



DPC: 25/30510772 DC

BSI Group Headquarters

389 Chiswick High Road London W4 4AL

Tel: +44 (0)20 8996 9000

Fax: +44 (0)20 8996 7400

www.bsigroup.com

Date: 27 November 2025

Origin: International

Latest date for receipt of comments: 31 December 2025

Project No. 2025/00657

Responsible committee: CH/62/4 Electromedical equipment

Interested committees:

Title: Draft BS EN 80601-2-77 Ed.2.0 BS EN IEC 80601-2-77 ED2 Medical electrical equipment. Part 2-77: Particular requirements for the basic safety and essential performance of robotically assisted surgical equipment.

Please notify admin.start@bsigroup.com if you are aware of any keywords that might assist in clarifying or identifying the standard or of the content of this standard:

- i) has any issues related to 3rd party IPR, patent or copyright
- ii) affects other national standard(s)
- iii) requires additional national guidance or information

WARNING: THIS IS A DRAFT AND MUST NOT BE REGARDED OR USED AS A BRITISH STANDARD. THIS DRAFT IS NOT CURRENT BEYOND 31 December 2025

This draft is issued to allow comments from interested parties; all comments will be given consideration prior to publication. No acknowledgement will normally be sent. **See overleaf for information on the submission of comments.**

No copying is allowed, in any form, without prior written permission from BSI except as permitted under the Copyright, Designs and Patent Act 1988 or for circulation within a nominating organization for briefing purposes. Electronic circulation is limited to dissemination by e-mail within such an organization by committee members.

Further copies of this draft may be purchased from BSI Shop <http://shop.bsigroup.com> or from BSI Customer Services, Tel: +44(0) 20 8996 9001 or email cservices@bsigroup.com. British, International and foreign standards are also available from BSI Customer Services.

Information on the co-operating organizations represented on the committees referenced above may be obtained from <https://standardsdevelopment.bsigroup.com/>.

E-mail: admin.start@bsigroup.com

Introduction

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

For national standards, comments will be reviewed by the relevant UK national committee and the resulting standards published as a British Standard.

UK Vote

Please indicate whether you consider the UK should submit a negative (with supporting technical reasons) or positive vote on this draft. Please indicate if you are aware of any reason why this draft standard should not be published as a British Standard.

Submission of Comments

- **Annotated drafts are not acceptable and will be rejected.**
- All comments should be submitted online at <https://standardsdevelopment.bsigroup.com/>. You will need to register in order to comment.

Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx
------------------	------------------------

1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/ Figure/Table/Note	Type of comment	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	



62D/2277/CD

COMMITTEE DRAFT (CD)

PROJECT NUMBER:

IEC 80601-2-77 ED2

DATE OF CIRCULATION:

2025-11-21

CLOSING DATE FOR COMMENTS:

2026-01-30

SUPERSEDES DOCUMENTS:

62D/2157/RR

IEC SC 62D : PARTICULAR MEDICAL EQUIPMENT, SOFTWARE, AND SYSTEMS

SECRETARIAT:

United States of America

SECRETARY:

Ms Ladan Bulookbashi

OF INTEREST TO THE FOLLOWING COMMITTEES:

HORIZONTAL FUNCTION(S):

ASPECTS CONCERNED:

Safety

This document is still under study and subject to change. It should not be used for reference purposes.

Recipients of this document are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

Recipients of this document are invited to submit, with their comments, notification of any local regulations or technical reasons that may exist and should be considered should this proposal proceed, recognizing that failure to address such requirements could result in the need for new or existing "In Some Countries" clauses. (SEE AC/22/2007 OR NEW GUIDANCE DOC).

TITLE:

Medical electrical equipment - Part 2-77: Particular requirements for the basic safety and essential performance of robotically assisted surgical equipment

NOTE FROM TC/SC OFFICERS:

Please note that changes are highlighted in red.

Copyright © 2025 International Electrotechnical Commission, IEC. All rights reserved. It is permitted to download this electronic file, to make a copy and to print out the content for the sole purpose of preparing National Committee positions. You may not copy or "mirror" the file or printed version of the document, or any part of it, for any other purpose without permission in writing from IEC.

