



NSAI
Standards

Irish Standard
I.S. EN IEC 80601-2-78:2020

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

I.S. EN IEC 80601-2-78:2020

Incorporating amendments/corrigenda/National Annexes issued since publication:

The National Standards Authority of Ireland (NSAI) produces the following categories of formal documents:

I.S. xxx: Irish Standard — national specification based on the consensus of an expert panel and subject to public consultation.

S.R. xxx: Standard Recommendation — recommendation based on the consensus of an expert panel and subject to public consultation.

SWiFT xxx: A rapidly developed recommendatory document based on the consensus of the participants of an NSAI workshop.

This document replaces/revises/consolidates the NSAI adoption of the document(s) indicated on the CEN/CENELEC cover/Foreword and the following National document(s):

NOTE: The date of any NSAI previous adoption may not match the date of its original CEN/CENELEC document.

This document is based on:

EN IEC 80601-2-78:2020

Published:

2020-04-03

This document was published under the authority of the NSAI and comes into effect on:

2020-05-06

ICS number:

NOTE: If blank see CEN/CENELEC cover page

NSAI
1 Swift Square,
Northwood, Santry
Dublin 9

T +353 1 807 3800
F +353 1 807 3838
E standards@nsai.ie
W NSAI.ie

Sales:
T +353 1 857 6730
F +353 1 857 6729
W standards.ie

Údarás um Chaighdeáin Náisiúnta na hÉireann

National Foreword

I.S. EN IEC 80601-2-78:2020 is the adopted Irish version of the European Document EN IEC 80601-2-78:2020, Medical electrical equipment - Part 2-78: Particular requirements for basic safety and essential performance of medical robots for rehabilitation, assessment, compensation or alleviation

This document does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

For relationships with other publications refer to the NSAI web store.

Compliance with this document does not of itself confer immunity from legal obligations.

In line with international standards practice the decimal point is shown as a comma (,) throughout this document.

This page is intentionally left blank

EUROPEAN STANDARD

EN IEC 80601-2-78

NORME EUROPÉENNE

EUROPÄISCHE NORM

April 2020

ICS 11.040.01

English Version

**Medical electrical equipment - Part 2-78: Particular requirements
for basic safety and essential performance of medical robots for
rehabilitation, assessment, compensation or alleviation
(IEC 80601-2-78:2019)**

Appareils électromédicaux - Partie 2-78: Exigences
particulières pour la sécurité de base et les performances
essentiels des robots médicaux dédiés à la rééducation,
l'évaluation, la compensation ou l'atténuation
(IEC 80601-2-78:2019)

Medizinische elektrische Geräte - Teil 2-78: Besondere
Festlegungen an die Sicherheit, einschließlich der
wesentlichen Leistungsmerkmale von medizinischen
Robotern zur Rehabilitation, Beurteilung, Kompensation
oder Linderung
(IEC 80601-2-78:2019)

This European Standard was approved by CENELEC on 2019-08-13. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.



European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

EN IEC 80601-2-78:2020 (E)**European foreword**

The text of document 62D/1676/FDIS, future edition 1 of IEC 80601-2-78, prepared by SC 62D "Electromedical equipment" of IEC/TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 80601-2-78:2020.

The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2020-10-03
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2023-04-03

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC shall not be held responsible for identifying any or all such patent rights.

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For the relationship with EU Directive(s) see informative Annex ZZ, which is an integral part of this document.

Endorsement notice

The text of the International Standard IEC 80601-2-78:2019 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

ISO 13482:2014	NOTE	Harmonized as EN ISO 13482:2014 (not modified)
ISO 9999:2016	NOTE	Harmonized as EN ISO 9999:2016 (not modified)
ISO 10535:2006	NOTE	Harmonized as EN ISO 10535:2006 (not modified)
IEC 60601-2-33	NOTE	Harmonized as EN 60601-2-33
ISO 10218-1:2011	NOTE	Harmonized as EN ISO 10218-1:2011 (not modified)
IEC 60601-1-9:2007	NOTE	Harmonized as EN 60601-1-9:2008 (not modified)
IEC 61924-2:2012	NOTE	Harmonized as EN 61924-2:2013 (not modified)
ISO 11064-7:2006	NOTE	Harmonized as EN ISO 11064-7:2006 (not modified)

Annex ZA (normative)

Normative references to international publications with their corresponding European publications

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE 1 Where an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cenelec.eu.

