BS EN 60601-2-47:2015

BSI Standards Publication

Medical electrical equipment

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

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National foreword

This British Standard is the UK implementation of EN 60601-2-47:2015. It is identical to IEC 60601-2-47:2012. It supersedes BS EN 60601-2-47:2001, which will be withdrawn on 14 April 2018.

The UK participation in its preparation was entrusted by Technical Committee CH/62, Electrical Equipment in Medical Practice, to Subcommittee CH/62/4, Electromedical equipment.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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EN 60601-2-47

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English Version

Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems (IEC 60601-2-47:2012)

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)

Medizinische elektrische Geräte - Teil 2-47: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von ambulanten elektrokardiographischen Systemen (IEC 60601-2-47:2012)

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European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

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Foreword

The text of document 62D/963/FDIS, future edition 2 of IEC 60601-2-47, prepared by SC 62D "Electromedical equipment", of IEC/TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 60601-2-47:2015.

The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2016-01-14
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2018-04-14

This document supersedes EN 60601-2-47:2001.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights.

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For the relationship with EU Directive 93/42/EEC, see informative Annex ZZ, which is an integral part of this document.

Endorsement notice

The text of the International Standard IEC 60601-2-47:2012 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

IEC 60601-2-25	NOTE	Harmonized as EN 60601-2-25.
IEC 60601-2-27	NOTE	Harmonized as EN 60601-2-27.

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE 1 When an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cenelec.eu.

Annex ZA of EN 60601-1:2006 applies, except as follows:

Publication	Year	Title	EN/HD	Year
In Annex ZA of EN 60601-1:2006 replace IEC 60601-1-2 by:				
IEC 60601-1-2 (mod)	2007	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2	2007
-	-		+ corrigendum Mar.	2010

Annex ZZ
(informative)

Coverage of Essential Requirements of EU Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and within its scope the Standard covers all relevant essential requirements given in Annex I of EU Directive 93/42/EEC of 14 June 1993 concerning medical devices.

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directive concerned.

WARNING: Other requirements and other EU Directives can be applied to the products falling within the scope of this standard.

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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.

201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

Clause 9 of the general standard applies.

201.10 Protection against unwanted and excessive radiation HAZARDS

Clause 10 of the general standard applies.

201.11 Protection against excessive temperatures and other HAZARDS

Clause 11 of the general standard applies.

201.12 Accuracy of controls and instruments and protection against hazardous outputs

Clause 12 of the general standard applies, except as follows:

201.12.1 Accuracy of controls and instruments

Addition:

201.12.1.101 *Algorithm testing

201.12.1.101.1 General

This subclause describes what constitutes a complete test of an algorithm. The term “test report” refers to the evaluation procedure described in this subclause and not to the clinical report that the physician receives.

201.12.1.101.1.1 *Databases

201.12.1.101.1.1.1 General description of available databases

At the time this document was developed, five databases were available for evaluation of cardiac arrhythmia and ST algorithms:

– AHA: The American Heart Association Database for Evaluation of Ventricular Arrhythmia Detectors (80 records of 35 min each);

– MIT–BIH: The Massachusetts Institute of Technology – Beth Israel Hospital Arrhythmia Database (48 records of 30 min each);

– ESC: The European Society of Cardiology ST-T Database (90 records of 2 h each);

– NST: The Noise Stress Test Database (12 ECG records of 30 min each plus 3 records of noise only supplied with the MIT–BIH database);

– CU: The Creighton University Sustained Ventricular Arrhythmia Database (35 records of 8 mins each – supplied with the MIT–BIH database with incomplete annotations).

Sources for these databases are:

– ECRI, 5200 Butler Pike, Plymouth Meeting, PA 19462, USA (AHA database);

– MIT–BIH Database Distribution, MIT Room E25-505, Cambridge, MA 02139, USA (MIT–BIH, NST, CU databases and the ESC database inside North America—Internet site: http://ecg.mit.edu);

– CNR Institute of Clinical Physiology, Computer Laboratory, via Trieste, 41 56100 Pisa, Italy (ESC database outside North America).

The first four of these databases (AHA, MIT–BIH, ESC, and NST) consist of digitized excerpts of two-channel Holter type recordings, with each beat labelled. This set of annotation files, in which each beat has been identified by expert cardiologist-annotators, are referred to as “reference” annotations. The CU database contains digitized single channel ECG recordings with rhythm changes labelled.

Database elements have been referred to as tapes and records. For the purpose of this document, the term “tapes” refers only to physical taped recordings of ECGs. Database elements are referred to as “records.”

This list of standard databases is not intended to exclude others, which may become available in the future. It is, however, a list of those that were both adequate and available at the time of this document’s publication.

Databases should be:

- fully described (standard digital format);
- clearly identifiable by name, version, date, etc.; and
- annexed with utilities and instructions for use.

If any records from a given database are used to fulfil the requirements of 201.12.1.101.1.5, device performance shall be tested and reported on a record-by-record basis for all records from that database except as excluded by 201.12.1.101.1.1.2. The first 5 min of each record are designated as a learning period. The remainder of each record is the test period. Device performance is measured only during the test period of each record; the entire test period shall be used for this purpose, except as noted in 201.12.1.101.1.1.2

201.12.1.101.1.1.2 *Records to be excluded during testing

Of the 80 available records in the AHA database, two are recorded from patients with pacemakers. Of the 48 records in the MIT–BIH database, four are from patients with pacemakers. In these databases, records with paced beats do not retain sufficient signal quality for reliable processing by systems for pace artifact detection or enhancement, optimized on live signals. For such systems, testing shall exclude these six records containing paced beats from the reporting requirements. Performance on these records shall be reported for devices that are intended to analyze paced analogue ECG recordings made without pacer artifact detection or enhancement, but aggregate performance statistics shall exclude these records in all cases. This exclusion of records with paced beats applies to arrhythmia algorithms as well as to ST SEGMENT measurement algorithms.

The NST database contains three records (BW, EM, and MA) that are noise recordings only and are not intended for use in standard tests. The remaining 12 records are those on which device performance shall be tested and reported.

Segments of data in which ventricular flutter or fibrillation (VF) is present are excluded from beat-by-beat comparisons (for QRS and VEB detection) only. Well-defined QRS complexes necessary for a beat-by-beat comparison are not present during these segments, which are marked by rhythm labels in the database annotation files. These segments are included, however, in the tests of consecutive VEB detection and VF detection. Other segments of these records (i.e. those that do contain labeled beats) shall be included in the beat-by-beat comparisons.

201.12.1.101.1.2 *Testing requirements

201.12.1.101.1.2.1 The accuracy of QRS detection shall be tested using the AHA DB, the MIT–BIH DB, and the NST DB at a minimum.

201.12.1.101.1.2.2 The accuracy of heart rate measurements shall be tested using the AHA DB, the MIT–BIH DB, and the NST DB.

201.12.1.101.1.2.3 The accuracy of VEB detection shall be tested using the AHA DB, the MIT–BIH DB, and the NST DB at a minimum.

201.12.1.101.1.2.4 If the device is claimed to detect ventricular flutter or fibrillation (VF), its ability to do so shall be tested using the CU DB, the AHA DB, and the MIT–BIH DB at a minimum.

201.12.1.101.1.2.5 If the device is claimed to detect supraventricular ectopic beats, or atrial flutter or fibrillation (AF), its ability to do so shall be tested using the MIT–BIH DB and the NST DB at a minimum. If the device is claimed to measure ST SEGMENT deviations or to detect ST SEGMENT changes, its ability to do so shall be tested using the ESC DB at a minimum, unless the characteristics of the database conflict with the algorithm under test.

201.12.1.101.1.3 *Test environment

Algorithm testing using standardized digital databases occurs, by definition, outside the context of the complete monitoring device's clinical setting. Yet, a correlation between algorithm performance and the device's actual clinical performance shall be ensured for the results to be meaningful.

To conduct an evaluation that accurately reflects the capabilities of the algorithm as implemented in a monitoring device, it is preferable to perform the test using hardware comparable to the monitoring device although it is recognized that the nature of the algorithm testing process might require modifications of the hardware or software. Additionally, signals should be presented to the algorithm in a method comparable to the method employed in clinical settings. The computational environment used to perform algorithm testing shall be disclosed.

When algorithm evaluations are conducted under conditions or constraints grossly different from those encountered by the monitoring device in an actual clinical setting, the algorithm results might not represent the true performance of the device. Actual devices can have limited processor speed, computational precision, filtering, etc. Testing or analysis shall be performed indicating that the algorithm performance in an actual monitoring device can reasonably be expected to correlate with performance in the simulated test environment. This validation shall be disclosed.

201.12.1.101.1.4 Multiple-lead analysis

For any database, which has more leads available than can be simultaneously analyzed, the actual combination of channels used shall be disclosed. For any system that can analyze more channels than are available in the database, the disclosure shall state how the data were entered. At no time during the processing of the entire database is the operator allowed to change the combination of leads used. Results shall be reported on a record-by-record basis.

201.12.1.101.1.5 *Requirements for the evaluation report

201.12.1.101.1.5.1 *Required statistics

For each record, the statistics below shall be reported as required in 201.12.1.101.1.5.2 and 201.12.1.101.1.5.3. Aggregate statistics based on the record-by-record reports summarizing the performance of the algorithm under test for each of the databases employed shall be reported as required. Formal definitions of the statistics are provided in the annex as noted.

The following symbols and abbreviations are used in the following tables:

- R = required reporting of this statistic from this database;

- O = optional reporting of this statistic from this database;
- – = no reporting of this statistic required from this database;
- V = aggregate statistic required.

201.12.1.101.1.5.2 *Requirements for all arrhythmia algorithms

The requirements for all algorithms are given in Table 201.103.

Table 201.103 – Requirements for all arrhythmia algorithms

Record-by-record statistics required for each record	Rationale in Annex AA	Gross statistic	Average statistic	AHA DB	MIT–BIH DB	NST DB	CU DB	ESC DB
QRS sensitivity	201.12.1.101.1.5.2	V	V	R	R	R	–	O
QRS positive predictivity	201.12.1.101.1.5.2	V	V	R	R	R	–	O
VEB sensitivity	201.12.1.101.1.5.2	V	V	R	R	R	–	O
VEB positive predictivity	201.12.1.101.1.5.2	V	V	R	R	R	–	O
VEB false positive rate	201.12.1.101.1.5.2	V	V	R	R	R	–	O
RMS heart rate error	201.12.1.101.1.5.3	V	V	R	R	R	–	O
Ventricular couplet sensitivity	201.12.1.101.1.5.3	V	V	R	R	–	–	–
Ventricular couplet positive predictivity	201.12.1.101.1.5.3	V	V	R	R	–	–	–
Ventricular short run sensitivity	201.12.1.101.1.5.3	V	V	R	R	–	–	–
Ventricular short run positive predictivity	201.12.1.101.1.5.3	V	V	R	R	–	–	–
Ventricular long run sensitivity	201.12.1.101.1.5.3	V	V	R	R	–	–	–
Ventricular long run positive predictivity	201.12.1.101.1.5.3	V	V	R	R	–	–	–
% beats missed during SHUTDOWN	201.12.1.101.1.5.2	V	V	R	R	R	–	O
% N missed during SHUTDOWN	201.12.1.101.1.5.2	V	V	R	R	R	–	O
% V missed during SHUTDOWN	201.12.1.101.1.5.2	V	V	R	R	R	–	O
% F missed during SHUTDOWN	201.12.1.101.1.5.2	V	V	R	R	R	–	O
Total SHUTDOWN time	201.12.1.101.1.5.2	V	V	R	R	R	–	O

201.12.1.101.1.5.3 *Requirements for algorithms with optional capabilities

Requirements for algorithms with optional capabilities are given in Table 201.104

Table 201.104 – Requirements for algorithms with optional capabilities

Record-by-record statistics required for each record	Rationale in Annex AA	Gross statistic	Average statistic	AHA DB	MIT–BIH DB	NST DB	CU DB
HRV or RRV result	201.12.1.101.1.5.3	–	–	–	R	–	–
VF episode sensitivity	201.12.1.101.1.5.3	V	O	R	R	–	R
VF episode positive predictivity	201.12.1.101.1.5.3	V	O	R	R	–	R
VF duration sensitivity	201.12.1.101.1.5.3	V	O	R	R	–	R
VF duration positive predictivity	201.12.1.101.1.5.3	V	O	R	R	–	R
VF false positive report	201.12.1.101.1.5.3	–	–	R	R	–	R
VF time to detection	201.12.1.101.1.5.3	–	V	R	R	–	R
SVEB sensitivity	201.12.1.101.1.5.2	V	V	–	R	–	–
SVEB positive predictivity	201.12.1.101.1.5.2	V	V	–	R	–	–
SVEB false positive rate	201.12.1.101.1.5.2	V	V		R	–	–
Supraventricular couplet sensitivity	201.12.1.101.1.5.3	V	V	–	R	–	–
Supraventricular couplet positive predictivity	201.12.1.101.1.5.3	V	V	–	R	–	–
Supraventricular short run sensitivity	201.12.1.101.1.5.3	V	V	–	R	–	–
Supraventricular short run positive predictivity	201.12.1.101.1.5.3	V	V	–	R	–	–
Supraventricular long run sensitivity	201.12.1.101.1.5.3	V	V	–	R	–	–
Supraventricular long run positive predictivity	201.12.1.101.1.5.3	V	V	–	R	–	–
AF episode sensitivity	201.12.1.101.1.5.3	V	–	–	R	R	–
AF episode positive predictivity	201.12.1.101.1.5.3	V	–	–	R	R	–
AF duration sensitivity	201.12.1.101.1.5.3	V	–	–	R	R	–
AF duration positive predictivity	201.12.1.101.1.5.3	V	–	–	R	R	–
AF false positive report	201.12.1.101.1.5.3	–	–	–	O	O	–
AF time to detection	201.12.1.101.1.5.3	–	–	–	O	O	–

RMS measurement errors and mean reference measurements shall be reported separately for each type of heart rate measurement made by the device under test.

Results shall be reported separately for each type of HRV and/or RRV measurement made by the device under test. The definitions of each index and alternative units (i.e. ms or ms² or μV) shall be disclosed.

For devices claiming ST SEGMENT measurement capabilities, the time and voltage resolution of ST SEGMENT amplitude and/or slope measurements, the number of leads analyzed, the filtering employed, and the treatment of ectopic and noisy beats by the ST SEGMENT analysis algorithm shall be disclosed.

201.12.1.101.1.6 Simulated test patterns

Some aspects of algorithm performance are best evaluated with simple deterministic test patterns. For these patterns, the proper algorithm result can be predicted. This was recommended by the ESC/NASPE special report[2].

If the device is claimed to measure heart-rate variability (HRV) or RR interval variability (RRV), its ability to do so shall be tested using special simulated ECG patterns with predictable variability. One pattern (test pattern 1; see 201.12.1.101.2.3.3.2) establishes a noise floor measurement and gives guidance as to how sensitive the system can be for very low variability patients. Other patterns (test patterns 2–5; see 201.12.1.101.2.3.3.2) establish accuracy of calculation and a minimum upper range for high variability patients.

201.12.1.101.2 *Automated analysis

The requirement that evaluations be reproducible implies that evaluations shall be performed without human intervention. Any user facility to change the automatic analysis mode shall be deactivated.

201.12.1.101.2.1 Use of standard databases

Each record shall be supplied to the algorithm continuously from the beginning to the end (i.e. without rewinding or “fast forwarding”). This requirement applies only to the manner in which the evaluator presents ECG samples to the device under test and in no way is to be construed as a restriction on the manner in which the device performs its analysis.

If the digitized ECG signals from the database records are preprocessed in any way before they are presented as input to the device under test, the preprocessing shall be disclosed in sufficient detail to permit a third party to reproduce the test. Preprocessing includes, but is not limited to:

- resampling (i.e. conversion to a sampling rate different from that used in the standard database files);
- reformatting (i.e. conversion of byte order, sample precision, or numeric coding);
- rescaling (altering the signal amplitude, i.e. changing the GAIN);
- filtering performed by software or hardware not employed in the normal operating mode of the device under test;
- conversion from digital to analogue signals.

