

UL 2601-1

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Medical Electrical Equipment, Part 1: General Requirements for Safety

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UL Standard for Safety
for
Medical Electrical Equipment,
Part 1: General Requirements for Safety, UL 2601-1

Second Edition, Dated October 24, 1997

Announcement Bulletins: This Standard contains the announcement bulletins dated July 16, 1997, May 10, 1999, and June 16, 2000. The announcement bulletins are located at the end of the Standard.

The new and revised requirements are substantially in accordance with UL's Bulletin on this subject dated May 6, 1996 and February 6, 1997. These bulletins are now obsolete and may be discarded.

UL is adding IEC 601-1 Amendment 2 requirements to UL 2601-1 with an effective date for compliance of February 6, 1999 (see page 277). The effective date for compliance with use of SI units per subclause 6.3.9 g) in Amendment 2 is February 6, 2004. The revisions to the US Deviations, including the revision of the Deviation for subclause 6.6 a) regarding color coding of compressed gas cylinders, becomes effective on the date of printing of this Standard.

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The requirements in this Standard are now in effect, except for those paragraphs, sections, tables, figures, and/or other elements of the Standard having future effective dates as indicated in the note following the affected item. The prior text for requirements that have been revised and that have a future effective date are located after the Standard, and are preceded by a "SUPERSEDED REQUIREMENTS" notice.

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, Recognition, Classified and Follow-Up Services after the effective date, and understanding of this should be signified in writing.

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Page	Date
tr1, tr2	June 16, 2000
1	October 24, 1997
2 – 326	October 24, 1997

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1

UL 2601-1

Standard for

**Medical Electrical Equipment,
Part 1: General Requirements for Safety**

First Edition – August, 1994

Second Edition

October 24, 1997

An effective date included as a note immediately following certain requirements is one established by Underwriters Laboratories Inc.

Revisions of this standard will be made by issuing revised or additional pages bearing their date of issue. A UL Standard is current only if it incorporates the most recently adopted revisions, all of which are itemized on the transmittal notice that accompanies the latest set of revised requirements.

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UL INTRODUCTION

This is an explanation of the intended implementation of Particular and Collateral Requirements associated with product evaluation using this standard. For continuity some of the introductory information from IEC 601-1 is repeated here.

PARTICULAR STANDARDS:

UL 2601-1 contains requirements for safety which are generally applicable to all medical electrical equipment. For certain types of equipment, these requirements are to be supplemented or modified by the special requirements of a Particular Standard. Where Particular Requirements exist, the General Standard should not be used alone. Special care is required in applying the General Standard to equipment for which no Particular Standard exists.

COLLATERAL STANDARDS:

When the equipment falls within the scope of one or more Collateral Standards, such standard(s) may, optionally, also be used.

Note: Where any of these (Collateral and Particular) standards are not yet published by UL, then the corresponding IEC Publications are used.

UL PREFACE

In this Standard:

- requirements are printed in roman type.
- explanatory material regarding the requirements is printed in smaller roman type.
- *test specifications are printed in italic type.*

Deviations from the text of the International Electrotechnical Commission Publication 601-1, Medical Electrical Equipment, Part 1: General Requirements for Safety, 2nd edition, 1988, and Amendment No. 1 and Amendment No.2 to IEC 601-1, are indicated in the following section named US DEVIATIONS.

The text, Figures and Tables of IEC 601-1, 2nd edition, 1988, are used in the Standard with the consent of the International Electrotechnical Commission. Copies of IEC 601-1 (soon to be renumbered 6060-1) may be purchased from the International Electrotechnical Commission, 3 rue de Varembe, CH-1211 Geneva 20, Switzerland, or the American National Standards Institute (ANSI), 11 West 42nd Street, New York, New York 10036.

With the exception of the last four paragraphs of the Introduction, the International Electrotechnical Commission Foreword, Preface, and Introduction are not part of the requirements of this Standard but are included for information purposes only.

UL 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 differing from those detailed in the requirements of this Standard may be examined and tested according to the intent of the requirements and, if found to be substantially equivalent, 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.

Glossary of Equivalent Terms

The following is a list of terms used within IEC Standard 601-1 for which equivalent North American terms are presented.

IEC TERM	EQUIVALENT NORTH AMERICAN TERM
----------	--------------------------------

AUXILIARY MAINS SOCKET OUTLET	auxiliary supply receptacle
CLASS I EQUIPMENT	grounded equipment
CLASS II EQUIPMENT	double-insulated equipment
DETACHABLE POWER SUPPLY CORD	cordset
earth	ground
earthing	grounding
FUNCTIONAL EARTH CONDUCTOR	functional ground conductor
FUNCTIONAL EARTH TERMINAL	functional ground terminal
MAINS	supply
MAINS PART	primary supply part
MAINS PLUG	attachment plug
MAINS VOLTAGE	supply voltage
OVER-CURRENT RELEASE	overcurrent protective device
PROTECTIVE EARTH CONDUCTOR	protective ground conductor
PROTECTIVE EARTH TERMINAL	protective ground terminal
PROTECTIVELY EARTHED	protectively grounded
socket outlet	receptacle
SUPPLY MAINS	source of supply

US DEVIATIONS

MEDICAL ELECTRICAL EQUIPMENT

Part 1: General requirements for safety

SECTION ONE – GENERAL

1 Scope and object

1.1 Scope

Add the following text in place of the sentence "SAFETY HAZARDS resulting from ... ":

SAFETY HAZARDS resulting from intended physiological function of *EQUIPMENT* covered by this Standard are not considered. These requirements do not contemplate the investigation of protection against ionizing radiation or radioactive isotopes. Such *EQUIPMENT* is subject to Federal radiation Standards (21CFR Part 1020) promulgated under the Radiation Control for Health and Safety Act of 1968.

New 2.10.100 and 2.10.101

To reflect definitions in the NEC add the following to this sub-clause:

2.10.100 X-RAY INSTALLATIONS (LONG-TIME RATING)

A rating based on an operating interval of 5 minutes or longer.

2.10.101 X-RAY INSTALLATIONS (MOMENTARY RATING)

A rating based on an operating interval that does not exceed 5 seconds.

2.12 Miscellaneous

Add the following definitions:

2.12.100 PATIENT CARE EQUIPMENT

EQUIPMENT intended for use in or likely to be used in the *PATIENT VICINITY*.

2.12.101 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 1.83 m (6 feet) beyond the perimeter of the bed (examination table, dental chair, treatment booth, and the like) in its intended location, and extending vertically 2.29 m (7-1/2 feet) above the floor.

- 2.12.102 An Internationally Harmonized Component Standard is a standard satisfying U.S. national and international safety concerns and may include national deviations (exceptions) which modify the requirements of the relevant internationally recognized safety standard, (such as an IEC/ISO standard). When necessary, due to national safety concerns, the national deviations may include the unique U.S. national safety, regulatory, and legal requirements taken from the relevant nationally recognized safety standard (such as an ANSI/UL standard).

