

Medical electrical equipment —

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

The European Standard EN 60601-2-51:2003 has the status of a
British Standard

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National foreword

This British Standard is the official English language version of EN 60601-2-51:2003. It is identical with IEC 60601-2-51:2003.

The UK participation in its preparation was entrusted by Technical Committee CH/62, Electromedical equipment in medical practice, to Subcommittee CH/62/4, Electromedical equipment, which has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;
- monitor related international and European developments and promulgate them in the UK.

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

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Medical electrical equipment
Part 2-51: Particular requirements for safety,
including essential performance, of recording and analysing
single channel and multichannel electrocardiographs
(IEC 60601-2-51:2003)

Appareils électromédicaux
Partie 2-51: Règles particulières
de sécurité et performances essentielles
des électrocardiographes enregistreurs
et analyseurs mono et multi-canaux
(CEI 60601-2-51:2003)

Medizinische elektrische Geräte
Teil 2-51: Besondere Festlegungen
für die Sicherheit, einschließlich
wesentlicher Leistungsmerkmale von
aufzeichnenden und interpretierenden
Einkanal- und Mehrkanal-
Elektrokardiographen
(IEC 60601-2-51:2003)

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Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CENELEC member.

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CENELEC

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

Central Secretariat: rue de Stassart 35, B - 1050 Brussels

Foreword

The text of document 62D/469/FDIS, future edition 1 of IEC 60601-2-51, prepared by SC 62D, Electromedical equipment, of IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 60601-2-51 on 2003-04-01.

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with the EN have to be withdrawn (dow) 2006-04-01

Annexes designated "normative" are part of the body of the standard.

Annexes designated "informative" are given for information only.

In this standard, annexes GG, HH, ZA and ZB are normative, annexes AA to FF and annex II are informative.

Annexes ZA and ZB have been added by CENELEC.

In this particular standard, the following print types are used:

- requirements, compliance with which can be tested, and definitions: roman type;
- notes, explanations, advice, introductions, general statements, exceptions and references: small roman type;
- *test specifications: italic type;*
- TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD OR THIS PARTICULAR STANDARD: SMALL CAPITALS.

Endorsement notice

The text of the International Standard IEC 60601-2-51:2003 was approved by CENELEC as a European Standard without any modification.

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INTRODUCTION

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

A “General guidance and rationale” for the requirements of this Particular Standard is included in Annex AA.

It is considered that a knowledge of the reasons for these requirements will not only facilitate the proper application of the standard but will, in due course, expedite any revision necessitated by changes in clinical practice or as a result of developments in technology. However, this annex does not form part of the requirements of this Standard.

An asterisk (*) by a clause or subclause number indicates that some explanatory notes are given in Annex AA.

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

SECTION ONE – GENERAL

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

1 Scope and object

This clause of the General Standard applies except as follows:

***1.1 Scope**

Addition:

This Particular Standard specifies requirements for the safety, including essential performance, of RECORDING AND ANALYSING SINGLE CHANNEL AND MULTICHANNEL ELECTROCARDIOGRAPHS as defined in 2.101, 2.111, 2.117, 2.123, 2.126, hereinafter referred to as EQUIPMENT. The EQUIPMENT may be attended or unattended.

This Particular Standard complements IEC 60601-2-25 and its Amendment 1 (1999).

1.2 Object

Replacement:

The object of this Particular Standard is to establish particular requirements, in addition to the requirements of IEC 60601-2-25, for the safety, including essential performance of RECORDING AND ANALYSING SINGLE CHANNEL AND MULTICHANNEL ELECTROCARDIOGRAPHS.

These requirements shall apply particularly to

- RECORDING ELECTROCARDIOGRAPHS;
- ELECTROCARDIOGRAPHS which are part of other MEDICAL ELECTRICAL EQUIPMENT, for example exercise testing systems, if this EQUIPMENT is used to record ECGs for diagnostic purposes;
- ELECTROCARDIOGRAPHS which are used as output units for ECG data base management systems or ELECTROCARDIOGRAPHS which are used as output units located at other places than the recording unit;
- ANALYSING ELECTROCARDIOGRAPHS, systems, and computing devices which by means of electronic data processing and pattern recognition derive measurements (e.g. intervals and amplitudes) and diagnostic statements from the ECG;
- those parts of PATIENT monitors or other specialised ELECTROCARDIOGRAPHS that are capable of performing the functions of the ANALYSING ELECTROCARDIOGRAPHS.

This standard shall not apply to Holter ELECTROCARDIOGRAPHS, invasive electrocardiography, PATIENT monitoring systems and high-resolution ELECTROCARDIOGRAPHS (e.g. HIS bundle ELECTROCARDIOGRAPHS, ELECTROCARDIOGRAPHS for late potential detection) other than stated above.

1.3 Particular Standards

Addition:

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

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

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

The numbering of sections, clauses or subclauses of this Particular Standard corresponds with that of the General Standard. The changes to the text of the General Standard are specified by the use of the following words:

“Replacement” means that the clause or subclause of the General Standard is replaced completely by the text of this Particular Standard.

“Addition” means that the text of this Particular Standard is additional to the requirements of the General Standard.

