



IEC 80601-2-78

Edition 1.1 2024-03  
CONSOLIDATED VERSION

# INTERNATIONAL STANDARD

## NORME INTERNATIONALE



**Medical electrical equipment –**

**Part 2-78: Particular requirements for basic safety and essential performance of medical robots for rehabilitation, assessment, compensation or alleviation**

**Appareils électromédicaux –**

**Partie 2-78: Exigences particulières pour la sécurité de base et les performances essentielles des robots médicaux dédiés à la rééducation, l'évaluation, la compensation ou l'atténuation**



## THIS PUBLICATION IS COPYRIGHT PROTECTED

Copyright © 2024 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, graphical symbols and the glossary. 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 22 500 terminological entries in English and French, with equivalent terms in 25 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, symboles graphiques et le glossaire. 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 22 500 articles terminologiques en anglais et en français, ainsi que les termes équivalents dans 25 langues additionnelles. Egalement appelé Vocabulaire Electrotechnique International (IEV) en ligne.



IEC 80601-2-78

Edition 1.1 2024-03  
CONSOLIDATED VERSION

# INTERNATIONAL STANDARD

## NORME INTERNATIONALE



**Medical electrical equipment –**

**Part 2-78: Particular requirements for basic safety and essential performance of medical robots for rehabilitation, assessment, compensation or alleviation**

**Appareils électromédicaux –**

**Partie 2-78: Exigences particulières pour la sécurité de base et les performances essentielles des robots médicaux dédiés à la rééducation, l'évaluation, la compensation ou l'atténuation**

INTERNATIONAL  
ELECTROTECHNICAL  
COMMISSION

COMMISSION  
ELECTROTECHNIQUE  
INTERNATIONALE

ICS 11.040.01

ISBN 978-2-8322-8522-0

**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.**

## CONTENTS

|   |    |
|---|----|
| FOREWORD.....   | 4  |
| INTRODUCTION.....   | 7  |
| INTRODUCTION to Amendment 1 .....   | 7  |
| 201.1 Scope, object and related standards .....   | 8  |
| 201.2 Normative references.....   | 10 |
| 201.3 Terms and definitions.....  | 11 |
| 201.4 General requirements .....  | 14 |
| 201.5 General requirements for testing of ME EQUIPMENT .....  | 15 |
| 201.6 Classification of ME EQUIPMENT and ME SYSTEMS.....  | 16 |
| 201.7 ME EQUIPMENT identification, marking and documents .....  | 16 |
| 201.8 Protection against electrical HAZARDS from ME EQUIPMENT.....  | 16 |
| 201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS.....   | 17 |
| 201.10 Protection against unwanted and excessive radiation HAZARDS .....  | 22 |
| 201.11 Protection against excessive temperatures and other HAZARDS .....  | 22 |
| 201.12 Accuracy of controls and instruments and protection against hazardous outputs.....   | 22 |
| 201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT .....   | 23 |
| 201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS).....  | 23 |
| 201.15 Construction of ME EQUIPMENT .....   | 24 |
| 201.16 ME SYSTEMS .....   | 25 |
| 201.17 ELECTROMAGNETIC COMPATIBILITY of ME EQUIPMENT and ME SYSTEMS .....   | 25 |
| 202 ELECTROMAGNETIC DISTURBANCES – Requirements and tests .....   | 25 |
| 206 USABILITY.....  | 26 |
| 208 * General requirements, tests and guidance for alarm systems in MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS ..... | 26 |
| 210 * Process requirements for the development of PHYSIOLOGIC CLOSED-LOOP CONTROLLERS.....  | 27 |
| 211 * Requirements for MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS used in the HOME HEALTHCARE ENVIRONMENT .....      | 27 |
| Annexes .....   | 29 |
| Annex A (informative) General guidance and rationale.....   | 29 |
| Annex AA (informative) Particular guidance and rationale.....   | 30 |
| Annex BB (informative) Guidance and examples of SITUATION AWARENESS.....  | 59 |
| Bibliography.....   | 74 |
| Index of defined terms used in this particular standard.....  | 77 |
| Figure AA.1 – Relationship of the terms used to describe equipment, accessories or equipment parts.....                               | 31 |
| Figure AA.2 – Endsley's model of SITUATION AWARENESS (based on [10], drawn by Dr. Peter Lankton, May 2007).....                       | 35 |
| Figure AA.3 – Model of user-medical device interaction .....  | 36 |
| Figure AA.4 – RACA ROBOT shared control system block diagram: control by PATIENT and RACA ROBOT .....                                 | 40 |