3 General requirements

To explain the intended method of evaluation of components add the following new sub-clauses to this clause:

3.100 Components

- 3.100.1 In addition to compliance with this standard, the following components shall meet nationally recognized standards (such as ANSI/UL standards) or internationally harmonized component standards:

- a) Printed wiring boards
- b) Lithium batteries
- c) Optical isolators
- d) Wiring and Tubing
- e) CRTs > 5 inches

Exception: Items a), c) and d) are exempt from this requirement if they are connected totally in an SELV circuit limited to 15 W, or less, maximum available power and whose failure will not result in a *SAFETY HAZARD*.

3.101 Primary Circuit Components

- 3.101.1 In addition to compliance with this basic standard, components in the primary circuit up to the isolation transformer shall meet nationally recognized standards (such as ANSI/UL standards) or internationally harmonized component standards.

- 3.102 Supplement A tabulates UL component Standards covering components as specified in sub-clauses 3.100.1 and 3.101.

6 Identification, Marking and Documents

Add the following requirements to this Clause:

The text of the marking prefaced with an upper case signal word "CAUTION", "WARNING", or "DANGER", shall consist of upper and lower case letters, in English, that comply with the following:

- a) All words comprising the text of the marking, excluding the signal word, shall be in letters not less than 1.6 mm (1/16 inch) high, based upon upper case,
- b) The signal word shall be in letters at least 2.8 mm (7/64 inch),
- c) The letters shall be in contrast color to the background. Letters that are raised or indented and do not have a contrasting color to the background are not acceptable.

EQUIPMENT capable of emitting ionizing radiation shall bear a warning statement concerning the risk of injury to persons from X-radiation. The control panel containing the main power switch shall bear the warning statement, legible and accessible to view: "WARNING: This X-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."

If a manufacturer produces or assembles *EQUIPMENT* at more than one factory, the *EQUIPMENT* shall have a distinctive marking – which may be in code – by means of which it may be identified as the product of a particular factory.

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.

6.2

- l) (Wiring compartment marking)

Replace 75• C by 60• C.

6.6 To reflect agreement with ANSI/NFPA 99, Replace 6.6 a) with the following:

- a) Identification of the content of gas cylinders used in medical practice as part of electrical *EQUIPMENT*, if accomplished through color coding, shall be in accordance with the color coding requirements of ANSI/NFPA 99. See also sub-clause 56.3a.

6.8 Cord-connected *EQUIPMENT* shall be provided with instructions to indicate the type of attachment plug that should be used for connection to the alternate voltage.

10.2.2 Power supply

a)

To reflect agreement with the NEC, replace the reference to "500 V" with "600 V" in both locations in the text associated with the first dash, and in the text of the last dash of this sub-clause, add "and the NEC" after the reference to "IEC Publication 364".

14 Requirements related to classification

To reflect agreement with the NEC add the following requirement to this Clause:

– All *FIXED EQUIPMENT* and *PERMANENTLY INSTALLED EQUIPMENT* shall be *CLASS I EQUIPMENT*.

18 Protective earthing, functional earthing and potential equalization

Add the following to this Clause:

- m) All parts of X-ray *EQUIPMENT* operating at over 600 V ac, 850 V dc, or 850 V peak shall be enclosed within protectively earthed (grounded) enclosures. The connections from the high-voltage *EQUIPMENT* to X-ray tubes and other high-voltage components shall be made with high-voltage shielded cables intended for operation at over 600 V ac, 850 V dc, or 850 V peak.
- n) All accessible non-current carrying conductive parts, likely to become energized, of X-ray and associated *EQUIPMENT* (controls, tables, transformer tanks, shields of shielded cables, tube heads and supports, etc.) shall be protectively earthed (grounded) in accordance with Clause 18.

19 Continuous LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS

In addition to the Clause 19 requirements, the following requirements apply, except that X-ray EQUIPMENT and EQUIPMENT covered by note 3) on Table IV of the base standard need only comply with Clause 19 requirements.

The leakage currents specified in Tables 19.100 and 19.101 are not to be exceeded when the *EQUIPMENT* is tested in accordance with Clause 19 except:

– The *EQUIPMENT* is to be connected to the highest RATED MAINS VOLTAGE ¹⁾

– The footnotes in Tables 19.100 and 19.101 apply.

1) Minimum 120 VAC and 240 VAC for *EQUIPMENT* with marked voltage ranges of 105-120 VAC and 210-240 VAC respectively.

Table 19.100 – ^{a)} Patient care equipment maximum leakage current (microamperes)

Earth and Enclosure ^{b)}	
Class I ^{c)} EQUIPMENT	Class II ^{d)} EQUIPMENT
AC or DC RMS	AC or DC RMS
300 (500) ^{e)}	150 (250) ^{e)}
a) See 2.12.100 of UL deviations – definition of <i>PATIENT CARE EQUIPMENT</i>. b) Metal enclosure or metal foil over insulating material as per sub-clause 19.4 g 5). c) Measured with and without the loss of <i>PROTECTIVE EARTH</i> with the supply conductors normal or reversed. d) Measured with supply conductors normal and reversed. When measured with either <i>BASIC</i> or <i>SUPPLEMENTARY INSULATION</i> effectively bypassed, the allowable leakage current is twice that shown. e) <i>EQUIPMENT</i> with all surfaces, likely to be contacted by someone in the <i>PATIENT VICINITY</i> (2.12.101), constructed of nonconductive materials may comply with the bottom number (in parentheses) instead of the top one. If the <i>EQUIPMENT</i> is marked or identified in the installation instructions for use on a center-tapped, 240 V, single phase circuit, the leakage current may be measured from a center-tapped circuit.	

Table 19.101 – Nonpatient EQUIPMENT maximum leakage current (microamperes)

Earth and Enclosure ^{a)}	
Class I EQUIPMENT ^{b)}	Class II EQUIPMENT ^{c)}
AC or DC RMS	AC or DC RMS
500	250
a) Metal enclosure or metal foil over insulating material as per sub-clause 19.4 g 5). b) Measured with all combinations of: – <i>PROTECTIVE EARTH</i> connection connected or not connected – One supply connection, at a time, connected or not connected – <i>SUPPLY CONNECTIONS</i> normal or reversed c) Measured with all combinations of: – One supply connection at a time connected or not connected – <i>SUPPLY CONNECTIONS</i> normal or reversed. – When measured with either <i>BASIC</i> or <i>SUPPLEMENTARY INSULATION</i> effectively bypassed, the acceptable leakage current is twice that shown. If the <i>EQUIPMENT</i> is marked or identified in the installation instructions for use on a center-tapped, 240 V, single phase circuit, the leakage current may be measured from a center-tapped circuit.	

