INTERNATIONAL STANDARD

IEC 60601-2-47

First edition
2001-07

Medical electrical equipment –

Part 2-47:
Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems

Appareils électromédicaux –

Partie 2-47:
Règles particulières de sécurité et performances essentielles des systèmes d'électrocardiographie ambulatoires

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems

FOREWORD

1) The IEC (International Electrotechnical Commission) is a world-wide organisation for standardisation comprising all national electrotechnical committees (IEC National Committees). The object of the IEC is to promote international co-operation on all questions concerning standardisation 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 organisations liaising with the IEC also participate in this preparation. The IEC collaborates closely with the International Organisation for Standardisation (ISO) in accordance with conditions determined by agreement between the two organisations.
2) The formal decisions or agreements of the 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 National Committees.
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.
4) In order to promote international unification, IEC National Committees undertake to apply IEC International Standards transparently to the maximum extent possible in their national and regional standards. Any divergence between the IEC Standard and the corresponding national or regional standard shall be clearly indicated in the latter.
5) The IEC provides no marking procedure to indicate its approval and cannot be responsible for any equipment declared to be in conformity with one of its standards.
6) Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. The IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC 60601-2-47 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 upon the following documents:

FDIS	Report on voting
62D/408/FDIS	62D/411/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.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 3.

Annex AA is for information only.

In this Particular Standard the following print types are used:

– requirements, compliance with which can be tested, and definitions: in roman type,

– notes, explanations, advice, introductions, general statements, exceptions and references: in smaller type,

– *test specifications: in 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 2005. At this date, the publication will be

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

A bilingual edition of this publication may be issued at a later date.

INTRODUCTION

This Particular Standard concerns the safety of AMBULATORY ELECTROCARDIOGRAPHIC SYSTEMS. It amends and supplements IEC 60601-1 (second edition 1988): *Medical electrical equipment – Part 1: General requirements for safety*, as amended by its amendment 1 (1991) and its amendment 2 (1995), hereinafter referred to as the General Standard. The requirements of this Particular Standard take priority over those of the General Standard.

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 of this Particular Standard.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems

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 the particular safety requirements for AMBULATORY ELECTROCARDIOGRAPHIC SYSTEMS, as defined in 2.101.

Within the scope of this standard are systems of the following types:

a) systems that provide continuous recording and continuous analysis of the ECG allowing full re-analysis giving essentially similar results. The systems may first record and store the ECG and analyse it later on a separate unit, or record and analyse the ECG simultaneously. The type of storage media used is irrelevant with regard to this standard;

b) systems that provide continuous analysis and only partial or limited recording not allowing a full re-analysis of the ECG.

The safety aspects of this standard apply to all types of systems falling in one of the above-mentioned categories.

If the ambulatory electrocardiographic system offers automatic ECG analysis, minimal performance requirements for measurement and analysis functions apply. Medical electrical equipment covered by IEC 60601-2-25 and IEC 60601-2-27 are excluded from the scope of this standard.

This standard does not apply to systems that do not continuously record and analyse the ECG (for example, 'intermittent event recorders').

1.2 Object

Replacement:

The object of this Particular Standard is to establish particular requirements for the safety, including essential performance, of AMBULATORY ELECTROCARDIOGRAPHIC SYSTEMS.

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 its amendment 2 (1995).

For brevity, IEC 60601-1 is referred to in this Particular Standard either as the General Standard including its collateral standards or as the General Requirement(s).

The numbering of sections and subclauses of this Particular Standard corresponds to that of the General Standard. Changes to the text of the General Standard are specified by 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.

Clauses, subclauses, tables and figures which are additional to those of the General Standard are numbered starting from 101, additional appendices are lettered AA, BB, etc., and additional items aa), bb), etc.

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

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.

1.5 Collateral Standards

Addition:

IEC 60601-1-2:1993, *Medical electrical equipment – Part 1: General requirements for safety – 2. Collateral standard: Electromagnetic compatibility – Requirements and tests*

*2 Terminology and definitions

This clause of the General standard applies except as follows:

Additional definitions:

2.101
AMBULATORY ELECTROCARDIOGRAPHIC SYSTEM (EQUIPMENT)
AMBULATORY RECORDER and a PLAYBACK EQUIPMENT, both of which may contain an analysis function

NOTE This EQUIPMENT is often referred to as Holter monitoring equipment after its inventor Dr. Norman Holter.

2.102
AMBULATORY RECORDER
recording EQUIPMENT worn or carried by the PATIENT including associated ELECTRODES and cables for recording or recording and analysing heart action potentials

2.103
PLAYBACK EQUIPMENT
EQUIPMENT for monitoring and documenting functions into which data from the RECORDER is fed

NOTE This EQUIPMENT is usually stationary and commonly includes computing facilities.

2.104
ELECTROCARDIOGRAM (ECG)
visual record of heart action potentials

[IEC 60601-2-25:1993, definition 2.101]

2.105
LEAD
ELECTRODE and LEAD WIRE combination(s) used for a certain recording of ECG. Examples: Einthoven limb LEAD II, Unipolar chest LEAD V5

[IEC 60601-2-25:1993, definition 2.103, modified]

2.106
PATIENT ELECTRODE
means in contact with a specified part of the body to detect heart action voltage in combination with another means

[IEC 60601-2-25:1993, definition 2.104]

2.107
NEUTRAL ELECTRODE
reference point for differential amplifiers and/or interference suppression circuits, not forming part of any ELECTROCARDIOGRAPH LEAD

[IEC 60601-2-25:1993, definition 2.107]

2.108
PATIENT CABLE
multiwire cable and associated connector(s) to connect the ELECTRODES to the AMBULATORY RECORDER

[IEC 60601-2-25:1993, definition 2.109]

2.109
LEAD WIRE(S)
cable connected between the ELECTRODE and the AMBULATORY RECORDER.

2.110
CONTINUOUS RECORDER
EQUIPMENT which performs continuous analysis and/or recording of the ECG.

5 Classification

This clause of the General Standard applies except as follows:

5.6

Amendment:

Delete all but CONTINUOUS OPERATION.