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

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

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

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

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

2 Terminology and definitions

This clause of the General Standard applies except as follows:

Additional definitions:

2.101

ANALYSING ELECTROCARDIOGRAPH

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

2.102

CALIBRATION ("CAL")

facility enabling the CALIBRATION VOLTAGE and zero voltage to be recorded in place of the ELECTROCARDIOGRAM

2.103

CALIBRATION VOLTAGE

voltage step recorded for amplitude CALIBRATION purposes

2.104

CENTRAL TERMINAL ACCORDING TO WILSON (CT)

terminal at the average potential of the R, L and F potentials

2.105

CHANNEL

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

2.106

COMMON MODE REJECTION

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

2.107

COMMON MODE DC OFFSET VOLTAGE

DC voltage appearing on LEAD ELECTRODES with respect to the NEUTRAL ELECTRODE resulting from ELECTRODE-skin voltages

2.108

ECG RECORD

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

2.109

EFFECTIVE RECORDING WIDTH

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

2.110

ELECTROCARDIOGRAM (ECG)

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

2.111

ELECTROCARDIOGRAPH (ecg)

MEDICAL ELECTRICAL EQUIPMENT and associated ELECTRODES intended for the production of ELECTROCARDIOGRAMS for diagnostic purposes

2.112

ELECTRODE(S)

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

2.113

FILTER(S)

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

2.114

LEAD WIRE(S)

cable(s) connected between ELECTRODE(s) and the ELECTROCARDIOGRAPH

2.115

LEAD(S)

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

2.116

LEAD SELECTOR

system to select certain LEADS and CAL

2.117

MULTICHANNEL ELECTROCARDIOGRAPH

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

2.118

NEUTRAL ELECTRODE

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

2.119

NOISE

unwanted signals of any frequency present in the ELECTROCARDIOGRAM

2.120

NORMAL SENSITIVITY

SENSITIVITY of 10 mm/mV

2.121

OVERLOAD TOLERANCE

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

2.122

PATIENT CABLE

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

2.123

RECORDING ELECTROCARDIOGRAPH

MEDICAL ELECTRICAL EQUIPMENT intended for the production of ECG RECORDS

2.124**REFERENCE POINT ACCORDING TO GOLDBERGER**

reference point at an average potential of two limbs (e.g. average of L and F)

2.125**SENSITIVITY**

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

2.126**SINGLE CHANNEL ELECTROCARDIOGRAPH**

EQUIPMENT for the recording of one ECG LEAD at a time

2.127**TEST**

other designation for CAL

2.128**TIME CONSTANT**

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

NOTE This definition is derived from a first order network.

2.129**WAVE RECOGNITION POINTS**

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

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

4 General requirements for tests

This clause of the General Standard applies except as follows:

4.6 Other conditions

Addition:

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

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

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

- resistors $\pm 2 \%$
- capacitors $\pm 10 \%$
- inductors $\pm 10 \%$
- test voltages $\pm 1 \%$

4.11 Sequence

Addition:

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

6 Identification, marking and documents

This clause of the General Standard applies except as follows:

***6.1 Marking on the outside of EQUIPMENT or EQUIPMENT parts**

Addition:

- aa) In order to minimize the possibility of incorrect connections, the PATIENT CABLE shall be permanently marked with one of the identifiers (ELECTRODE identifier and/or colour code) specified in Table 101;
- bb) The PATIENT CABLE to EQUIPMENT connector shall be so constructed or marked as to enable the USER to identify the EQUIPMENT to which the PATIENT CABLE is intended to be connected.

6.8.2 Instructions for use

Addition:

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

- the way amplitude values for the P-, QRS-, ST- and T-waves are determined as required in 50.101.2;
- the way isoelectric segments within the QRS complex are treated as required in 50.101.3;
- the criteria applied in the EQUIPMENT for acceptance of minimum waves and stability of the measurements in the presence of NOISE as required in 50.101.4;
- the intended use of the analysing electrocardiograph as required in 50.102.2;
- the cardiac abnormalities of low prevalence that were not included in the test contour diagnostic data base as required in 50.102.3.1;
- the ECG categories and the number of ECGs tested in these categories as required in 50.102.3.2 (see also 50.102.3.1);
- accuracy measures for diagnostic interpretative statements, non-ECG means for validation of cardiac diagnosis and the group statistics of patient demographics (such as age, gender, race etc.) as required in 50.102.3.2;
- the cardiac rhythms of low prevalence that were not included in the test rhythm ECG database as required in 50.102.4.1;
- the ECG categories and the number of ECGs tested in these categories as required in 50.102.4.2 (see also 50.102.4.1);
- accuracy measures for rhythm interpretative statements and the group statistics of patient demographics (such as age, gender, race etc.) as required in 50.102.4.2;
- the instructions for regular testing of the SENSITIVITY, when the CALIBRATION does not check the overall SENSITIVITY as required in 51.103.2;
- if the ELECTROCARDIOGRAPH must have FILTERS set, the arrangements to pass the distortion test, and the effect of these FILTER settings on ECG signal distortion as required in 51.109.1;
- the minimum length of time that the ELECTROCARDIOGRAPH will conform to the requirements of this Particular Standard under the conditions required in Clause 56.

