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**Electrocardiographic
monitoring equipment**

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monitors

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Foreword

This translation has been made based on the original Japanese Industrial Standard revised by the Minister of International Trade and Industry and Minister of Health and Welfare through deliberations at Japanese Industrial Standards Committee in accordance with the Industrial Standardization Law:

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Electrocardiographic monitoring equipment

1 Scope This Japanese Industrial Standard specifies the electrocardiographic monitoring equipment (hereafter referred to as “monitoring equipment”) aiming at monitoring electrocardiogram for a long time for catching abnormality by detecting cardiac rhythm.

Remarks 1 The following standards contain provisions applicable to this Standard:

JIS C 1102-2 *Direct acting indicating analogue electrical measuring instruments and their accessories Part 2 : Special requirements for ammeters and voltmeters*

JIS T 1001 *General requirements for safety of medical electrical equipment*

JIS T 1002 *General rules of testing methods for safety of medical electrical equipment*

JIS T 1005 *Style manual for instruction manuals*

JIS T 1006 *Graphical symbols for medical electrical equipment*

JIS T 1011 *Glossary of terms used in medical electrical equipment (general terms)*

JIS T 1031 *General rules for alarms of medical equipment*

JIS T 1301 *General requirements for patient monitors*

2 The following standard is the corresponding International Standard to this Standard:

IEC 60601-2-27 (1994) *Medical electrical equipment Part 2 : Particular requirements for the safety of electrocardiographic monitoring equipment*

3 The terms defined in 2 of **JIS T 1001** and 2 of this Standard are printed in bold letters.

2 Definitions For the purpose of this Standard, the definitions given in **JIS T 1001** and **JIS T 1011** and the following definitions apply:

- (1) **lead** To induce the heart action potential in order to display and record the electrocardiogram.
- (2) **lead selector** Change-over system for selecting an optional **lead**.
- (3) **lead electrode** Electrode to be attached to a specified part of **patient** for detecting electrical **impedance variation** of heart action potential and chest wall (hereafter referred to as “**electrode**”).
- (4) **electrode potential** Voltage generated on the boundary face between **electrode** and the skin of **patient** or between **electrode** and electrolytic solution or the like. It is called in general “polarization voltage”.

- (5) **neutral electrode** Electrode used for the reference point for differential amplifiers and/or interference suppression circuits.
- (6) **lead cord** Cord for connecting **electrode** electrically to monitoring equipment.
- (7) **input circuit** Circuit from **lead cord** to amplifier. It contains high frequency excluding filter, protective circuit, buffer amplifier, lead circuit network, etc.
- (8) **standard voltage** Square wave voltage generated by standard voltage generator for test.
- (9) **reference load signal** Signal generated by reference load signal generator for test.
- (10) **time constant** Quantity to indicate the response in low range of AC amplifier i.e. the time required after applying square wave voltage until its amplitude reduces down to 37 % of the initial amplitude.
- (11) **electrocardiogram normal sensitivity** Sensitivity which displays and records an amplitude of 10 mm when applying the **standard voltage** of 1 mV_{P-P} to the monitoring equipment from the signal generator independent of the monitoring equipment.
- (12) **respiration curve normal sensitivity** Sensitivity which displays and records an amplitude of 10 mm when applying the **reference load signal** of 1 Ω to the monitoring equipment from the signal generator independent of the monitoring equipment.
- (13) **hum excluding filter** Filter to exclude selectively the noise of commercial power supply frequency mixing into electrocardiogram.
- (14) **impedance system** Method for measuring the change of the voltage proportional to the **impedance variation** of patient resulted from the respiration when carrying a minute high frequency electric current into the living body as the change of respiration.
- (15) **impedance variation** Change of impedance between the **electrodes** or quantity of the change.
- (16) **carrier frequency** Frequency of carrier wave, namely transmission frequency.
- (17) **type of electric wave** Character of signal modulating the carrier wave and type of transmitted information. Express with a specified symbol.
- (18) **antenna power** Electric power supplied to supply line in an antenna system from a transmitter in usual operation that is the rated electric power averaged for a fully long time compared with the cycle of the lowest frequency used in modulation.
- (19) **allowable deviation of frequency** The maximum allowable deviation from the frequency to which the frequency at the middle of the frequency band occupied by emission is assigned.

