessory Receptacles

21.1 An unused receptacle provided for the attachment of an accessory that involves hazardous energy shall be designed so that no bare live parts are accessible, and if of the conventional parallel–slot type, it shall involve line power only.

21.2 Receptacles that will accommodate single–prong, shielded–type plugs generally employed for audio signal applications shall not involve hazardous energy. See 5.1.3.

21.3 A 15– or 20–A attachment–plug receptacle in an appliance provided with a means for grounding (a permanently wired appliance or a cord–connected appliance with a grounding conductor in the cord) shall be of the grounding type. The grounding contact of the receptacle shall be positively and reliably electrically connected to the grounding means of the appliance.

21.4 On line–powered cord–connected equipment, receptacles involving line power shall conform to the configuration applicable to the attachment plug on the supply cord.

Exception: If a receptacle is intended for an accessory which cannot be employed separately, other configurations may be acceptable.

21.5 Receptacles provided on patient care equipment having a Hospital Grade plug, shall be a Hospital Grade type.

22 Transformers

22.1 General

22.1.1 A transformer shall be of thoroughly substantial construction. The coils shall be wound in a workmanlike manner and impregnated or otherwise enclosed to exclude moisture.

22.1.2 A transformer intended to be connected across a supply circuit shall be housed within its own enclosure or within the overall enclosure of the appliance.

22.2 Construction

22.2.1 Transformers having separate windings shall be constructed so that there is not any electrical connection, under normal and overload conditions, between primary and secondary windings or between separate adjacent secondary windings if such connection would result in a risk of fire or electric shock.

22.3 Patient care equipment

22.3.1 To comply with the requirements in 22.2.1, a transformer is to be constructed in accordance with one or more of the following methods and is to meet the test requirements in 49.3.1 – 49.3.9.

a) Windings are to be wound on separate bobbins of basic insulation, see 2.2, on separate legs of a transformer core.

b) Separately wound (not concentrically wound) primary and secondary windings, or adjacent secondary windings, are each to be wound on basic insulation, see 2.2, on the same leg of the transformer core, and the ends of each of the windings are to be separated by basic insulation.

c) Concentrically wound primary and secondary windings, or adjacent secondary windings, are to be provided with protection from overheating and are to be separated by a grounded copper shield at least 0.13 mm (0.005 inch) thick or the equivalent. The copper shield is to completely isolate the adjacent windings, splices, and cross–over leads.

d) Concentrically wound primary and secondary windings, or adjacent secondary windings, separated by two layers of mica having a total thickness of 0.18 mm (0.007 inch), or of other insulating material having equal resistance to ignition. The insulating material, type and thickness, is also to be provided for the splices and cross–over leads.

e) Concentrically wound primary and secondary windings, or adjacent secondary windings, are to be provided with protection from overheating and are to be separated by three layers of insulating material. Any combination of two layers of the insulation is to be capable of withstanding a 3500–V, 60 Hz dielectric voltage–withstand test potential for 1 minute. The insulating material – type, combination and thickness – is also to be provided for the splices and cross–over leads.

f) Concentrically wound primary and secondary windings or adjacent secondary windings that are separated by insulation complying with the requirements in the Standard for Double Insulation Systems for Use in Electrical Equipment, UL 1097.

g) Other constructions are to be shown to be equivalent to those in (a) – (f) by examination and tests.

22.3.2 Protection from overheating where required in 22.3.1 (c) or (e) is to be such that the temperature of the insulating material used to separate the primary and secondary, or adjacent secondary windings, from grounded metal or each other cannot exceed the values indicated in 49.1.1 during performance of the overload and short circuit tests described in 49.3.1 – 49.3.9.

22.3.3 Patient–connected equipment only

22.3.3.1 A transformer having a part (core or winding) that is considered to be a patient–connected part shall have insulating material or spacings, or both, that comply with the requirements for double or reinforced insulation and shall comply with the tests outlined in 49.3.1 – 49.3.9 (see 46.4.1 and 49.1.5) The insulating material or spacings, or both, shall completely isolate the part considered to be patient–connected from all parts not considered to be patient–connected.

22.4 Nonpatient equipment

22.4.1 Compliance with 22.2.1 shall be determined by the tests outlined in 49.3.1 – 49.3.9.

23 Spacings

23.1 Field–wiring terminals

23.1.1 The spacings between field–wiring terminals of opposite polarity and the spacings between a field–wiring terminal and any other uninsulated metal part (dead or live) not of the same polarity shall not be less than indicated in Table 23.1.

Table 23.1
Minimum acceptable spacings in inches at field-wiring terminals

Potential involved in volts (RMS)	Between wiring terminals air or over surface[a]	Between terminals and other uninsulated metal parts not always of the same polarity[a]	
		Over surface	Through air
250 or less	1/4	1/4	1/4
More than 250	1/2[b]	1/2[b]	3/8

[a] Applied to the sum of the spacings involved where an isolated dead metal part is interposed.
[b] A spacing of not less than 3/8 inch, through air and over surface is acceptable at wiring terminals in a wiring compartment or terminal box if the compartment or box is integral with a motor.

23.2 Primary circuits

23.2.1 In primary circuits other than at field–wiring terminals, the spacings between uninsulated live parts of opposite polarity and between an uninsulated live part and any other uninsulated conductive part, (dead metal part or live part) not of the same polarity shall not be less than indicated in Table 23.2 except that internal motor spacings shall comply with spacing requirements in the requirements for electric motors (UL 1004). If an uninsulated live part is not rigidly fixed in position by a means other than friction between surfaces or if a movable part is in proximity to an uninsulated live part, the construction shall ensure maintenance of at least the minimum acceptable spacings shown regardless of the position of the movable part.

23.2.2 At closed–in points only, where contamination is unlikely to occur (such as the screw–and–washer construction of an insulated terminal mounted in metal), a spacing of 3/64 is acceptable in an appliance rated at 250 V or less. Within a thermostat, except at contacts, the spacings between uninsulated live parts on opposite sides of the contacts are not to be less than 1/32 inch through air and 3/64 inch over the surface of insulating material, and the construction is to be such that the spacings will be maintained permanently.

23.2.3 The spacing requirements given in Table 23.2 do not apply to the inherent spacings of a component of the appliance, such as a snap switch; such spacings are judged on the basis of the requirements for the component in question.

23.2.4 At terminal screws and studs to which connection can be made in the field by means of wire connectors, eyelets, or the like indicated in 2.6, it is required that the spacings be not smaller than shown in Table 23.2 while such connectors, eyelets, etc. are in such position that minimum spacings (opposite polarity and to dead metal) exist.

23.2.5 An insulating liner or barrier of vulcanized fiber or similar material employed where a spacing would otherwise be less than the minimum acceptable value shall not be less than 1/32 inch (0.8 mm) thick, and shall be so located or of such material that it will not be adversely affected by arcing; except that vulcanized fiber not less than 1/64 inch (0.4 mm) thick may be used in conjunction with an air spacing of not less than 50–percent of the minimum acceptable through–air spacing.

23.2.6 Insulating material having a thickness less than that specified in 23.2.5 may be used if, upon investigation, it is found to be suitable for the particular application.

23.2.7 The barriers shall be reliably held in place by means more secure than friction between surfaces. The elasticity of tubing shall not be depended upon to hold the tubing in place, but dilated or heat–shrunk tubing is acceptable.

23.2.8 Unless protected from mechanical abuse during any user assembly or servicing and normal functioning of an appliance, a barrier of mica shall be 0.010 inch (0.25 mm) or more thick.

Table 23.2
Minimum acceptable primary-circuit spacings in inches other than field-wiring terminals and in motors

Potential involved in volts RMS (Peak)	Minimum spacings, inch (mm)	
	Over surface	Through air
0 – 125 (0 – 176.8)	1/16 (1.6)[d]	1/16 (1.6)[d]
126 – 250 (178.2 – 353.5)	3/32 (2.4)[a,d]	3/32 (2.4)[a,d]
251 – 600 (354.9 – 848.4)	1/2 (12.7)[a,b]	3/8 (9.5)[a,b,c,d]

[a] In appliances employing heaters, such as sterilizer, warmers, etc. the spacings may be 1/16 inch (up to 250 volts) and 1/4 inch (up to 600 volts).

[b] A spacing of 1/16 inch is permissible at the heating element only in an appliance rated for 300 volts or less.

[c] Film-coated wire is considered to be an uninsulated live part. However, a spacing of not less than 3/32 inch (2.4 mm) over surface and through air is acceptable between a dead metal part and film-coated wire that is rigidly supported and held in place on a coil.

[d] On printed-wiring boards, their connectors, and board-mounted electrical components, wired on the load side of line filters or similar voltage peak reduction networks and components. A minimum spacing of 0.0230 inch (0.580 mm) plus 0.0002 inch (0.005 mm) per volt peak shall be maintained over surface and through air between uninsulated live parts any other uninsulated live parts not of the same polarity, except patient connected circuits.

23.3 Secondary circuits

23.3.1 The spacings outlined in 23.2.1 and Table 23.2 shall apply in all secondary circuits that are safety circuits, for example, interlocks, thermostats, etc. The spacings in all other secondary circuits, except for patient–connected circuits covered in 23.4.1, are judged on the basis of the dielectric withstand tests mentioned in 46.1.1 – 46.5.3.

23.4 Patient–connected circuits

23.4.1 The spacings between uninsulated parts of patient–connected circuits and adjacent circuits derived from different sources shall be twice the spacings outlined in 23.2.1 and Table 23.2 (See 10.1.2).

24 Grounding

24.1 Appliances shall be provided with the means for grounding as outlined in 24.2 – 24.7, or be provided with double insulation complying with the applicable requirements in the Standard for Double Insulation Systems for use in Electrical Equipment, UL 1097.

24.2 In the following paragraphs a conductive metal surface is not intended to include isolated metal nameplates or handles, isolated metal trim of cabinets, or isolated screws or other hardware which are fastened into plastic or otherwise nonconductive enclosures.

24.3 An appliance identified as being double insulated and having exposed conductive metal surfaces, if provided with a means for grounding such surfaces, the grounding shall be by means of a separate terminal consisting of a pressure wire connector or wire binding screw. The pressure wire connector or wire binding screw shall be capable of securing a No. 10 AWG or smaller grounding conductor.

24.4 For an appliance not identified as being double insulated, all exposed conductive metal parts which are likely to become energized from within and all dead metal parts within the enclosure which are exposed to contact during any user servicing operation and which are likely to become energized, shall be reliably connected to the grounding means. The grounding means of a cord connected appliance shall be a part of the flexible cord and attachment plug, or the cord set. See 48.1 and 73.1.

24.5 A grounded appliance also having isolated exposed conductive metal surfaces not likely to become energized from within need not be provided with a means for the grounding of such surfaces. If a means of grounding is provided it shall be by a separate terminal consisting of either a pressure wire connector or wire binding screw. The pressure wire connector or wire binding screw shall be capable of securing a No. 10 AWG or smaller grounding conductor.

24.6 For an appliance intended to be permanently connected by a metal or a nonmetal–enclosed wiring system, a separate equipment grounding terminal or lead properly identified (see 7.2.11 and 7.2.12) shall be provided as the means for grounding.

24.7 A grounding conductor of the flexible cord shall have the green with or without one or more yellow stripes identification required by the American National Standard National Electrical Code ANSI/NFPA 70 for such a conductor. The grounding conductor shall be secured to the frame or enclosure of the appliance which is intended to be grounded by means of a screw that is not likely to be removed during any servicing operation not involving the power–supply cord, or by other equivalent means. Ordinary solder alone shall not be used for securing the grounding conductor. The grounding conductor shall be connected to the grounding blade or equivalent contacting member of an attachment–plug cap.

25 Voltage Impulses Applied to Patients

25.1 Certain appliances, for example, defibrillators, by their very nature involve the application of electric potentials to the patient that exceed the normally acceptable shock hazard levels. The following requirements shall apply to these appliances.

a) Unless the configuration of hand–held paddles, pads, probes, or other electrodes is such that they can be logically grasped at one location during use, to effectively prevent inadvertent contact of the operator with the active elements of the electrodes, the arrangement of the patient circuit shall be such that the person holding the electrodes has sole and complete control of the initiation of the voltage impulse.

b) A suitable meter or other indicator shall be provided to inform the operator that the appliance is ready for use and indicate the magnitude and the nature of the energy available.

c) The output leads (electrodes) shall be effectively isolated from ground potential for the duration of the voltage impulse (see 23.4.1). It is recommended that the isolation be maintained during quiescent periods also.

d) The appliance shall be marked in accordance with 71.1.

PROTECTION AGAINST INJURY TO PERSONS

26 General

26.1 The requirements in Sections 26 and 27 – 36 are intended to minimize the likelihood of injury to a patient, operator, and a service person while retaining the intended function of the product.

26.2 If the operation and maintenance of a product by the operator involves a risk of injury to persons, including risks resulting from the presence of oxygen, radiation and the like, means shall be provided to reduce the risk.

26.3 Determining compliance of a product with the requirement in 26.2, consideration shall be given to reasonably foreseeable misuse of the product.

26.4 An attachment that is made available or indicated by the manufacturer for use with the basic product shall be included when determining compliance of the product with the requirements of this section. Unless the manufacturer indicates that two or more attachments can be used at the same time, only one attachment at a time is to be evaluated with the product.

26.5 Whether a guard, a release, an interlock, or the like is required and whether such a device is adequate shall be determined from an investigation of the complete product, its operating characteristics, and the likelihood of a risk of injury to persons resulting from a cause other than gross negligence. The investigation shall include consideration of the results of breakdown or malfunction of any component; but not more than one component at a time, unless one event contributes to another. If the investigation shows that breakdown or malfunction of a particular component can result in a risk of injury to persons, that component shall be investigated for reliability.

26.6 Features and constructions not covered herein are to be examined and tested to determine whether they are acceptable for the purpose.

27 Enclosures, Guards, and Barriers

27.1 The rotor of a motor, a pulley, a belt, a gear, or other moving part that could cause injury to persons shall be enclosed or provided with other means to reduce the likelihood of unintentional contact.

Exception: A part or portion of a part that is necessarily exposed to perform its intended function.

27.2 The degree of protection required by 27.1 depends upon the general construction and intended use of a product.

27.3 A moving part that may involve a risk of injury to persons shall comply with the requirements specified in this Section, and shall be considered with respect to:

a) The degree of exposure necessary to perform its intended function;

b) The sharpness of the moving part;

c) The likelihood of unintentional contact with the moving part;

d) The speed of the moving part; and

e) The likelihood:

1) That a part of the body would be endangered, or

2) That clothing could be entangled, resulting in a risk of injury to persons.

The above factors are to be considered with respect to both intended operation and reasonably foreseeable misuse of the product.

27.4 An enclosure or guard over a rotating part shall:

a) Retain a part that, because of breakage or other reasons, may become loose or may separate from the rotating part; and

b) Retain a foreign object that may be struck and propelled by the rotating part.

See 32.2.

27.5 An opening in a guard or enclosure around a part that can result in injury to persons is acceptable if the minor dimension is less than 1 inch (25.4 mm) and the probe illustrated in Figure 5.2, when inserted into the opening, cannot be made to touch the moving part. The probe is to be applied in all possible articulated configurations before, during, and after insertion.

27.6 The probe mentioned in 27.5 shall be used as a measuring instrument to judge the accessibility provided by an opening, and not as an instrument to judge the strength of a material; it shall be applied with the minimum force necessary to determine accessibility.

27.7 If the articulate probe illustrated in Figure 5.2 cannot enter the opening described in 27.5, the rigid probe illustrated in Figure 5.4 shall be applied to the opening with force of 6.75 lbf (30 N). The articulate probe shall then be applied through any opening introduced by the rigid probe – including an opening that would close after removal of the rigid probe.

27.8 The probe shown in Figure 5.2 is also to be applied to all openings in the bottom of the enclosure of a bench–or table–top supported appliance. The product is to be oriented in any position necessary to permit the bottom of the enclosure to be accessible for application of the probe.

27.9 The probe shown in Figure 5.2 is also to be applied to all openings in the bottom of the enclosure of a floor supported product under the conditions determined with the product standing in its intended position on the floor.

a) When the front, sides, or back of the product extends to within 3 (76.2 mm) to 6 inches (152.4 mm) of the floor the probe is to be applied only to bottom openings located within 10 inches (254 mm) of the plane formed by the front, sides, or back and the floor. The probe is to be inserted directly through the bottom opening, to the extent that any part of the probe's 3 inch (76.2 mm) diameter stop plate does not pass through the plane of the bottom opening. The product may be positioned to facilitate the application of the probe.

b) When the front, sides, or back of the product extends to within less than 3 inches (76.2 mm) of the floor, the probe is to be applied at the opening formed by the bottom edge of the product and the floor. The probe is to be inserted to the extent that any part of the 3 inch (76.2 mm) diameter stop plate does not pass through the vertical plane of the opening formed by the product and the floor. The product may be tilted, if necessary to permit application of the probe up to the 3 inch (76.2 mm) diameter stop plate.

c) When the space formed between the floor and the lower edge of the product front, sides or back exceeds 6 inches (152.4 mm) and the minor dimension of the opening in the bottom is less than 1 inch (25.4 mm), the probe is to be applied as in (a) above.

Exception: When the minor dimension of opening in the bottom is more than 1 inch (25.4 mm), the distance to a moving part that involves a risk of injury shall comply with accessibility requirements in 5.2.6.

27.10 A product having a moving part that presents a risk of injury to persons, and is located behind a service or loading door or panel that the operator may – with or without use of a tool – open, shall be provided with a means to deactivate the part so that it does not present a risk of injury when the door or panel has been opened for a period of 3 seconds or longer. See 29.2.1.

27.11 A guard, or portion of the enclosure acting as a guard, for a part that can cause injury to persons shall be either:

a) Mounted to the assembly so that the part that can cause injury to persons cannot be operated with the guard removed.

b) Secured to the assembly using fasteners that require a tool for removal, or

c) Provided with an interlock to protect against access to the part. See 29.2.1 – 29.2.6.

28 Edges and Projections

28.1 Each edge, projection, and corner of an enclosure, opening, frame, guard, knob, handle, or the like, shall not be sufficiently sharp to constitute a risk of injury to persons during intended use or operator maintenance of the product.

Exception: A part or portion of a part that must be exposed to perform its intended function.

28.2 Whenever referee measurements are necessary to determine that a part mentioned in 28.1 is not sufficiently sharp to constitute a risk of injury to persons, the method described in the requirements for determination of sharpness of edges on equipment (UL 1439) is to be employed.

29 Switches, Controls, and Interlocks

29.1 Switches and controls

29.1.1 A product shall be constructed so as to reduce the likelihood of unexpected operation of a part capable of causing injury to persons.

29.1.2 A device that automatically starts a product, such as a timer or an automatically reset overload–protective device, shall not be employed unless it can be demonstrated that automatic starting is not likely to result in a risk of injury to persons.

29.1.3 Each function of a multiple–function product is to be considered in determining whether the product complies with the requirements in 29.1.1.

29.1.4 A switch that controls moving parts of a product, including the type that controls the modes of bed operation, shall be of a momentary–contact type if sustained movement can result in risk of injury to persons.

Exception No. 1: Switches controlling parts whose sustained operation would not result in risk of injury to persons, need not be of a momentary–contact type if marked to indicate the "off" position. The marking shall comply with the requirements in 60.1, 60.2 and 65.1.

Exception No. 2: A hospital bed switch intended to be actuated by hospital personnel during emergency procedures relative to patient care is not required to be of the momentary–contact type if:

a) It cannot be actuated by the patient from any position associated with lying in bed, and

b) The movement controlled by the switch can be stopped from any location around the perimeter of the bed.

Exception No. 3: A switch need not be of the momentary–contact type if it complies with all (a) – (d) of the following:

a) It actuates only lowering the level of a hospital bed,

b) It is located in the nurse control area at the foot of the bed, and

c) It can be actuated only by use of:

1) A designated key or device, or other equal means,

2) A sequence keying arrangement of 3 or more manipulations, or

3) A system that requires not less than two manipulations and is provided with the following:

i) A momentary–contact–on type "enable" switch that is located in the nurse's control panel, and is required to be operated first in order to engage the "walk–away" down feature,

ii) A second switch (of any type)– which actuates lowering of the bed – that is located at a position other than the nurse's control panel and is not less than 18 inches (457 mm) from the "enable" switch (part i), and

iii) The "walk–away" down feature is automatically disengaged when any one of the following occurs:

1) The bed has completed its travel to the lowest position,

2) The bed travel is stopped – by use of an overriding stop switch, or the like – before completing its travel to the lowest position, or

3) The full procedure needed to initiate movement of the bed is not completed within 10 seconds – such as when the "enable" switch circuit has been energized but the second switch (part ii) has not been actuated. It shall be required that the completed procedure be repeated in order to re–activate the "walk–away" down feature, and

d) It is used on a bed construction in compliance with the requirement in 29.1.5.

29.1.5 A hospital bed that has a maintain–contact–on switch as described in Exception No. 3 of 29.1.4 shall provide protection from contact of any other parts – such as rods, levers, re–start switches, or the like – that can be manipulated so as to initiate a sustained downward movement of the bed. The protection may be provided by an enclosure, a fitted cover or shroud, or the like.

29.1.6 If unintentional operation of a switch can result in a risk of injury to persons, the actuator of the switch shall be located or guarded so that unintentional movement to the on position is unlikely. See 29.1.8.

Exception: Electrosurgical devices intended for use only by operating personnel – doctors, nurses, or the like – need not comply with this requirement.

29.1.7 The requirement in 29.1.6 shall apply to switches that are:

a) Readily accessible from the position normally assumed by the operator while setting up or using the product, and

b) Capable of being turned on with a single straight–line motion, push, or other action similar to the operation of adjacent switches or controls.

29.1.8 The actuator of a switch may be guarded by recessing, ribs, barriers, or the like. The construction is acceptable if the switch actuator is not moved to the on position when struck at with the palm of the hand.