CONTENTS

1		
2	CONTENTS	1
3	FOREWORD	5
4	INTRODUCTION	8
5	INTRODUCTION to Edition 2	9
6	201.1 Scope, object and related standards	10
7	201.1.1 Scope	10
8	201.1.2 Object	10
9	201.1.3* Collateral standards	10
10	201.1.4 Particular standards	11
11	201.2 Normative references	12
12	201.3 Terms and definitions	12
13	201.4 General requirements	15
14	201.4.1 Conditions for application to ME EQUIPMENT or ME SYSTEMS	15
15	201.4.1.101* ROBOTIC SURGICAL INSTRUMENTS and other ME EQUIPMENT	15
16	201.4.3* ESSENTIAL PERFORMANCE	15
17	201.4.6* ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT	15
18	201.4.7 SINGLE FAULT CONDITION for ME EQUIPMENT	15
19	201.5 General requirements for testing of ME EQUIPMENT	15
20	201.5.4 Other conditions	15
21	201.5.7 Humidity preconditioning treatment	16
22	201.6 Classification of ME EQUIPMENT and ME SYSTEMS	16
23	201.7 ME EQUIPMENT identification, marking and documents	16
24	201.7.2.2 Identification	16
25	201.7.2.2.101 Marking of maximum PATIENT mass and SAFE WORKING LOAD	16
26	201.7.2.2.102 Marking of the mass of MOUNTED PART	16
27	201.7.2.9* IP classification	16
28	201.7.2.10 APPLIED PARTS	17
29	201.7.2.101 Alternative marking	17
30	201.7.4.2 Control devices	17
31	201.7.8.1* Colours of indicator lights	17
32	201.7.9.2.2 Warning and safety notices	18
33	201.7.9.2.101 Release of PATIENT	19
34	201.8 Protection against electrical HAZARDS from ME EQUIPMENT	19
35	201.8.3 Classification of APPLIED PARTS	19
36	201.8.5.1.1 General	19
37	201.8.5.2 Separation of PATIENT CONNECTIONS	19
38	201.8.5.2.101* F-Type insulation	19
39	201.8.6.3 Protective earthing of moving parts	20
40	201.8.9.1.1* General	20
41	201.9 * Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS	20
42	201.9.2.2.4.4* Other RISK CONTROL measures	20
43	201.9.2.2.5* Continuous activation	20
44	201.9.2.2.6* Speed of movement(s)	21
45	201.9.2.3.2* Overtravel end stops	21
46	201.9.2.4 Emergency stopping devices	21
47	201.9.2.5* Release of PATIENT	21

48	201.9.2.101* RASE PROTECTIVE STOP functions	22
49	201.9.3MECHANICAL HAZARD associated with surfaces, corners and edges	22
50	201.9.4.2* Instability – overbalance	22
51	201.9.4.2.2Instability excluding transport position	22
52	201.9.4.2.4.3* Movement over a threshold	22
53	201.9.4.3.2* Instability excluding transport position	22
54	201.9.8.1* General	23
55	201.9.101Person collision with RASE.....	23
56	201.9.102RASE collision with itself and other objects	23
57	201.10 Protection against unwanted and excessive radiation HAZARDS	23
58	201.11 Protection against excessive temperatures and other HAZARDS	24
59	201.11.1.1Maximum temperature during NORMAL USE	24
60	201.11.6.1* General	24
61	201.11.6.7Sterilization of ME EQUIPMENT and ME SYSTEMS	24
62	201.11.101INTERACTION CONDITIONS	24
63	201.11.101.1General.....	24
64	201.11.101.2Thermal and other HAZARDS from INTERACTION CONDITIONS with lasers	24
65	201.11.101.3 * Thermal and other HAZARDS from INTERACTION CONDITIONS	
66	with HF SURGICAL EQUIPMENT	25
67	201.12 Accuracy of controls and instruments and protection against hazardous	
68	outputs	25
69	201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT	25
70	201.13.1.4Specific MECHANICAL HAZARDS	25
71	201.13.1.4.101Additional MECHANICAL HAZARDS	25
72	201.13.1.101* Information essential to perform SURGERY	25
73	201.13.1.102* Motion control of the ROBOTIC SURGICAL INSTRUMENT	25
74	201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS).....	25
75	201.15 Construction of ME EQUIPMENT	26
76	201.15.3.1General.....	26
77	201.15.4ME EQUIPMENT components and general assembly	26
78	201.15.4.101Fixing, prevention of maladjustment of MECHANICAL INTERFACE	26
79	201.16 * ME SYSTEMS	26
80	201.17 * ELECTROMAGNETIC COMPATIBILITY of ME EQUIPMENT and ME SYSTEMS	26
81	202 ELECTROMAGNETIC DISTURBANCES – Requirements and tests	26
82	202.8.1General	26
83	202.8.101IMMUNITY pass/fail criteria	27
84	202.8.102IMMUNITY to HF SURGICAL EQUIPMENT EMISSIONS.....	27
85	206 * USABILITY	27
86	206.4.2USABILITY ENGINEERING PROCESS for ME EQUIPMENT	27
87	206.5Replacement of requirements given in IEC 62366.....	27
88	Annexes	28
89	Annex D (informative) Symbols on marking.....	29
90	Annex AA (informative) Particular guidance and rationale	30
91	AA.1General guidance	30
92	AA.2Rationale for particular clauses and subclauses	30
93	Subclause 201.7.8.1 – Colours of indicator lights	37
94	Annex BB (informative) Equations for the calculation of the overall system stopping	
95	performance and minimum distances	46