If the evaluation of the device under test is performed using signals converted into analogue form and supplied to the normal analogue inputs of the device, the device’s automatic GAIN control (AGC) will be allowed to adjust the GAIN automatically. If the evaluation is performed using digital data and the AGC is not digital but part of the analogue front end of the device, the device may simulate its AGC capabilities by an alternative method. This alternative method allows the “test mode” that generates the “test annotations” to emit an announcement that a “GAIN adjustment” would be required prior to proceeding with analyzing the ECG for each patient record. This announcement should instruct the evaluator to adjust the GAIN of the ECG for one or all of the ECG channels. The evaluator shall then run the “xform”[3] (or equivalent) program to adjust the ECG’s GAIN based on the instructions provided by the program. (If another program is used, then this shall be disclosed and made available.) This process shall be repeated until “no GAIN change” is announced; the device under test shall then automatically proceed with the ECG analysis.

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2 Heart Rate Variability, Standards of Measurement, Physiological Interpretation, and Clinical Use, by the European Society of Cardiology and the North American Society of Pacing and Electrophysiology, Circulation, 1996; 93:1043-1065. See especially page 1061.

3 “xform” is a utility program provided with the MIT–BIH database CD-ROM. It is used to transform the database record sample rate and amplitude (this program may be downloaded freely from http://ecg.mit.edu).

Beat-by-beat comparisons, following the protocol described in 201.12.1.101.2.3, shall be used to derive QRS Sensitivity (QRS Se), QRS positive predictivity (QRS +P), VEB Sensitivity (VEB Se), VEB positive predictivity (VEB +P), VEB false positive rate (VEB FPR), supraventricular ectopic beat false positive rate (SVEB FPR), and, where applicable, supraventricular ectopic beat sensitivity (SVEB Se) and supraventricular ectopic beat positive predictivity (SVEB +P). Run-by-run comparisons, following the protocol described in 201.12.1.101.2.4, shall be used to derive VE couplet Se and +P, VE short run Se and +P, VE long run Se and +P, and, where applicable, SVE couplet Se and +P, SVE short run Se and +P, and SVE long run Se and +P. The protocol described in 201.12.1.101.2.5 shall be used to derive VF and AF episode Se and +P, and VF and AF duration Se and +P, where applicable.

201.12.1.101.2.2 *Use of annotation files

The test protocols described in 201.12.1.101.2.3 through 201.12.1.101.2.5 require that, for each record, the clinical report has been recorded in an annotation file (the “test annotation file”), in the same format as the reference annotation file for that record. The device need not produce this file directly. Any automated procedure for doing so is acceptable as long as it is disclosed. The programs “bxb,” “rxr,” “epic,” and “mxm”[4] (either the versions supplied on the MIT–BIH Arrhythmia Database CD-ROM or any later versions released by MIT) or equivalent should be used to perform the comparisons between the test annotation files and the reference annotation files as described in 201.12.1.101.2.3 through 201.12.1.101.2.5. The reference annotation files distributed with the databases and used as input to these programs may not be altered in any way, except that (where applicable) corrected reference annotation files obtained from the database suppliers may be substituted for those originally distributed with the databases. An exception to this is that location data will be altered by the “xform” program when resampling. The source of the annotation shall be disclosed.

Within annotation files, beat labels (N, S, V, F, and Q), rhythm labels (], [), and other labels (U, X, and O) are defined as follows:

– N = any beat that does not fall into the S, V, F, or Q categories described below (a normal beat or a bundle branch block beat);

– S = a supraventricular ectopic beat (SVEB): an atrial or nodal (junctional) premature or escape beat, or an aberrated atrial premature beat;

– V = a ventricular ectopic beat (VEB): a ventricular premature beat, an R-on-T ventricular premature beat, or a ventricular escape beat;

– F = a fusion of a ventricular and a normal beat;

– Q = a paced beat, a fusion of a paced and a normal beat, or a beat that cannot be classified.

Other labels are needed to facilitate the beat-by-beat comparison process defined in 201.12.1.101.2.3:

– U = a label that marks a segment of unreadable data.

U labels appear in the databases where beats cannot be located because of excessive noise or signal loss in the signals. In the MIT–BIH and ESC databases, a pair of U labels mark the beginning and end of each unreadable segment. In the AHA database, a single U label marks the (approximate) center of each unreadable segment, which is assumed for testing purposes to begin 150 ms after the previous beat label and to end 150 ms before the following beat

[4] The programs “bxb,” “rxr,” “epic” and “mxm” and their use are described in the ECG Database Application Guide, available with the MIT–BIH database (these programs may be downloaded freely from http://ecg.mit.edu).

label. Devices may also generate U labels to mark segments during which that device's analysis is suspended (shut down) for any reason (e.g., excessive noise, signal loss). Beat labels are never paired with U labels during beat-by-beat comparisons.

Extra beats are sometimes detected (false positive QRSs), and reference beats are sometimes missed (false negative QRSs). In order to perform beat-by-beat comparisons, pseudo-beat labels are added to those in the reference and test annotation files to preserve a one-to-one correspondence between beat labels. They represent the absence of a beat label. There are two types:

– X = a pseudobeat label generated during a segment marked as unreadable,

– O = a pseudobeat label generated at any other time.

In beat-by-beat comparisons, all beat labels are paired up. If either the reference or the test annotation file contains an extra beat label that has no match in the other file, the appropriate O or X label is paired with the extra label. This corresponds to a QRS detection error – either a false detection (if the extra label is in the test annotation file) or a missed beat (if it is in the reference annotation file). All such beat label pairs are counted, including those that involve O or X labels. O and X labels are not used in run-by-run comparisons (see 201.12.1.101.2.4), or for VF, AF, or ST SEGMENT comparisons (see 201.12.1.101.2.5 and 201.12.1.101.3.6), as it is not necessary in these instances to pair individual beat labels.

Rhythm labels mark segments of ventricular flutter or fibrillation (VF) in the AHA and MIT–BIH databases:

– [= beginning of VF,

–] = end of VF.

Beat labeling is discontinued between "[" and "]" labels. VF segments are excluded from beat-by-beat comparisons. Additional rhythm labels mark changes in rhythm in the MIT–BIH and ESC databases. Those which mark segments of atrial flutter or fibrillation (AF; see the documentation which accompanies each database) are used for evaluation of AF detection; others are ignored. Beat labels are never paired with rhythm labels.

201.12.1.101.2.3 Beat-by-beat comparison

201.12.1.101.2.3.1 General description

During a beat-by-beat comparison, reference beat labels and device beat labels are matched by pairs. To be considered a match, the absolute value of the difference between the device's estimate of the time of occurrence of a beat and the time as recorded in the reference annotation file shall not exceed 150 ms. If matching does not occur within this window, the candidate beat is considered to have been missed or to be an extra detection. The end product of a beat-by-beat comparison is a matrix in which each element is a correct count of the number of beat label pairs of the appropriate type.

Table 201.105 – Beat label classifications

		Algorithm label						
		N	**s**	**v**	**f**	**q**	**o**	**x**
Reference Label	N	Nn	Ns	Nv	Nf	Nq	No	Nx
	S	Sn	Ss	Sv	Sf	Sq	So	Sx
	V	Vn	Vs	Vv	Vf	Vq	Vo	Vx
	F	Fn	Fs	Fv	Ff	Fq	Fo	Fx
	Q	Qn	Qs	Qv	Qf	Qq	Qo	Qx
	O	On	Os	Ov	Of	Oq	–	–
	X	Xn	Xs	Xv	Xf	Xq	–	–

201.12.1.101.2.3.2 Method for beat-by-beat comparison

In performing the beat-by-beat comparison, follow the steps given below:

a) Set the variable *T* to the time of the first reference beat label after the end of the learning period and set the variable *t* to the time of the first test beat label after the end of the learning period. Set all elements of the matrix to zero.

   If *T* is within 150 ms of the beginning of the test period, it is possible that a matching test beat label may be placed before the beginning of the test period. If this occurs, it is counted as a match (*t* is set to the time of the matching test beat label before going on to step b). On the other hand, if *t* is within 150 ms of the beginning of the test period and there is no matching reference beat label after the beginning of the test period, the test annotation at *t* is not counted (*t* is set to the time of the next test beat label before going on to step b).

b) One of the following cases shall apply:

   1) If *t* precedes *T*, set *t*' to the time of the next test beat label (or to a time beyond the end of the record if there are no more test beat labels). There are now two possibilities:

      - If *T* is closer to *t* than to *t*' and *t* is within 150 ms (the match window) of *T*, the beat labels at *T* and *t* are paired. The variable *T* is reset to the time of the next reference beat label.
      - Otherwise, the test beat label at *t* is an extra detection. The extra label is paired with an O or X "pseudobeat" label. The variable *t* is reset to the value of *t*'.

   2) If *t* does not precede *T*, set *T*' to the time of the next reference beat label (or to a time beyond the end of the record if there are no more reference beat labels). There are again two possibilities:

      - If *t* is closer to *T* than to *T*' and *t* is within 150 ms of *T*, the beat labels at *T* and *t* are paired. The variable *t* is reset to the time of the next test beat label.
      - Otherwise, the device has missed the beat at *T*. The extra reference beat label is paired with an O or X "pseudobeat" label. The variable *T* is reset to the value of *T*'.

c) The matrix element corresponding to the beat label pair which was generated in step b is incremented.

d) Steps b and c are repeated until both *t* and *T* are set to times beyond the end of the record.

During the derivation of the matrix, the procedure shall keep track of segments that have been marked as unreadable or as VF in either the reference or the test annotation file. During unreadable segments, pseudo beat labels are X; at all other times, pseudo beat labels are O. Test beat labels generated during reference VF segments are not counted for these purposes. Reference beat labels present during device-marked VF segments are paired with O pseudo

beat labels and counted like all other missed beats. In principle, an unreadable segment or a VF segment may begin during the learning period; this possibility shall be taken into account by software designed to perform beat-by-beat comparisons.

NOTE The reference definition of a beat appears in upper case and the algorithm annotation in lower case (e.g., REFERENCE/algorithm).

201.12.1.101.2.3.3 Heart rate, and heart rate or RR interval variability

201.12.1.101.2.3.3.1 *Heart rate measurement

To evaluate the accuracy of heart rate measurement, the evaluator shall implement and disclose a method for obtaining heart rate measurements using the reference annotation files (the ‘reference heart rate’). This method need not be identical to the method used by the device under test, but in general it will be advantageous if it matches that method as closely as possible. If the method is not identical, the reason for using an alternate method shall be disclosed. If the device produces a continuous heart rate signal (rather than a set of discrete measurements), this signal shall be sampled, either periodically at no less than 2 Hz, or for each beat, in order to obtain a set of discrete measurements for evaluation purposes. Each calculation of the reference HR shall be compared to the corresponding (in time) measurement of HR by the device under test. The comparison of each measurement results in a measured error expressed as a percentage of the mean of the reference heart rate measurements. If the device under test provides more than one type of heart rate measurement as an output, the provisions of this paragraph apply separately to each such type of measurement.

201.12.1.101.2.3.3.2 *Heart rate variability or RR interval variability measurement test patterns

It is important to evaluate the accuracy of an algorithm based on a data set, which has a deterministic and known measure. This is accomplished by using an artificially created analogue waveform and a set of annotation test patterns that can be presented to an algorithm and for which an expected output can be specified.

Analogue test pattern: Test pattern 1 is intended to be applied through the complete signal path of the instrument. In other words, test pattern 1 is produced as an analogue ECG waveform, recorded, digitized, and processed by the QRS detector. The noise floor measurement thus reveals the contributions due to sampling effects, phase lock loops, arithmetic precision, and perhaps other effects.

a) To measure HRV noise floor, connect a signal generator to the appropriate ECG inputs of the device. Adjust the signal generator to obtain a 1 mV triangular pulse with a width at the baseline of 100 ms. The repetition rate shall be between 55 and 75 pulses per minute. The repetition rate shall be stable within 0,01 percent over 24 h.

b) Acquire enough signal duration to complete each HRV calculation three times. For example, if one HRV calculation is the standard deviation of all intervals in a 5 min period, then more than 15 min of data shall be acquired so three separate calculations of that index can be made. Some HRV calculations are defined only for a 24 h period. Three separate 1 day acquisitions shall be used to get the three calculations.

c) Perform three analyses of each HRV index by the device under test. Be sure each analysis is of a different segment of acquired simulated ECG data.

d) For each HRV index, record the worst case measurement (maximum variability) of the three trials. This worst case measure is the noise floor.

The following list defines the HRV index in table 201.106 below.

Time domain indices:

- Mean: mean of all the intervals in ms;
- SDNN: standard deviation all intervals over the complete test duration in ms;

- SDANN: standard deviation of the 5 min means in ms;
- ASDNN: mean of the 5 min standard deviations in ms;
- NN50: the number of interval differences of successive intervals greater than 50 ms;
- PNN50: NN50 as a percentage of all allowed intervals;
- RMSSD: root mean square of successive differences in ms;
- TINN: triangular index interval is the baseline width of the distribution measured as a base of a triangle approximating the interval distribution (the minimum square difference is used to find such a triangle).

Frequency domain indices:

- VLF: very low frequency power (0,00333 Hz to 0,040 Hz) in ms^2;
- LF: low frequency power (0,040 Hz to 0,150 Hz) in ms^2;
- HF: high frequency power (0,150 Hz to 0,400 Hz) in ms^2.

Table 201.106 – Example of noise floor calculation results

HRV index	Trial 1	Trial 2	Trial 3	Noise Floor
SDNN	4,7 ms	4,8 ms	4,1 ms	4,8 ms
ASDNN	4,1 ms	3,9 ms	4,0 ms	4,1 ms
SDANN	0,2 ms	0,4 ms	0,5 ms	0,5ms
RMSSD	5,6 ms	6,1 ms	5,7 ms	6,1 ms
pNN50	0 %	0 %	0 %	0 %
TINN	24 ms	24 ms	16 ms	24 ms
VLF	0,04 ms^2	0,04 ms^2	0,04 ms^2	0,04 ms^2
LF	0,13 ms^2	0,13 ms^2	0,13 ms^2	0,13 ms^2
HF	1,30 ms^2	1,30 ms^2	1,25 ms^2	1,30 ms^2

Digital Test Patterns: Test patterns 2 through 5 are expected to be applied in the digital domain after the QRS detector/classifier. This is to test the validity of the arithmetic in the absence of effects characterized elsewhere and to avoid the need to build an analogue waveform simulator of the required complexity.

e) Define a sinusoidal test pattern as a sequence of NN interval that obeys the following rules. The values rravg, rrdev, and hrvfreq will assume different values for the different test patterns.

   rravg = average rr interval in s

   rrdev = magnitude of rr variability in s

   hrvfreq = the frequency of variability in cycles per s

   T( ) = QRS times sequence

   T(0) = 0,0

   rr(k) = rravg + rrdev * sin(2*π*hrvfreq*T(k))

   T(k+1) = T(k) + rr(k)

   Specify rr() and T() in s and use double floating point (64 bit) arithmetic in order to have sufficient precision.

Table 201.107 – Example of HRV test results

Test pattern	rravg	rrdev	hrvfreq	hrvperiod
2	0,800	0,035	0,25	4 s
3	1,000	0,070	0,10	10 s
4	3,000	0,280	0,033333	30 s
5	1,500	0,140	0,000278	1 h

f) Quantize the intervals. The QRS times sequence shall be quantized, and the interval sequence recomputed from the quantized times to avoid an accumulation of round-off error.

sampletime = time in seconds between allowable interval values for the algorithm under test

Tq(k) = sampletime * integer((T(k) / sampletime) + 0.5)

rrq(k+1) = Tq(k+1) – Tq(k)

g) Define all beats to be N, normal sinus initiated, and disable all rules that would exclude intervals based on relationships such as ratios or maximum and minimum limits. If a maximum limit is required to avoid arithmetic overflow, that limit shall be disclosed. Test pattern intervals range from 0,765 s to 3,28 s.

h) Construct enough duration of each of the following test patterns to satisfy the requirements of each HRV index. The maximum possible computable duration shall be tested. Test pattern 5 is not required when durations as long as 60 min are not testable by the HRV index under consideration.

i) For each test pattern, predict an expected value for each HRV index (see 201.12.1.101.1.5.3).

j) Process each list of quantized intervals for each HRV index. Compare the measured HRV index to that expected for each test pattern (see 201.12.1.101.1.5.3).

201.12.1.101.2.4 Run-by-run comparison

201.12.1.101.2.4.1 General description

Run-by-run comparisons are used to measure a device's ability to detect runs of consecutive ectopic beats. For each type of ectopic beat (VEB and SVEB), two run-by-run comparisons are required, one for sensitivity and another for positive predictivity. The end product of a run-by-run comparison is a pair of matrices in which each element is a count of the number of run pairs of the appropriate type.

