INTERNATIONAL STANDARD

IEC 60601-2-51

First edition
2003-02

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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CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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

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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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.

1.3 Particular Standards

Addition:

This Particular Standard refers to IEC 60601-1:1988, *Medical electrical equipment – Part 1: General requirements for safety*, as amended by its Amendment 1 (1991) and Amendment 2 (1995), hereafter referred to as the General Standard, and to IEC 60601-2-25:1993, *Medical electrical equipment – Part 2-25: Particular requirements for the safety of electrocardiographs* and its Amendment 1 (1999).

The General Standard also takes into account IEC 60601-1-2:1993, *Medical electrical equipment – Part 1: General requirements for safety – 2. Collateral Standard: Electromagnetic compatibility – Requirements and tests*, and IEC 60601-1-4:1996, *Medical electrical equipment – Part 1: General requirements for safety – 4. Collateral Standard: Programmable electrical medical systems*.

The term “this Standard” is used to make reference to the General Standard and this Particular Standard taken together.

The numbering of sections, clauses or subclauses of this Particular Standard corresponds with that of the General Standard. 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 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.

“Amendment” means that the clause or subclause of the General Standard is amended as indicated by the text of this Particular Standard.

Subclauses or figures which are additional to those of the General Standard are numbered starting from 101, additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Where there is no corresponding section, clause or subclause in this Particular Standard, the section, clause or subclause of the General Standard, although possibly not relevant, applies without modification.

Where it is intended that any part of the General Standard, although possibly relevant, is not to be applied, a statement to that effect is given in this Particular Standard.

The requirements of this Particular Standard take priority over those of the General Standard and Collateral Standard mentioned above.

2 Terminology and definitions

This clause of the General Standard applies except as follows:

Additional definitions:

2.101
ANALYSING ELECTROCARDIOGRAPH
ELECTROCARDIOGRAPH capable of analysing heart action potentials, deriving measurements from them and/or making interpretative statements. These may be also capable of communicating ECGs and/or analysis results

2.102
CALIBRATION ("CAL")
facility enabling the CALIBRATION VOLTAGE and zero voltage to be recorded in place of the ELECTROCARDIOGRAM

2.103
CALIBRATION VOLTAGE
voltage step recorded for amplitude CALIBRATION purposes

2.104
CENTRAL TERMINAL ACCORDING TO WILSON (CT)
terminal at the average potential of the R, L and F potentials

2.105
CHANNEL
hardware and/or software selection of a particular electrocardiographic LEAD for purposes of display, recording, or transmission

2.106
COMMON MODE REJECTION
ability of the ELECTROCARDIOGRAPH including the PATIENT CABLE and LEAD ELECTRODES, high frequency FILTERS, protection networks, LEAD networks, amplifier input, etc., to discriminate between signals with differences between amplifier inputs (differential signal) and signals common to amplifier inputs (common signal), in the presence of LEAD ELECTRODE impedance imbalance

2.107
COMMON MODE DC OFFSET VOLTAGE
DC voltage appearing on LEAD ELECTRODES with respect to the NEUTRAL ELECTRODE resulting from ELECTRODE-skin voltages

2.108
ECG RECORD
a registration (e.g. a hard copy write-out or a display) of an ECG signal including the associated data such as date and time of the registration, name and identification of the PATIENT, etc.

2.109
EFFECTIVE RECORDING WIDTH
width of the recording paper within which the signal of a CHANNEL can be recorded according to this performance standard

2.110
ELECTROCARDIOGRAM (ECG)
visible recording of heart action potentials as measured at the body surface (see also definition 2.108 'ECG RECORD')

2.111
ELECTROCARDIOGRAPH (ecg)
MEDICAL ELECTRICAL EQUIPMENT and associated ELECTRODES intended for the production of ELECTROCARDIOGRAMS for diagnostic purposes

2.112
ELECTRODE(S)
means (typically, an electrical sensor) in contact with a specified part of the body to detect heart action voltage in combination with another means (see also Table 109). Both means (electrical sensors) are connected to the ELECTROCARDIOGRAPH via a PATIENT CABLE

2.113
FILTER(S)
means, realized in hardware, firmware or software, to attenuate unwanted components in the signal being recorded, e.g. muscle action voltages in ECG signal

2.114
LEAD WIRE(S)
cable(s) connected between ELECTRODE(s) and the ELECTROCARDIOGRAPH

2.115
LEAD(S)
Combination(s) of ELECTRODES and LEAD WIRES used for a certain ECG recording (see also Table 110)

2.116
LEAD SELECTOR
system to select certain LEADS and CAL

2.117
MULTICHANNEL ELECTROCARDIOGRAPH
EQUIPMENT for the simultaneous recording of two or more ECG LEADS. This EQUIPMENT may also provide facilities for phonocardiography and pulse recording, etc.

