INTERNATIONAL

RECOMMENDATION

OIML R 90

Edition 1990 (E)

Electrocardiographs - Metrological characteristics Methods and equipment for verification

Electrocardiographes - Caractéristiques métrologiques - Méthodes et moyens de vérification

OIML R 90 Edition 1990 (E)

ORGANISATION INTERNATIONALE
DE MÉTROLOGIE LÉGALE

INTERNATIONAL ORGANIZATION
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Foreword

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ELECTROCARDIOGRAPHS

METROLOGICAL CHARACTERISTICS

METHODS and EQUIPMENT for VERIFICATION

1. Scope

1.1. This Recommendation concerns single-channel and multi-channel electrocardiographs with analogue circuits which linearly amplify and display cardiac potential signals at the body surface, with respect to time.

1.2. This Recommendation does not apply to non-linear systems such as digital electrocardiographs, vectorcardiographs, heart monitors, information-processing portions of electrocardiographs and other associated special-purpose instruments. Instruments with internal signal storage with non-linear processing are also outside the scope of this Recommendation.

1.3. This Recommendation is intended for the use of metrological services and other responsible governmental agencies. It specifies the metrological characteristics to be determined, methods and equipment for testing, and initial and subsequent verifications of electrocardiographs that are regulated by laws. Metrological characteristics include errors in measuring voltage signals and time intervals among other characteristics that affect measurement accuracy. Procedures are given for determining the relative error of mesurement of sixteen instrument characteristics. These testing and control procedures provide a basis for ensuring that electrocardiographs of adequate accuracy are available for clinical measurements.

1.4. This Recommendation does not address pattern approval, terminology, technical requirements, electrical safety and the associated test methods. Some of these matters are being considered by the International Electro technical Commission (IEC) in the Publication 601.2.xx "Medical electrical equipment — Part 2: Particular requirements for safety for electrocardiographs" and Draft 62D "Performance requirements for single and multichannel electrocardiographs".

2. Characteristics to be verified

The characteristics shown in Table 1 should be measured during verification of electrocardiographs.

Table 1

Metrological characteristics to be verified

Metrological characteristics	Point	Verified during	
		Initial	Subsequent verification
Relative voltage-measurement error	5.3.1	+	+
Relative sensitivity-setting error	5.3.2	+	–
Relative time-interval measurement error	5.3.3	+	+
Relative error of the recording speed	5.3.4	+	–
Recording hysterisis	5.3.5	+	–
Relative errors of internal calibrator and time marker	5.3.6	+	+
Overshoot	5.3.7	+	–
Time constant	5.3.8	+	–
Amplitude-frequency response curve	5.3.9	+	+
Input impedance	5.3.10	+	–
Recorded-voltage error introduced by the weighting networks	5.3.11		
- for Golberger and Wilson leads	5.3.11.1	+	–
- for Frank leads	5.3.11.2	+	–
Common-mode rejection ratio	5.3.12	+	+
Baseline width	5.3.13	+	–
Baseline drift	5.3.14	+	+
Intrinsic noise level referred to the input	5.3.15	+	+
Interchannel crosstalk coefficient	5.3.16	+	–

At initial verification the current in the patient circuit and protection against effects of defibrillation on the instrument should also be checked (See points 5.4. and 5.5).

3. Measuring instruments used for verification

The measuring instruments listed in Table 2 are recommended for the verification of electrocardiographs.

Table 2

Measuring instruments used for verification

Measuring instrument	Symbol	Main characteristics
Sine-wave signal generator (*)	G1	Frequency range 0.01 Hz — 150 Hz Max.frequency error ± 1 % Voltage range 50 mV — 20 V RMS Max. voltage error ± 2 % Double-ended output
Square-wave signal generator (*)	G2	Frequency range 0.01 Hz — 150 Hz Max. frequency error ± 1 % Voltage range 50 mV — 5 V Max. voltage error ± 2 % Double-ended output
Voltage divider (**)	D1	Division factor 1 000 (R2 = 100 kΩ; R3 = 100 Ω) Max.error of division ± 0.5 %
Simulated skin-electrode impedance (***)	Z1	R1 and C1 in parallel R1 = 51 kΩ ± 5 %; C1 = 47 nF ± 10 %)
DC voltage source	U1	Voltage 1.5 V ± 5 %
Length-measuring device		Range 0 mm — 100 mm Max.error ± 0.1 mm for length from 0 mm to 10 mm, and ± 1 % for length from 10 mm to 100 mm.
Magnifying glass		Magnification × 5
Resistors	R4-R12	R4 = 50 Ω ; R5 = 200 Ω ; R6 = 100 kΩ ; R7 = 620 kΩ , R8 = 10 kΩ , R9 = 470 kΩ ; R10 = 50 Ω; R11 = 50 Ω ; R12 = 10 Ω Max. error ± 5 %
Capacitors	C2-C5 C_T	C2 = 0.5 μF; C3 = 4.7 nF C4 = 100 pF; C5 = 32 μF Max. error ± 10 % C_T variable 0-200 pF
Inductance	L	L = 25 mH ± 10 %
AC voltmeter	V	Voltage range 0 V — 20 V RMS $R_{inp} \geq 300$ MΩ Max.error ± 10 % Frequency 10 Hz — 100 Hz
DC voltage source	U2	Voltage 5 kV ± 10 %

(*) If the voltage or frequency of generator G1 or G2 do not meet the specifications of Table 2, a voltmeter and a frequency meter with the accuracy specified for the generator output voltage and frequency should be provided.

(**) See Figure 1.

(***) Impedance Z1 (called in the text "patient skin-electrode impedance" is intended to simulate the electrical characteristics of the electrode-skin interface.

4. Verification conditions and preparation for verification

4.1. The recommended conditions for verification are as follows:
— ambient temperature: 15 °C to 25 °C,
— ambient pressure: 96 kPa to 104 kPa,
— relative humidity of air: 60 % to 80 % (no condensation),
— mains voltage fluctuations: ± 2 % of nominal voltage,
— mains frequency: (60 Hz or 50 Hz) ± 2 %.

The ranges of atmospheric conditions may be extended for regions with extreme temperatures (or climatic conditions) or high altitude.

4.2. Deviations of the power-supply voltage should not exceed the values indicated in the manufacturer's manual.

4.3. Before the electrocardiographs are verified, they and the measuring instruments required for verification should be assembled according to the requirements of the national metrological service or other officially authorized organizations. Measuring instruments used during verification should be checked by authorized personnel.

5. Verification

5.1. External examination

External examination includes a check that the manufacturer's manual, which should provide the necessary information on the electrocardiograph, is available and includes the following:
— values of commonly accepted characteristics, their tolerance limits and procedures for their determination,
— diagrams and construction details necessary for carrying out verification procedures,
— operating and maintenance instructions,
— instructions for special medical applications.

External examination includes checks for:
— absence of corrosion and mechanical damage,
— freedom from any trace of deterioration of the lead cables,
— required colour coding and identification of the patient cable in accordance with IEC draft Publication "Performance requirements for single-channel and multichannel electrocardiographs". (See Appendix 1).

5.2. Testing

The electrocardiograph shall be tested after the warm-up period specified by the manufacturer.

The testing shall include checks for the presence and deflection of the recording trace, the capability of establishing a recording speed [(*)], the availability of an internal calibration signal and the operation of the sensitivity switch.

The patient cable recommended by the manufacturer shall be used for all applicable tests.

[(*)] When the electrocardiograph has an intermediate memory for information storage for subsequent recording at the same or different speed, it may be more accurate to use the term "time base" instead of "recording speed".

5.3. Determination of metrological characteristics

To determine the metrological characteristics, each measurement shall be repeated at least three times and each of the measured values shall lie within specified limits. Measurements shall be repeated for each channel of the electrocardiograph. Unless otherwise stated, the lead selector or programme shall be set so as to apply an input test signal to each channel simultaneously. The recorded output shall be measured in a way that excludes the effect of the trace line width (see Figure 11).

The limiting values of error include both the errors of the EUT [*] and of the reference instruments.

For those instruments for which the manufacturer specifies values and ranges that are different from those indicated in this Recommendation the tests shall be made according to claimed performance.

5.3.1. Determination of relative voltage-measurement error

Definition: The relative voltage-measurement error is the difference between the voltage recorded by an electrocardiograph and the voltage applied to its input (whose reference value is taken as a conventional true value) divided by the input voltage.

Method of measurement: The relative voltage-measurement error shall be determined directly by measuring the amplitude of the square-wave signal recorded, dividing it by the sensitivity-setting and comparing the result with the amplitude of the input voltage as determined by the reference voltmeter (conventional true value).

Measurement circuit: The measurement set-up is shown in Figure 1.