96	BB.1General	46
97	BB.2Overall system stopping performance	46
98	BB.3Stopping distance	47
99	Annex CC (informative) Stopping functions of the RASE	48
100	CC.1General	48
101	CC.2Introduction of RASE PROTECTIVE STOP	48
102	CC.3Stopping RASE	49
103	Annex DD (informative) Alternative method to demonstrate structural integrity	
104	throughout the EXPECTED SERVICE LIFE of the RASE	50
105	Annex EE (informative) Example of a testing method of the IMMUNITY test for HF	
106	SURGICAL EQUIPMENT emissions	53
107	EE.1General	53
108	EE.2Electromagnetic (EM) Phenomena aspects in RASE applications	53
109	EE.3Testing conditions	53
110	EE.3.1Conditions of RASE	53
111	EE.3.2Selection and conditions of HF SURGICAL EQUIPMENT	54
112	EE.3.3Test settings	54
113	Annex FF (informative) Image-guided RASE	56
114	FF.1General	56
115	FF.2Reference data for image-guided RASE	56
116	FF.2.1Image and data requirements for image-guided RASE	56
117	FF.2.2Date and time format	56
118	FF.2.3RASE data boundaries	56
119	FF.2.4Verification of data coherence	56
120	FF.2.5Correctness of data transfer	57
121	FF.2.6correctness of spatial coordinates	57
122	FF.3Imaging for image-guided RASE	57
123	FF.3.1Image quality	57
124	FF.3.2Image degradation due to artefacts and warping	57
125	FF.4.1General requirements for operational safety	57
126	FF.4.1.1Distances and linear and angular dimensions	57
127	FF.4.1.2Coordinate systems, movements, and scales	58
128	FF.4.2Security	58
129	FF.4.2.1Protection against unauthorized use	58
130	FF.4.3Interfaces	58
131	FF.5Image-guided adjustment and correction	59
132	FF.5.1intraoperative image-guided adjustment and correction	59
133	Bibliography	60
134	Index of defined terms used in this particular standard	62
135		
136	Figure 201.101 – Graphic symbol for maximum PATIENT mass and SAFE WORKING LOAD	16
137	Figure 201.102 – Graphic symbol for mass of MOUNTED PART	16
138	Figure 201.AA.101 – Examples of MECHANICAL INTERFACE attachments	31
139	Figure 201.AA.102 – Example 1 of ROBOTIC SURGERY CONFIGURATION: a case of	
140	laparoscopic RASS	33

141	Figure 201.AA.103 – Example 2 of ROBOTIC SURGERY CONFIGURATION: a case of bone	
142	milling RASE	33
143	Figure 201.AA.104 – Typical ESSENTIAL PERFORMANCE items of RASE.....	35
144	Figure 201.AA.105 – Example of RISK ASSESSMENT related to structural component	42
145	Figure 201.BB.101 – Relationship between t_1 and t_2	47
146		
147	Table 201.101 – List of ESSENTIAL PERFORMANCE requirements.....	15
148	Table 201.102 – Colours and meanings of indicator lights for RASE and RASS.....	18
149	Table 201.D.101 – Symbols for marking RASE or its parts.....	29
150	Table 201.CC.101 – Different stopping functions	48
151	Table 201.DD.101 – Alternative to safety factors: life testing	50
152		
153		

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-77: Particular requirements for the BASIC SAFETY and essential performance of ROBOTICALLY ASSISTED SURGICAL 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 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.

198 International Standard IEC 80601-2-77 has been prepared by subcommittee 62D: Particular
 199 medical equipment, software, and systems62:Medical equipment, software, and systems, and
 200 ISO technical committee 299: Robotics.

201 This publication is published as a double logo standard.

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

203 In this document, the following print types are used:

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

210 In referring to the structure of this document, the term

- 211 – "clause" means one of the nineteen numbered divisions within the table of contents,
 212 inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
- 213 – "subclause" means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all
 214 subclauses of Clause 7).

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

217 In this document, the conjunctive "or" is used as an "inclusive or" so a statement is true if any
 218 combination of the conditions is true.

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

- 221 – "shall" means that compliance with a requirement or a test is mandatory for compliance with
 222 this document;
- 223 – "should" means that compliance with a requirement or a test is recommended but is not
 224 mandatory for compliance with this document;
- 225 – "may" is used to describe a permissible way to achieve compliance with a requirement or
 226 test.

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

229 A list of all parts of the IEC 60601 and IEC 80601 International Standard, published under the
 230 general title *Medical electrical equipment*, can be found on the IEC website.

231

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 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.

248

INTRODUCTION

249 This part of IEC 80601 is written at a time when technical evolution of medical robots is in rapid
250 progress and the scientific foundation of safe use is still being expanded.

