

ISBN 978-0-626-30395-2

SANS 80601-2-60:2014

Edition 1

IEC 80601-2-60:2012

Edition 1

SOUTH AFRICAN NATIONAL STANDARD

Medical electrical equipment

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

This national standard is the identical implementation of IEC 80601-2-60:2012, and is adopted with the permission of the International Electrotechnical Commission.

WARNING
This document references other
documents normatively.

Published by SABS Standards Division
1 Dr Lategan Road Groenkloof ☒ Private Bag X191 Pretoria 0001
Tel: +27 12 428 7911 Fax: +27 12 344 1568

www.sabs.co.za

© SABS

SABS

SANS 80601-2-60:2014

Edition 1

IEC 80601-2-60:2012

Edition 1

Table of changes

Change No.	Date	Scope

National foreword

This South African standard was approved by National Committee SABS/TC 072, *Safety of electrical appliances and electronic equipment*, in accordance with procedures of the SABS Standards Division, in compliance with annex 3 of the WTO/TBT agreement.

This document was published in September 2014.



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

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

PRICE CODE
CODE PRIX



ICS 11.040.01

ISBN 978-2-88912-914-0

**Warning! Make sure that you obtained this publication from an authorized distributor.
Attention! Veuillez vous assurer que vous avez obtenu cette publication via un distributeur agréé.**

CONTENTS

FOREWORD.....	3
201.1 Scope, object and related standards.....	5
201.2 Normative references	6
201.3 Terms and definitions	7
201.4 General requirements.....	8
201.5 General requirements for testing of ME EQUIPMENT.....	8
201.6 Classification of ME EQUIPMENT and ME SYSTEMS	9
201.7 ME EQUIPMENT identification, marking and documents.....	9
201.8 Protection against electrical HAZARDS from ME EQUIPMENT.....	10
201.9 Protection against mechanical HAZARDS of ME EQUIPMENT and ME SYSTEMS	14
201.10 Protection against unwanted and excessive radiation HAZARDS.....	16
201.11 Protection against excessive temperatures and other HAZARDS.....	16
201.12 Accuracy of controls and instruments and protection against hazardous outputs	20
201.13 HAZARDOUS SITUATIONS and fault conditions	20
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	21
201.15 Construction of ME EQUIPMENT	21
201.16 ME SYSTEMS.....	21
201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS.....	21
201.101 Cordless HAND-HELD and foot-operated control devices	21
Annexes	21
Annex AA (informative) Particular guidance and rationale	22
Bibliography.....	31
Index of defined terms used in this particular standard.....	32
Figure AA.1 – Example of APPLIED PARTS for DENTAL EQUIPMENT	23
Figure AA.2 – Calculation of LEAKAGE CURRENT	24
Figure AA.3 – Insulation problem of commutator DENTAL ELECTRICAL MOTOR.....	25
Figure AA.4 – Loading fan construction.....	29
Figure AA.5 – Load diagram with loading fan	30
Table 201.101 – Test voltages for solid insulation for SECONDARY CIRCUITS according to 201.8.5.2	10
Table 201.102 – Determination of TENSILE SAFETY FACTOR.....	15
Table 201.103 – Mass distribution	16
Table 201.104 – Allowable maximum temperatures for DENTAL HANDPIECE.....	17

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: 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.