Measurement procedure: The recording speed is set at 50mm/s. The lead selector or programme is set to each available position in turn. P1 and P2 are connected to the patient cable as specified in Table 3. Switch S1 is set at position 2 (Z1 in circuit). Switch S2 is set at position 3 and generator G2 is set at a frequency of 10 Hz. The sensitivity and the peak-to-peak amplitude of the input square-wave signal are set as specified in Table 4. For each value of the input signal indicated in Table 4 the peak-to-peak amplitude of the recorded signal is measured. Then the measurements are repeated with the switch S2 in positions 1 and 2 in turn which applies a DC voltage of ± 300 mV to simulate the maximum value of electrode polarization.

Table 3

Positions of the lead selector and connection of electrodes
while determining the measurement errors of voltage and input resistance

Leads designed for measurements	Leads with zero deviation	Lead electrode connected to P1	Lead electrode connected to P2
I, II, aVR, aVL, aVF	III	R	all others
I, III, aVR, aVL, aVF	II	L	
II, III, aVR, aVL, aVF	I	F	
$V_1 - V_6$	I, II, III	C_i	

[*] Equipment under test.

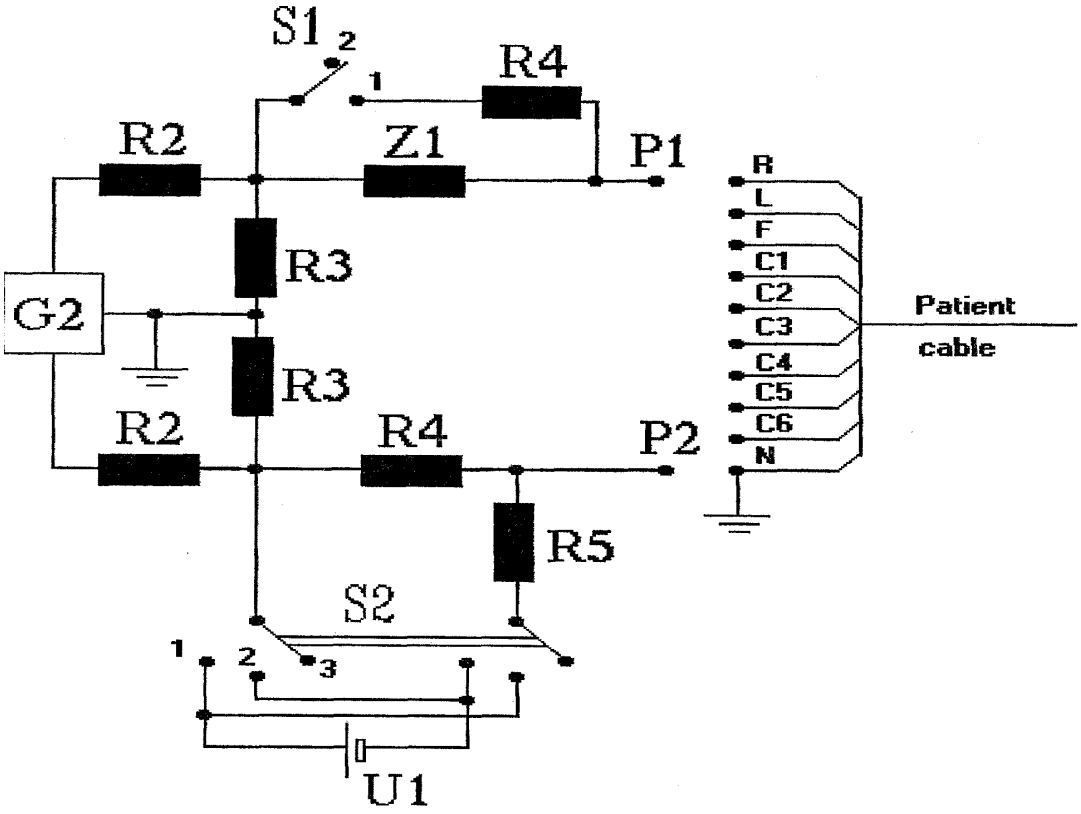

Figure 1

Measurement set-up for determining the relative voltage-measurement error, time constant and overshoot, the relative time-interval measurement error, the relative errors of the internal calibrator and time marker.

Table 4

Sensitivity-setting and input-signal voltage for determining the relative voltage-measurement error

Input voltage (at the divider D1 output) mV (peak-to-peak)			Sensitivity-setting mm/mV
0.4	2	4	5
0.2	1	2	10
0.1	0.5	1	20

Calculation: The relative voltage measurement error, in percent, shall be calculated by the following formula:

$$\delta_u = \frac{U_m - U_{in}}{U_{in}} \cdot 100 \qquad (1)$$

where:

$U_m = h_m/S_n$ is the recorded peak-to-peak voltage, in mV,
h_m is the peak-to-peak amplitude of the recorded output signal, in mm,
S_n is the nominal value of the sensitivity-setting, in mm/mV,
U_{in} is the peak-to-peak amplitude of the input voltage, in mV.

Requirement: For the signal recorded with and without constant DC voltage, the error given by formula (1) shall not exceed the value:

$$10\ (1 + U_1 / U_{in}) \qquad (2)$$

where:

U_1 is the lowest value of the voltage measurement range, i.e. 0.1 mV.

5.3.2. Determination of relative sensitivity-setting error

Definition: The relative sensitivity-setting error is the difference between the measured and nominal values of the sensitivity, divided by the nominal value.

Method of measurement: The relative sensitivity setting error shall be determined directly by measuring the peak-to-peak amplitude of the recorded sine-wave signal and of the stimulus, calculating the value of sensitivity and comparing it with the nominal value.

Measurement circuit: The measurement set-up is shown in Figure 2.

Measurement procedure: The lead selector is set at position $V_1 - V_6$. The .recording speed is set at 50 mm/s and the sensitivity is set at 20 mm/mV. A sine-wave signal from generator G1 and voltage divider D1 with a peak-to-peak amplitude of 1 mV and a frequency of 10 Hz is applied to the input. The recorded signal amplitude is measured. The measurements are repeated for sensitivities of 10 mm/mV and 5 mm/mV and for input signals with peak-to-peak amplitudes of 2 mV and 4 mV respectively.

Calculation: The relative sensitivity-setting error (in percent) shall be calculated by the following formula:

$$\delta_S = \frac{S_m - S_n}{S_n} \cdot 100 \qquad (3)$$

where:

$S_m = h_m/U_{in}$ is the measured sensitivity value, in mm/mV,

h_m is the recorded signal peak-to-peak amplitude, in mm,

U_{in} is the input peak-to-peak amplitude, in mV,

S_n is the nominal sensitivity value, in mm/mV.

Requirement: The relative sensitivity setting error as determined by formula (3) shall not exceed ± 5 %.

5.3.3. Determination of relative time-interval measurement error

Definition: The relative time-interval measurement error is the difference between the recorded and conventional true values of the input signal period, divided by the latter.

Method of measurement: The relative time-interval measurement error shall be determined directly by measuring the period (linear length) of the recorded square-wave signal, dividing it by the nominal recording speed and comparing it with the reciprocal of the input frequency.

Measurement circuit: The measurement set-up is shown in Figure 1.

Measurement procedure: The switches S1 and S2 are set at positions 2 and 3 respectively. The lead selector is set at V_1 — V_6. The sensitivity is set at 10 mm/mV. A square-wave signal from generator G2, voltage divider D1 and the simulated patient skin-electrode impedance Z1 with a peak-to-peak amplitude of 1 mV is applied to the input. The frequency of generator G2 and the recording speed are set as specified in Table 5. The linear dimensions of the recorded signal are measured for three cycles.

Table 5

Generator G2 frequencies to be set and time intervals to be measured

Time intervals to be measured, s	3.84	1.92	0.96	0.48	0.48	0.24	0.12	0.06
Generator G2 frequency, Hz	0.78	1.56	3.12	6.25	6.25	12.5	25	50
Recording speed, mm/s	25				50			

Calculation: The relative time-interval measurement error, in percent, shall be calculated by the following formula:

$$\delta_T = \frac{T_m - T_{in}}{T_{in}} \cdot 100 \qquad (4)$$

where:

$T_m = L_m/V_n$ is the measured time interval, in s,

L_m is the length of 3 cycles, in mm,

V_n is the recording speed, in mm/s,

T_{in} is the time interval corresponding to 3 cycles of the input signal, in s.

Requirement: The relative time-interval measurement error as determined by formula (4) shall not exceed the value:

$$10 (1 + T_1 - T_{in}) \qquad (5)$$

where:

T_1 is the lower limit of the time-interval measurement range, equal to 0.06 s.

5.3.4. Determination of relative error of the recording speed

Definition: The relative error of the recording speed is the difference between the measured recording speed value and the nominal value, divided by the nominal value.

Method of measurement: The relative error of the recording speed shall be determined directly by measuring the recorded sine-wave signal period, calculating the value of the recording speed from the generator frequency, and comparing it with the nominal value.