29.2 Interlocks

29.2.1 A moving part that:

a) Can cause injury to persons,

b) Is behind a service or loading door that may be opened by the user, and

c) That is interlocked such that the part is deactivated when the door is opened,

is acceptable if one of the following conditions is met:

1) Within 3 seconds after the door is opened, the moving part has stopped or slowed to a speed such that risk of injury to persons is not likely, or

2) The interlock construction is such that the door cannot be opened until the moving part has stopped.

29.2.2 An interlock actuated by movement of a guard shall enable operation of the part being guarded only if the guard is in place. With the guard removed, the interlock shall comply with the requirements in 29.2.4 and 29.2.6.

29.2.3 The actuator of an interlock switch shall be so located or guarded that unintentional operation that would restart a moving part is unlikely. The guarding means may be in the form of recessing, ribs, barriers, or the like.

29.2.4 Operation of an interlock in normal use shall not inconvenience the operator so as to encourage deliberate defeat of the interlock.

29.2.5 An interlock shall not be capable of being defeated by materials that could accumulate in normal use.

29.2.6 An electromechanical interlock shall withstand 100,000 cycles of operation, controlling a load not less than that controlled in the product, and shall function as intended upon completion of the test.

29.3 Pendant switches

29.3.1 The actuator of a pendant control switch shall be guarded by recessing, ribs, barriers, or the like so that it is unlikely that the switch can be operated unintentionally.

29.3.2 Unless the risk of injury to persons described in 29.1.1 is not present, a hook or holder shall be provided to hold the pendant control when it is not in use, and the control shall be marked in accordance with 75.1.

30 Electronically Produced Radiation

30.1 Medical and dental products may involve different types of radiation such as light, radio frequency, sound, ultra–violet, infrared, or even particles that may be applied to patients for diagnostic or therapeutic purposes under medical supervision.

30.2 A product that produces ionizing or non–ionizing radiation or sonic, infrasonic, or ultrasonic vibrations as a result of operation of an electronic circuit in the appliance is subject to the requirements of the Center for Devices and Radiological Health (CDRH), Department of Health and Human Services. The product shall comply with these specified limits. This may be determined by a review of the report of the CDRH review.

30.3 Shields, barriers, and the like shall be provided to protect the operator and other personnel in the vicinity of the product against harmful extraneous radiation from the product.

Exception: If the construction and function of the product is such that scatter radiation from the treatment source cannot be avoided, provision shall be made to caution the operator and other personnel in the vicinity of the product against the possibility of harmful extraneous radiation during treatment. See 76.1.

30.4 Unless marked as indicated in 76.1, extraneous X–radiation, when measured as described in 44.1, shall not exceed a dose rate, averaged over an area of 10 cm^2, of 0.5 milliroentgen per hour at any point located 5 cm from the outer surface of the product enclosure under any intended conditions of operation, including no load.

30.5 Unless a marking is provided to warn the service personnel of the risk of X–radiation (see 69.1), the product shall comply with the requirements in 30.4 under all conditions of servicing by service personnel. Servicing by service personnel includes the removal of shields, windows, cages, covers and – with or without the chassis removed from its enclosure – the setting to any position of all adjustments that are intended to be made by service personnel.

31 Radioactive Materials

31.1 In the United States, the manufacture, importation, distribution, and disposal of medical and dental products containing or handling radioactive material are subject to requirements of state radiation control agencies, the U.S. Nuclear Regulatory Commission or both.

31.2 Verification of the acceptance of such equipment by the regulatory agency involved is required prior to, or may be concurrent with, the establishment of compliance with the requirements of this Standard.

32 Rotating or Moving Members

32.1 A rotating or moving part that, if it becomes disengaged, may create a risk of injury to persons shall be provided with a means to retain the part in place under conditions of use.

32.2 A rotating member, breakage of which may create a risk of injury to persons, shall be constructed so as to reduce the likelihood of breakage, or the release or loosening of a part that could become a risk of injury to persons.

32.3 A product employing a series motor shall be tested as described in 32.4 to determine whether it complies with the requirement in 32.2. A part that can become a risk of injury is to be tested as described in 32.4. A part that can become a risk of injury shall not work loose as a result of the test.

32.4 For the test required by 32.3, a product employing a series motor is to be operated for 1 minute at the no–load speed resulting from application of 1.3 times rated voltage. A product in which the rotating load may be varied is to be tested for each condition of loading that can occur.

32.5 An operator–removable rotating part that is secured by a nut shall be constructed so that the direction of rotation tends to tighten the nut.

33 Power–Driven Equipment

33.1 Parts that close under power in normal use and that can cause injury to persons shall be provided with a means to reduce the risk of injury to persons (for example, telescoping guards, interlocks, trip switches, and the like), or shall comply with the requirements for clearance in 33.2 – 33.8.

33.2 A construction in which a power driven part crosses another part (movable or fixed) and the location at which they cross is less than 4 inches (101.6 mm) from a plane of the edge of the product, a minimum 2 inches (50.8 mm) clearance shall be provided between the two parts at any location at which they can cross.

Example: Crossing parts on the underside of a hospital bed mattress support surface, that are located less than 4 inches (101.6 mm) inside the perimeter of the support surface shall comply with the minimum 2 inch (50.8 mm) clearance.

Exception: Operating room tables that have the locations representing a risk of injury to persons clearly identified in the operator's manual.

33.3 When determining whether a product complies with the requirement for the minimum 2 inches (50.8 mm) clearance described in 33.2, additional consideration is to be given to constructions and arrangements that include restraining devices.

33.4 A pinch point that is subject only to finger contact, shall comply with one of the following:

a) The parts shall not separate more than 3/8 inch (9.5 mm),

b) A sliding guard or the equivalent shall be provided to reduce the likelihood of a finger being caught between the two parts if the separation between parts is more than 3/8 inch (9.5 mm) but less than 3/4 inch (19.1 mm), or

c) The distance between the parts in any position shall be 3/4 inch (19.1 mm) or more.

Exception: Operating room tables having the locations representing the risk of injury to persons clearly identified in the operator's manual.

33.5 A pinch point located such that entanglement of hands or feet or both is likely, shall not be recessed less than 4 inches (101.6 mm) from the plane of the edge of the product.

33.6 The clearance between the mattress support surface and the headboard, side rail and footboard of a hospital bed shall be such that the entanglement of arms, head, or legs is unlikely when the bed position is being changed.

33.7 The head or foot end of a power–driven mattress support on a hospital bed shall not move more than 3 inches (76.2 mm) below the lower edge of any headboard, footboard, or other fixed member.

33.8 If a crank, lever, wheel, or the like is provided for manual operation of a motor–driven part of a hospital bed, it shall not cause a risk of injury to persons due to unintentional, deliberate, or automatic starting of the motor.

33.9 If a risk of injury to persons can result, a mechanism controlling a moving part on a product shall be of a reversible type and shall not continue operation of the moving part in the same direction when a switch or lever is actuated to initiate operation in the opposite direction.

34 Stability

34.1 Under all conditions of servicing and intended use, a product intended to be free–standing – not bolted to other units or secured to a bench, floor or other part of the building – shall not overturn when tipped through an angle of 10 degrees as described in 34.1 – 34.4.

34.2 To determine compliance with the requirements in 34.1, any free–standing product is to be subjected to the test outlined in 34.3. The product is not to be energized during the test. The test is to be conducted under conditions most likely to cause the product to overturn. The following conditions are to be such as to result in the least stability:

a) The position of all doors, drawers, casters, and other movable or adjustable parts including that of the supply cord resting on the surface supporting the product.

b) Connection of, or omission of, any attachment made available or recommended by the manufacturer.

c) Provision of, or omission of, any intended load if the product is intended to contain a liquid or other mechanical load.

d) Direction in which the product is tipped or the supporting surface is inclined.

34.3 In conducting the stability test, the product is to be:

a) Placed on a plane inclined at an angle of 10 degrees from the horizontal; or

b) Tipped through an angle of 10 degrees from an at rest position on a horizontal plane.

34.4 With reference to the requirement in 34.3 (b), for a product that is constructed so that while being tipped through an angle of 10 degrees, a part or surface of the product not normally in contact with the horizontal supporting surface touches the supporting surface before the product has been tipped through the required angle, the tipping is to be continued until the surface or plane of the surface of the product originally in contact with the horizontal supporting surface is at an angle of 10 degrees from the horizontal supporting surface.

34.5 A free–standing product that is subject to an external force during use – such as a patient entering or exiting a hospital bed, an examining table, or a dental chair, and the like – shall not tilt when subjected to a downward force of 300 lbf (1322 N). The force is to be uniformly applied over a 12 inch (305 mm) by 12 inch (305 mm) area – or the entire surface if less than 12 inches by 12 inches – where the external force could normally appear. During this test; wheel, caster or floor locks provided as part of the appliance shall be activated or locked.

34.6 A product equipped with wheels, casters, or the like, shall have at least two manually–operated locks for the wheels, a floor lock, or the like.

Exception No. 1: Emergency–use equipment and carts, attended bench–or table–top equipment intended for use for examination (as opposed to monitoring) purposes or short time treatment during which movement is unlikely or not likely to cause risk of injury to the patient or attendant.

Exception No. 2: Equipment not normally subject to movement and whose size and weight make unintentional movement unlikely.

34.7 If it is necessary that the product be fastened to the floor, or other part of the building to maintain stability, the manufacturer's instructions shall clearly indicate the steps to be performed.

35 Pressure Vessels and Parts Subject to Pressure

35.1 General

35.1.1 A pressure vessel having an inside diameter of more than 6 inches (152 mm) and subject to a gauge pressure of more than 15 psi (102 kPa) shall be certified by the National Board of Boiler and Pressure–Vessel Inspectors and marked in accordance with the appropriate boiler and pressure–vessel code symbol of the American society of Mechanical Engineers (ASME) (H, M, S, or U) and shall have a value of working pressure not less than the pressure determined by applying the applicable procedures of 35.2.1.

Exception No. 1: A pressure–vessel certified by a manufacturer, stamped with the UM symbol of the ASME, and complies with the requirements outlined in 35.2.1.

Exception No. 2: A pressure–vessel, because of its application, is not covered by the scope of the inspection procedures of the ASME Code, shall be so constructed that it complies with the requirements in 35.2.1.

35.1.2 A pressure–vessel bearing the ASME Code inspection symbol (H, M, S, or U) or the Department of Transportation (DOT) inspection symbol is considered to comply with the requirement in 35.1.1 if the vessel is marked with a value of working pressure not less than that to which it is subject during normal or abnormal operation.

35.2 Parts subject to pressure by air, vapor or other gases

35.2.1 A part that is subjected to pressure by air, vapor (including the vapor pressure in a vessel containing only a super–heated fluid) or other gases, during normal or abnormal operation, shall withstand a pressure equal to the highest of the following that is applicable: See Figure 35.1:

a) Five times the pressure corresponding to the maximum setting of the pressure–reducing valve provided as part of the assembly, but not more than 5 times the marked maximum supply pressure from an external source and not more than 5 times the pressure setting of a pressure–relief device provided as part of the assembly.

b) Five times the marked maximum supply pressure from an external source, but not more than 5 times pressure setting of a pressure–relief valve or of a pressure–reducing device.

c) Five times the pressure setting of a pressure–relief device provided as part of the assembly.

d) Five times the maximum pressure that can be developed by a compressor that is part of the assembly, unless the pressure is limited by a pressure–reducing valve or a pressure–relief device, but not more than 5 times the pressure setting of a pressure–relief valve or of a pressure–reducing device.

e) Five times the working pressure marked on the part.

Exception: A test need not be performed on an unmarked pressure vessel or part if:

a) Study and analysis indicate that the strength of the part is acceptable for the purpose as a result of its material, application, and dimensions, or

b) Leakage or rupture would not result in a risk of injury to persons nor wetting of live parts due to vapor pressure.

For example, copper or steel tubing of standard size and provided with standard fittings may be considered to have the needed strength, see Table 35.1. Likewise, nonrigid containers such as blood–pressure cuffs, polymeric tubing, and similar devices handling air only would normally be exempt from this requirement.

Table 35.1
Maximum pressure vs. minimum wall thickness of tubing

Outside diameter,		Minimum wall thickness,		Maximum gauge pressure to which tubing is subjected, psi (MPa)					
				Seamless copper		Butt-welded steel		Seamless steel	
inch	(mm)	inch	(mm)						
3/8 or smaller	(9.5)	0.016	(0.41)	500	(3.45)	600	(4.14)	1000	(6.90)
1/2	(12.7)	0.016	(0.41)	400	(2.76)	480	(3.31)	800	(5.52)
5/8	(15.9)	0.016	(0.41)	320	(2.21)	384	(2.65)	640	(4.42)
5/8	(15.9)	0.021	(0.53)	420	(2.90)	504	(3.48)	840	(5.80)
3/4	(19.0)	0.021	(0.53)	360	(2.48)	432	(2.98)	720	(4.97)
3/4	(19.0)	0.025	(0.64)	420	(2.90)	504	(3.48)	840	(5.80)
1	(25.4)	0.021	(0.53)	260	(1.79)	312	(2.15)	520	(3.59)
1	(25.4)	0.025	(0.64)	320	(2.21)	384	(2.65)	640	(4.42)

35.2.2 Where a test is necessary to determine whether a part complies with the requirement in 35.2.1, two samples of the part are to be subjected to a hydrostatic–pressure test. Each sample is to be so filled with water as to exclude air and is to be connected to a hydraulic pump. The pressure is to be raised gradually to the specified test value and is to be held at that value for one minute. The results are not acceptable if either sample bursts or leaks.

Exception: Leakage at a door gasket of a sterilizer during the hydrostatic–pressure test is acceptable if it does not occur at a pressure lower than 40 percent of the required test value and further pressure build up does not occur.

35.3 Parts subject to hydraulic fluid or water pressure

35.3.1 A part that is subject to a gauge pressure of less than 100 psi (689.5 kPa) of hydraulic fluid or water pressure during normal or abnormal operation, shall withstand a pressure as determined by 35.2.1. A part shall be tested as described in 35.2.2. See Figure 35.2.

Exception No. 1: The test pressure may be reduced to 40 percent of the test pressure determined by 35.2.1 if, upon rupture of the part in question,

a) There is not wetting of uninsulated live parts or insulation that may be adversely affected by moisture or the hydraulic fluid,

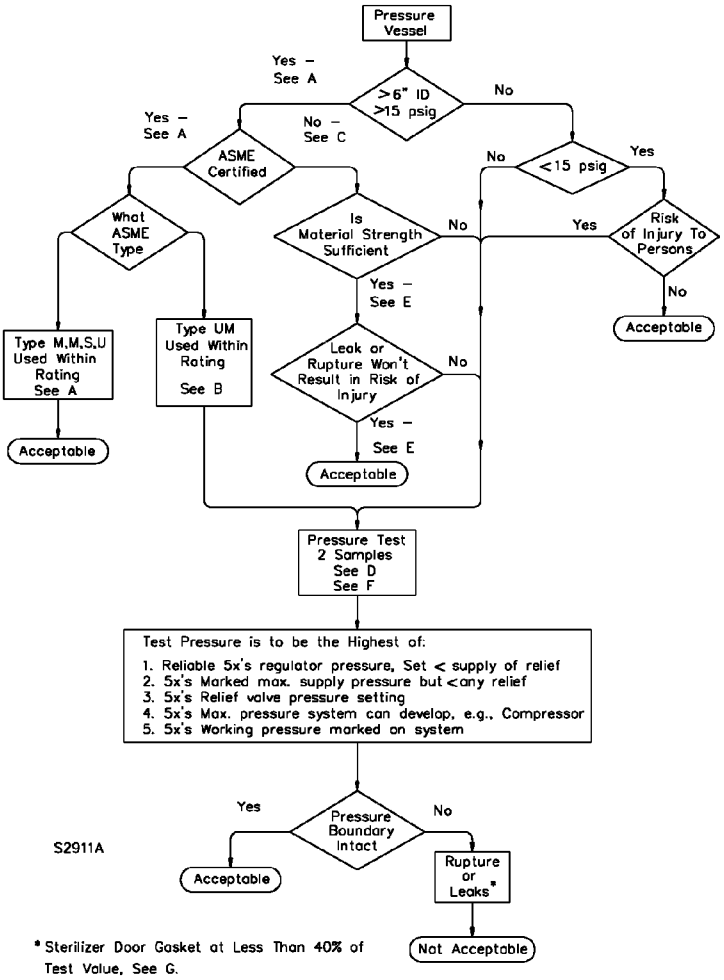
b) There is wetting, but the fluid has been found to be nonconductive, and

c) There is no risk of injury to persons due to loss of hydraulic pressure.

Exception No. 2: This requirement does not apply to a part if study and analysis indicate that the strength of the part is acceptable for the purpose as a result of its material, application, and dimensions.

35.3.2 Parts subject to a gauge pressure of more than 100psi (689.5 kPa) shall be subjected to consideration, including the possibility of risk of injury to persons in the event of rupture or bursting of the part.

Figure 35.1
Flow diagram for pressure vessels and components subjected to pneumatic pressure



A – 35.1.1

B – 35.1.1 Exception No. 1

C – 35.1.1 Exception No. 2

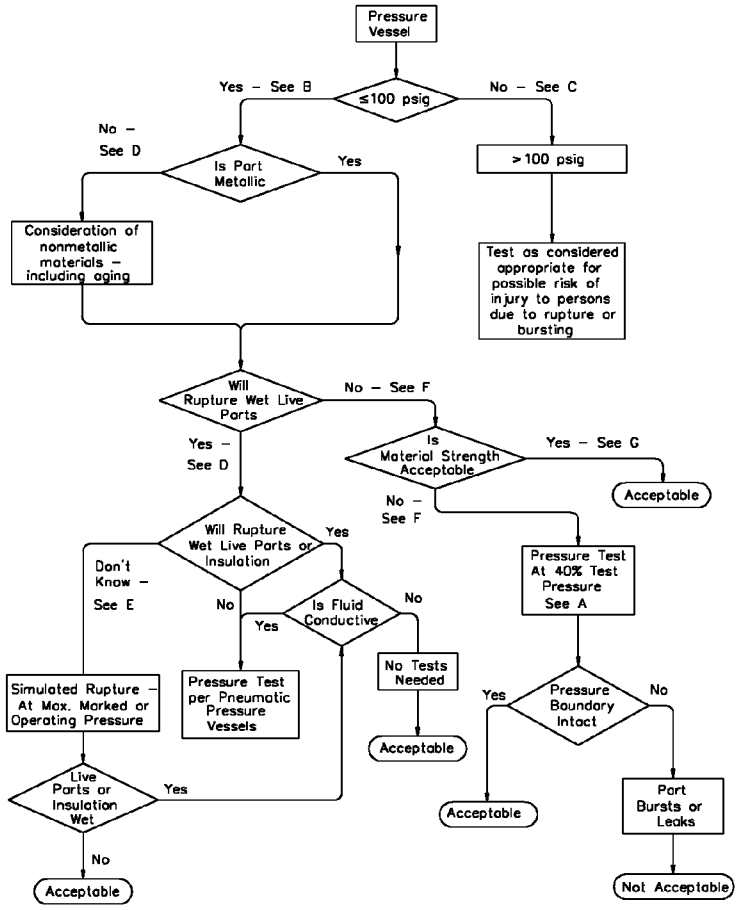
D – 35.2.1

E – 35.2.1 Exception

F – 35.2.2

G – 35.2.2 Exception

Figure 35.2
Flow diagram for pressure vessels and components subjected to hydraulic fluid or water pressure



A – 35.2.1

B – 35.3.1

C – 35.3.2

D – 35.3.3

E – 35.3.4

F – 35.3.1 Exception No. 1

G – 35.3.1 Exception No. 2

35.3.3 Consideration of a nonmetallic part discussed in 35.3.1 – the bursting or rupture of which could result in the wetting or uninsulated live parts – shall include aging properties of the material. The part shall be capable of withstanding the pressure required by 35.3.1, following applicable aging test.

35.3.4 If it cannot be determined by study and analysis that an acceptable degree of protection is provided by guards or barriers, as in Exception No. 1 of 35.3.1, the system is to be filled with water and, if applicable, pressurized with the maximum marked or operating pressure of the appliance, and the parts that are in question are to be punctured or cut, or the tubing couplings and fittings loosened, or both, to simulate the malfunctions likely.

35.4 Pressure relief devices – all pressure systems

35.4.1 A means for relieving pressure as described in 35.4.5 shall be provided for all parts in which pressure might be generated by an external source of heat.

35.4.2 A pressure–relief device is considered to be a pressure–actuated valve or rupture member constructed so as to automatically relieve excessive pressures.

35.4.3 Pressure–relief devices, fusible plugs, soldered joints, nonmetallic tubing, or other equivalent pressure–relief means may be employed to comply with the requirements in 35.4.2.

Exception: A valve bearing an ASME marking (V or UV) is considered to comply with this requirement without further evaluation.

35.4.4 A shut–off valve shall not be located between the pressure–relief means and the parts that it is intended to protect.

35.4.5 A vessel having an inside diameter of more than 3 inches (76.2 mm) and subject to air or steam pressure generated or stored within the appliance, shall be protected by a pressure–relief device.

35.4.6 The start–to–discharge pressure setting of the pressure–relief device shall not be higher than the working pressure marked on the vessel. The discharge rate of the device shall be adequate to relieve the pressure.

35.4.7 A pressure–relief device shall comply with all four of the following:

a) Shall be connected as closely as possible to the pressure vessel or parts of the system that it is intended to protect.

b) Shall be so installed that it is readily accessible for inspection and repair and cannot be readily rendered inoperative.

c) Shall have its discharge opening so located and directed that the risk of scalding is reduced to a minimum.

d) Shall have its discharge opening so located and directed that operation of the device will not deposit moisture on uninsulated live parts or on insulation or components detrimentally affected by moisture.

35.4.8 A pressure–relief device having an adjustable setting is to be investigated on the basis of its maximum setting unless the adjusting means is sealed at a lower setting.

35.4.9 The control that limits the pressure in the vessel that requires a pressure–relief device shall be capable of:

a) Performing under rated load for 100,000 cycles of operation, and

b) Keeping the pressure from exceeding 90 percent of the relief–device setting under any condition of normal operation.

