

JIS

JAPANESE
INDUSTRIAL
STANDARD

Translated and Published by
Japanese Standards Association

JIS T 1304 : 1998

Electrocardiographic monitoring equipment

ICS 11.040.50

Descriptors : electrocardiographs, patient monitors, electrical medical equipment,
monitors

Reference number : JIS T 1304 : 1998 (E)

T 1304 : 1998

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:

Date of Establishment: 1985-03-15

Date of Revision: 1998-12-25

Date of Public Notice in Official Gazette: 1998-12-25

Investigated by: Japanese Industrial Standards Committee
Divisional Council on Medical and Safety
Technical Committee on Medical Electrical
Equipment

JIS T 1304:1998, First English edition published in 1999-10

Translated and published by: Japanese Standards Association
4-1-24, Akasaka, Minato-ku, Tokyo, 107-8440 JAPAN

In the event of any doubts arising as to the contents,
the original JIS is to be the final authority.

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Printed in Japan

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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”.