Measurement circuit: The measurement set-up is shown in Figure 2.

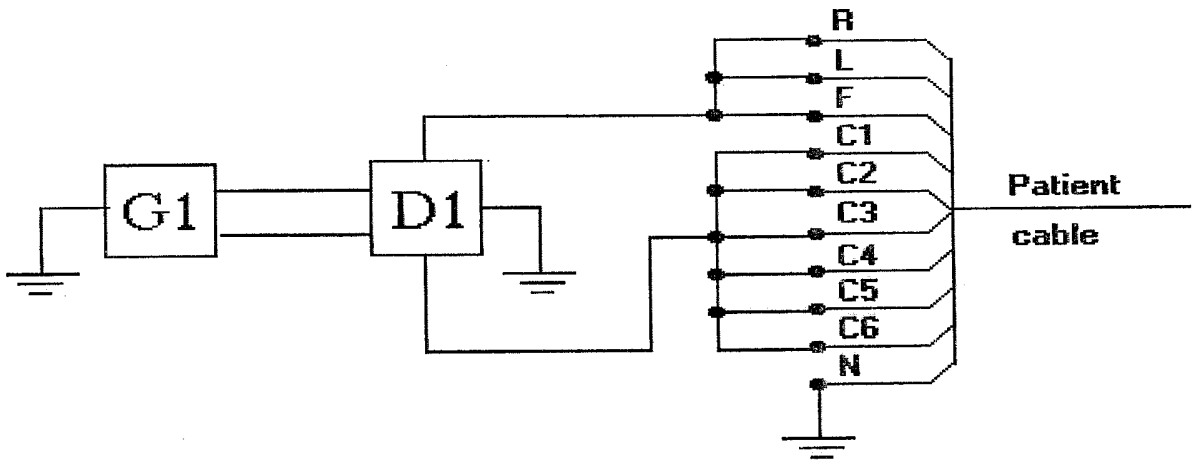

Figure 2

Measurement set-up for determining the relative sensitivity-setting error,
the relative error of the recording speed, and the amplitude-frequency response curve

Measurement procedure: The sensitivity is set at 10 mm/mV and the lead selector is set at position $V_1 - V_6$. A sine-wave signal from generator G1 and divider D1 with a peak-to-peak amplitude of 1 mV and a frequency of 10 Hz is applied to the input. Measurements are made at recording speeds of 25 mm/s and 50 mm/s and each additional recording speed provided on the device. The frequency of generator G1's input signal is chosen so as to obtain a period on the recorded output of not less than 1 mm. At least ten cycles are recorded for each recording speed.

Calculation: The relative error of the recording speed, in percent, shall be calculated by the following formula:

$$\delta_v = \frac{V_m - V_n}{V_n} \cdot 100 \qquad (6)$$

where:

$V_m = L_m/nT_e$ is the measured value of the recording speed, in mm/s,

L_m is the length of the section recorded for n cycles ($n \geq 10$), in mm,

T_e is the period of the input signal as set by G1, in s,

V_n is the nominal value of the recording speed, in mm/s.

Requirement: The relative error of the recording speed as determined by formula (6) shall not exceed ± 5 %.

5.3.5. Determination of recording hysteresis

Definition: The recording hysteresis or reversibility of indication is the distance between the base lines of a trace obtained, respectively, after a positive and a negative input signal is returned to zero (see Figure 3).

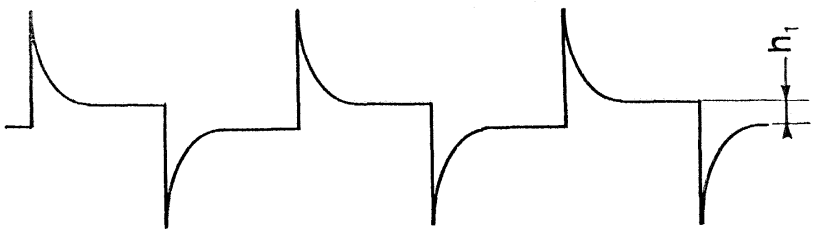

Figure 3

Determination of recording hysteresis

Method of measurement: The recording hysteresis shall be determined directly by measuring the distance between the base lines obtained respectively after a positive and a negative input signal is returned to zero.

Measurement circuit: The measurement set-up is shown in Figure 4.

Measurement procedure: For the determination of the recording hysteresis, a differentiating circuit with the time constant equal to 50 ms (e.g. R6 = 100 kΩ, C2 = 0.5 μF), is connected between voltage divider D1 and the input. The sensitivity is set at 10 mm/mV, and the recording speed is set at 25 mm/s. The lead selector is set at position $V_1 - V_6$. A differentiated signal of 1.5 mV and 1 Hz is applied to the electrocardiograph input.

Requirement: The recording hysteresis hi shall not exceed 0.5 mm.

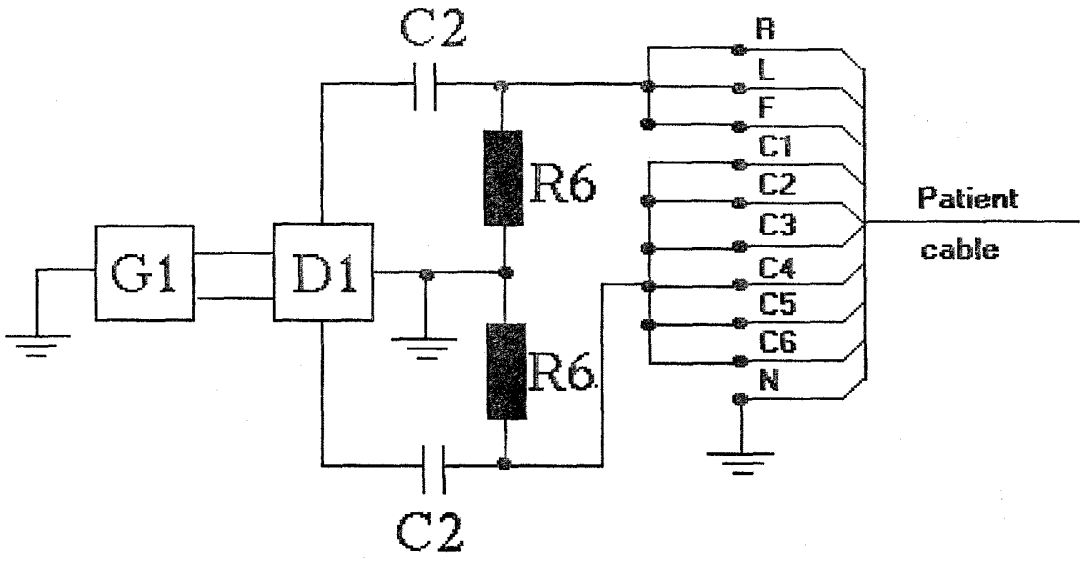

Figure 4

Measurement set-up for determining the recording hysteresis

5.3.6. Determination of relative errors of the internal calibrator and time marker

Definition: The relative error of the internal calibrator or of the time marker is the difference between the nominal and measured values of voltage output of the internal calibrator or of time interval of the time marker divided by their respective nominal values.

Method of measurement: The relative errors of the internal calibrator and of the time marker shall be determined by comparing the voltage and time interval nominal values of the internal signals of the instrument with the amplitude and time interval of a signal applied to the input, the recorded value of the signal being made equal to the recorded internal value.

Measurement circuit: The measurement set-up is shown in Figure 1.

Measurement procedure: Switches S1 and S2 are set at positions 1 and 3 respectively. The lead selector is set at the position which allows recording of the electrocardiograph's internal 1 mV calibration signal. The sensitivity is set at 10 mm/mV and the recording speed is set at 50 mm/s. Signals are recorded from the internal calibrator and time marker. Then the lead selector is set at position $V_1 - V_6$. A square wave signal from generator G2 and voltage divider D1 with a peak-to-peak amplitude of 1 mV and a duration of 1 s is applied to the input. The amplitude and period of the input are then set so that the linear dimensions of the recorded outputs from the internal calibrator and time marker are equal, in amplitude and period respectively, to the amplitude and period of the recorded signals induced by generator G2.

Calculation: The relative internal calibrator error, in percent, shall be calculated by the following formula:

$$\delta_{U_C} = \frac{U_{cm} - U_{cn}}{U_{cn}} \cdot 100 \qquad (7)$$

where:

U_{cm} is the measured value of the internal calibrator voltage, in mV,

U_{cn} is the nominal value of the internal calibrator voltage, in mV.

The relative time-marker error, in percent, shall be calculated by the following formula:

$$\delta_{T_C} = \frac{T_{cm} - T_{cn}}{T_{cn}} \cdot 100 \qquad (8)$$

where:

T_{cm} is the measured value of the time-marker interval, in s,

T_{cn} is the nominal value of the time-marker interval, in s.