Table 201.108 – Run sensitivity summary matrix

		Algorithm run length						
		0	1	2	3	4	5	> 5
Reference run length	0		S_{01}	S_{02}	S_{03}	S_{04}	S_{05}	S_{06}
	1	S_{10}	S_{11}	S_{12}	S_{13}	S_{14}	S_{15}	S_{16}
	2	S_{20}	S_{21}	S_{22}	S_{23}	S_{24}	S_{25}	S_{26}
	3	S_{30}	S_{31}	S_{32}	S_{33}	S_{34}	S_{35}	S_{36}
	4	S_{40}	S_{41}	S_{42}	S_{43}	S_{44}	S_{45}	S_{46}
	5	S_{50}	S_{51}	S_{52}	S_{53}	S_{54}	S_{55}	S_{56}
	> 5	S_{60}	S_{61}	S_{62}	S_{63}	S_{64}	S_{65}	S_{66}

Table 201.109 – Run positive predictivity summary matrix

		Algorithm run length						
		0	**1**	**2**	**3**	**4**	**5**	**> 5**
Reference run length	0		P_{01}	P_{02}	P_{03}	P_{04}	P_{05}	P_{06}
	1	P_{10}	P_{11}	P_{12}	P_{13}	P_{14}	P_{15}	P_{16}
	2	P_{20}	P_{21}	P_{22}	P_{23}	P_{24}	P_{25}	P_{26}
	3	P_{30}	P_{31}	P_{32}	P_{33}	P_{34}	P_{35}	P_{36}
	4	P_{40}	P_{41}	P_{42}	P_{43}	P_{44}	P_{45}	P_{46}
	5	P_{50}	P_{51}	P_{52}	P_{53}	P_{54}	P_{55}	P_{56}
	> 5	P_{60}	P_{61}	P_{62}	P_{63}	P_{64}	P_{65}	P_{66}

NOTE Each entry corresponds to a combination of reference run length and algorithm run length. All run lengths greater than 5 are condensed into the last column (row). Each element is named according to the matrix to which it belongs (S or P) followed by two subscripted numerals corresponding to the reference and algorithm run lengths.

201.12.1.101.2.4.2 Terms and symbols

In the rest of this subclause, the general term “run” refers to a sequence of consecutive V or F labels, as defined in 201.12.1.101.2.2, (which may be mixed in any order) delineated by surrounding N, S, or Q labels (or by the beginning or end of the test period or of an unreadable segment). Recall that O and X pseudo-beat labels are used only for beat-by-beat comparisons; they are completely ignored in run-by-run comparisons and do not delineate runs. The following terms and abbreviations are used to denote runs of specific lengths:

- Couplet (C) = a run of two consecutive V or F labels;
- Short run (S) = a run of three, four, or five consecutive V or F labels;
- Long run (L) = a run of six or more consecutive V or F labels.

A segment of ventricular fibrillation or flutter marked by “[” and “]” labels is considered to be equivalent to a VE long run for the purposes of this subclause; any adjacent V or F labels are considered to be part of the same run. Similarly, a segment of atrial fibrillation or flutter marked by rhythm labels is considered to be equivalent to an SVE long run, and any adjacent S labels are considered to be part of the same run.

201.12.1.101.2.4.3 Run sensitivity summary matrix

This paragraph describes how to derive the VEB run sensitivity summary matrix.

a) The reference annotation file defines the location of all runs. For each reference run, a match window is defined, beginning 150 ms before the time of first beat label of the reference run and ending 150 ms after the time of the last beat label of the reference run.

b) For each reference run, the reference run length is the number of consecutive V or F reference beat labels within the match window.

c) For each reference run, the test run length is the number of consecutive V or F test beat labels within the match window. If more than one detected run occurs during a single reference run, the test run length is determined by the longest detected run within the match window. If there are no V or F test beat labels during a reference run, the test run length is zero.

d) Each possible combination of reference run length and test run length corresponds to a cell in the run sensitivity summary matrix. For each reference run, the count in the appropriate cell is incremented.

To derive the SVE run sensitivity summary matrix, follow the same procedure, replacing each “V” or “F” with “S” in the description above.

201.12.1.101.2.4.4 Run positive predictivity summary matrix

This paragraph describes how to derive the VEB run positive predictivity summary matrix.

a) The test annotation file defines the location of all runs. For each test run, a match window is defined, beginning 150 ms before the time of the first beat label of each test run and ending 150 ms after the time of the last beat label of the test run.

b) For each test run, the test run length is the number of consecutive V or F test beat labels within the match window.

c) For each test run, the reference run length is the number of consecutive V or F reference beat labels within the match window. If more than one reference run occurs during a single test run, the reference run length is determined by the longest reference run during the match window. If there are no V or F reference beat labels during a test run, the reference run length is zero.

d) Each possible combination of reference run length and test run length corresponds to a cell in the run positive predictivity summary matrix. For each reference run, the count in the appropriate cell is incremented.

To derive the SVE run positive predictivity summary matrix, follow the same procedure, replacing “V” or “F” with “S” in the description above.

201.12.1.101.2.5 VF and AF comparisons

For devices, which are claimed to detect VF, a VF comparison shall be performed. This test requires the production of an annotation file based on the device’s outputs, containing (at a minimum) the times when the device has determined that episodes of VF have begun or ended. Overlap exists during any interval in which both the reference and algorithm annotations indicate that VF is in progress.

Measurement of VF episode sensitivity and positive predictivity: Each reference episode for which overlap exists is counted as a true positive for purposes of determining VF episode sensitivity; any other reference episodes are counted as false negatives. Similarly, each algorithm-marked episode for which overlap exists is counted as a true positive for purposes of determining VF episode positive predictivity; any other algorithm-marked episodes are counted as false positives.

Measurement of VF duration sensitivity and positive predictivity requires determination of the total duration of reference and algorithm-marked VF and of the total duration of periods of overlap as defined above.

Additionally, the following information shall be disclosed for each record:

a) the subclause of record used for testing;

b) whether an alarm was generated for the test record;

c) what the alarm was, if one occurred (e.g., asystole, ventricular tachycardia, or ventricular fibrillation);

d) the gradation of alarms, if applicable;

e) the interval between the onset of the arrhythmia to the time the alarm was activated, if one occurred. (This last requirement only applies to devices that perform real-time monitoring.)

In addition, for algorithms that attempt to detect ventricular fibrillation/flutter, any false positive detection that occurs on any record in the database shall be reported.

For devices that are claimed to detect AF, an AF comparison shall be performed. This test is performed in the same manner as the VF comparison, with the substitution of “AF” for each occurrence of “VF” in the description above.

201.12.1.101.3 *Physician report – minimum requirements

Any properties in the items listed below that an ME SYSTEM is capable of detecting shall be reported. The report shall also list all OPERATOR selected parameters. The report shall summarise each item of the ambulatory procedure at regular time intervals defined by the manufacturer and then as a procedure total at the end of the procedure.

201.12.1.101.3.1 Heart rate

Lowest, mean, and highest heart rates shall be reported. The summary information shall also reflect the total number of heart beats detected.

201.12.1.101.3.2 Supraventricular ectopy

Totals for SVEBs, single SVEBs, paired SVEBs, runs of SVT and some form of SVT duration (either beat totals or time duration) shall be reported. Summary information shall include the total number of each event that occurred during the procedure. The report shall summarise each item at least once for each hour of the ambulatory procedure and then as a procedure total at the end of the procedure.

201.12.1.101.3.3 Ventricular ectopy

Totals of ventricular ectopic beats (VEBs), single VEBs, paired VEBs, and runs of three or more VEBs, and the duration of runs (either number of beats or time duration) shall be reported. For episodes of ventricular tachycardia, rate and duration (either beat totals or time duration) of each episode shall be reported. The number of minutes (and optionally seconds) that were analysed on each channel shall be reported (the manufacturer may substitute the amount of time not analysed).

201.12.1.101.3.4 Bradycardia data

Hourly presentation of the total of bradycardia episodes is required, specifying rate and duration of the episodes. Bradycardia episodes (heart rate less than 50/min for 15 s or manufacturer-selected parameters or user-defined parameters) shall be reported.

201.12.1.101.3.5 PAUSES

The total number of PAUSEs detected based upon an OPERATOR selectable absolute threshold or manufacturer selected parameter shall be reported. The location and duration of the longest of PAUSEs shall be reported.

201.12.1.101.3.6 *ST SEGMENT shifts

If the manufacturer claims that ME EQUIPMENT is capable of detecting and measuring ST SEGMENT shifts, a suitable report with the manufacturer-claimed parameters shall be generated and included in the ACCOMPANYING DOCUMENTS.

201.12.1.101.3.7 ECG hard copy

OPERATOR selectable, 25 mm/s, multichannel ECG strips shall be available with each report in sufficient quantity to support all meaningful clinical conclusions. LEAD configuration for each channel shall be provided either with each ECG strip or as part of the procedure settings information. ECG strips shall, minimally, include the following labelling:

– time of strip,
– heart rate on strip,
– strip annotation.

Additionally, each ”page” of ECG strips shall contain the PATIENT identification. A ”page” in this context might be a single ECG strip or several strips contained on a A4-sized or ”letter”-size

sheet of paper. Each channel calibration signal shall be present in each report for which a subsequent ST SEGMENT analysis is to be done.

201.12.4 Protection against hazardous output

201.12.4.4 Incorrect output

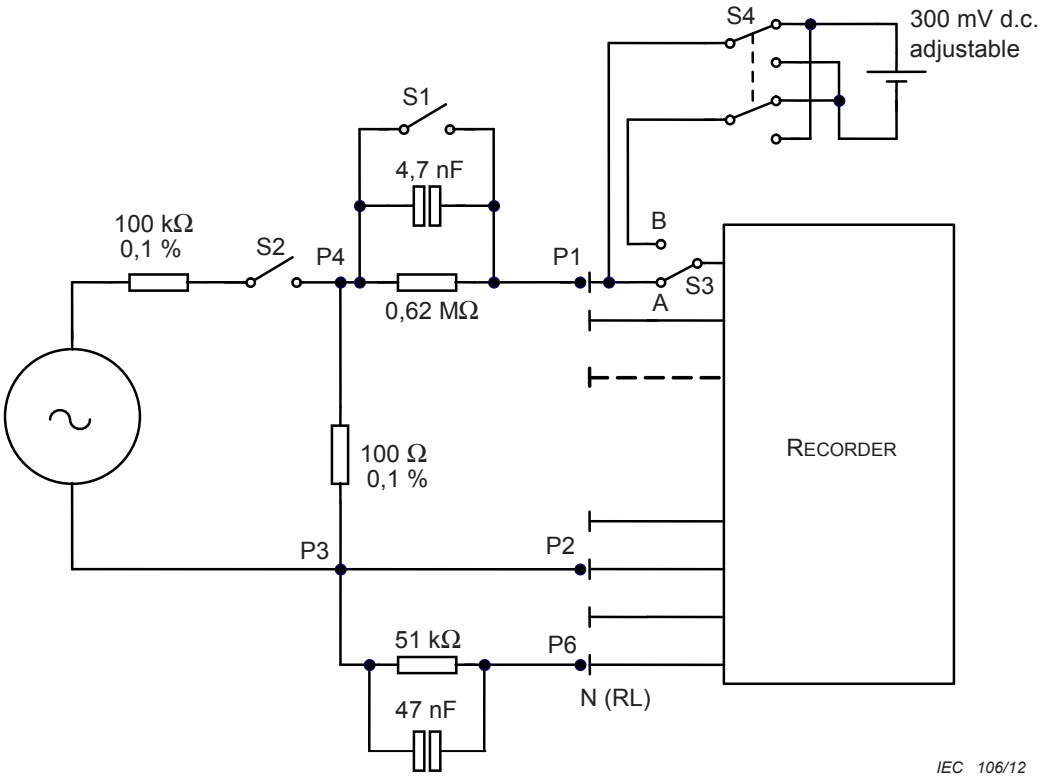


Figure 201.101 – General test circuit for 201.12.4.4

Addition:

201.12.4.4.101 *Linearity and dynamic range

Analogue AMBULATORY RECORDERS shall be capable of responding to and displaying input signal of 6 mV peak-to-valley (p-v) in amplitude (when set to the 5 mm/mV GAIN setting) and varying at a rate of 125 mV/s in the presence of a direct current (d.c.) offset voltage of ± 300 mV. The indicated time-varying output signal amplitude referred to input shall not change by more than 10 % or 50 μV, whichever is greater.

Compliance is checked by the following test:

a) *Set the GAIN to 5 mm/mV. Feed a 10,4 Hz triangular wave with amplitudes of 0,.5 mV, 1 mV, 2 mV, and 6 mV p-v (Figure 201.102) into the test circuit between P4 and P3 of Figure 201.101 with switches S1 and S2 closed, S3 in position A and the positive PATIENT ELECTRODE connection for each channel joined to P1.*

b) *Join the negative PATIENT ELECTRODE connection of each channel through P2 to the NEUTRAL ELECTRODE LEAD WIRE through a parallel combination of a 51 kΩ resistor and a 47 nF capacitor. Record the triangular wave.*

c) *Set switch S3 to position B and use switch S4 to add an offset voltage of 300 mV, wait for 30 s and repeat the recording.*

d) Set switch S3 to position B and use switch S4 to subtract a 300 mV offset, wait for 30 s and repeat the recording.

e) Confirm that in the playback signal display the triangular waves have a minimum amplitude p-v difference to the input signal of less than 10 % or 50 μV, whichever is smaller.

Alternatively:

Test with a 4 Hz sine wave, with same amplitudes as above, either continuous or consisting of isolated cycles repeated once a second.

Digital AMBULATORY RECORDERS shall be capable of responding to and displaying input signal of 10 mV peak-to-valley (p-v) in amplitude (when set to the 5 mm/mV GAIN setting) and varying at a rate of 125 mV/s in the presence of a direct current (d.c.) offset voltage of ± 300 mV. The indicated time-varying output signal amplitude referred to input shall not change by more than 10 % or 50 μV, whichever is greater.

Compliance is checked by the following test:

f) Set the GAIN to 5 mm/mV. Feed a 6,25 Hz triangular wave with an amplitude of 0,5 mV, 1 mV, 2 mV, and 10 mV p-v (Figure 201.102) into the test circuit between P4 and P3 of Figure 201.101 with switches S1 and S2 closed, S3 in position A and the positive PATIENT ELECTRODE connection for each channel joined to P1.

g) Join the negative PATIENT ELECTRODE connection of each channel through P2 to the NEUTRAL ELECTRODE LEAD WIRE through a parallel combination of a 51 kΩ resistor and a 47 nF capacitor. Record the triangular wave.

h) Set switch S3 to position B and use switch S4 to add an offset voltage of 300 mV, wait for 30 s and repeat the recording.

i) Set switch S3 to position B and use switch S4 to subtract a 300 mV offset, wait for 30 s and repeat the recording.

j) Confirm that in the playback signal display the triangular waves have a minimum amplitude p-v difference to the input signal of less than 10 % or 50 μV, whichever is smaller.

Alternatively:

Test with a 4 Hz, with same amplitudes as above, either continuous or consisting of isolated cycles repeated once a second.

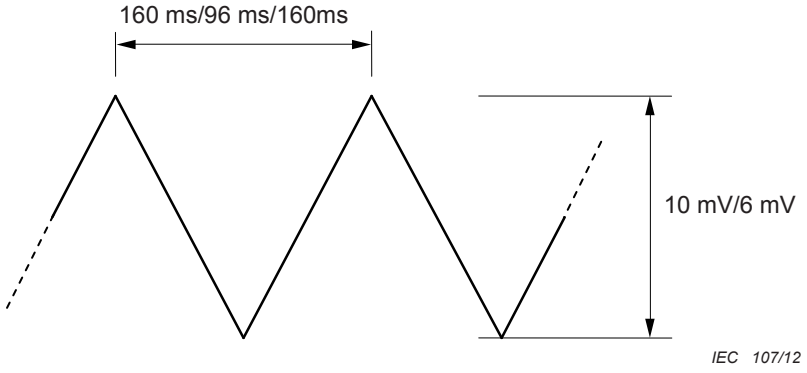


Figure 201.102 – Test signal for input dynamic range test according to 201.12.4.4.101

201.12.4.4.102 *Input impedance

The input impedance shall be greater than 10 MΩ for the frequency specified in the test and for all input channels. This requirement shall be met across the total required d.c. offset range capabilities.

