BS EN IEC 80601-2-60:2020

BSI Standards Publication

Medical electrical equipment

Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment

Documents
Document Sharing Hub

Full document details: BS EN IEC 80601-2-60:2020

National foreword

This British Standard is the UK implementation of EN IEC 80601-2-60:2020. It is identical to IEC 80601-2-60:2019. It supersedes BS EN 80601-2-60:2015, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/106/4, Dental Instruments and Equipment.

A list of organizations represented on this committee can be obtained on request to its secretary.

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

© The British Standards Institution 2020
Published by BSI Standards Limited 2020

ISBN 978 0 580 93041 6

ICS 11.040.01

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 30 April 2020.

Amendments/corrigenda issued since publication

Date	Text affected

Documents
Document Sharing Hub

Full document details: BS EN IEC 80601-2-60:2020

Contents

Page

© ISO 2020 – All rights reserved

Documents
Document Sharing Hub
Full document details: BS EN IEC 80601-2-60:2020

Documents
Document Sharing Hub

Full document details: BS EN IEC 80601-2-60:2020

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN IEC 80601-2-60

April 2020

ICS 11.040.01

Supersedes EN 80601-2-60:2015 and all of its amendments and corrigenda (if any)

English Version

Medical electrical equipment - Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment (IEC 80601-2-60:2019)

Appareils électromédicaux - Partie 2-60: Exigences particulières pour la sécurité de base et les performances essentielles des équipements dentaires (IEC 80601-2-60:2019)

Medizinische elektrische Geräte - Teil 2-60: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Dental-Geräten (IEC 80601-2-60:2019)

This European Standard was approved by CENELEC on 2019-08-01. 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

© 2020 CENELEC All rights of exploitation in any form and by any means reserved worldwide for CENELEC Members.

Ref. No. EN IEC 80601-2-60:2020 E

Documents
Document Sharing Hub

Full document details: BS EN IEC 80601-2-60:2020

European foreword

The text of document 62D/1683/FDIS, future edition 2 of IEC 80601-2-60, 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 80601-2-60:2020.

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

This document supersedes EN 80601-2-60:2015 and all of its amendments and corrigenda (if any).

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.

Endorsement notice

The text of the International Standard IEC 80601-2-60:2019 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:

IEC 60038	NOTE	Harmonized as EN 60038
IEC 60601-1-10	NOTE	Harmonized as EN 60601-1-10
IEC 61810-7:2006	NOTE	Harmonized as EN 61810-7:2006 (not modified)
ISO 7494-2:2015	NOTE	Harmonized as EN ISO 7494-2:2015 (not modified)
ISO 13732-1:2006	NOTE	Harmonized as EN ISO 13732-1:2008 (not modified)
ISO 17664:2017	NOTE	Harmonized as EN ISO 17664:2017 (not modified)
ISO 18397:2016	NOTE	Harmonized as EN ISO 18397:2016 (not modified)
ISO 21530:2004	NOTE	Harmonized as EN ISO 21530:2004 (not modified)

Documents
Document Sharing Hub

Full document details: BS EN IEC 80601-2-60:2020

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.

Clause 2 of EN 60601-1:2006 applies, except as follows:

Publication	Year	Title	EN/HD	Year
Replace				
IEC 60825-1	2014	Safety of laser products - Part 1: Equipment classification and requirements	EN 60825-1	2014
			+EN 60825-1:2014/AC:2017-06	
			+A11	2020
Addition				
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006
			+A12	2014
			+EN 60601-1:2006/corrigendum Mar. 2010	2010
			+AC	2014
			+A11	2011
IEC 60601-2-2	2017	Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories	EN IEC 60601-2-2	2018
IEC 60601-2-22	2007	Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment	EN 60601-2-22	2013
IEC 60601-2-57	2011	Medical electrical equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use	EN 60601-2-57	2011
IEC 60664-1	2007	Insulation coordination for equipment within low-voltage systems - Part 1: Principles, requirements and tests	EN 60664-1	2007

AVA Documents
Document Sharing Hub

Publication	Year	Title	EN/HD	Year
IEC 60664-4	2005	Insulation coordination for equipment within low-voltage systems - Part 4: Consideration of high-frequency voltage stress	EN 60664-4	2006
			+EN 60664-4:2006/corrigendum Oct. 2006	2006
IEC 61180	2016	High-voltage test techniques for low-voltage equipment - Definitions, test and procedure requirements, test equipment	EN 61180	2016
IEC 61810-1	2015	Electromechanical elementary relays - Part 1: General and safety requirements	EN 61810-1	2015
ISO 1942	2009	Dentistry -- Vocabulary	EN ISO 1942	2010
ISO 14457	2017		EN ISO 14457	2017

