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Foreword

This translation has been made based on the original Japanese Industrial Standard revised by the Minister of Health and Welfare, through deliberations at the Japanese Industrial Standards Committee in accordance with the Industrial Standardization Law. Consequently, JIS T 1203 : 1985 is replaced with this Standard.

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Electroencephalographs

Introduction This Japanese Industrial Standard has been prepared based on the first edition of IEC-60601-2-26 *Medical electrical equipment —Part 2 : Particular requirements for the safety of electroencephalographs* published in 1994.

1 Scope This Standard specifies electroencephalographs that record the activity potential of brain for diagnostic purposes. This Standard shall not be applied to any instruments that measure brain waves for other purposes, such as cerebral function monitor, brain-wave telemeter, brain-wave data recorder and player, and special brain-wave monitor for electric therapy.

When photic stimulators for electroencephalographs are incorporated, JIS T 1213 shall be applied to the corresponding parts.

Remarks 1 The normative references to this Standard are as follows.

- JIS C 1102-1 *Direct acting indicating analogue electrical measuring instruments and their accessories Part 1: Definitions and general requirements common to all parts*
- JIS C 1102-2 *Direct acting indicating analogue electrical measuring instruments and their accessories Part 2: Special requirements for ammeters and voltmeters*
- JIS C 1102-3 *Direct acting indicating analogue electrical measuring instruments and their accessories Part 3: Special requirements for wattmeters and varmeters*
- JIS C 1102-4 *Direct acting indicating analogue electrical measuring instruments and their accessories Part 4: Special requirements for frequency meters*
- JIS C 1102-5 *Direct acting indicating analogue electrical measuring instruments and their accessories Part 5: Special requirements for phase meters, power factor meters and synchrosopes*
- JIS C 1102-6 *Direct acting indicating analogue electrical measuring instruments and their accessories Part 6: Special requirements for ohmmeters (impedance meters) and conductance meters*
- JIS C 1102-7 *Direct acting indicating analogue electrical measuring instruments and their accessories Part 7: Special requirements for multi-function instruments*
- JIS C 1102-8 *Direct acting indicating analogue electrical measuring instruments and their accessories Part 8: Special requirements for accessories*

- JIS C 1102-9 *Direct acting indicating analogue electrical measuring instruments and their accessories Part 9: Recommended test methods*
- 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 1213 *Photoc stimulators for electroencephalographs*

2 The International Standard corresponding to this Standard is as follows.

IEC 60601-2-26 : 1994 *Medical electrical equipment—Part 2: Particular requirements for the safety of electroencephalographs*

3 The terms defined in clause 2 of JIS T 1001 and clause 2 of this Standard are boldfaced.

4 In this Standard, the contents that indicate **type B equipment**, **type BF equipment** and **type CF equipment** of JIS T 1001 and JIS T1002 shall be **type B applied part**, **type BF applied part** and **type CF applied part**, respectively.

2 Definition of terms For the purposes of this Standard, the definitions given in JIS T 1001 and JIS T 1011 and the following definitions apply.

- (1) **brain-wave electrode** a pair or a combination of **electrodes** that are applied to or inserted into a region of the scalp or the brain to detect activity potential of the brain (hereafter referred to as **electrodes**)
- (2) **neutral electrode** electrode used as a reference point for differential amplifier or interference suppressing circuit which is not involved in **electrode** combination. This is also called a TYŪSEI (in Japanese) electrode
- (3) **channel** a system that has functions to amplify and record the potential between a pair or a combination of **electrodes**
- (4) **pattern** a preset connection type to connect any one pair from among several montages to the amplifier input terminal, a montage being defined as a combination type to form multiple combinations from plural **electrodes**
- (5) **electrode connector** a connector that is provided with receptacles for electrode leads
- (6) **electrode selector** a selector that permits to sequentially switch the preset **patterns**

- (7) **single-pole plug** a single-pole plug that is connected to receptacles for electrode leads on the **electrode connector**
- (8) **square-wave voltage** a voltage obtained when a d.c. voltage is opened or closed with a switch
- (9) **recording sensitivity** a magnitude of record per unit of input voltage
- (10) **calibrator** a device that applies a reference **square-wave voltage** to know the magnitude of input voltage of electroencephalograph
- (11) **input circuit** a circuit that is composed by an **electrode connector**, an **electrode selector**, an input unit of amplifier, etc. of electroencephalograph
- (12) **d.c. input circuit current** a sum of d.c. components of the amplifier input unit current and the **leakage current** from the amplifier power source, etc.
- (13) **sensitivity coarse adjustor** a stepwise adjustor to change the sensitivity of amplifier step by step
- (14) **sensitivity fine adjustor** an adjustor to equally adjust the sensitivity of each channel
- (15) **time constant** a quantity to indicate the response of low pass of a.c. amplifier. The time required from application of the **square-wave voltage** until its amplitude is attenuated to 37% of the initial amplitude
- (16) **filter** a filter for high-band attenuation of amplifier
- (17) **in-phase discrimination ratio** an ability to suppress the in-phase voltage. The ratio of in-phase input versus the antiphase input that gives the equal magnitude of deviation.
- (18) **stabilizing mechanism** a mechanism that erases instantly the fluctuation of baseline accompanying variation of polarization voltage and switching of the **electrode selector** during recording of brain waves
- (19) **direct-writing recorder** a recorder that can record a phenomenon as soon as it occurs, instead of using photographic development, etc.
- (20) **arc distortion** a distortion of waveform on a chart that is caused by an arc motion of a pen tip of pen-writing recorder. **Arc distortion** shall be determined by turning-radius of a pen tip and feed speed of a chart.
- (21) **clock signal** a signal that is applied to know the time sequence of brain waves, which records the time interval of constant reference
- (22) **auxiliary input** an analogue signal input that is an auxiliary addition for connection with external equipment
- (23) **auxiliary output** an analogue signal output that is an auxiliary addition for connection with external equipment