Compliance is checked by the following test:

a) Refer to the test circuit of Figure 201.101.

b) Close switches S1 and S2, put S3 in position A. Apply a 10 Hz sinusoidal signal of 5 mV amplitude p-v across P3 and P4.

c) Connect the PATIENT ELECTRODE connections of the first channel to P1 and P2. Connect all other PATIENT ELECTRODE connections to P6.

d) Open S1 and measure the output amplitude change. The steady-state output amplitude shall not decrease by more than 6 %.

e) Repeat the test with offset voltages of 300 mV and –300 mV respectively.

f) Repeat all these tests for all other ECG channels.

g) Measure the output amplitudes on the manufacturer's PLAYBACK EQUIPMENT.

201.12.4.4.103 *Common mode rejection

Common mode rejection shall be at least 60 dB for a sinusoidal signal at the SUPPLY MAINS frequency and at least 45 dB at twice the SUPPLY MAINS frequency. The common mode rejection capability is defined as the ratio of the p-v value of the interfering SUPPLY MAINS frequency to the p-v value of the resulting signal in any ECG input channel, referred to input.

Compliance is checked by the following test:

Refer to the test circuit of Figure 201.103.

a) Use the manufacturer's recommended PATIENT CABLE or equivalent. Enclose the ME EQUIPMENT under test in a conductive foil wrap and connect this to earth. The foil shall fully enclose the ME EQUIPMENT, except where the PATIENT CABLE enters and shall conform to the contours of the ME EQUIPMENT within 3 mm. The PATIENT CABLE shall be enclosed throughout its entire length by a similar foil shield connected to the shield driven by the simulated SUPPLY MAINS frequency source. The same driven shield shall enclose the various resistor/capacitor networks, d.c. offset source and switches. An additional earth referenced shield shall enclose the entire test set-up. Within this outer shield the placements of the parts in the driven shield shall all be well controlled and repeatable after fixture is calibrated in order to minimize changes in the fixture's calibration. Set the interference signal initially at the SUPPLY MAINS frequency. Any supply frequency notch filters in the ME EQUIPMENT shall be disabled during these tests, even if it requires software not available to the customer to do so.

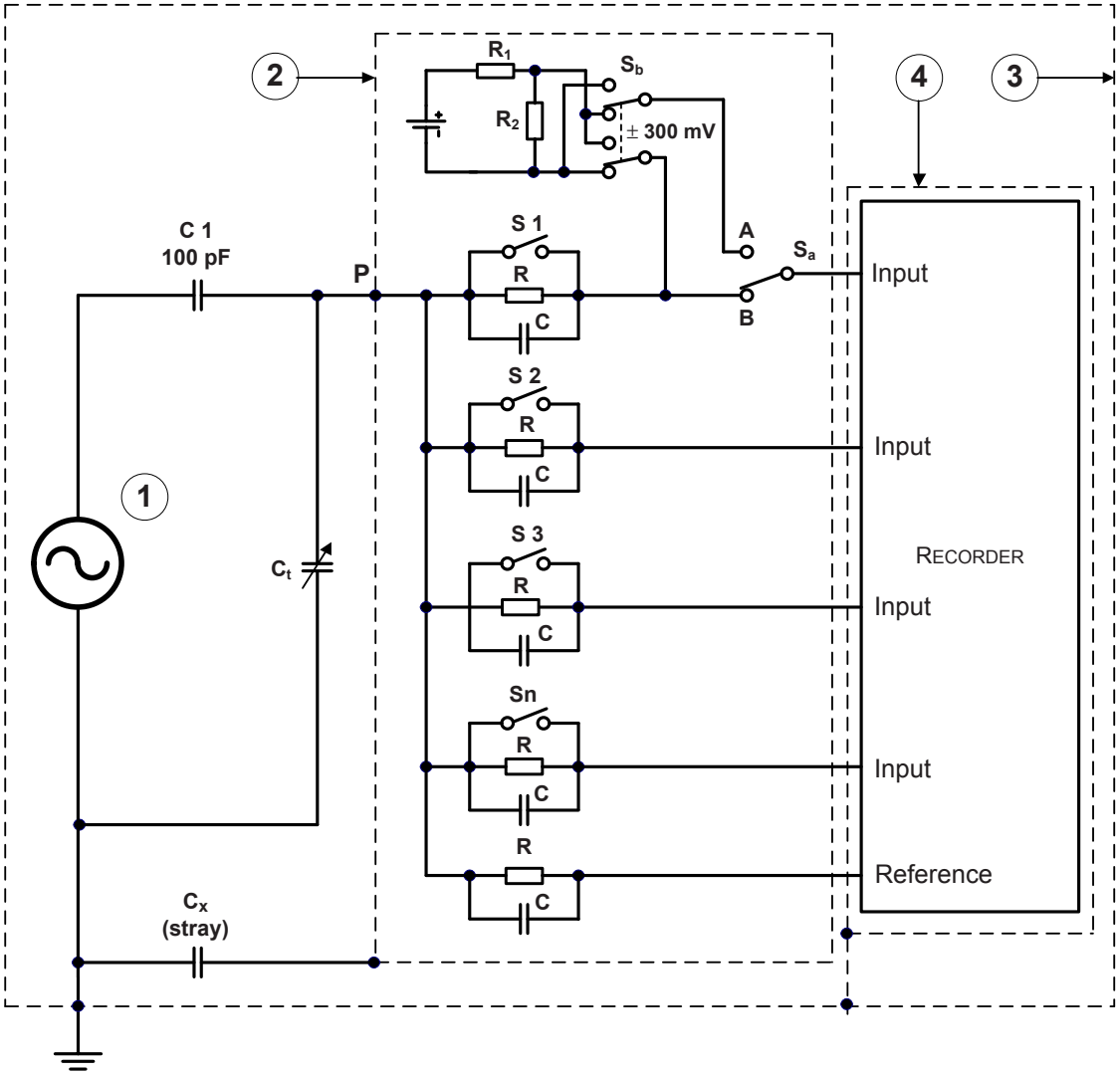
b) Connect all PATIENT ELECTRODE LEADS to a common node, each one in series with a parallel combination of a 51 kΩ resistor, a 47 nF capacitor and a switch. Connect any common or reference ELECTRODE, if supplied, through a 51 kΩ resistor in parallel with a 47 nF capacitor to the same common node. Apply the interference test signal to the common node through a 100 pF capacitor. Connect the low side of the generator to earth. Switches S1 to Sn inclusive are open, switch Sa is in position B. Adjust C_t until the resulting test voltage across C_t is half of the signal generator voltage. This adjustment shall be done while the ME EQUIPMENT under test is totally removed from the test set-up, and the PATIENT CABLE, the foil around the PATIENT CABLE, and the fixture are all in place inside the earth grounded outer shield in the positions they will occupy when the ME EQUIPMENT is added after calibration. The outer shield shall be closed in the position that will be used during the actual tests. Open the outer shield, connect the ME EQUIPMENT, and close the outer shield. Record sufficient signal to allow measurement of worst case

interference, taking into account any possible aliasing and the reproducer's maximum OPERATOR *selectable playback speed.*

c) *Repeat the test with a d.c. offset of 300 mV and –300 mV in series with the imbalance impedance by setting Sa in position A and testing with* S_b *in each position. Repeat with offset in series with each input.*

d) *First close all switches S1 to Sn. Then do and repeat the test with switch S1 to Sn opened, in turn. Repeat the tests at twice the* SUPPLY MAINS *frequency.*

The measured output during each test period shall not exceed 4 mV p-v at SUPPLY MAINS *frequency with a generator voltage of 8 V p-v. At twice the* SUPPLY MAINS *frequency the measured output shall not exceed 4 mV p-v with a generator voltage of 1,422 V p-v.4.*



Components

①	Signal generator; output impedance < 1 kΩ and linearity ± 1 %
②	Driven shield
③	Earth referenced shield around entire test configuration
④	Shield (foil) wrapped around RECORDER
P	Driven shield connected at this point
$R_{1,2}$	Voltage divider;
S_a	Switch, connects/disconnects the d.c. offset voltage source
S_b	Switch, changes polarity of d.c. offset voltage source
S1, Sn	Switches; Switches; invoke unbalance circuit consisting of C and R
C	47 nF
R	51 kΩ

Figure 201.103 – Test circuit for common mode rejection according to 201.12.4.4.103

201.12.4.4.104 *GAIN accuracy

The output at all possible GAIN settings shall be reproduced with a maximum amplitude error of ± 10 % compared to the test signal, referred to the input.

Compliance is checked by the following test:

Apply a 5 Hz, 2 mV p-v sinusoidal signal to all ECG input channels. The output shall comply with the above requirement at each possible GAIN setting.

201.12.4.4.105 *GAIN stability

One minute after energizing the ME EQUIPMENT, the GAIN change shall not exceed 3 % over a 24 h period (in stable ambient conditions).

Compliance is checked by the following test:

Apply a 5 Hz, 2 mV p-v sinusoidal signal to all ECG input channels for a period of 24 h. With each possible GAIN setting, verify that the output is within the requirements at any time during the first hour (or test at 1 min, 2 min, 5 min, 10 min, 20 min, 30 min, 45 min and 60 min) and once every following hour up to 24 h.

201.12.4.4.106 *System noise

The internal noise referred to input shall not exceed 50 μV p-v over any 10 s period when all inputs are connected through a 51 kΩ resistor in parallel with a 47 nF capacitor in series with each PATIENT ELECTRODE connection. Any SUPPLY MAINS frequency notch filters in the ME EQUIPMENT, if so equipped, shall be operating at the appropriate SUPPLY MAINS frequency during this test.

Compliance is checked by the following test:

Insert in series which each PATIENT ELECTRODE *connection a 51 kΩ resistor in parallel with a 47 nF capacitor, as shown in Figure 201.103, and then connect all PATIENT ELECTRODE connections including the reference connection together. Do not connect the input signal generator and the 100 pF capacitor for this test. At the highest GAIN possible, record for 2 min. Ignore the first 10 s and last 10 s of the recording. Divide the remaining 100 s into 10 intervals of 10 s each, then check the output for noise levels in each interval. The p-v noise level shall be within the limit for at least nine of the ten intervals.*

201.12.4.4.107 *Multichannel crosstalk

The crosstalk between the channels of the ME EQUIPMENT shall not produce in any channel an output referred to input greater than 5 %.

Compliance is checked by the following test:

a) Connect the AMBULATORY RECORDER to the test circuit of Figure 201.101 with switches S1 and S2 closed, switch S3 in position A. Join the positive PATIENT ELECTRODE connections for each channel to P1.

b) Join the reference PATIENT ELECTRODE connections for each channel through P2 to the NEUTRAL ELECTRODE LEAD WIRE through a 51 kΩ resistor in parallel with a 47 nF capacitor.

c) Adjust the signal generator to produce a sinusoidal signal amplitude of 4 mV p-v and a frequency of 10 Hz across P1 and P2. Record at least 10 s of signal.

d) Reconnect all but one of the positive PATIENT ELECTRODE connections from P1 to P2. Record at least 10 s of signal.

e) Repeat this for as many channels as can be recorded. Join only one positive PATIENT ELECTRODE connection to P1 at a time.

The output of the channels with the positive PATIENT ELECTRODE connection connected to P2 shall not exceed 5 % referred to input.

201.12.4.4.108 *Frequency response

The ME EQUIPMENT shall meet the following requirements:

a) Response of a AMBULATORY RECORDER to a 3 mV 100 ms rectangular pulse shall not show a baseline amplitude displacement after the pulse of more than 0,1 mV referred to the baseline before the pulse. The slope outside the pulse shall be less than 0,3 mV/s. The leading edge overshoot shall be less than 10 %.

And either:

b) The amplitude response to sinusoidal signals within the frequency range 0,67 Hz to 40 Hz shall be between 140 % and 70 % (+3 dB to –3 dB) of the response at 5 Hz.

   If the manufacturer claims ST SEGMENT measurement capability for the ME EQUIPMENT, lower cut-off frequency shall be 0,05 Hz for a first-order high-pass filter or its functional equivalent.

   If the manufacturer claims that the ME EQUIPMENT is capable of recording ECGs from infants weighing less than 10 kg, the upper cut-off frequency shall be at least 55 Hz.

Or

c) Responses to all pulses of a 1,5 mV, 40 ms triangular pulse train, which simulates a series of narrow R-waves, shall be within 70 % to 110 % of the maximum amplitude in a train of 1,5 mV, 200 ms triangular pulses.

   If the manufacturer claims that the ME EQUIPMENT is capable of recording ECGs from infants weighing less than 10 kg, the response to the 1,5 mV × 40 ms triangular wave shall be within 80 % to 110 % of the maximum amplitude in a train 1,5 mV × 200 ms triangular pulses.

Compliance is checked by the following tests:

The system input is at the PATIENT ELECTRODE; the output is measured on the system's hard copy ECG record.

a) Record at least 20 s of zero volt baseline, and then a single 3 mV 100 ms rectangular pulse. Continue recording for at least another 20 s of zero volt baseline.

b) With the test set-up of Figure 201.101, record for at least 5 s a 2 mV p-v sinusoidal signal at 0,67 Hz. Repeat this for 1 Hz, 2 Hz, 5 Hz, 10 Hz, 20 Hz and 40 Hz.

   If the manufacturer claims ST SEGMENT measurement capability for the ME EQUIPMENT, replace in the above series of tests the lower test frequency of 0,67 Hz by 0,05 Hz.

   If the manufacturer claims that the ME EQUIPMENT is capable of recording ECGs from infants weighing less than 10 kg, replace in the above series of tests the upper test frequency of 40 Hz by 55 Hz.

c) Record for at least 5 s a train of triangular 1,5 mV, 200 ms base width pulses with a repetition rate of 1/s. Then adjust the base width of the triangular pulses to 40 ms. Record at least 5s.

Verify the following measures on the hard copy record:

a) The output baseline following the 3 mV rectangular pulse is displaced no more than 0,1 mV from the baseline preceding the pulse. The slope outside the region of the pulse does not exceed 0,3 mV/s.

b) The p-v amplitude responses at the frequencies of 0,67 Hz, 1 Hz, 2 Hz, 10 Hz, 20 Hz, 40 Hz are between 70 % and 140 % of the response at 5 Hz.

If the manufacturer claims ST SEGMENT measurement capability for the ME EQUIPMENT, replace the lower test frequency of 0,67 Hz by 0,05 Hz or its functional equivalent.

If the manufacturer claims that the ME EQUIPMENT is capable of recording ECGs from infants weighing less than 10 kg, replace the upper test frequency of 40 Hz by 55 Hz.

c) The lowest peak-to base amplitude of the 1,5 mV, 40 ms base width triangle pulse train is no less than 60 % of the highest peak-to base amplitude of the 1,5 mV 200 ms base width triangle pulse train.

If the manufacturer claims that the ME EQUIPMENT is capable of recording ECGs from infants weighing less than 10 kg, the lowest peak-to base amplitude of the 1,5 mV, 40 ms base width triangle pulse train is no less than 80 % of the highest peak-to-base amplitude of the 1,5 mV 200 ms base width triangle pulse train.

201.12.4.4.109 *Function in the presence of pacemaker pulses

If the manufacturer claims that the AMBULATORY RECORDER is capable of recording ECG signal in the presence of implanted pacemaker pulses, the function of the ME EQUIPMENT shall not be adversely affected by the operation of an implanted pacemaker.

Compliance is checked by the following test:

a) Connect the ME EQUIPMENT to the circuit of Figure 201.104, with the positive PATIENT ELECTRODE connection for each channel connected to P1 and the negative ELECTRODE connection for each channel, as well as the reference ELECTRODE connection, to P2.

b) Adjust the sine wave generator so that a 10 Hz (2,0 ± 0,2) mV p-v sinusoidal signal is present across the 111 Ω resistor. The pulse generator adds 200 mV ± 25 mV pulses with a duration of 1,0 ms ± 0,1 ms, a rise time ≤ 100 μs and a repetition rate of 100 pulses/min.

c) Record at least 30 s.

d) Reverse the positive and negative ELECTRODE connections in a) and repeat the recording.