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

Additional item:

aa) LEAD identification

The LEAD(S) shall be permanently marked in such a manner that the proper LEAD can be directly determined at both the ELECTRODE attachment end, and so constructed or marked as to avoid incorrect connection to the EQUIPMENT.

If independent bipolar leads are being used, the channel assignment shall be clearly annotated on the EQUIPMENT for reference. Also, the LEAD(S) shall be colour coded according to one of the colour coding schemes of table 101.

Table 101 – LEAD colour codes

	ELECTRODE	Code 1[a]	Code 2[b]
Channel 1	Positive ELECTRODE	green	red
	Negative ELECTRODE	red	white
Channel 2	Positive ELECTRODE	white	brown
	Negative ELECTRODE	yellow	black
Channel 3	Positive ELECTRODE	orange	orange
	Negative ELECTRODE	blue	blue
NEUTRAL ELECTRODE		black	green

[a] Code 1 is widely used in Europe and internationally.

[b] Code 2 is widely used in North America – see AHA guidelines of 1985.

NOTE The desired polarity assignments are presented here, but equipment can deviate as long as the deviation is properly labelled.

6.8.2 Instructions for use

Additional items:

aa) Advice shall be given on the following:

1) the procedures necessary for safe operation, drawing attention in the case of TYPE B APPLIED PARTS to the safety hazard which may occur as a result of an inadequate electrical installation;

2) the type of electrical installation to which the EQUIPMENT may be safely connected, including the connection to any POTENTIAL EQUALIZATION CONDUCTOR;

3) that conductive parts of ELECTRODES and associated connectors for TYPE BF APPLIED PARTS or TYPE CF APPLIED PARTS, including the NEUTRAL ELECTRODE, should not contact other conductive parts including earth;

4) the possible hazard caused by the summation of LEAKAGE CURRENTS when several EQUIPMENTS are interconnected by coupling and/or a multiple portable socket-outlet.

bb) Clear instructions shall be provided if a specific type of battery or battery charging procedure has to be used in order to fulfil the requirements of this Particular Standard.

cc) Clear instructions shall be provided for any use of the RECORDER in wet environments.

dd) The EQUIPMENT labelling shall clearly indicate whether or not its use is intended for infants weighing less than 10 kg.

ee) The manufacturer shall disclose the method for calculating the heart rate.

ff) The manufacturer shall disclose the method for determining a pause.

gg) If the equipment is designed to detect and/or measure ST segment shifts, the manufacturer shall disclose in the operating manual or physician's guide the following:

- whether the ST analysis is performed on all LEADS using any or all calibration signals,
- whether there are OPERATOR selectable detection criteria for ST segment shifts (such as displacement and slope parameters),
- how frequently ST segment shifts are summarised in the report (e.g., hourly) and whether numbers of episodes, types of episodes (elevation or depression), and durations of episodes are reported, or whether the report presents this information episode by episode,
- whether ranges of heart rates, ranges of displacements and/or slope values during each episode are reported.

SECTION TWO – ENVIRONMENTAL CONDITIONS

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

*10 Environmental conditions

10.2.1 Environment

Amendment:

For RECORDERS:

a) An ambient temperature range of 10 °C to 45 °C.

b) A relative humidity of 10 % to 95 %, without condensation.

SECTION THREE – PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

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

20 Dielectric strength

This clause of the General Standard applies except as follows:

20.2 Particular requirements for EQUIPMENT with an APPLIED PART

Amendment:

B-b Does not apply to EQUIPMENT.

20.3 Values of test voltages

Addition:

B-d1 The test voltage shall be 1 500 V (CLASS I, CLASS II, and INTERNALLY POWERED EQUIPMENT) between F-TYPE APPLIED PARTS and SIGNAL INPUT PARTS and SIGNAL OUTPUT PARTS. This test does not apply if the I/O parts cannot be connected to external EQUIPMENT while the device is PATIENT connected.

B-d2 The test voltage between F-TYPE APPLIED PARTS and ENCLOSURE other than SIGNAL INPUT PARTS shall be determined by the MAINS VOLTAGE of the device and table V of the General Standard. The requirement from the General Standard for a minimum reference voltage of U = 250 V for INTERNALLY POWERED EQUIPMENT does not apply.

SECTION FOUR – PROTECTION AGAINST MECHANICAL HAZARDS

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

21 Mechanical strength

***21.5**

Replacement:

Data acquisition by the AMBULATORY RECORDER may be interrupted during shock but data acquired prior to the shock shall be unaffected and normal data acquisition shall resume within 60 s after the completion of the following test.

Compliance is tested as follows:

The RECORDER is dropped once from a height of 75 mm onto a 50 mm thick hardwood board (for example, hardwood >600 kg/m^3) lying flat on a rigid base such as a concrete floor and making solid contact with the base on every face, edge and corner. If the recorder is normally used with a pouch, the same type of pouch can be used during the testing. The RECORDER shall be unaffected and shall resume normal data acquisition within 60 s of the shock.