

INTERNATIONAL STANDARD

NORME INTERNATIONALE



Medical electrical equipment –

Part 2-75: Particular requirements for the basic safety and essential performance of photodynamic therapy and photodynamic diagnosis equipment

Appareils électromédicaux –

Partie 2-75: Exigences particulières pour la sécurité de base et les performances essentielles des appareils de thérapie photodynamique et de diagnostic photodynamique



THIS PUBLICATION IS COPYRIGHT PROTECTED

Copyright © 2023 IEC, Geneva, Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either IEC or IEC's member National Committee in the country of the requester. If you have any questions about IEC copyright or have an enquiry about obtaining additional rights to this publication, please contact the address below or your local IEC member National Committee for further information.

Droits de reproduction réservés. Sauf indication contraire, aucune partie de cette publication ne peut être reproduite ni utilisée sous quelque forme que ce soit et par aucun procédé, électronique ou mécanique, y compris la photocopie et les microfilms, sans l'accord écrit de l'IEC ou du Comité national de l'IEC du pays du demandeur. Si vous avez des questions sur le copyright de l'IEC ou si vous désirez obtenir des droits supplémentaires sur cette publication, utilisez les coordonnées ci-après ou contactez le Comité national de l'IEC de votre pays de résidence.

IEC Secretariat
3, rue de Varembe
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
info@iec.ch
www.iec.ch

About the IEC

The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

About IEC publications

The technical content of IEC publications is kept under constant review by the IEC. Please make sure that you have the latest edition, a corrigendum or an amendment might have been published.

IEC publications search - webstore.iec.ch/advsearchform

The advanced search enables to find IEC publications by a variety of criteria (reference number, text, technical committee, ...). It also gives information on projects, replaced and withdrawn publications.

IEC Just Published - webstore.iec.ch/justpublished

Stay up to date on all new IEC publications. Just Published details all new publications released. Available online and once a month by email.

IEC Customer Service Centre - webstore.iec.ch/csc

If you wish to give us your feedback on this publication or need further assistance, please contact the Customer Service Centre: sales@iec.ch.

IEC Products & Services Portal - products.iec.ch

Discover our powerful search engine and read freely all the publications preview. With a subscription you will always have access to up-to-date content tailored to your needs.

Electropedia - www.electropedia.org

The world's leading online dictionary on electrotechnology, containing more than 22 300 terminological entries in English and French, with equivalent terms in 19 additional languages. Also known as the International Electrotechnical Vocabulary (IEV) online.

A propos de l'IEC

La Commission Electrotechnique Internationale (IEC) est la première organisation mondiale qui élabore et publie des Normes internationales pour tout ce qui trait à l'électricité, à l'électronique et aux technologies apparentées.

A propos des publications IEC

Le contenu technique des publications IEC est constamment revu. Veuillez vous assurer que vous possédez l'édition la plus récente, un corrigendum ou amendement peut avoir été publié.

Recherche de publications IEC -

webstore.iec.ch/advsearchform

La recherche avancée permet de trouver des publications IEC en utilisant différents critères (numéro de référence, texte, comité d'études, ...). Elle donne aussi des informations sur les projets et les publications remplacées ou retirées.

IEC Just Published - webstore.iec.ch/justpublished

Restez informé sur les nouvelles publications IEC. Just Published détaille les nouvelles publications parues. Disponible en ligne et une fois par mois par email.

Service Clients - webstore.iec.ch/csc

Si vous désirez nous donner des commentaires sur cette publication ou si vous avez des questions contactez-nous: sales@iec.ch.

IEC Products & Services Portal - products.iec.ch

Découvrez notre puissant moteur de recherche et consultez gratuitement tous les aperçus des publications. Avec un abonnement, vous aurez toujours accès à un contenu à jour adapté à vos besoins.

Electropedia - www.electropedia.org

Le premier dictionnaire d'électrotechnologie en ligne au monde, avec plus de 22 300 articles terminologiques en anglais et en français, ainsi que les termes équivalents dans 19 langues additionnelles. Egalement appelé Vocabulaire Electrotechnique International (IEV) en ligne.



IEC 60601-2-75

Edition 1.1 2023-01
CONSOLIDATED VERSION

INTERNATIONAL STANDARD

NORME INTERNATIONALE



Medical electrical equipment –

Part 2-75: Particular requirements for the basic safety and essential performance of photodynamic therapy and photodynamic diagnosis equipment

Appareils électromédicaux –

Partie 2-75: Exigences particulières pour la sécurité de base et les performances essentielles des appareils de thérapie photodynamique et de diagnostic photodynamique

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

ICS 11.040.01

ISBN 978-2-8322-6438-6

**Warning! Make sure that you obtained this publication from an authorized distributor.
Attention! Veuillez vous assurer que vous avez obtenu cette publication via un distributeur agréé.**

Currently in preview, click buy full version

REDLINE VERSION

VERSION REDLINE



Medical electrical equipment –

Part 2-75: Particular requirements for the basic safety and essential performance of photodynamic therapy and photodynamic diagnosis equipment

