

UL187

ADOPTION NOTICE

UL187, "X-Ray Equipment", was adopted on 31-OCT-94 for use by the Department of Defense (DoD). Proposed changes by DoD activities must be submitted to the DoD Adopting Activity: Staff Director, Defense Medical Standardization Board, Fort Detrick, Frederick, MD 21702-5013. DoD activities may obtain copies of this standard from the Standardization Document Order Desk, 700 Robbins Avenue, Building 4D, Philadelphia, PA 19111-5094. The private sector and other Government agencies may purchase copies from the Underwriters Laboratories, Inc., 333 Pfingsten Road, Northbrook, IL 60062-2096.

Custodians:

Army - MD
Navy - MS
Air Force - 03

Adopting Activities:

Other - MB

FSC 6525

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Subjects 2601 (187, 544, 1262, 3101-1)

12 Laboratory Drive
 Research Triangle Park, NC 27709
 February 5, 1997

TO: Electrical Council of Underwriters Laboratories Inc.,
 Subscribers to UL's Standards and Listings Services for
 Medical Electrical Equipment;
 X-Ray Equipment;
 Medical and Dental Equipment; and
 Laboratory Equipment

SUBJECT: Announcement of an Adjunct Certification Service for Programmable Systems in Medical Devices

UL announces the availability of a new adjunct Programmable Systems Certification Service (PSCS) for medical devices. The service is an audit of the process used by the manufacturer in developing medical device software. The software includes that which addresses the delivery of therapy, provides information pertinent to diagnosis and treatment, and performs other safety-related functions. The service is available at the request of:

- Manufacturers that produce medical devices or medical laboratory equipment which are UL Listed or Classified
- Developers of medical device software accessories.

Manufacturers and developers whose product has demonstrated compliance with European or United States requirements would receive a Programmable Systems certificate. Additionally, they would benefit from an established measure of system integrity and a demonstrated level of compliance to published criteria.

Under the Medical Devices Directive (MDD), the Active Implantables Directive (AID), and the draft In Vitro Diagnostics Directive (IVDD), the European Union specifically calls out software as a component of a medical device, or as a medical device itself. To satisfy these directives for programmable medical devices, the European Committee for Electrotechnical Standardization, CENELEC, adopted IEC 601-1-4, Medical Electrical Equipment Part 1: General Requirements for Safety 4. Collateral Standard: Programmable Electrical Medical Systems, as EN 60601-1-4 for programmable electrical medical systems in July of 1996.

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UL will evaluate the development phases of Programmable Systems in medical devices in accordance with the EN 60601-1-4 requirements to meet the European Union's medical devices directives (MDD, AID, and IVDD). Additionally, installation, operation, and maintenance, including software change control, may be covered at the manufacturer's request.

As an initial step in the adjunct Certification Service, UL works in conjunction with the device manufacturer to determine the appropriate Standards Profile. The Certification Service also consists of a review of system documentation and an on-site witnessing of the operational system for compliance with the applicable requirements. UL's *Programmable Systems Certificate* is awarded upon the demonstration of compliance. The certificate describes the programmable system and lists the Standards Profile applied during the review.

Requests or inquiries concerning this new service should be addressed to one of the following individuals.

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UNDERWRITERS LABORATORIES INC.

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Subject 2601-1 (187, 544)

1285 Walt Whitman Road
 Melville, NY 11747
 January 30, 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,
 Medical and Dental Equipment,
 X-Ray Equipment

SUBJECT: Announcement of Medical Electrical Equipment Also Classified In Accordance With
 Specified Medical Standards

UL announces a willingness to accept submittals of Listed or Classified Medical Electrical Equipment for additional Classification in accordance with one or more of the applicable Federal Regulations, sections of Federal Regulations, or US National standards as indicated in the individual Classifications.

This new service will allow manufacturers to have their products evaluated for compliance with performance and regulatory requirements. Upon successful evaluation and testing by UL, acting as an independent third party testing agency, products will be eligible to bear a marking that demonstrates compliance to the indicated standards. Investigations of this type will be covered under the newly established category PIKF, Medical Equipment Classified in Accordance with Specified Medical Standards.

