

JAPANESE INDUSTRIAL STANDARD

Translated and Published by Japanese Standards Association

 $JIS\ T\ 1303^{\,:\,2018}$

(JEITA)

Fetal monitors

ICS 11.040.55

Reference number: JIS T 1303: 2018 (E)

T 1303: 2018

Date of Establishment: 1984-03-15

Date of Revision: 2018-10-01

Date of Public Notice in Official Gazette: 2018-10-01

Investigated by: Japanese Industrial Standards Committee

Standards Board for ISO area

Technical Committee on Medical Equipment

JIS T 1303: 2018, First English edition published in 2019-03

Translated and published by: Japanese Standards Association Mita MT Building, 3-13-12, Mita, Minato-ku, Tokyo, 108-0073 JAPAN

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

© JSA 2019

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from the publisher.

Printed in Japan HN

Contents

	Page
Intro	duction ······ 1
1	Scope 1
2	Normative references · · · · · · · · · · · · · · · · · · ·
3	Terms and definitions · · · · · · 1
4	Safety4
5	Classification ····· 4
6	Configuration · · · · 4
6.1	Configuration of basic monitors · · · · · 4
6.2	Configuration of expanded monitors · · · · · 5
6.3	Additional parts · · · · · 5
7	Construction ····· 6
8	Performance ······ 7
8.1	Driving frequency of ultrasonic probe · · · · · · 7
8.2	Fetal heart sound converter · · · · · · · · 7
8.3	Ultrasonic doppler signal detection amplifier · · · · · · 7
8.4	ECG amplifier · · · · · · 7
8.5	Fetal heart sound amplifier ······ 8
8.6	Heart rate counter ·····8
8.7	Heart rate calibrator ······11
8.8	External measurement labour converter ·······11
8.9	Intrauterine pressure converter ················11
8.10	External measurement labour amplifier ······11
8.11	Intrauterine pressure labour amplifier · · · · · · · · · · · · · · · · · · ·
8.12	Recorder
8.13	Telemeter function
8.14	Test
9	Test condition
9.1 9.2	Safety-related test ··································
9.3	Performance-related test ·······15
10	Marking20
11	Accompanying documents · · · · · 20
12	Environmental conditions and power supply20

Foreword

This Japanese Industrial Standard has been revised by the Minister of Health, Labour and Welfare and the Minister of Economy, Trade and Industry through deliberations at the Japanese Industrial Standards Committee as the result of proposal for revision of Japanese Industrial Standard submitted by Japan Electronics and Information Technology Industries Association (JEITA) with the draft being attached, based on the provision of Article 12 Clause 1 of the Industrial Standardization Law applicable to the case of revision by the provision of Article 14.

Consequently **JIS T 1303**: 2005 is replaced with this Standard.

However, **JIS T 1303**: 2005 remains valid for three years from the date of public notice of the revision of this Standard.

This **JIS** document is protected by the Copyright Law.

Attention is drawn to the possibility that some parts of this Standard may conflict with patent rights, applications for a patent after opening to the public or utility model rights. The relevant Ministers and the Japanese Industrial Standards Committee are not responsible for identifying any of such patent rights, applications for a patent after opening to the public or utility model rights.

Fetal monitors

JIS T 1303: 2018

Introduction

This Japanese Industrial Standard was established in 1984, has been gone through revision in 1994 and 2005. This revision is intended to revise the contents corresponding to the revision of **JIS T 0601-1** made in 2017.

No corresponding International Standard has been established at this point.

1 Scope

This Standard specifies fetal monitors (hereafter also referred to as monitors) that record continuously the **fetal heart rate** curves and the **external measurement** labour curves by **ultrasonic doppler method** on charts to obtain fetal information and maternal information.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this Standard. The most recent editions of the standards (including amendments) indicated below shall be applied.

- JIS T 0601-1 Medical electrical equipment Part 1: General requirements for basic safety and essential performance
- JIS T 60601-1-8 Medical electrical equipment Part 1-8: General requirements for basic safety and essential performance Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
- IEC 61161 Ultrasonics Power measurement Radiation force balances and performance requirements

3 Terms and definitions

For the purposes of this Standard, the terms and definitions given in Clause 3 of **JIS T 0601-1** and the following apply.

The terms defined in **JIS T 0601-1** are bold-faced in this Standard. When a term defined in this Standard **JIS T 0601-1** is not bold-faced, the given definition is not applied, and the meaning shall be interpreted from the context.

3.1

ultrasonic doppler method

the method that uses the ultrasonic doppler effect

3.2