Appareils électromédicaux –

Partie 2-75: Exigences particulières pour la sécurité de base et les performances essentielles des appareils de thérapie photodynamique et de diagnostic photodynamique

CONTENTS

| | |
|--|----|
| FOREWORD..... | 3 |
| INTRODUCTION to Amendment1 | 6 |
| 201. 1 Scope, object and related standards | 7 |
| 201. 2 Normative references..... | 9 |
| 201. 3 Terms and definitions..... | 9 |
| 201. 4 General requirements | 13 |
| 201. 5 General requirements for testing ME EQUIPMENT | 13 |
| 201. 6 Classification of ME EQUIPMENT and ME SYSTEMS..... | 13 |
| 201. 7 ME EQUIPMENT identification, marking and documents | 14 |
| 201. 8 Protection against electrical HAZARDS from ME EQUIPMENT | 16 |
| 201. 9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS | 16 |
| 201. 10 Protection against unwanted and excessive radiation HAZARDS | 16 |
| 201. 11 Protection against excessive temperatures and other HAZARDS | 17 |
| 201. 12 Accuracy of controls and instruments and protection against hazardous OUTPUTS..... | 17 |
| 201. 13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT | 21 |
| 201. 14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS) | 22 |
| 201. 15 Construction of ME EQUIPMENT..... | 22 |
| 201. 16 ME SYSTEMS | 22 |
| 201. 17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS | 22 |
| Annexes | 23 |
| Annex AA (informative) General guidance and rationale | 24 |
| Annex BB (informative) Specific HAZARDOUS SITUATIONS and HARMS and RISK ASSESSMENT guidance | 28 |
| Bibliography..... | 30 |
| Index of defined terms used in this particular standard..... | 32 |
| | |
| Table AA.1 – Characteristics relevant to parameters..... | 25 |
| Table BB.1 – Specific HAZARDOUS SITUATIONS and HARMS | 28 |

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

**Part 2-75: Particular requirements for the basic safety
and essential performance of photodynamic therapy
and photodynamic diagnosis equipment**

FOREWORD

- 1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of 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, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). 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 preparatory work. 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 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 IEC National Committees.
- 3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
- 4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
- 5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, accept to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
- 6) All users should ensure that they have the latest edition of this publication.
- 7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
- 8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
- 9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

This consolidated version of the official IEC Standard and its amendment has been prepared for user convenience.

IEC 60601-2-75 edition 1.1 contains the first edition (2017-05) [documents 62D/1477/FDIS and 62D/1490/RVD] and its amendment 1 (2023-01) [documents 62D/2006/FDIS and 62D/2017/RVD].

In this Redline version, a vertical line in the margin shows where the technical content is modified by amendment 1. Additions are in green text, deletions are in strikethrough red text. A separate Final version with all changes accepted is available in this publication.

International Standard IEC 60601-2-75 has been prepared by subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard, the following print types are used:

- requirements and definitions: roman type;
- *test specifications: italic type;*
- informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type;
- TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

- “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.)
- “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Clause 7 of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;
- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
- “may” is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

A list of all parts of the IEC 60601 series, published under the general title *Medical electrical equipment*, can be found on the IEC website.

The committee has decided that the contents of the base publication and its amendment will remain unchanged until the stability date indicated on the IEC web site under webstore.iec.ch in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

INTRODUCTION to Amendment1

At the October 2019 meeting of IEC SC 62D in Shanghai, China, the subcommittee discussed the need for administrative/technical changes to most 62D standards after completion of the amendment projects within the IEC 60601-1 series. Those projects were all completed and the amendments published in 2020.

The full list of IEC SC 62D documents that will be amended or revised may be found within the IEC document 62D/1792/DC. The results and comments on the DC may be found within 62D/1808/INF. The review report for this amendment is 62D/1812/RR.

Currently in preview, click buy full version

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-75: Particular requirements for the basic safety and essential performance of photodynamic therapy and photodynamic diagnosis equipment

201.1 Scope, object and related standards

Clause 1 of the general standard¹ applies, except as follows:

201.1.1 Scope

Replacement:

This part of IEC 60601 applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of PHOTODYNAMIC THERAPY AND PHOTODYNAMIC DIAGNOSIS EQUIPMENT.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this document are not covered by specific requirements in this document except in 7.2.13 and 8.4.1 of the general standard.

NOTE See also 4.2 of the general standard.

This document applies to PHOTODYNAMIC THERAPY AND PHOTODYNAMIC DIAGNOSIS EQUIPMENT used for compensation or alleviation of disease, injury or disability.

In the case of combined equipment (e.g. equipment additionally provided with a function or an APPLIED PART for the target area) such equipment shall also comply with any particular standard specifying safety requirements for the additional function.

This particular standard does not apply to:

- light therapy equipment intended for use in photothermal ablation, coagulation, and hyperthermia;
- low-level laser therapy equipment not intended for use with a PHOTOSENSITIZER;
- illumination equipment intended for use in observation, monitoring, and diagnosis, not intended for use with a PHOTOSENSITIZER.

¹ The general standard is IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.*