22 Moving parts

Add the following requirement to this Clause:

– Where a risk of injury to the patient or operator can occur as a result of a moving part, in addition to the other requirements in this clause, there shall be end stops or other mechanical means to act as the ultimate travel limiting means (example: the end points of a movable ceiling suspension).

End stops or other mechanical means shall have the mechanical strength to withstand the conditions of maximum intended loading and reasonably foreseeable abusive operation.

Compliance with these requirements shall be determined by the following tests.

The EQUIPMENT shall be loaded with (1) the maximum intended load, (2) unloaded, or (3) loaded to any intermediate level that is likely to provide the most severe test result. The moving part is to be driven against each end stop or other mechanical means for the number of cycles and conditions shown in the following Table. The end stops or other mechanical means required shall be capable of performing their intended function upon completion of the following tests.

Table 22.100 – Number of Test Cycles

Construction	No. Cycles	Test Conditions
Motor driven		
1. No limit system provided ^a	6000	Run at maximum speed
2. Non-independent limit system or systems provided ^{a,b}	50	Defeat all switches simultaneously, and run at maximum speed
3. Two or more independent limit systems ^{a,b}	No Test	
Manually driven or manually driven power assisted	50	Run at any speed, including reasonable overspeed considered to be abusive
^a A limit system consists of all components required to stop motion, for example, it may consist of (1) a limit switch, (2) sensing circuits, and (3) related mechanical actuating mechanism. ^b To qualify as an independent limit system, each system shall, in addition to the criteria in note ^a, comply with both of the following: 1. The system is capable of de-energizing the motor(s) directly; that is, the switch or motor controller circuit interrupts the motor's rotor or stator current, or both, and 2. The system provides a means by which a malfunction of one limit system is made obvious to the operator. This may be an audible, visual or otherwise discernible indicator.		

22.4

In addition to "PATIENT" add "or OPERATOR" to the requirement in this sub-clause.

22.7

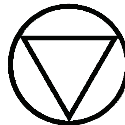
Add the following requirements to this sub-clause:

– A device intended to be designated as an emergency off, emergency switching or stopping device shall comply with each of the following:

- a) The device shall be constructed in accordance with all of the following:

- 1) The device shall have an actuator, colored red as per 6.7, designed to be distinctive and easily identifiable from that of other controls, and that will open the circuit(s) when actuated,
 - 2) The device, once actuated, shall maintain the *EQUIPMENT* in the off (open) condition until a deliberate action, different from that used to actuate it, is performed, and,
 - 3) Actuators shall be readily accessible to the OPERATOR and positioned at each operating station.
- b) An actuator that interrupts/opens mechanical movements shall be marked with the word "STOP" or with symbol 5110 from IEC 878 (shown below) on or immediately adjacent to, the face of the actuator and shall be marked in compliance with all the requirements (permanence, letter height, and the like) for cautionary markings in Clause 6.

Graphical symbol 5110: Stop (of Action)



S4018

Exception: A switch need not be marked with the word "STOP" or the equivalent symbol, if the switch interrupts all movements, including the generation of X-rays and any other condition that could result in a risk of injury.

– The emergency switching means, in the first dashed paragraph shall be separate and independent of the intended movement control.

28.3 Suspension system with *SAFETY DEVICES*

Add the following to this sub-clause:

To comply with the requirements of sub-clause 28.3, *EQUIPMENT* relying on a *SAFETY DEVICE* shall additionally be tested as follows:

A chain, cable, band, spring, belt, jack screw nut, pneumatic or hydraulic hoses, or the like, employed to support a load, is to be defeated by any convenient means, thereby causing the maximum normal load to fall from the most adverse position permitted by the construction of the EQUIPMENT. There shall be no evidence of damage to a safety catch or other restraining means that would affect its ability to perform its intended function. If it cannot be demonstrated that a safety catch or other restraining means can perform its intended function after the test, a permanent marking shall be provided in accordance with paragraph below. If the load is a PATIENT, the load is to be as specified by the manufacturer, or 1.33 kN or 136 kgf (300 lbf) if not specified.

The *EQUIPMENT* shall be marked with signal word "WARNING" and the following text or the equivalent - "For Continued Protection Against Injury to Persons, Repair or Replace Safety Catch (or specific restraining means, as appropriate) After It Has Been Activated. Refer to Instructions in the Service Manual Provided With the Equipment." The marking shall be readily visible during any approach to servicing or resetting of the safety catch. More than one such marking may be required.

28.4 Suspension systems of metal without *SAFETY DEVICES*

Add the following to this sub-clause:

To comply with the required *SAFETY FACTORS*, the suspensions shall be subjected to a loading test.

The suspension shall be loaded as in normal use with its SAFE WORKING LOAD multiplied by the applicable SAFETY FACTORS. There shall be no damage to structural parts that would create a risk of injury to a PATIENT or OPERATOR. The support system shall be in equilibrium one minute after application of the test load. The test may be conducted on previously untested samples.

28 Suspended masses

Replace the last paragraph (after 28.4) with the following:

Compliance with the requirements of sub-clause 28.3 and 28.4 is checked by test performance, design data and inspection of any maintenance instructions.

Exception: Where the complexity of the system is such that the design data can be reasonably evaluated so as to determine that compliance is met, demonstration of test performance may not be necessary.

SECTION FIVE – PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

Add the following explanation to this Section:

The requirements of sub-clause 29.2 shall be considered when evaluating *EQUIPMENT*. The remaining SECTION FIVE items are considered the responsibility of the proper authorities. See sub-clause 1.1 of the UL Deviations.

SECTION SEVEN – PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER SAFETY HAZARDS

Add the following to this section:

400 Oxygen

400.0 General – These requirements only apply to EQUIPMENT that is normally used or recommended for use with oxygen or oxygen enriched atmospheres and for which no Particular requirements exist that address the EQUIPMENT'S use with oxygen or oxygen enriched atmospheres. Sub-clauses 400.8.1 – 400.8.5 are relevant to installation and the product's end use and can be addressed by their inclusion in the product's operation and installation manual. The manual's reference should cover those details needed to reduce the risk of oxygen related hazards.

400.1 In order to reduce the risk of fire caused by electrical components which might be a source of ignition in oxygen- enriched atmospheres, at least one of the following requirements shall be satisfied in enclosed compartments of EQUIPMENT containing such atmospheres:

– Electrical components shall be separated from compartments in which accumulation of oxygen can occur, by a barrier complying with the requirements of sub-clause 400.2.

– Compartments containing electrical components shall be ventilated according to the requirements of Sub-clause 400.3.

– Electrical components which, in *NORMAL USE* or *SINGLE FAULT CONDITIONS* can be a source of ignition, shall comply with the requirements of Sub-clause 400.4.

Exception: EQUIPMENT that is marked as specified in sub-clauses 400.6 and 400.7 or does not contain an oxygen enriched environment within the EQUIPMENT need not comply with sub-clauses 400.1 – 400.5 and 400.8.1 – 400.8.5.

