

# INTERNATIONAL STANDARD

# IEC 60601-2-51

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## Medical electrical equipment –

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

#### *Appareils électromédicaux –*

#### *Partie 2-51: Règles particulières de sécurité et performances essentielles des électrocardiographes enregistreurs et analyseurs mono et multi-canaux*

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## 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

- 1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the 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, the IEC publishes International Standards. 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. The 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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- 3) The documents produced have the form of recommendations for international use and are published in the form of standards, technical specifications, technical reports or guides and they are accepted by the National Committees in that sense.
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International Standard IEC 60601-2-51 has been prepared by subcommittee 62D: Electro-medical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

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

FDIS	Report on voting
62D/469/FDIS	62D/473/RVD

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

This Particular Standard concerns additional safety of recording and analysing single channel and multichannel electrocardiographic equipment. It amends and supplements IEC 60601-1 (second edition, 1988), including its amendments 1 (1991) and 2 (1995) hereinafter referred to as the General Standard. The requirements of this Particular Standard take priority over those of the General Standard, entitled *Medical electrical equipment – Part 1: General requirements for safety*.

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.