These products must also be investigated in accordance with one of the following UL Safety Standards:

Medical and Dental Equipment, UL 544, (KFBQ)
 Medical Electrical Equipment, UL 2601-1, (PIDF)
 X-Ray Equipment, UL 187, (ZQOR)

Unless otherwise noted, the products covered by this category 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 specified 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.

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Subject 2601-1 (187, 544)

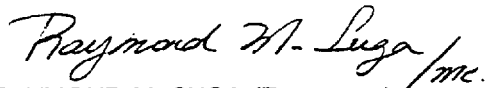
-2-

January 30, 1997

Questions regarding products covered by this category or standards eligible, should be directed to the responsible UL Staff.

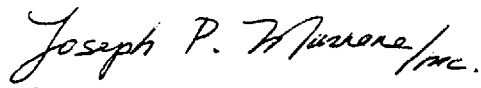
Please see Appendix A of this bulletin regarding designated responsibility for the subject product categories.

UNDERWRITERS LABORATORIES INC.



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SR:PKW

2601BUL.R02;RMS;mc

A P P E N D I X ADESIGNATED 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.

The Industry Advisory Conference (IAC) Chairman for the subject categories 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
KFBQ ^a	Camas	P. Scherwinski	55654
	Melville	J. MURNANE	22247
	Northbrook	G. Gillerman	42545
	RTP	K. Donohue	11645
	Santa Clara	K. Tang	32965
	Japan	L. Jungblut	(03) 5351-1971
	Taiwan	J. Lee	886-2-896-7790

CCN	Office/Subsidiary	Responsible Engineer	Extension
PIDF ^a	Camas	P. Scherwinski	55654
	Melville	J. MURNANE	22247
	Northbrook	G. Gillerman	42545
	RTP	K. Donohue	11645
	Santa Clara	K. Tang	32965

CCN	Office/Subsidiary	Responsible Engineer	Extension
ZQOR ^a	Camas	P. Scherwinski	55654
	Melville	J. MURNANE	22247
	Northbrook	G. Gillerman	42545
	RTP	K. Donohue	11645
	Santa Clara	D. Klinker	32965

^a See previous page for an explanation of the type of equipment covered under this category.



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July 1, 1994

Revision pages for

Standard for

X-Ray Equipment

UL 187, Sixth Edition

Attached to this transmittal notice is a reprinted title page for the Sixth edition of UL 187.

Attention is directed to the note on the title page of this standard outlining the procedure to be followed to retain the approved text of ANSI/UL 187-1994.

Revised and/or additional pages may be issued from time to time.

With the inclusion of the accompanying material, the standard consists of pages dated as shown in the following checklist:

Page	Date
1	April 22, 1993 (Reprinted July 1, 1994)
2 – 52	April 22, 1993
A1	April 22, 1993



Documents

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APRIL 22, 1993
(Title Page Reprinted: July 1, 1994)



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UL 187

Standard for
X-Ray Equipment

First Edition – April, 1949
Second Edition – November, 1957
Third Edition – February, 1971
Fourth Edition – October, 1974
Fifth Edition – July, 1983

Sixth Edition

April 22, 1993

Approval as an American National Standard (ANSI) covers the numbered paragraphs on pages dated April 22, 1993. These pages should not be discarded when revised or additional pages are issued if it is desired to retain the ANSI approved text.

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

Approved as ANSI C33.67-1971, January 20, 1971
Approved as ANSI/UL187-1985, April 2, 1985
Approved as ANSI/UL187-1994, April 13, 1994

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 published set of revision pages.

ISBN 1-55989-401-6

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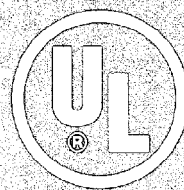
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Standard for Safety

UL 187

● X-Ray Equipment

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Underwriters Laboratories Inc., founded in 1894, is chartered as a not-for-profit organization without capital stock, under the laws of the State of Delaware, to establish, maintain, and operate laboratories for the examination and testing of devices, systems and materials to determine their relation to hazards to life and property, and to ascertain, define and publish standards, classifications and specifications for materials, devices, products, equipment, constructions, methods, and systems affecting such hazards.