- (20) **occupied frequency bandwidth** Upper limit and lower limit frequency band width equal to 0.5 % of the total average power radiated by the emission given respectively to the average power radiated beyond its upper limit and to the average power radiated at less than its lower limit frequency.
- (21) **adjacent channel leakage power** Electric power radiated into a specified band in the adjacent channel at intervals of a specified frequency from the **carrier frequency**.
- (22) **spurious emission** The emission of electric wave, of one or two or more frequency(ies) out of the frequency band required the level of which can be reduced with no influence on the transmission of information.
- (23) **B-type applied part** The **applied part** which conforms to the requirements for **type B equipments** specified in **JIS T 1001** and marks the graphic symbol of **02-02** specified in **JIS T 1006** in order to secure the protection against electric shock relating in particular to **allowable leakage current**.
- (24) **BF-type applied part** **F-type applied part** which conforms to the requirements for **type BF equipments** specified in **JIS T 1001** and marks the graphic symbol of **02-03** specified in **JIS T 1006** in order to secure the protection against electric shock stronger than that of **B-type applied part**.
- (25) **CF-type applied part** **F-type applied part** which conforms to the requirements for **type CF equipments** specified in **JIS T 1001** and marks the graphic symbol of **02-05** specified in **JIS T 1006** in order to secure the protection against electric shock stronger than that of **BF-type applied part**.

3 Environmental condition and electrical power supply 3 of **JIS T 1001** applies.

4 Classification of monitoring equipments **Monitoring equipments** shall be classified into the following types according to composition and function:

- (1) Classification according to the types of input amplifiers
 - (a) Wire type
 - (b) Wireless type
 - (c) Wire/wireless type
- (2) Classification according to the measuring function
 - (a) Electrocardiogram use only
 - (b) Electrocardiogram/respiration use

5 Safety

5.1 General The general requirements for safety shall be as specified in **5** of **JIS T 1001**, **12** of **JIS T 1001** and **13** of **JIS T 1001**.

5.2 Classification 4 of JIS T 1001 and the following shall apply:

- (1) The classification according to the degree of protection against electric shock of the **applied part** of the **monitoring equipment** shall be **CF-type applied part**.
- (2) The classification according to the mode of operation shall be **continuous operation** equipment.

5.3 Insulation and dielectric strength 7 of JIS T 1001 shall apply. However, 7.7.1, (2.2) B-b: insulation between parts of **applied parts** and/or between **applied parts** shall not apply.

5.4 Protection against mechanical hazards 8 of JIS T 1001 shall apply.

5.5 Protection against excessive temperature and other hazards

5.5.1 Excessive temperature 11.1 of JIS T 1001 shall apply. This does not apply to the thermal pen and printing element of the printing part.

5.5.2 Spillage 11.3 (Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization and disinfection) of JIS T 1001 applies. However, the monitoring equipments used in an environment where a liquid is used at the time of **normal use** shall normally operate when testing in accordance with 13 of JIS T 1002, placing in a state of **normal use** and removing visible water drops on the monitoring equipment immediately after pouring constantly artificial rain for 30 s at a speed of 3 mm/min vertically on an optional part from a point 50 cm high from the upper surface of the monitoring equipment.

5.5.3 Ultraviolet radiation If a monitoring equipment provided with an ultraviolet lamp, the equipment shall be so designed and constructed as to prevent ultraviolet emission of wavelengths below 320 nm.

6 Performance

6.1 Electrocardiogram display part

6.1.1 Display sensitivity of electrocardiogram Taking a sensitivity 1 (10 mm/mV) as the **electrocardiogram normal sensitivity**, the display sensitivity shall be able to be switched at least over three stages of $\frac{1}{2}$ (5 mm/mV), 1 (10 mm/mV) and 2 (20 mm/mV). The maximum sensitivity of a continuously variable type shall be 20 mm/mV or more.

When testing in accordance with 8.5.1, the amplitude shall be (10 ± 1) mm at the sensitivity 1 and the error when switching to $\frac{1}{2}$ and 2 shall be $\pm 5 \%$.

6.1.2 Linearity of electrocardiogram When testing in accordance with 8.5.2, the error of linearity shall be $\pm 10 \%$ up to ± 15 mm to the center of vertical axis.

6.1.3 Sweep speed When testing in accordance with 8.5.3, the error of sweep speed shall be $\pm 10 \%$.

Even when switching to other speed, the error shall be $\pm 10 \%$.

6.1.4 Error of calibration device If an equipment is provided with a calibration device, the deflection caused by the calibration voltage shall be (10 ± 0.5) mm when testing in accordance with 8.5.4.

6.1.5 Internal noise of electrocardiogram When testing in accordance with 8.5.5, the internal noise converted to an input shall be $35 \mu V_{P-P}$ or under.

6.1.6 Input impedance When testing in accordance with 8.5.6, the impedance between the terminals on which respective **electrodes** are mounted shall be $5 M\Omega$ or over.