251 This document is the result of work that began in ISO/TC 184/SC 2/WG 7 in October 2006 on
252 personal care robots, to address an emerging type of medical robot that was used outside of
253 an industrial environment¹. That group was working on a new standard, ISO 13482[1]², which
254 was published as an International Standard (IS) in 2014. While initially focused on non-medical
255 applications, WG 7 recognized that work was likely to be needed on medical devices utilizing
256 robotic technology. In October 2009, ISO/TC 184/SC 2 established a WG 7, Study Group (SG)
257 on Medical care robots, comprised of experts from Canada, France, Germany, Japan, Korea,
258 Romania, Switzerland, UK and USA.

259 The work of ISO/TC 184/SC 2/WG 7 SG cumulated in a proposal to form a Joint Working Group
260 (JWG 9) with IEC/TC 62/SC 62A focusing on MEDICAL ELECTRICAL EQUIPMENT using robotic
261 technology. This JWG began developing a technical report (IEC TR 60601-4-1:2017[2]) dealing
262 with degree of autonomy. While developing this document, a particular standard was proposed
263 for robotic equipment used in surgical applications. This led to the creation of a Joint Working
264 Group 35 in April 2015 within IEC/TC 62/SC 62D to develop particular requirements of safety
265 of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS that utilize robotic
266 technology. The work would include medical robots for SURGERY. This proposal was approved,
267 resulting in the formation of Joint Working Group (JWG 35).

268 During IEC/TC 62/SC 62D discussion, there was a strong opinion that some types of MEDICAL
269 ELECTRICAL EQUIPMENT could be a medical robot, but not all MEDICAL ELECTRICAL EQUIPMENT were
270 medical robots. According to this opinion, JWG 35 discussed and agreed that the majority of
271 existing MEDICAL ELECTRICAL EQUIPMENT, including those used for surgical PROCEDURES, were
272 not considered medical robots, so it would be better to capture this type of ME EQUIPMENT
273 through a different definition – ROBOTICALLY ASSISTED SURGICAL EQUIPMENT (RASE).

274 JWG 9 defined medical robots as ME EQUIPMENT with a degree of autonomy
275 (IEC TR 60601-4-1:2017). JWG 35 found that some RASE have zero autonomy. Therefore, by
276 definition, RASE could not be equivalent to a medical robot. Regulatory agencies objected to
277 employ the term robot as defined in IEC TR 60601-4-1 and felt that it implied that the RASE were
278 performing the surgical PROCEDURE rather than the surgeon. The consensus in JWG 35 was
279 that the RASE only assists the surgeon. The surgeon maintains some level of control or
280 supervision of the RASE.

281 The minimum safety requirements specified in this particular standard for ROBOTICALLY ASSISTED
282 SURGICAL EQUIPMENT are presumed to establish that the RESIDUAL RISKS have been reduced to
283 acceptable levels unless there is OBJECTIVE EVIDENCE to the contrary.

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

285

¹ ISO TC 184/SC 2 was reorganized as ISO TC 299 in 2016.

² Numbers in square brackets refer to the Bibliography.

INTRODUCTION to Edition 2

During the September 21, 2023, meeting of IEC SC 62D Plenary in Seoul, Republic of Korea, the subcommittee discussed the need to proceed with a new edition of IEC 80601-2-77. The need for a new edition was to include/modify the standard based on the latest ROBOTICALLY ASSISTED SURGICAL EQUIPMENT (RASE).

A resolution was taken to proceed towards the 2nd edition of the IEC 80601-2-77.

The review report for the new edition can be found in the IEC document 62D/2157/RR.

This 2nd edition of the IEC 80601-2-77 supersedes the IEC 80601-2-77 edition 1.1 standard. Major changes in this edition are;

- Extend the scope of this document by extending the definition of ROBOTIC SURGICAL INSTRUMENT,
- Clarify the definition of SURGERY in the Annex AA.
- Add guidance on image-guided RASE in the Annex FF

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-77: Particular requirements for the BASIC SAFETY and essential performance of ROBOTICALLY ASSISTED SURGICAL EQUIPMENT

201.1 Scope, object and related standards

Clause 1 of the general standard³ applies, except as follows:

201.1.1 Scope

Replacement:

This part of IEC 80601 applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of ROBOTICALLY ASSISTED SURGICAL EQUIPMENT (RASE) and ROBOTICALLY ASSISTED SURGICAL SYSTEMS (RASS), hereafter referred to as ME EQUIPMENT and ME SYSTEMS together with their INTERACTION CONDITIONS and INTERFACE CONDITIONS. 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.

If RASE or RASS, or its ACCESSORIES fall within scope of another particular standard, then the particular standard applies in addition to this standard.

EXAMPLES IEC 60601-2-2[3] for HF SURGICAL EQUIPMENT; IEC 60601-2-18[4] for ENDOSCOPIC EQUIPMENT; IEC 60601-2-22[5] for laser equipment; IEC 60601-2-37[6] for ultrasound equipment; IEC 60601-2-46[7] for operating tables, etc.