|   |    |
|---|----|
| Figure AA.5 – RACA ROBOT shared control system block diagram: control by PATIENT, OPERATOR and RACA ROBOT .....   | 41 |
| Figure AA.6 – RACA ROBOT shared control system block diagram: control by PATIENT and RACA ROBOT, and control modulation by OPERATOR .....   | 42 |
| Figure AA.7 – WALKING RACA ROBOT using motion-related biosignal input.....  | 43 |
| Figure AA.8 – System block diagram of a WALKING RACA ROBOT using a motion-related biosignal as input.....   | 43 |
| Figure AA.9 – RACA ROBOT that is an arm exoskeleton for REHABILITATION that applies a PATIENT-cooperative shared control strategy .....   | 44 |
| Figure AA.10 – System block diagram of an arm exoskeleton for REHABILITATION that applies a PATIENT-cooperative shared control strategy .....   | 45 |
| Figure AA.11 – Cane-type RACA ROBOT for REHABILITATION of walking .....   | 46 |
| Figure AA.12 – System block diagram of a cane-type RACA ROBOT .....   | 46 |
| Figure AA.13 – Example of ROBOT arm type RACA ROBOT for lower extremities .....   | 47 |
| Figure AA.14 – Example of ROBOT arm type RACA ROBOT for upper extremities .....   | 48 |
| Figure AA.15 – Example of exoskeleton type RACA ROBOT for upper extremities .....   | 49 |
| Figure AA.16 – Example of exoskeleton type RACA ROBOT for knee joint.....   | 51 |
| Figure AA.17 – Example of soft artificial muscle-type RACA ROBOT for knee joint .....   | 52 |
| Figure AA.18 – Example of exoskeleton-type WALKING RACA ROBOT .....   | 53 |
| Figure AA.19 – Example of RACA ROBOT for balance control .....  | 54 |
| Figure AA.20 – Example of a body-weight support-type RACA ROBOT with gait following function.....   | 56 |
| Figure BB.1 – All the proximate causes of loss of SITUATION AWARENESS [19] .....  | 60 |
| Figure BB.2 – Relationship between SITUATION AWARENESS, the RISK MANAGEMENT PROCESS (ISO 14971:2007/2019) and the USABILITY ENGINEERING PROCESS (IEC 62366-1:2015 and IEC 62366-1:2015/AMD1:2020) ..... | 63 |
| Figure BB.3 – Relationship between GDTA and RISK MANAGEMENT and USABILITY ENGINEERING PROCESSES.....  | 66 |
| Figure BB.4 – WALKING exoskeleton RACA ROBOT .....  | 72 |
| Table 201.101 – List of potential ESSENTIAL PERFORMANCES .....  | 15 |
| Table 19 – MECHANICAL HAZARDS covered by this clause .....  | 17 |
| Table 201.102 – Overview of different stopping procedures .....   | 17 |
| Table 28 – Mechanical strength test applicability .....   | 24 |
| Table 1 – Mechanical strength test applicability, non-TRANSIT-OPERABLE .....  | 27 |
| Table 2 – Mechanical strength test applicability, TRANSIT-OPERABLE .....  | 28 |
| Table AA.1 – Correlation mapping between Figure AA.2 and Figure AA.3 .....  | 37 |
| Table BB.1 – Example of using GDTA in BB.5.2 .....  | 68 |
| Table BB.2 – Example of using GDTA in BB.5.3 .....  | 69 |
| Table BB.3 – Example of using GDTA in BB.5.4 .....  | 71 |
| Table BB.4 – Example of using GDTA in BB.5.5 .....  | 73 |

