Medical electrical equipment –

Part 2-51:
Particular requirements for safety, including essential performance, of recording and analysing single channel and multichannel electrocardiographs

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CONTENTS

FOREWORD ....................................................................................................................... 4
INTRODUCTION ................................................................................................................... 6

SECTION ONE – GENERAL
1 Scope and object ............................................................................................................. 7
2 Terminology and definitions ........................................................................................... 8
4 General requirements for tests ....................................................................................... 11
6 Identification, marking and documents .......................................................................... 12

SECTION TWO – ENVIRONMENTAL CONDITIONS

SECTION THREE – PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

SECTION FOUR – PROTECTION AGAINST MECHANICAL HAZARDS

SECTION FIVE – PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

SECTION SIX – PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANAESTHETIC MIXTURES

SECTION SEVEN – PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER SAFETY HAZARDS

SECTION EIGHT – ACCURACY OF OPERATING DATA AND PROTECTION AGAINST HAZARDOUS OUTPUT

50 Accuracy of operating data ........................................................................................... 14

50.101 Automated measurements on ECGs (for ANALYSING ELECTROCARDIOGRAPHS) ........14
50.102 Automated ECG interpretation (for ANALYSING ELECTROCARDIOGRAPHS) ................. 19

51 Protection against hazardous output .............................................................................. 23

51.101 LEADS ................................................................................................................ 23
51.102 Input circuit ......................................................................................................... 27
51.103 CALIBRATION ....................................................................................................... 28
51.104 SENSITIVITY ........................................................................................................ 29
51.105 Reduction of the effects of unwanted external voltages ............................................ 29
51.106 Base-line ............................................................................................................. 30
51.107 Distortion ............................................................................................................. 32
51.108 Printing, electronic storage and transmission ....................................................... 34
51.109 Use with cardiac pacemakers .............................................................................. 36

SECTION NINE – ABNORMAL OPERATION AND FAULT CONDITIONS; ENVIRONMENTAL TESTS

SECTION TEN – CONSTRUCTIONAL REQUIREMENTS

56 Components and general assembly ............................................................................ 37
56.7 BATTERIES .............................................................................................................. 37

Appendix L (normative) References – Publications mentioned in this standard ............. 43
Annex AA (informative) General guidance and rationale .................................................. 44
Annex BB (informative) ELECTRODES, their positions, identifications and colour codes ......51
Annex CC (informative) LEADS and their identification (other than described in 51.101) ....... 53
Annex DD (informative) Polarity of PATIENT LEADS (other than those specified in 51.101) ....... 55
Annex EE (informative) Additional marking of electrodes ............................................... 56
Annex FF (informative) Noise .......................................................................................... 58
INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-51: Particular requirements for safety, including essential performance, of recording and analysing single channel and multichannel electrocardiographs

FOREWORD

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International Standard IEC 60601-2-51 has been prepared by subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

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

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<th>FDIS</th>
<th>Report on voting</th>
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<tr>
<td>62D/469/FDIS</td>
<td>62D/473/RVD</td>
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</tbody>
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Full information on the voting for the approval of this standard can be found in the report on voting indicated in the above table.

In this Particular Standard, the following print types are used:

- requirements, compliance with which can be tested, and definitions: roman type;
- notes, explanations, advice, introductions, general statements, exceptions and references: small roman type;
- test specifications: italic type;
- TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD OR THIS PARTICULAR STANDARD: SMALL CAPITALS.
The committee has decided that the contents of this publication will remain unchanged until 2007. At this date, the publication will be

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

A bilingual version of this standard may be issued at a later date.
INTRODUCTION


A “General guidance and rationale” for the requirements of this Particular Standard is included in Annex AA.

It is considered that a knowledge of the reasons for these requirements will not only facilitate the proper application of the standard but will, in due course, expedite any revision necessitated by changes in clinical practice or as a result of developments in technology. However, this annex does not form part of the requirements of this Standard.

An asterisk (*) by a clause or subclause number indicates that some explanatory notes are given in Annex AA.
MEDICAL ELECTRICAL EQUIPMENT – Part 2-51: Particular requirements for safety, including essential performance, of recording and analysing single channel and multichannel electrocardiographs

SECTION ONE – GENERAL

The clauses and subclauses of this section of the General Standard apply except as follows:

1 Scope and object

This clause of the General Standard applies except as follows:

*1.1 Scope

Addition:

This Particular Standard specifies requirements for the safety, including essential performance, of RECORDING AND ANALYSING SINGLE CHANNEL AND MULTICHANNEL ELECTROCARDIOGRAPHS as defined in 2.101, 2.111, 2.117, 2.123, 2.126, hereinafter referred to as EQUIPMENT. The EQUIPMENT may be attended or unattended.

This Particular Standard complements IEC 60601-2-25 and its Amendment 1 (1999).

1.2 Object

Replacement:

The object of this Particular Standard is to establish particular requirements, in addition to the requirements of IEC 60601-2-25, for the safety, including essential performance of RECORDING AND ANALYSING SINGLE CHANNEL AND MULTICHANNEL ELECTROCARDIOGRAPHS.

These requirements shall apply particularly to

- RECORDING ELECTROCARDIOGRAPHS;
- ELECTROCARDIOGRAPHS which are part of other MEDICAL ELECTRICAL EQUIPMENT, for example exercise testing systems, if this EQUIPMENT is used to record ECGs for diagnostic purposes;
- ELECTROCARDIOGRAPHS which are used as output units for ECG data base management systems or ELECTROCARDIOGRAPHS which are used as output units located at other places than the recording unit;
- ANALYSING ELECTROCARDIOGRAPHS, systems, and computing devices which by means of electronic data processing and pattern recognition derive measurements (e.g. intervals and amplitudes) and diagnostic statements from the ECG;
- those parts of PATIENT monitors or other specialised ELECTROCARDIOGRAPHS that are capable of performing the functions of the ANALYSING ELECTROCARDIOGRAPHS.

This standard shall not apply to Holter ELECTROCARDIOGRAPHS, invasive electrocardiography, PATIENT monitoring systems and high-resolution ELECTROCARDIOGRAPHS (e.g. HIS bundle ELECTROCARDIOGRAPHS, ELECTROCARDIOGRAPHS for late potential detection) other than stated above.