36 External Surface Temperatures

36.1 During the temperature test (see 45.1.1 – 45.1.3), the temperature on an external surface of a product that may be contacted by the user – but not the patient – shall not be more than the value indicated in Table 36.1 If the test is conducted at a room temperature of other than 25°C(77°F), the results are to be corrected to that temperature.

Exception No. 1: A surface that, because of its functions, or location, or both is known to be hot.

Exception No. 2: A product provided with a marking that complies with the requirements in Sections 65 and 77, may have a surface temperature that exceeds the limits specified in Table 36.1 subject to unintentional contact.

Table 36.1
Maximum acceptable temperatures of external surfaces not applied to patients

Surface function and material[a]	Temperature[b]	
	°C	°F
1. A part of the appliance that is intended to be grasped for lifting, carrying, or holding the appliance		
A. Metal	55	131
B. Porcelain or vitreous material	55	149
C. Molded material, rubber, or wood	75	167
2. A handle or knob that is contacted but does not involve lifting, carrying or holding the appliance,and any other surface normally subject to contact in operation or user maintenance		
A. Metal	60	140
B. Porcelain or vitreous material	70	158
C. Molded material, rubber, or wood	85	185
3. A surface other than a heating function surface and subject to only casual or unintentional contact		
A. Metal	70	158
B. Other than Metal	85	185

[a] A handle, knob, or the like made of a material other than metal, which is plated or clad with metal having a thickness of 0.005 inch (0.13 mm) or less, is considered to be a nonmetallic part.
[b] Temperatures shown are referenced to 25°C and 77°F room ambient.

36.2 During the temperature test, the temperature on a part that is necessary to be applied to the patient so as to perform its intended function, but not intended to supply heat to patient, shall not exceed 41°C (106°F). A part that can be subjected to casual contact by a patient, but is not intended to provide heat, shall not operate above 50°C (122°F).

Exception: Infant incubators as detailed in 45.2.21.

37 Oxygen

37.1 Unless an investigation shows the circuits to be energy limited as defined in 2.11, all electrical components shall be separated from oxygen–enriched atmospheres that may be encountered during any likely use of the equipment. An oxygen–enriched atmosphere is considered to exist if the oxygen concentration exceeds 21 percent by volume.

Exception: An electrical circuit or component that is necessarily exposed to an oxygen–enriched atmosphere (OEA) for proper operation of the product need not comply with the requirement in this paragraph if, under normal and abnormal operating conditions, the risk of fire is not increased. Considerations include, but are not limited to, the presence of combustible materials in proximity to a potential thermal or electrical source of ignition, and the concentration, pressure, temperature, and the direction and rate of flow of oxygen in the area of the electrical circuit or component.

37.2 In applying 37.1 to equipment such as incubators, respirators, and the like, it will generally be necessary to provide barriers between the oxygen–enriched atmosphere and those areas containing electrical components. Small neoprene or impregnated asbestos gaskets and grommets are considered acceptable on a motor mounting plate and shaft and may be employed, as applicable, when used in conjunction with thermal sensing devices extending into the oxygen–enriched atmosphere provided there is ventilation of outside air into the electrical compartment to limit the oxygen concentration.

38 Water Submersible Equipment

38.1 A cord–connected appliance, the normal use of which requires that the enclosure of live parts be all or partially submerged in water that is in contact with a patient – such as some types of hydrotherapy equipment – shall not depend solely on parts subject to wear such as shaft seals or parts subject to deterioration with age such as gaskets, "O" rings, and the like, to keep water from contacting live parts or bridging insulation or spacings.

PERFORMANCE

39 General

39.1 An appliance with one supply circuit frequency rating is to be tested at that frequency. An appliance with a dual frequency rating is to be tested at 60 Hz if 60 Hz is included in the rating and may also be tested at the second frequency if such testing is warranted.

39.2 Values of voltage and current are root–mean–square (rms) values, unless otherwise stated.

39.3 Unless otherwise indicated or primary–circuit adjustments are not provided, all operational tests are to be conducted with the appliance connected to a supply circuit of maximum rated voltage and rated frequency, except that if the marked voltage is in the 105 – 120 volt range, the potential of the supply circuit is to be 120 volts, and if the marked voltage is in the 210 – 240–volt range, the potential of the supply circuit is to be 240 volts. If primary–circuit adjustments are provided, they are to be set for the minimum voltage in the 105 – 120–volt range, or in the 210 – 240–volt range, and the potential of the supply circuit is to be 120 volts, or 240 volts, whichever is applicable.

39.4 Normally, voltage measurements in other than the primary supply circuit are to be made with a voltmeter or voltmeter–multiplier combination having a resistance of not less than 2000 ohms per volt for potentials of 1000 volts or less and not less than 20,000 ohms per volt for potentials of more than 1000 volts. Meters having higher input impedances are to be employed whenever it is warranted by the impedance of the circuit under test.

39.5 The cheesecloth mentioned in this Standard is untreated cotton cloth 36 inches wide, running 14–15 yards per pound and having what is known to the trade as a count of 32 by 28. Tests involving cheesecloth are to be made in a closed room with no forced air circulation.

39.6 For tests involving the use of water – such as, immersion, spillage, reservoir overflow, and the like – the water solution shall have a resistivity adjusted to 19.8 – 24.2 ohm–centimeters. The resistivity is to be adjusted by the addition of sodium–chloride or an equivalent salt to tap water.

40 Starting Current

40.1 An appliance shall be capable of starting and operating normally on a circuit protected by an ordinary (not time–delay) fuse having a current rating corresponding to that of the branch circuit to which, in accordance with the National Electrical Code, ANSI/NFPA No. 70, the appliance should be connected.

Exception: The requirement in 40.1 does not apply if:

a) The construction of the appliance or the nature of its usage is such that it is likely to be used continually on the same branch circuit after installation,

b) The appliance will start and operate normally on a circuit protected by a time–delay fuse, and

c) The appliance is marked in accordance with 64.4.

40.2 In a test to determine whether or not an appliance complies with the requirement in 40.1 the appliance is to be started three times, with the appliance at room temperature at the beginning of the test. Each start of the motor is to be made under conditions representing the beginning of normal operation (the

beginning of the normal operation cycle, in the case of an automatic appliance), and the motor is to be allowed to come to rest between successive starts. The performance is unacceptable if the fuse is blown. Tripping of an overload protector provided as part of the appliance is also considered to constitute failure.

41 Input

41.1 The current or wattage input to an appliance shall not be more than 110 percent of the rated value when the appliance is operated under the condition of maximum normal load as described in 45.2.1 – 45.2.21 and when connected to a supply circuit as described in 39.3.

42 Leakage Current

42.1 General

42.1.1 All medical and dental equipment shall be investigated for leakage current. Each appliance shall comply, depending upon its intended use, with 42.3.2 (patient care equipment) or 42.5.1 (nonpatient equipment).

42.2 Permanently connected equipment

42.2.1 Leakage current measurements in accordance with 42.6.1.1 – 42.6.3.2 normally are not made between the equipment frame and ground on equipment intended for permanent connection to the supply, provided all accessible metal parts that are likely to become energized (except electrodes, probes and the like) are reliably connected to the equipment grounding means. However, measurements are to be made between accessible ungrounded parts (such as patient–connected electrodes, probes etc.) and between such parts and ground in the manner described in 42.6.1.1 – 42.6.3.2.

Exception: The total impedance of capacitors and other electronic components connected from one or more sides of the line to the frame or enclosure of a permanently connected appliance shall be large enough to prevent the flow of more than 0.5 mA of leakage current measured through a 1000 ohm resistance in the grounding conductor for frequencies up to and including 1 kHz and equivalent values at higher frequencies with a restriction of 10 mA (see also 42.4.1).

42.3 Cord–connected equipment

42.3.1 All accessible parts of a cord–connected appliance are to be tested for leakage current between the parts and between the parts and the ground. The measurements are to be made in the manner described in 42.6.1.1 – 42.6.3.2.

42.3.2 When a patient care appliance is tested in the manner described in 42.6.1.1 – 42.6.2.1 the available leakage currents shall not exceed the values in Table 42.1.

Exception No. 1: Electrosurgical units – The leakage current requirements do not apply to patient electrodes or chassis of electrosurgical units in the operational mode where radio frequency output is intentionally produced. However, the leakage current from patient electrodes and chassis shall be evaluated in the quiescent (or standby) mode. The load employed is to be as indicated in 45.2.18.

Exception No. 2: Equipment may have a chassis leakage current greater than 300 microamperes – but not more than 500 microamperes – measured in the equipment grounding conductor, when equipment provided with a device that is intended to detect the loss of equipment ground and open all ungrounded conductors. The device shall comply with the applicable requirements in the Standard for Ground–Fault Sensing and Relaying Equipment, UL 1053.

42.3.3 The AC values in Table 42.1 are based on data obtained with 60 Hz sinusoidal voltages and apply for frequencies up to 1 kHz. For frequencies above 1 kHz* the acceptable levels of leakage current are equal to the values indicated in Table 42.1 times the frequency in kilohertz up to a maximum multiplier of 100.

Table 42.1
Patient care equipment maximum leakage current (microamperes)

Patient connection[a]				Enclosure or chassis[b,c]			
Isolated[d]		Ordinary[e]		Grounded[f]		Double insulated[g]	
AC RMS	DC	AC RMS	DC	AC RMS	DC	AC RMS	DC
10	14	50	70	300	420	150	210

[a] Measured between patient leads (applied part) or between patient leads and ground. Value indicated is acceptable for each particular body function or parameter measured or monitored.

[b] Metal enclosure or metal foil over insulating material, per 42.6.1.3.

[c] See 2.5 Enclosure.

[d,e] See 2.17, Patient Connections.

[f] Measured with loss of ground per 42.6.1.2 (see 7.3.2.3 for appropriate plug cap).

[g] When measured with either functional or supplementary insulation effectively bypassed, the allowable leakage current is twice that shown.

42.4 Isolated patient connections

42.4.1 When equipment having an isolated patient connection is subjected to the test outlined in 42.4.2, the available current shall not exceed 20 microamperes when measured at the patient end of the connecting cables.

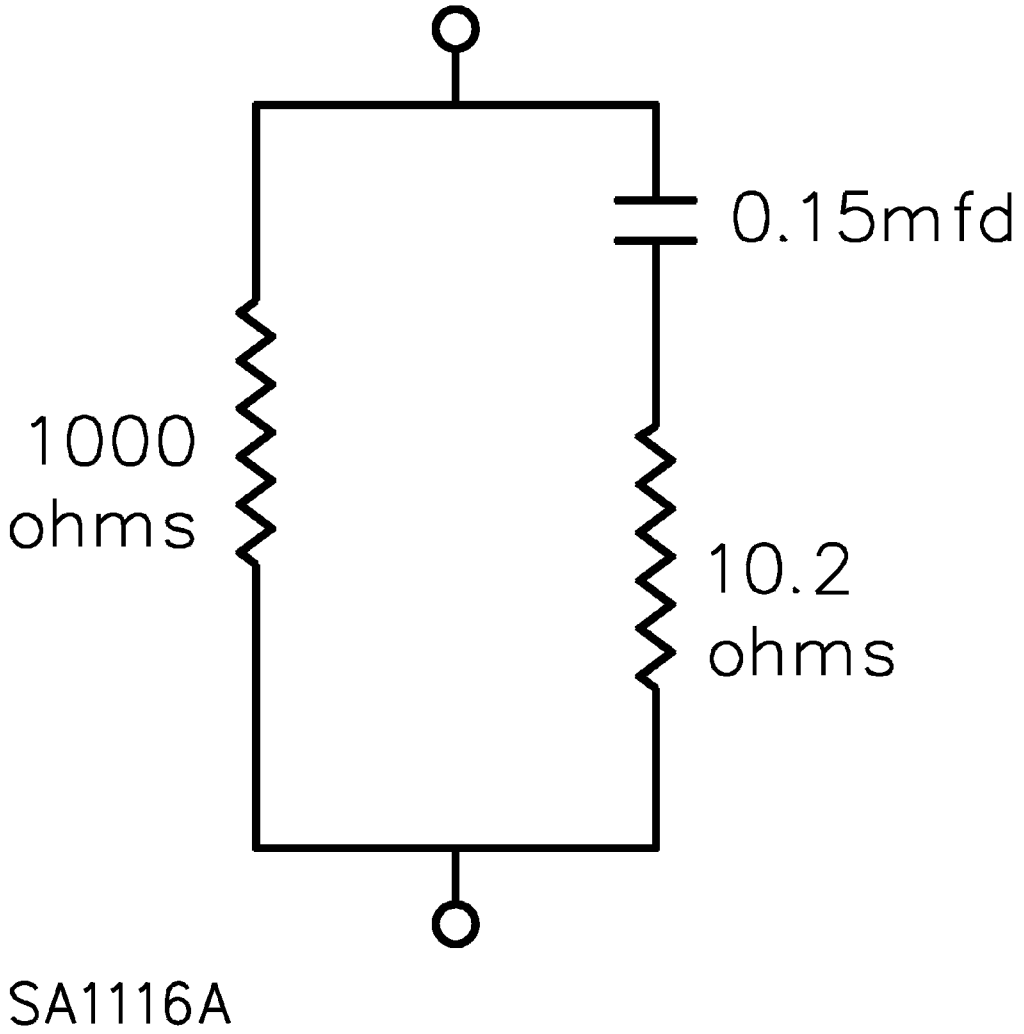
Exception: When equipment having isolated patient connection terminals but no cables is subjected to the test outlined in 42.4.2, the available current shall not exceed 10 microamperes rms when measured at the terminals.

42.4.2 A 120 V, 60 Hz potential shall be applied between each isolated patient connection and ground in series with the measurement circuit (1000 ohm resistor and meter) described in 42.6.2.1. This test shall be conducted with the appliance on and operating and also with the appliance off but connected to the supply circuit. The test shall be repeated with the polarity of the supply connections reversed.

42.5 Nonpatient equipment

42.5.1 When a nonpatient appliance is tested in the manner described in 42.6.1.1 – 42.6.1.4, 42.6.3.1 and 42.6.3.2, and if the open–circuit voltage between the parts in question exceeds 42.4 V peak (30 V rms if the waveform is sinusoidal) the available leakage currents shall not exceed the values in Table 42.2.

Figure 42.1
Input circuit



* In the type of testing of equipment, detailed measurements of leakage currents at all frequencies are necessary. However, to evaluate currents at frequencies over 1 kilohertz it is sometimes desirable to use an approximation during routine equipment testing.

The measurement circuit described in 42.6.2.1 would be employed in recording the actual leakage current determinations in 42.6.1.1 – 42.6.2.1. However, for a rapid approximate evaluation, an appropriate meter input circuit may be employed having an impedance–frequency characteristic that approximates the inverse of the allowable leakage current versus frequency relationships described in 42.3.3 and automatically provides the appropriate multiplying factor for frequencies greater than 1 kilohertz.

A sample input circuit is shown in Figure 42.1 which would be applicable to measurements usually made. The 1000 ohm resistor shown is the same test load as noted in 42.6.2.1. A series resistor–capacitor combination is placed in parallel with the 1000 ohm resistor across the meter input terminals.

Table 42.2
Nonpatient equipment maximum leakage current (microamperes)

Enclosure or chassis[a]			
Grounded equipment[b]		Double-insulated equipment[c]	
AC RMS	DC	AC RMS	DC
500	700	250	350

[a] Metal enclosure or metal foil over insulating material as per 42.6.1.3.

[b] Measured with loss of ground per 42.6.1.2.

[c] When measured with either functional or supplementary insulation effectively by-passed, the acceptable leakage current is twice that shown.

42.6 Test methods

42.6.1 General

42.6.1.1 Prior to making the measurements outlined in 42.6.1.2 – 42.6.3.2, the appliance circuits are to be analyzed and a preliminary review made by oscilloscope to determine the nature of the available currents. The measurement circuits described in 42.6.2.1 and 42.6.3.1 are to be employed for essentially sinusoidal currents. A direct–current meter is to be employed for the recording of direct–currents. Complex wave shapes, pulses, and the like, are to be subject of further oscilloscope evaluation with respect to the intent of these requirements. For test purposes only, the grounded supply conductor (neutral), is used as the ground reference point. See Figure 42.2.

42.6.1.2 In making the measurements outlined in 42.6.1.3 – 42.6.1.4, the following single fault conditions likely to increase the leakage current are to be introduced:

a) The loss of ground in a cord–connected appliance.

b) The loss of either functional insulation or of supplementary insulation in a double–insulated appliance.

42.6.1.3 If an insulating material is used for the enclosure or part of the enclosure, the leakage current is to be measured using a metal foil with an area not exceeding 10 by 20 centimeters in contact with accessible surfaces of insulating material. Where the accessible surface of insulating material is less than 10 by 20 centimeters the metal foil shall be the same size as the surface. The accessible parts shall be tested individually, collectively, and from one part to another. Parts are considered accessible unless guarded by an enclosure as defined in 5.2.1 – 5.2.8.

42.6.1.4 A sample of the appliance shall be tested for leakage current as indicated in 42.1.1. Starting with the as–received condition, the as–received condition being without prior energization except as may occur as part of production line testing, the test sequence, with reference to the measurement circuit in Figure 42.2, shall be as follows. Nonpatient equipment is tested in accordance with (a), (b) and (c) below. Patient care equipment is tested in accordance with (b) and (c).

a) With Switch S1 open, the appliance shall be connected to the measurement circuit. Leakage current shall be determined using both positions of switch S2, with the appliance switching devices and variable controls in all their normal operating positions, and with switch S3 in both the open and closed positions.

b) With switch S1 closed to energize the appliance, leakage current shall be determined using both positions of switch S2, with the appliance switching devices and variable controls in all their normal operating positions, and with switch S3 in both the open and closed positions.

c) Leakage current shall be monitored at sufficient intervals to determine the maximum leakage current from the time of the previous measurement to the conditions under which the normal temperature test would be terminated. Both positions of switch S2 shall be used in determining this measurement.

42.6.2 Patient care equipment

42.6.2.1 The measurement circuit for leakage current on patient care equipment is to be as follows:

a) Normally the measuring circuit is to have a resistive input impedance (R) of 1000 ohms. If, in the preliminary analysis and review mentioned in 42.6.1.1, an appliance circuit is found to have a low source impedance, it will be evaluated using a 500 ohm resistance.

b) The meter is to be average–responding and indicate rms value of a pure sine wave within an overall measuring circuit error of not more than 5 percent at indications of 10, 50, 100 and 500 microamperes (10, 50, 100 and 500 millivolts, respectively, when using a 1000 ohm resistor) at frequencies from 10 Hz to 100 kHz.

c) Unless the measuring circuit is being used to measure leakage current from one part of the appliance to another, the resistor and meter are to be connected between the accessible parts and the grounded supply conductor.

d) The supply voltage is to be adjusted to the test voltage as specified in 39.3.

42.6.3 Nonpatient equipment

42.6.3.1 The measurement circuit for leakage current from nonpatient equipment is to be as follows. The ideal measurement instrument is defined in (a) – (c). The meter which is actually used for a measurement need only indicate the same numerical value for a particular measurement as would the ideal instrument. The meter used need not have all of the attributes of the ideal instrument.

a) The measuring circuit is to have an input impedance (Z) of 1500 ohms resistive shunted by a capacitance of 0.15 microfarad.

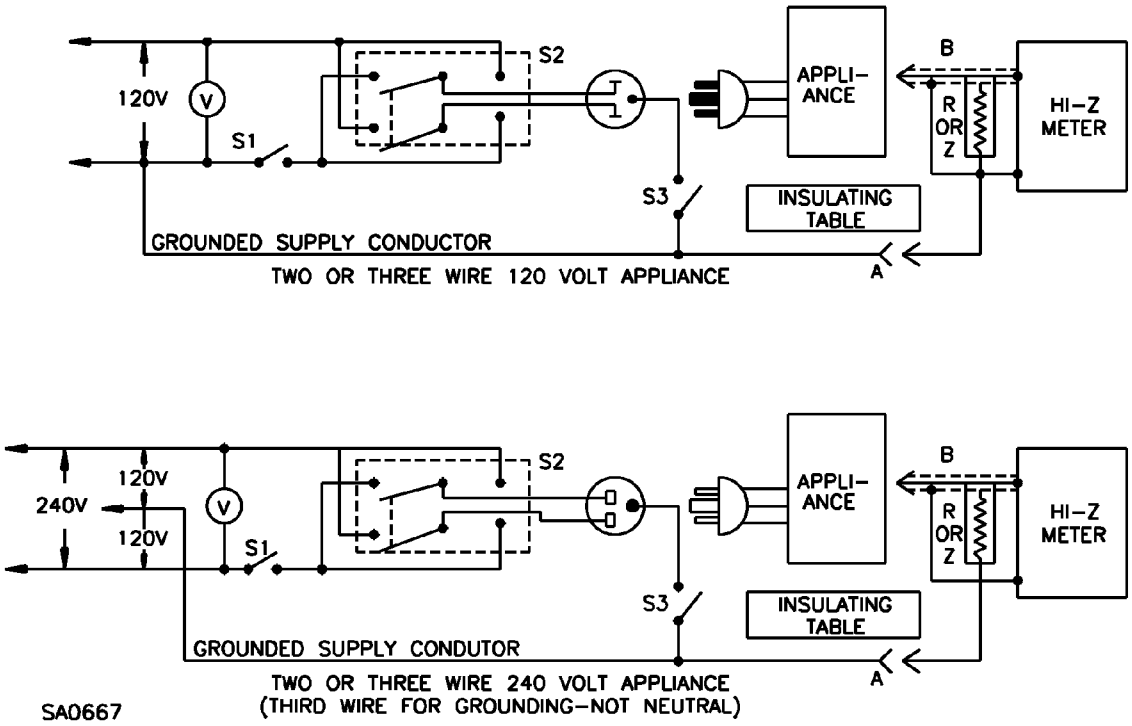
b) The meter is to indicate 1.11 times the average of the full–wave rectified composite wave–form of voltage across the resistor or current through the resistor.

c) Over a frequency range of 0–100 kilohertz, the measurement circuitry is to have a frequency response (ratio of indicated to actual value of current) that is equal to the ratio of the impedance of a 1500 ohm resistor shunted by a 0.15 microfarad capacitor to 1500 ohms. At an indication of 0.5 mA the measurement is to have an error of not more than 5 percent at any frequency within the range of 0–100 kilohertz.

d) Unless the measuring circuit is being used to measure leakage current from one part of the appliance to another, the impedance and meter are to be connected between the accessible parts and the grounded supply conductor.

e) The supply voltage is to be adjusted to the test voltage as specified in 39.3.

