



JAPANESE
INDUSTRIAL
STANDARD

Translated and Published by
Japanese Standards Association

JIS Z 4930 : 2011

(JIRA/JSA)

**Phantoms for performance
evaluation of X-ray bone
densitometer**

ICS 11.040.55

Reference number : JIS Z 4930 : 2011 (E)

PROTECTED BY COPYRIGHT

Date of Establishment: 2005-03-25

Date of Revision: 2011-06-27

Date of Public Notice in Official Gazette: 2011-06-27

Investigated by: Japanese Industrial Standards Committee
Standards Board
Technical Committee on Medical Equipment

JIS Z 4930:2011, First English edition published in 2013-10

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.

© JSA 2013

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 FY COPYRIGHT

Contents

	Page
1 Scope.....	1
2 Normative references	1
3 Terms and definitions	1
3.1 Terms related to X-ray bone densitometer	1
3.2 Terms related to output data of X-ray bone densitometer	1
3.3 Terms related to the measuring-object	2
4 Types of phantoms used for respective tests	2
5 Specification	3
5.1 Appearance	3
5.2 Dimensions	3
5.3 Calculation value of bone mineral density	3
5.4 Bone mineral density uniformity	3
6 Structure, dimensions and material	3
6.1 Phantom used for the reproducibility/linearity test.....	3
6.2 Phantom used for the uniformity test.....	7
6.3 Phantom used for the body thickness dependence test	8
6.4 Phantom used for the height dependence test from the bed surface	9
7 Tests	11
7.1 Environmental conditions	11
7.2 Test items	11
7.3 Test methods	11
8 Inspection	12
9 Marking.....	12
10 Instruction manual and test result document	12
Annex A (informative) Example of testing method for performance evaluation of X-ray bone densitometer	14

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 Imaging and Radiological Systems Industries Association (JIRA)/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 Z 4930:2005** is replaced with 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.

Phantoms for performance evaluation of X-ray bone densitometer

1 Scope

This Japanese Industrial Standard specifies the **phantoms** to evaluate the performance of the table type and peripheral bone type **X-ray bone densitometer** (hereafter referred to as “**phantoms**”).

NOTE 1 The evaluation procedures are indicated in Annex A (informative).

NOTE 2 In this Standard, the terms in boldface in the text are those defined in this Standard and **JIS Z 4005**. Where the terms defined in this Standard and **JIS Z 4005** are not boldfaced, the given definitions do not apply and the meaning shall be interpreted in context.

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 Z 4005 *Medical radiology—Terminology*

JIS Z 8103 *Glossary of terms used in measurement*

3 Terms and definitions

For the purposes of this Standard, the terms and definitions given in **JIS Z 4005** and **JIS Z 8103** and the following apply.

3.1 Terms related to 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

NOTE : Synonyms: Bone mineral quantitative analysis X-ray equipment or X-ray bone mineral quantitative analyzer

3.2 Terms related to output data of X-ray bone densitometer

3.2.1 bone area

area of the bone which is obtained by projecting a measuring-object range by X-ray (unit: cm²)

3.2.2 Bone Mineral Density (BMD)

mass of the mineral element per unit **bone area**, which is contained in the bone of a measuring-object range (unit: g/cm² or mg/cm²)

NOTE 1 It may be expressed with the mass of the mineral element per unit volume (the unit in that case: g/cm³ or mg/cm³).

3.3 Terms related to the measuring-object

3.3.1 soft tissue

component within the body other than bone (excluding teeth)

3.3.2 body thickness

thickness of both bone and **soft tissue** combined

NOTE : It may affect the **bone mineral density** 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 Types of phantoms used for respective tests

The types of **phantoms** used for the reproducibility/linearity test, the uniformity test, the **body thickness** dependence test and the height dependence test from bed surface shall be as shown in tables 1, 2 and 3.

Table 1 Phantom for table type Types of T

Type	Use
Phantom for table type T-1	It is intended for the reproducibility/linearity test of bone mineral density measured value (see figure 1).
Uniformity phantom for table type T-2	It is intended for the uniformity test of bone mineral density measured value (see figure 4).
Plate phantom for table type T-3	It is intended for the body thickness dependence test of bone mineral density measured value (see figures 5 and 6). It is used in combination with T-1 phantom .
Phantom stand for table type T-4	It is intended for the height dependence test from bed surface of bone mineral density measured value (see figures 7 and 8). It is used in combination with T-1 phantom .
NOTE : The phantom for table type is mainly used for the X-ray bone densitometer to measure lumbar vertebra, thighbone and the whole body, etc.	