6.1.7 Suppression of in-phase signal When testing in accordance with 8.5.7, the deflection shall be $10 mm_{P-P}$ at **electrocardiogram normal sensitivity**.

6.1.8 Time constant When testing in accordance with 8.5.8, the **time constant** shall be 0.3 s or over.

6.1.9 Frequency characteristic When testing in accordance with 8.5.9, the frequency characteristic shall be that the alteration of amplitude shall be from -30 % to +10 % within a range of 0.5 Hz to 40 Hz when taking 10 Hz as a reference.

In the case of the equipment provided with **hum excluding filter**, when the **hum excluding filter** is switched on, the frequency at which the amplitude becomes -30 % taking 10 Hz as a reference shall be 20 Hz or over.

6.1.10 Auxiliary output To the case where an auxiliary output terminal is equipped for outputting electrocardiogram signal to the outside, 4.4 of JIS T 1301 applies.

6.1.11 Change of display sensitivity Change of display sensitivity shall be as follows:

- (1) **Change due to electrode potential (differential component)** When testing in accordance with 8.5.10 (1), the change of display sensitivity shall be $\pm 5 \%$.
- (2) **Change due to electrode potential (in-phase component)** When testing in accordance with 8.5.10 (2), the change of display sensitivity shall be $\pm 5 \%$.

6.2 Respiration curve display part

6.2.1 Display sensitivity of respiration curve Taking sensitivity 1 ($10 mm/\Omega$) as the **respiration curve normal sensitivity**, the display sensitivity shall be able to be switched at least over three stages of $\frac{1}{2}$ ($5 mm/\Omega$), 1 ($10 mm/\Omega$) and 2 ($20 mm/\Omega$). The maximum sensitivity of continuously variable type shall be $20 mm/\Omega$ or over.

The error of display sensitivity when testing in accordance with 8.5.11 shall be $\pm 20 \%$.

6.2.2 Linearity of respiration curve When testing in accordance with 8.5.12, the error shall be $\pm 10 \%$.

6.2.3 Internal noise of respiration When testing in accordance with 8.5.13, the internal noise converted to the input shall be 0.2Ω or under.

6.2.4 Auxiliary output To the case where an auxiliary output terminal is equipped for outputting respiration curve signal to the outside, 4.4 of JIS T 1301 applies.

6.3 Heart rate display part

6.3.1 Detection of cardiac rhythm When testing in accordance with 8.5.14, the cardiac rhythm shall be able to be detected with the signals of both plus and minus polarity of 0.3 mV and 3 mV at **electrocardiogram normal sensitivity**. With this signal, the heart rate from 30 beats/min to 200 beats/min shall be able to be counted and displayed.

6.3.2 Heart rate display error When testing in accordance with 8.5.15, the heart rate display error shall be ± 3 beats/min.

6.3.3 Heart beat alarm setting error When testing in accordance with 8.5.16, the error of alarm setting value shall be ± 5 beats/min.

6.3.4 Heart beat alarm raising condition When testing in accordance with 8.5.17, the time required until an alarm is raised shall be 12 s or under.

6.4 Respiration rate display part

6.4.1 Detection of respiratory rhythm When testing in accordance with 8.5.18, the respiratory rhythm shall be able to be detected with a respiratory **reference load signal** of 0.3 Ω .

In addition, respiration rate of 10 times/min to 90 times/min shall be counted and displayed by this signal.

6.4.2 Respiration rate display error When testing in accordance with 8.5.19, the error shall be ± 3 times/min.

6.4.3 Apnoea alarm setting error When testing in accordance with 8.5.20, the error of apnoea alarm setting time shall be ± 2 s.

The apnoea alarm setting time shall be able to be set at least at 10 s, 15 s and 20 s or more.

6.5 Electrocardiogram record part

6.5.1 Direction of record of electrocardiogram Record wave form shall be drawn from the left to the right of the horizontal axis of orthogonal coordinate.

6.5.2 Recording speed Feeding speed of record paper shall be 25 mm/s at least for one and, when testing in accordance with 8.5.21, the error of recording speed shall be ± 5 %.

6.5.3 Record sensitivity of electrocardiogram Taking sensitivity 1 (10 mm/mV) as the **electrocardiogram normal sensitivity**, the record sensitivity shall be able to be switched at least over three states of $\frac{1}{2}$ (5 mm/mV), 1 (10 mm/mV) and 2 (20 mm/mV).

In addition, when testing in accordance with 8.5.22, the amplitude at the time of sensitivity 1 shall be (10 ± 1) mm and the error when switched to $\frac{1}{2}$ and 2 shall be ± 5 %.