400.2 Any barrier required under the provision of Sub-clause 400.1 shall be sealed at all joints and at any holes for cables, shafts or for other purposes.

Compliance is checked by inspection and, if applicable, by the compliance test described in the General Standard, Sub-clause 40.5, for enclosures with restricted breathing.

The internal overpressure of 4 hPa specified in Sub-clause 40.5 of the General Standard is not applicable when, in *NORMAL CONDITION*, a pressure difference exists between the spaces separated by the barrier. In such cases the compliance test of Sub-clause 400.3 of this Particular Standard applies.

400.3 The ventilation required under the provisions of Sub-clause 400.1 shall be such that the oxygen content in the compartment containing electrical components shall not exceed 4 per cent volume above the ambient level. If this requirement is met by forced ventilation a ventilation failure alarm shall be provided.

Compliance is checked by the following test:

The oxygen concentration is measured under the following conditions and for such a period that the highest possible concentration of oxygen occurs:

– *SINGLE FAULT CONDITION.*

– *The oxygen flow shall be equal to the maximum set-point value in NORMAL USE.*

– *Selection of the least favorable control settings.*

– *Mains supply voltage deviations of ± 10 percent.*

The measurements shall be repeated after 18 h during which the time the supply voltage shall have been switched off and the gas supply shall have remained on.

– *The rate of air exchange in the test room shall be between 3 and 10 times per hour.*

- 400.4 Electrical circuits which can produce sparks or generate increased surface temperatures or which might otherwise be a source of ignition shall be so designed that no ignition occurs. At least the following requirements shall be satisfied in *NORMAL CONDITIONS* and *SINGLE FAULT CONDITIONS*:

The product of the value of the rms no load voltage and the rms value of the short circuit current shall not exceed 10 VA.

– The surface temperature of components shall not exceed 300°C.

Compliance is checked by the following test:

Voltages and currents in steady-state condition are measured or calculated and surface temperatures shall be measured in NORMAL CONDITIONS and SINGLE FAULT CONDITIONS.

Note – Short- and open-circuiting of resistors, capacitors and inductances complying with the requirements of IEC Publication 65, fourth edition, Clause 14, shall not be considered as *SINGLE FAULT CONDITIONS*.

- 400.5 External exhaust gas outlets shall be located at least 20 cm from any electrical component mounted on the outside of the *EQUIPMENT* which can spark in *NORMAL CONDITION* or *SINGLE FAULT CONDITION*.

Compliance is checked by inspection and/or measurement.

- 400.6 Hospital beds intended for use with oxygen administering *EQUIPMENT* 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 administering equipment," or similar wording shall be included where applicable (see sub-clause 400.4). The letter height shall not be less than 2.8 mm (7/64 inch) for the word "CAUTION" and not less than 2.4 mm (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.

- 400.7 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 2.8 mm (7/64 inch) for the word "CAUTION" and not less than 2.4 mm (3/32 inch) for the remainder of the notice.

400.8 Installation Related Items

- 400.8.1 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 and burn rapidly in high concentrations of oxygen. Accordingly, for safety it is necessary that all sources of ignition be kept away from *EQUIPMENT*, such as an incubator, and preferably out of the room in which it is being used. "NO SMOKING" signs should be prominently displayed.
- 400.8.2 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*.
- 400.8.3 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.
- 400.8.4 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.
- 400.8.5 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 operating and delivery rooms. Refer to Article 517 of the ANSI/NFPA 70, National Electrical Code, for the use of flammable anesthetics.

42 Excessive temperatures

Add the following requirements to this Clause:

Insulating systems (such as on transformers, motors, solenoids, inductors and the like) where the measured temperatures exceed Class A (105°C) limits during normal use and normal condition shall comply with the requirements in the Standard for Systems of Insulating Materials - General (UL 1446).

52.4.1

Editorial: Replace the reference to "Table XII" in the text adjacent to the third dash with "Table XI".

Replace the second paragraph of this sub-clause with the following text:

The requirements of sub-clause 52.1 and the corresponding tests shall not be applied to components when their construction or the supply circuit limits the power dissipation in *SINGLE FAULT CONDITION* to 15W or less.

Editorial: Replace the information in the first column, lower box, adjacent to the first dash (-) with the following text:

- if impedance-protected, maximum value.

54 General

Editorial: Replace the second sentence of the third paragraph with the following text:

The requirements of this Section are not to be considered the only means of achieving the required degree of safety and the term "shall", where used, should be understood accordingly.

55 ENCLOSURES and covers

Add the following requirement to this Clause:

The following requirements are additionally used to evaluate polymeric enclosures and covers:

Conductive coatings applied to nonmetallic surfaces shall comply with the applicable requirements in the Standard for Polymeric Materials – Use in Electrical Equipment Evaluations, UL 746C, unless it can be determined by investigation that flaking or peeling of the coating does not result in the reduction of spacings or the bridging of live parts that may present a risk of injury.

– Flame Spread – An external surface of combustible material having an area of more than 9.47 sqM (100 sq-ft) or a single dimension of 3.7 M (12 feet) – including a diagonal – shall have a flame spread rating of 75 or less when subjected to the Steiner Tunnel Test in ASTM E 84, Test Method for Surface Burning Characteristics of Building Materials).

An external surface of combustible material having an area of more than 4.74 sqM (50 sq-ft) but not exceeding 9.47 sqM (100 sq-ft) shall have a flame spread rating of 75 or less when subjected to the radiant panel test (ASTM E 162, Test Method for Surface Flammability of Materials Using a Radiant Heat Energy Source), or the steiner tunnel test (ASTM E 84, Test Method for Surface Burning Characteristics of Building Materials).

Flammability, Mechanical Abuse and Mold Stress Relief - In addition to the other requirements in this Standard, flammability, mechanical abuse and mold stress tests shall be conducted. Polymeric enclosures and covers shall comply with the requirements for resistance to impact and drop as indicated below, and the requirements for mold stress release distortion, in the Standard for Polymeric Materials – Use in Electrical Equipment Evaluations, UL 746C. The minimum flammability rating for *TRANSPORTABLE EQUIPMENT* shall be V-2, and V-0 for *FIXED EQUIPMENT* or *STATIONARY EQUIPMENT*.

Exception for Flammability. Enclosures housing only circuits supplied from a source which is separated from the SUPPLY MAINS by one of the methods described in Subclause 17g, and where the available power does not exceed 15 W.

The top, sides, and front of the enclosure shall withstand a single impact of 6.78 N•m (5 ft-lb) without exposing live electrical components or connections or developing a risk of electric shock, fire, or injury to persons. The impact applied is to be obtained from a solid, smooth, steel sphere 50.8 mm (2 inch) in diameter and weighing approximately 0.535 kg (1.18 lb). 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 6.78 N•m (5 ft-lb). 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.

