

**ציוד חשמלי לשימוש רפואי: דרישות מיוחדות לבטיחות בסיסית  
ולביצועים חיוניים של ציוד ריפוי הפועל בגלים קצרים**

Medical electrical equipment: Particular requirements for the basic safety and essential performance of short-wave therapy equipment

*מסמך זה הוא הצעה בלבד*

גיליון תיקון זה הוכן ואושר על ידי הוועדה הטכנית 5801 – ציוד חשמלי לשימוש רפואי, בהרכב זה:

- אייל גרינבאום, אורנה שרון
- מיכאל שיזף
- ולנטין ויינטראוב, יוסי פרי פז
- אירנה אנטונוב
- אלכסנדר וילנסקי (יו"ר)
- שלומי אביסרור
- מינוי לשכות המסחר
- המועצה הישראלית לצרכנות
- מינוי אישי
- מעבדה
- משרד הבריאות
- משרד הכלכלה והתעשייה

כמו כן תרם להכנת גיליון התיקון דני אבן-חן.

זיוה שלו ריכזה את עבודת הכנת גיליון התיקון.

פרסומים

## הודעה על גיליון תיקון

גיליון תיקון זה, למעט השינויים והתוספות הלאומיים המצוינים בו, זהה לגיליון התיקון של הנציבות הבין-לאומית לאלקטרוטכניקה IEC 60601-2-3:2012/AMD2: 2022-09

גיליון תיקון זה מעדכן את התקן הישראלי ת"י 60601 חלק 2.3 מאוגוסט 2018

## עדכניות התקן

התקנים הישראליים עומדים לבדיקה מזמן לזמן, ולפחות אחת לחמש שנים, כדי להתאימם להתפתחות המדע והטכנולוגיה. המשתמשים בתקנים יודאו שבידיהם המהדורה המעודכנת של התקן על גיליונות התיקון שלו. מסמך המתפרסם ברשומות כגיליון תיקון, יכול להיות גיליון תיקון נפרד או תיקון המשולב בתקן.

## תוקף התקן

תקן ישראלי על עדכוניו נכנס לתוקף החל ממועד פרסומו ברשומות. יש לבדוק אם התקן רשמי או אם חלקים ממנו רשמיים. תקן רשמי או גיליון תיקון רשמי (במלואם או בחלקם) נכנסים לתוקף 60 יום מפרסום ההודעה ברשומות, אלא אם בהודעה נקבע מועד מאוחר יותר לכניסה לתוקף.

## סימון בתו תקן

כל המייצר מוצר, המתאים לדרישות התקנים הישראליים החלים עליו, רשאי, לפי היתר ממכון התקנים הישראלי, לסמנו בתו תקן:



## זכויות יוצרים

© אין לצלם, להעתיק או לפרסם, בכל אמצעי שהוא, תקן זה או קטעים ממנו, ללא רשות מראש ובכתב ממכון התקנים הישראלי.



**THIS PUBLICATION IS COPYRIGHT PROTECTED**  
**Copyright © 2022 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.

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

Tel.: +41 22 919 02 11  
[info@iec.ch](mailto:info@iec.ch)  
[www.iec.ch](http://www.iec.ch)

## הקדמה לגיליון התיקון הישראלי

גיליון תיקון ישראלי זה הוא גיליון התיקון של הנציבות הבין-לאומית לאלקטרוטכניקה IEC 60601-2-3:2012/AMD2 מספטמבר 2022, שאושר כגיליון תיקון ישראלי בשינויים ובתוספות לאומיים. גיליון התיקון של הנציבות הבין-לאומית לאלקטרוטכניקה מובא להלן בשפה האנגלית.

**שינויים לחלק העברי של התקן:**

בסוף החלק העברי של התקן יוסף:

## פירוט השינויים והתוספות הלאומיים לסעיפי התקן הבין-לאומי

### 201.2 Normative references

במקום אחד התקנים הבין-לאומיים המאוזכרים בתקן והמפורטים בסעיף זה חל תקן ישראלי, כמפורט להלן:

התקן הישראלי החל במקומו	התקן הבין-לאומי המאוזכר
ת"י 60601 חלק 1 – ציוד חשמלי לשימוש רפואי: דרישות כלליות לבטיחות בסיסית ולביצועים חיוניים	IEC 60601-1:2005 IEC 60601-1:2005/AMD1:2012 IEC 60601-1:2005/AMD2:2020

# INTERNATIONAL STANDARD

# NORME INTERNATIONALE

AMENDMENT 2  
AMENDEMENT 2

**Medical electrical equipment –  
Part 2-3: Particular requirements for the basic safety and essential performance  
of short-wave therapy equipment**

**Appareils électromédicaux –  
Partie 2-3: Exigences particulières pour la sécurité de base et les performances  
essentielles des appareils de thérapie à ondes courtes**



## THIS PUBLICATION IS COPYRIGHT PROTECTED

Copyright © 2022 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](mailto:info@iec.ch)  
[www.iec.ch](http://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](http://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](http://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](http://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](mailto:sales@iec.ch).

