

JIS

JAPANESE INDUSTRIAL STANDARD

Electrocardiographs

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1. Scope

This Japanese Industrial Standard specifies electrocardiographs for recording type single channel or multi-channel clinical examination to record the cardiac action voltage, hereinafter referred to as the "cardiographs".

Remark: The units and numerical values given in { } in this standard are in accordance with the International System of Units (SI), and are appended for reference.

2. Definitions

Besides in accordance with JIS T 1001, JIS T 1002, JIS T 1003 and JIS T 1004, for the purposes of this standard, the following definitions apply:

- (1) single channel cardiograph Equipment to record the electrocardiogram of single channel.
- (2) multi-channel cardiograph Equipment to record electrocardiograms of induction of several kinds simultaneously.
- (3) induction To induce the cardiac action voltage in order to record the electrocardiogram.
- (4) induction electrode Electrode to be fixed to certain part of living body to detect the cardiac action voltage.
- (5) induction cord Cord to connect the induction electrode with the cardiograph.
- (6) induction selector Change-over switch to select arbitrary induction.
- (7) input circuit This means a circuit from induction cord to amplifier of cardiograph, inclusive of high frequency illuminating filter, protective circuit, buffer amplifier, inductive network etc.
- (8) input circuit current Leakage current which flows between input circuit and right foot terminal.
- (9) reference voltage Square wave voltage to be applied for calibration, at the time to record electrocardiogram.

Applicable Standards: See page 24.

- (10) recording sensitivity Sensitivity of cardiograph expressed by the magnitude of deflection indicated on the recording paper, divided by the input voltage. The unit shall be mm/mV.
- (11) reference sensitivity Sensitivity of cardiograph which can make a record of 10 mm amplitude when a reference voltage of 1 mV is applied from an independent signal source outside the cardiograph.
- (12) sensitivity selector Switch used for change-over the sensitivity.
- (13) calibrating apparatus An apparatus by which the reference voltage is recorded on the electrocardiogram.
- (14) stabilizing mechanism Such mechanism that makes the variation of terminal potential and fluctuation of base line due to induction selection in recording of electrocardiogram disappear.
- (15) direct straight line recording A recording system wherein the phenomenon is directly described on a rectangular-coordinate system.
- (16) allowable overload voltage Signal input voltage which will not damage the cardiograph.
- (17) time constant Quantity to express the responsibility of a.c. amplifier, in low frequency band which is shown by the time duration required to attenuate the amplitude of square wave to 37 % of the initial value (It is realized when the coupling circuit consists of one-stage CR only.).
- (18) electrode potential This is generally called as "polarizing voltage", and means the electromotive force generated at the boundary surface between electrode and living body, electrode and electrolyte, and the like.
- (19) buffer amplifier An amplifier the purpose of which is to keep the impedance of input circuit viewed from electrode connection terminal side not so low.
- (20) external power source Such power source as commercial power source, emergency power source, batteries which are installed, not exclusive by used for medicoelectrical machinery and apparatus, but for connection with unspecified machinery and apparatus.
- (21) external power source part Every possible parts of machinery and apparatus conductively connected with the external power source. In this definition, protective earthing conductor is not regarded as a part of external power source part.
- (22) supplementary protective earthing terminal An earthing terminal supplemented to the normal protective earthing conductor.
- (23) supplementary protective earthing conductor The conductor used for supplemented protective earthing of inside and outside of the machinery and apparatus.

3. Working Conditions

The working conditions of the cardiograph shall be as given in 3. of JIS T 1001.

4. Safety

4.1 Electrical Safety Besides in accordance with 3. of JIS T 1001, the following items shall apply:

(1) Protection against Electric Shock

- (a) As for the type and grade against electric shock, cardiographs shall belong any one of Class I, Class II, Class III or inner power source equipment and the type shall be any one of Type B, Type BF or Type CF. Especially, the cardiograph used for examination of cardiocatheter shall be Type CF.
- (b) Even if unexpected short circuit is caused inside of the cardiograph, a measure to prevent the danger and injury owing to the electric shock shall be provided so as not to pass current which will give danger and injury to subject and operator.
- (c) For the external power source equipment, the supplementary protective earthing terminal shall be prepared at a conspicuous place on the outer surface of the equipment and the terminal shall be able to earth the accessible conductive part securely at the time of working.

(2) Induction Electrode Circuit and Induction Cord

- (a) For the circuit (including right foot terminal) to connect the induction electrode, safety resistor or the like to protect human body from denager and injury shall be connected in series.
- (b) All cords such as induction cord, power source cord shall be protected with insulators.

- (3) Protective Earthing As the supplementary earthing conductor is important from the view point of safety countermeasure, such earthing device shall employ the wire having mechanical strength of not less than 20 kgf(196.13 N) in tensile strength, be able to earth the accessible conductive part securely, and shall be so constructed that the earthing conductor will not be easily disconnected.