ME EQUIPMENT and ME SYSTEMS intended to be used for diagnostic imaging only or radiotherapy applications are excluded from the scope of this document.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for ROBOTICALLY ASSISTED SURGICAL EQUIPMENT and ROBOTICALLY ASSISTED SURGICAL SYSTEMS.

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.

IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020, IEC 60601-1-6:2010, IEC 60601-1-6:2010/AMD1:2013 and IEC 60601-1-6:2010/AMD2:2020 apply as modified in Clauses 202 and 206 respectively.

IEC 60601-1-3:2008, IEC 60601-1-3:2008/AMD1:2013 and IEC 60601-1-3:2008/AMD2:2021 [8], IEC 60601-1-9:2007, IEC 60601-1-9:2007/AMD1:2013 and

³ 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*.

338 IEC 60601-1-9:2007/AMD2:2020 [9], and IEC 60601-1-11:2015 and
 339 IEC 60601-1-11:2015/AMD1:2020 do not apply.

340 **201.1.4 Particular standards**

341 *Replacement:*

342 In the IEC 60601 series, particular standards may modify, replace or delete requirements
 343 contained in the general standard and collateral standards as appropriate for the particular ME
 344 EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE
 345 requirements.

346 A requirement of a particular standard takes priority over the general standard.

347 For brevity, IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-
 348 1:2005/AMD2:2020 are referred to in this particular standard as the general standard. Collateral
 349 standards are referred to by their document number.

350 The numbering of clauses and subclauses of this particular standard corresponds to that of the
 351 general standard with the prefix "201" (e.g. 201.1 in this document addresses the content of
 352 Clause 1 of the general standard) or applicable collateral standard with the prefix "20x", where
 353 x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this particular
 354 standard addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 in
 355 this particular standard addresses the content of Clause 4 of the IEC 60601-1-3 collateral
 356 standard, etc.). The changes to the text of the general standard are specified by the use of the
 357 following words:

358 "*Replacement*" means that the clause or subclause of the general standard or applicable
 359 collateral standard is replaced completely by the text of this particular standard.

360 "*Addition*" means that the text of this particular standard is additional to the requirements of the
 361 general standard or applicable collateral standard.

362 "*Amendment*" means that the clause or subclause of the general standard or applicable
 363 collateral standard is amended as indicated by the text of this particular standard.

364 Subclauses, figures or tables which are additional to those of the general standard are
 365 numbered starting from 201.101. However, due to the fact that definitions in the general
 366 standard are numbered 3.1 through 3.147, additional definitions in this document are numbered
 367 beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items
 368 aa), bb), etc.

369 Subclauses, figures or tables which are additional to those of a collateral standard are
 370 numbered starting from 20x, where "x" is the number of the collateral standard, e.g. 202 for
 371 IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

372 The term "this document" is used to make reference to the general standard, any applicable
 373 collateral standards and this particular standard taken together.

374 Where there is no corresponding clause or subclause in this particular standard, the clause or
 375 subclause of the general standard or applicable collateral standard, although possibly not
 376 relevant, applies without modification; where it is intended that any part of the general standard
 377 or applicable collateral standard, although possibly relevant, is not to be applied, a statement
 378 to that effect is given in this particular standard.

201.2 Normative references

NOTE Informative references are listed in the Bibliography.

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

Replacement:

IEC 60601-1-2:2014, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests*
IEC 60601-1-2:2014/AMD1:2020

IEC 60601-1-6:2010, *Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability*
IEC 60601-1-6:2010/AMD1:2013
IEC 60601-1-6:2010/AMD2:2020

IEC 62366-1:2015, *Medical devices – Part 1: Application of usability engineering to medical devices*
IEC 62366-1:2015/AMD1:2020

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

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at <http://www.electropedia.org/>
- ISO Online browsing platform: available at <http://www.iso.org/obp>

NOTE An index of defined terms is found beginning on page 62.

Addition:

201.3.201

*** CAPACITIVELY COUPLED HF LEAKAGE CURRENT**

unavoidable HF LEAKAGE CURRENT flowing due to capacitive coupling from the APPLIED PART of HF SURGICAL EQUIPMENT to another part of the RASE or RASS

[SOURCE: IEC 60601-2-18:2009, 201.3.201, modified – Replacement of " from an ENERGIZED ENDOTHERAPY DEVICE that is the APPLIED PART of HF SURGICAL EQUIPMENT to the ENDOSCOPE" by "from the APPLIED PART of HF SURGICAL EQUIPMENT to another part of the RASE or RASS", **insertion of "leakage".**]

201.3.202

ENDOSCOPIC EQUIPMENT

energized endoscope together with its supply unit(s), as required for its INTENDED USE

419 [SOURCE: IEC 60601-2-18:2009, 201.3.204]

420 **201.3.203**

421 **HIGH FREQUENCY**

422 **HF**

423 frequencies less than 5 MHz and generally greater than 200 kHz

424 [SOURCE: IEC 60601-2-2:2017, 201.3.220]

425 **201.3.204**

426 **HF SURGICAL ACCESSORY**

427 ACCESSORY intended to conduct, supplement or monitor HF energy applied to the PATIENT from
428 HF SURGICAL EQUIPMENT

429 [SOURCE: IEC 60601-2-2:2017, 201.3.223, modified – The notes have been deleted.]