Table 101 – ELECTRODES and NEUTRAL ELECTRODES, their position, identification and colour code

System	CODE 1 (usually European)		CODE 2 (usually American)		Position on body surface
	ELECTRODE identifier	Colour code	ELECTRODE identifier	Colour code	
Limb	R L F	Red Yellow Green	RA LA LL	White Black Red	Right arm Left arm Left leg
Chest according to Wilson	C C1 C2 C3 C4 C5 C6	White White/red White/yellow White/green White/brown White/black White/violet	V V1 V2 V3 V4 V5 V6	Brown Brown/red Brown/yellow Brown/green Brown/blue Brown/orange Brown/violet	Single movable chest ELECTRODE Fourth intercostal space at right border of sternum Fourth intercostal space at left border of sternum Fifth rib between C2 and C4 Fifth intercostal space on left midclavicular line Left anterior axillary line at the horizontal level of C4 Left midaxillary line at the horizontal level of C4
Position according to Frank (see Figure 1)	I E C A M H F	Light blue/red Light blue/yellow Light blue/green Light blue/brown Light blue/black Light blue/violet Green	I E C A M H F	Orange/red Orange/yellow Orange/green Orange/brown Orange/black Orange/violet Red	At the right midaxillary line a) At the front midline a) Between front midline and left midaxillary line at an angle of 45 degrees a) At the left midaxillary line a) At the back midline a) ^a On the back of the neck On the left leg
	N	Black	RL	Green	Right leg (NEUTRAL)
NOTE Additional recommendations are given in Annex BB and Annex EE.					
^a Located at the transverse level of the ventricles, if known, or otherwise at the fifth intercostal space					

SECTION TWO – ENVIRONMENTAL CONDITIONS

The clauses and subclauses of this section of the General Standard (and of IEC 60601-2-25 including its Amendment 1 (1999)) apply.

SECTION THREE – PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

The clauses and subclauses of this section of the General Standard (and of IEC 60601-2-25 including its Amendment 1 (1999)) apply.

SECTION FOUR – PROTECTION AGAINST MECHANICAL HAZARDS

The clauses and subclauses of this section of the General Standard (and of IEC 60601-2-25 including its Amendment 1 (1999)) apply.

SECTION FIVE – PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

The clauses and subclauses of this section of the General Standard (and of IEC 60601-2-25 including its Amendment 1 (1999)) apply.

SECTION SIX – PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANAESTHETIC MIXTURES

The clauses and subclauses of this section of the General Standard (and of IEC 60601-2-25 including its Amendment 1 (1999)) apply.

SECTION SEVEN – PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER SAFETY HAZARDS

The clauses and subclauses of this section of the General Standard (and of IEC 60601-2-25 including its Amendment 1 (1999)) apply.

SECTION EIGHT – ACCURACY OF OPERATING DATA AND PROTECTION AGAINST HAZARDOUS OUTPUT

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

50 Accuracy of operating data

Addition:

***50.101 Automated measurements on ECGs (for ANALYSING ELECTROCARDIOGRAPHS)**

If automated measurements are provided by the ELECTROCARDIOGRAPH, their accuracy shall meet the requirements as stated in this section. If the stated requirement(s) is (are) only for disclosure, the manufacturer shall disclose the required performance accuracy in the ACCOMPANYING DOCUMENTS.

50.101.1 Standard databases to evaluate accuracy of automated ECG measurements

50.101.1.1 Standard databases to evaluate accuracy of amplitude measurements

Calibration and analytical ECGs of Table HH.1 of Annex HH shall be used to evaluate the accuracy of amplitude measurements (see 50.101.2).

50.101.1.2 Standard databases to evaluate the accuracy of absolute interval and wave duration measurements

Calibration and analytical ECGs of Table HH.1 of Annex HH shall be used to evaluate the accuracy of absolute interval and wave duration measurements (see 50.101.3.1).

50.101.1.3 Standard databases to evaluate the accuracy of interval measurements on biological ECGs

ECGs of Table HH.2 of Annex HH shall be used to evaluate the accuracy of interval measurements on biological ECGs (see 50.101.3.2).

50.101.1.4 Standard databases to evaluate stability of measurements against NOISE

ECGs of Table HH.3 of Annex HH shall be used to evaluate the stability of measurements against NOISE (see 50.101.4).

***50.101.2 Requirements for amplitude measurements**

The manufacturer shall disclose in the ACCOMPANYING DOCUMENTS in which way amplitude values for the P-, QRS-, ST- and T-waves are determined.

If an ANALYSING ELECTROCARDIOGRAPH provides measurements, their accuracy shall be tested. Amplitude measurements given for P, Q, R, S, ST and T shall not deviate from the reference values by more than $\pm 25 \mu\text{V}$ for amplitudes $\leq 500 \mu\text{V}$ or by more than 5 % for amplitudes $> 500 \mu\text{V}$.

