STANDARDS FOR VECTORCARDIOGRAPHIC INSTRUMENTS

by
Japanese Circulation Society
and
Japanese Society for Medical Electronics
and Biological Engineering

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1. GENERAL

1.1. Scope of Application

This set of standards deals with the vectorcardiograph as used for clinical diagnosis. The vectorcardiograph projects and records the bioelectric activity of the heart in the form of vector loops which are projected on three mutually orthogonal planes.

1.2. Classification

Vectorcardiographs can be classified into two general types. First, there are those in which the spatial vector loop is projected upon and recorded from only one plane at a time. The choice of plane of projection is under operator control. Second, in other types of instruments all three planar projections can be recorded simultaneously.

1.3. Ambient Conditions

The vectorcardiograph should perform according to specifications under the following range of ambient conditions: temperature 10°~35°C, and relative humidity 45~85 per cent.

1.4. Definition of Terms

The terms used in the standards shall be defined as follows:

- (1) Sensitivity of Recording—The ratio of vertical or horizontal deflection resulting from a given input voltage; for example, 2.5 cm per millivolt, 2.5 cm per 500 microvolts, etc.
- (2) Common Mode Rejection—This is the ability of an amplifier to reject signals which appear on the differential input leads in phase. It is frequently specified as the ratio of response with the input signals in phase to the response amplitude obtained when the same signal is 180° out of phase.
- (3) Planes of Registration: Frontal, Sagittal, and Transverse (horizontal) Planes—Various planar projections are obtained by the following combination of axes: frontal plane by combination of X and Y, sagittal plane by Z and Y, and transverse (or horizontal) plane by X and Z.

2. COMPOSITION AND REQUIREMENTS

2.1. Components

The vectorcardiograph shall consist of patient cable and electrodes, vectorcardiograph amplifiers, and cathode ray tube oscilloscope, with recording camera, hood, timing circuits, gating circuits, etc., as accessories.

2.2. Safety

The vectorcardiogram shall meet the Provisional Safety Standards for Medical Electronics Equipment which deal for the protection of subjects and operator against various potential electrical hazards.

2.3. Overload

After applying a sinusoidal wave of 1.0 V (peak to peak), 50 Hz/60 Hz to vectorcardiograph input for 2 seconds, the instrument must meet the specifications.

2.4. Power Requirements

Rated line voltage and line frequency shall be 100 V, 50 Hz/60 Hz. The operation of the vectorcardiograph shall not be affected by fluctuation of line voltage from 90 V to 110 V.

2.5. Leads

2.5.1. The vectorcardiograph shall be provided with the Frank lead connections which are illustrated in Fig. 1. The standard value of the resistors shall be 100 kilohms or higher. The standard sagittal recording shall be the left, but the right sagittal plane should be available optionally. In addition a selection shall be provided for at least two other lead systems.

Fig. 1.

Polarity required for constructing frontal, sagittal and transverse planes is illustrated in Fig.2. $R = 100\text{ K}\Omega$ or higher

Fig. 2.

Note: It is desirable that the Z-axis scalar ECG be recorded so that anterior precordial potentials produce an upward deflection and thus provide a waveform which is similar to that of V_2 in the precordial leads. However, the transverse and vertical leads shall be recorded so that positivity to the left will produce upward deflection in the X lead and positivity footward will produce upward deflection in the Y lead. In this manner, the X and Y leads will tend to resemble the deflections of leads I and aV_F respectively.

2.5.2. Resistors with a tolerance of 5 per cent or better should be used in forming the voltage dividing network.

Note: 1) A means for checking the values of the resistor network.

would be desirable.

2) It is highly desirable that a buffer amplifier be interposed between each electrode and its corresponding connection to the resistor network.

2.6. Display and Recording Equipment

2.6.1. Cathode ray tube specifications

In both the 3-plane and 1-plane types of vectorcardiograph, the face of the cathode ray tube should be at least 75 mm in diameter. (In the following description the numerical values given will refer to this 75 mm diameter CRT. For larger tube faces, the value should be augmented proportionally).

2.6.2. Monitoring CRT

In case of the 3-plane type vectorcardiograph, a monitoring CRT shall be provided for monitoring one of the X, Y, and Z scalar ECG's by the selector.

2.6.3. Timer Specifications

Selectable time markings shall be provided as indicated below.

- 1) Time marking by intensity modulation of the trace into a series of tear drop or comet shaped dashes shall be incorporated in the vectorcardiographic loop.
- 2) Time marks shall be available according to the following four selections: 10, 5, 2.5 and 1.25 msec.
- 3) The direction of inscription of the loop shall be indicated by the blunt end of the comet or tear drop shaped head; that is to say, the tails of these structures will appear to trail backward in time.
- 4) In regard to the duration of the time pips, the ratio of the on-off intervals will be approximately unity.

2.6.4. Intensity Modulation

Provision should be made for modulating the intensity of the beam so that fast moving and slow moving portions of the trace will be recorded at about the same brightness on the photographic materials which are used for the purpose.

2.6.5. Interval Selection

A trigger and gating mechanism should be provided so that the whole vector loop or any part thereof can be selected for registration. The trigger signal should be derived from the R-wave. Provision for this type of mechanism is especially important in the 3-plane type of vectorcardiograph.

2.7. Sensitivity Control

2.7.1. Fine Sensitivity Control

A fine sensitivity control shall be provided for easily adjusting the amplifier gain within 5 per cent accuracy. In case of 3-plane type, the

difference in gains of the amplifier for three planes shall be held within 5 per cent.