An appliance intended to be hand-held or hand-guided shall withstand a drop test without exposing live electrical components or connections or developing a risk of electric shock, fire, or injury to persons. Each of three samples of the appliance is to be dropped three times from a height of 1.22 m (4 ft) onto an 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.

– See also Clause 16, Clause 21 and sub-clause 59.2

56.3 Connections – General

a) Construction of connectors

Add the following requirement to this sub-clause:

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.

In addition to the above requirement, 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 to make contact with the live parts of a power receptacle outlet or separable cord set.

57 MAINS PARTS, components and layout

Add the following requirement to this Clause:

General – Permanently connected *EQUIPMENT* shall have provision for the connection of one of the wiring systems that is in accordance with the National Electrical Code, ANSI/NFPA 70.

Exception: Fixed and stationary X-ray *EQUIPMENT* supplied from a branch circuit rated at 30 A or less, and *EQUIPMENT* that is not strictly portable but obviously is intended to be stationary, may be acceptable if provided with a length of attached hard service flexible cord - such as Type S, or the equivalent, for supply connection.

57.2 MAINS CONNECTORS, APPLIANCE INLETS and the like

Add the following new requirements to this Sub-clause:

For patient care equipment, where a "Hospital Grade" or "Hospital Only" MAINS PLUG exists for the particular electrical rating in question, the *MAINS PLUG* of non-PERMANENTLY INSTALLED *EQUIPMENT* with a protective earth connection shall comply with the requirements for a hospital grade attachment plug (mains plug) or the non-hazardous location locking type designated "Hospital Only" as specified in the Standard for Attachment Plugs and Receptacles UL 498 and the product shall comply with the following:

Cord connected *EQUIPMENT* employing "Hospital Only" or "Hospital Grade" attachment plugs 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 *EQUIPMENT* itself or on a tag attached to the supply cord of the *EQUIPMENT*.

– For *EQUIPMENT* intended for radiography and in which the plug constitutes the control-disconnecting means, the attachment plug shall be acceptable for a current not less than 50 percent of the maximum current input to the *EQUIPMENT* for radiographic settings.

– Except for X-ray *EQUIPMENT*, the attachment plug shall be acceptable for use with a current not less than 125 percent of the rated current, when measured at a voltage equal to the rated voltage of the *EQUIPMENT* (corresponding to the plug cap configuration). If the *EQUIPMENT* 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 *EQUIPMENT* shall be acceptable for the voltage for which the *EQUIPMENT* is configured to be connected when shipped from the factory.

– 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 *EQUIPMENT* so that any of the following devices used in the primary circuit shall be connected in an ungrounded side of the line: the center contact of an edison-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 application, it may be placed in the grounded side of the line.

57.3 POWER SUPPLY CORDS

Replace the text of b) and c) of this sub-clause with the following requirements:

b) Types

A *DETACHABLE POWER SUPPLY CORD* for non-*PERMANENTLY INSTALLED EQUIPMENT* (cord-connected *EQUIPMENT*) shall be of a type that can be shown to be unlikely to become detached accidentally, unless it can be shown that detachment will not constitute a *SAFETY HAZARD* to a *PATIENT* or *OPERATOR*.

A *POWER SUPPLY CORD* shall comply with the following requirements:

- 1) 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. It shall be constructed in accordance with the Standard for Flexible Cords and Fixture Wire (UL 62) or the equivalent Appliance Wiring Material (AWM).
- 2) The flexible cord shall be not smaller than No. 18 AWG, and the mechanical serviceability shall be
 - i) not less than that of Type SJE, SJT, SJO, or equivalent cord, for *TRANSPORTABLE EQUIPMENT* such as hospital beds and instrument carts; and
 - ii) not less than that of Type SV for light-duty *EQUIPMENT* where extreme flexibility or weight is a factor. *EQUIPMENT* weighing 567 g (1-1/4 lb) or less would qualify for consideration.
 - iii) An oil-resistant cord is required if the *EQUIPMENT* is likely to be subjected to grease or oil.

57.5 MAINS TERMINAL DEVICES and wiring of MAINS PARTS**b) Arrangement of MAINS TERMINAL DEVICES**

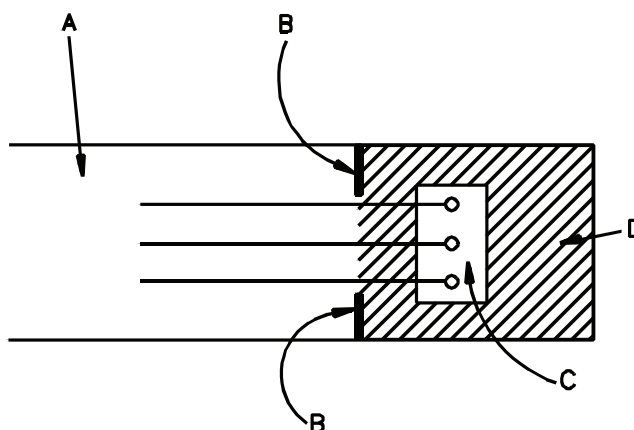
Add the following requirements to this Sub-clause:

– If leads are provided for connection to the branch circuit and one end of the lead terminates in a wire binding screw, a terminal block, or the like within the *EQUIPMENT*, the free end shall be in a compartment separate from that containing the wire binding screws, terminal block, or the like. This may be in a separate wiring compartment provided as part of the *EQUIPMENT*, a separate recessed mounted splice (junction) box described in the installation instructions, or the like. See the below figure.

– The free length of a lead inside an outlet box or field-wiring compartment shall be 152 mm (6 inches) or more.

Exception: A lead may be less than 152 mm (6 inch) in length if it is evident that the use of a longer lead might result in a risk of fire or electric shock.

Figure for sub-clause 57.5, b) of U.L. DEVIATIONS



- A – Field Wiring Compartment**
- B – Barrier**
- C – Terminal Block Not Intended for Field Wiring**
- D – Factory Wire Compartment**

S2274

57.9.1 Overheating

(Transformer Short Circuit and Overload): Add the following explanation to this sub-clause:

For an electronic circuit used to comply with the requirements of this sub-clause a fuse or manual reset protector may be left in the circuit. If such components have not been investigated (such as those not investigated for calibration of opening for time vs. current or temperature) and functions to terminate the test, the test shall be repeated two additional times. For the overload test the maximum loading not resulting in the circuit switching to its limiting mode is to be used until the ultimate results. This requirement is not an alternative to enable the use of fuses, breakers, and the like that do not comply with the U. S. Deviation to Clause 3.

A positive temperature coefficient resistive device (PTC) is to be left in the circuit for the short circuit test until ultimate results. For the overload test the maximum loading not resulting in the PTC switching to its high resistance mode is to be used until ultimate results are known.

58.2

Add the following requirements to this sub-clause:

Soldering alone shall not be used. Connections shall be made mechanically secure as well as being soldered.