The calibration and analytical ECGs listed in Table HH.1 of Annex HH shall be fed into the ELECTROCARDIOGRAPH under test and shall be recorded for at least 8 s (see guidelines at the end of Annex AA for inputting ECGs). The differences between the amplitude measurements and the reference values for LEADS I, II, V1, ..., V6 shall be determined for all provided P-, Q-, R-, S-, ST- and T-waveforms.

If the calibration and analytical ECGs are fed into the system after digital to analogue conversion via the ELECTRODE cables (see guidelines at the end of Annex AA for inputting ECGs), the tests shall be performed five times. If the ELECTROCARDIOGRAPH can be tested with digital input of calibration and analytical ECGs, the test needs to be performed only once. The differences between measurements and reference values shall be calculated either from the single test or from the mean values of the five tests.

If there are obvious fiducial point (P-, QRS-ONSET/OFFSET and T-OFFSET) errors, exclude the differences in the affected amplitude measurements. Exclusion of differences resulting from not more than two fiducial point errors shall be allowed. The difference for each remaining amplitude measurement shall not deviate from the reference value by more than $\pm 25 \mu\text{V}$ for reference values $\leq 500 \mu\text{V}$, or by more than 5 % or $\pm 40 \mu\text{V}$ (whichever is greater) for reference values $> 500 \mu\text{V}$.

NOTE For the calibration ECGs CAL20100, CAL20200, and CAL20260, an offset voltage for ST and T amplitudes of approximately $20 \mu\text{V}$ is to be considered if the signals are fed through a first order high pass FILTER (e.g. an analogue amplifier) with a TIME CONSTANT of 3,2 s as shown in Table 102.

Table 102 – Offset voltage for ST and T amplitude reference values if the signals are fed through a first order high pass FILTER with a TIME CONSTANT of 3,2 s

Calibration ECG	Offset voltages μV			
	LEADS I, II, V1 ... V6	LEAD III	LEAD aVR	LEADS aVL, aVF
CAL05000	0	0	0	0
CAL10000	0	0	0	0
CAL15000	0	0	0	0
CAL20000	0	0	0	0
CAL20002	0	0	0	0
CAL30000	0	0	0	0
CAL20100	-20	0	+20	-10
CAL20200	20	0	-20	10
CAL20260	20	0	-20	10
ANE20000				
ANE20001				
ANE20002				

NOTE If, due to the artificial nature of the CAL ECGs, the ELECTROCARDIOGRAPH suppresses printing of measurements, then the measurement values that are obtained but not printed shall be used for these tests.

50.101.3 Requirements for interval measurements

The manufacturer shall disclose in the ACCOMPANYING DOCUMENTS in which way the isoelectric segments within the QRS complex are treated: whether they are included into or excluded from the Q-, R- or S-waves. He shall specifically explain whether isoelectric parts (I-wave) after global QRS-ONSET or before global QRS-OFFSET (K-wave) are included in the duration measurement of the respective adjacent waveform.

If the measurements are provided for the ECG RECORD, their accuracy shall be tested as follows.

*50.101.3.1 Requirements for absolute interval and wave duration measurements

These measurements shall be derived from the global interval and the wave duration measurements (see Table HH.1) on the calibration and analytical ECGs. Acceptable tolerances for the mean differences of global durations and intervals and Q-, R- and S-duration measurements are given in Table 103.

Table 103 – Acceptable mean differences and standard deviations for global intervals and Q-, R-, S-durations on calibration and analytical ECGs

All dimensions in ms

Measurement	Acceptable mean difference	Acceptable standard deviation
P-duration	± 10	8
PQ-interval	± 10	8
QRS-duration	± 6	5
QT-interval	± 12	10
Q-duration	± 6	5
R-duration	± 6	5
S-duration	± 6	5

The calibration and analytical ECGs listed in Table HH.1 shall be fed into the electrocardiograph under test; simultaneous acquisition of all LEADS is assumed.

If the calibration and analytical ECGs are fed into the system after digital to analogue conversion via the ELECTRODE cables (see guidelines at the end of Annex AA for inputting ECGs), the tests shall be performed five times. If the ELECTROCARDIOGRAPH can be tested with digital input of the test ECGs, the test need be performed only once. The differences between measurements and reference values shall be calculated either from the single test or from the mean values of the five tests.

For each of the global measurements (P-duration, PQ-interval, QRS-duration, and QT-interval) there will be 16 difference numbers. If there are obvious fiducial point (P-, QRS-ONSET/OFFSET and T-OFFSET) errors, exclude the differences in the affected global and individual LEAD intervals. Exclusion of differences resulting from not more than two fiducial point errors shall be allowed. From the remaining differences, remove the two largest deviations from the mean (outliers) for each measurement. The means and standard deviations of the remaining differences are computed and shall not exceed the tolerances given in Table 103.

For each of the individual LEAD measurements (Q-, R-, and S-durations) compute the differences for LEADS I, II, V1 ... V6 (if the wave is present) for all the calibration and analytical ECGs listed in Table HH.1. Exclude differences resulting from fiducial point errors as described above. From the remaining differences remove the two largest deviations from the mean (outliers) for each measurement. The means and standard deviations of the remaining differences are computed and shall not exceed the tolerances given in Table 103.