Documents
Document Sharing Hub

Full document details: BS EN IEC 80601-2-60:2020

CONTENTS

FOREWORD 3
201.1 Scope, object and related standards 6
201.2 Normative references 8
201.3 Terms and definitions 8
201.4 General requirements 10
201.5 General requirements for testing of ME EQUIPMENT 10
201.6 Classification of ME EQUIPMENT and ME SYSTEMS 10
201.7 ME EQUIPMENT identification, marking and documents 10
201.8 Protection against electrical HAZARDS from ME EQUIPMENT 11
201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS 16
201.10 Protection against unwanted and excessive radiation HAZARDS 19
201.11 Protection against excessive temperatures and other HAZARDS 19
201.12 Accuracy of controls and instruments and protection against hazardous outputs 23
201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT 23
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS) 24
201.15 Construction of ME EQUIPMENT 24
201.16 ME SYSTEMS 25
201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS 25
201.101 Cordless HAND-HELD and foot-operated control devices 25
Annexes 26
Annex AA (informative) Particular guidance and rationale 27
Bibliography 39
Index of defined terms used in this document 40

Figure AA.1 – Example of APPLIED PARTS for DENTAL EQUIPMENT 28
Figure AA.2 – Calculation of LEAKAGE CURRENT 29
Figure AA.3 – Insulation problem of commutator DENTAL ELECTRICAL MOTOR 31
Figure AA.4 – Loading fan construction 37
Figure AA.5 – Load diagram with loading fan 37

Table 201.101 – Test voltages for solid insulation for SECONDARY CIRCUITS according to 201.8.9.1.12 12
Table 201.102 – Determination of TENSILE SAFETY FACTOR 18
Table 201.103 – Mass distribution 19
Table 201.104 – Allowable maximum temperatures for the OPERATOR SIDE of DENTAL HANDPIECES 20
Table AA.1 – RATED impulse voltage for equipment energized directly from the low-voltage mains 32

Documents
Document Sharing Hub

Full document details: BS EN IEC 80601-2-60:2020

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-60: Particular requirements for the basic safety and essential performance of dental 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.

International standard IEC 80601-2-60 has been prepared by a Joint Working Group of subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice, and subcommittee 6: Dental equipment, of ISO technical committee 106: Dentistry.

This second edition cancels and replaces the first edition published in 2012. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

a) alignment with IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012.

Documents
Document Sharing Hub

Full document details: BS EN IEC 80601-2-60:2020

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

FDIS	Report on voting
62D/1683/FDIS	62D/1691/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.

This publication is published as a double logo standard.

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 60601 series, published under the general title: *Medical electrical equipment*, can be found on the IEC website.

Documents
Document Sharing Hub

Full document details: BS EN IEC 80601-2-60:2020

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.

Documents
Document Sharing Hub

Full document details: BS EN IEC 80601-2-60:2020

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment

201.1 Scope, object and related standards

Clause 1 of the general standard[1] applies, except as follows:

201.1.1 Scope

Replacement:

This part of IEC 80601 applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE OF DENTAL UNITS, DENTAL PATIENT CHAIRS, DENTAL HANDPIECES AND DENTAL OPERATING LIGHTS, hereafter referred to as DENTAL EQUIPMENT.

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.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this document are not covered by specific requirements in this document except in 7.2.13 and 8.4.1 of the general standard.

NOTE See also 4.2 of the general standard.

201.1.2 Object

Replacement:

The object of this particular standard is to establish BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for DENTAL EQUIPMENT (as defined in 201.3.202.)

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 60601-1-3 and IEC 60601-1-10 do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

[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.*

AVA Documents
Document Sharing Hub

201.1.4 Particular standards

Replacement:

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

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

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

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

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

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

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

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

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

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

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

Documents
Document Sharing Hub

Full document details: BS EN IEC 80601-2-60:2020

201.2 Normative references

NOTE Informative references are listed in the Bibliography.

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

Replacement:

IEC 60825-1:2014, *Safety of laser products – Part 1: Equipment classification and requirements*

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 60601-2-2:2017, *Medical electrical equipment – Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories*

IEC 60601-2-22:2007, *Medical electrical equipment – Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser* equipment
IEC 60601-2-22:2007/AMD1:2012

IEC 60601-2-57:2011, *Medical electrical equipment – Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use*

IEC 60664-1:2007, *Insulation coordination for equipment within low-voltage systems – Part 1: Principles, requirements and tests*

IEC 60664-4:2005, *Insulation coordination for equipment within low-voltage systems – Part 4: Consideration of high-frequency voltage stress*

IEC 61180:2016, *High-voltage test techniques for low-voltage equipment – Definitions, test and procedure requirements, test equipment*

IEC 61810-1:2015, *Electromechanical elementary relays – Part 1: General and safety requirements*

ISO 1942:2009, *Dentistry – Vocabulary*

ISO 14457: 2017, *Dentistry – Handpieces and motors*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, IEC 60601-2-2:2017 and ISO 1942 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

Documents
Document Sharing Hub

Full document details: BS EN IEC 80601-2-60:2020