2.118
NEUTRAL ELECTRODE
reference point for differential amplifiers and/or interference suppression circuits. Any electrocardiographic LEAD is independent of the potential of this reference point

2.119
NOISE
unwanted signals of any frequency present in the ELECTROCARDIOGRAM

2.120
NORMAL SENSITIVITY
SENSITIVITY of 10 mm/mV

2.121
OVERLOAD TOLERANCE
maximum input-circuit voltage which does not alter the functioning of the ELECTROCARDIOGRAPH

2.122
PATIENT CABLE
multiwire cable and associated connector(s) to connect the ELECTRODES to the ELECTROCARDIOGRAPH

2.123
RECORDING ELECTROCARDIOGRAPH
MEDICAL ELECTRICAL EQUIPMENT intended for the production of ECG RECORDS

2.124
REFERENCE POINT ACCORDING TO GOLDBERGER
reference point at an average potential of two limbs (e.g. average of L and F)

2.125
SENSITIVITY
ratio of the amplitude of a recording to the amplitude of the signal producing it, expressed in mm/mV

2.126
SINGLE CHANNEL ELECTROCARDIOGRAPH
EQUIPMENT for the recording of one ECG LEAD at a time

2.127
TEST
other designation for CAL

2.128
TIME CONSTANT
time taken for the output waveform step to decay to $\frac{1}{e}$ (37 %) of the initial amplitude. It is used to define the low frequency response of an a.c. coupled amplifier to a d.c. step input

NOTE This definition is derived from a first order network.

2.129
WAVE RECOGNITION POINTS
reference points on the time axis of the ECG waveform for interval and amplitude measurements on an ECG cycle:

- P-ONSET: beginning of the P-wave (atrial depolarisation);
- P-OFFSET: end of the P-wave;
- QRS-ONSET: beginning of the QRS-complex (ventricular depolarisation);
- QRS-OFFSET: end of the QRS-complex;
- T-OFFSET: end of the T-wave (end of ventricular repolarisation).

4 General requirements for tests

This clause of the General Standard applies except as follows:

4.6 Other conditions

Addition:

aa) Unless otherwise stated, tests shall be carried out with the accessories and the recording materials specified by the manufacturer.

bb) EQUIPMENT with an INTERNAL ELECTRICAL POWER SOURCE shall be tested with the maximum and minimum INTERNAL ELECTRICAL POWER SOURCE voltages specified by the manufacturer. If necessary for the purpose of conducting this test, an external battery of specified minimum or maximum voltage may be connected.

cc) The values used in test circuits shall have at least an accuracy as given below:

- resistors ±2 %
- capacitors ±10 %
- inductors ±10 %
- test voltages ±1 %

4.11 Sequence

Addition:

Tests called for in this Particular Standard shall be performed after the tests of the General Standard and the tests of IEC 60601-2-25 and its Amendment 1 (1999).

6 Identification, marking and documents

This clause of the General Standard applies except as follows:

*6.1 Marking on the outside of EQUIPMENT or EQUIPMENT parts

Addition:

aa) In order to minimize the possibility of incorrect connections, the PATIENT CABLE shall be permanently marked with one of the identifiers (ELECTRODE identifier and/or colour code) specified in Table 101;

bb) The PATIENT CABLE to EQUIPMENT connector shall be so constructed or marked as to enable the USER to identify the EQUIPMENT to which the PATIENT CABLE is intended to be connected.

6.8.2 Instructions for use

Addition:

aa) Manufacturer shall disclose the following in the ACCOMPANYING DOCUMENTS:

– the way amplitude values for the P-, QRS-, ST- and T-waves are determined as required in 50.101.2;

– the way isoelectric segments within the QRS complex are treated as required in 50.101.3;

– the criteria applied in the EQUIPMENT for acceptance of minimum waves and stability of the measurements in the presence of NOISE as required in 50.101.4;

– the intended use of the analysing electrocardiograph as required in 50.102.2;

– the cardiac abnormalities of low prevalence that were not included in the test contour diagnostic data base as required in 50.102.3.1;

– the ECG categories and the number of ECGs tested in these categories as required in 50.102.3.2 (see also 50.102.3.1);

– accuracy measures for diagnostic interpretative statements, non-ECG means for validation of cardiac diagnosis and the group statistics of patient demographics (such as age, gender, race etc.) as required in 50.102.3.2;

– the cardiac rhythms of low prevalence that were not included in the test rhythm ECG database as required in 50.102.4.1;

– the ECG categories and the number of ECGs tested in these categories as required in 50.102.4.2 (see also 50.102.4.1);

– accuracy measures for rhythm interpretative statements and the group statistics of patient demographics (such as age, gender, race etc.) as required in 50.102.4.2;

– the instructions for regular testing of the SENSITIVITY, when the CALIBRATION does not check the overall SENSITIVITY as required in 51.103.2;

– if the ELECTROCARDIOGRAPH must have FILTERS set, the arrangements to pass the distortion test, and the effect of these FILTER settings on ECG signal distortion as required in 51.109.1;

– the minimum length of time that the ELECTROCARDIOGRAPH will conform to the requirements of this Particular Standard under the conditions required in Clause 56.