IEC 60601-2-47

Edition 2.0 2012-02

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment –
Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems

Appareils électromédicaux –
Partie 2-47: Exigences particulières pour la sécurité de base et les performances essentielles des systèmes d'électrocardiographie ambulatoires

IEC 60601-2-47:2012

IEC Central Office
3, rue de Varembé
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
Fax: +41 22 919 03 00
info@iec.ch
www.iec.ch

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MEDICAL ELECTRICAL EQUIPMENT –

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

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.

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International standard IEC 60601-2-47 has been prepared by subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This second edition cancels and replaces the first edition published in 2001. It constitutes a technical revision. This edition was revised to align structurally with the 2005 edition of IEC 60601-1.

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

FDIS	Report on voting
62D/963/FDIS	62D/980/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.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard, the following print types are used:

– Requirements and definitions: roman type.
– *Test specifications: italic type.*
– Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.
– TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

– "clause" means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
– "subclause" means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term "Clause" followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, the conjunctive "or" is used as an "inclusive or" so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

– "shall" means that compliance with a requirement or a test is mandatory for compliance with this standard;
– "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;

– "may" is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

A list of all parts of the IEC 60601 series, published under the general title *Medical electrical equipment*, can be found on the IEC website.

The committee has decided that the contents of this publication will remain unchanged until the stability date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

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

INTRODUCTION

This particular standard concerns the basic safety and essential performance of AMBULATORY ELECTROCARDIOGRAPHIC SYSTEMS. It amends and supplements IEC 60601-1 (third edition 2005): *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*, 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.

MEDICAL ELECTRICAL EQUIPMENT –

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

201.1 Scope, object and related standards

Clause 1 of the general standard[1] applies, except as follows:

201.1.1 Scope

Replacement:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of AMBULATORY ELECTROCARDIOGRAPHIC SYSTEMS, hereafter referred to as ME SYSTEMS

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this standard are not covered by specific requirements in this standard except in 7.2.13 and 8.4.1 of the general standard.

NOTE See also 4.2 of the general standard.

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').

201.1.2 Object

Replacement:

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1 The general standard is IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.*

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for AMBULATORY ELECTROCARDIOGRAPHIC SYSTEMS.

201.1.3 Collateral Standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.

IEC 60601-1-2 applies as modified in Clause 202. IEC 60601-1-3, IEC 60601-1-8 and IEC 60601-1-10 do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard and collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard.

For brevity, IEC 60601-1 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix "201" (e.g. 201.1 in this standard addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix "20x" where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). 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 or applicable collateral 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 or applicable collateral standard.

"Amendment" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 through 3.139, additional definitions in this standard are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where "x" is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this standard" is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding clause or subclause in this particular standard, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

201.2 Normative references

Clause 2 of the general standard applies, except as follows:

Amendment:

IEC 60601-1-2:2007, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests*.

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005, apply, except as follows:

NOTE An index of defined terms is found beginning on page 64.

Additional definitions:

201.3.201
AF
ATRIAL FIBRILLATION
ATRIAL FLUTTER
ECG rhythm involving either no P-waves and irregular RR intervals (atrial fibrillation) or high frequency flutter waves and regular or irregular RR intervals (atrial flutter)

201.3.202
AMBULATORY ELECTROCARDIOGRAPHIC SYSTEM
ME SYSTEM, AMBULATORY RECORDER and a PLAYBACK EQUIPMENT, both of which may contain an analysis function

Note 1 to entry: This ME SYSTEM is often referred to as Holter monitoring system after its inventor Dr. Norman Holter.

201.3.203
AMBULATORY RECORDER
recording ME EQUIPMENT worn or carried by the PATIENT including associated ELECTRODES and cables for recording heart action potentials

Note 1 to entry: An AMBULATORY RECORDER may also analyse the heart action potentials. It may record selectively when significant events are detected, or continuously.

201.3.204
CONTINUOUS RECORDER
ME EQUIPMENT, which performs continuous recording of the ECG

201.3.205
DATABASE
DB
sampled ECGs or artificial signals of one or more channels together with descriptive (clinical) information

201.3.206
ELECTROCARDIOGRAM
ECG
graphical presentation of one or more LEADs over time

201.3.207
ELECTRODE
sensor in contact with a specific part of the body that is used to detect electrical activity

201.3.208
GAIN
ratio of the amplitude of the output signal (usually on the PLAYBACK EQUIPMENT) to the amplitude of the AMBULATORY RECORDER input signal

Note 1 to entry: GAIN is expressed in mm/mV.