430 **201.3.205**

431 **HF SURGICAL EQUIPMENT**

432 MEDICAL ELECTRICAL EQUIPMENT which generates HIGH FREQUENCY currents intended for the
433 performance of surgical tasks, such as the cutting or coagulation of biological tissue by means
434 of these HIGH FREQUENCY currents

435 [SOURCE: IEC 60601-2-2:2017, 201.3.224, modified – The notes have been deleted.]

436 **201.3.206**

437 *** INTERACTION CONDITIONS**

438 conditions that shall be fulfilled to achieve BASIC SAFETY when RASE or RASS is used
439 simultaneously with multiple ROBOTIC SURGICAL INSTRUMENTS or with an APPLIED PARTS of other
440 ME EQUIPMENT, at least one APPLIED PART of which uses energy for providing its INTENDED USE,
441 e.g. HF current, ultrasound, or laser

442 **201.3.207**

443 *** INTERFACE CONDITIONS**

444 conditions that shall be fulfilled to achieve BASIC SAFETY for any FUNCTIONAL CONNECTION
445 between RASE or RASS and other ME EQUIPMENT or non-ME EQUIPMENT in the ROBOTIC SURGERY
446 CONFIGURATION

447 [SOURCE: IEC 60601-2-18:2009, 201.3.211, modified – Replacement of "endoscopic
448 EQUIPMENT" by "RASE or RASS", and of "configuration for ENDOSCOPIC EQUIPMENT" by "ROBOTIC
449 SURGERY CONFIGURATION".]

450 **201.3.208**

451 *** MECHANICAL INTERFACE**

452 mounting surface on RASE or RASS that allows for attachment of detachable ACCESSORIES,
453 components, or parts that are mechanically manipulated by the RASE or RASS

454 Note 1 to entry: A MECHANICAL INTERFACE can be used to attach items that are sterile.

455 Note 2 to entry: A MECHANICAL INTERFACE can provide insulation and other functions (e.g., sterile boundary) to
456 achieve BASIC SAFETY.

457 Note 3 to entry: RASE or RASS can have zero, one, or more MECHANICAL INTERFACE per each ROBOTIC SURGICAL
458 INSTRUMENT.

459 **201.3.209**

460 **MOUNTED PART**

461 any part of RASE or RASS, including ACCESSORIES intended to be mounted to an operating table
462 or on another supporting structure which is not part of the RASE or RASS

201.3.210**RASE PROTECTIVE STOP**

type of interruption of operation that allows a cessation of motion as a RISK CONTROL measure and which retains the ability of PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS) to facilitate resumption of the operation of the RASE or RASS

Note 1 to entry: A RASE PROTECTIVE STOP can be manually initiated, or automatically initiated by means of PEMS.

Note 2 to entry: A RASE PROTECTIVE STOP can be coordinated with deactivation of energy of ROBOTIC SURGICAL INSTRUMENT and ACCESSORIES if required as a RISK CONTROL measure.

Note 3 to entry: Annex CC tabulates differences between emergency stop and RASE PROTECTIVE STOP.

201.3.211*** ROBOTICALLY ASSISTED SURGICAL EQUIPMENT****RASE**

MEDICAL ELECTRICAL EQUIPMENT that incorporates PEMS actuated mechanism intended to facilitate the placement or manipulation of ROBOTIC SURGICAL INSTRUMENT(s)

Note 1 to entry: "Placement" includes INTENDED PURPOSE of positioning, maintaining, or holding of a ROBOTIC SURGICAL INSTRUMENT.

Note 2 to entry: RASE can be referred to as surgical robots, robotically assisted surgical devices, computer-assisted surgical systems, surgical manipulators, etc.

Note 3 to entry: A ROBOTIC SURGICAL INSTRUMENT is considered to be a part of the RASE or RASS in this document.

Note 4 to entry: This note applies to the French language only.

201.3.212**ROBOTICALLY ASSISTED SURGICAL SYSTEM****RASS**

MEDICAL ELECTRICAL SYSTEM that incorporates PEMS actuated mechanism intended to facilitate the placement or manipulation of ROBOTIC SURGICAL INSTRUMENT(s)

Note 1 to entry: This note applies to the French language only.