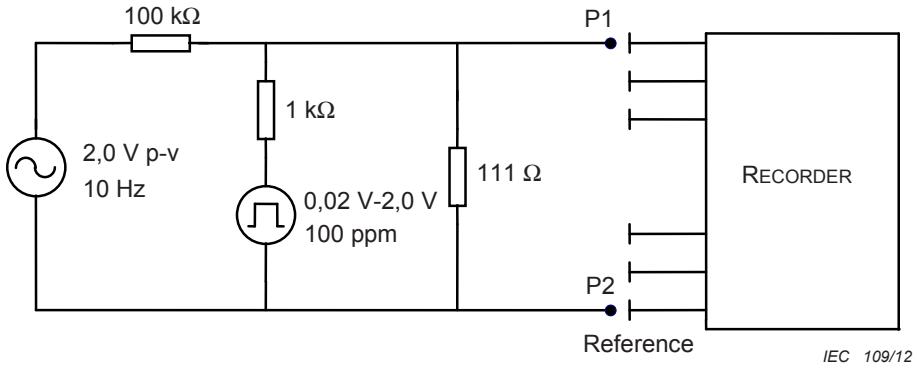
e) Confirm on playback that for all pulses the height of the second peak of the sine wave after the pulse does not differ more than 0,2 mV from the height of the sine wave peak immediately preceding the pulse.

If the manufacturer claims that ME EQUIPMENT is capable of recording the activity of an implanted pacemaker, the ME EQUIPMENT shall produce a visible recording for pacemaker pulses with amplitudes between 2 mV and 200 mV, durations between 0,1 ms and 2,0 ms and a rise time of < 100 μs.

Compliance for such ME EQUIPMENT is checked by the following test:

Tests with four different pulses with a rise time of < 100 μs shall be made: a first pulse having an amplitude of 2 mV and a duration of 2,0 ms, a second pulse having an amplitude of 200 mV and a duration of 2,0 ms, a third pulse having an amplitude of 20 mV and a duration of 0,1 ms and a fourth pulse having an amplitude of 2 mV and a duration of 0,1 ms.

Record at least 30 s with the sinusoidal generator settings of item b) above and a repetition rate of the pulses of 100/min and verify that for every pulse, a mark at least 2 mm high is printed on the hard copy record at the same repetition frequency and same inter-pulse interval as the pulses input into the ME EQUIPMENT.



Key

ppm = pulse per minute

Figure 201.104 – Test circuit for pacemaker pulse tolerance according to 201.12.4.4.109

201.12.4.4.110 *Timing accuracy

The overall error during 24 h shall not exceed 30 s.

Compliance is checked by the following test:

The ME EQUIPMENT is arranged to record a signal from an ECG simulator or operate in the calibration mode for 24 h. At 1 h ± 1 s, 8 h ± 1 s and 23 h ± 1 s into the test, insert an event mark on the recording. This can be achieved by inserting the event mark by means of a radio clock with an accurate time base. Inspect the full disclosure report and verify that each event marks actual time of day within 30 s of the 1st, 8th, and 23rd hour of the report.

201.12.4.4.111 *GAIN settings and switching

The GAIN used shall be printed out on the printout. Analogue systems shall provide a calibration pulse on the printout. At least GAINS of 10 mm/mV and 5 mm/mV shall be provided. If additional GAINS are provided, at least the GAIN of 20 mm/mV shall be provided

Compliance is checked by inspection of the printout.

201.12.4.4.112 *Temporal alignment

When the amplifiers for all channels are set to the same frequency response limits, the channel to channel skew shall, except as indicated below, be less than ± 20 ms or ± 0,5 mm (at 25 mm/s time axis scale). This applies to the whole system and all its individual component parts (AMBULATORY RECORDER, PLAYBACK EQUIPMENT, etc.).

If the skew exceeds the above stated limit, then a suitable warning shall be included in the record to indicate that channel to channel temporal comparison is not advised.

Compliance is checked by the following test:

a) Connect the AMBULATORY RECORDER to the test circuit of Figure 201.101. Switches SI and S2 are closed, switch S3 is in position A. Connect all positive LEAD connections to point P1 and all negative LEAD connections to point P2. The signal source is adjusted to provide a train of rectangular pulses that have an amplitude of 1,0 ± 0,05 mV across PI and P2, a duration of 200 ms, a rise- and fall-time of < 1,0 ms and a repetition rate of 1/s.

b) If the AMBULATORY RECORDER or the PLAYBACK EQUIPMENT has switchable amplifier filters, adjust them such that all channels have the same frequency response.

c) Record at least 1 h of pulses on all the channels of the RECORDER. Print out the signal of each channel and print the signals of at least two channels at a time (or display them) with a resolution of 25 mm/s and 10 mm/mV. Verify that the skew of the rising and falling edges of the signal between each of the channels is less than 20 ms (0,5 mm). Make this measurement at three distinct points for each channel in the 1 h record. Repeat this test for all playback speeds available in the scanning ME EQUIPMENT.

d) Verify that a warning is printed or displayed by the PLAYBACK EQUIPMENT if the measured skew exceeds 20 ms (0,5 mm).

201.13 HAZARDOUS SITUATIONS and fault conditions

Clause 13 of the general standard applies.

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

Clause 14 of the general standard applies.

201.15 Construction of ME EQUIPMENT

Clause 15 of the general standard applies, except as follows:

201.15.3 Mechanical strength

201.15.3.4.1 HAND HELD ME EQUIPMENT

AMBULATORY RECORDERS are not regarded as HAND-HELD ME EQUIPMENT. Subclause 15.3.4.1 of the general standard does not apply.

201.15.3.4.2 PORTABLE ME EQUIPMENT

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 AMBULATORY RECORDER is dropped once from a height of 5 cm 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. The AMBULATORY RECORDER is connected to a signal source for a period before being dropped and either remains connected or is reconnected after the drop. If the AMBULATORY 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. Check that the data acquired before and after the drop (except for the allowed 60 s gap) remains available and uncorrupted.

During transport or storage, or when not operating, the RECORDER shall not be damaged after being subjected to shocks resulting from an 0,8 m drop onto a hard surface on any face, edge or corner (pouch may be used, as above).

The AMBULATORY RECORDER shall not suffer obvious damage as a result of this test and shall meet the requirements of this particular standard.

Compliance is tested as follows:

The AMBULATORY RECORDER is allowed to fall freely once from each of three different starting positions from a height of 0,8 m onto a 50 mm thick hardwood board (for example, hardwood > 600 kg/m^3) which lies flat on a rigid base such as a concrete floor. If the AMBULATORY RECORDER is normally used with a pouch, the same type of pouch can be used during testing. After being dropped, if inspection identifies any obvious damage the AMBULATORY RECORDER testing for compliance with any requirements of this standard that could have been affected is performed.

201.15.4 ME EQUIPMENT components and general assembly

201.15.4.3 Batteries

Additional subclauses:

201.15.4.3.101 Monitoring time and retention of data

201.15.4.3.101.1 *Monitoring time

AMBULATORY RECORDERs shall be capable, with a fully charged INTERNAL ELECTRICAL POWER SOURCE as specified by the manufacturer, of monitoring for at least 24 h continuously or any longer period that is specified in the instructions for use.

Compliance is checked by measurement.

201.15.4.3.101.2 *Data retention

AMBULATORY RECORDERs using volatile memory support shall be capable of retaining the stored information without any external power supply for at least 72 h after completion of the monitoring time.

Compliance is checked by:

a) Perform the test as per the requirement of 201.15.4.3.101.1.

b) Leave the ME EQUIPMENT isolated for 72 h after recording at a temperature of 25 °C and a humidity of 70 %.

Read the recorded data at the end of this period and verify that no change of the data is apparent.

201.16 ME SYSTEMS

Clause 16 of the general standard applies, except as follows:

201.16.5 SEPARATION DEVICES

Addition:

If the AMBULATORY RECORDER may be connected simultaneously to the PLAYBACK EQUIPMENT and the PATIENT, a SEPARATION DEVICE shall be provided.

201.17 *Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

Clause 17 of the general standard applies.

202 Electromagnetic compatibility – Requirements and tests

IEC 60601-1-2:2007 applies, except as follows:

202.6.1.1 Protection of radio services

202.6.1.1.1 Requirements

Replacement of first paragraph:

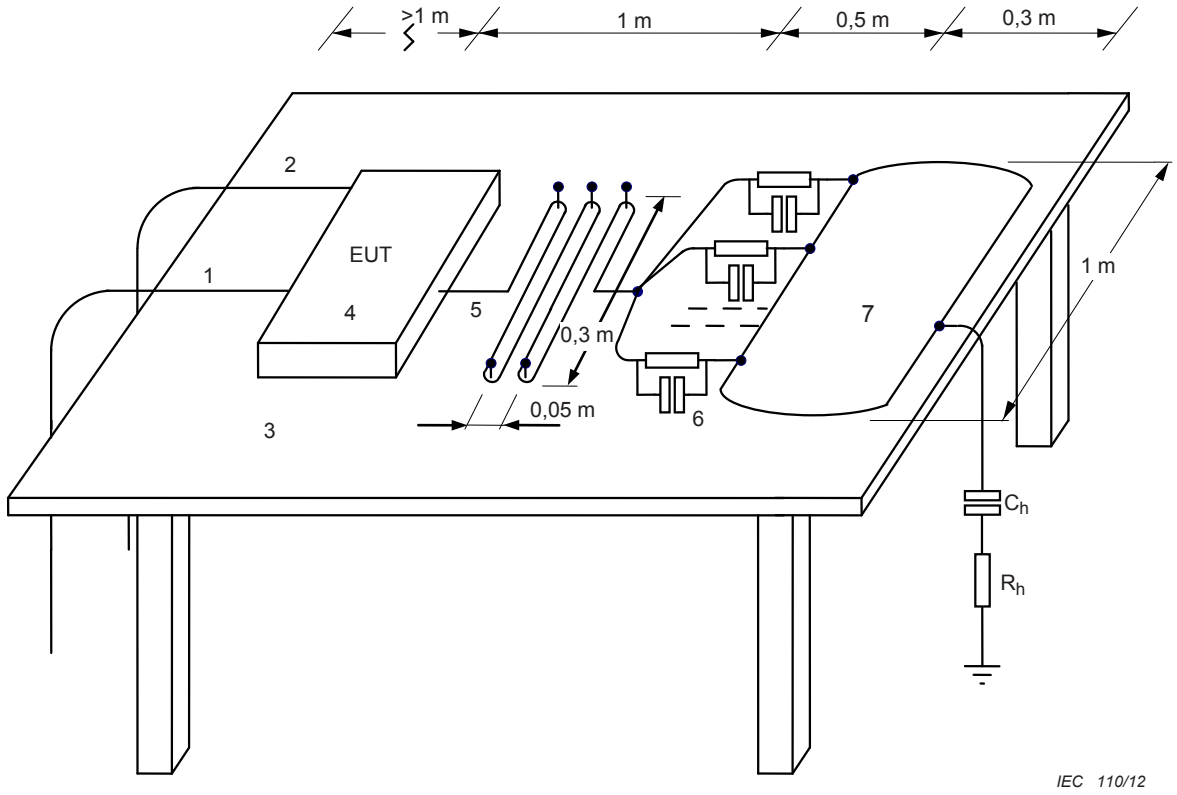
AMBULATORY ELECTROCARDIOGRAPHIC SYSTEMS (ME SYSTEMS), except as specified in a) through c) below, shall be classified as Group 1 and Class B in accordance with CISPR 11, based on their intended use, as specified by the MANUFACTURER, using the guidelines in Annex D. ME EQUIPMENT and ME SYSTEMS shall comply with CISPR requirements, based upon their classification, with the exceptions and clarifications specified in d), e), and f) below.

202.6.1.1.2 Tests

Replacement of item a):

a) PATIENT-COUPLED ME EQUIPMENT AND/OR ME SYSTEMS shall be tested with the PATIENT CABLES, transducers, LEAD(S) and ELECTRODES attached to the ME EQUIPMENT and terminated in a load simulating the PATIENT (Figure 202.101).

   Signal input/output cables (if applicable) shall be attached to the ME EQUIPMENT during the test.



Key

1 POWER SUPPLY CORD
2 Signal cable
3 Table made of insulating material
4 Me EQUIPMENT under test (AMBULATORY RECORDER)
5 PATIENT CABLE
6 Load simulating the PATIENT (51 kΩ in parallel with 47 nF)
7 Metal plate
C_h = 220 pF
R_h = 510 Ω (C_h in series with R_h simulates a hand.)

NOTE C_h and R_h are connected only for conductive emissions tests 202.6.1.1.2.

NOTE If the patient cable is too short for the shown 2,5 loops, than apply fewer loops

Figure 202.101 – Test set-up for conductive emission test according to 202.6.1.1.2 and radiated emission and radiated immunity test according to 202.6.1.1.2 and 202.6.2.3.2

202.6.2 IMMUNITY

202.6.2.3 *Radiated RF electromagnetic fields

Addition:

The AMBULATORY RECORDER (ME EQUIPMENT) shall continue to record the signal without loss of any stored data.

Compliance is checked

a) with an operating AMBULATORY RECORDER;

b) after the test, by inspection, if the stored data of the AMBULATORY RECORDER are available.

NOTE During the distortion phases the data might be corrupted.

202.6.2.3.2 Tests

Amendment of item a):

The ME EQUIPMENT cables shall be bundled non-inductively to 1 m overall length and the signal cable (if applicable) and POWER SUPPLY CORD (if applicable) shall be arranged horizontally and vertically from the ME EQUIPMENT according to Figure 202.101.

Annexes

The annexes of the general standard apply.

Annex AA
(informative)

Particular guidance and rationale

AA.1 General

This annex provides a concise rationale for the important requirements of this standard. It is intended for those who are familiar with the subject of the standard but who have not participated in its development. An understanding of the reasons for the main requirements is considered to be essential for the proper application of the standard. Furthermore, as clinical practice and technology change, it is believed that a rationale for the present requirements will facilitate any future revision of the standard necessitated by these developments.

AA.2 Rationale for particular clauses and subclauses

The following are rationales for specific clauses and subclause in this particular standard, with clause and subclause numbers parallel to those in the body of the document.

Subclause 201.7.9.2.101 – Additional instructions for use

Some equipment is delivered with an operator's manual only, some with an additional physician's guide. If a physician's guide is available, the information listed in paragraph g) are normally found there.

Subclause 201.12.1.101.1 – Algorithm testing

A credible evaluation must be reproducible. For this reason, evaluations of these devices must be performed without human intervention, i.e. a strictly reproducible "hands-off" evaluation is required. (With human intervention allowed, perfect results are achievable in principle for any device that provides "full-disclosure" output. Thus, evaluations that allow human intervention measure only the persistence and expertise of the operator and are of no value in assessing the performance of the device; for this reason, such evaluations are neither required nor encouraged.)

Full disclosure of the procedure for generating annotation files for clinical evaluation enables an independent (third-party) evaluator to use the procedure, thereby permitting verification of test results when the same test data are used. It also permits the use of additional test data of the evaluator's choice as such data become available.

The evaluation methodology of automated analysis 201.12.1.101.2 requires the combination of the device with an interface. In principle, the interface might include significant analytical components when processing the outputs of the device, thereby "improving" its apparent performance. Full disclosure of the methodology will provide a disincentive for having the interface do anything other than straightforward translations of the device's normal outputs into standard annotation files.

Subclause 201.12.1.101.1.1 – Databases

As performance is highly dependent on the characteristics of the particular ECGs that are analyzed, evaluations need to be performed using standard recordings so that the results of those evaluations have value for purposes of comparison among devices or against a performance standard.

Most devices need a certain amount of time to learn the underlying rhythm. For this reason, a 5 min learning period is allocated at the beginning of each record and is excluded from calculated performance statistics. If the long version of the AHA DB (containing 2,5 h of unannotated signals per record immediately preceding the 30 min test periods) is used, only the final 35 min of each record (equivalent to the standard version) may be presented to the device under test.

Subclause 201.12.1.101.1.1.2 – Records to be excluded during testing

The exclusion of records with paced beats is permitted only for devices that are not designed to analyze paced analogue ECG recordings made without pacer artifact detection or enhancement, because the original analogue tapes do not reproduce pacemaker artifacts with sufficient fidelity to permit the use of common techniques for recognition of such artifacts in “live” signals.

