

JIS

JAPANESE
INDUSTRIAL
STANDARD

Translated and Published by
Japanese Standards Association

JIS T 9233 : 1997

**Testing methods
for ostomy aids**

ICS 11.180

Reference number : JIS T 9233 : 1997 (E)

PROTECTED BY COPYRIGHT



Documents

Document Sharing Hub

Foreword

This translation has been made based on the original Japanese Industrial Standard established by the Minister of International Trade and Industry and the Minister of Health and Welfare, through deliberations at the Japanese Industrial Standards Committee in accordance with the Industrial Standardization Law:

Date of Establishment: 1997-07-25

Date of Public Notice in Official Gazette: 1997-07-25

Investigated by: Japanese Industrial Standards Committee
Divisional council on Medical and Safety

JIS T 9233 : 1997, First English edition published in 2004-08

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 2004

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

M&T

PROTECTED BY COPYRIGHT

Testing methods for ostomy aids

1 Scope This Japanese Industrial Standard defines test methods for ostomy appliance, skin barrier disk (wafer, sheet, ring, roll) (hereafter referred to as “skin barrier”), and irrigation set among ostomy aids.

Remarks 1 The normative references of this Standard are shown below.

JIS B 7503 *Dial gauges*

JIS B 7516 *Metal rules*

JIS K 6250 *General rules for physical testing methods for rubber vulcanized or thermoplastic*

JIS K 6253 *Hardness testing methods for rubber, vulcanized or thermoplastic*

JIS K 6258 *Testing methods of the effect of liquids for vulcanized rubber*

JIS K 6718 *Polymethyl methacrylate sheets*

JIS K 6735 *Polycarbonate sheets*

JIS K 7100 *Standard atmospheres for conditioning and testing of plastics*

JIS K 7126 *Testing method for gas transmission rate through plastic film and sheeting*

JIS T 9232 *Glossary of terms used in ostomy aids*

JIS Z 0237 *Testing methods of pressure sensitive adhesive tapes and sheets*

JIS Z 8102 *Names of non-luminous object colours*

JIS Z 8401 *Rules for rounding off of numerical values*

JIS Z 8802 *Methods for determination of pH of aqueous solutions*

2 The units and numerical values given in { } in this Standard are based on the traditional unit system and are appended for information.

2 Definitions For the purposes of this Standard, the definitions given in JIS T 9232 and the following definitions apply.

- (1) **test volume** the maximum volume obtained in a specified test
- (2) **static durability** the durability under the situation where the increase of load or the deformation velocity of a sample is extremity slow and the deformity progresses as the equilibrium between an external force and a stress are always kept
- (3) **engagement type bag junction portion** the part at which a bag and face plate engage by an engagement method
- (4) **adhesion** a temporal adhesion, one type adhesion (a term generally used for permanent adhesion)
- (5) **adhesive property** three basic physical properties expressed as adhesive power, tuck, and holding power

- (6) **adhesive power** a power produced by contact between an adhesive face and adherend
- (7) **peel adhesion** a power needed to peel after a test fragment is pasted on a test plate and crimped of which measurement, a peel angle is 90 or 180 degrees
- (8) **tuck** a adhesive power to an adherend in a short time by a very light power
- (9) **holding power** a tolerable power of an adhesive against slippage when a static load is imposed to a longitudinal direction of an adherend and generally expressed as a distance which shifts in a certain time or a time which shifts with a certain distance
- (10) **deodorization of ostomy bag** a nature which prevents to permeate gas as a odor source produced from feces or urine collected in a ostomy bag and those changes (hydrogen sulfide, mercaptan, scatol, ammonia, or others)
- (11) **test plate** a plate having a certain quality, size, and surface condition used for measurement of adhesive power and holding power, made of stainless steels and also phenol resin laminates and acryl resin coating plate
- (12) **surface pH** hydrogen ion concentration at a skin side contacting with the surface of a skin barrier

3 Test method for ostomy aids

3.1 Test items

- (1) Measurement of test volume of ostomy bag
- (2) Measurement and observation of thickness, form size, colour name, and transparency of ostomy bag
- (3) Non-load static durability test of ostomy bag
- (4) Load static durability test of ostomy bag
- (5) Load static durability test of engagement type bag junction portion of two-piece ostomy appliance
- (6) General adhesive property test of skin contact side
- (7) Deodorization test of ostomy bag

3.2 General conditions of the test

3.2.1 Standard conditions of test place The test shall be conducted under the standard temperature condition second grade ($23\pm 2^{\circ}\text{C}$) specified in 2.2 (standard temperature condition in difference grades) of JIS K 7100.

3.2.2 Standard conditions of a sample A sample shall be left for three hours or more under the standard conditions of 3.2.1 before being provided for study.

3.2.3 Rounding method of test results The test results obtained in each test shall be rounded as shown in JIS Z 8401 and expressed in number of digits shown in table 1.