Requirement: The relative internal calibrator error and the relative time-marker error as determined respectively by formulae (7) and (8) shall not exceed ± 5 %.

5.3.7. Determination of overshoot

Definition: The overshoot is the difference between the maximum peak-to-peak amplitude of a recorded square-wave signal and its minimum value divided by twice the minimum value (see Figure 5).

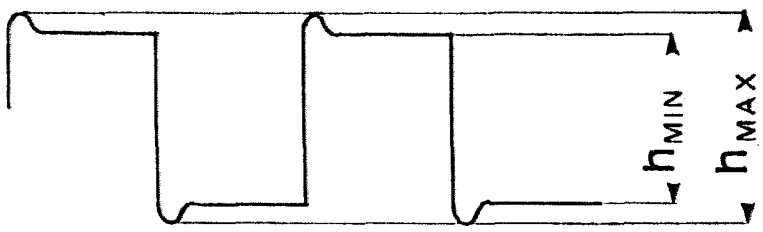

Figure 5
Determination of overshoot

Method of measurement: The overshoot shall be determined directly by measuring the peak-to-peak amplitude of the recorded square-wave signal.

Measurement circuit: The measurement set-up is shown in Figure 1.

Measurement procedure: Switches S1 and S2 are set at position 1 and 3 respectively. The lead selector is set at position $V_1 - V_6$. The sensitivity is set at 10 mm/mV and the recording speed is set at 50 mm/s. A square-wave signal from generator G2 and voltage divider D1 with a peak-to-peak amplitude of 1 mV and a frequency of 10 Hz is applied to the electrocardiograph input. At least 3 cycles are recorded, and the maximum and minimum peak-to-peak amplitude of each cycle is measured.

Calculation: The overshoot, in percent, shall be calculated by the following formula:

$$\delta_o = \frac{h_{max} - h_{min}}{2\, h_{min}} \cdot 100 \qquad (9)$$

where:

h_{max} and h_{min} are the measured values of the maximum and minimum peak-to-peak amplitudes respectively of each cycle recorded, in mm.

Requirement: The overshoot as determined by formula (9) shall not exceed 10 %.

5.3.8. Determination of time constant

Definition: The electrocardiograph time constant is defined as the time required for a recorded square-wave signal amplitude to decay to 1/e (37 %) of its initial value (see Figure 6).

Method of measurement: The time constant shall be determined directly by measuring the linear dimensions of the decay of the recorded square-wave signal following the overshoot.

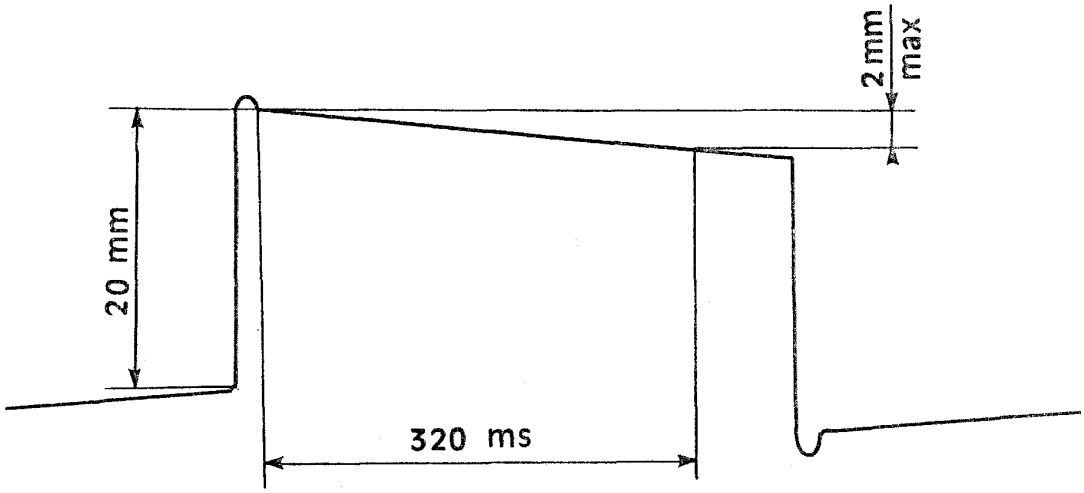

Figure 6
Determination of time constant

Measurement circuit: The measurement set-up is shown in Figure 1.

Measurement procedure: Switches S1 and S2 are set at positions 1 and 3 respectively. The lead selector is set at position $V_1 - V_6$. The sensitivity is set at 10 mm/mV and the recording speed is set at 50 mm/s. A square-wave signal from generator G2 and voltage divider D1 with a peak-to-peak amplitude of 2 mV and a frequency of 1.25 Hz is applied to the input. Decay of the recorded signal is measured for 320 ms, starting at the end of overshoot.

Requirement: The decay of the recorded square-wave signal for 320 ms shall be less than 2 mm (i.e. 200 μV), which corresponds to requiring a time constant greater than 3.2 s.

5.3.9. Determination of the amplitude-frequency response curve

Definition: The amplitude-frequency response curve is the variation with frequency of the recorded output signal amplitude, the input signal amplitude being constant.

Method of measurement: The amplitude-frequency response curve shall be determined directly by measuring the peak-to-peak amplitude of the sine-wave signal recorded at different frequencies, at a constant input amplitude.

Measurement circuit: The measurement set-up is shown in Figure 2.

Measurement procedure: The sensitivity is set at 10 mm/mV and the recording speed is set at 25 mm/s for frequencies below 10 Hz and 50 mm/s for all other frequencies. The lead selector is set at position $V_1 - V_6$. A sine-wave signal from generator G1 and voltage divider D1 with peak-to-peak amplitude of 1 mV (held constant) is applied to the input, successively at frequencies of 0.5, 1.5, 5, 10, 30, 60 and 75 Hz (or 100 Hz if specified by the manufacturer). The recorded signal peak-to-peak amplitude is measured.

The entire amplitude-frequency characteristics of the electrocardiograph up to 200 Hz (or 300 Hz) should be provided in the manufacturer's manual.

Requirement: The peak-to-peak amplitude of the signals recorded at different frequencies relative to the peak-to-peak amplitude of a signal recorded at 10 Hz (in percent) shall be as follows:

a) from 0.5 Hz to 60 Hz: between 90 % and 105 %,

b) from 60 Hz to 75 Hz (or 60Hz to 100 Hz): between 70 % and 105 %.

The frequency range between 75 Hz and 200 Hz (or 100 Hz and 500 Hz) shall be checked to confirm that the frequency response curve rolls off smoothly and has no prominent resonances. The relative output amplitude shall not exceed 110 % of the amplitude at 50 Hz.

5.3.10. Determination of input impedance

Definition: The input impedance is an impedance measured between one patient lead and all others connected together.

Method of measurement: The input impedance shall be determined by comparing recorded sine-wave signal peak-to-peak amplitudes, with and without fixed impedance connected in series with the input.

Measurement circuit: The measurement set-up is shown in Figure 7.

Measurement procedure: The sensitivity is set at 5 mm/mV and the recording speed is set at 25 mm/s. A sine-wave signal from generator G1 and voltage divider D1 with a peak-to-peak amplitude of 2 mV and frequencies of 0.5 Hz, 10 Hz and 75 Hz (100 Hz) is applied in turn to the input. Switches S1 and S2 are set at positions 1 and 3 respectively, and the recording length is at least 25 mm. The recorded signal peak-to-peak amplitude is measured. Then the measurement is repeated with S1 at position 2. The measurements are made for all connections of the points P1 and P2 and associated positions of the lead selector as specified in Table 6. The measurements are repeated in presence of a D.C. voltage ± 300 mV, with S2 at positions 1 and 2 in turn.