59.1 Internal wiring

f) Applicable requirements

Replace the requirement contained in sub-section f) with the following:

The installation of connecting cords between *EQUIPMENT* parts shall meet the requirements of the NEC, as applicable.

In addition to the requirements in this standard, a cable used as external interconnection between units shall be as follows:

- 1) If exposed to abuse, the cable shall be Type SJT, SJTO, SJO, ST, SO, STO, or equivalent flexible cord or similar multiple-conductor appliance-wiring material such as computer cable.
- 2) If not exposed to abuse, the cable shall be as indicated in item 1) above or shall be:
 - i) Type SPT-2, SP-2, or SPE-2, or equivalent,
 - ii) Type SVT, SVTO, SVE, or equivalent flexible cord or similar multiple-conductor appliance-wiring material, or

- iii) An assembly of insulated wires each with a nominal insulation thickness of 0.8 mm (1/32 inch) or more, enclosed in acceptable insulating tubing having a nominal wall thickness of 0.8 mm (1/32 inch) or more.

Exception: Interconnecting cables operating at a voltage not exceeding 25 Vac (RMS) or 60 Vdc or peak supplied from a source which is separated from the SUPPLY MAINS by one of the methods described in Subclause 17g.

If exposed to abuse, flexible cord or cable is considered protected from abuse from a rolling table or similar *EQUIPMENT* at a time when such *EQUIPMENT* is likely to be used in the vicinity of the *EQUIPMENT* if one or more of the following conditions are met:

- a) The entire cord or cable is 914 mm (3 ft) or more above the floor.
- b) The cord or cable is guarded from contact by such *EQUIPMENT*. A cord or cable that may touch the floor under any condition of intended use is to be considered exposed to abuse, or
- c) The entire cord or cable, which may be a retractable helically coiled type constructed so as to retain its retractability, supplies a hand-held device. The cord length is limited so that the unstretched cord does not contact the floor while the control device is in the stored position or while the control device is positioned 610 mm (2 ft) above the floor.

Add the following Clause:

600 Separate Power Units

600.1 General

A separate power unit (adapter, power supply, battery charger, or the like) employing a separable connector for supplying the *EQUIPMENT* shall be, (a) packaged with the *EQUIPMENT*, or , (b) be referenced by the following or equivalent marking on the *EQUIPMENT*:

"_____ (equipment descriptive name) _____ Model _____." "Use only with (manufacturer's name or equivalent) Model _____ Adapter (power supply, battery charger, or the like)", or "Use only with adapters (or the like) noted in the instruction manual." If a reference is made to a manual, the manual shall be provided with the *EQUIPMENT* and shall clearly tabulate the adapters (or the like) with which the *EQUIPMENT* is intended to be used by manufacturer's name and model number. Also, the *EQUIPMENT* shall be marked with Symbol 14 of Table DI in Appendix D, if a reference is made to a manual.

600.2 Direct Plug-In Units

These requirements supplement the requirements in this Standard.

600.2.1 Construction

A direct plug-in unit shall comply with the mechanical assembly, enclosure, input connections, accessibility of live parts, and grounding requirements specified in UL 1310, the Standard for Class 2 Power Units.

600.2.2 Performance

A direct plug-in unit shall comply with the direct plug-in requirements for blade secureness, security of input contacts, and abuse tests specified in UL 1310, the Standard for Class 2 Power Units.

During the tests specified in Sub-clause 57.9.1 a) and 57.9.1 b), the external enclosure temperature rise of a direct plug-in unit shall not exceed 65°C, except a temperature rise of 125°C is acceptable if the unit permanently opens within one hour after initiation of the test.

600.2.3 Markings

A direct plug-in unit provided with a mounting tab shall be marked in accordance with the requirements for semipermanent mounted units specified in UL 1310, the Standard for Class 2 Power Units.

FIG. 18 – Measuring Circuit for the *ENCLOSURE LEAKAGE CURRENT* of *EQUIPMENT*

Editorial: In order to be consistent with Figure 19, replace the script "S5" at the top of the Figure with "S9".

Legends of Symbols for FIGS. 10 to 27

Editorial: Add to the list of legends the following text.

R Impedance for protection of user of test apparatus.

MANUFACTURING AND PRODUCTION TESTS

Note – Clauses 700 through 702 are informative and are not to be considered an integral part of the U.S. Deviations.

700 Production-Line Dielectric Voltage-Withstand Test

700.1 Each appliance shall withstand without an indication of unacceptable performance, as a routine production-line test, the application of a 40 – 70 Hz potential or a d.c. potential of 1.414 times the stated a.c. value between:

- a) The primary wiring, including connected components, and accessible dead metal parts that are likely to become energized, and
- b) Primary and accessible low voltage (42.4 volt peak or less) metal parts, including terminals, and, where applicable
- c) Primary circuits and patient-connected circuits.

700.2 The production-line test shall be in accordance with either condition A or condition B of Table 700.1.

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

Table 700.1
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.				

700.4 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.

700.5 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 700.1. 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.

700.6 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.

700.7 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.

700.8 In addition, 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 1) has a sinusoidal waveform, 2) has a frequency that is within the range of 40 – 70 Hz, and 3) has 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, or is a d.c. input.
- 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.

700.9 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.

700.10 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.

701 Production-Line Grounding-Continuity Test

701.1 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.

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

701.3 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 701.1.

702 Single Suspension Test

702.1 In addition to the requirements in sub-clause 28.4, a single suspension without a *SAFETY DEVICE* construction shall be subject to a production-line loading test.

702.2 *Each production unit's single suspension shall be subjected to a loading test as described in sub-clause 28.4 of the deviations with a load of 1.0 multiplied by its SAFE WORKING LOAD.*

Subclause 702 relocated from 28.4 of US Deviations effective October 24, 1997

SUPPLEMENT A**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

Attachment Plugs and Receptacles, Electrical – UL 498
Cathode-Ray Tubes, Implosion-Protected, for Television-Type Appliances – UL 1418
Circuit Breakers, Molded-Case, and Circuit-Breaker Enclosures – UL 489
Conduit, Electrical Flexible Metal – UL 1
Conduit, Electrical, Liquid-Tight Flexible Steel – UL 360
Controls, Limit – UL 353
Cord Sets and Power-Supply Cords – UL 817
Determination of Sharpness of Edges on Equipment – UL 1439
Flexible Cord and Fixture Wire – UL 62
Fuseholders – UL 512
Ground-Fault Circuit Interrupters – UL 943
Lampholders, Edison-Base – UL 496
Lithium Batteries – UL 1642
Motors, Impedance-Protected – UL 519
Optical Isolators – UL 1577
Outlet Boxes and Fittings, Electrical – UL 514
Outlet Boxes, Flush-Device Boxes and Covers, Nonmetallic – UL 514C
Printed-Wiring Boards, Electrical – UL 796
Protectors for Electric Motors, Thermal – UL 547
Protectors, Supplementary, for Use in Electrical Equipment – UL 1077
Switches, Clock-Operated – UL 917
Switches, Snap, General-Use – UL 20
Switches, Special-Use – UL 1054
Tape, Insulating – UL 510
Terminals, Quick-Connect – UL 310
Thermal Cutoffs for Use in Electrical Appliances and Components – UL 1020
Tubing, Extruded Insulating – UL 224
Wire and Cables, Thermoplastic-Insulated – UL 83
Wire Connectors and Soldering Lugs for Use With Copper Conductors – UL 486A
Wire Connectors for Use With Aluminum Conductors – UL 486B

APPENDIX B

RATIONALE STATEMENT – GENERAL

The cover document for UL's IEC 601 based standard has been edited for content. The attached represents the rationale for including the remaining deviations to the basic IEC 601 text.