***50.101.3.2 Requirements for interval measurements on biological ECGs**

One hundred (100) real test ECGs (MA1_ or MO1_ series from the CSE study, listed in Table HH.2) shall be fed into the ELECTROCARDIOGRAPH (either digitally or after D/A-conversion) and analysed by the system under test (see guidelines at the end of Annex AA for inputting ECGs). Measurement results shall be analysed according to the following rules.

If there are obvious fiducial point (P-, QRS-ONSET/OFFSET and T-OFFSET) errors, exclude the differences in the affected global intervals. Exclusion of differences resulting from not more than four fiducial point errors shall be allowed. From the remaining differences, remove the four largest deviations from the mean (outliers) for each measurement. The means and standard deviations of the remaining differences are computed and shall not exceed the tolerances given in Table 104.

Table 104 – Acceptable mean differences and standard deviations for global durations and intervals for biological ECGs

Dimensions in ms

Global measurement	Acceptable mean difference	Acceptable standard deviation
P-duration	±10	15
PQ-interval	±10	10
QRS-duration	±10	10
QT-interval	±25	30

***50.101.4 Disclosure requirements for stability of measurements against NOISE**

The manufacturer shall disclose in the ACCOMPANYING DOCUMENTS the criteria applied in the EQUIPMENT for acceptance of minimum waveforms.

If measurements are provided, the stability of the measurements in the presence of NOISE shall be disclosed in the ACCOMPANYING DOCUMENTS according to Table 105.

Table 105 – Disclosed changes of measurements caused by NOISE on ECGs according to Table HH.3

Global measurement	Type of added NOISE	Disclosed differences	
		Mean ms	Standard deviation ms
P-duration	High frequency		
P-duration	Line frequency		
P-duration	Base-line		
QRS-duration	High frequency		
QRS-duration	Line frequency		
QRS-duration	Base-line		
QT-interval	High frequency		
QT-interval	Line frequency		
QT-interval	Base-line		

The ten ELECTROCARDIOGRAMS listed in Table HH.3, shall be fed into the ELECTROCARDIOGRAPH under test:

- a) *without NOISE;*
- b) *with 25 µV r.m.s.. high frequency NOISE generated as specified in Clause HH.3;*
- c) *with 50 µV peak to valley 50/60 Hz sinusoidal line frequency NOISE;*
- d) *with 1 mV peak to valley 0,3 Hz sinusoidal base-line NOISE.*

If the biological ECGs are fed into the system after digital to analogue conversion via the ELECTRODE cables, the tests shall be performed five times (see guidelines at the end of Annex AA for inputting ECGs). If the ELECTROCARDIOGRAPH can be tested with digital input of biological ECGs the test need be performed only once. The differences between measurements and reference values shall be calculated either from the single test or from the mean values of the five tests.

For each NOISE level the differences of measurements according to Table 105 between the NOISE-free ECGs and the ECGs with NOISE shall be determined and their mean value and standard deviation shall be calculated. The two largest deviations from the mean (outliers) shall be eliminated before calculation of mean and standard deviation of differences.

***50.102 Automated ECG interpretation (for ANALYSING ELECTROCARDIOGRAPHS)**

If automated ECG interpretation is provided by the ELECTROCARDIOGRAPH, the manufacturer shall disclose the required interpretation accuracy measures in the ACCOMPANYING DOCUMENTS as stated in this subclause.

50.102.1 Definition of accuracy measures for automated ECG interpretation

For the purpose of this document, four key accuracy measures are explained below.

It is assumed that the true diagnosis for a PATIENT is known ("truth"). The ECG interpretation (classification) is called "Test". The following designations are applied to characterise the performance of a test (respectively of an ECG interpretation system), see Table 106:

- a) a "Normal" correctly classified as "Normal" is called "True normal" (TN);
- b) a "Normal" incorrectly classified as "Pathologic" is called "False pathologic" (FP);
- c) a "Pathologic" incorrectly classified as "Normal" is called "False normal" (FN);
- d) a "Pathologic" correctly classified as "Pathologic" is called "True pathologic" (TP).

Table 106 – Tabulation of test results

Reference	Test	
	"Normal"	"Pathologic"
"Normal"	TN	FP
"Pathologic"	FN	TP

The following equations are calculated from a two (or multi-) category test:

- a) *Sensitivity*: probability that a "True pathologic" would be classified as a "Pathologic".

$$Sensitivity = \frac{TP}{TP+FN} \times 100 \%$$

NOTE The term "*Sensitivity*" here and in related requirements stands for "ECG interpretation sensitivity" and it is not to be mistaken for NORMAL SENSITIVITY as defined in 2.120 or SENSITIVITY as defined in 2.125

- b) *Specificity*: probability that a "True normal" would be classified as "Normal".

$$Specificity = \frac{TN}{TN+FP} \times 100 \%$$

NOTE For simplification in Table 107, the *Specificity* designation is denoted as "*Sensitivity*" for Normals.

- c) *Positive predictive value (P⁺)*: probability that a classified "Pathologic" is a "True pathologic".

$$P^+ = \frac{TP}{TP+FP} \times 100 \%$$

Note that the explanation above can be made general by substituting "Negative" for "Normal", and "Positive" for "Pathologic".