UL Standards for Safety are developed under a procedure which provides for participation and comment from the affected public as well as industry. The procedure takes into consideration a survey of known existing standards and the needs and opinions of a wide variety of interests concerned with the subject matter of the standard. Thus manufacturers, consumers, individuals associated with consumer-oriented organizations, academicians, government officials, industrial and commercial users, inspection authorities, insurance interests and others provide input to UL in the formulating of UL Standards for Safety, to keep them consonant with social and technological advances.

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Underwriters Laboratories Inc.®

An independent, not-for-profit organization testing for public safety

April 22, 1993

Standard for

X-Ray Equipment

UL 187, Sixth Edition

Accompanying this transmittal notice is a copy of the Sixth edition of UL 187.

THIS EDITION OF THE STANDARD IS NOW IN EFFECT.

Revised and/or additional pages may be issued from time to time.

Subscribers to UL's services in the area covered by this standard will receive these revised and/or additional pages automatically. Others may receive such pages by subscribing to UL's subscription service for revisions. See UL's CATALOG OF STANDARDS FOR SAFETY for a description of the revision subscription service, the cost of the service for this standard, and ordering information.

APRIL 22, 1993

1

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April 22, 1993

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UL's Standards for Safety are copyrighted to protect UL's publication rights, not to restrict their use in product design or evaluation. See paragraph E of the Foreword.

(1 – 04/22/93 – 04/22/93)

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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 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.

INTRODUCTION

1 Scope

1.1 These requirements cover X-ray equipment for medical, commercial, and industrial use to be employed in accordance with the National Electrical Code.

1.2 These requirements cover enclosed equipment intended for connection to supply circuits of 600 V or less, including controls, high-voltage transformers, tube units, and similarly related components such as foot switches, bucky diaphragms, tables, tube stands, tube-head cooling units, tube protectors, stereo-shifters, cassette changers, spot-film devices, camera stands, photo-tube detectors, timers, and the like, which are directly concerned with the generation and application of X-radiation. X-ray equipment intended for use in a hazardous location is investigated under these requirements and, in addition, is investigated with respect to its acceptability for the particular application.

1.3 These requirements do not cover allied apparatus such as film viewers and similar accessories, which are covered by other applicable requirements. These requirements do not cover equipment in which the radiation is obtained from radioactive isotopes.

1.4 Except for equipment not used for medical or dental diagnosis or treatment — such as cabinet equipment, baggage inspection systems and the like — these requirements do not contemplate the investigation of protection against X-radiation except as noted in 48.1.

1.5 A product that contains features, characteristics, components, materials, or systems new or different from those in use when the Standard was developed, 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 as determined necessary to maintain the level of safety for the user of the product as originally anticipated by the intent of this Standard.

2 Components

2.1 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.

3 Units of Measurement

3.1 If a value for measurement is followed by a value in other units in parentheses, the second value may be only approximate. The first stated value is the requirement.

4 References

4.1 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.

5 Glossary

- 5.1 The terms and associated definitions as used in this document are applicable only to this Standard.
- 5.2 **ACCESSORY** — An optional component part intended for attachment to or use with X-ray equipment, which when attached, affects or modifies the general characteristics of the equipment.
- 5.3 **BREAKDOWN LOAD** — The product of the average calculated tensile strength and the effective cross-sectional area.
- 5.4 **CONTINUOUS PRESSURE SWITCH** — A device so constructed that a closed circuit can be maintained only with continuous pressure applied by the operator.
- 5.5 **CONTROL PANEL** — Any part of the X-ray equipment upon which are mounted the switches, knobs, pushbuttons, and other components necessary for selecting the conditions of operation.
- 5.6 **DEAD METAL** — A metal part not intended to carry current under normal operating conditions.
- 5.7 **DYNAMIC LOAD** — The load caused by acceleration or deceleration of moving masses.
- 5.8 **INTERLOCK** — A device or arrangement whose operation controls the functioning of a second part such that neither part can be operated independently.
- 5.9 **RISK OF INJURY TO PERSONS** — A condition that exists when stationary parts (such as sharp metal edges and projections), moving parts (such as gears, chains, or linkages), falling objects, inadequate mechanical strength of material, or the physical instability of the equipment are such that injury to persons may result.
- 5.10 **SAFETY CATCH** — A device restraining the motion of a suspended mass in case of a breakdown of the suspension means.
- 5.11 **SOURCE ASSEMBLY** — The tube housing assembly with a beam-limiting device attached.
- 5.12 **TUBE HOUSING ASSEMBLY** — The tube housing with X-ray tube installed. It includes the high-voltage or filament transformers or both and other appropriate elements when they are contained within the tube housing.
- 5.13 **TUBE RATING CHART** — The set of curves that specifies the rated limits of operation of the X-ray tube terms of the technique factors.
- Note: Technique factors are the conditions of operation involving the peak x-ray tube potential (kv) and the tube current (mA) or exposure time (seconds) or product of tube current and exposure time (mAs).
- 5.14 **X-RAY TUBE** — An electron tube which is designed for the conversion of electrical energy into X-ray energy.

