

UL 61010A-2-042

ISBN 0-7629-0424-0

Electrical Equipment for
Laboratory Use; Part
2: Particular Requirements for
Autoclaves and Sterilizers
Using Toxic Gas for the
Treatment of Medical
Materials, and for Laboratory
Processes



Documents
Document Sharing Hub

.....

Underwriters Laboratories Inc. (UL)
333 Pfingsten Road
Northbrook, IL 60062-2096

UL Standard for Safety for Electrical Equipment for Laboratory Use; Part 2: Particular Requirements for Autoclaves and Sterilizers Using Toxic Gas for the Treatment of Medical Materials, and for Laboratory Processes, UL 61010A-2-042

First Edition, Dated August 29, 2002

The entire standard will be effective March 27, 2004.

The master for this Standard at UL's Northbrook Office is the official document insofar as it relates to a UL service and the compliance of a product with respect to the requirements for that product and service, or if there are questions regarding the accuracy of this Standard.

UL's Standards for Safety are copyrighted by UL. Neither a printed copy of a Standard, nor the distribution diskette for a Standard-on-Diskette and the file for the Standard on the distribution diskette should be altered in any way. All of UL's Standards and all copyrights, ownerships, and rights regarding those Standards shall remain the sole and exclusive property of UL.

All rights reserved. No part of this publication may be reproduced, stored in a retrieval system, or transmitted in any form by any means, electronic, mechanical photocopying, recording, or otherwise without prior permission of UL.

Revisions of UL Standards for Safety are issued from time to time. A UL Standard for Safety is current only if it incorporates the most recently adopted revisions.

UL provides this Standard "as is" without warranty of any kind, either expressed or implied, including but not limited to, the implied warranties of merchantability or fitness for any purpose.

In no event will UL be liable for any special, incidental, consequential, indirect or similar damages, including loss of profits, lost savings, loss of data, or any other damages arising out of the use of or the inability to use this Standard, even if UL or an authorized UL representative has been advised of the possibility of such damage. In no event shall UL's liability for any damage ever exceed the price paid for this Standard, regardless of the form of the claim.

UL will attempt to answer support requests concerning electronic versions of its Standards. However, this support service is offered on a reasonable efforts basis only, and UL may not be able to resolve every support request. UL supports the electronic versions of its Standards only if they are used under the conditions and operating systems for which it is intended. UL's support policies may change from time-to-time without notification.

UL reserves the right to change the format, presentation, file types and formats, delivery methods and formats, and the like of both its printed and electronic Standards without prior notice.

Purchasers of the electronic versions of UL's Standards for Safety agree to defend, indemnify, and hold UL harmless from and against any loss, expense, liability, damage, claim, or judgement (including reasonable attorney's fees) resulting from any error or deviation introduced while purchaser is storing an electronic Standard on the purchaser's computer system.

If a single-user version electronic Standard was purchased, one copy of this Standard may be stored on the hard disk of a single personal computer, or on a single LAN file-server or the permanent storage device of a multiple-user computer in such a manner that this Standard may only be accessed by one user at a time and for which there is no possibility of multiple concurrent access.

If a multiple-user version electronic Standard was purchased, one copy of the Standard may be stored on a single LAN file-server, or on the permanent storage device of a multiple-user computer, or on an Intranet server. The number of concurrent users shall not exceed the number of users authorized.

Electronic Standards are intended for on-line use, such as for viewing the requirements of a Standard, conducting a word search, and the like. Only one copy of the Standard may be printed from each single-user version of an electronic Standard. Only one copy of the Standard may be printed for each authorized user of a multiple-user version of an electronic Standard. Because of differences in the computer/software/printer setup used by UL and those of electronic Standards purchasers, the printed copy obtained by a purchaser may not look exactly like the on-line screen view or the printed Standard.

An employee of an organization purchasing a UL Standard can make a copy of the page or pages being viewed for their own fair and/or practical internal use.

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

Copyright © 2002 Underwriters Laboratories Inc.

This Standard consists of pages dated as shown in the following checklist:

Page	Date
1-40	August 29, 2002

AUGUST 29, 2002

1

UL 61010A-2-042

**Standard for Electrical Equipment for Laboratory Use; Part 2: Particular
Requirements for Autoclaves and Sterilizers Using Toxic Gas for the
Treatment of Medical Materials, and for Laboratory Processes**

First Edition

August 29, 2002

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.

ISBN 0-7629-0424-0

COPYRIGHT © 2002 UNDERWRITERS LABORATORIES INC.