The Annex ZA of EN 60601-1:2006 is applicable, except as follows:

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
<i>Replacement</i>				
IEC 60601-1-2	2014	Medical electrical equipment - Part 1-2:EN 60601-1-2 General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests		2015
IEC 60601-1-6	2010	Medical electrical equipment - Part 1-6:EN 60601-1-6 General requirements for basic safety and essential performance - Collateral standard: Usability		2010
IEC 60601-1-8	2006	Medical electrical equipment_ Part_1-8:- General requirements for basic safety and essential performance_ - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems		-
ISO 14971	2007	Medical devices_ - Application of risk-management to medical devices		-
<i>Addition:</i>				
IEC 60601-1-10	2007	Medical electrical equipment - Part 1-10:EN 60601-1-10 General requirements for basic safety and essential performance - Collateral Standard: Requirements for the development of physiologic closed-loop controllers		2008
IEC 60601-1-11	2015	Medical electrical equipment_ - Part_1-11:- General requirements for basic safety and essential performance_ - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment		-

EN IEC 80601-2-78:2020 (E)

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
IEC 62366-1	2015	Medical devices - Part 1: Application of usability engineering to medical devices	EN 62366-1	2015
ISO 22523		External limb prostheses and external orthoses – Requirements and test methods	+AC EN ISO 22523	2015 2006



IEC 80601-2-78

Edition 1.0 2019-07

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
essentielle des robots médicaux dédiés à la rééducation, l'évaluation, la
compensation ou l'atténuation**



THIS PUBLICATION IS COPYRIGHT PROTECTED

Copyright © 2019 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 Central Office
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.

Electropedia - www.electropedia.org

The world's leading online dictionary on electrotechnology, containing more than 22 000 terminological entries in English and French, with equivalent terms in 16 additional languages. Also known as the International Electrotechnical Vocabulary (IEV) online.

IEC Glossary - std.iec.ch/glossary

67 000 electrotechnical terminology entries in English and French extracted from the Terms and Definitions clause of IEC publications issued since 2002. Some entries have been collected from earlier publications of IEC TC 37, 77, 86 and CISPR.

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

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.

Electropedia - www.electropedia.org

Le premier dictionnaire d'électrotechnologie en ligne au monde, avec plus de 22 000 articles terminologiques en anglais et en français, ainsi que les termes équivalents dans 16 langues additionnelles. Egalement appelé Vocabulaire Electrotechnique International (IEV) en ligne.

Glossaire IEC - std.iec.ch/glossary

67 000 entrées terminologiques électrotechniques, en anglais et en français, extraites des articles Termes et Définitions des publications IEC parues depuis 2002. Plus certaines entrées antérieures extraites des publications des CE 37, 77, 86 et CISPR de l'IEC.



IEC 80601-2-78

Edition 1.0 2019-07

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 978-2-8322-7000-4

**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.....	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 of ME EQUIPMENT	14
201.6 Classification of ME EQUIPMENT and ME SYSTEMS.....	14
201.7 ME EQUIPMENT identification, marking and documents	14
201.8 Protection against electrical HAZARDS from ME EQUIPMENT.....	15
201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS.....	15
201.10 Protection against unwanted and excessive radiation HAZARDS	21
201.11 Protection against excessive temperatures and other HAZARDS	21
201.12 Accuracy of controls and instruments and protection against hazardous outputs	21
201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT	22
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS).....	22
201.15 Construction of ME EQUIPMENT	22
201.16 ME SYSTEMS	24
201.17 ELECTROMAGNETIC COMPATIBILITY of ME EQUIPMENT and ME SYSTEMS	24
202 ELECTROMAGNETIC DISTURBANCES – Requirements and tests	24
206 USABILITY	24
208 * General requirements, tests and guidance for alarm systems in MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS	25
210 * Process requirements for the development of PHYSIOLOGIC CLOSED-LOOP CONTROLLERS	25
211 * Requirements for MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS used in the HOME HEALTHCARE ENVIRONMENT	26
Annexes	27
Annex A (informative) General guidance and rationale.....	27
Annex AA (informative) Particular guidance and rationale.....	28
Annex BB (informative) Guidance and examples of SITUATION AWARENESS.....	57
Bibliography.....	71
Index of defined terms used in this particular standard.....	74
Figure AA.1 – Relationship of the terms used to describe equipment, accessories or equipment parts	29
Figure AA.2 – Endsley's model of SITUATION AWARENESS (based on [10], drawn by Dr. Peter Lankton, May 2007).....	33
Figure AA.3 – Model of user-medical device interaction	34
Figure AA.4 – RACA ROBOT shared control system block diagram: control by PATIENT and RACA ROBOT	38
Figure AA.5 – RACA ROBOT shared control system block diagram: control by PATIENT, OPERATOR and RACA ROBOT	39