CONSTRUCTION

6 General

- 6.1 X-ray equipment shall employ materials throughout 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.

7 Frame and Enclosure

7.1 X-ray equipment shall be so formed and assembled that it has the strength and rigidity necessary to resist the abuses to which it is likely to be subjected without increasing the risk of electric shock or fire due to total or partial collapse with resulting reduction of spacings, loosening or displacement of parts, or other serious defects. The enclosure shall be so formed or provided with barriers that the supporting surface is protected against ignition by falling brands or molten material in the event of malfunction of the equipment.

7.2 For unreinforced, flat surfaces in general, cast metal shall be not less than 1/8 inch (3.2 mm) thick, except that malleable iron may be not less than 3/32 inch (2.4 mm) thick and die-cast metal may be not less than 5/64 inch (2.0 mm) thick. Corresponding thicknesses of not less than 3/32, 1/16 and 3/64 inch (2.4, 1.6, and 1.2 mm), respectively, may be acceptable if the surface is curved, ribbed, or otherwise reinforced, or if the shape or size of the surface is such that equivalent mechanical strength is provided.

7.3 Sheet metal employed as an enclosure for X-ray equipment shall be of such thickness, or shall be so formed or reinforced, that its strength and rigidity is not less than that of a flat steel sheet having a thickness of 0.026 inch (0.66 mm).

7.4 An enclosure of material other than metal may be acceptable if it has been shown to have mechanical strength, resistance to impact, noncombustibility, and other properties appropriate for the application.

7.5 High-voltage equipment containing oil shall not be installed in a wood cabinet.

7.6 The wires of a screen shall be not smaller than No. 16 AWG (1.3 mm²) if the screen openings are 1/2 square inch (323 mm²) or less in area, and shall not be smaller than No. 12 AWG (3.3 mm²) for larger screen openings.

7.7 Sheet metal employed for expanded-metal mesh, and perforated sheet metal, shall have a thickness of not less than 0.042 inch (1.07 mm) if the mesh openings or perforations are 1/2 square inch (323 mm²) or less in area, and not less than 0.080 inch (2.03 mm) for larger openings, except that if the area of each perforation is 0.01 square inch (0.65 mm²) or less, the metal may have thickness not less than that indicated in paragraph 7.3 if shown by acceptable tests to have strength and rigidity needed for the intended purpose.

7.8 Electrical parts of the equipment shall be so located or enclosed that protection is provided against unintentional contact with uninsulated live parts.

7.9 An opening in an enclosure, including a perforated hole, a louver, and an opening protected by means of wire screening, expanded metal, or perforated covers, shall be of such size or shape that it does not permit passage of a rod having a diameter larger than 1/2 inch (12.7 mm); except that if the distance between the uninsulated live parts and the nearest edge of the opening is more than 4 inches (102 mm), the opening may be larger than that previously mentioned, provided that it does not permit passage of a rod having a diameter larger than 3/4 inch (19.1 mm). Larger openings may be accepted if the distance between the edge of the opening and uninsulated live part is at least five times the smaller dimension of the opening.

8 Mechanical Assembly

8.1 A switch, a lampholder, an attachment-plug receptacle, a motor-attachment plug, or similar component shall be mounted securely and, except as noted in paragraphs 8.2 and 8.3, shall be kept from turning. See paragraph 8.4.