- (24) **type B applied part** an applied part that meets requirements for **type B equipment** specified in JIS T 1001 to provide an adequate degree of protection against electric shock particularly regarding **allowable leakage currents**, and that displays graphic symbols of 02-02 of JIS T 1006
- (25) **type BF applied part** a **type F applied part** that meets requirements for **type BF equipment** specified in JIS T 1001 to provide a higher degree of protection against electric shock than **type B applied part**, and that displays graphic symbols of 02-03 of JIS T 1006
- (26) **type CF applied part** a **type F applied part** that meets requirements for **type CF equipment** specified in JIS T 1001 to provide a higher degree of protection against electric shock than **type BF applied part**, and that displays graphic symbols of 02-05 of JIS T 1006

3. Environmental conditions and power supply The environmental conditions and power supply shall be subjected to clause 3 (Environmental conditions and power supply) of JIS T 1001, except that, regarding clause 5 of this Standard, the relative humidity of the working environmental conditions shall be 25% to 95% (excluding dew condensation).

4 Type and classification of equipment

4.1 Type Electroencephalographs shall be of two types: a dedicated type for recording of brain waves and a universal type for recording brain waves and other biophenomena.

Each type has an anti-defibrillation electroencephalograph.

4.2 Classification of equipment Classification of equipment shall be subjected to clause 4 (Classification of equipment) of JIS T 1001. In terms of classification by operation mode, electroencephalographs shall be classified as **continuous operation equipment**.

5 Safety

5.1 General General matters related to safety shall be subjected to clause 5 (Requirements for safety), clause 6 (Power supply input), clause 7 (Protection against electric shock), clause 8 (Protection against mechanical hazards), clause 10 (Protection against hazards of ignition of inflammable anesthetic mixtures) and clause 13 (Abnormal operation and fault conditions) of JIS T 1001.

5.2 Protection against electric shock The protection against electric shock shall be subjected to clause 7 of JIS T 1001 and the following.

- (1) **Protection against discharge of defibrillator** The protection against discharge of defibrillator shall be as follows. In case of defibrillator type electroencephalographs, **electrodes, enclosures, signal input unit, signal output unit, and metallic foil** under a electroencephalograph that is larger than the base area of electroencephalograph shall be protected against hazardous electric energy at the

time of discharge of a defibrillator. When tested in 8.4.20, the measured voltage shall be within 1 V.

- (2) **Continuous leakage current and patient auxiliary current** Continuous leakage current and **patient auxiliary current** shall be subjected to 7.6.3 (Allowable values) of JIS T 1001 and the following additionally.

In all combinations of the **electrode selector** and the **pattern selector**, the **patient leakage current** that flows from the **applied part** of electroencephalograph having **functional earth terminal** to the earth, shall not exceed 5 mA for **type B** and **BF applied parts**, and 0.05 mA for **type CF applied part**, when 110% voltage of maximum **rating voltage** is applied between the **functional earth terminal** and the earth. This provision, however, does not apply when the **functional earth terminal** and the **protective earth terminal** are directly connected within an electroencephalograph. The test shall be subjected to 8.4.21.

- (3) **Insulation** Insulation shall be subjected to 7.7.1 (Insulation) of JIS T 1001. However, this shall not apply to between B and b (between parts of **applied part** and between **applied parts**).
- (4) **Withstand voltage** Withstand voltage shall be subjected to 7.7.2 (Dielectric voltage) of JIS T 1001. However, the test voltage between B and d (between **type F applied part** and the **enclosure** including the **signal input output unit**) shall be 1500 V.

5.3 Protection against excessive temperature and other hazards The protection against excessive temperature and other **hazards** shall be subjected to clause 11 (Protection against excessive temperatures and other hazards) of JIS T 1001 and the following.

- (1) **Guard of hot parts** The guard of hot parts shall not apply to the thermal pen or the print recording elements.
- (2) **Spillage** The spillage shall not apply.

5.4 Protection against hazardous output The protection against hazardous output shall be subjected to clause 12 (Protection against hazardous output) of JIS T 1001 and the following.

An defibrillation-proof type electroencephalograph shall meet the provision of clause 5 even after the test specified in 8.4.22.

6 Performance

6.1 Input circuit When tested in 8.4.1, the input impedance of each **channel** shall be 5 M Ω or more, and the **d.c. input circuit current** shall be 10 nA or less.

6.2 Feed speed of chart When tested in 8.4.2, the feed speed of a chart shall be correct against the preset value within the error of $\pm 5\%$, and the speed fluctuation shall be within $\pm 2.5\%$ of the average speed for 20 s.

6.3 Position of record When tested in 8.4.3, the starting point of record on chart for each **channel** shall be positioned on a line that is rectangular to the chart feeding direction, and the deviation shall be less than 0.5 mm.

6.4 Clock device When tested in 8.4.4, the clock device shall be able to record