

JIS

JAPANESE INDUSTRIAL STANDARD

**General requirements for
patient monitors**

JIS T 1301—1991

Translated and Published

by

Japanese Standards Association

In the event of any doubt arising,
the original Standard in Japanese is to be final authority.

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General requirements for patient monitors

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1. Scope

This Japanese Industrial Standard specifies the requirements common to the patient monitoring system monitoring for long period the physiological informations of patients. However, it does not apply for the centralized patient monitoring system.

Further, when this differs from the specifications of particular standard, the specifications of individual standard have preference.

Remarks: The applicable standards for this standard are shown in the following.

JIS C 7612-Illuminance Measurements for Lighting Installations

JIS T 1001-General Requirements for Safety of Medical Electrical Equipment

JIS T 1002-General Rules for Safety Testing Procedures of Medical Electrical Equipment

JIS T 1003-Testing Methods for Electrical Safety of Medical Electrical Equipment

JIS T 1004-Testing Methods for Mechanical Safety of Medical Electrical Equipment

JIS T 1005-Style Manual for Instruction Manuals

JIS T 1031-General Rules for Alarms of Medical Equipment

JIS Z 9110-Recommended Levels of Illumination

2. Definitions

For the purpose of this standard, the following definitions apply other terms are defined in JIS T 1001.

- (1) patient monitoring system System to detect the physiological information of patient (electrocardiogram, body temperature, blood gas, etc.) and monitor the state of patient for long period by this system. The devices equipped with functions to conduct record, alarm, etc. are included.
- (2) centralized patient monitoring system System to collect the signals from plural patient monitoring systems and monitor simultaneously the physiological informations of plural patients for long period.
- (3) measuring part The part to input and amplify the electric signals from the attached part. The part to process the signals is included.
- (4) visible angle Range of angle able to ascertain the displayed signal when the display part of device is viewed in inclined direction.

3. Safety

The items relating to the safety shall comply with JIS T 1001. However, the type of protection against electric shock hazard shall comply with Class I equipment, Class II equipment or internal power equipment.

4. Performance

4.1 Display part

4.1.1 Sweep speed The accuracy of sweep speed of wave form tested according to 6.4.1 shall be $\pm 10\%$.

4.1.2 Deviation from straightness of display The deviation from straightness of display tested according to 6.4.2. shall be $\pm 10\%$.

4.2 Alarming part The accuracy of alarm setting of alarming part tested according to 6.4.3 shall be $\pm 3\%$.