2.7.2. Stepwise Sensitivity Control

A stepwise sensitivity control shall be provided to adjust simultaneously gains of X-, Y- and Z-amplifiers in steps for the standard sensitivity 2 cm/1 mV in the following sequence: 1/4X, 1/2X, 1X, 2X, 4X and 8X.

2.8. Stabilizing Mechanism

A stabilizing mechanism shall be provided to eliminate transient disturbance of the origin within 1 second.

2.9. Calibrator

In order to calibrate the input voltage, calibrating voltage generator circuits shall be provided as specified below.

2.9.1. Calibration voltage shall be available at least in two levels: 1 mV and 200 μ V (peak to peak)

2.9.2. Calibration in horizontal and vertical, or a 45°-inclined direction shall be conducted with calibration voltage waveforms maintaining deflection constantly.

2.10. Position Control

A position control shall be provided to shift the origin of the vector loop to a desired position on CRT.

2.11. External Input Terminal

External input terminals shall be provided for testing the characteristics of X-, Y- and Z-amplifiers.

2.12. Phase Characteristics Checking Circuit

In order to check phase characteristics of the amplifier, a phase characteristics checking circuit shall be provided as specified below. When a sinusoidal signal of 1 Hz or 500 Hz is fed inphase into the inputs of vertical and horizontal amplifiers from the built-in oscillator, a straight line inclining by 45° shall be obtained. This straight line deflection may be used for voltage calibration.

3. OUTPUT TERMINAL

Output terminals shall be provided for easily supplying the output to the magnetic recorder, heat-stylus recorder, etc. The voltage and impedance shall be clearly indicated.

4. ELECTRODES

The electrodes shall be fixed easily or attached securely to the skin. Material must be salt-resistant. Contact area of the electrode shall be 30 mm or less in diameter. For the limb lead, electrodes, refer to the JIS for Electrocardiograph.

Note: 1) It is desirable to provide a means for checking the contact resistance of the electrodes.

2) When no buffer amplifier is provided, rub the skin with paste before fitting electrodes, so that the contact resistance of electrodes is 50 K Ω or less.

5. PERFORMANCE

5.1. Maximum Sensitivity

The maximum sensitivity shall be 160 mm/1 mV or higher.

5.2. Stability

5.2.1. Drift of Origin of Vector Loops

The horizontal and vertical drift in 10 seconds shall be within ± 1 mm from the original point after warming up the instrument for 5 minutes at 100 V line voltage and maximum sensitivity.

5.2.2. Drift of Origin Caused by Fluctuation of Line Voltage

When line voltage is changed by ± 5 V at the maximum sensitivity, the drift of the origin in 10 seconds shall be less than 50 μ V as referred to input.

5.2.3. Deviation of Sensitivity

1. When line voltage is changed ± 10 per cent at the specified voltage, the deviation of sensitivity shall be within ± 10 per cent.
2. When ± 100 mV DC voltage is superimposed on the input signal, the deviation shall be within 5 per cent.
3. When ± 100 mV DC voltage is fed in across two inputs and grounding terminals of the amplifier, the deviation shall be within 5 per cent.

5.3. Linearity

Within the effective area of CRT screen, the deflection of the spot shall be proportional to input voltage with deviation errors less than 5 per cent in both vertical and horizontal directions from the center of the CRT.

5.4. Overall Frequency Characteristics

5.4.1. Sinusoidal Wave Characteristics

The frequency characteristic of the amplifier shall be flat from 1 Hz to 500 Hz within 100 per cent accuracy when referred to standard frequency of 10 Hz.

Note: It is desirable that selectable high cut filters are provided for obtaining 3 dB attenuation at 100 Hz and 30 Hz, or at 30 Hz only.

5.4.2. Time Constant

Time constant shall be 2.0 seconds or longer. Time constants for respective amplifiers shall be equal within 10 per cent accuracy. (For the output terminal, time constant is not specified)

5.4.3. Phase Characteristics

The phase characteristics shall be checked in the procedure given below:

Form an ellipse on the screen using the phase characteristic checking circuit. Trace circle around the longer axis of the ellipse taking it as the diameter of the circle. Draw two straight lines AD and CB that pass the center of the circle at angle of $45^\circ + 3^\circ$ and $45^\circ - 3^\circ$ respectively. Let their intersecting points with the circumference of the circle be A, D, C and B respectively.

The ellipse obtained using the phase characteristic circuit must be included within rectangle ABDC.

Fig. 3 When $r = 30$ mm, EF is 3.1 mm

$$\text{since } EF \approx \frac{\pi r}{30}$$

5.5. Interference among Amplifiers

When 2 mV input voltage is fed into one of amplifiers through the external input terminals, deflection of the other non-signal supplied amplifiers due to interference shall be 20 μ V or less, as referred to input voltage.

5.6. Internal Noise

Noises shall not exceed 10 μ V as referred to input voltage.

5.7. Common Mode Rejection Ratio

Common Mode Rejection Ratio shall be 1000 or more.

5.8. Input Circuit

5.8.1. Input Resistance

The input resistance as seen from an input terminal to the ground

terminal with the other input terminal grounded shall be $5\text{ M}\Omega$ or more.

5.8.2. Input Offset Current

The input offset current of an amplifier shall be $1 \times 10^{-8}\text{ A}$ or less. The input offset current called here shall be the sum of amplifier input current with leakage current from the high voltage power supply.

5.8.3. Calibrator

The allowance of calibration voltage shall be within ± 5 per cent.

5.9. Characteristics of Observing and Recording CRT

The observing and recording CRT shall meet the characteristics specified in the Standards of Electronic Equipment Industries Association MEA-27.

5.10. Leakage

AC voltage due to leakage current across a $100\text{ K}\Omega$ resistor connected between the instrument case and the ground shall be 20 V or less.

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