4.2 Mechanical Safety The mechanical safety shall be as given in 7. of JIS T 1001.

5. Performances

5.1 Recording Sensitivity

5.1.1 Reference Sensitivity The reference sensitivity can be easily adjust within an error of 0.2 mm, and the switching error when the sensitivity change-over switch is set to the position of $\frac{1}{2}$ and 2 shall be within $\pm 5\%$, when the cardiograph is tested in accordance with the test method specified in (1) of 7.3.1.

5.1.2 Detectable Minimum Input Voltage Input voltage which will give the minimum detectable deflection shall be not more than $20 \mu\text{V(p-p)}$, when the cardiograph is tested in accordance with the test method of (2) of 7.3.1.

5.2 Stability

5.2.1 Drift of Recording Original Point (Exposed Drift) The drift of base line shall be not more than 5 mm within 15 min after the power source is switched on and the pen position is aligned with central position. Moreover, the base line shall not change by 2 mm or more in addition to previous change during the other 45 min, when the cardiograph is tested in accordance with the test method of (1) of 7.3.2.

5.2.2 Drift of Base Line due to Temperature (Temperature Drift) The fluctuation of the base line shall not exceed 1 mm/5°C over 15°C to 25°C when the cardiograph is tested in accordance with the test method of (2) of 7.3.2. Moreover, the change of base line shall not exceed 2 mm/5°C over 10°C to 15°C and 25°C to 40°C.

5.2.3 Drift of Base Line due to Fluctuation of Power Source Voltage In the case of external power source type cardiograph, when the source voltage of cardiograph is changed by 5 V positive or negative, in accordance with the test method of (3) of 7.3.2, the drift of base line caused by it shall be within ± 3 mm for 20 sec.

5.2.4 Change of Recording Sensitivity

- (1) In the case of external power source type cardiograph, when the power source voltage is changed by ± 10 V from 100 V, in accordance with the test method of (4) of 7.3.2, the change of recording sensitivity shall be within ± 10 %.
- (2) When d.c. voltages of ± 300 mV are superposed on the input of cardiograph, in accordance with the test method of (4) of 7.3.2, the change of recording sensitivity shall be within ± 5 %.
- (3) When d.c. voltages of ± 300 mV are superposed between 2 input terminals and terminal for fitting RF (N) electrode of cardiograph, in accordance with the test method of (4) of 7.3.2, the change of recording sensitivity shall be within ± 5 %.

5.3 Amplitude Characteristic

5.3.1 D.C. Characteristic When the test is carried out in accordance with the test method of (1) of 7.3.3, the equipment shall deflect by 15 mm or more in up and down directions, and the error shall be within $5\% \pm 0.2$ mm relative to the reference line shown in 7.3.3, within the deflections of 15 mm in up and down directions.

5.3.2 A.C. Characteristic When the test is carried out in accordance with the test method of (2) of 7.3.3, the change of amplitude shall be within ± 1 mm.

5.4 Overall Frequency Characteristic

5.4.1 Sine Wave Characteristic When the test is carried out in accordance with (1) of 7.3.4, by taking an amplitude of 10 mm at 10 Hz as 100 %, the amplitude shall be not less than 90 % at frequencies of 0.14 Hz to 50 Hz, and not less than 70 % at 75 Hz.

Moreover, there shall be no frequency at which the amplitude becomes 106 % or more, through whole band of test frequencies.

5.4.2 Transient Characteristic When the test is carried out in accordance with the method of (2) of 7.3.4, by applying reference voltage of 1 mV the recorded wave form shall be as follows:

- (1) When the wave form descends exponentially (what is called as the time constant measurement), the recorded amplitude after 3.2 sec shall be not less than 37 % of the amplitude obtained after 0.04 sec from application of the reference voltage.
- (2) When the wave form does not descend exponentially, the variation of deflection caused during the period after 0.04 sec to 0.38 sec from voltage application shall lie within the range of + 5 % to - 10 % of the deflection at 0.04 sec.
- (3) The overshoot shall be not more than 10 % in any cases of (1) and (2).

5.5 Interference between Channels When the multi-channel cardiograph is tested in accordance with the test method of 7.3.5, by applying from outside, input voltage of 2 mV between arbitrary one input terminal and terminal for fitting RF (N) electrode, the deflection of non-input channel due to interference shall be not more than 0.2 mm.

5.6 Internal Noise When the test is carried out in accordance with the test method of 7.3.6, the magnitude of noise traced on the straight line shall be within 0.4 mm (p-p) [$20 \mu\text{V(p-p)}$ converted in input].

5.7 Suppression of In-phase Signal When the test is carried out in accordance with the test method of 7.3.7, deflection of the record shall be not more than 10 mm (p-p) at the reference sensitivity.