50.102.2 Disclosure of the intended use

The manufacturer shall disclose in the ACCOMPANYING DOCUMENTS the intended use of the ANALYSING ELECTROCARDIOGRAPH. This disclosure shall include all the attributes of intended use such as, but not limited to, the following:

- a) diagnostic application(s) for which the ELECTROCARDIOGRAPH is intended (e.g.: screening for cardiac abnormalities in the general population, detecting acute myocardial ischemia and infarction in chest pain patients, etc.);
- b) population(s) for whom the ANALYSING ELECTROCARDIOGRAPH is intended (e.g.: adults, children, infants, neonates, etc. – specify the age limits of the targeted population where applicable);
- c) location(s) for which the ANALYSING ELECTROCARDIOGRAPH is intended (e.g.: hospital, general physician's office, out-of-hospital locations such as ambulance, home-care, etc.);
- d) emphasis of the accuracy of the interpretation program in the ANALYSING ELECTROCARDIOGRAPH (e.g.: high-specificity program intended for low-risk patients; high-sensitivity program for detecting cardiac abnormalities in high-risk patients, balanced sensitivity/specificity program, etc.).

If the ANALYSING ELECTROCARDIOGRAPH has more than one intended use with different attributes, all the intended uses and associated attributes shall be disclosed.

50.102.3 Accuracy of contour (morphology) diagnostic interpretative statements

*50.102.3.1 Contour diagnostic ECG database

The ELECTROCARDIOGRAMS for testing the ANALYSING ELECTROCARDIOGRAPH shall be acquired from normals and heart disease patient population(s) for whom the ELECTROCARDIOGRAPH is intended. The prevalence of cardiac abnormalities in the patients whose ECGs are tested shall be similar to the prevalence of these abnormalities in the population(s) for whom the ELECTROCARDIOGRAPH is intended.

NOTE The manufacturer is not required to include in the test contour diagnostic ECG database ECGs of cardiac abnormalities with low prevalence in the intended population. However, the manufacturer is required to disclose in the ACCOMPANYING DOCUMENTS the cardiac abnormalities that were not included in the test contour diagnostic ECG database.

The ECGs of normals shall have their diagnosis verified by standard clinical methods to establish the absence of disease, particularly heart disease. These methods may include normal physical examination, absence of cardiac symptoms, and absence of history of any known disease with a known influence on cardiac function or morphology. Other methods to confirm absence of heart disease, such as normal exercise tolerance test, can also be used if appropriate. The manufacturer shall disclose the means employed to define and select normals whose ECGs were used in their testing.

The ECGs of heart disease patients used in testing the accuracy of the ANALYSING ELECTROCARDIOGRAPH shall have their true diagnosis verified by an appropriate confirmatory non-ECG means. The manufacturer shall disclose the non-ECG confirmatory means (e.g.: cardiac catheterization, angiography, echocardiography, nuclear imaging, cardiac enzymes, etc.) employed in establishing a true diagnosis of patients whose ECGs were used in their testing.

The number of ECGs tested in each diagnostic category, group statistics (mean $\pm$ standard deviation, percentages, etc.) of PATIENT demographics such as age, gender, and race, etc. and details of the non-ECG means for validation of the cardiac diagnosis shall be disclosed.

For certain disease categories (e.g.: normal, old myocardial infarction, ventricular hypertrophy), the CSE diagnostic database may be used.

50.102.3.2 Disclosure requirements for accuracy of diagnostic interpretative statements

The manufacturer shall disclose in the ACCOMPANYING DOCUMENTS of the ANALYSING ELECTROCARDIOGRAPH the following accuracy measures for the diagnostic interpretative statements whose interpretation is claimed by the manufacturer.

- a) sensitivity, specificity, and positive predictive value for all the major diagnostic interpretative statements;
- b) sensitivity, specificity and positive predictive values for more detailed diagnostic interpretative statements whose interpretation is claimed by the manufacturer. For example, if the manufacturer claims interpretation of the location of myocardial infarction such as anterior, antero-lateral, lateral, inferior, infero-posterior, etc., the accuracy figures for the location of infarction shall also be disclosed in addition to the presence of myocardial infarction.

NOTE For diagnostic interpretative statements of cardiac abnormalities with low prevalence in the intended population, the manufacturer is not required to disclose the accuracy measures for these statements. However, the manufacturer is required to disclose in the ACCOMPANYING DOCUMENTS the diagnostic interpretative statements that do not have accuracy measures.

If the ANALYSING ELECTROCARDIOGRAPH is intended for more than one diagnostic application (see 50.102.2), the manufacturer shall disclose in the ACCOMPANYING DOCUMENTS the accuracy measures for each of these applications.

For each diagnostic ECG category tested, the manufacturer shall also disclose in the ACCOMPANYING DOCUMENTS the details of the non-ECG means for validation of the cardiac diagnosis, the number of ECGs tested and the group statistics of PATIENT demographics such as age, gender, and race, etc.