Table AA.1 – Records to be included in a complete test

Database	Record ID	Description	Number of records
AHA database	1201–1210	No VEBs	10
(included)	2201, 2203–2210	Isolated uniform VEBs	9
	3201–3210	Isolated multiform VEBs	10
	4201–4210	Bigeminy	10
	5201–5210	R-on-T VEBs	10
	6201–6210	Ventricular couplets	10
	7201–7210	Ventricular tachycardia	10
	8201–8204, 8206–8210	Ventricular fibrillation	9
	AHA records in complete test		78
(excluded)	2202, 8205	Paced beats	2
MIT-BIH database	100, 101,103, 105, 106, 108, 109, 111–119, 121–124	Records include no or common arrhythmias	20
	200–203, 205, 207–210, 212–215, 219–223, 228, 230–234	Records include less common but clinically important arrhythmias	24
	MIT–BIH records in complete test		44
(excluded)	102, 104, 107, 217	Paced beats	4
NST database	118e00, 119e00, 118e06, 119e06, 118e12, 119e12, 118e18, 119e18, 118e24, 119e24, 118e_6, 119e_6,	Noise Stress Test Database	12
CU database	cu01-cu35	Ventricular Tachyarrhythmia Database	35
NOTE The AHA record ID numbers given refer to the 35 min version of the AHA database. The second digit from left in the ID numbers is "0" (rather than "2") for the corresponding 3 h records. Only the last 35 min of the 3 h records (equivalent to the 35 min records) may be presented to the algorithm as part of a complete test if the 3 h records are used.			

Subclause 201.12.1.101.1.2 – Testing Requirements

The incidence and variety of arrhythmias and ectopic beats in the 90 records of the ESC DB are insufficient to allow that database to serve as a substitute for the AHA and MIT–BIH databases for the purposes of assessing QRS detection and classification performance. An evaluation using the 90 records of the ESC DB and the same beat-by-beat and run-by-run comparison protocols, however, can supplement the required AHA and MIT–BIH database

evaluation. Such a test can be particularly useful for assessing the robustness of QRS detection and classification performance in the presence of ST SEGMENT and T-wave changes.

The AHA, MIT–BIH, NST, CU, and ESC databases are not accompanied by reference heart rate variability (HRV) values. The accuracy of the HRV calculation is best evaluated from controlled inputs for which the exact reference HRV parameters can be predicted. The databases do provide a set of defined QRS times and labels that can be used as common, realistic, easily available, standard input sequences for HRV algorithms. If just the HRV results were available from two different HRV algorithms, comparisons of equivalence could be made. Where discrepancies are observed, the discussion of differences in algorithm implementation or differences in index definitions could begin with a real focus. Over time, a consensus set of correct results for every well-defined index of HRV should evolve.

This recommended practice cannot address all measures of HRV that might be in use at the time of this document's publication or that could be invented in the future. The test methods and reporting requirements described here, however, are considered to be sufficient for assessing the measurements of the other indices.

The diagnostic utility of HRV analysis, if any, remains to be determined. The requirements of this recommended practice with respect to HRV analysis are not to be construed as definitions of criteria for diagnostically useful measurements. The sole purpose of these requirements is to establish a standard methodology for assessing the numerical accuracy of specific device outputs and not to impute any diagnostic value to those outputs. Such diagnostic value, if any, can only be determined on the basis of clinical studies that are beyond the scope of this recommended practice.

The incidence and variety of VF in the AHA and MIT–BIH databases are insufficient to allow those databases to serve as substitutes for the CU DB for the purposes of subclause 201.12.1.101.2.5. An evaluation of VF detection using the 80 records of the AHA DB and the 48 records of the MIT–BIH DB should supplement the required CU DB evaluation, as the CU DB does not contain a sufficient sample of signals likely to provoke false VF detections.

Subclause 201.12.1.101.1.3 – Test environment

The test environment might use digital or analogue database ECG. MIT-BIH DB and AHA DB contain more than 60 h of ECG and the time increases with additional databases. Feeding an analogue ECG into the ME EQUIPMENT is time consuming and error prone, because all kinds of strays and ambient disturbances can be captured and may disturb the analysis.

It has some advantages to test the algorithms only with the digital database ECGS. Advantages are a short test time, which can be in the range of a few seconds, and the reproducibility, because ambient disturbances have no influence. Clauses 201.12.4.4.101 to 201.12.4.4.112 guarantee the properties of the analogue part of the ME EQUIPMENT. Together with a separate algorithm test, an overall test would be equivalent to an overall test with analogue ECG feed into the ME EQUIPMENT.

Subclause 201.12.1.101.1.5 – Requirements for the evaluation report

There are four possible outcomes of an experiment in which a detector is presented with an input that is either an event or a nonevent. A correctly detected event is called a true positive (TP); an erroneously rejected (missed) event is called a false negative (FN); an erroneously detected nonevent is called a false positive (FP); and a correctly rejected nonevent is called a true negative (TN). In many detection problems, nonevents cannot be counted, so that the number of true negatives is undefined. In such problems, the commonly used detector performance measures are sensitivity (Se, the fraction of events which are detected) and positive predictivity (+P, the fraction of detections which are events):

$$Se = \frac{TP}{TP+FN} \qquad +P = \frac{TP}{TP+FP}$$

Subclause 201.12.1.101.1.5.1 – Required statistics

It is useful, particularly when the total number of events is small, to define aggregate statistics that describe the performance of a detector on an entire database as a whole. Two types of aggregate statistics are commonly used: gross statistics, in which each event or detection is given equal weight, and average statistics, in which each record (subject) is given equal weight. If the incidence of events and detections were equal in all subjects, these statistics would be equivalent.

When considering detection statistics for persistent events (such as episodes of fibrillation or ST SEGMENT deviation), it is of interest to know how many episodes are detected as well as the total duration of the detected events. Event statistics give equal weight to each episode, irrespective of length. Duration statistics give weight to each event or detection in proportion to its duration. Thus, event statistics for persistent events are roughly analogous to average statistics for discrete events, and duration statistics are similarly analogous to gross statistics.

Although the MIT–BIH DB has been available since 1980, and the AHA DB since 1982, it remains a difficult task to determine minimal acceptable levels of performance for ECG analyzers. Users should understand clearly that diagnostic outputs of these devices cannot be accepted uncritically. Given that review is necessary in any case, what constitutes “acceptable” performance depends to a significant extent on how much effort the user is willing to devote to assessing the accuracy of a device’s outputs. (The effort required of the user will, in turn, depend on the quality of the review and editing facilities provided by the device, if any.)

Performance is often characterized in terms of aggregate statistics, which provide a convenient summarization of device performance on many records. To extrapolate from an aggregate statistic to a prediction of real-world performance is difficult, because the selection criteria used by database developers vary, as do subject populations among clinical practices. It might be expected that average statistics, in which each record is equally weighted, would be better predictors of real-world performance than gross statistics. The record-by-record statistics on which average statistics are based are often unreliable, however, as the number of events in each record may be small. As a result, average statistics can be extraordinarily sensitive to single errors and are usually less robust estimators of performance than are the gross statistics, which are based on larger numbers of events. For this reason, most of the reporting requirements are specified as gross statistics, and reporting requirements for statistics such as average VEB positive predictivity have been omitted intentionally.

The distribution of record-by-record statistics is a somewhat better basis for predicting real-world performance to the extent that the records studied are representative of the subject population in clinical practice. Informally, it is clear that performance on a previously untested subject can be predicted with more confidence given a narrow distribution of performance on tested subjects than given a wide distribution. These distributions are rarely normal (Gaussian), however, and classical parametric models (e.g., measures such as sample variance) are inadequate for characterizing or comparing them. Bootstrap estimation is a nonparametric method for determining confidence limits on performance, which has been applied to this problem; it is also useful when comparing the robustness of different statistics.

Several issues cannot be addressed adequately using existing test methodology. Automated P-wave detection, though desirable, is beyond the current state-of-the-art for ECG analyzers that rely on body-surface leads alone. The MIT–BIH DB includes five records with annotated nonconducted P-waves; no other P-wave annotations are present in any of the available databases. Similarly, T-wave annotations are wholly absent, except for annotations that indicate possibly significant changes in T-wave morphology in the ESC DB. Conduction

disturbances exist and are annotated in nine records of the MIT–BIH DB and in two records of the European ST-T DB, but it is not clear how accuracy in analysis of conduction disturbances can be confidently measured with a sample of this size. Similar concerns arise with respect to junctional rhythms (annotated in three MIT–BIH DB records) and SVTA (annotated in seven MIT–BIH DB records and three ESC DB records). Major concerns are evaluation of arrhythmia detectors in the context of paced beats and the corollary issue of evaluation of pacer function analysis algorithms and pacer malfunction detectors. A modern database of high-fidelity pacer recordings, including examples of pacer malfunction, is needed in order to address these issues.

Subclause 201.12.1.101.1.5.2 – Requirements for all arrhythmia algorithms

QRS sensitivity and positive predictivity: Using the beat-by-beat comparison matrix definitions from 201.12.1.101.2.3, QRS sensitivity and positive predictivity are derived as follows:

QTP = Nn + Ns + Nv + Nf + Nq +
Sn + Ss + Sv + Sf + Sq +
Vn + Vs + Vv + Vf + Vq +
Fn + Fs + Fv + Ff + Fq +
Qn + Qs + Qv + Qf + Qq

QFN = No + Nx +
So + Sx +
Vo + Vx +
Fo + Fx +
Qo + Qx

QFP = On + Os + Ov + Of + Oq +
Xn + Xs + Xv + Xf + Xq

$$\text{QRS Se} = \frac{\text{QTP}}{\text{QTP+QFN}} \qquad \text{QRS+P} = \frac{\text{QTP}}{\text{QTP+QFP}}$$

VEB and SVEB Sensitivity, Positive Predictivity, and False Positive Rate: Using the beat-by-beat comparison matrix definitions from 201.12.1.101.2.3, VEB sensitivity and positive predictivity are derived as follows:

VTP = Vv
VFN = Vn + Vs + Vf + Vg + Vo + Vx
VFP = Nv + Sv + Ov + Xv
VTN = Nn + Nf + Ng + Ns +
Sn + Sf + Sg + Ss +
Fn + Ff + Fg + Fs +
Qn + Qf + Qq + Qs +
On + Of + Oq + Os +
Xn + Xf + Xg + Xs

$$\text{VEB Se} = \frac{\text{VTP}}{\text{VTP+VFN}} \qquad \text{VEB+P} = \frac{\text{VTP}}{\text{VTP+VFP}}$$

$$\text{VEB FPR} = \frac{\text{VFP}}{\text{VTN+VFP}}$$

Note that VTP and VFP do not include Fv or Qv; thus, a detector is neither penalized nor rewarded for its treatment of ventricular fusion beats and ambiguous beats.

The example below, based on hypothetical data, shows one way of presenting the information required by this subclause. Details of formatting the evaluation report are left to the discretion of the tester.

SVEB sensitivity and positive predictivity are similarly defined:

SVTP = Ss
SVFN = Sn + Sv + Sf + Sq + So + Sx
SVFP = Ns + Vs + Fs + Os + Xs
SVTN = Nn + Nv + Nf + Nq +
Vn + Vv + Vf + Vg +
Fn + Fv + Ff + Fg +
Qn + Qv + Qf + Qg +
On + Ov + Of + Og +
Xn + Xv + Xf + Xg

$$\text{SVEB Se} = \frac{\text{SVTP}}{\text{SVTP+SVFN}} \qquad \text{SVEB+P} = \frac{\text{SVTP}}{\text{SVTP+SVP}}$$

$$\text{SVEB} = \frac{\text{SVFP}}{\text{SVTN+SVFP}}$$

Note that Qs is excluded from SVTP and SVFP, so that a detector's treatment of ambiguous beats does not influence its measured SVEB detection performance.

Table AA.2 – Example of a line-format, beat-by-beat performance report

Record	Nn′	Vn′	Fn′	On′	Nv	Vv	Fv′	Ov′	No′	Vo′	Fo′	Q Se	Q+P	V Se	V+P	V FPR
100	1 900	0	0	0	1	1	0	0	0	0	0	100,000	100 000	100 000	50 000	0,053
101	1 521	0	0	0	0	0	2	0	0	0	0	100,000	100 000	–	–	0,000
103	1 723	0	0	0	2	0	0	35	4	0	0	99,77	98,01	–	0,00	2,102
105	2 036	2	1	4	78	27	4	39	7	0	0	99,68	98,04	93,10	18,75	5,422
106	1 235	2	0	0	0	452	0	5	1	6	0	99,59	99,70	98,26	98,97	–
Sum	73235	250	450	4 104	200	5 605	37	95	4 018	45	136					
Gross												95,00	95,00	95,00	95,00	0,378
Average												95,00	95,00	95,00	95,00	0,500
Beat summary statistics for MIT–BIH database Total QRS complexes: 83976 Total VEBs: 5900 Summary of results from 44 records																

For definition of parameters see table AA.3.

Table AA.3 – Condensed beat-by-beat summary matrix containing 11 elements

		Algorithm		
		N+f+q	V	O+x
Reference	N	Nn′	Nv	No′
	V	Vn′	Vv	Vo′
	F+Q	Fn′	Fv′	Fo′
	O+X	On′	Ov′	–

NOTE The linear format performance (Table AA.2) is based on a condensed matrix.

Table AA.4 – Summary table (matrix format) of beat-by-beat comparison

		Algorithm					
		n	**v**	**f**	**q**	**o**	**x**
Reference	**N**	Nn	Nv	Nf	Nq	No	Nx
	V	Vn	Vv	Vf	Vq	Vo	Vx
	F	Fn	Fv	Ff	Fq	Fo	Fx
	Q	Qn	Qv	Qf	Qq	Qo	Qx
	S	Sn	Sv	Sf	Sq	So	Sx
	O	On	Ov	Of	Oq	Oo	Ox
	X	Xn	Xv	Xf	Xq	Xo	Xx

SHUTDOWN statistics: SHUTDOWN is defined as that period of time when the algorithm is not performing its detection/classification function. The following SHUTDOWN statistics are derived using the beat-by-beat comparison matrix definitions from 201.12.1.101.2.3:

$$\%\ \text{beats missed during shutdown} = \frac{Nx + Vx + Fx + Qx + Sx}{QTP + QFN}$$

$$\%\ \text{N and S missed during shutdown} = \frac{Nx + Sx}{Nn + Nv + Nf + Nq + No + Nx + So + Sx + Sn + Sv + Sf + Sq}$$

$$\%\ \text{V missed during shutdown} = \frac{Vx}{Vn + Vv + Vf + Vq + Vo + Vx}$$

$$\%\ \text{F missed during shutdown} = \frac{Fx}{Fn + Fv + Ff + Fq + Fo + Fx}$$

TOTAL SHUTDOWN TIME is defined as the amount of time during the test period for each record that the algorithm is not performing its detection/classification function. For each record, it is expressed in minutes and seconds in the format MM:SS.

The example below, based on hypothetical data, shows one way of presenting the information required by this subclause: a line-format SHUTDOWN report. The formatting of this report is left to the discretion of the tester.

Table AA.5 – Example of a line-format SHUTDOWN report

Record	Nx + Sx	Vx	Fx	Qx	% beats missed	% N and S missed	% V missed	% F missed	Total SHUTDOWN time
AH8006	3	0	0	0	0,26	0,32	0,00	–	16 s
AH8007	0	0	0	0	0,00	0,00	0,00	0,00	6 s
AH8008	0	0	0	0	0,00	0,00	0,00	–	4 s
AH8009	0	0	0	0	0,00	0,00	0,00	–	0 s
AH8010	0	0	0	0	0,00	0,00	–	–	1 s
Sum	129	5	0	0	–	–	–	–	136 s
Gross									
Average									
Summary of results from 78 records									

Subclause 201.12.1.101.1.5.3 – Requirements for algorithms with optional capabilities

The RMS heart rate error is derived from the results of the methods of 201.12.1.101.2.3.3.1. Although HR and HRV measurements depend on RR interval measurements, some algorithms for obtaining these measurements are robust with respect to occasional RR interval measurement errors, while others are particularly sensitive to such errors. The purpose of testing HR and HRV measurements based on algorithm-derived RR intervals is to establish if the measurement algorithms are robust, at least with respect to the particular errors committed by the device under test.

The purpose of testing HRV measurements based on simulated analogue ECG data is to establish the noise floor for these measurements, i.e. the sum of the contributions of analogue and sampling noise to errors in these measurements. The purpose of testing HRV measurements based on the simulated (digital) RR interval sequences specified in subclause 201.12.1.101.2.3.3.2 is to demonstrate the extent to which these measurements agree with predictions based on the stated measurement definitions and on known statistical properties of the simulations; hence, this test indirectly establishes whether the implementation of the measurement algorithms is likely to be correct.

VF and AF detection: From the counts of true positives, false negatives, and false positives derived according to the methods of subclause 201.12.1.101.2.5, VF and AF episode sensitivity and positive predictivity are derived in the usual way.

The VF duration sensitivity and positive predictivity are calculated as:

$$\text{VF duration Se} = \frac{\text{duration of overlap}}{\text{duration of reference - annoted VF}}$$

$$\text{VF duration + P} = \frac{\text{duration of overlap}}{\text{duration of algorithm - annoted VF}}$$

The AF duration sensitivity and positive predictivity are calculated in a similar way.