Table 1 Rounding method of test results

Test items		Test results obtained
Test volume	ml	Integer number position
Thickness	μ m	Integer number position
Form size	cm	Integer number position
Colour name / transparency (sensory observation)		Colour name , transparency
Non-load static durability of ostomy bag (sensory observation)		Presence or absence of water leak, time, place
Load static durability of ostomy bag (sensory observation)		Presence or absence of water leak
Load static durability of two-piece type (sensory observation)		Presence or absence of water leak, time, place
General adhesive property of contact skin side		
180-degree peel adhesion	N/cm(gf/cm)	double – digit after decimal point (integer number)
Holding power (length of slippage)	mm	one digit after decimal point
(falling time)	min	Integer number position
Tilting ball tack		Integer number position
Mihashi method	N/gf	one digit after decimal point (integer number 10 th position)
Deodorizing condition		
Permeability mol/m ² ·s·Pa {cm ³ /cm ² ·24h·atm}		three digits after decimal point
Permeability coefficient mol·m/m ² ·s·Pa {cm ³ ·cm/cm ² ·s·cmHg}		three digits after decimal point

3.2.4 Records In test results, conditions used shall be recorded.

3.3 Measurement method of test volume of ostomy bag

3.3.1 Device An example of test equipment is shown in figure1. Making a set plate and cleansing method of the surface shall be conducted as follows:

- (1) A set plate used shall be one with 5mm in thickness, 25cm in width, and 40cm in length specified in JIS K 6718 for general use or JIS K 6735 for general use.
- (2) A set plate has an inflow hole of 10mm in diameter at the position of 13cm from the top edge and the centre of the width direction. A flexible tube of 10 mm in internal diameter is connected through a three-directional valve. The set plate is held vertically and a fine line is drawn through the centre of the inflow hole horizontally [see figure 1(2)].
- (3) Ethanol ⁽¹⁾ is applied to the surface of the set plate and the surface is wiped off by a new gauze or others ⁽²⁾. After drying the surface, ethanol is applied to it again and then it is wiped off by a new gauze or others till its drying completely. This procedure is repeated three times or more until the surface is evaluated to become clean.

In addition, precautions must be taken against the following matters on use.

- (a) When dirt on the surface of the set plate doesn't disappear, it should not be used.
- (b) Cleansing procedures of the surface of the set plate should be conducted at each test.

Notes ⁽¹⁾ Use one for test

- ⁽²⁾ Use one in which fibres will not cut, or short fibres will not be eliminated and additives being soluble in ethanol ⁽¹⁾ are not contained.

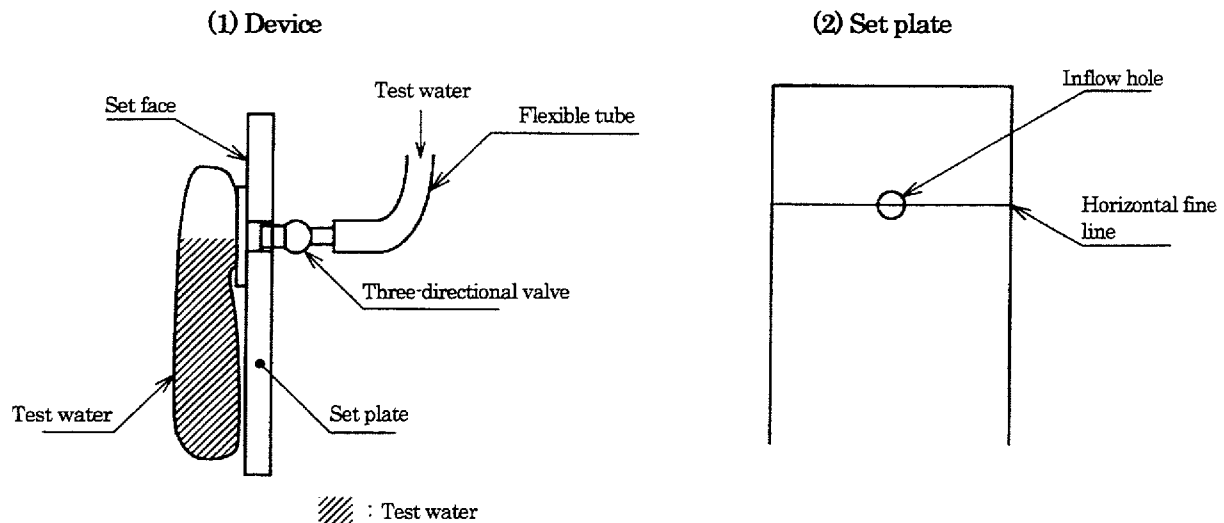


Figure 1 A test volume measurement device of ostomy bag

3.3.2 Preparation

(1) **Preparation of samples** The preparation of samples shall be conducted as follows.

- (a) As for an ostomy appliance in which an ostomy hole of 10mm or more in diameter is not made at skin side, an ostomy hole of 10mm in diameter is made at the centre of skin side.
- (b) A two-piece ostomy appliance is connected and installed by a method recommended by the manufacturer or distributor.
- (c) In the case of non-adhesive ostomy appliance, to prevent fluid leak by inflow of test water coloured with methylene blue, an adhesive or both-side adhesive tape is used.
- (d) In the case of an ostomy appliance having a bottom open-ended ostomy bag, the appliance is closed by a method recommended by the manufacturer or distributor. However, the closed position must be at 3 ± 0.5 cm from the lower edge of the appliance.
- (e) All air contained in an ostomy appliance is exhausted. However, an air retained for usual use such as molded article part doesn't need to be exhausted.
- (f) In the case of presence of flatus vent, the part is closed to prevent leak of test water with an adhesive tape or others.

(2) **Installation of a sample** In an ostomy appliance, a fine line is drawn horizontally through the centre of an ostomy hole at skin side. A sample is installed in such a manner that this fine line and the fine line of the set plate come in succession and the ostomy hole of skin side and the inflow hole of the set plate become concentric circular.

3.3.3 Procedures

- (1) The plate set an ostomy appliance is weighed with the accuracy of ± 1 g.
- (2) A test fluid is infused from a flexible tube at the flow velocity of 25 ± 5 ml/s.