5.8 Recording Device

5.8.1 Feed Speed of Recording Paper When the test is carried out in accordance with the test method of (1) of 7.3.8, at the feed speeds of 25 mm/s and 50 mm/s, the error shall be within ± 5 % each.

Moreover, error in signal scale width obtained by applying a sine wave signal voltage of period 0.08 sec ± 1 % shall be within 20 % of the minimum signal scale width during arbitrary duration of 10 sec.

5.8.2 Position of Record In the multi-channel cardiograph, when the test is carried out in accordance with the test method of (2) of 7.3.8, the positions of record shall be aligned on the surface of recording paper, on the line perpendicular to the feeding direction within ± 0.2 mm.

5.9 Input Circuit

5.9.1 Input Impedance When the test is carried out in accordance with the test method of (1) of 7.3.9, at arbitrary induction, the impedance between terminals for fitting electrode shall be not less than 5 M Ω .

5.9.2 Input Circuit Current When the test is carried out in accordance with the test method of (2) of 7.3.9, the input circuit current shall be not more than 1×10^{-7} A.

5.9.3 Calibration Instrument When the test is carried out in accordance with the test method of (3) of 7.3.9, the error between the deflection due to reference voltage of self-contained calibration instrument and the deflection due to reference voltage generator for test, shall be within ± 5 %.

5.9.4 Induction Selector When the test is carried out in accordance with the test method of (4) of 7.3.9, the difference in deflections at any positions of induction selector shall be within ± 5 %.

5.9.5 Allowable Overload Voltage The cardiograph shall comply with the provision of this standard without being damaged, even after a sine wave voltage of 1.0 V (p-p) at 50 or 60 Hz has been applied for 2 sec as the input of cardiograph.

5.10 Stabilizing Mechanism The fluctuation of base line due to change-over of induction shall disappear within 1 sec.

Moreover, when the induction is changed-over with a d.c. voltage of 300 mV b being applied, the base line shall return to a position 1 mm or less from that before change-over of induction within 1 sec and the deviation afterwards shall be within 5 mm.

5.11 Auxiliary Output

5.11.1 Output Level When the test is carried out in accordance with the test method of (1) of 7.3.11, the output of $0.5 \text{ V} \pm 5$ % shall be obtainable, at the reference sensitivity.

Further, the offset voltage when the pen is at the central position of record shall be ± 0.2 V, and the protection against short-circuit of output shall be provided.

5.11.2 Output Impedance When the test is carried out in accordance with the test method of (2) of 7.3.11, the output impedance shall be not more than 1 k Ω .

5.11.3 Frequency Characteristic When the test is carried out in accordance with the test method of (3) of 7.3.11, by taking the amplitude at 10 Hz as the reference, at the reference sensitivity, the output voltage shall be 90 % or more at frequencies from 0.14 Hz to 100 Hz.

Moreover, there shall be no frequency at which the output voltage becomes 106 % or more, through whole band of test frequencies.

5.12 Protection of Equipment Used in Combination with Defibrillator For the cardiograph marked that it is possible to use in combination with the defibrillator, the high tension pulse and then the sine-wave test voltage are applied on the induction cord of the cardiograph as specified in the test method of 7.3.12, and the sine-wave test voltage so applied shall be recorded on the recording paper with 80 % or more of the normal amplitude within 5 sec from the application.

6. Composition and Construction

6.1 Composition The cardiograph shall be composed of input circuit, amplifier, calibration apparatus, recorder, accessories and the like.

6.2 Construction

6.2.1 Induction Electrode and Induction Cord

- (1) Induction Electrode The induction electrode so constructed that it can be fitted surely and closely to the skin in an easy manner and it employs material not easily attacked by salt or the like. The voltage measured between 2 electrode through the electrode paste shall be not more than 200 mV.
- (2) Induction Cord The identification symbol and colour of induction cord shall be as follows:

Right hand	R	Red
Left hand	L	Yellow
Left foot	F	Green
Right foot	RF or N	Black
Chest	C	White

- (3) Terminal for Fitting Electrode When the terminal for fitting electrode is cylindrical plug-in type, the dimensions shall be 3.0 ± 0.1 mm in diameter and 15 to 30 mm in length.

6.2.2 Induction Selector For the cardiograph, the induction selector, by which at least the induction given in Table 1 can be obtained shall be provided.

Moreover, such change-over switch shall be provided in a multi-channel cardiograph, that is able to obtain the combinations shown in Table 2 quickly so as to record each induction simultaneously.

Further, in the single channel cardiograph, when an induction selector is provided in the input circuit without employing buffer amplifier, the coupling resistance to be used for single pole limb induction and single pole chest induction shall be not less than 300 k Ω ; and in the multi-channel cardiograph a buffer amplifier shall be used.