Figure 42.2
Leakage–current measurement circuit



Notes:

A – Separated and used as clip when measuring voltages (currents) from one part of appliance (including patient leads, probes, etc.) to another.

B – Probe with shielded lead.

42.6.3.2 Generally, a peak reading voltmeter having an input impedance of one megohm or greater is to be employed in measuring the open circuit voltage between the parts in question. However, where the voltage is sinusoidal, the peak voltage can be computed from the rms or average value.

43 Applied Patient Current

43.1 The available applied patient current shall be measured for an appliance which involves the application of an electric potential to a patient (see 2.15). If the available current measured exceeds the leakage current value in Table 42.1, the appliance shall be marked in accordance with 71.1.

43.2 In making the measurement required in 43.1, the circuit is to be as described in 42.6.2.1 except that the 1000 ohm input impedance may be increased or lowered (but to not less than 500 ohms) if it can be shown that maximum output would be obtained at some different level of measuring circuit input impedance.

44 X–Radiation

44.1 X–radiation measurements are to be made with suitable instruments, under the following conditions:

a) The appliance is complete, except that mechanical parts that need to be removed during user servicing may be omitted if they are:

1) Not necessary for the functioning of the appliance,

2) Not exposed to view during normal operation, and

3) Not held captive by a chain, hinge, loose rivet, etc.

b) The voltage of the supply circuit is 130 V if the rating of the appliance is within the range 105–130 V, and 260 V if the rating of the appliance is within the range 210–260 V.

c) After measurements have been made with the supply voltage specified in (b), the supply voltage is adjusted to any other voltage within the mentioned ranges that results in greater X–radiation.

d) All user adjustments are positioned to cause maximum X–radiation during appliance operation.

e) In addition to the adjustments described in (d), all controls regardless of location, are adjusted for maximum X–radiation during appliance operation.

44.2 Unless there is a suitable marking to warn the service personnel of the potential X–radiation hazard, the appliance shall comply with 44.1 under all conditions of a serviceman's servicing (see 69.1). Serviceman's servicing includes the removal of shields, windows, cages, covers with or without the chassis removed from its enclosure.

45 Normal Temperature

45.1 General

45.1.1 An appliance, when operated under the conditions of maximum normal load as described in 45.2.1 – 45.2.21, and while connected to a supply circuit as described in 39.3, shall not attain a temperature at any point sufficiently high to constitute a fire hazard or to affect injuriously any materials employed in the appliance, nor shall the appliance show greater temperature rises at specific points than indicated in Table 45.1.

45.1.2 In conducting a test to determine whether or not an appliance complies with the temperature requirements, the appliance is to be mounted or supported as in service, including recessed wall mounting if required. Installation against a wall, in a right–angle corner of a room, or in an alcove is to be simulated if the appliance lends itself to such placement and if such placement results in restricted ventilation. Walls are to be formed by black–painted vertical sheets of plywood not less than 3/8 inch thick and having such width and height that they extend not less than two feet beyond the physical limits of the appliance.

45.1.3 A permanently–connected appliance is to be installed so that it is located as close to the wall or corner as the construction will permit. A portable (cord–connected) appliance is to be placed on a horizontal supporting surface and spaced one inch from a vertical wall surface of wood or comparable material, unless the arrangement of ventilation and similar cooling factors is such that operation against a wall (as compared with operation in the open) will not increase operating temperatures, or unless the design of the device is such that a spacing greater than one inch is assured. Doors and covers which may be closed during operation of the appliance are to be closed during the test, except that consideration may be given to the actual conditions of normal operation of the appliance, wherein doors or covers must be opened after each cycle of operation.

45.1.4 All values in the table are based on an assumed ambient (room) temperature of 25°C (77°F), but a test may be conducted at any ambient temperature within the range of 10°C – 40°C (50°F – 104°F). However, if the operation of an automatic thermal control during the tests limits the temperatures under observation, no temperature higher than 25°C (77°F) plus the specified maximum rise is acceptable.

45.1.5 A short length of rubber– or thermoplastic–insulated flexible cord exposed to a temperature higher than that for which it is suitable, such as at terminals, is acceptable if supplementary heat–resistant insulation of adequate dielectric withstand is employed on the individual conductors of the cord to safeguard the appliance against deterioration of the conductor insulation.

Table 45.1
Maximum acceptable temperature rise

Materials and Components		°C	°F
1.	Varnished-cloth insulation	60	108
2.	Fuses	65	117
3.	Fiber employed as electrical insulation	65	117
4.	Wood and other combustible material	65	117
5.	Any point on or within a terminal box on a stationary unit (see 64.5)	65	117
6.	A surface upon which a permanently wired unit might be mounted in service, and surfaces that might be adjacent to the unit when it is so mounted	65	117
7.	Class A insulation systems on coil windings of a-c motors having a frame diameter of more than 7 inches and of d-c and universal motors:		
	A. In open motors:		
	Thermocouple method	65[a,g]	117[a,g]
	Resistance method	75[a,g]	135[a,g]
	B. In totally enclosed motors:		
	Thermocouple method	70[a,g]	126[a,g]
	Resistance method	80[a,g]	144[a,g]
8.	Class 105 (A) insulation systems on coil windings of a-c motors having a frame diameter of 7 inches or less (not including universal motors) and on vibrator coils:		
	A. In open motors and on vibrator coils (thermocouple or resistance method)	75[a,g]	135[a,g]
	B. In totally enclosed motors (thermocouple or resistance method)	80[a,g]	144[a,g]
9.	Class 105 (A) insulation systems on windings of relays, solenoids, magnets, etc.:		
	Thermocouple method	65[a,g]	117[a,g]
	Resistance method	85[a,g]	153[a,g]
10.	Class 130 (B) insulation systems on coil windings of a-c motors having a frame diameter of more than 7 inches and of d-c universal motors;		
	A. In open motors:		
	Thermocouple method	85[a,g]	153[a,g]
	Resistance method	95[a,g]	171[a,g]
	B. In totally enclosed motors:		
	Thermocouple method	90[a,g]	162[a,g]
	Resistance method	100[a,g]	180[a,g]
11.	Class 130 (B) insulation systems on coil windings of a-c motors having a frame diameter of 7 inches or less (not including universal motors) and other vibrator coils:		

Table 45.1 Continued on Next Page

Table 45.1 Continued

	Materials and Components	°C	°F
	A. In open motors and on vibrator coils (thermocouple or resistance method)	95[a,g]	171[a,g]
	B. In totally enclosed motors (thermocouple or resistance method)	100[a,g]	180[a,g]
12.	Class 130 (B) insulation systems on windings of relays, solenoids, magnets, etc.:		
	Thermocouple method	85[a]	153[a]
	Resistance method	105[a]	189[a]
13.	Phenolic composition employed as electrical insulation or as a part whose failure would result in a hazardous condition:		
	Molded composition	125[b]	225[b]
	Laminated composition	100[b]	180[b]
14.	Rubber- or thermoplastic-insulated wires and cords	35[b,c]	63[b,c]
15.	On the surface of a capacitor casing:		
	Electrolytic	40[d]	72[d]
	Other types	65[e]	117[e]
16.	Transformers:		
	A. With Class 105 (A) insulation systems:		
	Thermocouple method	65[a]	117[a]
	Resistance method	75[a]	135[a]
	B. With Class 130 (B) insulation systems:		
	Thermocouple method	85[a]	153[a]
	Resistance method	95[a]	171[a]
	C. With Class 155 (F) insulation systems:		
	Thermocouple method	110[a]	193[a]
	Resistance method	120[a]	216[a]
	D. With Class 180 (H) insulation systems:		
	Thermocouple method	125[a]	225[a]
	Resistance method	135[a]	243[a]
17.	Reserved		
18.	Reserved		
19.	Sealing compound	f	f
20.	Selenium rectifiers	50[b]	90[b]
21.	Silicon rectifiers	75[b]	135[b]

[a] See 45.1.4, 45.1.6, and 45.1.8

[b] This limitation does not apply to an insulated conductor, a rectifier or a material, which has been investigated and accepted for a higher temperature.

[c] Rubber-insulated conductors within a motor having a Class A insulation system, rubber-insulated motor leads, and a rubber-insulated flexible cord entering a motor can be subjected a temperature rise of more than 35°C (63°F) if suitable braid is employed on each individual conductor. This does not apply to thermoplastic insulated wires or cord.

[d] For an electrolytic capacitor that is physically integral with or attached to a motor, the temperature rise on insulating material integral with the capacitor enclosure is not to be higher than 65°C (117°F).

[e] A capacitor that operates at a temperature rise of more than 65°C (177°F) can be judged on the basis of its marked temperature limit.

Table 45.1 Continued on Next Page

Table 45.1 Continued

Materials and Components	°C	°F
† Unless a thermosetting material, the maximum sealing compound temperature, when corrected to a 25°C (77°F) ambient temperature is 15°C (27°F)less than the softening point of the compound as determined by the Vicat Softening Temperature of Plastic, ANSI/ASTM D1525.		
g This is the diameter, measured in the plane of the lamination of the circle circumscribing the stator frame, excluding lugs, boxes, etc. used solely for motor mounting assembly or connection.		

45.1.6 Ordinarily, coil or winding temperatures are to be measured by thermocouples unless the coil is inaccessible for mounting these devices (for example, a coil enclosed in sealing compound) or unless the coil wrap includes thermal insulation, such as asbestos, or more than two layers (1/32 inch maximum) of cotton, paper, rayon, or the like. For the thermocouple–measured temperature of a coil in a 7–inch–diameter or smaller frame alternating–current motor other than a universal motor (item 8 in Table 45.1), the thermocouple is to be mounted on the insulation on the conductor. At a point on the surface of a coil where the temperature is affected by an external source of heat, the temperature rise measured by means of a thermocouple may be 15°C (27°F) more than the maximum indicated in items 7 and 9 of Table 45.1 and 5°C (9°F) more than the maximum indicated in items 8 and 11 of Table 45.1 if the temperature rise of the coil, as measured by the resistance method, is not more than specified in Table 45.1.

45.1.7 When thermocouples are used in the determination of temperatures in connection with the heating of electrical appliances, it is common practice to employ thermocouples consisting of No.30 AWG iron and constantan wire and a potentiometer–type indicating instrument; and such equipment will be used whenever reference temperature measurements by thermocouples are necessary.

45.1.8 For tests that are to be continued until constant temperatures are attained, thermal equilibrium is to be considered to exist only if three successive readings indicate no change when taken at the conclusion of each of three consecutive equal intervals of time, the duration of each interval being whichever of the following is longer:

a) Five minutes, or

b) Ten percent of the total test time elapsed previous to the start of the first interval.

The thermocouples and related instruments are to be accurate and calibrated in accordance with good laboratory practice. The thermocouple wire is to conform with the requirements for special thermocouples as listed in the table of limits of error of thermocouples in the American National Standard, Temperature-Measurement Thermocouple, C96.1

45.1.9 A thermocouple junction and adjacent thermocouple lead wire are to be securely held in good thermal contact with the surface of the material whose temperature is being measured. In most cases, adequate thermal contact will result from securely taping or cementing the thermocouple in place but, if a metal surface is involved, brazing or soldering the thermocouple to the metal may be necessary.

45.1.10 An automatic temperature–regulating or – limiting control or other protective device provided as a part of an appliance is to be shunted out of the circuit, unless the results of an investigation which would include overload and endurance tests, show the control to be rugged, reliable, and unlikely to be defeated by the user.

45.1.11 Rubber and other material subject to deterioration is to be removed from feet and other supports of the appliance if absence of the material might result in the appliance or the supporting surface attaining higher temperatures.

45.1.12 If the design of an appliance is such that heating of a liquid is a determining factor in the temperature attained (such as in a sterilizer or paraffin bath), the intended duty of the appliance is to be taken into consideration. Normal operating conditions cannot be obtained if certain types of appliances are operated continuously and in a dry condition. Accordingly, in determining whether or not an appliance complies with the requirements in 45.1.1 actual service conditions or an approximation thereof are to be employed. Unless otherwise specifically indicated:

a) If the appliance is controlled by an adjustable thermostat, the thermostat is to be set to give maximum temperatures, and

b) If the appliance is controlled by a nonadjustable thermostat, it is to be allowed to operate at whatever temperature the thermostat permits.

In each case, operation is to be continued until temperatures are stabilized.

45.2 Maximum normal load

45.2.1 In tests on an appliance, maximum normal load is considered to be that load which approximates as closely as possible the most severe conditions of normal use. It is not a deliberate overload except as the conditions of actual use are likely to be somewhat more severe than the maximum load conditions which are recommended by the manufacturer of the appliance. Usually a program designed to test all functions of the appliance suffices.

45.2.2 Test loads which have been found to be close approximations of the most severe conditions of normal use are indicated in 45.2.3 – 45.2.21 for some common forms of appliances. Appliances not mentioned having features not contemplated, are to be tested as necessary to meet the intent of these requirements with consideration given to the probable intermittent or short–term operation of appliances obviously not intended for continuous operation.

45.2.3 ULTRASONIC GENERATORS – The appliance is to be operated through repeated cycles of 5 minutes on and 5 minutes off until constant temperatures have been attained. For this test the transducer may be immersed in a water bath to prevent damage.

45.2.4 AMALGAMATORS – The appliance is to be operated through repeated cycles of one minute on and fourteen minutes off until constant temperatures have been attained.

45.2.5 DENTAL ENGINES – The appliance is to be operated through repeated cycles of 30 minutes of intermittent operation and 30 minutes off until constant temperatures have been attained. In each case the 30 minutes of intermittent operation shall consist of cycles of two minutes on and one minute off.

45.2.6 ELECTROCARDIOGRAPHS – The appliance is to be operated with the amplifiers continuously energized and with the chart drive motor operating with a duty cycle of one minute on and five minutes off until constant temperatures are attained.

45.2.7 DIATHERMY UNITS – The appliance is to be operated through repeated cycles of 30 minutes (or maximum setting of timer) on and five minutes off until constant temperatures have been attained. During the off period, the unit should remain energized in a standby condition, if the construction permits this mode of operation.

45.2.8 CHARGER UNITS FOR BATTERY – OPERATED APPLIANCES – The input is to be measured while the unit is charging a completely discharged battery. The temperature test is to be conducted with the output of the charger unit short–circuited and operation continued until constant temperatures have been attained.

45.2.9 MOTOR – OPERATED BEDS, CHAIRS, EXAMINING TABLES – For the temperature test, a 200-pound person is to be placed on the appliance to obtain a distributed load. Nine complete cycles of adjustment of the appliance through its complete range of motion are to be performed, without pause between cycles, except as noted below. A five–minute period (with the motor running but with the appliance not operating, if it can be so controlled, otherwise, with the motor de–energized) is to be interposed between the third and fourth cycles and between the sixth and seventh cycles. If the speed of operation of the appliance can be controlled, the test is to be performed at such speed that maximum heating will result. An appliance that is capable of more than one mode of motion is to be tested for each such mode.

45.2.10 DEFIBRILLATORS – The appliance is to be operated once every 10 seconds for a period of 30 seconds followed by a stand–by period of 30 seconds and this cycle is to be repeated for a total of 15 minutes. For this test a 55 ohm resistive load is connected between the "internal" patient electrodes or terminals to simulate the impedance presented by the heart. If this test does not represent operation through the "external" patient electrode circuitry also, the appliance is to be allowed to cool to room temperature and the test is to then be repeated using the same duty cycle as above but the resistive load, 100 ohms in this instance, is to be connected between the "external" patient electrodes.

45.2.11 DENTAL LATHES – The appliance is to be operated without load until constant temperatures have been attained.

45.2.12 MOTOR – OPERATED INSTRUMENT STANDS – The appliance is to be operated through the same adjustment cycles outlined for motor–operated beds, etc., (45.2.9). During the test the stand is to be fully equipped with all the instruments normally provided plus any accessories (or equivalent loads) intended for use with the stand.

45.2.13 DENTAL STAND EQUIPMENT – With the exception of cuspidor valves, stand lighting, instrument transformers and similar features for which continuous operation is to be considered the normal mode, the probably intermittent operation of stand equipment is to be taken into consideration in the conduct of the normal temperature test. In applying the specific duty cycles in 45.2.14 – 45.2.17 to these parts the 30 minute operating period described is to be followed by a 30 minute off period and this overall cycle repeated until constant temperatures have been attained.

45.2.14 CUP FILLER VALVE – Two cycles of two minutes on and 13 minutes off in each 30 – minute operating period.

45.2.15 SYRINGE – Five cycles of one minute on and five minutes off in each 30 – minute operating period.

45.2.16 ASPIRATOR – Continuous operation during each 30 – minute operating period.

45.2.17 HIGH–SPEED DRILLS AND WATER–COOLANT NEEDLE VALVES – Ten cycles of one minute on and two minutes off in each 30–minute operating period. For slow–speed, belt– driven drills see Dental Engines, 45.2.5.

45.2.18 ELECTROSURGICAL UNITS – For hospital type electrosurgical machines having scalpel output settings, the appliance is to be operated with a duty cycle of one minute on and one minute off for a period of 30 minutes. The appliance should be permitted to idle during the off period, if the construction permits this mode of operation. The load employed across the patient electrodes is to be one which represents the maximum load condition on the appliance that would be encountered in service, (usually 100 – 200 ohms).

45.2.19 For light duty equipment not exceeding 100 watts input as measured in accordance with 41.1 the appliance is to be operated with a duty cycle of one second on and five seconds off for sixty operations followed by a five–minute rest or idle and followed by an additional sixty operations of one second on and five seconds off. The load employed is to be as indicated in 45.2.18.

45.2.20 INFANT INCUBATORS – The appliance is to be operated continuously under the following conditions until constant temperatures have been attained:

a) All air vents are to be closed,

b) The mattress supplied is to be in the position which results in maximum temperatures, within the compartment housing the electrical components. If a mattress is not provided with the incubator, a hair felt pad 1 inch thick shall be used for the test,

c) The control thermostat is to be set at its maximum setting unless this results in operation of a limiting thermostat in which case, the control thermostat shall be adjusted to the point where the limiting thermostat begins to operate and the limiting thermostat is then rendered inoperable for the duration of the temperature test;

d) Humidifier pans are to be filled with water to the proper level. The test is to be repeated with the water reservoirs dry;

e) After constant temperatures have been attained and recorded, the alarm circuits provided, if any, are to be actuated for a period of 1 hour and the temperatures of the associated relays, buzzers, etc., recorded at the end of that period.

45.2.21 In addition to compliance with the temperature rise limitations outlined in Table 45.1, operating temperatures in infant incubators shall not exceed the following:

a) Within the infant compartment:

1) All surfaces accessible to the infant, including the surface of the mattress, (or felt pad if no mattress provided), 39°C (102°F).

2) Air temperature, 39°C (102°F).

b) On any surface (including the heater itself) exposed to the circulating air within the incubator assembly, 121°C (250°F).

46 Dielectric Withstand

46.1 General

46.1.1 The insulation and spacings of an appliance shall be capable of withstanding for a period of 1 minute the application of the test potentials described in 46.2.1 – 46.4.1 for 1 minute without an indication of unacceptable performance. For a definition of unacceptable performance see 46.1.3.

Exception: Where an investigation shows that unacceptable performance will not result in a risk of fire or electric shock.

46.1.2 Where a separate source is employed to supply the required test potential, the source is to have sufficient capacity to maintain the potential indicated, except in case of unacceptable performance. The voltage source is to be increased and, starting at zero, the test potential is to be increased gradually at a substantially uniform rate so as to arrive at the specified test potential in approximately 5 seconds or until unacceptable performance is indicated.

46.1.3 Unacceptable performance will normally be indicated by the tripping of an appropriate overload protector in the test equipment but an abrupt decrease or retarded nonlinear advance of the voltmeter reading or an abrupt increase in current could also be indicative of insulation failure. Particular attention shall be paid to high impedance circuits in the appliance so that breakdowns resulting in risk of fire or electric shock conditions are detected.

46.1.4 The sensitivity of the test equipment shall be such that when a 120,000 ohm resistor is connected across the output, the equipment does not indicate unacceptable performance for any output voltage less than the specified test voltage, and indicates unacceptable performance for any output voltage equal to or greater than the specified test voltage. The calibrating resistor is to be adjusted as close to 120,000 ohms as instrumentation accuracy can provide, but not more than 120,000 ohms.

Exception No. 1: The sensitivity of the test equipment may be reduced (a lower value of calibrating resistance used) if the circuits or components under test do not involve accessible conductive parts.

Exception No. 2: The sensitivity of the test equipment may be increased (a higher value of calibrating resistance used) if agreeable to those concerned.

46.2 Primary circuits

46.2.1 A 60–Hz essentially sinusoidal potential is to be applied between live parts conductively connected to the supply circuit and dead metal parts, and across each capacitor, winding separation, or other insulation in the primary circuit that is required for the elimination of electric shock or, if short–circuited, would involve a risk of fire either directly or indirectly. The test potential is to be:

a) 1000 V for an appliance rated 250 V or less provided that:

1) Any motor employed is rated 1/2 hp or less, and

2) The appliance is not applied to or in contact with persons in intended use.

b) 1000 V plus twice the maximum rated voltage for an appliance:

1) Applied to or in contact with persons in the intended use,

2) Rated more than 250 V, or

3) Employing a motor rated at more than 1/2 hp.