## INTERNATIONAL ELECTROTECHNICAL COMMISSION

---

MEDICAL ELECTRICAL EQUIPMENT –**Part 2-78: Particular requirements for basic safety and essential performance of medical robots for rehabilitation, assessment, compensation or alleviation**

## 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) IEC and ISO draw attention to the possibility that the implementation of this document may involve the use of (a) patent(s). IEC and ISO take no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, IEC and ISO had not received notice of (a) patent(s), which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at <https://patents.iec.ch> and [www.iso.org/patents](http://www.iso.org/patents). IEC and ISO 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 80601-2-78 edition 1.1 contains the first edition (2019-07) [documents 62D/1676/FDIS and 62D/1688/RVD] and its amendment 1 (2024-03) [documents 62D/2085A/FDIS and 62D/2109/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 80601-2-78 has been prepared by IEC subcommittee 62D: Electromedical equipment, of IEC Technical Committee 62: Electrical equipment in medical practice, and ISO Technical Committee 299: Robotics.

This publication is published as a double logo standard.

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

In this document, 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 document, 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 document are preceded by the term "Clause" followed by the clause number. References to subclauses within this particular standard are by number only.

In this document, 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 document conform to usage described in Clause 7 of the ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

- "shall" means that compliance with a requirement or a test is mandatory for compliance with this document;
- "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;
- "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 80601 and IEC 60601 International Standard, published under the general title *Medical electrical equipment*, can be found on the IEC website.

The committee has decided that the contents of this document and its amendment 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, or
- revised.

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 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 committees that the content of this publication be adopted for implementation nationally not earlier than 3 years from the date of publication.

**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

This part of IEC 80601 International Standard was written at a time when technical evolution of MEDICAL ROBOTS was in rapid progress and the scientific foundation of safe use was still being expanded.

This document is the result of work that began in ISO/TC 184/SC 2/WG 7 in October 2006 on personal care ROBOTS, to address an emerging type of MEDICAL ROBOT that was used outside of an industrial environment. That group was working on a new standard, ISO 13482, which was published as an International Standard (IS) in 2014. While initially focused on non-medical applications, WG 7 recognized that work was needed on medical devices utilizing robotic technology. In October 2009, ISO/TC 184/SC 2 established a WG 7, *Study Group (SG) on Medical care robots*, comprised of experts from Canada, France, Germany, Japan, Korea, Romania, Switzerland, UK and USA.

The work of ISO/TC 184/SC 2/WG 7 SG cumulated in a proposal to form a Joint Working Group (JWG 9) with IEC/TC 62/SC 62A focusing on MEDICAL ELECTRICAL EQUIPMENT using robotic technology. This JWG began developing a technical report (IEC TR 60601-4-1) dealing with degree of autonomy. While developing this document, a particular standard was deemed required for REHABILITATION type ROBOTS. This led to the creation of a Joint Working Group 36 (MEDICAL ROBOTS for REHABILITATION) in April, 2015 within IEC/TC 62/SC 62D to develop particular requirements of SAFETY of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS for REHABILITATION type ROBOTS. ISO/TC 184/SC 2 has since been promoted to ISO/TC 299, and JWG 9 has merged with JWG35 and 36 to form JWG 5 (MEDICAL ROBOT Safety) on the ISO side. This proposal was approved from both IEC and ISO and work began.

The minimum safety requirements specified in this particular standard are presented to provide for an acceptable degree of BASIC SAFETY and ESSENTIAL PERFORMANCE for MEDICAL ROBOTS that physically interact with a PATIENT with an IMPAIRMENT, to support or perform REHABILITATION, ASSESSMENT, COMPENSATION or ALLEVIATION related to the PATIENT'S MOVEMENT FUNCTIONS .

The requirements are followed by particular specifications for the relevant tests.

## INTRODUCTION to Amendment 1

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 can be found within the IEC document 62D/1792/DC. The results and comments on the DC can be found within 62D/1808/INF. The review report for this amendment is 62D/1882/RR.