IEC 80601-2-60

Edition 1.0 2012-02

INTERNATIONAL STANDARD

NORME INTERNATIONALE

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

Appareils électromédicaux –
Partie 2-60: Exigences particulières pour la sécurité de base et les performances essentielles des équipements dentaires

IEC 80601-2-60:2012

IEC Central Office
3, rue de Varembé
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
Fax: +41 22 919 03 00
info@iec.ch
www.iec.ch

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

The text of this particular standard is based on the following documents:

FDIS	Report on voting
62D/964/FDIS	62D/984/RVD

Full information on the voting for the approval of this particular standard can be found in the report on voting indicated in the above table. In ISO, the standard has been approved by 16 P-members out of 17 having cast a vote.

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

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

In this standard, 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 standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

– "shall" means that compliance with a requirement or a test is mandatory for compliance with this standard;

– "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;

– "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.

The committee has decided that the contents of this publication will remain unchanged until the stability date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

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 International Standard 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.

Excluded are amalgamators, sterilizers and dental X-ray 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 standard are not covered by specific requirements in this standard 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, IEC 60601-1-9[2)] and IEC 60601-1-10[3)] do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

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

2) IEC 60601-1-9:2007, *Medical electrical equipment – Part 1-9: General requirements for basic safety and essential performance – Collateral Standard: Requirements for environmentally conscious design*

3) IEC 60601-1-10:2007, *Medical electrical equipment – Part 1-10: General requirements for basic safety and essential performance – Collateral Standard: Requirements for the development of physiologic closed-loop controllers*

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 is 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 standard 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 3.139, additional definitions in this standard 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 standard" 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.

201.2 Normative references

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

Replacement:

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

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

Addition:

IEC 60601-2-2:2009, *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, therpeutic and diagnostic laser equipment*

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

IEC 61180-1, *High-voltage test techniques for low-voltage equipment – Part 1: Definitions, test and procedure requirements*

IEC 61180-2, *High-voltage test techniques for low-voltage equipment – Part 2: Test equipment*

IEC 61810-1:2008, *Electromechanical elementary relays – Part 1: General requirements*

IEC 62471, *Photobiological safety of lamps and lamp systems*

ISO 1942, *Dentistry – Vocabulary*

ISO 7785-2, *Dental handpieces – Part 2: Straight and geared angle handpieces*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005, IEC 60601-2-2:2009 and ISO 1942 apply, except as follows:

NOTE An index of defined terms is found beginning on page 31

Addition:

201.3.201
DENTAL ELECTRICAL MOTOR
handheld part of the DENTAL HANDPIECE electrically powered by the DENTAL UNIT

201.3.202
DENTAL EQUIPMENT
ME EQUIPMENT with any combination of DENTAL HANDPIECES, DENTAL UNITS, DENTAL PATIENT CHAIRS and DENTAL OPERATING LIGHTS

201.3.203
DENTAL HANDPIECE
handheld instrument used in dentistry for use in PATIENT treatment and connected to the DENTAL UNIT

201.3.204
DENTAL OPERATING LIGHT
device designed for use by an OPERATOR for illuminating the oral cavity, consisting of a luminaire and one or more lamps

201.3.205
DENTAL PATIENT CHAIR
device designed to support and position the PATIENT for treatment and therefore provided with a range of movements

201.3.206
DENTAL UNIT
device through which electrical power and/or various fluids or gasses are supplied to a number of DENTAL HANDPIECE S and devices

Note to entry It is usually fitted with conveniently oriented instrument holders and controls, and consists of interconnected sub-units of DENTAL EQUIPMENT and instruments providing a functional unit for dental use.

201.3.207
OPERATOR SIDE OF DENTAL HANDPIECE
part of DENTAL HANDPIECE which is designed to be handheld by the OPERATOR in NORMAL USE

201.3.208
PATIENT SIDE OF DENTAL HANDPIECE
part of DENTAL HANDPIECE which is designed to be introduced into the oral cavity where all parts of the DENTAL HANDPIECE within 80 mm of the tip shall be considered as an APPLIED PART

201.4 General requirements

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

201.4.3 ESSENTIAL PERFORMANCE

Addition:

DENTAL EQUIPMENT does not have ESSENTIAL PERFORMANCE.