For each deviation the rationale is stated in the following pages. Where "editorial" is mentioned no further explanation is given as there is no deviation for the intent of the basic standard and the reason is self-explanatory. Where "NEC" (National Electrical Code) is mentioned no further explanation is given as these deviations are considered of critical importance in installation compatibility, building wire sizing, branch circuits overcurrent levels, etc. for U.S. located applications.

1.1 Scope

This is an explanation of UL's procedures for handling certain types and/or aspects of equipment and for handling equipment not envisioned (or existing) at the time the standard was written. Legal aspects are taken into consideration here as the U.S. legal system differs from most of the legal systems in other countries.

New 2.10.100 *LONG–TIME RATING #*

NEC

New 2.10.101 *MOMENTARY RATING #*

NEC

- These will be removed from this document when incorporated into the particular standards as they become covered.

2.12 Miscellaneous

(Definitions)

PATIENT VICINITY

By introducing this definition the types of equipment subject to the 300 micro–ampere leakage current requirement can be reduced as only equipment intended for use in the patient care vicinity need comply with this requirement.

3 General requirements

A significant part of the standards development effort has been devoted to refining the component handling procedures. A compromise was sought which would facilitate the component acceptance aspects while still fulfilling industry's original request for world-wide acceptance of the standard. A component handling section has been incorporated in the Cover Document. While this information is considered part of the standard, the determination of compliance with the component requirements is a certification issue which is stated in the following paragraphs.

Evidence of compliance with UL component standards will be the appropriate UL mark. Evidence of compliance with the IEC component standards will be any of the marks of the "known" agencies, without UL follow-up. A "known" agency is one with which UL is knowledgeable about their testing and certification procedures, as described by internal guidelines. The "known" agencies include but are not necessarily limited to the following, at this time:

BSI (Britain)	KEMA (Netherlands)	SEV (Swiss)
DEMKO (Denmark)	NEMKO (Norway)	UTE (France)
IMQ (Italy)	SEMKO (Sweden)	VDE (Germany)
OVE (Austria)	CEBEC (Belgium)	TUV (Product Service) (Germany)

As UL's experience with these and other agencies develops, modifications to this list will be made.

6 Identification, marking and documents

In the U.S. legal system the concept of "failure to warn" has historically proved to be an area associated with negligence if not addressed. Therefore, the letter height and legibility criteria should be no less than previously accepted. The X-radiation marking will be removed when the particular standards are adopted. The long-time and momentary rating markings are for NEC reasons concerning conductor sizing. The remaining two paragraphs are self-explanatory.

6.2

l) (Wiring compartment marking)

The IEC 601 standard permits a 75°C temperature (normal condition) in wiring compartments. As 60°C rated building wiring is still permitted in North America, the measured maximum value should be reduced to 60°C.

6.6

a) (Color Coding Marking)

Color coding may be employed as a supplementary means of identification only; however, to reduce the risk of mis-indentification and resulting improper connections, any color coding used needs to be in accordance with U.S. National Codes for medical equipment used in the U.S. market, such as the CGA-9 color coding scheme specified ANSI/NFPA 99.

10.2.2 Power Supply

a)

NEC

14 – Requirements related to Classification

NEC

18 – Protective Earthing, etc.

These additions (M and N) will be moved to the X-Ray particular standards when they are adopted; these are NEC related.

19 – Continuous Leakage and Patient Aux. Currents

The present US position on leakage current is as stated in the ANSI/AAMI Safe Current Limits (SCL) and ANSI/NFPA 99 Health Care Facilities Standards. Any departure from these limits should be with the agreement of those experts responsible for the establishment and maintenance of these ANSI Standards. UL believes that the safe current limits should be based on technical factors only and any departure from these limits should be accomplished through the existing balloting procedures of AAMI and NFPA.

UL cannot promote the change in leakage current limits to those favored by certain industry segments, due to the nature of the leakage current issue. It should also be noted that not all industry representatives favored a move to the IEC values.

UL discussed leakage current limits for medical electrical equipment with the Chief of the Medical Electronics branch of the FDA. It had been suggested to UL that FDA was in full support of the IEC leakage current limits. The FDA Chief indicated that the FDA had not taken a position on ANSI versus IEC leakage current limits. However, the FDA does favor harmonization with IEC standards, in general. The FDA Chief was unaware of the activities going on within NFPA and AAMI with regard to leakage currents, but he believes that those organizations would ultimately move toward IEC limits and resolve the difference between the current ANSI and IEC limits.

UL has incorporated decisions made as a result of the recent activity within the ANSI/NFPA 99 and ANSI/AAMI groups into this Standard. See the UL Deviations to the values in Clause 19 of IEC 601-1.

19.4 Tests

a)

Editorial

22 Moving Parts (including 22.4 and 22.7) and 28 Suspended Masses (including 28.3 and 28.4)

These additions were developed approximately 10 years ago based on the existing IEC 601–1 requirements and on then anticipated changes which are reflected in the second (1988) IEC 601–1 edition.

These additions represent the IAC (UL 187) interpretations and desirable requirements taking into account what was written, what was anticipated and single fault acceptance criteria. Inspection of design data alone is not considered the equivalent of actual (physical) test performance. However, by way of compromise the paragraph after 28.4 in the cover document has been modified to include design data in conjunction with test performance. In other words a single test may represent several similar constructions.

SECTION SEVEN – PROTECTION AGAINST ...

400 Oxygen

The safety hazards associated with oxygen are well known. Materials which burn in air (and some that will not) are easily ignited and burn rapidly in high concentration of oxygen. Although some IEC 601 particular standards provide guidelines for equipment evaluations with oxygen not enough information is provided in the part one standard. Common information from part two standards has been compiled and replaces much of the information that had been in the UL cover document under Sub-clause 700 (which has been re-numbered 400 for consistency). As this is all IEC 601 developed information a minimum of conflict/duplicity should be encountered. Once the oxygen guidelines are fully covered by IEC 601 documents, the corresponding information in the UL cover document can be removed. Note that much of the oxygen related "requirements" in the cover document involve warning markings the importance of which was cited in the rationale for Clause 6. For ease of reference the oxygen related information is in one location in the UL cover document.