Table 6

Input and lead-selector connections with points P1 and P2

Position of the lead selector	Lead electrode connected to P1	Lead electrode connected to P2
I	L	R and all others
II	F	R ″
III	F	L ″
aVR	R	L, F ″
aVL	L	R, F ″
aVF	F	L, R ″
V	C	L, R, F ″
$V_{i\ (i=1-6)}$	$C_{i\ (i=1-6)}$	L, R, F ″
x, y, z	A, C, F, M	I, E, H ″

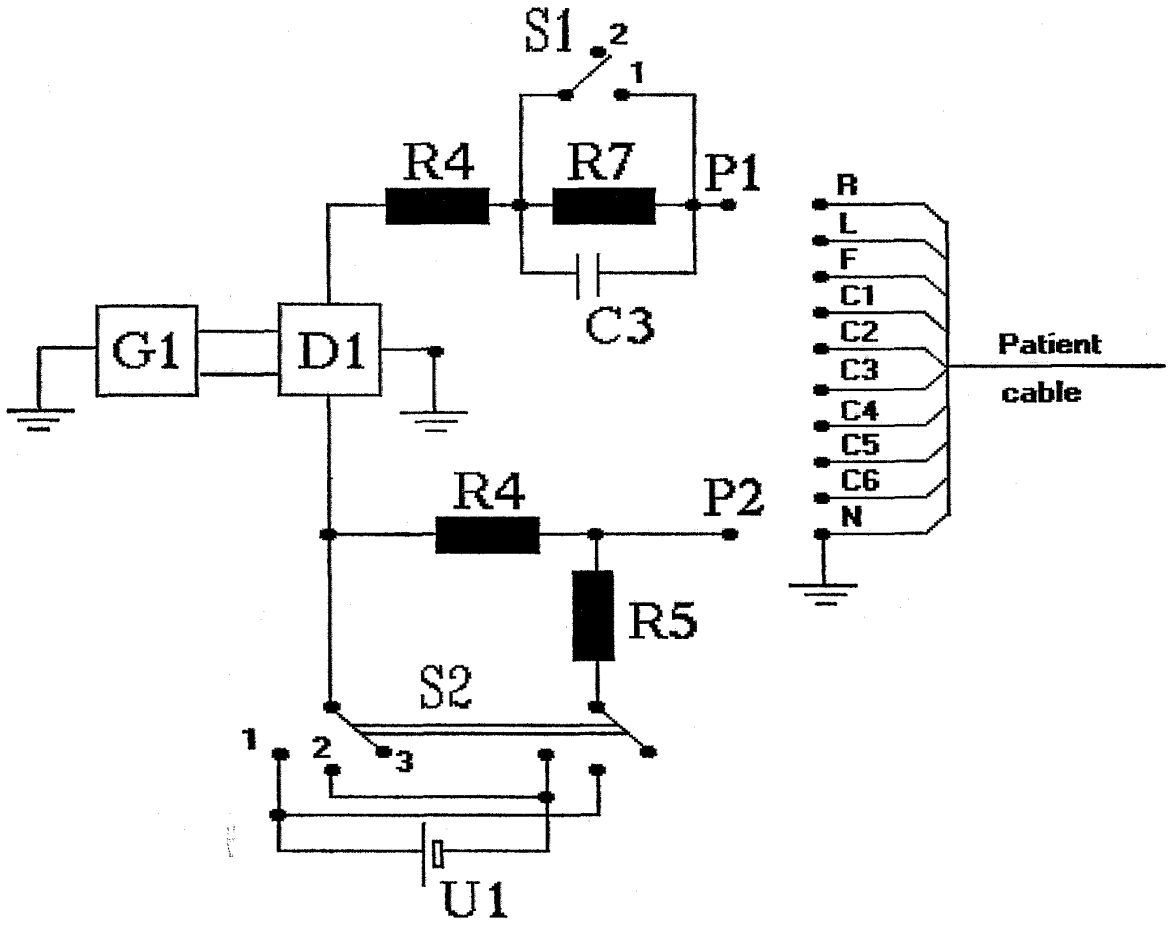

Figure 7
Measurement set-up for determining the input impedance

Calculation: The input impedance, in MΩ, shall be calculated by the following formula:

$$Z_{in} = Z_2 \frac{h_2}{2h_1 - h_2} \quad (10)$$

where:

h_1 is the peak-to-peak amplitude, recorded with S1 at position 1, in mm,

h_2 is the peak-to-peak amplitude with S1 at position 2, in mm,

Z_2 (R7 and C3 are connected in parallel) is the impedance connected in series with the input, in MΩ.

Requirement: The input impedance as determined by formula (10) shall be greater than 2.5 MΩ.

5.3.11. Determination of recorded-voltage error introduced by the weighting networks

Definition: The recorded-voltage error introduced by the weighting networks is the difference between the maximum and minimum amplitudes of the sine-wave signals recorded on different leads.

Method of measurement: The recorded-voltage error due to the weighting networks shall be determined directly by measuring the peak-to-peak amplitude of the recorded sine-wave signal.

Measurement circuit : The measurement set-up is shown in Figure 8.

Measurement procedure: The sensitivity is set at 10 mm/mV and the recording speed is set at 50 mm/s. Inputs R, L, F, C1, C2, C3 are successively connected to P1 in each of the configurations listed in Tables 7a and 7b. All other inputs are connected to the neutral electrode.

The base line control is adjusted so as to record the signal in the centre of the recording channel. A sine-wave signal from generator G1, voltage divider D1 and simulated skin-electrode impedance Z1 with a frequency of 10 Hz and amplitudes corresponding to the values listed in Tables 7a and 7b is applied to the input.

Requirement: The amplitudes of the recorded peak-to-peak signal shall be within the range of values indicated in Table 7a (Goldberger and Wilson) and 7b (Frank) as appropriate.

Table 7a.

Weighting networks for Goldberger and Wilson leads [*]

Lead selector position	Test condition	Input voltage (peak-to-peak) mV	Lead electrode connected to P1	Lead electrode connected to P2
aVR	normal	2	R	L, F
aVR	modified	4	L	R,F
aVL	normal	2	L	F, R
aVL	modified	4	F	R, L
aVF	normal	2	F	L, R
aVF	modified	4	F	L, F
V1	normal	2	C1	L, R, F
V1	modified	6	L	C1, R, F
V2	normal	2	C2	L, R, F
V2	modified	6	R	C2, L, F
V3	normal	2	C3	L, R, F
V3	modified	6	F	C3, L, R

[*] For all lead-selector positions the peak-to-peak amplitude of the signal shall be between 18 mm and 22 mm, and the amplitude resulting from substracting the normal from the modified lead-signal peak-to-peak amplitude shall not exceed 1 mm.

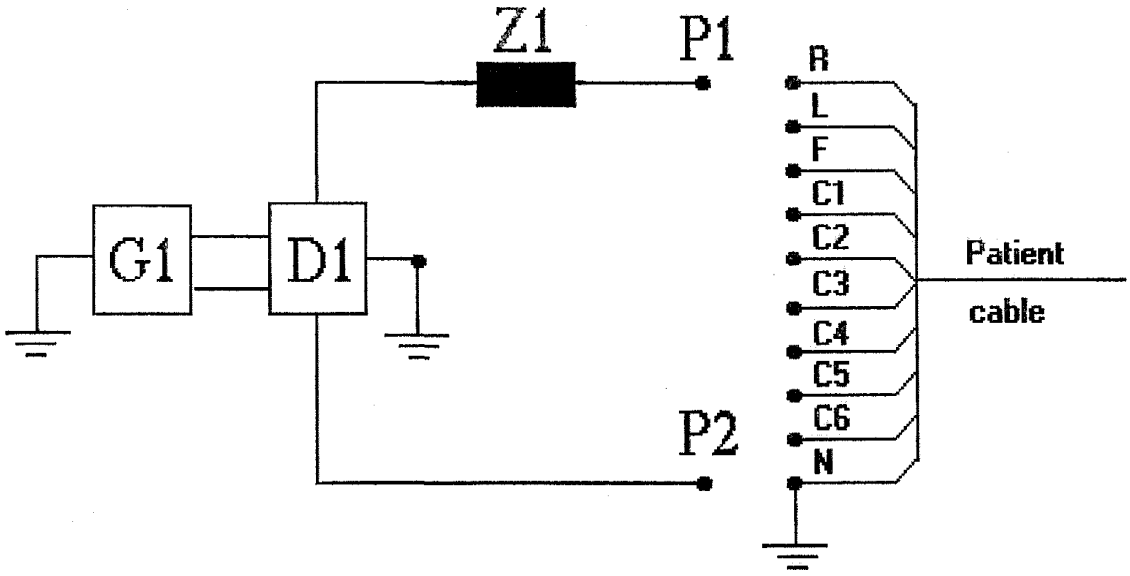

Figure 8

Measurement set-up for determining the recorded-voltage error introduced by the weighting networks

Table 7b

Weighting networks for Frank Leads (*)

Output lead connected	Input voltage (peak-to-peak) in mV	Lead electrodes connected to P1	Lead electrodes connected to P2	Allowable peak-to-peak amplitude in mm
V_x V_y V_Y	2	A, C, F, M	I, E	14-17 18-22 11-14
V_x V_y V_z	4	A	I, E, C, M, H, F	22-27 0-2 5-6
V_x V_y V_z	10	C	I, E, A, M, H, F	15-19 0-3 21-25.5
V_x V_y V_z	6	E	I, C, A, M, H, F	0-2 0-2 21-24
V_x V_y V_z	4	A,F	I, E, C, M, H	22-27 24-29 5-6
V_x V_y V_Z	3	I	E, C, A, M, H, F	21-26 0-2 7-8.5
V_x V_y V_z	3	M	I, E, C, A, H, F	0-2 9-11.5 20-24
V_x V_y V_z	2	H	I, E, C, A, M, F	0-1 18-22 0-1

(*) Symbols in this Table are explained in Appendix 2.

