



**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:*

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*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

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## 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

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EUROPEAN STANDARD  
NORME EUROPÉENNE  
EUROPÄISCHE NORM

**EN IEC 80601-2-78**

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.

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**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

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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.

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*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	EN 60601-1-2	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	EN 60601-1-6	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	EN 60601-1-10	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		-

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

## 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
			+AC	2015
ISO 22523		External limb prostheses and external orthoses – Requirements and test methods	EN ISO 22523	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 essentielles des robots médicaux dédiés à la rééducation, l'évaluation, la compensation ou l'atténuation**



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**IEC 80601-2-78**

Edition 1.0 2019-07

# INTERNATIONAL STANDARD

## NORME INTERNATIONALE



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**Medical electrical equipment –**

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**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

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## 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

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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.

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- "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.

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## 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 standard<sup>1</sup> 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.

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<sup>1</sup> 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*.

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