201.3.209
HEART RATE VARIABILITY
HRV
statistical results calculated from consecutive RR intervals

201.3.210
LEAD
voltage between ELECTRODES

201.3.211
LEAD WIRE(S)
cable(s) connected between ELECTRODES and either a PATIENT CABLE or the ME EQUIPMENT

201.3.212
NEUTRAL ELECTRODE
reference point for differential amplifiers and/or interference suppression circuits, not intended to be used to calculate any LEAD

201.3.213
PATIENT CABLE
multiwire cable and associated connector(s) used to connect the LEAD WIRE(S) to the AMBULATORY RECORDER

201.3.214
PAUSE
absence of a heart action potential for a prolonged time interval

201.3.215
PLAYBACK EQUIPMENT
equipment with monitoring and documenting functions into which ECG and measurements derived from the AMBULATORY RECORDER are fed

Note 1 to entry: This ME EQUIPMENT is usually stationary and commonly includes computing facilities.

201.3.216
QRS COMPLEX
QRS
the waveform presented in an ECG during ventricular depolarization

201.3.217
ROOT-MEAN SQUARED
RMS
root of the average of the squares of the original values

201.3.218
RR INTERVAL VARIABILITY
RRV
statistical results calculated from consecutive RR intervals

201.3.219
SHUTDOWN
period of time when detection/classification function are not performed

201.3.220
ST SEGMENT
segment of the ECG between the end of the QRS complex and the start of the T-wave

201.3.221
SUPRAVENTRICULAR ECTOPIC BEAT
SVEB
a premature or an escape (late) beat with a shape similar to that of normal beats

201.3.222
SUPRAVENTRICULAR TACHYCARDIA
SVTA
sustained or not sustained chain of consecutive supraventricular ectopic beats

201.3.223
VENTRICULAR ECTOPIC BEAT
VEB
a premature or an escape (late) beat with a wider shape than that of normal beats

201.3.224
VF
VENTRICULAR FIBRILLATION or VENTRICULAR FLUTTER
life-threatening ECG rhythm irregular in shape and frequency

201.4 General requirements

Clause 4 of the general standard applies, except as follows:

201.4.3 ESSENTIAL PERFORMANCE

Addition:

201.4.101 Additional ESSENTIAL PERFORMANCE requirements

Additional ESSENTIAL PERFORMANCE requirements are found in the subclauses listed in Table 201.101.

Table 201.101 – Distributed additional ESSENTIAL PERFORMANCE requirements

Requirement	Subclause
Heart rate	201.12.1.101.3.1
Supraventricular ectopy	201.12.1.101.3.2
Ventricular ectopy	201.12.1.101.3.3
Bradycardia data	201.12.1.101.3.4
PAUSES	201.12.1.101.3.5
ST SEGMENT shifts	201.12.1.101.3.6
ECG hard copy	201.12.1.101.3.7

201.5 General requirements for testing of ME EQUIPMENT

Clause 5 of the general standard applies, except as follows:

201.5.3 Ambient temperature, humidity, atmospheric pressure

Addition to item a):

The AMBULATORY RECORDER shall fulfil the requirements of this standard under the following ambient conditions:

– an ambient temperature range of 10 °C to 45 °C;

– a relative humidity of 10 % to 95 %, without condensation.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of the general standard applies, except as follows:

201.6.2 Protection against electrical shock

Replacement:

Applied parts shall be classified as TYPE BF APPLIED PARTS or TYPE CF APPLIED PARTS (see 7.2.10 and 8.3).

201.6.6 Mode of operation

Replacement:

ME EQUIPMENT shall be classified for CONTINUOUS OPERATION.

201.7 ME EQUIPMENT identification, marking and documents

Clause 7 of the general standard applies, except as follows:

201.7.2 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts

Additional subclause:

201.7.2.101 LEAD WIRE identification

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

If independent bipolar LEADS are being used, the channel assignment shall be clearly annotated on the ME EQUIPMENT for reference. Also, the LEAD WIRE(S) shall be colour coded according to one of the colour coding schemes of Table 201.102

Table 201.102 – LEAD WIRE 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 shall be used in Europe and internationally.

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

201.7.9.2 Instructions for use

Additional subclause:

201.7.9.2.101 *Additional instructions for use

a) Advice shall be given on the following:

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

2) 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;

b) 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.

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

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

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

f) The manufacturer shall disclose the method for determining a PAUSE.

g) If the ME 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 SEGMENT analysis is performed on all LEADS or only some LEADS,
- 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 clinical report (e.g., hourly) and whether numbers of episodes, types of episodes (elevation or depression), and durations of episodes are reported, or whether the clinical report presents this information episode by episode,
- whether ranges of heart rates, ranges of displacements and/or slope values during each episode are reported.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

Clause 8 of the general standard applies.