

JIS

JAPANESE
INDUSTRIAL
STANDARD

Translated and Published by
Japanese Standards Association

JIS Z 4930 : 2005
(JIRA/JSA)

Phantoms for performance evaluation of X-ray bone densitometer

ICS 11.040.55

Reference number : JIS Z 4930 : 2005 (E)

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Foreword

This translation has been made based on the original Japanese Industrial Standard established by the Minister of Health, Labour and Welfare and the Minister of Economy, Trade and Industry through deliberations at the Japanese Industrial Standards Committee according to the proposal of establishing a Japanese Industrial Standard from Japan Industries Association of Radiological Systems (JIRA)/Japanese Standards Association (JSA), with a draft being attached, based on the provision of Article 12 Clause 1 of the Industrial Standardization Law.

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Date of Establishment: 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 4930 : 2005, First English edition published in 2006-04

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

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Printed in Japan

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Phantoms for performance evaluation of X-ray bone densitometer

1 Scope This Japanese Industrial Standard specifies the **phantoms** (hereafter referred to as “**phantoms**”) used to evaluate the performance of the **X-ray bone densitometer** to be manufactured or imported, for the purpose of the type approval test, the performance test and the daily accuracy management.

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 any supplements) indicated below shall be applied.

JIS T 0601-1 *Medical electrical equipment—Part 1: General requirements for safety*

JIS Z 4005 *Medical radiology—Terminology*

JIS Z 8103 *Glossary of terms used in measurement*

3 Terms and definitions For the purpose of this Standard, the definitions given in JIS Z 4005 and JIS Z 8103 and the following definition apply.

3.1 Terms on the X-ray bone densitometer

3.1.1 X-ray bone densitometer measurement equipment whose main purpose is to quantify the **bone mineral density** of a human body by measuring attenuation of the X-ray photon flux of one or two kinds of energies

Remarks : Synonymous words : Bone mineral quantitative analysis X-ray equipment, X-ray bone mineral quantitative analyzer

3.2 Terms on the output data of X-ray bone densitometer

3.2.1 bone area area equivalent to the area of the bone which is obtained by projecting a measuring-object range by parallel X-rays

Remarks : Unit: cm^2

3.2.2 BMD = Bone Mineral Density mass of the mineral element per unit **bone area**, which is contained in the bone of a measuring-object range. Unit : g/cm^2

Remarks : It may be expressed with the mass of the mineral element per unit volume. The unit in that case : g/cm^3

3.3 Terms on the measuring-object

3.3.1 soft tissue composition in the living body other than a bone

3.3.2 body thickness thickness of both bone and **soft tissue** combined. It may affect the measured value in measurement of truncal bone, etc.

3.3.3 bone equivalent substance tissue-equivalents whose X-ray absorption is equivalent to bone

Example : Hydroxyapatite CAS No.1306-06-5

3.3.4 soft tissue equivalent substance tissue-equivalents whose X-ray absorption is equivalent to **soft tissue**

Example : Polyurethane resin

4 Phantom composition and name classified by test The composition and the name of the **phantoms** which are used for the reproducibility/linearity test, the uniformity test, the **body thickness** dependence test and height dependence test from bed surface shall be as per tables 1, 2 and 3.

Table 1 Composition of the phantom for lumbar

Composition and name	Use
To be used for the reproducibility/linearity test — The phantom for lumbar	It is intended for reproducibility and linearity test of bone mineral density measured value.
To be used for the uniformity test — The phantom for uniformity lumbar	It is intended for the uniformity test of bone mineral density measured value.
To be used for the body thickness dependence test — The phantom for lumbar — The board-like single body phantom	It is intended for the body thickness dependence test of bone mineral density measured value.
To be used for the height dependence test from bed surface — The phantom for lumbar — The phantom stand for lumbar	It is intended for the height dependence test from bed surface of bone mineral density measured value.

Table 2 Composition of the phantom for forearms

Composition	Use
To be used for the reproducibility/linearity test — The phantom for forearms High density phantom for forearms Medium density phantom for forearms Low density phantom for forearms	It is intended for reproducibility and linearity test of bone mineral density measured value.

Table 3 Composition of the phantom for heel bones

Composition	Use
To be used for the reproducibility/linearity test — The phantom for heel bones High density phantom for heel bones Medium density phantom for heel bones Low density phantom for heel bones	It is intended for reproducibility and linearity test of bone mineral density measured value.

5 Performance

5.1 Dimension When it is tested by the method of 7.3.1, it shall conform to 6.1 to 6.4.