No Text on This Page

CONTENTS

Preface (UL)	5
Foreword (UL)	6
NATIONAL DIFFERENCES	7
FOREWORD	8
INTRODUCTION	10
1 Scope and object	11
1.1 Scope	11
1.2 Object	12
1.4 Environmental conditions	12
2 Normative references	12
2.1 IEC standards	12
2.2 ISO standards	13
3 Definitions	13
3.1 Equipment and states of equipment	13
3.2 Parts and accessories	13
4 Tests	13
4.3.5 Covers and removable parts	14
4.4.2.4 Motors	14
4.4.2.10 Heating devices	14
4.4.2.12 Interlocks	14
4.4.2.101 Failure, or partial failure, of the mains supply	14
4.4.2.102 Failure of other supplies	15
5 Marking and documentation	15
5.1.1 General	15
5.1.2 Identification	15
5.1.3 Mains supply	15
5.1.6 TERMINALS and operating devices	16
5.1.101 Overpressure safety device	16
5.1.102 PRESSURE VESSEL markings	16
5.2 Warning markings	17
5.4.1 General	17
5.4.2 Equipment RATINGS	18
5.4.3 Equipment installation	18
5.4.4 Equipment operation	19
5.4.5 Equipment maintenance	21
6 Protection against electric shock	21
6.1 General	21
6.10.2.2 Cord anchorage	21
6.10.101 Connection of non-detachable mains cords to TERMINALS	21
6.12.101 Disconnection by interruption of the mains supply	22
7 Protection against mechanical hazards	22
7.1 General	22
7.2.101 Powered doors	22
7.4.101 Provision for transferring the LOAD into and out of the CHAMBER	23
7.101 Door interlocks	24

7.102	<i>Doors with inflatable or pressure-activated seals</i>	25
7.103	<i>Prevention of door closure</i>	25
8	Mechanical resistance to shock and impact	25
8.4.1	<i>Equipment other than HAND-HELD EQUIPMENT</i>	26
9	Equipment temperature limits and protection against the spread of fire	26
9.1	<i>General</i>	26
9.5	<i>Overtemperature protection devices</i>	26
10	Resistance to heat	26
11	Protection against hazards from fluids	26
11.1	<i>General</i>	26
11.7.4	<i>Overpressure safety device</i>	27
11.7.101	<i>Instruments and indicating devices</i>	27
11.101	<i>Discharge from pressure-venting valves and overpressure safety devices</i>	28
11.102	<i>Interruption of supplies and services</i>	28
12	Protection against radiation, including laser sources, and against sonic and ultrasonic pressure	28
12.1	<i>General</i>	28
13	Protection against liberated gases, explosion and implosion	28
13.1	<i>Poisonous and injurious gases</i>	28
13.2	<i>Explosion and implosion</i>	32
13.101	<i>CHAMBER exhaust system</i>	34
13.102	<i>LOAD access after a fault</i>	34
13.103	<i>Interruption of supplies and services</i>	34
13.104	<i>Sterilant supply system</i>	35
14	Components	36
14.2.1	<i>Motor temperatures</i>	36
14.8	<i>Overpressure safety device</i>	36
14.101	<i>PRESSURE VESSEL</i>	37
14.102	<i>Visibility and readability of instruments and indicating devices</i>	38
14.103	<i>Control system</i>	38
14.104	<i>Microprocessors</i>	39
14.105	<i>Access ports</i>	39
15	Protection by interlocks	39
16	Measure circuits	39

Annexes

Annex L

Annex M



Preface (UL)

This UL Standard 61010A-2-042, Standard for Safety for Electrical Equipment for Laboratory Use; Part 2: Particular Requirements for Autoclaves and Sterilizers Using Toxic Gas for the Treatment of Medical Materials, and for Laboratory Processes, is to be used in conjunction with the first edition of UL 61010A-1. The requirements for autoclaves and sterilizers using toxic gas for the treatment of medical materials, and for laboratory processes are contained in this part 2 Standard and UL 61010A-1.

Requirements of this part 2 Standard, where stated, amend the requirements of UL 61010A-1.

Where a particular subclause of UL 61010A-1 is not mentioned in UL 61010A-2-042, the UL 61010A-1 subclause applies.

The text, figures and tables of IEC Publication Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use; Part 2-042: Particular Requirements for Autoclaves and Sterilizers Using Toxic Gas for the Treatment of Medical Materials, and for Laboratory Processes, IEC 61010-2-042 copyright 1997 are used in this Standard with the consent of the IEC and the American National Standards Institute (ANSI). The IEC copyrighted material has been reproduced with permission from ANSI. ANSI should be contacted regarding the reproduction of any portion of the IEC material. The IEC Foreword and Introduction are not a part of the requirements of this Standard but are included for information purposes only. Copies of IEC Publication 61010-2-042 may be purchased from ANSI, 11 West 42nd Street, New York, New York, 10036, (212) 642-4900.