46.2.2 If an isolating type of power transformer is employed (wherein the primary and secondary windings are not conductively connected), a 60–Hz essentially sinusoidal potential is to be applied between any live part of the primary or power–supply circuit and any live part of the secondary circuits. The potential is to be twice maximum rated primary voltage plus 1000 V.

46.2.3 A power transformer is to be capable of operating without an indication of unacceptable performance when potential is applied to the primary of the transformer to produce the opposite polarity test potentials indicated in 46.3.1 and Table 46.1 (except that the 500 V minimum is not to apply) or when tested separately using an appropriate supply on the primary to develop a secondary voltage comparable to that which would have existed had the transformer been tested with the balance of the circuit.

46.3 Secondary circuits

46.3.1 The test potential indicated in Table 46.1 is to be applied between:

a) Secondary circuits and grounded metal – with grounded secondary windings of transformers disconnected – and

b) Between secondary circuit parts of opposite polarity.

A 60–Hz essentially sinusoidal source is to be used for testing alternating–current circuits. A direct–current source may be used for testing a direct–current circuit but, if possible, the transformer in the appliance should be employed to supply the alternating current to the rectifier (or substitute high voltage rectifier, if necessary) for the opposite polarity test on direct–current circuits.

Table 46.1
Magnitude of test potential

Maximum voltage in circuit[a]	Test voltage
0–1000 volts	3E (500 minimum)
Over 1000 volts	1.25 E + 1750
[a] Maximum voltage measured with the appliance operated under the conditions described in 46.5.1 – 46.5.3	

46.3.2 All lamps and tubes are to be removed, and ballast tubes or other automatic regulating devices are to be rendered inoperative, if necessary, to carry out the test. All selector or other operating switches are to be adjusted to the various operating positions which ensure the connection of these parts in the circuit under test. Bleeder resistors, electrolytic capacitors, transistors, and other power consuming devices are to be opened at the common return side of the circuit.

46.3.3 If the appliance transformer is included in this test, as per 46.2.3, the appliance is to be connected to a variable alternating current source of supply. The test frequency is not to be less than three times the rated frequency of the appliance in order to permit the secondary voltage of the transformer to reach the required potential without being limited by the saturation of the iron of the transformer core.

46.3.4 In the testing of rectified (d–c) secondary circuits, a high voltage rectifier and suitable filter network is to be substituted for the rectifier of the appliance, if necessary, and the appliance electrolytic capacitors removed from the circuit.

46.4 Patient–connected circuit

46.4.1 In addition to any applicable tests noted in 46.2.1 – 46.3.4, a 60 Hz essentially sinusoidal potential of 2500 V is to be applied between primary circuits and the patient–connected circuits (see 2.16).

46.5 Maximum voltage

46.5.1 The maximum voltage to be used as a basis for the calculation of the dielectric withstand potentials specified in 46.3.1 is to be determined in accordance with 46.5.2 – 46.5.3.

46.5.2 To obtain the maximum voltage, any combination of tubes and fuses may be removed. An automatic voltage–regulating device is to be rendered inoperative unless, upon investigation, it is found that it can be relied upon to prevent an increase in voltage. The investigation is to take into consideration any likely failures in either the regulating device or the appliance, and the possibility of the device being disconnected, if it is not permanently connected in the circuit.

46.5.3 A connector or comparable part that is likely to be disconnected during normal operation or user servicing is to be both connected and disconnected during the test, in order that the maximum voltage may be obtained.

47 Immersion

47.1 After being subjected to the immersion test described in 47.2, a hospital bed pendant control or a similar device likely to be taken into a patient's bed, shall comply with the leakage current requirements of 42.1.1, and the dielectric withstand requirements of 46.1.1.

47.2 Each of three samples of the pendant control or other device is to be immersed for a period of 24 hours in a solution containing 1/2 gram of common table salt per liter of distilled water. Immediately thereafter, the samples are to be subjected to the tests outlined in 47.1 and disassembled for examination for compliance with 47.3.

47.3 The test described in 47.2 shall not result in the entrance of water into the interior of the sample in such manner that it might come into contact with uninsulated live parts or enamel–insulated wire.

48 Grounding Impedance

48.1 For equipment without a power supply cord the impedance at 60 Hz between the ground terminal and any accessible metal part which is grounded, shall not exceed 0.1 ohm. For equipment with an appliance inlet the impedance between the grounding pin in the appliance inlet and any accessible metal part which is grounded, shall not exceed 0.1 ohm.

48.2 For equipment with a non–detachable power supply cord, the impedance at 60 Hz between the grounding pin of the attachment plug and any other metal part of the appliance that is required to be grounded (see 24.1) shall not be more than 0.2 ohm when measured in accordance with 48.3.

48.3 Compliance is checked by the following test: A current of 25 A derived from a 60 Hz source with a no–load voltage not exceeding 6 V is passed for at least 5 s through the grounding terminal or the grounding contact in the appliance inlet or the grounding pin in the attachment plug and each accessible metal part which could become live in case of failure in basic insulation.

48.4 The voltage drop between the parts described is measured and the impedance determined from the current and voltage drop. It shall not exceed the values indicated.

49 Abnormal Operation

49.1 General

49.1.1 If the conditions of normal operation are not representative also of abnormal conditions that can occur in actual service, an appliance shall not become a fire or shock hazard when operated under abnormal conditions, nor shall a transformer experience temperature rises higher than indicated in Table 49.1.

49.1.2 To determine whether or not a fire or shock hazard actually exists, separate tests are to be conducted with the appliance, or specific portion thereof, operating until the ultimate results have been observed. Unless otherwise indicated, each test is to be conducted with the applied voltage, method of mounting, and thermostat connection in accordance with 39.3, 45.1.2, 45.1.3 and 45.1.10. The appliance is to be connected in series with a nontime–delay fuse of the maximum current rating that can be accommodated by the fuseholder of the branch circuit to which the appliance can properly be connected. For each test of cord–connected equipment, the grounding means shall be interrupted and a separate connection, which includes a one–ampere fuse, shall be made between the enclosure and ground. For permanently connected equipment normal grounding means shall be employed. In most cases, continuous operation for seven hours will be necessary to insure that the ultimate result has been observed. A cord–connected appliance is to be placed on white tissue paper on a softwood surface.

49.1.3 Fuses which are marked in accordance with 61.1, and other over–current (overload) protective devices may be left in the circuit during testing.

49.1.4 When operated under such abnormal conditions, an appliance is to be considered to involve a risk of fire if there is any emission of flame or molten metal (other than drops of melted solder), or if the operation of the appliance results in the glowing or flaming of combustible material upon which the appliance may be placed, or which may be placed around it, or (in the case of a permanently installed appliance) which may be in proximity to the appliance installed.

49.1.5 An appliance is to be considered to involve a risk of electric shock if:

a) The ground fuse opens during the test (cord–connected appliances only), or

b) It is or appears to be useable and it does not comply with both the dielectric voltage–withstand test as specified in 46.1.1 and the leakage current test as specified in 42.6.1.1 – 42.6.3.2.

49.1.6 An appliance which is obviously not useable, or which involves exposure of current–carrying parts, is to be considered to involve a risk of electric shock if the leakage current at an accessible part is more than 0.5 mA when measured in accordance with 42.6.1.1 – 42.6.3.2.

49.1.7 Opening of the branch circuit fuse noted in 49.1.2 or the appliance protective device noted in 49.1.3 before a risk of fire or electric shock results is considered to be an acceptable conclusion of a test.

Table 49.1
Acceptable temperature rises

Type of protection	°C Maximum				°C Average			
	Class 105 or A insulation	Class 130 or B insulation	Class 155 or F insulation	Class 180 or H insulation	Class 105 or A insulation	Class 130 or B insulation	Class 155 or F insulation	Class 180 or H insulation
Impedance	135	160	185	210	–	–	–	–
Thermal Cut-Out Automatic Reset								
1. During first hour of operation	175	200	215	235	–	–	–	–
2. After first hour of operation	150	175	190	210	125	150	165	185
Manual Reset								
1. During first hour of operation or during the first ten cycles of operation mentioned in 49.3.9 whichever is the shorter interval.	175	200	215	235	–	–	–	–
2. After first hour of operation, if the first ten cycles of operation mentioned in 49.3.9 require more than one hour for completion.	150	175	190	210	–	–	–	–
Fusible Device, and Nonresettable Device and Electronic Limiting Circuit								
1. Before opening during first hour of operation	175	200	215	235	–	–	–	–
2. Opening after first hour of operation	150	175	190	210	–	–	–	–

49.1.8 Some specific abnormal test conditions are described in 49.2.1 – 49.5.1. However, appliances having features not contemplated in these test procedures may be tested as necessary to meet the intent of these requirements.

49.2 Intermittent duty appliances

49.2.1 An appliance intended for intermittent duty, but which may inadvertently be left in an energized condition, and/or operated in excess of the prescribed duty cycle, is to be subjected to a test consisting of continuous operation until ultimate results are noted, but for not more than seven hours. The test is to be conducted as noted in 49.1.2 and if the test terminates during the seven–hour period, two additional samples are to be similarly tested.

49.3 Transformers

49.3.1 A transformer as noted in 22.2.1 is to be subjected to continuous operation under applicable overload conditions, including short–circuiting of the secondary, or patient circuit, winding or windings.

Exception: For products involving a transformer whose primary winding is not continuously energized during normal operation, and conditions of transformer overload that result in malfunction that is obvious to the user, the transformer may be subjected to the overload conditions for the following periods of time:

a) Thirty seconds for equipment that is hand held, or controlled by a user–actuated momentary contact switch, or continuously loaded by hand.

b) Five minutes, or for the maximum period of a timer, whichever is less, if a timer terminates the operation for other equipment which is attended in normal use.

49.3.2 If a transformer has more than one secondary winding, or a tapped secondary winding, separate tests are to be performed for each winding, or each section of the tapped winding, with the other windings loaded and unloaded, as may occur in actual service, unless it can be determined that one condition will produce the most unfavorable result.

49.3.3 In conducting the tests noted in 49.3.1, a transformer with inherent temperature–limiting characteristics is to be operated continuously with the secondary winding, or sections of a tapped winding, short–circuited and the primary connected to a supply circuit in accordance with 39.3. Temperature is to be determined by the resistance method.

49.3.4 If a transformer is not inherently temperature limited but is used with thermal or overcurrent protection, the tests are to be made with the secondary winding or windings loaded to result in the maximum current input to the transformer without causing the protective device to open, and also with the secondary winding or windings short–circuited. See Table 49.2.

49.3.5 When testing a transformer employing a thermal protective device that is needed for compliance with the requirements of 22.3.1 (c) and (e), the overload test 49.3.4 is to be immediately followed by a short circuit. To determine compliance with the requirements for the opening time of the protective device described in Table 49.1, the amount of time is to be measured from the moment the short circuit is applied.

49.3.6 For transformers with thermal or overcurrent protection, temperatures are to be measured by means of thermocouples consisting of wires not larger than 30 AWG placed on the surfaces of coils of all windings. A thermocouple for measuring a coil temperature is to be applied to the conductor metal or it is to be separated from the metal material by, at most, the integral conductor insulation.

49.3.7 In conducting the short–circuited test on a transformer with an automatic–reset protector, the transformer is to be energized for 360 hours (15 days) with the secondary winding short–circuited. The transformer is to be at room temperature at the beginning of the test.

Table 49.2
Transformer abnormal tests

Protector	Short circuit	Overload
A. Thermal cutoff only (one shot)	Until ultimate results are known	7 h at rating of protector, Notes 1, 3
B. Automatic reset only	15 days, 49.3.7 – 49.3.8	Same as A
C. Fuse only	Until ultimate results are known	7 h at 110% fuse rating Notes 4, 8
D. Positive temperature coefficient (PTC) device	Until ultimate results are known	7 h at the maximum value of protector current that the device will conduct without opening.
E. Manual reset device only	49.3.9	7 h at 110% of full load protector rating Notes 4, 8
F. Fuse and thermal device	Until ultimate results are known	7 h at rating of protector or 110% of fuse rating, depending on which device limit is reached first, Notes 3, 6
G. Fuse and automatic reset device	a. If fuse opens, same as C	a. If fuse opens during short circuit test load secondary to 110% of fuse rating. If automatic reset device does then function, test for 15 days, see B above, with current held at 110% fuse rating
	b. If automatic reset device opens, same as B	b. Same as A
H. Manual reset device and thermal cutoff	a. If manual reset device opens, test as described in 49.3.9 for 50 total cycles or until thermal cutoff opens	Same as F except use 110% of manual reset device rating
	b. If manual reset device doesn't open, test until ultimate results are known	
I. Manual and automatic reset devices	a. If manual reset device opens, same as H	a. Same as G overload test Method "a"
	b. If automatic reset device opens, same as B	b. same as A
J. Electronic limiting circuit	Note 2	Note 7

1. To conduct test at rating of protector, temperature on the body of the protector is monitored. Secondary load is varied until protector body temperature approaches rated opening temperature (within 10°C).
2. Fuse or manual reset device may be left in circuit.
3. For transformers employing a thermal operating device to comply with construction requirements in 22.3.1 Parts c) and e), the overload test is followed by a short-circuit. See 49.3.5.
4. Protector current is monitored and load adjusted after 5 min. to maintain protector current at 110% of protector rating. No further adjustments of load are performed.
5. Protector shall comply with the applicable endurance requirement for the component.
6. Both the thermal protector body temperature and the current in the current sensitive protector are monitored as the secondary load is varied. Second load is held constant at the point where the thermal protector body temperature is approached (see Note 1) or current sensitive protector current reaches 100% of its rating.
7. If any unreliable component(s) opens to terminate the test, the test shall be repeated two additional times.
8. Fuse or manual rest device is shortened.

49.3.8 The average temperature rise noted in Table 49.1 is to be determined as follows. The curve or graph of temperature plotted against time is to be obtained for the second hour and also for the 360th hour. During each of these periods, the average temperature is to be determined by taking the arithmetic mean

a) Of the maximum temperatures, and

b) Of the minimum temperatures.

49.3.9 In conducting the short–circuit test on a transformer with a manual–reset protector, it is to be operated for 50 cycles under secondary short–circuit conditions, with the protector being reclosed as quickly as possible – but not more than once every 6 seconds – after it has opened the circuit. The test is to be started with the transformer at room temperature, and temperatures are to be measured after 10 cycles, as indicated in Table 49.1.

49.4 Electrolytic capacitor and rectifier short–circuit tests

49.4.1 Where an electrolytic capacitor, a rectifier (vacuum–tube or solid state), and a resistance are connected in series across a supply circuit tests, see 2.29, are to be performed involving short–circuiting singly of either the capacitor or the rectifier.

49.4.2 A single layer of cheesecloth is to be loosely draped over the appliance as a whole with the cloth within 1/8 inch of openings in the overall enclosure. The supply–circuit connection is to be such that the maximum potential exists between the series resistor and the chassis.

49.4.3 If a vacuum–tube rectifier is employed, the plate and cathode terminals of the rectifier are to be connected together. The test is to be repeated with only the cathode and heater terminals connected together if this condition was not represented by the first test. If a solid state rectifier is employed, tests are to be conducted with the rectifier terminals connected together. Three complete tests are to be made under each of the conditions described.

49.4.4 Three additional tests are to be conducted with the terminals of the electrolytic capacitor connected together.

49.5 Multiple voltage appliance

49.5.1 A portable appliance employing an input–voltage selector is to be subjected to continuous operation for seven hours, with the voltage selector set in any marked primary voltage position and with the appliance connected to a supply circuit as described in 39.3 of either 120 or 240 V, whichever will develop the most severe operating conditions. A single layer of cheesecloth is to be placed around the appliance. If the circuit is interrupted by the failure of a component before seven hours of operation is completed, the test is to be repeated twice using new components for each test.

50 Connector Cycling

50.1 A separable connector shall perform acceptably, without injuriously affecting any part of the device, when subjected to the specified number of cycles of make and break at six–second intervals. The appliance is to be operated as described in 39.3. A connector shall be operated for 10 cycles if it is in a circuit on the load side of a rectifier, and for 50 cycles if it is in the primary–input circuit.

50.2 A separable connector is considered to be one which is not held in place by a screw, clamp, or the like, and which does not require the use of a tool in order to accomplish the separation.

51 Reservoir Overflow

51.1 If an appliance (such as a sterilizer, incubator, or the like) incorporates a reservoir or liquid–storage chamber that can be overfilled in normal service, liquid overflowing from the reservoir or chamber shall not wet uninsulated live parts or enamel–insulated wires, and shall not wet electrical insulation which is likely to be adversely affected by the liquid normally used in the reservoir or chamber. (See 5.1.19).

51.2 To determine whether or not an appliance complies with the requirement in 51.1, it is to be tested as follows: water is to be used for the test, and is to be poured into the reservoir through an orifice 3/8 inch in diameter. The reservoir is to be filled to the level recommended by the manufacturer, if such level is plainly marked; otherwise, the reservoir is to be filled to maximum capacity. Additional water, equal to 50 percent of the volume just mentioned (but not more than one pint), is then to be poured into the reservoir. Ordinarily, determination of whether or not uninsulated live parts have become wet as a result of the overflow is to be by means of visual inspection, but this may be supplemented by a leakage current test, a dielectric withstand test, or both, if judged to be appropriate.

52 Cleaning and Sterilization

52.1 Each appliance, or portion of an appliance, which is intended to be cleaned by wiping, washing, or sterilizing shall be conditioned as outlined in 52.2 – 52.4, after which the leakage current test described in 42.6.1.3 – 42.6.3.1 shall be repeated with no increase in the previously observed leakage current values.

52.2 For appliances intended to be wiped clean, a folded cheese cloth applicator is to be saturated with the cleaning agent specified by the manufacturer. The cheese cloth is then to be wrung–out to the extent that the solution does not drip freely, and the surface of one unit is to be wiped thoroughly. The complete wiping procedure is to be repeated until a total of 5 operations has been completed.

52.3 For appliances intended to be washed, one sample of the appliance under test is to be submerged to the level indicated by the manufacturer in a liquid bath as recommended in the manufacturer's instructions. Immersion time is to be for a total of one hour, after which the appliance is to be removed and dried thoroughly on the outside using a soft absorbent cheesecloth pad. The immersion and drying procedure is to be repeated until a total of 5 washings and dryings have been completed.

52.4 For appliances intended to be sterilized by autoclaving or other methods, one sample is to be subjected to the sterilizing procedure outlined in the manufacturer's instructions until a total of 5 sterilization cycles has been completed. Between each successive cycle, the appliance is to be removed from the sterilizing equipment and allowed to adjust to room temperature before the cycle is repeated.

53 Thermostats

53.1 General

53.1.1 Unless it has been tested and found suitable for the application, a thermostat shall acceptably complete the test program outlined in 53.2.1 – 53.3.2 and, where applicable 53.3.3 and 53.4.1.

53.2 Overload

53.2.1 An automatic control for temperature regulating or temperature limiting shall be capable of performing successfully for 50 cycles of operation when the appliance is connected to a supply circuit having a potential of 120–percent of the voltage specified in 39.3. There shall be neither electrical nor mechanical failure of the control, nor undue burning, pitting, or welding of the contacts.

53.2.2 In a test to determine whether or not an automatic control complies with the requirements in 53.2.1, the appliance is to be connected to a grounded supply circuit; the enclosure of the appliance, if of metal, is to be connected to ground through a 3–ampere fuse; and the control, if single–pole, is to be connected in an ungrounded conductor of the circuit. The control is to be operated at the rate of ten cycles per minute, except that a faster rate of operation may be employed if agreeable to all concerned. The performance is unacceptable if the fuse in the grounding connection is ruptured during the test.

53.3 Endurance

53.3.1 A thermostat shall be capable of withstanding an endurance test which shall consist of the number of cycles indicated in Table 53.1. Unless it is specified that the test be made without load, the thermostat shall make and break its expected load in the appliance while connected to a circuit of rated voltage. There shall be neither electrical nor mechanical failure of the thermostat, nor undue burning, pitting, or welding of the contacts.

Exception: For an infant incubator, if, during the abnormal portion of the test outlined in 53.3.3, the operating temperatures in the infant compartment do not exceed 39°C (102°F) the thermostat may be tested for 6000 cycles of operation under load. If temperatures in excess of 39°C (102°F) are observed during the test, the thermostat shall be subjected to 100,000 cycles of operation and, further, shall comply with the requirement in 53.4.1.

53.3.2 With reference to 53.3.1 and Table 53.1, thermostats are classified as follows:

a) A temperature–regulating thermostat is one which functions only to regulate the temperature of the heating appliance under normal conditions of use and whose failure would not result in a fire hazard.

b) A temperature–limiting thermostat is one which functions only under conditions which produce abnormal temperatures. The failure of such a thermostat might or might not result in a fire hazard.

c) A combination temperature–regulating and–limiting thermostat is one which functions to regulate the temperature of the heating appliance under normal conditions of use, and also serves to prevent risk of fire which might result from conditions of abnormal operation of the appliance.

53.3.3 The infant incubator is to be operated as described in 45.2.20 until constant temperatures have been attained, at which time all temperature controls are to be rendered ineffective and operation in this manner continued for an additional two–hour period. Maximum operating temperatures in the infant compartment are to be determined during this period.

53.4 Calibration

53.4.1 In addition to the 100,000 cycles endurance test, an incubator thermostat employed to limit temperatures in the infant compartment to 39°C (102°F) or less shall be calibrated, exposed first to a temperature of 30°F for seven hours, recalibrated, then exposed to a temperature of 140°F for a period of 15 minutes, and, finally, recalibrated. There shall be no damage to the thermostat nor shall the calibration be significantly affected.

54 Printed Wiring Assemblies

54.1 Dielectric withstand

54.1.1 Where electrical breakdown would result in risk of electric shock, a printed wiring assembly shall be capable of withstanding without breakdown for a period of 1 minute the application of a direct potential of 2E + 1000 volts between printed wiring parts and between printed wiring parts and other parts.

54.1.2 E is the maximum peak potential between parts measured with the appliance connected to a supply circuit operated under the conditions described in 46.5.2 and 46.5.3.