The example below, based on hypothetical data, shows one way of presenting the information required by this subclause: a line-format report. Details of formatting this report are left to the discretion of the tester.

Table AA.6 – Example of a line-format report

Record	TPs	FN	TPp	FP	E Se	E + P	D Se	D + P	Reference duration	Test duration
231	0	0	0	0	–	–	–	–	0:00,000	0:00,000
232	0	0	0	0	–	–	–	–	0:00,000	0:00,000
233	0	0	0	0	–	–	–	–	0:00,000	0:00,000
234	0	0	0	0	–	–	–	–	0:00,000	0:00,000
Sum	1	0	2	1					1:37,900	1:01,000
Gross					100	67	47	75		
Average					100	50	47	45		
Summary of results from 44 records										

For algorithms that attempt to detect ventricular fibrillation/flutter, any false positive detections that occur on any record in the database needs to be reported.

The examples below, based on hypothetical data, show one way of presenting the information required by this subclause: a VF detection performance report and a false VF detection report, respectively. Details of formatting these reports are left to the discretion of the tester.

Table AA.7 – Example of VF performance report

Record	Reference Vfib segments		Algorithm labels				Alarm activity	
ID	**Start**	**Stop**	**N**	**V**	**F**	**Q**	**Time**	**Type**
207	00:40,73	00:50,97	1	15	0	0	00:48,39	Run
207	00:54,76	01:00,36	2	16	0	0	00:55,10	VFIB
207	04:02,14	04:06,43	0	0	0	0	04:02,42	Run
207	04:07,89	04:21,45	0	0	0	0	04:12,11	Run
207	04:29,46	04:40,90	0	0	0	0	04:29,82	VFIB
							04:35,87	Run
							04:38,70	Run

Table AA.8 – Example of false VF performance report

Record	False Vfib segments		Reference labels				
ID	**Start**	**Stop**	**N**	**V**	**F**	**Q**	**U**
8002	32:18,25	32:31,25	0	35	0	0	0
8002	32.36,25	32.40,62	0	13	0	0	0

Couplet and run sensitivity and positive predictivity: The results of run-by-run comparisons (201.12.1.101.2.4) can be used to derive VE couplet and run sensitivity and positive predictivity:

CTPs = S22+S23+S24+S25+S26 CFN = S20+S21
CTPp = P22+P32+P42+P52+P62 CFP = P02+P12

$$\text{VE Couplet Se} = \frac{\text{CTPs}}{\text{CTPs+CFN}} \qquad \text{VE Couplet+P} = \frac{\text{CTPp}}{\text{CTPp+CFP}}$$

STPs = S33 + S34 + S35 + S36 + S43 + S44 + S45 + S46 + S53 + S54 + S55 + S56

SFN = S30 + S31 + S32 + S40 + S41 + S42 + S50 + S51 + S52

STPp = P33 + P43 + P53 + P63 + P34 + P44 + P54 + P64 + P35 + P45 + P55 + P65

SFP = P03 + P13 + P23 + P04 + P14 + P24 + P05 + P15 + P25

$$\text{VE Short Run Se} = \frac{\text{STPs}}{\text{STPs+SFN}} \qquad \text{VE Short Run+P} = \frac{\text{STPp}}{\text{STPp+SFP}}$$

LTPs = S66 LFN = S60+S61+S62+S63+S64+S65
LTPp P66 LFP = P06+P16+P26+P36+P46+P56

$$\text{VE Long Run Se} = \frac{\text{LTPs}}{\text{LTPs+LFN}} \qquad \text{VE Long Run+P} = \frac{\text{LTPp}}{\text{LTPp+LFP}}$$

The example below, based on hypothetical data, shows one way of presenting the information required by this subclause: a line-format couplet and run performance report. Details of formatting this report are left to the discretion of the tester.

Table AA.9 – Example of a line-format couplet and run performance report

Record	CTs	CFN	CTp	CFP	STs	SFN	STp	SFP	LTs	LFN	LTp	LFP	CSe	C+P	SSe	S+P	LSe	L+P
AH8004	0	1	1	32	0	4	2	32	0	0	0	21	0	3	0	6	–	0
AH8006	1	1	1	9	2	1	2	6	1	1	2	5	50	10	67	25	50	29
AH8007	41	8	60	2	66	16	91	5	33	17	35	3	84	97	80	95	66	92
AH8008	0	1	1	2	0	0	1	1	0	0	0	4	0	33	–	50	–	0
AH8009	2	2	3	0	2	0	4	0	7	1	4	0	50	100	100	100	88	100
AH8010	0	0	0	0	0	0	0	0	0	0	0	0	–	–	–	–	–	–
Sum	956	54	968	126	400	41	457	101	53	24	61	81						
Gross													96	82	71	22	79	72
Average													75	67	91	53	76	68

Total couplets: 999
Total short runs: 464
Total long runs: 79

Summary of results from 78 records

SVEB couplet and run statistics are similarly defined.

Subclause 201.12.1.101.2 – Automated analysis

Holter exams in general allow the intervention of a human operator during the analysis of recorded data. For test purposes such interventions are not allowed.

Subclause 201.12.1.101.2.2 – Use of annotation files

Beats are labelled with Q when they cannot be classified as N, S, V, or F. This is sufficient for calculation of QRS sensitivity and positive predictivity, VEB and SVEB sensitivity, positive predictivity and false positive rate.

Subclause 201.12.1.101.2.3.3.1 – Heart rate measurement

Many definitions of heart rate are in common use, and none is accepted universally. Differences in the definitions are, for instance, in the number of RR intervals used and how the RR intervals are combined for the heart rate calculation. One method that is frequently used to combine RR intervals is the moving average. Other methods are also conceivable and might have advantages.

Subclause 201.12.1.101.2.3.3.2 – Heart rate variability or RR interval variability measurement test patterns

Following the testing methods of 201.12.1.101.2.3.3.2, results need to be reported separately for each HRV (RRV) measurement.

Table AA.10 – Example of device measurements of synthetic test patterns

HRV index	Noise floor	35 ms	70 ms	280 ms	140 ms
SDNN	4,8 ms	25	49	197	99
SDANN	0,5 ms	0	0	2	98
ASDNN	4,1 ms	25	49	197	14
rMSSD	6,1 ms	29	31	123	1
pNN50	0 %	0	0	79,9	0
TINN	24 ms	55 ms	89 ms	300 ms	155 ms
VLF	0,04 ms^2	0	0	39 106,82	4,64
LF	0,13 ms^2	0	2 438,36	7,86	0
HF	0,30 ms^2	579,45	0,17	0,29	0
NOTE Refer to definitions fromTable 201.106.					

Table AA.11 – Example of predicted ideal values for synthetic test patterns

HRV index	Noise floor	35 ms	70 ms	280 ms	140 ms
SDNN	0 ms	24,75	49,50	197,99	98,99
SDANN	0 ms	0,00	0,00	0,00	97,87
ASDNN	0 ms	24,75	49,50	197,99	14,00
rMSSD	0 ms	29,77	31,25	125,87	0,28
pNN50	0 %	0,0	0,0	87,0	0,0
VLF	0 ms^2	0,0	0,0	39 200,0	0,0
LF	0 ms^2	0,0	2 450,0	0,0	0,0
HF	0 ms^2	612,5	0,0	0,0	0,0
NOTE Refer to definitions from table 201.106.					

Table AA.12 – Example of choice of test patterns

Test pattern	1	2	3	4	5
Variation magnitude (ms)	0	35	70	280	140
Period of variation	N/A	4 s	10 s	30 s	1 hour
Frequency of variation (Hz)	N/A	0,25 s	0,1	0,033333	0,000278
Frequency range assignment	N/A	HF	LF	VLF	VLF
Average interval (s)	1	0,800	1,00	3,000	1,500
Beats per minute	60	75	60	20	40

The magnitudes of the test patterns were chosen to represent a useful range of real values. The magnitude of 0 ms was chosen to show the noise floor. The magnitude of 70 ms was chosen because the predicted SDNN value would be 50 ms, a popular choice for a possible clinical cut point. The correct assignment of positive and negative test results depends particularly on the accuracy near cut points. The magnitude of 35 ms was chosen to be a small value representing the range below 70 ms.

The magnitudes 140 and 280 ms represent large values of HRV. To make a reasonable prediction for the HRV indices, however, it is necessary that the variation in intervals be small compared to the intervals themselves. Large deviations from the average would cause the sampling of each sine wave cycle of variation to be more asymmetric, with many more short intervals during the low half cycle than long intervals in the other half cycle. The average intervals were chosen to be at least ten times longer than the variations. This means for a variation magnitude of 280 ms, the average interval must be almost 3s (20/min). To avoid more unrealistic low average heart rates, larger magnitudes of variation are not tested. The average intervals were rounded up slightly to produce test patterns that repeat every minute.

The largest magnitude of variation was applied to test pattern 4 instead of test pattern 5, because test pattern 5 might not be applicable for many algorithms due to the long duration of data required to test such a low frequency. It is desirable that all algorithms be evaluated by the maximum test magnitude of pattern 4.

Test pattern 1 is intended to be applied through the complete signal path of the instrument. In other words, test pattern 1 is produced as an analogue ECG waveform (see 201.12.1.101.2.3.3.2, items a–d), recorded, digitized, and processed by the QRS detector. The noise floor measurement thus reveals the contributions due to sampling effects, phase lock loops, arithmetic precision, and perhaps other effects.

Test patterns 2 through 5 are expected to be applied in the digital domain post QRS detector/classifier (see 201.12.1.101.2.3.3.2, items e)–j)). This is to test the validity of the arithmetic in the absence of effects characterized elsewhere and to avoid the need to build an analogue waveform simulator of the required complexity.

HRV frequencies for test patterns 2 and 3 were chosen to match the familiar 4-second and 10-second periods of HRV seen in many people and to exercise the HF and LF bands described on page 1047 of the ESC/NASPE special report[5]. The frequency of test pattern 4 should exercise the VLF band but still be of short enough duration to be useful to most short-term HRV algorithms. Test pattern 5 was designed to exercise an HRV index that senses variations over time periods much longer than 5 min (e.g., SDANN).

Prediction of some HRV indices for the synthetic test pattern QRS sequences: Throughout the following discussion, “intervals” is assumed to mean only those intervals selected for study. In the case of the synthetic test patterns, all beats have the “Normal” label, and all exclusion rules based on interval relationships are disabled, so all intervals are used by the algorithm. RRDEV refers to the zero-to-peak magnitude of the interval variations and takes on the values 0 ms, 35 ms, 70 ms, 140 ms, and 280 ms in the test patterns.

Some HRV indices have strong relationships to other indices. Two easy approximations are worth noting here. Variance is the square of standard deviation and Parseval’s theorem relates power to variance. These two relationships are approximate but can serve nicely as reality checks. Users of HRV programs should be aware of them.

Because of the similarity to an analysis of variance (ANOVA), the following is true.

$$SDNN^2 \text{ approximately equals } SDANN^2 + ASDNN^2$$

where:

$SDNN^2$ = variance of all intervals

$SDANN^2$ = between-group variance

$ASDNN^2$ = approximates the within-group variance

The above relationship is only approximate because the definition for ASDNN is the average of standard deviations, whereas an ANOVA would compute the average of variances.

Because of Parseval’s theorem, we can relate power computed in the time domain to power computed in the frequency domain. If power can be computed in the frequency domain over all frequencies down to 0 Hz, then that power can be compared to $SDNN^2$. If power can be computed in the frequency domain for only frequencies above 0,00333 Hz (5 min windows), then $ASDNN^2$ may be compared to the sum of the VLF, LF, and HF powers. ASDNN is computed from only 5 min windows in the time domain.

$$ASDNN^2 \text{ approximately equals } VLF + LF + HF$$

The above relationship is only approximate because the definition for ASDNN includes no detrending and the definition of HF is limited (< 0,40 Hz) to less than the highest frequencies that might be present.

SDNN: The standard deviation of all intervals (no subgrouping): The calculation of standard deviation is the same as root-mean-square (rrms) when the mean value is removed. The rrms value for a sine wave is the zero to peak value of the sine wave divided by the square root of two.

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5 Heart Rate Variability, Standards of Measurement, Physiological Interpretation, and Clinical Use, by the European Society of Cardiology and the North American Society of Pacing and Electrophysiology, Circulation, 1996; 93:1043-1065.

$$SDNN = \frac{RRDEV}{\sqrt{2}}$$

SDANN: The standard deviation of 5 min mean intervals (variation between 5 min subgroups): Whenever the test pattern repeats every minute (patterns 1, 2, 3, and 4), the average interval for each 5 min section need to be the same. The standard deviation of a set of constant numbers will be zero. Test pattern 5 is the only pattern that should produce a nonzero SDANN. Test pattern 5 produces a sinusoidal interval variation with a period of 60 min. There will be twelve different 5 min averages. The prediction is similar to the SDNN prediction except the 5 min averages apply a low pass filter with a rectangular impulse response. The amplitude response of such a filter is sin(x)/x. Because the period of variation is twelve times longer than the impulse response, the amplitude response is 0,9886 = sin(π/12) / (π/12).

$$SDANN = 0 \text{ for test patterns } 1, 2, 3, 4$$

$$SDANN = 0{,}9886\left(\frac{RRDEV}{\sqrt{2}}\right) \text{for test pattern } 5$$

ASDNN: The mean of 5 min standard deviations of intervals (variation within 5 min subgroups): When each 5 minutes is the same as every other 5 minutes, this result equals the rrms of the test pattern similar to SDNN. For the case of test pattern 5, ASDNN is not easily predicted. The test pattern repeats every hour, so there are twelve 5 min groups. The standard deviation for each twelfth of a sine wave cycle is not easy to predict. But determined numerically, RRDEV/10.1 is the average of the standard deviations of twelve sections from a sine wave cycle.

$$ASDNN = \frac{RRDEV}{\sqrt{2}} \text{for test patterns } 1, 2, 3, 4$$

$$ASDNN = \frac{RRDEV}{10{,}1} \text{for test pattern } 5$$

rMSSD: The root mean square of successive differences of intervals: The greatest rate of change for a sine wave is crossing through the baseline or average value. Because of the definition of the test patterns, the greatest change will be on the downward stroke of the sine wave, sin(p). We want to find the RR interval value just before and just after the variation function passes through the average interval value. Consider test pattern 4. If the average interval value is 3 000 ms, then a first approximation is that there is an RR interval to be computed 1 500 ms before and 1 500 ms after the sin(p). We learn the RR interval computed from the variation function at 1 500 ms before is 3 086,525 ms which is actually a little longer than our first estimate. After four iterations, the estimates are very similar.

$$rr1 = 3000 + 280\left(\sin\left(1500 \cdot 2 \cdot \frac{n}{30000}\right)\right) = 3000 + 86{,}525 = \frac{3086{,}525}{2} = 1543{,}262$$

$$rr1 = 3000 + 280\left(\sin\left(1543{,}262 \cdot 2 \cdot \frac{n}{30000}\right)\right) = 3000 + 88{,}934$$

$$rr1 = 3000 + 280\left(\sin\left(1544{,}467 \cdot 2 \cdot \frac{n}{30000}\right)\right) = 3000 + 89{,}001$$

$$rr1 = 3000 + 280\left(\sin\left(1544{,}501 \cdot 2 \cdot \frac{n}{30000}\right)\right) = 3000 + 89{,}003$$

$$rr2 = 3\ 000 - 89{,}003$$

maximum_successive_difference is 2 × 89.003 = 178,0ms

The derivative of a sine wave is also sinusoidal. The sequence of successive differences is like a derivative and will be approximately sinusoidal if there are enough intervals per period of the variation function. This assumption is weakest for test pattern 2 which has on average only 5 heart beats per variation period. If we accept the sinusoidal nature of the successive differences and we know the maximum successive difference, then we can estimate the root mean square of all successive differences. It will be the maximum divided by the square root of 2.

$$\text{rMSSD} = \frac{\text{max\_}scsv\_diff}{\sqrt{2}}$$

Table AA.13 – Example of RMS interval differences

Test pattern	1	2	3	4	5
Magnitude variation (ms)	0	35	70	280	140
Max successive difference (ms)	0	42,1	44,2	178,0	0,4
rMSSD (ms)	0,00	29,77	31,25	125,87	0,28

pNN50: The percentage of successive differences different by more than 50 ms (increase and decrease combined): This is easy to predict for all the test patterns except pattern 4. When the maximum successive difference is less than 50 ms, the pNN50 must be zero. When the sequence of successive differences has a maximum of 178 ms, we need to know what part of the time is the sequence above 50 ms. Consider a quarter cycle of a sine wave going from zero to 178. When does it cross 50?

$$\text{Arc sin}\left(\frac{50}{178}\right) = 0{,}2847 \text{ radians}$$

There are π/2 radians in a quarter cycle. So during each quarter cycle, the sequence spends 0,2847/(π/2) part of the time below 50 ms and 81,87 % of the time above 50 ms. All quarter cycles are symmetric, so:

– pNN50 = 0,0 for test patterns 1, 2, 3, 5
– pNN50 = 81,87 for test pattern 4
– VLF: The summed power of frequency components between 0,003 Hz and 0,04 Hz
– LF: The summed power of frequency components between 0,04 Hz and 0,15 Hz

– HF: The summed power of frequency components between 0,15 and 0,40 Hz

The expected power is very easy to compute for all of the test patterns because of Parseval's theorem, which tells us that the total power under the power spectral density curve is equal to the variance of the time domain signal. The only complication to this is when the spectral estimation technique usually cannot observe enough of the signal to see several cycles of the variation. This can easily be the case for some algorithms with test pattern 5, which requires 1 h to complete one cycle of heart-rate variation. Algorithms that estimate power from segments of data shorter than 1 h are likely to respond to test pattern 5 with various results, depending on what detrending strategy is used. Indeed, low responses to test pattern 5 might be considered evidence of good detrending strategies.

$$\text{VLF, LF, HF power} = \frac{\text{RRDEV}^2}{2}$$

Table AA.14 – Example of summary of frequency components

	Pattern 1	Pattern 2	Pattern 3	Pattern 4	Pattern 5
	0 ms	35 ms	70 ms	280 ms	140 ms
HRV index	0 Hz	0,25 Hz	0,10 Hz	0,033333Hz	0,000278 Hz
VLF power in ms^2	0	0,0	0,0	39 200,0	0,0
LF power in ms^2	0	0,0	2 450,0	0,0	0,0
HF power in ms^2	0	612,5	0,0	0,0	0,0

Subclause 201.12.1.101.3 – Physician report – minimum requirements

It is important to flag episodes of tachycardia, bradycardia, ectopy and ST SEGMENT shifts and to bring these episodes to the attention of the physician taking care of the PATIENT.