The ELECTROCARDIOGRAMS of the appropriate diagnostic categories from the contour diagnostic ECG database shall be fed in analogue or digital form into the ELECTROCARDIOGRAPH under test (see guidelines at the end of Annex AA for inputting ECGs). For each diagnostic category the diagnostic statements of the system are summed up and from the total figures, sensitivity and the specificity values shall be determined. If for a single ECG several interpretative statements are given, only the statement with the highest level of confidence (definite, probable or possible) shall be counted.

A possible guidance for the evaluation of the diagnostic statements and conducting the test is given in the December 1991 issue of the New England Journal of Medicine [1]¹, which describes the method used by the CSE project.

The format of Table 107 shall be used for disclosure of these accuracy measures.

¹ Figures in square brackets refer to the Bibliography.

Table 107 – Format for disclosure of accuracy measures for diagnostic interpretative statements

Diagnostic category	Number of ECGs tested	Sensitivity %	Specificity %	Positive predictive value %
NORMAL			X	
Old myocardial infarction				
Acute myocardial infarction				
Acute myocardial ischemia/ unstable angina				
Ventricular hypertrophy				
...				
...				

50.102.4 Accuracy of rhythm interpretative statements

*50.102.4.1 Rhythm ECG database

The ELECTROCARDIOGRAMS for testing the accuracy of rhythm statements shall be ECGs of a representative target population. Such a database shall contain at least 1 500 ECGs with sinus rhythms (normal sinus rhythm, sinus bradycardia, sinus tachycardia, etc.) and 100 ECGs with atrial fibrillation. Care shall be taken to include appropriate number of ECGs of sinus and non-sinus rhythms in proportion to their prevalence in the population for whom the ELECTROCARDIOGRAPH is intended.

ECGs of other major rhythm categories (e.g. atrial flutter, atrial tachycardia, paced rhythms, junctional rhythms, ventricular rhythms, etc.) whose interpretation is claimed by the manufacturer shall be included in this database in numbers proportional to their prevalence in the intended population.

Similarly, if the manufacturer claims detailed interpretation such as rhythm qualifiers (e.g.: first degree atrio-ventricular (AV) block, second degree AV blocks, AV dissociation, premature atrial complexes, etc.), ECGs of these categories shall also be included in sufficient numbers in this database.

NOTE The manufacturer is not required to include ECGs of cardiac rhythms with low prevalence in the intended population. However, the manufacturer is required to disclose in the ACCOMPANYING DOCUMENTS the cardiac rhythms that were not included in the test rhythm ECG database.

The “True” rhythm of these ECGs (“gold standard” used to compare the accuracy of the ANALYSING ELECTROCARDIOGRAPH) shall be confirmed by at least one trained cardiologist specialised in rhythm disorders after carefully reviewing rhythm from an ECG plot of at least two simultaneously plotted LEADS showing the atrial activity (e.g.: LEAD II and LEAD V1) for at least 10 s.

50.102.4.2 Disclosure requirements for accuracy of rhythm interpretative statements

The manufacturer shall disclose in the ACCOMPANYING DOCUMENTS of the ANALYSING ELECTROCARDIOGRAPH the following accuracy measures for rhythm categories.

- sensitivity, specificity, and positive predictive value for sinus rhythms and atrial fibrillation;
- sensitivity, specificity, and positive predictive value for all other major rhythm categories (e.g.: atrial flutter, paced rhythms, junctional rhythms, ventricular rhythms, etc.) whose interpretation(s) is (are) claimed by the manufacturer;

- c) sensitivity, specificity, and positive predictive value for detailed rhythm categories including rhythm qualifiers (e.g.: second degree AV blocks, AV dissociation, etc.) whose interpretation(s) is (are) claimed by the manufacturer.

NOTE For interpretative statements of cardiac rhythms with low prevalence in the intended population, the manufacturer is not required to disclose the accuracy measures for these statements. However, the manufacturer is required to disclose in the ACCOMPANYING DOCUMENTS the rhythm interpretative statements that do not have accuracy measures.

The number of ECGs tested in each rhythm category and group statistics (mean $\pm$ standard deviation, percentages, etc.) of PATIENT demographics such as age, gender, race, etc. shall also be disclosed in the ACCOMPANYING DOCUMENTS.

The ELECTROCARDIOGRAMS of the rhythm ECG database shall be fed in analogue or digital form into the ELECTROCARDIOGRAPH under test (see guidelines at the end of Annex AA for inputting ECGs). The rhythm statement generated by the ELECTROCARDIOGRAPH shall be compared against the "True" rhythm for that ECG. Sensitivity and specificity shall be computed for sinus rhythms, atrial fibrillation and any other rhythm category(s) the recognition of which is claimed by the manufacturer.

The format of Table 108 shall be used for disclosure of accuracy of rhythm interpretative statements.

Table 108 – Format for disclosure of accuracy measures for rhythm interpretative statements

Rhythm category	Number of ECGs tested	Sensitivity %	Specificity %	Positive predictive value %
Sinus rhythms				
Atrial fibrillation				
Atrial flutter				
Paced rhythms				
...				
...				