54.2 Limited power

54.2.1 Unless the sources of power for printed wiring assemblies are limited so that they are not capable of delivering power of 50 watts (or more) for more than one minute into an external resistor connected between any two points on a complete assembly, the assembly shall comply with the requirements of 54.3 and 54.4.

Exception: A printed–wiring assembly that complies with 54.2.3 need not comply with 54.3.1.

Table 53.1
Number of cycles of operation for endurance test

Type of thermostat	Automatically reset thermostat	Manually reset thermostat
Temperature regulating	A number of cycles equivalent to 1000 hours of normal operation of the appliance,but not less than 30,000. However, the test may be omitted if, with the thermostat short-circuited, no temperatures higher than the limits given in Table 45.1 are attained during the normal temperature test of the appliance.	To be made the subject of special consideration. No value specified because of unlikely occurrence.
Temperature limiting	A number of cycles equivalent to 100 hours of operation of the appliance under any condition which causes the thermostat to function, or 100,000 cycles, whichever is greater. However, the test may be omitted if, with the thermostat short-circuited there is no evidence of risk of fire as described in 49.1.1 – 49.1.3 during the continuous abnormal operation of the appliance.	1000 cycles under load and 5000 cycles without load. However, the test may be omitted if, with the thermostat shore-circuited, there is no evidence of risk of fire as described in 49.1.1 – 49.1.4 during continuous abnormal operation of the appliance.
Combination temperature- regulating and limiting	100,000 if, with the thermostat short-circuit, there is evidence of fire hazard as described in 49.1.1 – 49.1.3 If there is no evidence of risk of fire under this condition, the thermostat is to be tested as a temperature-regulating thermostat. (See above).	To be made the subject of special consideration. No value is specified because of unlikely occurrence.

54.2.2 It is not necessary that a printed wiring assembly be regarded as a unit in applying the requirement in 54.2.1. For example, a part of the assembly may comply with 54.2.1, another part with 54.3.1 and the dielectric withstand test in 54.4.2 and 54.4.3, and another part with 54.3.1 and the arcing test in 54.4.4.

54.2.3 A printed–wiring assembly need not comply with the requirement of 54.3.1, as mentioned in the exception to 54.2.1, provided the printed–wiring assembly is powered from a secondary winding of an isolating transformer and the printed–wiring board of the assembly has a minimum flame classification of V–2 (as determined from the requirements for tests for flammability of plastic materials, UL 94). The enclosure of such printed–wiring assemblies is to comply with (d), and either (a), (b), or (c) as follows:

a) Enclosure is to be made of metal. See Section 5.

b) Enclosure is to be made of a polymeric material having a minimum flame classification of V–1.

c) Enclosure is to be made of solid or laminated wood, at least 3/8 inch thick with no edge exposed to internal electrical parts and spaced at least 1/2 inch from arcing parts and sources of ignition. Parts considered to be sources of ignition are those connected in circuits having a capability of over 50 watts and include resistor body, transistor body, diode body, inductor body (coil only), capacitor body, transformer (coil only), and integrated circuits.

d) Openings in the enclosure:

1) Are not to project vertically onto a horizontal plane above the product,

2) That are in the sides, are not to have a maximum minor dimension more than 1/8 inch, and

3) That are in the bottom, are to be protected by a solid barrier or screen complying with 5.1.11 and that extends not less than 1 inch beyond the horizontal projection.

A screen is to be No. 20 AWG mesh or equivalent with the maximum dimension of openings not greater than 3/32 inch. A barrier is to be of metal not less than 0.014 inch thick, polymeric material having a minimum flammability classification of V–1 or wood not less than 3/8 inch thick.

54.3 Abnormal operation

54.3.1 If the sources of power for a printed wiring assembly are not limited as described in 54.2.1, the assembly shall not produce risk of fire under both of the following conditions:

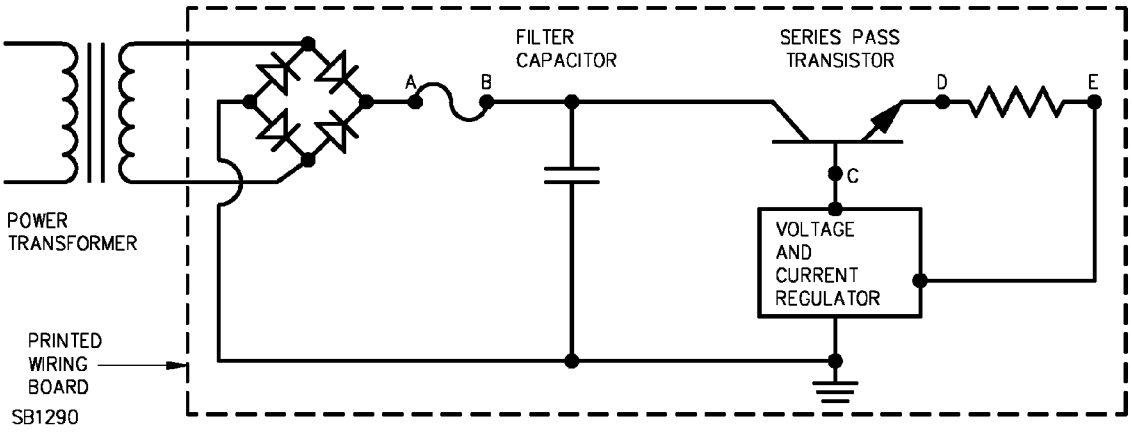
a) The short circuiting of those points of the power supply nearest the supply circuit that are not capable of delivering a power of 50 watts (or more) for a period of 1 minute into an external resistor. When the condition of short circuiting results in the failure of a component or the rendering of a circuit inoperative, such as the biasing–off of a transistor, a condition of loading to maximum power is also to be conducted between those points.

b) The short circuiting (singly) of any rectifier, vacuum tube, transistor, or electrolytic capacitor in the circuit between the points mentioned in (a) and the supply circuit.

54.3.2 The reference to the external resistor in 54.2.1 and 54.3.1 is generally a variable resistor which can be adjusted so that the resistance equals the resistive portion of the characteristic impedance of the circuit in question, and hence, the maximum power availability can be determined. The desired setting of the external variable resistor can be found with the aid of a suitable wattmeter or the plotting of a volt–ampere curve from several settings of the variable resistive load.

54.3.3 In conducting the test described in 54.3.1, a single layer of cheesecloth is to be loosely draped over the appliance as a whole with the cloth within 1/8 inch of openings in the overall enclosure. A cord–connected appliance is to be placed on a white tissue paper covered softwood surface. The test is to be continued until a fire has been developed, the circuit under test burns open, or until no further change is likely to take place, but in no case for more than 7 hours. A hazardous condition is considered to exist if the cheesecloth or tissue paper glows or flames. Note that 49.1.3 is used to determine whether the fuses or other overcurrent overload protective devices provided can be given credit for the purposes of these tests.

Figure 54.1
Power supply test example illustrating method of determination of the "less than 50 watt" points



Example No. 1 – Refer to Figure 54.1 as an example illustrating the method of determining the points referred to in 54.2.1. Assume that the maximum readings of power delivered to a variable external resistive load connected singly between the power supply return and the points A and B are 50 plus and 40 watts, respectively. The opening of the secondary fuse occurred at the 40 watt point. Since the power reading at point B is less than 50 watts, this is the point to be short–circuited and loaded to the maximum available power. Additionally, a single diode in the bridge rectifier is short circuited as this is a component between the first point less than 50 watts and the supply circuit.

Example No. 2 – Now consider that the maximum readings of power delivered to a variable resistive load connected between the power supply return and points C, D, and E are: 50 plus watts, 50 plus watts,and 20 watts, respectively. Since the reading at point E is less than 50 watts, this is the point to be short circuited and loaded to the maximum power. Shorting of the components back to the source of supply includes the series pass transistor, the voltage regulator, the first filter capacitor and a single diode in the bridge rectifier.

54.4 Second dielectric withstand or arcing

54.4.1 If the sources of power for a printed wiring assembly are not limited as described in 54.2.1, the assembly shall be capable of withstanding

a) A second dielectric withstand test as described in 54.4.2 and 54.4.3 or

b) An arcing test as described in 54.4.4.

54.4.2 For the second dielectric withstand test the printed wiring assembly is to be subjected to a direct potential of 2E + 1000 volts (see 54.1.1) between parts of different potential on the assembly where electrical breakdown involves a path over the surface of insulating material. Compliance is determined by maintaining the dielectric withstand for one minute without breakdown.

54.4.3 At the manufacturer's option, components need not be provided on the printed wiring boards subjected to the test outlined in 54.4.2 as it is a test of adequate spacings on the printed foil pattern. Boards submitted for test should have been subjected to the production soldering process, however.

54.4.4 For the arcing test on the printed wiring assembly, with the complete appliance connected to a supply source in accordance with 39.3, and using the energy available, an arc is to be drawn over the surface of the insulating material between parts of different polarity by means of carbon probe. The arc is to be maintained for a period of 15 minutes unless the circuit is interrupted by failure of a component such as a resistor in a shorter time. If the circuit is interrupted by failure of a component, the test is to be repeated twice using new components for each test. Compliance is determined by discontinuation of flaming of the material within one minute after interruption or discontinuation (15 minutes) of the test.

55 Display Vacuum Tube Enclosure

55.1 Implosion

55.1.1 General

55.1.1.1 To determine compliance with 5.1.14, two implosion methods are described in 55.1.2.1 – 55.1.3.3. If the implosion can be induced by either method, the thermal–shock method is to be used unless the high–energy–impact method is requested by the manufacturer. If neither method will induce the implosion, another appropriate method is to be used.

55.1.2 Thermal shock

55.1.2.1 To test the enclosure for the display vacuum tube implosion 5.1.14 by means of the thermal–shock method, the appliance is to be complete with all hardware and covers in place except for access holes required for test purposes. A table–model appliance is to be placed on a 30 inch (762 mm) high rigid table–like test stand. A floor–model appliance is to be tested standing on the floor. A barrier 1/2 inch (12.7 mm) thick, 9–1/2 inches (241 mm) high, and 72 inches (1.9 m) long is to be placed on the floor. The barrier is to be located at a distance of 6 inches (152 mm) from the plane of the front edge of the enclosure. A nonskid surface such as a blanket or rug is to be placed on the floor between the appliance and the barrier.

55.1.2.2 The thermal–shock method of inducing the implosion is as follows: The rim of the display vacuum tube adjacent to the seal is to be scratched with a glass cutter, diamond scriber or hard tool. Six 3/4 inch (19 mm) long scratches are made parallel to the central horizontal axis of the tube and spaced to occupy an area approximately 3/4 inch (19 mm) wide. The end of an ordinary glass rod, approximately 3/8 inch (9.5 mm) in diameter, is heated until nearly fluid. The heated end of the rod is passed through a

prepared access hole in the cabinet and pressed firmly on the scratched surface of the tube. If implosion does not occur within 10 seconds, the rod is to be withdrawn and cold water is poured slowly on to the scratched area. If implosion is not induced, the process is to be repeated twice.

55.1.2.3 The equipment complies with the requirement if, after the induced implosion by the thermal–shock method,there is no glass beyond the barrier.

Exception: Shale, slivers and other pieces of glass that are deflected or fall by gravity and are not projected or thrown as a result of the devacuation of the tube shall not be considered when determining compliance with 55.1.2.2.

55.1.3 High–energy impact

55.1.3.1 To test the enclosure for the display vacuum tube implosion 5.1.14 by means of the high–energy impact method, the appliance is to be complete with all hardware and covers in place except for access holes required for test purposes. A table–model appliance is to be placed on a 30 inch (762 mm) high rigid table–like test stand. A floor model appliance is to be tested standing on the floor. Two barriers each 1/2 inch (12.7 mm) thick, 9 1/2 inches (241 mm) high, and 72 inches (1.9 m) long are to be placed on the floor. The barriers are to be located at distances 3 and 5 feet (0.9 and 1.5 m) from the plane of the front edge of the enclosure, respectively. A nonskid surface such as a blanket or rug is to be placed on the floor beyond the second barrier.

55.1.3.2 The high–energy impact method of inducing implosion is as follows: A 1–inch (25.4 mm) diameter steel pin is to be inserted through a prepared hole in the cabinet and caused to rest on the rim of the tube near the face seal line. A weight of 10 lb (4.5 kg), or heavier if necessary to induce an implosion, is made to fall from a height of approximately 4–1/2 feet (1.37 m) and impact the pin at the end of its free fall. An equivalent impact may be used. The implosion pin is restricted so that its travel on impact is only enough to induce the implosion.

55.1.3.3 A unit complies with the implosion requirement by means of the high–energy impact method if, after the induced implosion of the display vacuum tube, all the following conditions exist:

a) A protective window has not fallen or been expelled from the cabinet as a unit, except for slivers;

b) No single piece of glass having mass more than 1/2 ounce (14.2 g) is between the two barriers;

c) The total mass of all the pieces of glass between the two barriers is not more than 1–1/2 ounces (42.5 g); and

d) No glass, except slivers, is beyond the barrier that is 5 feet (1.52 m) from the front edge of the enclosure.

55.2 Impact

55.2.1 To determine compliance with 5.1.16, the impact applied is to be obtained from a solid, smooth, steel sphere 2 inches (50.8 mm) in diameter and weighing approximately 1.18 lb (0.535 kg). The sphere is allowed to fall freely from rest through the distance required to cause it to strike the top of the enclosure with an impact of 5–ft–lb (6.78–N·m). For surfaces other than the top of the enclosure the sphere is to be suspended by a cord and allowed to fall as a pendulum through the distance required to strike the surface

with the specified impact. The enclosure is placed so that the surface tested is vertical and in the same vertical plane as the point of support of the pendulum. Parts of the enclosure that may interfere with the cord of the pendulum are to be removed.

56 Mechanical Abuse

56.1 Drop

56.1.1 To determine compliance with 5.1.25, each of three samples of the appliance is to be dropped three times from a height of 4 ft (1.22 m) onto a tile covered concrete surface, in such manner as to test the component whose failure would create a risk of fire or electric shock in the most severe manner.

56.2 Loading

56.2.1 To determine compliance with 5.1.26, the handle, and its means of securing to the appliance that it is intended to support, is to be subjected to a force of four times the weight of the appliance. The load is to be uniformly applied over a 3–inch (76 mm) width at the center of the handle, without clamping, started at zero and gradually increased so that the test value will be attained in 5 to 10 seconds and maintained for a period of 1 minute. If more than one handle is furnished on an appliance, the force is to be distributed between the handles. The distribution of forces is to be determined by measuring the percentage of the appliance weight sustained by each handle with the appliance in the intended carrying position. If an appliance is furnished with more than one handle but it is constructed so that it may readily be carried by only one handle, each handle is to be capable of sustaining the total force.

56.2.2 To determine compliance with 5.1.27 after the appliance is installed, the appliance is to be mounted in accordance with the manufacturer's installation instructions using fasteners and constructions as described. If no wall constructions are specified, 3/8 inch (9.5 mm) thick plasterboard – drywall on 2 by 4 (40 by 90 mm) studs at 16 inch (406 mm) centers is to be used as the support surface. Fasteners are to be applied as specified in the instructions and if not noted are to be positioned in the plasterboard between studs. An adjustable appliance is to be adjusted to the position that will give the maximum projection from the wall. A gradually increasing force is to be applied to act vertically through the center of gravity of the appliance in the extended position. The force is to be increased in a 5 to 10 second interval, until a load of four times the weight of the appliance is applied to the mounting system (weight of appliance plus force of three times the weight of the appliance) and is to be sustained for a period of 1 minute.

MANUFACTURING AND PRODUCTION TESTS

57 Production-Line Dielectric Voltage–Withstand Test

57.1 Each appliance shall withstand without an indication of unacceptable performance, as a routine production–line test, the application of a 40 – 70 Hz potential between

a) The primary wiring, including connected components, and accessible dead metal parts that are likely to become energized, and

b) Between primary and accessible low voltage (42.4 volt peak or less) metal parts, including terminals, and, where applicable

c) Between primary circuits and patient–connected circuits. For a definition of unacceptable performance see 57.8 (d).

57.2 The production–line test shall be in accordance with either condition A or condition B of Table 57.1.

57.3 The appliance may be in a heated or unheated condition for the test.

Table 57.1
Production line test conditions

Appliance rating and form	Condition A		Condition B	
	Potential volts	Time seconds	Potential volts	Time seconds
105–130 Volts with or without a motor rated 1/2 horsepower or less and not applied to or contacted by persons in normal use.	1000	60	1200	1
105–130 Volts and applied to or contacted by persons in the intended use or with a motor rated more than 1/2 horsepower	1000+2V[a]	60	1200+2.4V[a]	1
210–600 Volts	1000+2V[b]	60	1200+2.4V[b]	1
Patient connected circuits (Regardless of voltage rating)[c]	2500	60	3000	1

[a] Maximum marked voltage but not less than 120 volts.
[b] Maximum marked voltage but not less than 240 volts.
[c] Applied between primary circuits and patient connections only.

57.4 The test shall be conducted when the appliance is complete (fully assembled). It is not intended that the appliance be unwired, modified or disassembled for the test.

Exception No. 1: Parts such as snap covers or friction–fit knobs that would interfere with performance of the test need not be in place.

Exception No. 2: The test may be performed before final assembly if the test represents that for the completed appliance.

57.5 When the appliance employs a solid–state component that is not relied upon to reduce the risk of an electric shock and that can be damaged by the dielectric potential, the test may be conducted before the component is electrically connected provided that a random sampling of each day's production is to be tested at the potential specified in Table 57.1. The circuitry may be rearranged for the purpose of the test to minimize the likelihood of solid–state–component damage while retaining representative dielectric stress of the circuit.

57.6 The test equipment, when adjusted for production–line testing, is to produce an output voltage that is not less than the factory test value specified, nor is the magnitude of the test voltage to be greater than 120 percent of the specified test potential when the tester is used in each of the following conditions:

a) If the test duration is 1 second, the output voltage is to be maintained within the specified range:

1) When only a voltmeter having an input impedance of at least 2 megohms and a specimen of the product being tested are connected to the output terminals, and

2) When a relatively high resistance is connected in parallel with the voltmeter and the product being tested, and the value of the resistance is gradually reduced to the point where an indication of unacceptable performance just occurs.

b) If the test duration is 1 minute, the output voltage is to be maintained within the specified range, by manual or automatic means, throughout the 1 minute duration of the test or until there is an indication of unacceptable performance.

57.7 The specified control of the applied voltage, manual or automatic, shall be maintained under conditions of varying line voltage. Higher test potentials may be used if the higher dielectric stress is not likely to adversely affect the insulating system of the product.

57.8 In addition to the characteristics indicated in 57.6, the test equipment is to have the following features and characteristics:

a) A means of indicating the test voltage that is being applied to the appliance under test. This may be accomplished by sensing the voltage at the test leads or by an equivalent means.

b) An output voltage that has:

1) A sinusoidal waveform,

2) A frequency that is within the range of 40 – 70 Hz, and

3) A peak value of the waveform that is not to be less than 1.3 and not more than 1.5 times the root–mean–square value.

c) A means of effectively indicating unacceptable performance. The indication is to be:

1) Auditory if it can be readily heard above the background noise level,

2) Visual if it commands the attention of the operator, or

3) A device that automatically rejects an unacceptable product.

If the indication of unacceptable performance is auditory or visual, the indication is to remain active and conspicuous until the test equipment is reset manually.

d) When the test equipment is adjusted to produce the test voltage and a resistance of 120,000 ohms is connected across the output, the test equipment is to indicate an unacceptable performance within 0.5 second. A resistance of more than 120,000 ohms may be used to produce an indication of unacceptable performance, if the manufacturer elects to use a tester having higher sensitivity.

57.9 There is not to be any transient voltage applied to the appliance under test that results in the instantaneous voltage applied to the product exceeding 120 percent of the peak value of the test voltage that the manufacturer elects to use for this test. This requirement applies for the entire duration of the test, including the time that the voltage is first applied to the product and the time that the voltage is removed from the product.

57.10 During the test, a sufficient number of primary switching components shall be in the on position so that all primary circuitry will be stressed. Both sides of the primary circuit of the appliance are to be connected to one terminal of the test equipment. The second equipment terminal is to be connected to accessible dead metal.

58 Production–Line Grounding–Continuity Test

58.1 Each appliance that has provision for grounding by fixed wiring means or has a power–supply cord having a grounding conductor shall be tested, as a routine production–line test, to determine grounding continuity is provided between the point of connection of the equipment grounding means (grounding blade of the attachment plug in the case of a portable appliance) and the accessible dead metal parts of the appliance that are likely to become energized.

Exception: This test need not be conducted on appliances intended for permanent connection by fixed wiring means if the construction does not employ bonding jumpers or grounding wiring to remote units.

58.2 Only a single test need be made if the accessible metal selected is conductively connected to all other accessible metal.

58.3 Any indicating device (an ohmmeter, a battery–and–buzzer combination or the like) may be used to determine compliance with the grounding continuity requirement in 58.1.

RATINGS

59 Details

59.1 The electrical rating of an appliance shall include the supply voltage, frequency, and input in amperes, volt–amperes or watts. The rating in amperes shall always be included when the full–load power factor is less than 80 percent, except for a cord–connected appliance where the input is 50 watts or less.

59.2 The number of phases shall be indicated if an appliance is intended for use on a polyphase circuit. The number of wires (including the grounded circuit conductor but excluding the grounding conductor, if any) shall also be indicated if the appliance is intended for use on a circuit containing more than two circuit conductors.

59.3 The rating on the appliance shall include the combined inputs to all accessories or peripheral equipment that can be supplied through that appliance and can be operated simultaneously. If the accessory or peripheral equipment is not provided with a means for connection directly to the branch supply circuit, it need not be provided with an electrical rating.

59.4 The electrical rating for diagnostic low–voltage instrument transformers and similar equipment shall include the primary voltage and frequency, all secondary voltages, and the capacity in volt–amperes.