Table 2 Phantom for peripheral bone Types of PF

Type	Use
High density phantom for peripheral bone type PF-1	It is in the shape as shown in figure 2 and intended for the reproducibility/linearity test of the bone mineral density measured value. It is used for the X-ray bone densitometer of which the measuring part is structured to be suitable for the shape of phantom . For example, a X-ray bone densitometer for forearms bone, etc.
Medium density phantom for peripheral bone type PF-2	
Low density phantom for peripheral bone type PF-3	

Table 3 Phantom for peripheral bone type Types of PH

Type	Use
High density phantom for peripheral bone type PH-1	It is in the shape as shown in figure 3 and intended for the reproducibility/linearity test of the bone mineral density measured value. It is used for the X-ray bone densitometer of which the measuring part is structured to be suitable for the shape of phantom . For example, a X-ray bone densitometer for heel bone, etc.
Medium density phantom for peripheral bone type PH-2	
Low density phantom for peripheral bone type PH-3	

5 Specification

5.1 Appearance

When the test is performed in accordance with **7.3.1**, smoothness of wall and bonded part shall be maintained, and there shall not be any noticeable deformation, flaws, bubbles or cracks.

5.2 Dimensions

When the test is performed in accordance with **7.3.2**, dimensions shall conform to **6.1** to **6.4**.

5.3 Calculation value of bone mineral density

When the test is performed in accordance with **7.3.3**, the requirements in tables 4 and 5 shall be satisfied.

5.4 Bone mineral density uniformity

When the test is performed in accordance with **7.3.4**, the physical density of each **bone equivalent substance** material shall be within ± 0.5 % of the average value. Air bubbles shall not be present in each region of interest.

6 Structure, dimensions and material

6.1 Phantom used for the reproducibility/linearity test

6.1.1 Phantom for table type T-1

The **phantom** for table type: structure of T-1, dimensions and materials are shown in table 4 and figure 1.

Table 4 Specification of the phantom for table type T-1 and peripheral bone type PF

Item			Specification			
			Phantom for table type T-1	Phantom for peripheral bone type PF		
				Low density phantom for peripheral bone type PF-1	Medium density phantom for peripheral bone type PF-2	High density phantom for peripheral bone type PF-3
Bone equivalent substance ^{a)} (hydroxyapatite)	Low density bone equivalent substance ^{a)}	Shape	Cylinder type	Cylinder type	—	—
		Bone mineral density g/cm ²	0.70±0.01	0.30±0.01	—	—
		Number	1	2	—	—
		Dimensions (outside diameter × length) mm	(φ 50±0.2)× (30±0.2)	(φ 15±0.2)× (90±0.2)	—	—
		Bone area cm ²	15.0±0.2	13.5±0.2	—	—
	Medium density bone equivalent substance ^{a)}	Shape	Cylinder type	—	Cylinder type	—
		Bone mineral density g/cm ²	1.00±0.01	—	0.60±0.01	—
		Number	1	—	2	—
		Dimensions (outside diameter × length) mm	(φ 50±0.2)× (30±0.2)	—	(φ 15±0.2)× (90±0.2)	—
		Bone area cm ²	15.0±0.2	—	13.5±0.2	—
	High density bone equivalent substance ^{a)}	Shape	Cylinder type	—	—	Cylinder type
		Bone mineral density g/cm ²	1.30±0.01	—	—	0.90±0.01
		Number	1	—	—	2
		Dimensions (outside diameter × length) mm	(φ 50±0.2)× (30±0.2)	—	—	(φ 15±0.2)× (90±0.2)
		Bone area cm ²	15.0±0.2	—	—	13.5±0.2
Soft tissue equivalent substance (polyurethane resin)		Phantom thickness mm	150±1	40±1	40±1	40±1
— The following bone equivalent substances shall be used for the reproducibility test of X-ray bone densitometer : Phantom for table type T-1: All bone equivalent substances of low density, medium density and high density. Medium density phantom for peripheral bone type PF-2: Two bone equivalent substances of medium density.						
— For the linearity test of X-ray bone densitometer , each bone equivalent substance of low density, medium density, and high density shall be used individually.						
Note ^{a)} Bone equivalent substance , hydroxyapatite, is powdery substance, and is mixed into resin to adjust the density.						