6.5.4 Frequency characteristic of electrocardiogram When testing in accordance with 8.5.9, the frequency characteristic shall be from -30 % to +10 % within a range of 0.5 Hz to 40 Hz taking 10 Hz as a reference.

If **hum excluding filter** is equipped, when the **hum excluding filter** is switched on, the frequency at which the amplitude becomes -30 % shall be 20 Hz or over taking 10 Hz as a reference.

6.5.5 Internal noise of electrocardiogram When testing in accordance with 8.5.5, the internal noise converted to input shall be $35 \mu\text{V}_{\text{P-P}}$ or under.

6.6 Respiration curve record part

6.6.1 Direction of record of respiration curve Record wave form shall be drawn from the left to the right of the horizontal axis of orthogonal coordinate.

6.6.2 Record sensitivity of respiration curve Taking sensitivity 1 (10 mm/ Ω) as the **respiration curve normal sensitivity**, the record sensitivity shall be able to be switched at least over three stages of $\frac{1}{2}$ (5 mm/ Ω), 1 (10 mm/ Ω) and 2 (20 mm/ Ω).

In addition, when testing in accordance with 8.5.23, the amplitude at the time of sensitivity 1 shall be (10 ± 2) mm and the error when switched to $\frac{1}{2}$ and 2 shall be ± 5 %.

6.7 Protection of equipment when used together with defibrillator

6.7.1 Indication of possibility of joint use with defibrillator The monitoring equipment indicated to be usable together with a defibrillator shall have a means of protection against the high voltage pulse applied to the **input circuit** of the monitoring equipment and be in conformance with the specifications in 6.7.2 to 6.7.4.

6.7.2 Protection against joint use with defibrillator When testing in accordance with 8.5.24, the sinusoidal wave voltage for test applied shall be displayed on the display surface within 5 s.

6.7.3 Recovery time after discharge of defibrillator When testing in accordance with 8.5.25, the sinusoidal wave voltage for test applied shall be displayed within 10 s and its amplitude shall be at least 50 % of the initial value. That of input amplifier of wireless type is excluded.

6.7.4 Protection against discharge of defibrillator The space between the **electrodes** and the enclosure, **signal input part**, **signal output part** and metal foil larger than the bottom surface of the monitoring equipment which is placed under the monitoring equipment shall be protected against the hazardous electric energy at the time of discharge of defibrillator. When testing in accordance with 8.5.26, the measured voltage value shall be within 1 V.

6.8 Sending set

6.8.1 Change of electrocardiogram sensitivity due to fluctuation of power source voltage of transmitter When testing in accordance with 8.5.27, the change of the sensitivity due to the fluctuation of voltage of the cell shall be ± 7.5 %.

6.8.2 Protection against erroneous connection of battery Even after testing in accordance with 8.5.28, the monitoring equipment shall normally operate.

The battery shall not heat abnormally.

6.8.3 Allowable deviation of frequency When testing in accordance with 8.5.29, the **allowable deviation of frequency** shall be as given in Table 1.

Table 1 Allowable deviation of frequency

Division	Allowable deviation of frequency
Type A	$\pm 4 \times 10^{-6}$ (of occupied frequency bandwidth exceeding 4 kHz up to and including 8.5 kHz) $\pm 10 \times 10^{-6}$ (of occupied frequency bandwidth less than 4 kHz)
Type B	$\pm 4 \times 10^{-6}$ (of occupied frequency bandwidth exceeding 12 kHz up to and including 16 kHz) $\pm 10 \times 10^{-6}$ (of occupied frequency bandwidth less than 12 kHz)
Type C	$\pm 10 \times 10^{-6}$
Type D	$\pm 20 \times 10^{-6}$
Type E	$\pm 20 \times 10^{-6}$

6.8.4 Tolerance on occupied frequency bandwidth When testing in accordance with 8.5.30, the tolerance on **occupied frequency bandwidth** shall be as given in Table 2.

Table 2 Tolerance on occupied frequency bandwidth

Unit : kHz

Division	Tolerance on occupied frequency bandwidth
Type A	8.5
Type B	16
Type C	32
Type D	64
Type E	320

6.8.5 Tolerance on intensity of spurious emission When testing in accordance with 8.5.31, the tolerance on intensity of **spurious emission** shall be 2.5 μ W or under measuring at average electric power.

6.8.6 Deviation of antenna power When testing in accordance with 8.5.32, the deviation of **antenna power** shall be from -50 % to +20 %.

6.8.7 Adjacent channel leakage power When testing in accordance with 8.5.33, the **adjacent channel leakage power** shall be at least 40 dB lower than the carrier power.