201.3.213*** ROBOTIC SURGERY CONFIGURATION**

combination of RASE or RASS by means of INTERACTION CONDITIONS and INTERFACE CONDITIONS with one or more of the following:

- ACCESSORIES;
- other RASE or RASS;
- other ME EQUIPMENT;
- non-ME EQUIPMENT; or
- ME SYSTEM

201.3.214*** ROBOTIC SURGICAL INSTRUMENT**

device intended to be manipulated by the RASE or RASS to perform tasks in SURGERY

Note 1 to entry: Tasks include visualization.

Note 2 to entry: A ROBOTIC SURGICAL INSTRUMENT can be detachable by means of a MECHANICAL INTERFACE. See definition of MECHANICAL INTERFACE and Annex AA about the attachment of ROBOTIC SURGICAL INSTRUMENT to RASE.

Note 3 to entry: A ROBOTIC SURGICAL INSTRUMENT can be an ACCESSORY of RASE or RASS.

201.3.215*** SURGERY**

PROCEDURE involving the incision, excision, manipulation or suturing of tissue which usually requires regional or general anaesthesia or profound sedation to control pain

509 [SOURCE: WHO/IER/PSP/2008.07[12], modified – The words "conducted in the operating
510 room" have been deleted.]

511 **201.4 General requirements**

512 Clause 4 of the general standard applies, except as follows:

513 **201.4.1 Conditions for application to ME EQUIPMENT or ME SYSTEMS**

514 *Additional subclause:*

515 **201.4.1.101 * ROBOTIC SURGICAL INSTRUMENTS and other ME EQUIPMENT**

516 Where requirements for ROBOTIC SURGICAL INSTRUMENTS and other ME EQUIPMENT given in other
517 applicable particular standards conflict with the requirements for INTERACTION CONDITIONS of this
518 particular standard, the requirements of this particular standard shall take precedence.

519 **201.4.3 * ESSENTIAL PERFORMANCE**

520 *Addition:*

521 Additional ESSENTIAL PERFORMANCE requirements are found in the subclauses listed in
522 Table 201.101.

523 **Table 201.101 – List of ESSENTIAL PERFORMANCE requirements**

Requirement	Subclause
To ensure there is no unacceptable RISK if information essential to perform SURGERY is degraded.	201.13.1.101 Information essential to perform SURGERY
To ensure there is no unacceptable RISK if motion control of the ROBOTIC SURGICAL INSTRUMENT has performance degradation.	201.13.1.102 Motion control of the ROBOTIC SURGICAL INSTRUMENT

524

525 **201.4.6 * ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT**

526 *Addition:*

527 NOTE Additional information is provided in Annex AA.

528 **201.4.7 SINGLE FAULT CONDITION for ME EQUIPMENT**

529 *Addition:*

530 When applying 4.7, the INTERACTION CONDITIONS and INTERFACE CONDITIONS shall be taken into
531 account.

532 **201.5 General requirements for testing of ME EQUIPMENT**

533 Clause 5 of the general standard applies, except as follows:

534 **201.5.4 Other conditions**

535 *Addition to a):*

536 Before carrying out tests, RASE shall be prepared for operation as specified by the
537 MANUFACTURER.

201.5.7 Humidity preconditioning treatment*Addition:*

Single-use equipment drapes are not subject to humidity preconditioning treatment.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

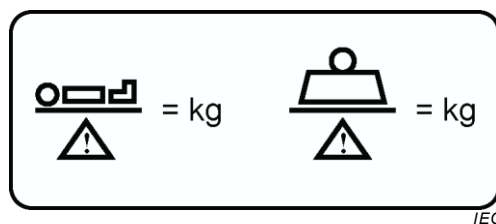
Clause 6 of the general standard applies.

201.7 ME EQUIPMENT identification, marking and documents

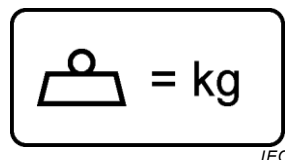
Clause 7 of the general standard applies, except as follows:

201.7.2.2 Identification*Additional subclauses:***201.7.2.2.101 Marking of maximum PATIENT mass and SAFE WORKING LOAD**

If an operating table is a part of RASE, it shall be marked with the corresponding maximum PATIENT mass and SAFE WORKING LOAD (for symbol, see Figure 201.101).

**Figure 201.101 – Graphic symbol for maximum PATIENT mass and SAFE WORKING LOAD****201.7.2.2.102 Marking of the mass of MOUNTED PART**

If RASE has one or more MOUNTED PARTS, each MOUNTED PART shall be marked with its maximum mass unless the HAZARD related to the mass would not lead to an unacceptable RISK (for example, when the mass is negligible) or the marking is not practicable (for symbol, see Figure 201.102).