201.5 General requirements for testing of ME EQUIPMENT

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

201.5.3 Ambient temperature, humidity, atmospheric pressure

Amendment of item a):

After the ME EQUIPMENT to be tested has been set up for NORMAL USE (according to 5.7), tests are performed within the range of environmental conditions indicated in the technical description (see 7.9.3.1) but at least at one temperature within an ambient temperature range +10 °C to 35 °C.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of the general standard applies, except as follows:

201.6.2 Protection against electric shock

Replacement:

ME EQUIPMENT energized from an external electrical power source shall be classified as CLASS I ME EQUIPMENT or CLASS II ME EQUIPMENT (see 7.2.6 (IEC 60601-1:2005)). Other ME EQUIPMENT shall be classified as INTERNALLY POWERED ME EQUIPMENT.

INTERNALLY POWERED ME EQUIPMENT having a means of connection to a SUPPLY MAINS shall comply with the requirements for CLASS I ME EQUIPMENT or CLASS II ME EQUIPMENT while so connected, and with the requirements for INTERNALLY POWERED ME EQUIPMENT while not so connected.

APPLIED PARTS of DENTAL EQUIPMENT which are connected through water lines shall be considered as TYPE B APPLIED PARTS.

201.7 ME EQUIPMENT identification, marking and documents

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

201.7.2.10 APPLIED PARTS

Addition:

If a DENTAL EQUIPMENT has only one APPLIED PART or APPLIED PARTS of all the same degree of protection against electric shock, it is sufficient to place the appropriate symbol once on the outside of the DENTAL EQUIPMENT.

201.7.2.11 * Mode of operation

Addition:

For DENTAL ELECTRICAL MOTORS no marking is necessary.

For DENTAL HANDPIECES no marking is necessary, if the RISK ASSESSMENT gives proof that the RISK is acceptable.

DENTAL HANDPIECES which incorporate lasers or are connected to lasers shall satisfy relevant requirements of IEC 60601-2-22.

201.7.9 ACCOMPANYING DOCUMENTS

201.7.9.2 Instructions for use

Additional subclause:

201.7.9.2.101 *Additional instructions for use

For DENTAL ELECTRICAL MOTORS no explanation of the duty cycle is necessary.

For DENTAL HANDPIECES no explanation of the duty cycle is necessary, if the RISK ASSESSMENT gives proof that the RISK is acceptable.

DENTAL HANDPIECES which incorporate lasers or are connected to lasers shall satisfy relevant requirements of IEC 60601-2-22.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

Clause 8 of the general standard applies except as follows:

201.8.5.2 Separation of PATIENT CONNECTIONS

Additional subclause:

201.8.5.2.101 * APPLIED PARTS that form one single APPLIED PART

In a DENTAL EQUIPMENT the DENTAL HANDPIECES may be considered as multiple functions of one APPLIED PART or PATIENT CONNECTIONS of one APPLIED PART.

The combination of several APPLIED PARTS to form one single APPLIED PART is only permitted if no HAZARD occurs when applying several APPLIED PARTS concurrently.

201.8.7 LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS

201.8.7.1 * General requirements

Addition:

aa) Water columns inside of an APPLIED PARTS or its multiple connections are considered as electric impedances according to their geometric dimensions and the resistance of the water. If this method is used the MANUFACTURER shall state the maximum fluid conductivity in the instructions for use and technical description (e.g.installation instructions).

201.8.8.3 * Dielectric strength

Addition:

For circuits according to 201.8.9.1.12 for SECONDARY CIRCUITS, the test voltages indicated in Table 201.101 shall be used for testing solid insulation:

Table 201.101 – Test voltages for solid insulation for SECONDARY CIRCUITS according to 201.8.9.1.12

PEAK WORKING VOLTAGE (U)	One MOPP U in RMS	Two MOPP U in RMS
≤ 71	500	500

For higher working voltages IEC 60601-1:2005 shall be applied.