5.3.12. Determination of common-mode rejection ratio

Definition: The common-mode rejection ratio is the ratio of the peak-to-peak amplitude of an in-phase signal applied at the input of the EUT to the peak-to-peak amplitude of the usual out-of phase signal that results in the same peak-to-peak amplitude of the recorded signal.

Method of measurement: The common-mode rejection ratio shall be determined indirectly by measuring the peak-to-peak amplitude of the signal recorded by the EUT, when a sine-wave signal with a frequency of 50 Hz or 60 Hz and of a given amplitude is applied in common mode (between input and ground or earth).

Measurement circuit: The measurement set-up is shown in Figure 9.

Measurement procedure: The sensitivity is set at 10 mm/mV, and the recording speed is set at 25 mm/s. The voltage of generator G1 is set at 20 V RMS with a frequency of 50 Hz or 60 Hz. Capacitor C_T is adjusted so that the voltage at point A with respect to ground (earth) is equal to 10 V RMS with the patient cable disconnected from the test circuit. After reconnecting the patient cable, the recorded signal amplitudes are measured for all leads specified in Table 3. The measurements are repeated in the presence of a D.C. voltage ± 300 mV (with S set at positions 1 and 2, in turn).

Calculation: The common-mode rejection ratio shall be calculated by the following formula:

$$K = \frac{U_A}{h} \cdot S_n \cdot 10^3 \qquad (11)$$

where:

h is the recorded signal amplitude, in mm,

S_n is the nominal value of the sensitivity setting, in mm/mV,

U_A is the peak-to-peak amplitude of the input voltage at point A, in volts.

Requirement: The common-mode rejection ratio as determined by the formula (11) shall not be less than 2.8×10^4 for each channel.

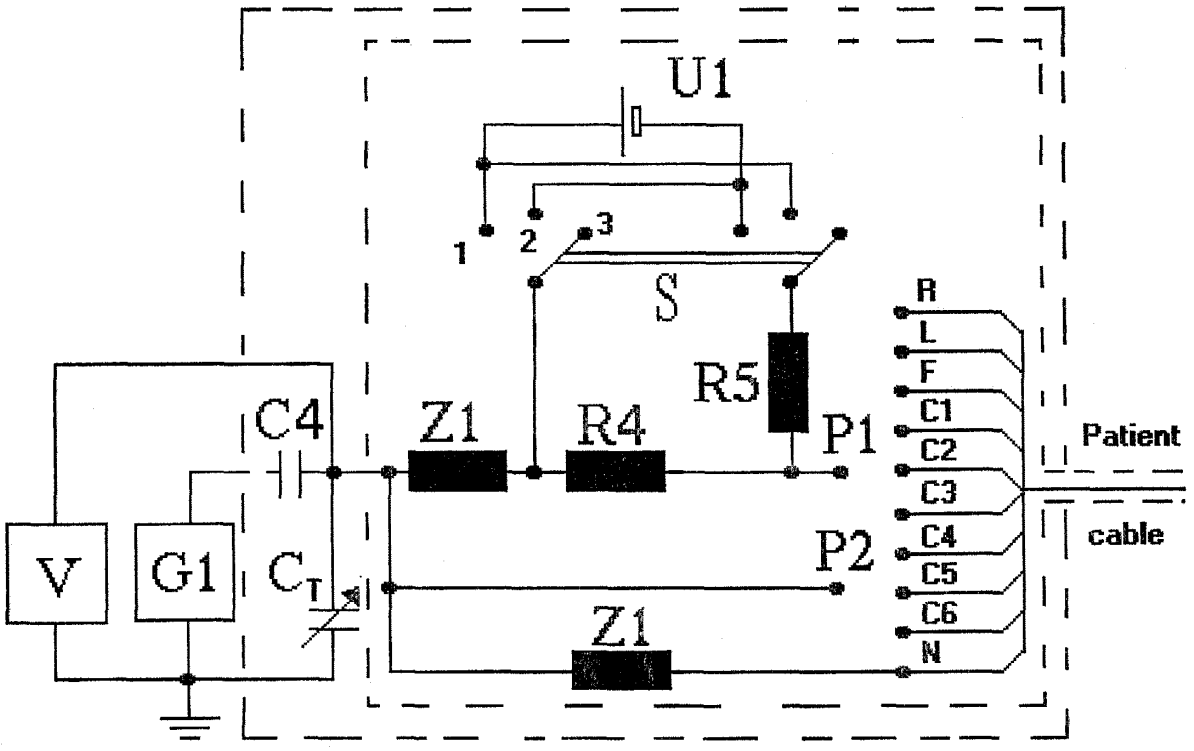

Figure 9

Measurement set-up for determining common-mode rejection ratio

5.3.13. Determination of baseline width

Definition: The baseline width is the width of the line on the recording medium with the input terminals of the EUT connected to neutral.

Method of measurement: The baseline width shall be determined directly by measuring it perpendicular to the trace (Figure 10).

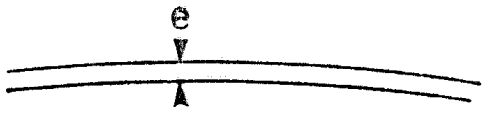

Figure 10
Determination of the baseline width

Measurement procedure: The sensitivity is set at 5 mm/mV and the recording speed is set at 25 mm/s. With the lead selector at any position a trace is produced for 10 s. The width of the recorded line is measured.

Requirement: The baseline width shall not exceed 1 mm.

5.3.14. Determination of baseline drift

Definition: The baseline drift is the deviation of the baseline during a given time interval with the input of the EUT connected to neutral (Figure 11).

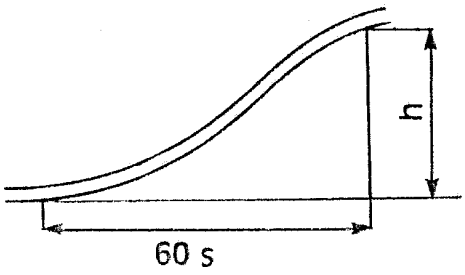

Figure11

Determination of the baseline drift

Method of measurement: The baseline drift shall be determined directly by measuring the baseline deviation during the time interval of 60 s.

Measurement procedure: The sensitivity is set at 20 mm/mV, and the recording speed is set at 25 mm/s. The lead selector is set at any position. After an initial warm-up period of 1 min, the deviation of the baseline is measured during 60 s.

Requirement: The baseline drift during 60 s shall not exceed 5 mm.

5.3.15. Determination of intrinsic noise level referred to the input

Definition: The intrinsic noise level referred to the input is the maximum peak-to-peak amplitude of the signal evaluated for a given time interval and referred to the input, with Z1 connected to the electrocardiograph inputs.

Method of measurement: The intrinsic noise level referred to the input shall be determined directly by measuring the maximum peak-to-peak amplitude of the signal recorded for a time interval of 10 s and referred to the input by dividing it by the sensitivity setting (Figure 12).

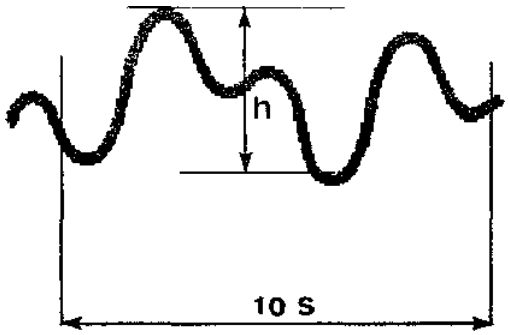

Figure 12

Determination of the intrinsic noise level referred to the input

Measurement circuit: The measurement set-up is shown in Figure 13.

Measurement procedure: The sensitivity is set at 20 mm/mV, and the recording speed is set at 50 mm/s. After impedance Z1 is connected to all inputs, the trace is recorded for 10 seconds for each lead selector position. The linear dimensions of the maximum peak-to-peak amplitude are measured for each recording.

Calculation: The intrinsic noise level referred to the input, in μV, shall be calculated by the following formula:

$$U_n = \frac{h_n}{S_n} \cdot 10^3 \qquad (12)$$

where:

h_n is the maximum peak-to-peak amplitude of noise measured on the recording, in mm,
S_n is the nominal value of the sensibility setting, in mm/mV.

Requirement: The intrinsic noise level referred to the input shall not exceed 35 μV.

