

JIS

JAPANESE
INDUSTRIAL
STANDARD

Translated and Published by
Japanese Standards Association

JIS T 1205 : 2005
(JMOIA/JSA)

**Ultrasound ophthalmic measuring
system for the axial length**

ICS 11.040.70

Reference number : JIS T 1205 : 2005 (E)

PROTECTED BY COPYRIGHT

AVA Documents
Document Sharing Hub
7 S

Foreword

This translation has been made based on the original Japanese Industrial Standard 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 Medical-optical Equipment Industrial Association (JMOIA) /Japanese Standards Association (JSA) 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 1205 : 1988 is replaced with this Standard.

In this revision, for the part concerning safety, JIS T 0601-2-37, that is translated from IEC 60601-2-37, *Medical electrical equipment—Part 2-37 : Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment*, has been referenced. There is no corresponding International Standard for the part concerning performance.

Attention is drawn to the possibility that some parts of this Standard may conflict with a patent right, application for a patent after opening to the public, utility model right or application for registration of utility model after opening to the public which have technical properties. The relevant Ministers and the Japanese Industrial Standards Committee are not responsible for identifying the patent right, application for a patent after opening to the public, utility model right or application for registration of utility model after opening to the public which have the said technical properties.

Date of Establishment: 1988-06-15

Date of Revision: 2005-03-25

Date of Public Notice in Official Gazette: 2005-03-25

Investigated by: Japanese Industrial Standards Committee

Standards Board

Technical Committee on Medical Equipment

JIS T 1205 : 2005, First English edition published in 2005-08

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.

© JSA 2005

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

PROTECTED BY COPYRIGHT

Contents

	Page
1 Scope	1
2 Normative references.....	1
3 Definitions	1
4 Performance.....	1
4.1 Length-measuring performance	1
4.2 Safety.....	3
5 Structure.....	3
6 Tests	3
6.1 Length-measuring performance test	3
6.2 Tests relating to safety	6
7 Markings.....	7
8 Appended documents.....	7

Ultrasound ophthalmic measuring system for the axial length

1 Scope This Japanese Industrial Standard specifies the ultrasound ophthalmic measuring system for the axial length (hereafter referred to as the “equipment”) for measuring the propagation time of echo from each part of eyeball according to the ultrasonic pulse-echo method and for marking by obtaining the axial length.

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 safety*

JIS T 0601-2-37 *Medical electrical equipment —Part 2-37 : Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment*

JIS T 1501 *General methods of measuring the performances of ultrasonic pulse-echo diagnostic equipment*

3 Definitions For the purpose of this Standard, the definitions given in JIS T 0601-1, JIS T 0601-2-37 and JIS T 1501, and the following definition apply:

- a) **axial length** the axial diameter from the front face of cornea to the front face of amphiblastrode (retina), which includes the axial lengths of composing elements such as anterior chamber, crystalline lens, corpus vitreum, etc. and is expressed by unit of mm

4 Performance

4.1 Length-measuring performance The length-measuring performance of the equipment shall, when tested according to the test method specified in 6.1, be inaccuracy δ (mm) $\leq \pm 0.1$ mm on all four classes of test reference devices: L₁₅, L₂₀, L₂₅ and L₃₀. The inaccuracy shall be calculated by the following formula.

$$\delta = L - L_0 \frac{V_0}{V}$$

where, δ : inaccuracy (mm)
 L_0 : reference length (mm)
 L : measuring length (mm)