42 Excessive temperature

It has been UL's experience that insulating system integrity, when exposed to elevated temperatures, depends partly on the interaction of system components. Acceptance criteria consisting of considering individual material characteristics alone is not sufficient to evaluate insulating systems. Please also refer to the IEEE Standard 1–1969, Rev. of AIEE No. 1, 1962 Part II, paragraphs 1 through 4.

54

Editorial

55 ENCLOSURES and covers

Industry concerns over referencing UL 746C as a general requirement are identified as:

1. Difficulty in working with the standard.
2. Availability of materials rated 5V.
3. Most UL 746C concerns not addressed in the IEC 601–1 standard.

Experience has demonstrated the need for these type evaluations in order to determine the integrity of the enclosure. The general references to UL 746C have been removed and only references to UL 746C for conductive coatings, flammability, mold stress and mechanical abuse have been retained. Also the 5V requirement has been replaced with a V–0 one for *FIXED* and *STATIONARY EQUIPMENT*.

In general, building officials have been expressing a concern that large masses of plastic used in electrical appliances should have the same burning characteristics as the room's building products.

It is important to assess the effect of plastic materials on the fire locale of a room fire, external to the product. There are two existing tests that can be used to provide Flame Spread Information, the ASTM E 84, Steiner Tunnel Test and the ASTM E 162 Radiant Panel Test. UL has begun accepting submittals for testing by these methods with the results published in the "plastics" Section of the UL Recognized Component Index.

UL has maintained that a Flame Spread of 75 be applied to products that may be used in a patient care environment. Considering the high probability that this equipment will be used attended in a sprinkler room and used by professional staff, UL suggests that E 162 Radiant Panel be required for surface areas greater than 50 square feet and that the E 84 Steiner Tunnel be required for surface areas greater than 100 square feet or single dimension of 12 feet, in view of the larger amount of fuel available.

Although the above sizes of polymeric parts on medical equipment are rarely encountered, the importance of addressing this issue is evident in view of fire safety concerns.

56.3 Connections – general

a)

This is a basic safety concern prompted by recent accidents involving patient injury, including infant deaths. Patients were accidentally being connected to hazardous circuits while being connected to applied parts of medical equipment, such as an apnea monitor.

57 Mains Parts, components and layout

NEC, enables certain types of installations.

57.2, 57.3 b) and 57.5 b)

NEC

57.9.1 Overheating

This provides an explanation as to how to conduct a test given the use of a PTC.

58.2

This is a basic construction requirement because of its importance and frequency of occurrence in safety related applications.

59.1 Internal Wiring

f)

NEC

600 – Separate Power Units

600.1 General

The additional concerns for separate power units are in one location for ease of reference and actually only involve markings and user manual information not specified in 601–1. These address safety concerns involving using the intended equipment instead of equipment not evaluated for proper use.

600.2, 600.2.1, 600.2.2 and 600.2.3

Direct Plug-In Units.

For NEC and compatibility of use reasons, only the applicable parts of UL 1310 have been referred to for the evaluation of direct plug-in units.

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT

Part 1: General requirements for safety

FOREWORD

- 1) The formal decisions or agreements of the IEC on technical matters, prepared by Technical Committees on which all the National Committees having a special interest therein are represented, express, as nearly as possible, an international consensus of opinion on the subjects dealt with.
- 2) They have the form of recommendations for international use and they are accepted by the National Committees in that sense.
- 3) In order to promote international unification, the IEC expresses the wish that all National Committees should adopt the text of the IEC recommendation for their national rules in so far as national conditions will permit. Any divergence between the IEC recommendation and the corresponding national rules should, as far as possible, be clearly indicated in the latter.

PREFACE

Preface revised December 2, 1994

This Standard has been prepared by Sub-Committee 62A: Common aspects of electrical equipment used in medical practice, of IEC Technical Committee No. 62: Electrical equipment in medical practice.

It forms the second edition of IEC Publication 601-1(1977), entitled "Safety of medical electrical equipment, Part I: General requirements".

The text of this Standard is based on the following documents:

Six Months' Rule	Report on Voting	Two Month's Procedure	Report on Voting
62A(CO)24	62A(CO)25	62A(CO)27	62A(CO)33

Full information on the voting for the approval of this Standard can be found in the Voting Reports indicated in the above table.

The list of IEC, ISO and other publications quoted in this Standard will be found in Appendix L.

In this Standard, the following print types are used:

Requirements, compliance with which can be tested and definitions: in roman type.

Explanations, advice, introductions, general statements, exceptions and references: in smaller type.

Test specifications: in italic type.

TERMS USED THROUGHOUT THIS STANDARD WHICH HAVE BEEN DEFINED IN CLAUSE 2 AND ALSO GIVEN IN THE INDEX: SMALL CAPITALS.

* Rationale (Appendix A).

INTRODUCTION

Aware of the need and the urgency for a General Standard covering electro-medical equipment, the majority of National Committees voted in 1977 in favor of the first edition of IEC Publication 601-1, based on a draft which at the time represented a first approach to the problem.

The extent of the scope, the complexity of the equipment concerned, and the specific nature of some of the protective measures and the corresponding tests for verifying them, had required years of effort in order to prepare this first Standard, which can now be said to have served as a universal reference since its publication.

However, its frequent application has revealed room for improvement, all the more desirable in view of the considerable success that this Standard has enjoyed since its publication. In fact it is now available in a dozen languages and forms an integral part of the National Standards of several countries.

The careful work of revision subsequently undertaken and continued over a number of years has finally resulted in this second edition. This incorporates all the improvements which can be reasonably expected at the present time, taking into account the level of current scientific knowledge. Further developments will remain under constant study.

The change of the title from "Safety of medical electrical equipment, Part 1: General requirements" in the first edition, to "Medical electrical equipment, Part 1: General requirements for safety", allows for subjects other than safety to be dealt with in other parts of IEC Publication 601.

This General Standard contains requirements of safety which are generally applicable to MEDICAL ELECTRICAL EQUIPMENT. For certain types of EQUIPMENT, these requirements are to be supplemented or modified by the special requirements of a Particular Standard. Where Particular Standards exist, the General Standard should not be used alone. Special care is required in applying the General Standard to EQUIPMENT for which no Particular Standard exists.

In some countries EQUIPMENT may only be certified as complying with this Standard if either a Particular Standard or an authorized document based on the General Standard is available stating which clauses are applicable for the EQUIPMENT concerned.

An appendix on "General guidance and rationale" is added (see Appendix A). It is not a part of this Standard and only gives additional information; it can never be the subject of testing.

Clauses and sub-clauses to which there is a rationale are marked with an asterisk*.

The statement "Not used" refers to clauses and sub-clauses in the first edition that have not been retained in this second edition.