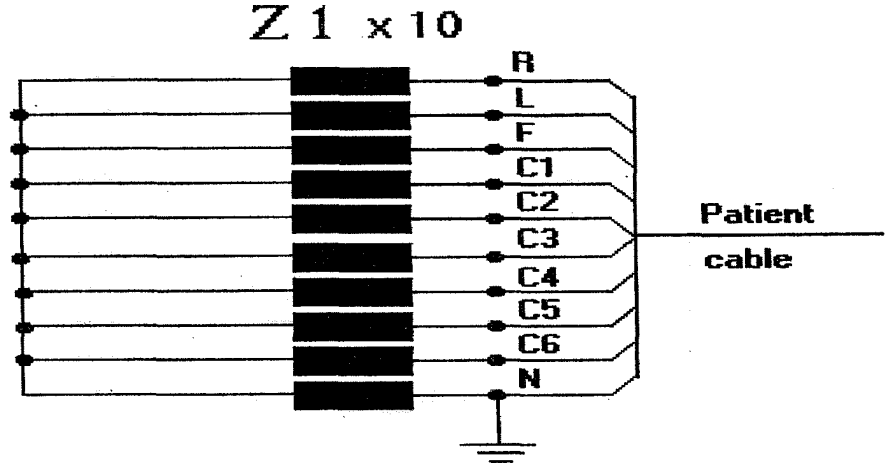

Figure 13

Measurement set-up for determining the intrinsic noise level referred to the input

5.3.16. Determination of interchannel crosstalk coefficient

Definition: The interchannel crosstalk coefficient is the ratio of the peak-to-peak amplitude of the voltage induced on the channel under test to the peak-to-peak amplitude of the voltage applied to all the other channels.

Method of measurement: The interchannel crosstalk coefficient shall be determined by comparing the peak-to-peak amplitude of signals recorded on the channel under test to the peak-to-peak amplitude of signals recorded on all the other channels.

Measurement circuit: The measurement set-up is shown in Figure 14.

Measurement procedure: The sensitivity is set at 10 mm/mV, and the recording speed is set at 25 mm/s. A sine-wave signal from generator G1 and voltage divider D1 with an amplitude of 4 mV and a frequency of 1 Hz and 40 Hz (in turn) is applied to the electrocardiograph inputs. The linear dimensions of signals recorded on the channels under test are measured. The entire measurement procedure is repeated in turn for all leads as specified in Table 8.

Table 8

Combinations of lead selector and lead electrode
to determine the interchannel crosstalk coefficient

Position of the lead selector	Lead electrode connected to P1	Lead electrode connected to P2
I	F, C1	R, L, C2, C3, C4, C5, C6
II	L, C1	R, L, F, C2, C3, C4, C5,C6
III	R, C1	L, F, C2, C3, C4,C5, C6
V2, V3, V4, V5, V6	C1	R, L, F, C2, C3, C4, C5, C6
……..	……	……
V1, V2, V3, V4, V5	C6	R, L, F, C1, C2, C3, C4, C5, C6
V_x , V_y	E	All others

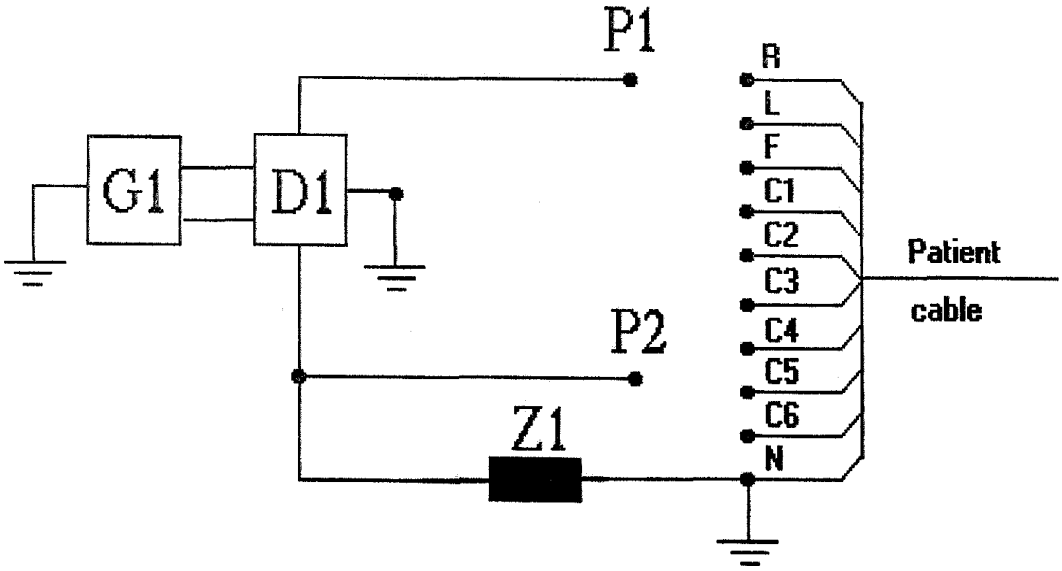

Figure 14

Measurement set-up for determining interchannel crosstalk coefficient

Calculation: The interchannel crosstalk coefficient, in percent, shall be calculated by the following formula:

$$W_i = \frac{h_i}{U_{in} \cdot S_n} \cdot 100 \qquad (13)$$

where:

i = 1,2,... n is the number of the channel under test,
n is the number of channels,
h_i is the peak-to-peak amplitude of the signal induced in the channel under test, in mm,
U_{in} is the peak-to-peak amplitude of the voltage applied to all the other channels, in mV,
S_n is the nominal value of the sensitivity setting, in mm/mV.

Requirement: The interchannel crosstalk coefficient at frequencies 1 Hz and 40 Hz as determined by formula (13) shall not exceed 2 %.

5.4. Determination of current in the patient circuit

Definition: The current in the patient circuit is defined as the current flowing through any lead connected to the patient.

Method of measurement: The current in the patient circuit shall be determined indirectly by measuring the voltage recorded by an electrocardiograph with a series resistor connected to the input and calculating the value of the current.

Measurement circuit: The measurement set-up is shown in Figure 15.

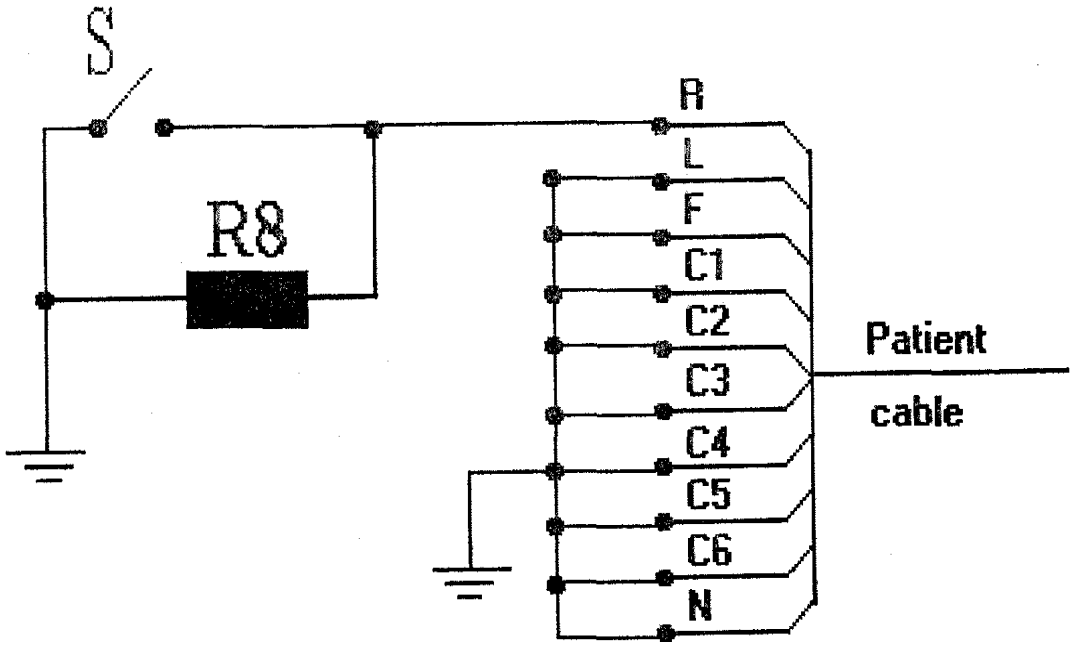

Figure 15

Measurement set-up for determining current in the patient circuit

Measurement procedure: The sensitivity is set at 10 mm/mV, and the recording speed is set at 25 mm/s. The baseline is first recorded, then switch S is opened and the deviation is measured. The measurements are repeated for all positions of the lead selector.

Calculation: The current in the patient circuit, in μA, shall be calculated by the following formula:

$$I = \frac{h}{S_n \cdot r} \qquad (14)$$

where:

h is the height of the recorded step, in mm,
S_n is the sensitivity setting, in mm/mV,
r is the value of the connected resistance, in kΩ.

Requirement: The current in the patient circuit as determined by formula (14) shall not exceed 0.1 μA.

5.5. Protection of the electrocardiograph from the effects of defibrillation of the patients

To verify protection of the electrocardiograph from the effects of defibrillation of the patient, the lead electrodes are connected with P1 and P2 in accordance with Table 9.

Test circuit: The test set-up is shown in Figure 16.