Since long-distance athletes (runners, swimmers, bikers) may often have resting rates below 50/min, it is important to have the capability for OPERATOR selected parameters, so that cardiac pathology is not falsely diagnosed in such cases. The capability for OPERATOR selected parameters may also be useful for ST SEGMENT analysis.

Subclause 201.12.1.101.3.6 – ST SEGMENT shifts

Because it is recognized that data with beat-by-beat reference ST SEGMENT measurements are not sufficiently available at this time, it has been left to the tester to determine how to best generate appropriate reference annotations for testing purposes and then to clearly disclose the chosen method. Algorithm measurements might not necessarily be reported on a beat-by-beat basis. To facilitate comparison, the generation of annotations for the reference and the test data at least should be approximately contemporaneous.

Summary statistics, such as the correlation coefficient or RMS error, can be ill-suited to the task of describing the accuracy of ST SEGMENT deviation measurements. They are highly sensitive to outliers, and do not distinguish between systematic errors (resulting from bias or nonlinearity) and nonsystematic errors (resulting from poor noise tolerance or unreliable measurement techniques). A better statistic, because of its robustness in the presence of outliers, is a confidence limit estimate over a focused range and over the entire signal range. Since the confidence limits are based on the standard deviation, the tester needs to provide the standard deviation in both the line format and on the scatter plot. Many other statistical methods such as Bland–Altman can then be generated from data provided.

The purpose of measuring the mean error and standard deviation over a focused range of reference ST SEGMENT amplitudes and slopes (as well as over the entire signal range applied

to the algorithm) is to determine the accuracy of the algorithm in the critical region of ST SEGMENT deviations and slopes where most clinical decisions are made, as well as to determine the overall accuracy of the algorithm.

The purpose of generating the scatter plots of ST SEGMENT measurements and ST SEGMENT errors is to summarize results of all individual measurements in a manner which allows rapid visual assessment of any systematic measurement bias, nonlinearity, or region of unreliable performance that could be exhibited by an ST SEGMENT deviation measurement algorithm. In addition, for any arbitrary definition of discrepancy, a rapid visual estimation of percentage discrepancy may be performed.

ST episode and duration detection: From the counts of true positives, false negatives, and false positives derived according to the methods of subclause 201.12.1.101.2.5, ST episode sensitivity and positive predictivity are derived in the usual way.

Subclause 201.12.4.4.101 – Linearity and dynamic range

ECG interpretations do not ordinarily involve analysis of the QRS in fine morphological details, hence a ± 3 mV input dynamic range and slew capability of 125 mV/s are quite sufficient. While less than the 320 mV/s slew rate specified for diagnostic ECGs and cardiac monitors, this ambulatory ECG requirement does exceed the 75 mV/s recommended by the 1985 AHA Report (Sheffield et al.).

It is essential that the AMBULATORY RECORDERs perform adequately in the presence of substantial d.c. offset voltages. This requirement originally arose from the need to deal with large ELECTRODE polarization voltages. The specification of ± 300 mV offset tolerance is sufficient for the ELECTRODE polarization encountered.

Subclause 201.12.4.4.102 – Input impedance

The input impedance is primarily set by effective skin-to-ELECTRODE impedance levels over the frequency range of the ECG signal. If conventional ECG ELECTRODEs are to be used, measuring systems should have sufficiently high input impedance that practically all subjects will be measured without significant errors.

Industry is able to meet these requirements easily. Although continued development of pre-gelled ELECTRODEs has resulted in even lower average impedance levels, the cited studies are still relevant for worst-case limits, as use of older style ELECTRODEs persists. The use of modern reduced impedance ELECTRODEs will decrease further the small number of subjects whose excessive ELECTRODE-to-skin impedance causes measurement error.

Skin-to-ELECTRODE impedances decrease with increasing frequency and with time after ELECTRODE application. The test method simulates the frequency dependent drop in impedance by means of a 4,7 nF capacitor connected in parallel with a 0,62 MΩ resistor. At 10 Hz, the impedance of this combination is about 610 kΩ. Hence, an ME EQUIPMENT whose 10 Hz single-ended input impedance magnitude is 9,55 MΩ or greater will pass this test.

Subclause 201.12.4.4.103 – Common mode rejection

The particular method of specifying and measuring common mode rejection (CMR) chosen for this standard produces a worse than normal configuration of capacitance to ground in relation to capacitance to PATIENT from the AMBULATORY RECORDER. The CMR requirement of 60 dB at line frequency is fairly conservative. In actual use where the dominant capacitance is that between the AMBULATORY RECORDER monitor and the PATIENT, significantly higher CMR performance can be expected. The line frequency harmonic measurements are included because of power line waveform distortion that can occur because of discontinuous loads from items such as SCR controllers and electronic equipment power supplies with capacitor input filters.

The AMBULATORY RECORDER is encapsulated in earth-grounded foil in order to define and stabilize the capacitance of the AMBULATORY RECORDER to earth. The input test components and the PATIENT CABLE are guarded by the driven shield that eliminates the effect of stray capacitance to earth ground from those components. Furthermore, the entire test set-up is enclosed in an earth referenced shield in order to stabilize the Cx stray capacitance.

The only remaining variable that will influence the test is the physical design of the particular AMBULATORY RECORDER, which fixes the size of the AMBULATORY RECORDER and also sets the spacing between the internal circuitry and the external foil wrap (that is, the thickness of the insulated case). The higher the resulting capacitance of the AMBULATORY RECORDER to the foil wrap, the greater the difficulty in meeting the requirements set forth with this particular test methodology. On the other hand, the guarding on the input test components and PATIENT CABLE reduces the difficulty in meeting this performance specification.

In order to check the common mode rejection of the ME EQUIPMENT's circuitry, it is necessary to disable any SUPPLY MAINS frequency notch filter. Otherwise, this test mostly checks the (differential mode) rejection of such a notch filter. It is desirable to achieve good common mode rejection at frequencies other than the SUPPLY MAINS frequency.

Subclause 201.12.4.4.104 – GAIN accuracy

The reference GAIN setting of 10 mm/mV reflects a well-established convention (AHA recommendations, Sheffield, 1985). Additional settings are not needed to guarantee safety and efficacy. However, the system output at all available GAIN settings has to be guaranteed to be reasonably close to that of an ideal system.

Subclause 201.12.4.4.105 – GAIN stability

In order to guarantee consistent interpretation, GAIN stability is especially important in ambulatory monitoring equipment where the typical monitoring period is 24 h or more. Changes in the ECG signal that do not stem from physiological or pathophysiological changes have to be minimized. The limits specified here represent a consensus on achievable levels established in practice.

Subclause 201.12.4.4.106 – System noise

Noise in electrocardiographic records is one of the most persistent detriments to a clean, diagnosable signal. This problem, however, can generally be traced to external interference (EMI), PATIENT movement (myographic signals) or poor technique in ELECTRODE application or routing of cables. Most manufacturers provide guidelines for correct techniques in measuring ECG. Shielded cables, as well as high-input impedance and common mode rejection, alleviate some of the noise problems. The driven right leg, which helps cancel the common mode noise from the signal sensed at the ELECTRODEs, further reduces the noise.

Subclause 201.12.4.4.107 – Multichannel crosstalk

The maximum level of crosstalk is determined by the requirements of accurate diagnosis and the incremental costs of noise suppression. This specification is based on that in the draft IEC ECG standard. The level specified is quite sufficient for diagnostic purposes and economically feasible in practice.

Subclause 201.12.4.4.108 – Frequency response

Complete specification of frequency response should address phase distortion, which is most critical for low frequency response. The impulse response requirement tests this capability with a relatively easy-to-apply procedure. Tests at higher frequencies are not proposed because measuring phase shift for frequencies above 25 Hz would be difficult at best at the

required time base of 25 mm/s. At 40 Hz an accurate measure would require a time base of 400 mm/s.

Historically, the phase response of a one pole 0,05 Hz high pass filter has been considered acceptable. The baseline offset allowed following the impulse represents the drop that can be expected from a 0,05 Hz filter. The slope requirement of 0,30 mV/s translates at standard GAIN and speed to a change of 0,3 mm across a typical ST SEGMENT interval of 100 ms and would not be clinically significant, particularly as a typical QRS complex has an impulse value closer to 0,1 mV × s (cf. 0,3 mV × s).

The high-frequency response limit of 40 Hz is based on two considerations. First, the primary purposes of the ambulatory ECG (which are [a] to identify rhythms and [b] to reveal displacements of the ST SEGMENT necessary to identify ischemic episodes) can be adequately accomplished without a higher frequency response. Second, the persistent problem of high-frequency noise from power line frequencies and from muscle artefact can be reduced with a 40 Hz bandwidth.

This standard proposes test methods to evaluate either the frequency response or the ability of the AMBULATORY ECG EQUIPMENT to deal with ECG-like signals such as a triangular wave simulating the R-wave. Allowing a 40 % reduction in the peak value of the triangular input signal corresponds to the expected reduction due to a digital sampling system that stores one 24 h channel in at least 14,4 million samples. The impulse response test is also employed to simulate the R-wave and to observe readily whether the monitor produces baseline changes following the impulse that, with a real ECG input signal, might result in artifactual displacements of the ST SEGMENT and lead to false interpretations regarding the presence of ischemia.

The low-frequency response of 0,67 Hz is based upon heart rate data from the Simonson studies[6]. These studies indicate that 44/min encompasses more than 99 % of adult heart rates with intra-individual RR interval variation less than 126 ms. Thus a lower bound of 40/min (0,67 Hz) exists for 99 % of adults 90 % of the time. Bailey *et al*. used these data to justify the 0,67 Hz low frequency bound in the 1990 AHA recommendations.

There is a boost in the frequency response of analogue tape AMBULATORY RECORDERs at approximately 0,2 Hz to 0,3 Hz. Selecting +3 dB as the upper limit for frequency response accuracy allow for this boost.

Subclause 201.12.4.4.109 – Function in the presence of pacemaker pulses

PATIENTs having large pacemaker pulse amplitudes at the body surface are prevalent in the population receiving ambulatory ECGs for diagnostic purposes. For this reason, the ECG recorded by ME EQUIPMENTs that are claimed to be suitable for use with such PATIENTs should not be unduly distorted by the presence of the pacemaker pulse signal.

If the manufacturer claims that the ME EQUIPMENT is capable of recording pacemaker pulses, tests with four different pulses have to be done to cover the range of possible pacemaker pulses on the surface ECG.

Subclause 201.12.4.4.110 – Timing accuracy

The correlation of the occurrence time of an external event (for example, drug administration, presence of symptoms, physical activity) and the PATIENTs ECG complexes is essential to clinical interpretation. Since the recorded ECG is reviewed retrospectively, the recording

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6 SIMONSON, E. *Differentiation between normal and abnormal in electrocardiography.* St. Louis:C.V. Mosby Co., 1961, p.158.

SIMONSON, E. et al. *Variability of the electrocardiogram in normal young men.* Am Heart, 1949, vol. 38, p.407.

ME EQUIPMENT and ME SYSTEM have to provide a mechanism for accurately indicating the actual occurrence time along with the ECG signals on both the display and printout.

The cumulative accuracy requirement of ± 30 s over 24 h ensures that the difference between the actual occurrence time and the recorded occurrence time is sufficiently small to allow clinical correlation and interpretation of the concomitant ECG complexes.

Subclause 201.12.4.4.111 – GAIN settings and switching

Variations in the recorded amplitude of a PATIENTs ECG (due to physiological factors or LEAD placement) warrant the selection of different scale factors. A NOMINAL scaling factor of 10 mm/mV has been traditionally used. The additional GAIN settings of 5 mm/mV and 20 mm/mV conform to both IEC and AHA recommendations. Other GAIN settings (for example, 40 mm/mV and 2,5 mm/mV) may be provided at the option of the manufacturer. Continuous GAIN control is generally not desirable.

Inclusion of the ECG calibration pulse in the display provides the OPERATOR with a means of verification of the reproduced ECG amplitude.

Subclause 201.12.4.4.112 –Temporal alignment

Clinical evaluation of the ECG recorded requires viewing the ECG complex in different planes. Certain features, such as pacemaker pulses, are sometimes only discernible in one plane. Concurrent analysis of two (or more) ECG channels requires that the channel-to-channel skew be sufficiently small so as not to influence the clinical interpretation of the ECG. The skew error of ± 0,5 mm corresponds to a maximum temporal skew of ± 20 ms (at a scale of 25 mm/s). This tolerance accounts for practical measurement errors and also for variations in the recording and PLAYBACK EQUIPMENT due to alignment of magnetic recording heads due to tape tracking and/or analogue-to-digital conversion skew.

Subclause 201.15.4.3.101.1 – Monitoring time

The minimal time for ambulatory ECG recording varies with the indication for the test. Events that occur frequently may be detected with short recording periods whereas those that occur infrequently or rarely may require prolonged recording. For most clinical uses, a minimum recording period of 24 consecutive hours is recommended. This period takes into account the circadian variability of the processes underlying the cardiac activity. This time-span permits detection of most episodes of intermittent arrhythmias during waking and sleeping phases with recognition of temporal variability in frequency while providing adequate protection from the effects of intermittent AMBULATORY RECORDER malfunction.

Subclause 201.15.4.3.101.2 – Data retention

The requirements for 72 h data retention are based on the assumption that a stored recording should be kept for at least the duration of a week-end which is a common case which occurs in practice.

Clause 201.17 – Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

EMC of ME EQUIPMENTs and ME SYSTEMs is a growing concern. The collateral standard IEC 60601-1-2 reflects this concern and provides general guidance on EMC requirements.

Subclause 202.6.2.3 – Radiated RF electromagnetic fields

Some PATIENTs may work in an environment that has unusually high electromagnetic fields. To avoid improper recordings, these PATIENTs should be advised by the physician not to expose these ME EQUIPMENT to such high fields. Furthermore, the ambulatory recording of ECGs is an elective procedure and may be repeated, if failed the first time.

Bibliography

IEC 60601-2-25, *Medical electrical equipment – Part 2: Particular requirements for the safety of electrocardiographs*

IEC 60601-2-27, *Medical electrical equipment – Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment*

Index of defined terms used in this particular standard

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