#### IEC Products & Services Portal - [products.iec.ch](http://products.iec.ch)

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

#### Electropedia - [www.electropedia.org](http://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 a 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](http://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](http://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](http://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](mailto:sales@iec.ch).

#### IEC Products & Services Portal - [products.iec.ch](http://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](http://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.



# INTERNATIONAL STANDARD

# NORME INTERNATIONALE

AMENDMENT 2  
AMENDEMENT 2

---

**Medical electrical equipment –  
Part 2-3: Particular requirements for the basic safety and essential performance  
of short-wave therapy equipment**

**Appareils électromédicaux –  
Partie 2-3: Exigences particulières pour la sécurité de base et les performances  
essentiels des appareils de thérapie à ondes courtes**

INTERNATIONAL  
ELECTROTECHNICAL  
COMMISSION

COMMISSION  
ELECTROTECHNIQUE  
INTERNATIONALE

---

ICS 11.040.60

ISBN 978-2-8322-5663-3

**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.**

## INTERNATIONAL ELECTROTECHNICAL COMMISSION

**MEDICAL ELECTRICAL EQUIPMENT –****Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment****AMENDMENT 2****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 preparation. 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, access 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 document may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

Amendment 2 to IEC 60601-2-3:2012 has been prepared by subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

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

Draft	Report on voting
62D/1846/CDV	62D/1959/RVC

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

The language used for the development of this Amendment is English.



This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at [www.iec.ch/members\\_experts/refdocs](http://www.iec.ch/members_experts/refdocs). The main document types developed by IEC are described in greater detail at [www.iec.ch/standardsdev/publications/](http://www.iec.ch/standardsdev/publications/).

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under [webstore.iec.ch](http://webstore.iec.ch) in the data related to the specific document. At this date, the document will be

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

NOTE The attention of users of this document is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised IEC or ISO publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for mandatory implementation nationally not earlier than 3 years from the date of publication.

---

## INTRODUCTION to Amendment 2

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 62D1808/INF. The review report for this amendment is 62D/1829/RR.

---

### 201.1 Scope, object and related standards

*Replace the existing text of footnote 1, modified by Amendment 1, with the following:*

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*.

#### 201.1.3 Collateral standards

*Replace, in the second paragraph, the first sentence with the following:*

IEC 60601-1-3 and IEC 60601-1-12 do not apply.

## 201.2 Normative references

*Replace the existing text with the following:*

Clause 2 of the general standard applies, except as follows:

*Addition:*

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

IEC 60601-1:2005/AMD1:2012

IEC 60601-1:2005/AMD2:2020

IEC TR 60878:2015, *Graphical symbols for electrical equipment in medical practice*

## 201.3 Terms and definitions

*Replace, in the first sentence, modified by Amendment 1, “IEC 60601-1” with “IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020”.*

## Index of defined terms used in this particular standard

*Replace the following entries, modified by Amendment 1, as follows:*

BASIC SAFETY .....	IEC 60601-1:2005, 3.10
ENCLOSURE .....	IEC 60601-1:2005, 3.26
ESSENTIAL PERFORMANCE .....	IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, 3.27
HAZARD .....	IEC 60601-1:2005 and IEC 60601-1:2005/AMD2:2020, 3.39
LEAKAGE CURRENT .....	IEC 60601-1:2005, 3.47
MAINS VOLTAGE .....	IEC 60601-1:2005, 3.54
MANUFACTURER .....	IEC 60601-1:2005 and IEC 60601-1:2005/AMD2:2020, 3.55
MEDICAL ELECTRICAL EQUIPMENT (ME EQUIPMENT) .....	IEC 60601-1:2005, 3.63
MEDICAL ELECTRICAL SYSTEM (ME SYSTEM) .....	IEC 60601-1:2005, 3.64
OPERATOR .....	IEC 60601-1:2005, 3.73
PATIENT .....	IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, 3.76
PATIENT AUXILIARY CURRENT .....	IEC 60601-1:2005, 3.77
PATIENT LEAKAGE CURRENT .....	IEC 60601-1:2005, 3.80
RATED .....	IEC 60601-1:2005, 3.97
RISK .....	IEC 60601-1:2005 and IEC 60601-1:2005/AMD2:2020, 3.102
SERVICE PERSONNEL .....	IEC 60601-1:2005, 3.113



INTERNATIONAL  
ELECTROTECHNICAL  
COMMISSION

3, rue de Varembé  
PO Box 131  
CH-1211 Geneva 20  
Switzerland

Tel: + 41 22 919 02 11  
[info@iec.ch](mailto:info@iec.ch)  
[www.iec.ch](http://www.iec.ch)