MARKINGS

60 General

60.1 Markings affixed to the appliance shall be of such nature as to resist the deleterious effects of handling, cleaning agents, and the like, expected in the intended use of the appliance. The markings required in Section 63 shall be permanently secured to the product. See, General, Section 65, for caution and warning notices.

60.2 Good contrast shall be maintained between the lettering and the background material and, unless the height of lettering is specifically indicated, the letters shall be of such a height that the information will be clear and legible under the actual conditions of use of the appliance.

61 Identification and Ratings

61.1 The marking on the appliance shall be readily visible and shall include the name or trade name of the manufacturer or other descriptive marking by which the organization responsible for the product may be identified, a distinctive catalog number or equivalent designation, and the electrical rating.

61.2 The marking may be located where it is visible only after removing a cover if the cover can be removed without the use of a tool, and may be a combination of chassis markings.

61.3 Multiple–voltage equipment intended for permanent connection to the branch circuit shall be marked to indicate the particular voltage for which it is connected when shipped from the factory. The marking may be in the form of a paper tag or any other nonpermanent material. Cord–connected equipment shall be provided with instructions to indicate the type of attachment–plug cap that should be used for connection to the alternate voltage (see 7.3.2.6).

61.4 An input–voltage selector shall be marked to indicate each individual voltage position.

61.5 If a manufacturer produces or assembles the same equipment at more than one factory, each equipment shall have a distinctive marking – which may be in code – by means of which it can be identified as the product of a particular factory.

62 Cord–Connected Equipment Marking

62.1 Cord connected equipment employing "Hospital Only" or "Hospital Grade" attachment plug caps shall be provided with instructions to indicate that grounding reliability can only be achieved when the equipment is connected to an equivalent receptacle marked "Hospital Only" or "Hospital Grade". The necessary instructions shall be included on the appliance itself or on a tag attached to the supply cord of the appliance.

63 Receptacles, Connectors and Patient Connections

63.1 A receptacle or connector with or without a jumpered plug that:

a) Is intended for the connection of an accessory,

b) In itself involves hazardous energy, or the use of which may produce a fire or shock hazard,

c) Is readily perceptible by the user, and

d) Is not utilized for the connection of part of the appliance, shall be marked, where readily visible, to indicate the specific acceptable accessory for which it is intended.

The letters shall not be less than 7/64 inch high.

Exception No. 1: On permanently connected appliances (appliances intended for electrical connection by fixed wiring methods) convenience receptacles of the conventional two-blade type with grounding-pin need not be marked for a specific accessory but shall be marked with the electrical load rating in volts, frequency and amperes or watts.

Exception No. 2: On stationary appliances (cord connected appliances not easily moved from one place to another – for example, dental and optical instrument stands and examination tables) having no patient connections, convenience receptacles of the conventional two-blade type with grounding-pin need not be marked for a specific accessory but shall be marked with the electrical load rating in volts, frequency and amperes or watts, if all of the following conditions are met:

a) Unless the appliance is provided with suitable supplementary protection appropriate for the wiring employed, all wiring (including the power supply cord conductors) from the supply circuit to the convenience receptacles shall be at least equivalent in size to the branch-circuit conductors which would be required for receptacle outlets of the same configuration in accordance with the National Electrical Code, ANSI/NFPA 70.

b) The wiring to the convenience receptacles shall be enclosed or otherwise protected from mechanical damage within the appliance, including strain relief where necessary.

c) The convenience receptacles and the supply cord attachment plug cap of the equipment shall be "Hospital Grade" type.

d) Except as noted in (e), a marking shall be located adjacent to the convenience receptacle(s) stating: "CAUTION – Grounding continuity should be checked periodically."

e) The marking in (d) is not necessary if a suitable ground-monitoring means is provided as part of the equipment.

Exception No. 3: On carts used to support portable equipment where more than one type of equipment is frequently interchanged (temporary cart use), convenience receptacles of the conventional two blade type with grounding pin need not be marked for a specific accessory, but shall be marked with the electrical load rating in volts, frequency and amperes or watts, if all of the following conditions are met:

a) All conditions of (a), (b) and (c) noted in Exception No. 2.

b) Except as noted in (c), the following statement may be placed in the operating instructions or marked on the equipment:

"CAUTION:

1) Grounding continuity should be checked periodically,

2) The combined leakage current of appliances used with this product should be checked periodically,

3) For Temporary Use Only,

4) Appropriate steps shall be taken to avoid creating an unstable assembly with respect to objects placed on this appliance,

5) Appropriate steps shall be taken to avoid placement of materials on the device which may drip, fall, and the like, and increase the risk of fire or electric shock."

The symbol ⚠ (IEC Publication 348) shall be marked on the equipment and located adjacent to the convenience receptacle(s) if the statement in (b) is not marked on the equipment. If used, the symbol shall be defined in the operating instructions provided with the equipment.

c) The text in the instructions in (b)(1) is not necessary if a suitable ground-monitoring means is provided as part of the equipment.

d) The user instructions shall provide explanations for the cautionary markings in (b).

63.2 A receptacle or connector which is utilized for a patient–connected cable or lead assembly in which components are employed to isolate the patient from fire and/or shock hazard, shall be marked to specifically indicate the cable assembly to be employed.

63.3 An appliance employing isolated patient connections (see 2.17) shall be prominently marked in letters at least 7/64 inch high with the following wording or equivalent: "Patient Connection Electrically Isolated". The marking shall be located adjacent to the integral patient cable or connectors associated with the circuit.

63.4 A receptacle or connector which is utilized for a simple patient connection, (that is, uninterrupted leads with no isolating or protective impedance components) need be marked only to indicate the intended function.

64 Installation and Operating Instructions

64.1 An installation diagram and operating instructions shall accompany an appliance if the connections and methods of operation are such that there may be any question regarding them; or if the product is provided with one or more marking symbols, see 64.6. Particular consideration shall also be given to directions relating to cleaning and sterilization procedures.

64.2 The operating instructions referenced in 64.1 shall be provided in the form of an operator's or user's manual with each appliance. The manual shall include, where applicable, step–by–step procedures for intended application of the equipment; illustrations showing the location of, and explanation of the function of, each control; instructions relating to proper connection to other equipment; and other features relating to risks involved in the intended use.

64.3 For equipment intended to be used under emergency conditions by personnel who may not fully understand its operation or who may not have immediate access to the instructions, information for acceptable, intended use of the equipment, including the identification and function of each switch and control, shall be clearly and prominently displayed on the equipment itself.

64.4 If an appliance does not start and attain running speed when connected to a circuit protected by an ordinary (not time–delay) fuse as described in 40.1, the appliance shall be plainly marked with the words "If connected to a circuit protected by fuses, use time–delay fuses with this appliance", or with an equivalent wording.

64.5 If, during the normal–temperature test, a point within a terminal box or compartment intended for power–supply connections (including the power supply conductors themselves) attains a temperature higher than 60°C (140°F), the appliance shall be marked with the following statement or the equivalent, at or near the point where the supply connections are to be made, and so located that it will be readily visible during and after installation: "For supply connections, use wires suitable for at least ___°C (___°F)." The temperature value to be used in the preceding statement shall be in accordance with Table 64.1.

64.6 The instructions required in 64.1 for a product that is provided with one or more of the symbols described in 18.2 and in General, Section 65, (CAUTION AND WARNING NOTICES) shall include an explanation of the intent of each symbol provided.

Table 64.1
Outlet–box marking

Temperature attained during test in terminal box or compartment	Temperature marking
61 – 75°C (142 – 167°F)	75°C (167°F)
76 – 90°C (168 – 194°F)	90°C (194°F)

CAUTION AND WARNING NOTICES

65 General

65.1 Unless otherwise indicated, the letter height for notices of this type shall not be less than 7/64 inch (2.8 mm) and good contrast shall be maintained between the lettering and the background material. Letter height is to be based on upper case capital letters and letters such as "d", "b", "h", and so forth for the type size used. Letters that are molded or stamped in a material not having a contrasting background color shall have a height of not less than 7/64 inch (2.8 mm) and a raised (or lowered) depth of not less than 0.020 inch (0.51 mm). It is intended that these markings be on metal tags or equivalent means, and secured by screws, rivets, or the equivalent. Decalcomanias, paper labels, and pressure–sensitive labels are not considered to provide the degree of attachment required unless an investigation shows that the nature and method of application are such as to comply with the Standard for Marking and Labeling Systems, UL 969, with regard to permanency and legibility.

65.2 The letters, numbers, and pictorial representation associated with a symbol – including that within the outline (triangle, circle, or the like) – shall have a height not less than 7/64 inch (2.8 mm), and shall provide good contrast between the background and the lettering, graphics, and border if provided.

65.3 The intent of any symbol that is provided on a product, shall be explained in a manual required to accompany the product. Refer to 64.6.

65.4 In place of the following specific notices, consideration will be given to equivalent notices of regulatory agencies or other authorities having jurisdiction, where such notices comply with the intent of these requirements.

66 Fuse Replacement

66.1 There shall be a legible and durable marking for each fuse used to meet the requirements in this standard indicating the ampere rating (and voltage if more than 125 volts) of the fuse to be used for replacement. The marking is to be located so that it is obvious to which fuse or fuseholder the marking applies, and shall consist of either:

a) The word "WARNING" and the following or equivalent text "Risk of fire. Replace fuse as marked." or

b) The symbol⚠

(triangular outline enclosing a pictorial representation of a fuse and its rating), and the following or equivalent text "Replace fuse as marked."

Exception No. 1: The symbol need not indicate either ___A, ___V, or both if the current, voltage or both ratings appear at the location of the fuse, of if the voltage rating is 125 volts or less.

Exception No. 2: Either marking [(a) or (b)] may be used once to represent a group of fuses, if each fuse is provided with its ampere and, if necessary, voltage rating.

67 Flammable Anesthetics

67.1 Medical and dental equipment intended for use in ordinary locations but likely to be brought into the operating or delivery room shall be prominently marked with either:

a) The word "DANGER", and the following or the equivalent text: "Risk of explosion if used in the presence of flammable anesthetics" (see 67.2), or

b) The symbol

[circular outline, letters AP (anesthetics proof) diagonally lined out left to right], accompanied by the word "DANGER" and the following or the equivalent text: "Explosion risk if used with flammable anesthetics".

67.2 The marking in 67.1 is to be applied to, but not specifically limited to, the following items: Defibrillators, Heart Pacers, Infant Incubators, Aspirators, Compressors, Surgical Pumps, Respirators and Pressure Breathing Assistors; Cautery Units and Electrosurgical machines; Hyperhypothermia Units, Compress Heater, Instrument Transformers and Warmers, Electrocardiographs, Electrocardioscopes, Electroencephalographs, and other patient monitoring equipment; Saws, and Cutters, Metal Locators, Ear, Nose, and Throat Treatment Machines, Headlights and associated power supplies, and Hypodermic Jet Apparatus.

68 Servicing

68.1 The extent of user or operator servicing is defined in 2.14. To deter attempts at further servicing of the appliance by unqualified personnel which will result in the exposure of live parts, suitable caution notice shall be provided on the appliance where readily visible during any approach to attempt servicing. The marking shall consist of either:

a) The word "CAUTION", and the following or equivalent text: "To reduce the risk of electric shock, do not remove cover (or back). Refer servicing to qualified service personnel.", or

b) The symbol

(lightning flash with arrowhead within an equilateral triangle), accompanied by the word "CAUTION".

69 X–Radiation – Serviceman

69.1 An appliance that does not comply with the requirements of 44.2 shall have a suitable warning located on the chassis where readily visible during servicing. The marking shall consist of "SERVICEMEN – WARNING" and the following or the equivalent: "To reduce the risk of exposure to X–radiation, take X–radiation protective measures for personnel during servicing".

70 Diathermy Machines, Ultrasonic Generators, and the Like

70.1 A marking, similar to the following, shall be prominently displayed on a diathermy machine, ultrasonic generators, or similar high frequency equipment: CAUTION – Risk of burns and fire – do not use near conductive materials such as metal bed parts, inner–spring mattresses, and the like. Renew electrode cables upon evidence of deterioration". The letter height shall not be less than 7/64 inch (2.8 mm) for the word "CAUTION" and not less than 3/32 inch (2.4 mm) for the remainder of the notice.

71 Defibrillators, Heart Pacers, and the Like.

71.1 Equipment that involves the application to a patient of electric currents or potentials that exceed ordinary acceptable levels (see 25.1 and 43.1) shall be prominently marked "WARNING" and the following or the equivalent "Hazardous electrical output. This equipment is for use only by qualified personnel". The letter height shall not be less than 7/64 inch (2.8 mm) for the word "WARNING" and not less than 3/32 inch (2.4 mm) for the remainder of the notice.

72 Double Insulated Products

72.1 An appliance that complies with the requirements for double insulation, shall be permanently marked with the words "DOUBLE INSULATION – CAUTION – when servicing use only identical replacement parts". The words "DOUBLE INSULATED" may be used instead of "DOUBLE INSULATION" in the marking. If the appliance includes a grounding terminal in accordance with 24.3, additional wording shall be provided in the marking stating "If grounding of the accessible metal parts is considered necessary, a separate ground lead should be employed".

Exception: An appliance that complies with the requirements for double insulation and employs a grounding conductor in the flexible supply cord in accordance with 24.3, shall be permanently marked with the words "DOUBLE INSULATION – EXTERNAL METAL GROUNDED – CAUTION – when servicing use only identical replacement parts".

73 Ungrounded (Isolated) Parts

73.1 If an appliance includes a combination of ungrounded isolated exposed dead metal parts and grounded dead metal parts which are not exposed during normal use or user servicing, it shall be marked with the following notice or the equivalent: "CAUTION – Accessible metal parts of this appliance are electrically isolated from the grounding conductor of the supply cord. If grounding of the accessible parts is considered necessary, a separate grounding lead should be employed".

74 Oxygen

74.1 Hospital beds

74.1.1 If intended for use with oxygen administering equipment the bed shall be marked with the following notice or equivalent wording: "CAUTION – Possible fire hazard when used with oxygen administering equipment of other than the nasal, mask or 1/2 bed length tent type. Oxygen tent should not extend below mattress support level". An additional statement "Lock hand control at foot of bed when using oxygen administrating equipment," or similar wording shall be included where applicable (see 74.1.2). The letter height shall not be less than 7/64 inch for the word "CAUTION" and not less than 3/32 inch for the remainder of the notice. The marking shall be located on the outside vertical surface of the foot panel of the bed where readily visible.

74.1.2 When provided on beds intended for use with oxygen administering equipment, pendant controls for patient use which have not been found suitable for use in oxygen atmosphere shall be marked "CAUTION – Possible fire hazard if hand control is not locked at foot of bed when using oxygen administering equipment", or with an equivalent wording. The letter height shall not be less than 7/64 inch for the word "CAUTION" and not less than 3/32 inch for the remainder of the notice. For additional markings on pendant controls see 75.1.

74.2 Incubators

74.2.1 If intended for use with oxygen–administering equipment, the incubator shall be marked: "WARNING – FIRE HAZARD – Keep matches, lighted cigarettes, and all other sources of ignition out of the room in which the incubator is located. Textiles, oils, and other combustibles are easily ignited and burn with great intensity in air enriched with oxygen." The letter height shall not be less than 7/64 inch for the word "WARNING" and the first sentence of the above notice, and not less than 3/32 inch for the remainder of the notice.

74.2.2 Additional statements relating to the use of oxygen with incubators (see 74.2.3 –74.2.7) shall contained in the operating instructions accompanying each incubator.

74.2.3 The use of oxygen in therapy requires that special care be taken to prevent fire. Any materials which will burn in air and some that will not are easily ignited an burn rapidly in high concentrations of oxygen. Accordingly, for safety it is necessary that all sources of ignition be kept away from the incubator, and preferably out of the room in which it is being used. "NO SMOKING" signs should be prominently displayed.

74.2.4 A spontaneous and violent ignition may occur if oil, grease or greasy substances come in contact with oxygen under pressure. These substances must be kept away from oxygen regulators, cylinder valves, tubing and connections, and all other oxygen equipment.

74.2.5 On high pressure oxygen cylinders, use only approved reducing or regulating valves marked for oxygen service. Do not use these valves for air or gases other than oxygen, since they may be hazardous when returned to oxygen service. Such equipment must be operated strictly in accordance with manufacturer's directions.

74.2.6 In view of these considerations, and to avoid the necessity for handling heavy cylinders in the nursery, it is recommended that wherever possible, the high pressure oxygen equipment be located outside the nursery. In any event, cylinders in use should be fixed in place so they will not be knocked over, and should be located as far as practicable from the incubator.

74.2.7 Mixtures of oxygen and flammable vapors, such as alcohol, ether, ethylene and cyclopropane may explode if ignited. Such mixtures may be ignited by electrical static spark discharges, or high temperature surfaces, in addition to all other more common sources of ignition. Only equipment designed for use in hazardous locations should be used in delivery rooms. Refer to Article 517 of the National Electrical Code, ANSI/NFPA 70, for the use of flammable anesthetics.

75 Pendant Controls

75.1 As required by 29.3.2, a pendant control shall be marked "CAUTION – Hang switch on hook (in holder) when not in use. Keep cord clear of moving parts", or with an equivalent wording. The letter height shall not be less than 7/64 inch for the word "CAUTION" and not less than 3/32 inch for the remainder of the notice (see 74.1.2).

76 Radiation

76.1 Whenever radiation from a treatment source is such that it cannot be directed solely toward the patient, acceptable warnings shall be provided on the equipment to alert the operator and other personnel to the necessity of vacating the room during the treatment or providing supplementary shielding around the patient and treatment source.

77 Hot Surface

77.1 To comply with the requirement for External Surface Temperatures, Exception No. 2 of 36.1, a legible and permanent marking consisting of:

a) The word "CAUTION," and the word "HOT" or the equivalent, or

b) Of the symbol⚠

(the pictorial representation of a hot surface – including the word HOT – within a triangle and the word "CAUTION" either within or adjacent to the triangle) shall be provided on or adjacent to the hot surface.

78 Hydrotherapy (Hydromassage) Units

78.1 Portable hydrotherapy (hydromassage) units shall be marked in letters not less than 7/64 inch (2.8 mm) high with the statement "For professional use only". In addition to this marking on the appliance, the following supplementary information shall be provided: "This equipment is intended only for professional use in hospitals, physical therapy locations, and the like, where the patient will be under the supervision of trained personnel." The supplementary notice may be provided on the appliance itself, the shipping carton, in the instruction booklet provided with the appliance, or on a separate sheet packaged with the appliance.

79 Pumps

79.1 General purpose air pumps, for example, pumps that are not provided with specific accessories or end use apparatus, shall be marked in letters not less than 1/16 inch high: "Listing by Underwriters Laboratories Inc. covers this air pump only. It does not cover any accessory equipment such as mattresses, pads, and the like."

80 External Supplies

80.1 Each connection point for an external fluid supply such as steam, air, or the like, shall be identified in accordance with the standard for compressed gas cylinder valve outlet and inlet connections, Standard for Compressed Gas Cylinder Valve Outlet and Inlet Connections, ANSI/CGA V-1–1987, or shall be marked in letters not less than 1/16 inch high to identify the fluid to be supplied and the maximum inlet pressure limitation.

81 Reference to Operating Instructions

81.1 Certain types of equipment involve the interconnection of signal circuitry with accessory equipment or the application of low–voltage potentials to patients for diagnostic, therapeutic, or measuring purposes. Such equipment shall be prominently and permanently marked with either

a) The word "CAUTION." and the following or the equivalent text, "Before connecting, read instructions" or

b) The symbol⚠

(exclamation mark within a triangle), accompanied by either a symbolic representation of the equipment intended for connection or reference type equipment intended for connection, or reference manual for instructions.

Standards for Components

Standards under which components of the products covered by this standard are evaluated include the following:

Title of Standard – UL Standard Designation

Title of Standard – UL Standard Designation

Attachment Plugs and Receptacles, Electrical – UL 498
Building Materials, Test for Surface Burning Characteristics of – UL 723
Cathode–Ray Tubes – UL 1418
Circuit Breakers Enclosures, Molded–Case Circuit–Breaker Enclosures – UL 489
Class 2 Power Units - UL 1310
Conduit, Flexible Metal – UL 1
Conduit, Liquid–Tight Flexible Steel – UL 360
Controls, Limit – UL 353
Cord Sets and Power–Supply Cords – UL 817
Double Insulation Systems for Use in Electrical Equipment – UL 1097
Filter Units, Air - UL 900
Filters, Electromagnetic Interference – UL 1283
Flammability of Liquids, Tests for Comparative - UL 340
Flexible Cord and Fixture Wire – UL 62
Fuseholders – UL 512
Fuses, Class H – UL 198B
Fuses, Class K - UL 198D
Fuses, Class R – UL 198E
Fuses, Class T – UL 198H
Fuses for Supplementary Overcurrent Protection – UL 198G
Fuses, Current-Limiting Types, High-Interrupting-Capacity – UL 198C
Fuses, Plug – UL 198F
Ground–Fault Sensing And Relaying Equipment – UL 1053
Industrial Control Equipment – UL 508
Lampholders, Edison-Base – UL 496
Lithium Batteries – UL 1642
Marking and Labeling Systems – UL 969
Motors, Electric – UL 1004
Motors, Impedance-Protected – UL 519
Outlet Boxes, Fittings for Conduit and – UL 514B
Outlet Boxes, Flush–Device Boxes and Covers, Nonmetallic – UL 514C
Outlet Boxes, Metallic - UL 514A
Plastic Materials for Parts in Devices and Appliances, Tests for Flammability of - UL 94
Polymeric Materials– Use in Electrical Equipment Evaluations – UL 746C
Printed–Wiring Boards – UL 796
Protectors for Motors, Thermal – UL 547
Protectors for Use in Electrical Equipment, Supplementary – UL 1077
Sharpness of Edges on Equipment, Test for – UL 1439
Switches, General Use Snap – UL 20
Switches, Special–Use – UL 1054

Tape, Electrical Insulating – UL 510
Temperature–Indicating and –Regulating Equipment – UL 873
Thermal Cutoffs for Use in Electrical Appliances and Components – UL 1020
Transformers Specialty – UL 506
Tubing, Extruded Insulating – UL 224
Wire Connectors and Soldering Lugs for Use with Copper Conductors – UL 486A
Wire Connectors for Use With Aluminum Conductors – UL 486B
Wires and Cables, Thermoplastic–Insulated – UL 83

Subjects 2601(187, 544)

1285 Walt Whitman Road
Melville, L.I., NY 11747
July 16, 1997

TO: **Casualty Council of Underwriters Laboratories Inc.,**
Electrical Council of Underwriters Laboratories Inc.,
Subscribers to UL's Listing and Classification Services for
Medical Electrical Equipment, (PIDF)
Medical and Dental Equipment, (KFBQ)
X-Ray Equipment (ZQOR)

SUBJECT: Announcement of UL Classification Service of Electrode Lead Wires and Patient Cables In Accordance With Code of Federal Regulations

Electrode Lead Wires and Patient Cables can be submitted for evaluation and Classification in accordance with Code of Federal Regulations 21 CFR Section 898.12.