Figure AA.6 – RACA ROBOT shared control system block diagram: control by PATIENT and RACA ROBOT, and control modulation by OPERATOR	40
Figure AA.7 – WALKING RACA ROBOT using motion-related biosignal input.....	41
Figure AA.8 – System block diagram of a WALKING RACA ROBOT using a motion-related biosignal as input.....	41
Figure AA.9 – RACA ROBOT that is an arm exoskeleton for REHABILITATION that applies a PATIENT-cooperative shared control strategy	42
Figure AA.10 – System block diagram of an arm exoskeleton for REHABILITATION that applies a PATIENT-cooperative shared control strategy	43
Figure AA.11 – Cane-type RACA ROBOT for REHABILITATION of walking.....	44
Figure AA.12 – System block diagram of a cane-type RACA ROBOT	44
Figure AA.13 – Example of ROBOT arm type RACA ROBOT for lower extremities	45
Figure AA.14 – Example of ROBOT arm type RACA ROBOT for upper extremities	46
Figure AA.15 – Example of exoskeleton type RACA ROBOT for upper extremities	47
Figure AA.16 – Example of exoskeleton type RACA ROBOT for knee joint.....	49
Figure AA.17 – Example of soft artificial muscle-type RACA ROBOT for knee joint	50
Figure AA.18 – Example of exoskeleton-type WALKING RACA ROBOT	51
Figure AA.19 – Example of RACA ROBOT for balance control	52
Figure AA.20 – Example of a body-weight support-type RACA ROBOT with gait following function.....	54
Figure BB.1 – All the proximate causes of loss of SITUATION AWARENESS [19]	58
Figure BB.2 – Relationship between SITUATION AWARENESS, the RISK MANAGEMENT PROCESS (ISO 14971:2007) and the USABILITY ENGINEERING PROCESS (IEC 62366-1:2015)	60
Figure BB.3 – Relationship between GDTA and RISK MANAGEMENT and USABILITY ENGINEERING PROCESSES.....	63
Figure BB.4 – WALKING exoskeleton RACA ROBOT	69
Table 201.101 – List of potential ESSENTIAL PERFORMANCES.....	14
Table 19 – MECHANICAL HAZARDS covered by this clause.....	16
Table 201.102 – Overview of different stopping procedures	16
Table 28 – Mechanical strength test applicability	23
Table 1 – Mechanical strength test applicability, non-TRANSIT-OPERABLE	26
Table 2 – Mechanical strength test applicability, TRANSIT-OPERABLE	26
Table AA.1 – Correlation mapping between Figure AA.2 and Figure AA.3.....	35
Table BB.1 – Example of using GDTA in BB.5.2	64
Table BB.2 – Example of using GDTA in BB.5.3	66
Table BB.3 – Example of using GDTA in BB.5.4	68
Table BB.4 – Example of using GDTA in BB.5.5	70

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) 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.

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.

The text of this International Standard is based on the following documents:

FDIS	Report on voting
62D/1676/FDIS	62D/1688/RVD

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

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 will remain unchanged until the stability date indicated on the IEC website under "<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 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.

MEDICAL ELECTRICAL EQUIPMENT –

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

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 80601 applies to the general requirements for BASIC SAFETY and ESSENTIAL PERFORMANCE of 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, as intended by the MANUFACTURER.

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.

NOTE See also 4.2 of the general standard.

This particular standard does not apply to

- external limb prosthetic devices (use ISO 22523),
- electric wheelchairs (use ISO 7176 (all parts)),
- diagnostic imaging equipment (e.g. MRI, use IEC 60601-2-33), and
- personal care ROBOTS (use ISO 13482).

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements 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.

201.1.3 Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.

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

This is a free preview. Purchase the entire publication at the link below:

[Product Page](#)

-
- [Looking for additional Standards? Visit Intertek Inform Infostore](#)
 - [Learn about LexConnect, All Jurisdictions, Standards referenced in Australian legislation](#)
-