**Figure 201.102 – Graphic symbol for mass of MOUNTED PART**

Mass of the MOUNTED PART should include the maximum mass of the attached instruments and ACCESSORIES.

201.7.2.9 * IP classification*Addition:*

If marking an IP classification is required for a RASE, and if a protective cover, for example, an equipment drape, is required to meet the classification, the IP symbol marking shall be applied to the protective cover. **If the protective cover is single use, the IP classification may be affixed to the individual packaging.**

ROBOTIC SURGICAL INSTRUMENTS supplied with specific instructions detailing allowable reprocessing methods and parameters are excluded from this requirement. No symbol is required to identify the reprocessing PROCEDURE by this particular standard. See also 7.9.2.12 of the general standard.

201.7.2.10 APPLIED PARTS

Addition:

If marking of an APPLIED PART is not practicable and the APPLIED PART is single-use, the required marking shall be on the individual packaging, or on the equipment adjacent to the connector for the APPLIED PART.

Compliance is checked by inspection.

Additional subclause:

201.7.2.101 Alternative marking

Information which is accessible by the OPERATOR on an output device (e.g. display) of ME EQUIPMENT is considered equivalent to marking on the equipment for requirements of 7.2 of the general standard, as long as the marking is visible at the time the information is required.

Compliance is checked by inspection.

201.7.4.2 Control devices

Addition:

Alternative or no markings of control devices (for example, multi-function buttons) is acceptable if the USABILITY ENGINEERING PROCESS demonstrates that this does not result in unacceptable RISK.

NOTE Visual cues such as colour, tactile, location, shape can be used in lieu of markings.

Compliance is checked by inspecting the USABILITY ENGINEERING FILE.

201.7.8.1 * Colours of indicator lights

Add row 2 and 3 of Table 201.102 above the note of Table 2, and add note ^e, ^f and ^g of Table 201.102 to the note of Table 2:

593

Table 201.102 – Colours and meanings of indicator lights for RASE and RASS

Name	On when	Indicator light ^a	Alarm indicator light	Accompanied by sound	OPERATOR requirement
Cutting mode ^e	Cutting activation	Yellow, flashing or not ^f	–	Yes ^g	–
Coagulation mode ^e	Coagulation activation	Blue, flashing or not ^f	–	Yes ^g	–
^a These indicator lights are INFORMATION SIGNALS and IEC 60601-1-8 requires that they be perceived as different than visual ALARM SIGNALS. ^e Applicable when RASE and RASS incorporate HF SURGICAL EQUIPMENT. ^f Yellow and blue indicator lights can also be used to indicate additional modes if multiple functions share the same control device, provided the USABILITY ENGINEERING PROCESS demonstrates that this does not result in unacceptable RISK. ^g As defined in 201.12.4.2.101 of IEC 60601-2-2:2017.					

594

595 *Addition at the end of subclause 201.7.8.1:*

596 In addition to Table 2, red, yellow, and blue indicator colours may be used as the following,
597 provided the USABILITY ENGINEERING PROCESS demonstrates that this does not result in
598 unacceptable RISK.

- 599 • Red for situations where immediate response by the OPERATOR is required,
- 600 • Yellow for situations where prompt response by the OPERATOR is required,
- 601 • Blue for any situations other than those for red or yellow colours as indicated above.

602 **201.7.9.2.2 Warning and safety notices**603 *Addition:*

604 In addition to requirements in other particular standards that can be relevant, the following
605 warning and safety notices shall be provided as applicable:

606 Warnings regarding INTERACTION CONDITIONS:

- 607 a) warning that, if the ROBOTIC SURGERY CONFIGURATION requires TYPE CF APPLIED PARTS,
608 the APPLIED PARTS of other ME EQUIPMENT used within the ROBOTIC SURGERY
609 CONFIGURATION shall be TYPE CF APPLIED PARTS;
- 610 b) warning that, if the ROBOTIC SURGERY CONFIGURATION requires TYPE BF APPLIED PARTS,
611 the APPLIED PARTS of other ME EQUIPMENT used within the ROBOTIC SURGERY
612 CONFIGURATION shall be F-TYPE APPLIED PARTS;
- 613 c) warning that, when other ME EQUIPMENT are used with ROBOTIC SURGICAL INSTRUMENTS,
614 PATIENT LEAKAGE CURRENTS can be additive;
- 615 d) warning that, when RASE or RASS is used with laser equipment, advice concerning their
616 safe use shall be given, including avoidance of potential injury, for example, wearing
617 suitable personal protective equipment, or by inserting a suitable filter for the ROBOTIC
618 SURGICAL INSTRUMENTS;
- 619 e) warning that, before each use, the compatibility of RASE or RASS with any ROBOTIC
620 SURGICAL INSTRUMENTS and other APPLIED PARTS including those of other ME EQUIPMENT
621 shall be checked according to any criteria for safe use defined in the instructions for
622 use;