Note – Although the intended primary application of this Standard is stated in its Scope, it is important to note that it remains the responsibility of the users of the Standard to judge its suitability for their particular purpose.

UL Effective Date

As of March 27, 2004 all products Listed or Recognized by UL must comply with the requirements in this standard.

Foreword (UL)

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

NATIONAL DIFFERENCES

GENERAL

National Differences from the text of International Electrotechnical Commission (IEC) Publication 61010-2-042, Safety Requirements for Electrical Equipment for Laboratory Use; Part 2-042: Particular Requirements for Autoclaves and Sterilizers Using Toxic Gas for the Treatment of Medical Materials, and for Laboratory Processes copyright 1997 are indicated by notations (differences) and are presented in bold text.

There are five types of National Differences as noted below. The difference type is noted on the first line of the National Difference in the standard. The standard may not include all types of these National Differences.

DR – These are National Differences based on the **National Electrical Code (NEC)** and **other U.S. Regulatory Requirements**.

D1 – These are National Differences which are based on **basic safety principles and requirements**, elimination of which would compromise safety for U.S. consumers and users of products.

D2 – These are National Differences based on **safety practices**. These are differences for IEC requirements that may be acceptable, but adopting the IEC requirements would require considerable retesting or redesign on the manufacturer's part.

DC – These are National Differences based on the **component standards** and will not be deleted until a particular component standard is harmonized with the IEC component standard.

DE – These are National Differences based on **editorial comments or corrections**.

INTERNATIONAL ELECTROTECHNICAL COMMISSION

SAFETY REQUIREMENTS FOR ELECTRICAL EQUIPMENT FOR MEASUREMENT, CONTROL, AND LABORATORY USE – Part 2-042: Particular requirements for autoclaves and sterilizers using toxic gas for the treatment of medical materials, and for laboratory processes

FOREWORD

1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, the IEC publishes International Standards. Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. The IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.

2) The formal decisions or agreements of the IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested National Committees.

3) The documents produced have the form of recommendations for international use and are published in the form of standards, technical reports or guides and they are accepted by the National Committees in that sense.

4) In order to promote international unification, IEC National Committees undertake to apply IEC International Standards transparently to the maximum extent possible in their national and regional standards. Any divergence between the IEC Standard and the corresponding national or regional standard shall be clearly indicated in the latter.

5) The IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with one of its standards.

6) Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. The IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC 61010-2-042 has been prepared by IEC technical committee 66: Safety of measuring, control, and laboratory equipment.

It has the status of a group safety publication in accordance with IEC Guide 104.

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

FDIS	Report on voting
66/154/FDIS	66/162/RVD

Full information on the voting for the approval of this standard can be found in the report of voting indicated in the above table.

This part 2 is intended to be used in conjunction with IEC 61010-1. It was established on the basis of the first edition (1990), its amendment 1 (1992) and its amendment 2 (1995). Consideration may be given to future editions of, or amendments to, IEC 61010-1.

This part 2 supplements or modifies the corresponding clauses in IEC 61010-1 so as to convert that publication into the IEC Standard: Safety requirements for autoclaves and sterilizers using toxic gas for the treatment of medical materials, and for laboratory processes.

Where a particular subclause of part 1 is not mentioned in this part 2, that subclause applies as far as is reasonable. Where this part states "addition", "modification" or "replacement", the relevant requirement, test specification or note in part 1 should be adapted accordingly.

In this standard:

1) the following print types are used:

- requirements: in roman type;
- Notes: in small roman type;
- *conformity*: in italic type;
- terms used throughout this standard which have been defined in clause 3: SMALL ROMAN CAPITALS.

2) subclauses or figures which are additional to those in part 1 are numbered starting from 101.

The word "Conformity" is used throughout this standard instead of "Compliance" in accordance with the requirements of ISO/IEC Guide 2: 1991, and all references in part 1 to "Compliance" should therefore be read as "Conformity". Part 1 will be changed to reflect "Conformity" when its next edition is published.

101DV DE Addition of the following after the second note in the part 2:

The numbering system in the Standard uses a space instead of a comma to indicate thousands and uses a comma instead of a period to indicate a decimal point. For example, 1 000 means 1,000 and 1,01 means 1.01.

INTRODUCTION

Sterilizing equipment utilizing toxic gas, above or below atmospheric pressure, has many potentially hazardous parts in its construction which require additional safety requirements to those given in IEC 61010-1. These particularly include protection of the operator and surroundings against the unintentional escape of toxic gas.

Other existing national and international standards and regulations also need to be considered since they may supplement this standard.