Test procedure: The sensitivity is set at 10 mm/mV and the recording speed is set at 25 mm/s. The switch S1 is initially set at position 1 with the source U2 switched off and switch S2 at position 2. A sine-wave signal from generator Gl through the divider formed by R9 and R1 1 with a frequency of 10 Hz and an amplitude of 1 mV is applied to the input. Then switch S2 is set at position 1 and switch S1 is set at position 2, source U2 is switched on to charge capacitor C5. Then switch S1 is set at position 1 for (200 ± 100) ms to discharge the capacitor across the input circuit. After 15 sec switch S2 is set at position 2 and the signal from generator G1 is recorded again. The test procedure is repeated, the polarity of source U2 having been changed. Circuit elements R12, R13, L, C5, U2 may be replaced in this test by a defibrillator with a voltage of 5 000 V ± 5 %. In performing this test safety rules shall be followed in accordance with the IEC Publication 601 "Particular requirements for safety for cardiac defibrillators and cardiac defibrillator-monitors".

Requirement: The peak-to-peak amplitude of the signal recorded after 5 s shall be at least 80 % of the peak-to-peak amplitude of the initially recorded signal.

Table 9

Position of the lead selector during verification of the protection
of the electrocardiograph from the effects of defibrillation of the patient

	Position of the lead selector	Lead electrode connected to P1	Lead electrode connected to P2
Five-electrode cable	I	L	R, F, N, C
	II	R	L, F, N, C,
	III	F	L, R, N, C
	V	C	L, R, F
	Test status	N	L, R, F, C
	I	All leads	Power ground
Ten-electrode cable	I, II, III	L	All others and the neutral
	I, II, III	R	″
	I, II, III	F	″
	V1, V2, V3	C1, C2, C3	″
	V4, V5, V6	C4, C5, C6	″
	Test status	N	L, R, F, C1, C2 C3, C4, C5, C6
	I	All leads	Power ground
Vector cable	V_x, V_y, V_z	E, C	All others and the neutral
	″ ″ ″	M, H	″
	″ ″ ″	F	″
	″ ″ ″	I	″
	″ ″ ″	A	″
	″ ″ ″	N	All others
	″ ″ ″	All leads	Power ground

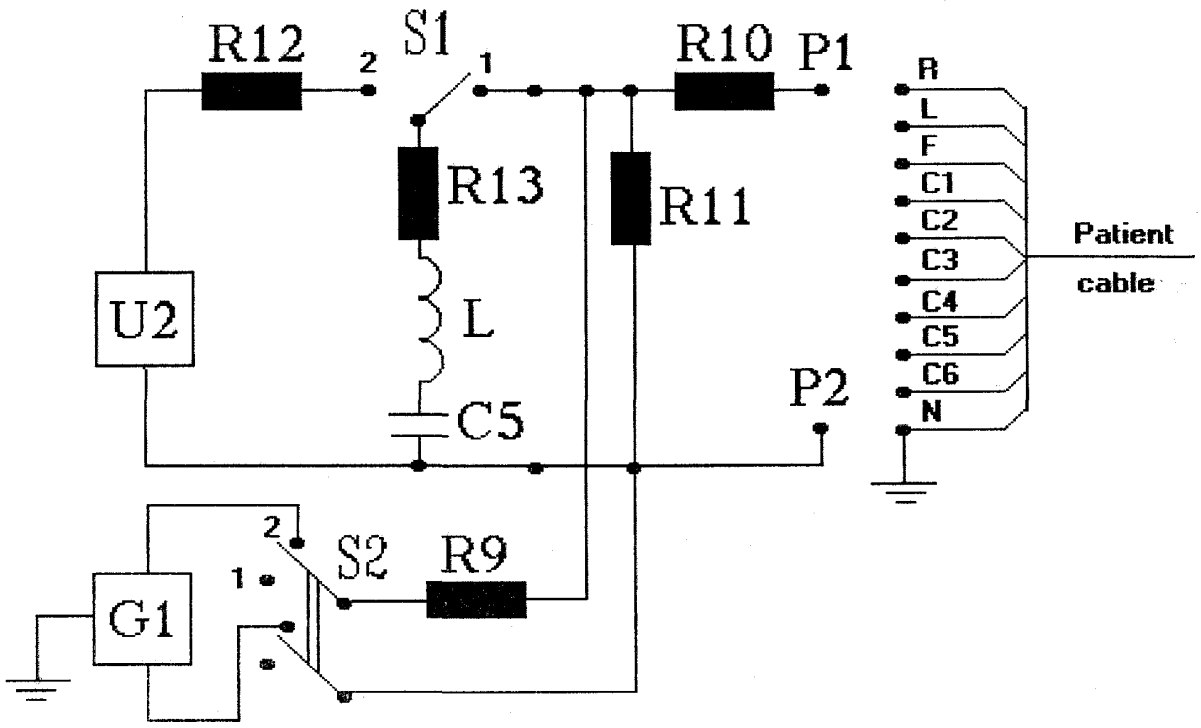

Figure 16

Test set-up for verification of protection of electrocardiograph
from the effects of defibrillation of the patient

Notes:

1. The resistance R13 is chosen to obtain R13 + R_L = 5.6 Ω ± 5 % where R_L is the resistance of inductance L.
2. When a power ground (earth) is not available, P2 should be connected to the metallic chassis of the electrocardiograph. If the chassis is non-conducting, a grounded (earthed) metal foil or a conducting pad may can be used to produce an electrical contact with the electrocardiograph.
3. A cable recommended by the manufacturer shall be used.
4. Switch S1 shall be able to withstand 5 000 V in the open position.

6. Verification report and certificate

6.1. A verification report shall include the following information:
(a) the designation and serial number of the instrument verified,
(b) the country of origin and manufacturer,
(c) the equipment used for verification,
(d) the date of verification,
(e) the references to the applicable regulations and the procedures used,
(f) the measurement results obtained for the various characteristics,
(g) the organizations and persons responsible for verification.

6.2. Electrocardiographs verified in accordance with this International Recommendation may be granted a certificate of verification in accordance with the established laws and regulations of a given country. The certificate shall specify the expiry date of the validity of the verification.

APPENDIX 1

IDENTIFICATION AND COLOUR CODE OF THE PATIENT CABLE

System	Electrode identifier	Colour code	Electrode identifier	Colour code
Limb	R	Red	RA	White
	L	Yellow	LA	Black
	F	Green	LL	Red
Chest according to Wilson	C	White	V	Brown
	C1	White/Red	V1	Brown/Red
	C2	White/Yellow	V2	Brown/Yellow
	C3	White/Green	V3	Brown/Green
	C4	White/Brown	V4	Brown/Blue
	C5	White/Black	V5	Brown/Orange
	C6	White/Violet	V6	Brown/Violet
Position according to Frank	I	Light Blue/Red	I	Orange/Red
	E	Light Blue/Yellow	E	Orange/Yellow
	C	Light Blue/Green	C	Orange/Green
	A	Light Blue/Brown	A	Orange/Brown
	M	Light Blue/Black	M	Orange/Black
	H	Light Blue/Violet	H	Orange/Violet
	F	Green	F	Red
	N	Black	RL	Green

Note: Columns 2 and 3: colour code system used in many European countries.
Columns 4 and 5: colour code system used in some other countries, including the USA.

APPENDIX 2

ELECTRODE POSITION according to FRANK

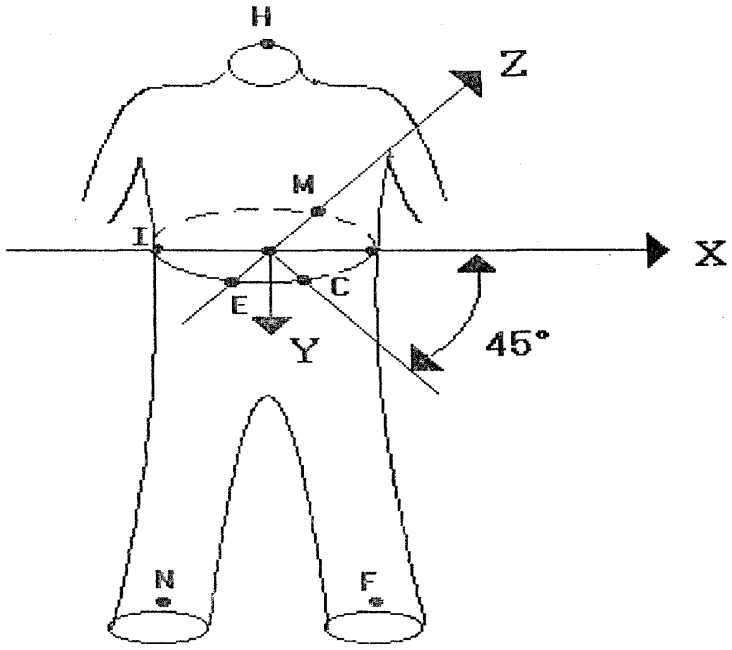

Figure 17
Electrode position according to Frank

TABLE of CONTENTS