On May 9, 1997, the U.S. FDA issued a final rule announcing the agency's first mandatory standard. The requirements concern the construction and performance of electrode lead wires and patient cables. The requirements are published in the Code of Federal Regulations 21 CFR Section 898.12. Electrode lead wires and patient cables must comply with Amendment 2 (1995) of IEC 601-1 (1988), subclause 56.3 paragraph c, which is shown in Appendix A.

This new service will allow manufacturers to have products evaluated in accordance with the performance and regulatory requirements indicated in 21 CFR Section 898.12. Upon successful evaluation and testing, by UL acting as an independent third-party testing agency, products will be eligible to bear UL's Classification Marking that indicates compliance with the indicated regulations. Investigations of these products will be covered under a new category, Electrode Lead Wires and Patient Cables, (PIEY). The compatibility of these devices for use with specific medical equipment has not been investigated. Equipment evaluated for fire, shock and mechanical hazards is covered in the following categories: Medical and Dental Equipment, (KFBQ), Medical Electrical Equipment, (PIDF), and X-Ray Equipment (ZQOR)

These products are designed for professional use by qualified personnel in hospitals, nursing homes, medical care centers, medical and dental offices, and similar health care facilities in accordance with the instructions provided by the manufacturer. The physiological effects of these products have not been investigated. The effect on a patient of simultaneous use of this equipment with other electrical apparatus has not been investigated.

The FDA compliance date for electrode lead wires and patient cables for use with the following devices is May 11, 1998 :

PRODUCT	PRODUCT CODE	21 CFR SECTION
Breathing Frequency Monitor	73BZQ	868.2375
Apnea Monitor	73FLS	868.2375
Electrocardiograph	74DPS	870.2340
Radio Frequency Physiological Signal Transmitter & Receiver	74DRG	870.2910
Cardiac Monitor (including Cardiotachometer & Rate Alarm)	74DRT	870.2300
Electrocardiograph Electrode	74DRX	870.2360
Patient Transducer and Electrode Cable (including connector)	74DSA	870.2900
Medical Magnetic Tape Recorder	74DSH	870.2800
Arrhythmia Detector and Alarm	74DSI	870.1025
Telephone Electrocardiograph Transmitter and Receiver	74DXH	870.2920

The FDA compliance date for electrode lead wires and patient cables for use with other devices is May 9, 2000.

Questions regarding products covered by this category or this new service, should be directed to the responsible UL Staff.

Please see Appendix B of this bulletin regarding designated responsibility for the subject product category.

UNDERWRITERS LABORATORIES INC.

RAYMOND M. SUGA (Ext. 22593)
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SR:PKW

2601BUL.R03;RMS;mc

APPENDIX A

EXCERPT OF REQUIREMENT FROM AMENDMENT 2 OF IEC 601-1

56.3 Connections - General

Add the following new item with an asterisk in front:

*c) Any connector in a lead having a CONDUCTIVE CONNECTION to a PATIENT shall be constructed in such a manner that no CONDUCTIVE CONNECTION of that part of the said connector which is remote from the PATIENT can contact earth or possible hazardous voltages.

Compliance is checked by inspection and by applying to the conductive connection of that part of the connector identified above those of the following tests which are applicable:

– the said part shall not come into contact with a flat conductive surface of not less than 100 mm diameter;

– for single-pole connectors, the straight unjointed test finger with the same dimensions as the standard test finger of figure 7 shall not make electrical contact with the said part if applied in the least favorable position against the access openings with a force of 10 N ± 2 N;

– if able to be plugged into a mains socket, the said part shall be protected from making contact with parts of mains voltage by insulating means providing a CREEPAGE DISTANCE of at least 1.0 mm and a dielectric strength of 1500 V.

APPENDIX B

DESIGNATED RESPONSIBILITY FOR UL PRODUCT CATEGORY

ELECTRODE LEAD WIRES AND PATIENT CABLES (PIEY)

The individuals shown below are involved with the investigation of products covered under the subject category. The Primary Designated Engineer (shown in UPPERCASE letters) coordinates the establishment and uniform interpretation of UL requirements applicable to the product category. The Designated Engineers (shown in lowercase letters) work with the Primary Designated Engineer to interpret requirements and maintain standards.

Should you have questions regarding products covered by this category or this new service, you are encouraged to contact the individual at the office to which you normally submit your products.

The IAC Chairman for the subject category is Steve Hewson at UL's Northbrook office. The IAC Chairman oversees the significant interpretations made by the Primary Designated Engineer and arbitrates any differences regarding interpretation of UL requirements.

CCN	Office/Subsidiary	Responsible Engineer	Extension
PIEY	Camas	P. Scherwinski	55654
	Melville	J. MURNANE	22247
	Northbrook	G. Gillerman	42545
	RTP	K. Donohue	11645
	Santa Clara	F. O'Brien	32358
	Japan	J. Jungblut	–
	Taiwan	J. Lee	–

Subjects 2601-1(544, 187, 3101-1)

1285 Walt Whitman Road
Melville, L.I., NY 11747
May 10, 1999

TO: **Electrical Council of Underwriters Laboratories Inc.,**
Subscribers to UL's Standards Services for
Medical Electrical Equipment
Medical and Dental Equipment
X-Ray Equipment
Manufacturers of
Medical and Dental Equipment, Professional (KFBQ)
Medical and Dental Equipment, Professional – Disposal Systems and Accessories (KFBY)
Power Supplies for Use in Health Care Facilities (KFCG)
Uninterruptible Power Supplies for Use In Health Care Facilities (KFFG)
Magnetic Resonance Imaging Equipment (PAZB)
Medical Equipment Classified in Accordance with Specified Medical Standards (PIKF)
Medical and Dental Equipment Power Supplies – Component (QQHM2)
X-Ray Equipment (ZQOR)
X-Ray Equipment, Accessories (ZQVQ)

SUBJECT: Reminder of Effective Date for Withdrawal of UL 544 and UL 187

UL announced, in its bulletin dated June 7, 1994, the schedule that would apply for the withdrawal of UL 544 and UL 187, the Standard for Medical and Dental Equipment and the Standard for X-Ray Equipment, respectively. These standards will eventually be replaced by UL 2601-1, the Standard for Medical Electrical Equipment; Part 1 - General Requirements. UL's June 7, 1994 bulletin stated that UL 544 and UL 187 could be used to evaluate medical and dental products until January 1, 2003, after which UL 2601-1 will be exclusively used for the evaluation of new products. As of January 1, 2005, all Listed, Classified and Recognized medical and dental products, where UL 544 or 187 was used to evaluate the product, must comply with UL 2601-1. It is the manufacturer's responsibility to re-submit these products to UL (for UL 2601-1 evaluation) if UL coverage is to be maintained. The UL coverage will be terminated for those products not found to comply by January 1, 2005.

Date	Action
Jan 1, 2003	New products will be evaluated to UL 2601-1
Jan 1, 2005	All products comply with UL 2601-1. UL 544 and 187 withdrawn

Though the first date is still three years away, UL recommends that manufacturers contact us as soon as practical to develop strategies for their products and the coming transfer dates. An early approach to this work will result in the smoothest transition, with lowest costs and least impact on the manufacturer's production.

There are several specialized UL product categories which presently reference UL 544 or UL 187 to assist in the investigation of any medical/dental aspects of product constructions. They are to be addressed as indicated below.

The following categories, and the corresponding component categories, will be withdrawn after January 1, 2005 since all products covered under them will be covered under category PIDF (following investigation to determine compliance with UL 2601-1). Consequently, any products in the following categories, which have not been evaluated to UL 2601-1, will no longer retain UL Listing or Classification after that date. No File Review will be conducted.

KFBQ – Medical and Dental Equipment, Professional

PAZB – Magnetic Resonance Imaging Equipment

ZQOR – X-Ray Equipment

ZQVQ – X-Ray Equipment, Accessories

The following categories will remain after January 1, 2005; therefore, it will be necessary for UL staff to contact manufacturers to review their products (conduct a File Review) to determine compliance of existing products with the UL 2601-1 requirements:

KFBY – Medical and Dental Equipment, Professional – Disposal Systems and Accessories

KFCG – Power Supplies for Use in Health Care Facilities

KFFG – Uninterruptible Power Supplies for Use In Health Care Facilities

QQHM2 – Medical and Dental Equipment Power Supplies – Component

The guide cards covering these categories (and any UL standards referencing UL 544 and/or UL 187 for medical/dental aspects of the product) will be revised to reference only UL 2601-1 and delete any references to UL 544 or UL 187. Accordingly, Listing, Recognition, or Classification of products that have not been evaluated to UL 2601-1 requirements will be discontinued as of January 1, 2005, and use of the UL Mark will cease on that date.

Similar Changes in "Certified for Canada" Product Categories

As a related issue, UL is also announcing similar changes in UL categories that cover the Listing, Recognition and/or Classification of products to Canadian National Standards. CSA 22.2 No. 114, which corresponds to UL 187, is being discontinued as of January 1, 2005. CSA 22.2 No. 125, which corresponds to UL 544, is also being discontinued by January 1, 2005. After that date, all equipment previously manufactured and certified to the requirements of standards C22.2 No. 114 or C22.2 No. 125 must comply with the requirements of CSA Standard C22.2 No. 601.1, Part 2 Series, and Collateral Standards, as applicable. Consequently, UL will have to review the following product categories to make sure all products comply with CSA 22.2 No. 601.1 as of January 1, 2005:

KFBQ7/8 – Medical and Dental Equipment, Professional, Certified for Canada – Components

KFBY7/8 – Professional Disposal Systems and Accessories, Certified for Canada – Components

KFCG7 – Power Supplies for Use in Health Care Facilities, Certified for Canada

KFFG7/8 – Uninterruptible Power Supplies for Use in Health Care Facilities, Certified for Canada

PAZB7/8 – Magnetic Resonance Imaging Equipment/Components

QQHM8 – Power Supplies, Medical and Dental, Certified for Canada – Components

ZQOR7/8 – X-Ray Equipment, Certified for Canada – Components

ZQVQ7 – X-Ray Equipment, Accessories, Certified for Canada

Non-Medical X-Ray Equipment

As announced above, UL product categories ZQOR and ZQVQ will cease to exist after the January 1, 2005 implementation date. It is anticipated that most of the medical-equipment x-ray-type products will relocated to category PIDF; however, there are some non-medical types of x-ray equipment (such as baggage inspection systems, open field inspection systems for air frames and piping, etc.) that will need to be relocated to a new UL product category (because of its non-medical application). UL has decided that category NYOK is a suitable place for that equipment. The base standard that UL uses to investigate products submitted under NYOK/NYOK2 is UL 3101-1 which corresponds to IEC 601010-1. The UL contact personnel for categories NYOK and NYOK2 is listed in Appendix C. Manufactures should contact UL staff well in advance of the implementation date to develop a plan for continued coverage.

This bulletin should be kept with your copy of the standard.

Questions regarding interpretation of requirements should be directed to the responsible UL Staff. Please see Appendix A, Appendix B, and Appendix C of this bulletin regarding designated responsibility for the subject product categories.

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APPENDIX A

DESIGNATED RESPONSIBILITY FOR UL

PRODUCT CATEGORIES

KFBQ, Medical and Dental Equipment, Professional
KFBY, Medical and Dental Equipment, Professional - Disposal Systems and Accessories
KFCG, Power Supplies for Use in Healthcare Facilities
KFFG, Uninterruptible Power Supplies for Use in Healthcare Facilities
NYOK, Inspection and Measuring Electrical Equipment
PAZB, Magnetic Resonance Imaging Equipment
PIKF, Medical Equipment Classified in Accordance with Specified Medical Standards
QQHM2, Medical and Dental Equipment Power Supplies
ZQOR, X-Ray Equipment
ZQVQ, X-Ray Equipment, Accessories

The individuals shown in the following tables are involved with the investigation of products covered under the subject categories. The Primary Designated Engineer (shown in UPPERCASE letters) coordinates the establishment and uniform interpretation of UL requirements applicable to the product categories. The Designated Engineers (shown in lowercase letters) work with the Primary Designated Engineer to interpret requirements and maintain standards.

Should you have questions regarding any adopted requirements that affect your product, you are encouraged to contact the individual at the office to which you normally submit your products.

The Responsible Department Manager for subject category KFBY is Raymond E. Burg at UL's Northbrook office

The Responsible Department Manager for subject category NYOK is Leonard B. Zafonte at UL's Melville office

The Industry Advisory Conference (IAC) Chairman for all remaining subject categories is Gary Schrempp at UL's RTP office. The IAC Chairman/Responsible Department Manager oversees the significant interpretations made by the Primary Designated Engineer and arbitrates any differences regarding interpretation of UL requirements.

CCN	Office/Subsidiary	Responsible Engineer	Extension
KFBQ	Camas	R. Boonstra	55652
	Melville	J. MURNANE	22247
	Northbrook	D. Hallerberg	43224
	RTP	P. Gwynn	11697
	Santa Clara	B. Blair	32024
	Canada	B. Black	416-757-3611
	UK	D. Bejnarowicz	44-1483-302-130
	Taiwan	J. Lee	886-2-896-7790

CCN	Office/Subsidiary	Responsible Engineer	Extension
KFBY	Northbrook	S. Sajid	43503

CCN	Office/Subsidiary	Responsible Engineer	Extension
KFCG	Melville	G. Luchen	22365
	Northbrook	D. THOMPSON	43686
	RTP	P. Gwynn	11697
	Santa Clara	B. Blair	32024
	Canada	B. Black	416-757-3611
	Taiwan	K. Chen	886-2-896-7790

CCN	Office/Subsidiary	Responsible Engineer	Extension
KFFG	Melville	T. Lanzisero	22464
	Northbrook	D. ACKERMAN	42907
	RTP	P. Gwynn	11697
	Santa Clara	C. Nelson	32625
	Canada	B. Black	416-757-3611
	Hong Kong	C. Chan	852-2695-9599
	Taiwan	C. Sun	886-2-896-7790

CCN	Office/Subsidiary	Responsible Engineer	Extension
NYOK	Melville	G. Luchen	22365
	Northbrook	S. Sajid	43503
	RTP	L. Green	11533
	Santa Clara	K. Jones	32371
	Camus	R. Boonstra	55652
	United Kingdom	D. Bejnarowicz	44-1483-302-130

CCN	Office/Subsidiary	Responsible Engineer	Extension
PAZB	Melville	J. MURNANE	22247
	Northbrook	D. Hallerberg	43224

CCN	Office/Subsidiary	Responsible Engineer	Extension
PIKF	Camas	R. Boonstra	55652
	Melville	J. MURNANE	22247
	Northbrook	D. Hallerberg	43224
	RTP	K. Donohue	11645
	Santa Clara	B. Blair	32024
	Taiwan	J. Lee	886-2-896-7790

CCN	Office/Subsidiary	Responsible Engineer	Extension
QQHM2	Camas	P. Scherwinski	55654
	Melville	G. Luchen	22365
	Northbrook	D. THOMPSON	43686
	RTP	P. Gwynn	11697
	Santa Clara	B. Blair	32024
	Canada	B. Black	416-757-3611
	UK	D. Bejnarowicz	44-1483-302-130

CCN	Office/Subsidiary	Responsible Engineer	Extension
ZQOR	Melville	J. MURNANE	22247
	Northbrook	D. Hallerberg	43224
	RTP	P. Gwynn	11697
	Santa Clara	B. Blair	32024
	Canada	B. Black	416-757-3611
	Europe	D. Bejnarowicz	44-1483-302-130

CCN	Office/Subsidiary	Responsible Engineer	Extension
ZQVQ	Melville	J. MURNANE	22247
	Northbrook	D. Hallerberg	43224
	RTP	P. Gwynn	11697
	Santa Clara	B. Blair	32024
	Canada	B. Black	416-757-3611

Subject 2601-1(187, 544)

1285 Walt Whitman Road
Melville, L.I.,NY 11747
June 16, 2000

TO: **Casualty Council of Underwriters Laboratories Inc.,**
Electrical Council of Underwriters Laboratories Inc.,
Subscribers to UL's Listing and Classification Services for
Medical Electrical Equipment,
Medical and Dental Equipment,
X-Ray Equipment

SUBJECT: Announcement Regarding Certification of Medical Electrical Equipment

This bulletin should be kept with your copy of the standard.

In accordance with the references shown below for UL 2601-1, all ACCESSORIES specifically noted in the ACCOMPANYING DOCUMENTS for the medical electrical equipment would be expected to comply with the relevant IEC (International Electrotechnical Commission) safety Standard. The resulting medical electrical equipment system would need to comply with IEC 60601-1-1.

IEC 60601-1	Introduction
UL 2601-1	Introduction
	Clause 2.2.15 (Amendment 2)
	6.8.2 a) - 4th dash
	6.8.2 c)
	19.2 b) - 1st dash
	19.2 c)

UL is announcing that the ACCESSORIES specifically noted in the ACCOMPANYING DOCUMENTS may optionally be shown to comply with UL 544, the Standard Medical and Dental Equipment, or UL 187, the Standard for X-Ray Equipment (which are not IEC harmonized). This means that products that are compliant with UL 544 and UL 187 will be considered to be equivalent to IEC - XXX Standards in the context of determining compliance with sub-clause BBB.4 (in the BBB Annex) in IEC 60601-1-1. As a result, such ACCESSORIES can be automatically considered as IEC-XXX equipment in UL 2601-1 evaluated products without being found, by separate investigation, to comply with the IEC-XXX Standard. Furthermore, by complying with the provisions below, it may not be necessary to evaluate the combination of products as a system unless specifically requested by a manufacturer.

* These ACCESSORIES are limited to those referenced in the ACCOMPANYING DOCUMENTS and are intended to be connected to SIPs/SOPs (Signal Input Ports/Signal Output Ports) of medical electrical equipment that bear the UL Mark (typically Classification).

* Any APPLIED PARTS that are directly connected to the product being UL Classified (whether shipped with the product or not) must meet all UL 2601-1 requirements.

* If an ACCESSORY is shipped with the medical electrical equipment (such as a foot switch) it must meet all UL 2601-1 requirements.

* This approach covers evaluations resulting in a UL Mark and/or a Mark for Canada (typically Classification). If asked to issue a CB Report for a product, this decision does not apply and all of the requirements in IEC 60601-1 must be met.

The decision to allow the use of certain types of ACCESSORIES to provide SIP/SOP interface to the medical electrical equipment is due to (1) the known and acceptable level of safety that UL 187 and UL 544 products provide and (2) a demonstrated field service record. This decision is also based on comments from manufacturers citing the above.

Other than this, there are no changes to the way these Standards are applied. This approach will remain in effect until UL 187 and UL 544 are withdrawn on January 1, 2005. After that, this option will be withdrawn and UL 2601-1 and IEC 60601-1 are to be applied as written (i.e., the ACCESSORIES will have to be compliant with IEC-XXX). This decision will also apply with regard to investigations resulting in a UL Mark for Canada involving CAN/CSA C22.2 No. 601.1 which covers similar medical electrical equipment.

Questions regarding products covered by this category or the standards eligible should be directed to the responsible UL Staff. Please see Appendix A of this bulletin regarding designated UL staff responsibility for the subject product categories.

UNDERWRITERS LABORATORIES INC.

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SR:LS

2601BUL.R06;RMS;mc

APPENDIX A

DESIGNATED RESPONSIBILITY FOR UL PRODUCT CATEGORIES

KFBQ, PROFESSIONAL MEDICAL AND DENTAL EQUIPMENT
PIDF, MEDICAL ELECTRICAL EQUIPMENT
ZQOR, X-RAY EQUIPMENT

The individuals shown on the back side of this sheet are involved with the investigation of products covered under the subject categories. The Primary Designated Engineer (shown in UPPERCASE letters) coordinates the establishment and uniform interpretation of UL requirements applicable to the product categories. The Designated Engineers (shown in lowercase letters) work with the Primary Designated Engineer to interpret requirements and maintain standards.

Should you have questions regarding products covered by this category or standards eligible, you are encouraged to contact the individual at the office to which you normally submit your products.

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CCN	Office/Subsidiary	Responsible Engineer	Extension
KFBQ[a]	Camas	B. Boonstra	55652
	Melville	J. MURNANE	22247
	Northbrook	D. Halleberg	43224
	RTP	P. Gwynn	11697
	Santa Clara	B. Blair	32024
	Japan	R. Tria	(03) 5351-1971
	Taiwan	J. Lee	886-2-896-7790

CCN	Office/Subsidiary	Responsible Engineer	Extension
PIDF[a]	Camas	B.Boonstra	55652
	Melville	J. MURNANE	22247
	Northbrook	D. Halleberg	43224
	RTP	P. Gwynn	11697
	Santa Clara	B. Blair	32024

CCN	Office/Subsidiary	Responsible Engineer	Extension
ZQOR[a]	Camas	B. Boonstra	55652
	Melville	J. MURNANE	22247
	Northbrook	D. Halleberg	43224
	RTP	P. Gwynn	11697
	Santa Clara	B. Blair	32024

[a] See previous page for an explanation of the type of equipment covered under this category.