51 Protection against hazardous output

Addition:

51.101 LEADS

51.101.1 Polarity of PATIENT LEADS

In a rectangular coordinate system, increasing time is in the positive x-direction and the positive deflection of the trace is in the positive y-direction when a polarised d.c. signal is connected to the LEAD ELECTRODES as shown in Table 109 (see Figure 102).

Table 109 – Connection of ELECTRODES for a particular LEAD

LEAD	Positive ELECTRODE	Negative ELECTRODE
I	L	R
II	F	R
III	F	L
V_i ($i = 1...6$)	C_i ($i = 1...6$)	L, R, F
-aVR ^a	L, F	R
aVR	R	L, F
aVL	L	R, F
aVF	F	R, L
^a Other negative LEADS may be used too.		

Compliance shall be checked by measurement.

The polarity of other PATIENT LEADS is specified in Annex CC.

***51.101.2 LEAD SELECTOR / LEAD selection**

For the twelve standard LEADS and for the Frank LEADS the nomenclature of Table 110 shall be used.

Compliance shall be checked by inspection.

Table 110 – LEADS and their identification (nomenclature and definition)

Code 1 LEAD Nomenclature ^a	Definition ^b	Name of the LEAD
I	$I = L - R$	
II	$II = F - R$	Bipolar extremity LEADS
III	$III = F - L$	(Limb LEADS Einthoven)
aVR	$aVR = R - (L + F)/2$	Augmented LEADS Goldberger
aVL	$aVL = L - (R + F)/2$	(From one of the ELECTRODES on the limbs to a REFERENCE POINT ACCORDING TO Goldberger)
aVF	$aVF = F - (L + R)/2$	
V1	$V1 = C1 - CT$	
V2	$V2 = C2 - CT$	Unipolar chest LEADS Wilson
V3	$V3 = C3 - CT$	From one of the ELECTRODES on the chest to the CENTRAL TERMINAL ACCORDING TO WILSON (CT) $CT = (L + R + F)/3$
V4	$V4 = C4 - CT$	
V5	$V5 = C5 - CT$	
V6	$V6 = C6 - CT$	
Vx	$Vx = 0,610A + 0,171C - 0,781 I$	
Vy	$Vy = 0,655F + 0,345M - 1,000H$	Orthogonal vector LEADS (Frank LEADS, see Figure 101)
Vz	$Vz = 0,133A + 0,736M - 0,264I - 0,374E - 0,231C$	
^a Other LEADS and their identifications are given in Annex CC.		
^b The definition is given in terms of algebraic equations assuming that the ELECTRODE identifier represents the voltage sensed by the ELECTRODE with respect to a potential reference point. The algebraic equations are in a form such that the result is independent of the potential of the chosen reference point. See Table 101 for a list of definitions of ELECTRODE identifiers.		

***51.101.2.1 Minimum required configuration**

In SINGLE CHANNEL ELECTROCARDIOGRAPHS, the selection (print out) of LEADS I, II, III, aVR, aVL, aVF and V.

In MULTICHANNEL ELECTROCARDIOGRAPHS, the selection (print out) of LEADS I, II, III, aVR or (-aVR), aVL, aVF, V1, V2, V3, V4, V5 and V6.

If means for a manual TEST facility for amplitude CALIBRATION is provided, it shall be indicated by TEST or CAL.

Compliance shall be checked by inspection.

51.101.2.2 Test of LEAD networks

CENTRAL TERMINAL ACCORDING TO WILSON, Goldberger and Frank networks shall satisfy the following requirements for their effect on SENSITIVITY and their weighting factor accuracy. The networks shall not introduce a deviation in voltages of greater than 5 %.

51.101.2.2.1 Goldberger and Wilson LEADS

For the Goldberger and Wilson networks, compliance shall be verified by one of the following tests as appropriate to the ELECTROCARDIOGRAPH.

The ELECTROCARDIOGRAPH at NORMAL SENSITIVITY is connected as shown in Figure 103 with S3 in position B and S1 closed. The LEAD ELECTRODES are connected to P1 and P2 in any one of the configurations listed in Table 111. All other LEAD ELECTRODES are connected to the NEUTRAL ELECTRODE. Adjust the amplitude of the sinusoidal generator (U) at a frequency of 10 Hz to give the value specified in Table 111 for U_{P1P2} for the LEAD ELECTRODE configuration under test. Adjust any baseline control so as to display the signal in the centre of the recording CHANNEL. Verify that the output peak to valley values are within the range of 19 to 21 mm in amplitude in each case. Also verify that the difference between the output amplitude is not greater than 1 mm for each pair of tests where the same LEAD SELECTOR setting is used. Test signal accuracy shall be within 1 %.

If the ELECTROCARDIOGRAPH, because of integrated signal processing, is not capable of handling sinusoidal signals for testing the calibration, CTS Test Atlas ECG waveforms CAL10000, CAL20000, CAL30000 and CAL50000 (see Annex II) can be fed into the ELECTROCARDIOGRAPH instead of the sinusoidal test voltage U. Since the peak amplitudes of the calibration ECGs are respectively ± 1 mV, ± 2 mV and ± 3 mV, the testing criteria on the ECG RECORD remain the same. Instead of the recorded amplitudes, the respective amplitude measurements shall be tested in the case of a numerical print out.