201.8.9 * CREEPAGE DISTANCES and AIR CLEARANCES

For CREEPAGE DISTANCES and AIR CLEARANCES Subclause 8.9 of the general standard shall be used without modification or with the following changes.

Alternatively CREEPAGE DISTANCES and AIR CLEARANCES of this particular standard may be applied. In this case Subclause 8.9 of the general standard applies except as follows:

201.8.9.1 Values

201.8.9.1.2 CREEPAGE DISTANCES and AIR CLEARANCES complying with IEC 60950-1

The subclause of the general standard does not apply.

201.8.9.1.3 CREEPAGE DISTANCES across glass, mica, ceramic and similar materials

For SECONDARY CIRCUITS the subclause of the general standard does not apply.

201.8.9.1.4 Minimum CREEPAGE DISTANCE

For SECONDARY CIRCUITS the subclause of the general standard does not apply.

201.8.9.1.5 ME EQUIPMENT RATED for high altitudes

Addition:

For SECONDARY CIRCUITS Table A.2 – Altitude correction factors of IEC 60664-1:2007 applies.

201.8.9.1.6 Interpolation

For SECONDARY CIRCUITS the subclause of the general standard does not apply.

201.8.9.1.7 Material groups classification

For SECONDARY CIRCUITS the subclause of the general standard does not apply.

201.8.9.1.8 Pollution degree classification

For SECONDARY CIRCUITS subclause 4.6.2 of IEC 60664-1:2007 applies.

201.8.9.1.9 Overvoltage category classification

The subclause of the general standard does not apply.

201.8.9.1.10 AIR CLEARANCE for MAINS PARTS

Replacement:

Tables 13 and 14 of the general standard apply.

For MAINS PARTS operating on RATED MAINS VOLTAGES up to 300 V, the required AIR CLEARANCE shall be the value in Table 13 for the r.m.s. or d.c. RATED MAINS VOLTAGE for

- 150 V < NOMINAL MAINS VOLTAGE ≤ 300 V (MAINS TRANSIENT VOLTAGE 2 500 V) or
- 300 V < NOMINAL MAINS VOLTAGE ≤ 600 V (MAINS TRANSIENT VOLTAGE 4 000V)

plus the additional AIR CLEARANCE in Table 14 for the PEAK WORKING VOLTAGE for

- 150 V r.m.s. or 210 V dc < NOMINAL MAINS VOLTAGE ≤ 300 V r.m.s. or 420 V d.c.

201.8.9.1.11 SUPPLY MAINS overvoltage

Replacement:

This particular standard relates to overvoltage category II according to IEC 60664-1:2007.

201.8.9.1.12 SECONDARY CIRCUITS

Replacement:

For separation between mains and SECONDARY CIRCUITS two MOPP according to Table 12 of IEC 60601-1 applies.

For the separation between mains and APPLIED PARTS two MOPP according to Table 12 of IEC 60601-1 shall be applied.

Within SECONDARY CIRCUITS, for the separation within and between APPLIED PARTS of DENTAL EQUIPMENT for AIR CLEARANCES and CREEPAGE DISTANCES, the following apply:

a) IEC 60664-1:2007 for rated frequencies up to 30 kHz with the following tables and conditions:

The DENTAL UNIT and DENTAL OPERATING LIGHT shall be capable of withstanding 4 kV withstand impulse voltage in mains supply circuits.

Table F.2 – Clearances to withstand transient overvoltages

- Condition A inhomogeneous field, pollution degree 2, up to a maximum impulse withstand voltage of 1,0 kV.
- For higher voltages IEC 60601-1:2005 shall be applied (Table 12 of general standard).

The transient impulse voltage of max. 1 kV shall be checked by testing as follows: Apply a test voltage of 4 kV of 1,2/50 µs waveform to the primary circuit (mains). Verify that a limit of 1 kV is not exceeded in the secondary circuit. The waveform has to be in accordance with IEC 61180-1. The generator must comply with IEC 61180-2 (internal resistance of 2 Ω).

Table F.7.a –Clearances to withstand steady-state voltages, temporary voltages or recurring peak voltages

- Condition A inhomogeneous field, voltage (peak voltage) up to a maximum of 2 kV.
- For higher voltages IEC 60601-1:2005 shall be applied (Table 12 of general standard).

Temporary voltages are not to be taken into account for SECONDARY CIRCUITS.

Table F.4 – Creepage distances to avoid failure due to tracking

- Pollution degree 2, voltage (rms-value) up to 2 kV
- For higher voltages the IEC 60601-1:2005 shall be applied (Table 12 of general standard).

The values for printed wiring materials of Table F.4 do not apply.

b) IEC 60664-4:2005 for rated frequencies above 30 kHz and up to 10 MHz with the following tables and conditions:

Table 1: Minimum values of clearances in air at atmospheric pressure for inhomogeneous field conditions, in connection with subclause 4.4.3, Dimensioning of clearances inhomogeneous field conditions, and Clause 8, Non-sinusoidal voltages

Table 2: Minimum values of creepage distances for different frequency ranges, in connection with subclause 5.2, Dimensioning of creepage distances, and Clause 8, Non-sinusoidal voltages

NOTE 1 Terminology and definitions of the IEC 60664 series apply.

Pollution degree 3 shall be applied if a higher pollution degree expected when cooling fans are incorporated.

NOTE 2 An appropriate air filter may reduce pollution degree to 2.

In any case the greater value of Tables F.2, F.7.a and F.4. of IEC 60664-1:2007 and Tables 1 and 2 of IEC 60664-4:2005 has to be selected.

For rated frequencies above 30 kHz and up to 10 MHz, values have to be checked with Tables F.2, F.4 and F.7.a of IEC 60664-1:2007 and Tables 1 and 2 of IEC 60664-4:2005. The greater value of IEC 60664-1:2007 and IEC 60664-4:2005 has to be selected.

Minimum AIR CLEARANCE and CREEPAGE DISTANCE is 0,2 mm for BASIC INSULATION.

Since AIR CLEARANCES and CREEPAGE DISTANCES are minimum values, account for manufacturing and component tolerances.

CREEPAGE DISTANCES and AIR CLEARANCE shall be determined based on the rules of the IEC 60664 series. The values given in tables are BASIC INSULATION or SUPPLEMENTARY INSULATION.

1 MOPP is equivalent to one BASIC INSULATION for AIR CLEARANCES and CREEPAGE DISTANCES.

2 MOPP is equivalent to

- DOUBLE INSULATION which is sum of BASIC INSULATION and SUPPLEMENTARY INSULATION for CREEPAGE DISTANCE;
- REINFORCED INSULATION which is two times BASIC INSULATION for CREEPAGE DISTANCE;
- DOUBLE INSULATION which is the sum of BASIC INSULATION and SUPPLEMENTARY INSULATION for AIR CLEARANCE;

- REINFORCED INSULATION which is dimensioned as specified in Table F.1 or Table F.7a to withstand 160 % of the withstand voltage required for BASIC INSULATION for AIR CLEARANCE for DOUBLE INSULATION where BASIC INSULATION and SUPPLEMENTARY INSULATION cannot be tested separately. The larger value of Table F.1 and Table F.7a applies.

C) AIR CLEARANCE and CREEPAGE DISTANCE for relays applied for separation of voltages up to 50 V AC

1) For pollution degree 2:

For the relays´ switching elements separating voltages up to 50 V AC AIR CLEARANCE is 0,2 mm/0,4 mm (BASIC INSULATION/DOUBLE INSULATION). For CREEPAGE DISTANCE Table F.4 of IEC 60664-1:2007 applies.

For open contact the test voltage is 500 V.

2) For pollution degree 3:

For the relays´ switching elements separating voltages up to 50 V AC AIR CLEARANCE is 0,8 mm/1,6 mm (basic insulation/double insulation). Alternatively an encapsulated relay shall be used according to IEC 61810-1 category RT III with AIR CLEARANCE 0,2 mm/0,4 mm (BASIC INSULATION/DOUBLE INSULATION). For CREEPAGE DISTANCE Table F.4 of IEC 60664-1:2007 applies.

For open contact the test voltage is 500 V.

201.8.9.1.13 PEAK WORKING VOLTAGES above 1 400 V peak or d.c.

The subclause of the general standard does not apply.