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Skin barrier for ostomy aids — Test methods —

Part 1: Size, surface pH and water-absorbency

Barrière cutanée pour appareillages stomiques — Méthodes d'essai —

Partie 1: Taille, pH de surface et absorbance d'eau

Reference number
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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 173, *Assistive products for persons with disability*, Subcommittee SC 3, *Aids for ostomy and incontinence*.

ISO 12505 consists of the following parts, under the general title *Skin barrier for ostomy aids — Test methods*:

— *Part 1: Size, surface pH and water-absorbency*

— *Part 2: Wet-integrity and adhesive strength*

Introduction

Skin barriers are made to seal the ostomy bag to the skin and stay on, protecting the peristomal skin from excrements and secretion, and keeping the skin physiology intact by absorbing or permeating sweat.

The skin characteristics vary from person to person, and the products behave differently from each other depending on type of stoma, purpose of use, atmosphere, and other environmental factors, care techniques, the user's way of daily living etc. These make the testing situation complex and a number of test methods have been developed — laboratory and clinically based. But despite the efforts and improvements made, there are still problems for the user of the products — trial and error can still be the prime method to find an adequate product.

The problem that we primarily focus upon is the possibility for the users — purchasers, professional staffs, persons with stoma etc. — to rationally evaluate the products and the test methods used.

The skin barrier is an important part of an ostomy product. It protects the peristomal skin and holds the ostomy bag in place. Skin barriers shall be flexible, erosion-resistant, skin-friendly, and having adhesion properties that allows the bag to stay in place and be removed. Skin barriers are manufactured in a number of shapes and degrees of convexity and flexibility. Understanding how skin barriers are designed and work will help to provide ostomy patients or consumers with the best products.

The properties of skin barriers differ and there is a need to evaluate them properly. Skin barriers can be evaluated by either clinical trials or by laboratory test methods. Clinical trials are not covered here but in other International Standards. Laboratory test methods found in other International Standards were not developed for skin barriers but for industrial tapes. Methods found elsewhere differ by manufacturer, consumer, and medical professional.

The test methods found in this International Standard covers the evaluation of size, pH, and absorption. The methods have been specifically designed for skin barriers for ostomy products.

Skin barrier for ostomy aids — Test methods —

Part 1:
Size, surface pH and water-absorbency

1 Scope

This part of ISO 12505 specifies test methods dealing with a face plate of skin barriers for ostomy aids.

It does not cover medical properties (cytotoxicity, sensitization, irritation/intracutaneous reactivity, buffering effect, microbiological effects, etc).

The test methods do not individually or collectively define or recommend a product of a specific design, style or size, and do not recommend medical affairs such as treatment, nursing, etc.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 554:1976, *Standard atmospheres for conditioning and/or testing — Specifications*

ISO 7886-1:1993, *Sterile hypodermic syringes for single use — Part 1: Syringes for manual use*

ISO 10523:2008, *Water quality — Determination of pH*

ISO 24214:2006, *Skin barrier for ostomy aids — Vocabulary*

3 Terms and definitions

For the purposes of this document, the terms and definitions in ISO 24214 and the following apply.

3.1
surface pH
value obtained with a glass electrode pH meter in the skin-contacting part of skin barrier in moisturized condition

3.2
water absorbency
possibility which allows water in the skin barrier

3.3
sample
small trial sheet representing a whole product of skin barrier, including test specimen that is a single typical part or example taken from the trial sheet as test piece

3.4
linear dimension
straight shortest distance between any two points selected on the sample

4 Evaluation of skin barriers

4.1 General

This part contains the following tests/measurements:

a) measurement of sizes;

b) measurement of surface pH;

c) water absorbency test.

4.2 General conditions of test

4.2.1 Standard conditions of test place: Follow ISO 554:1976; preferred standard test conditions shall be temperature (23 ± 2) °C and relative humidity (50 ± 5) %. If not available, state conditions used in the test report.

4.2.2 Pretreatment of a sample: The sample is left under the conditions in 4.2.1 for 24 h or more.

4.2.3 Accuracy requirement/rounding of test results: The results shall be rounded and expressed by number of digits as shown in Table 1.

Table 1 — Rounding method of test results

Test items	Test results obtained
Size: Length, width, and diameter (mm)	Integer number position in all
Thickness (mm)	One digit after decimal point
Surface pH	One digit after decimal point
Water absorbency (mg/cm^2)	Integer number position

4.3 Measurement of size

4.3.1 Principle

Following description of shape, length and width or diameter of the skin barrier is measured using a scale ruler. The area of the skin barrier can be calculated, if necessary. The diameter of the precut or starter hole and the flange can be measured and also the maximum diameter to which the hole can be cut if applicable. The thickness of the skin barrier is measured using a thickness gauge. Measurements shall always be performed in 3 samples to take the average.

4.3.2 Apparatus

4.3.2.1 **Scale ruler**, capable of measuring to the nearest 1 mm.

Alternatively, a caliper can be used. For diameter measurements, a diameter gage can also be used.

4.3.2.2 **Thickness gage**, dial indicator capable of measuring to the nearest 0,1 mm having a flat surface of 8 mm diameter and capable of exerting a pressure of 12 kPa (0,6 N) on the object measured.

It is recommended to have a flat surface of (8 ± 1) mm, but the actual diameter shall be measured with a precision of 0.1 mm.

To obtain 12 kPa pressures on the measured object, an 8,0 mm flat surface with a total weight of 61,2 g can be used. If other dimensions are used within ± 1 mm, the weight shall be recalculated.

4.3.3 Procedures

4.3.3.1 Description of shape

4.3.3.1.1 Skin barrier faceplate

Describe the shape of the skin barrier faceplate according to the following list:

a) square;

b) rectangle;

c) diamond;

d) triangle;

e) circle;

f) oval;

g) others.

4.3.3.1.2 Skin barrier cross section

Describe the shape of the skin barrier cross section according to the following list:

a) flat;

b) convex;

c) other.

4.3.3.1.3 Skin barrier edge

Describe the shape of the skin barrier edge according to the following list:

a) flat edge;

b) tapered edge;

c) others.

4.3.3.1.4 Fringe of the skin barrier

Describe the fringe of the skin barrier according to the following list:

a) no tape;

b) tape border.

4.3.3.2 Length, width, and diameter

Measure dimensions according to the list below in at least three samples, and take the average value. See Figure 1.

— rectangle/square: measure the length and width of the skin barrier;

— diamond: measure the longest and shortest diagonal dimensions of the skin barrier;

— circle: measure the diameter of the skin barrier;

— oval: measure the longest and shortest diameter dimensions of the skin barrier;

— triangle: measure base and height of the skin barrier;

— others: measure the diameter or the longest and shortest linear dimensions of the skin barrier.

Measure the diameter of the starter hole or stoma hole if necessary. See Figure 2.

As skin barriers come in different shapes, it is sometimes necessary to measure other dimensions in order to be able to describe the product and to calculate the surface area. These calculations and measurements shall then be reported in the test report.

NOTE The flange is a plastic coupling ring used for coupling together the skin barrier with the ostomy bag. Manufacturers have their own coupling system which is named according to the size. However, it is not possible to couple together products from different manufacturers, the couplings are manufacturer specific.

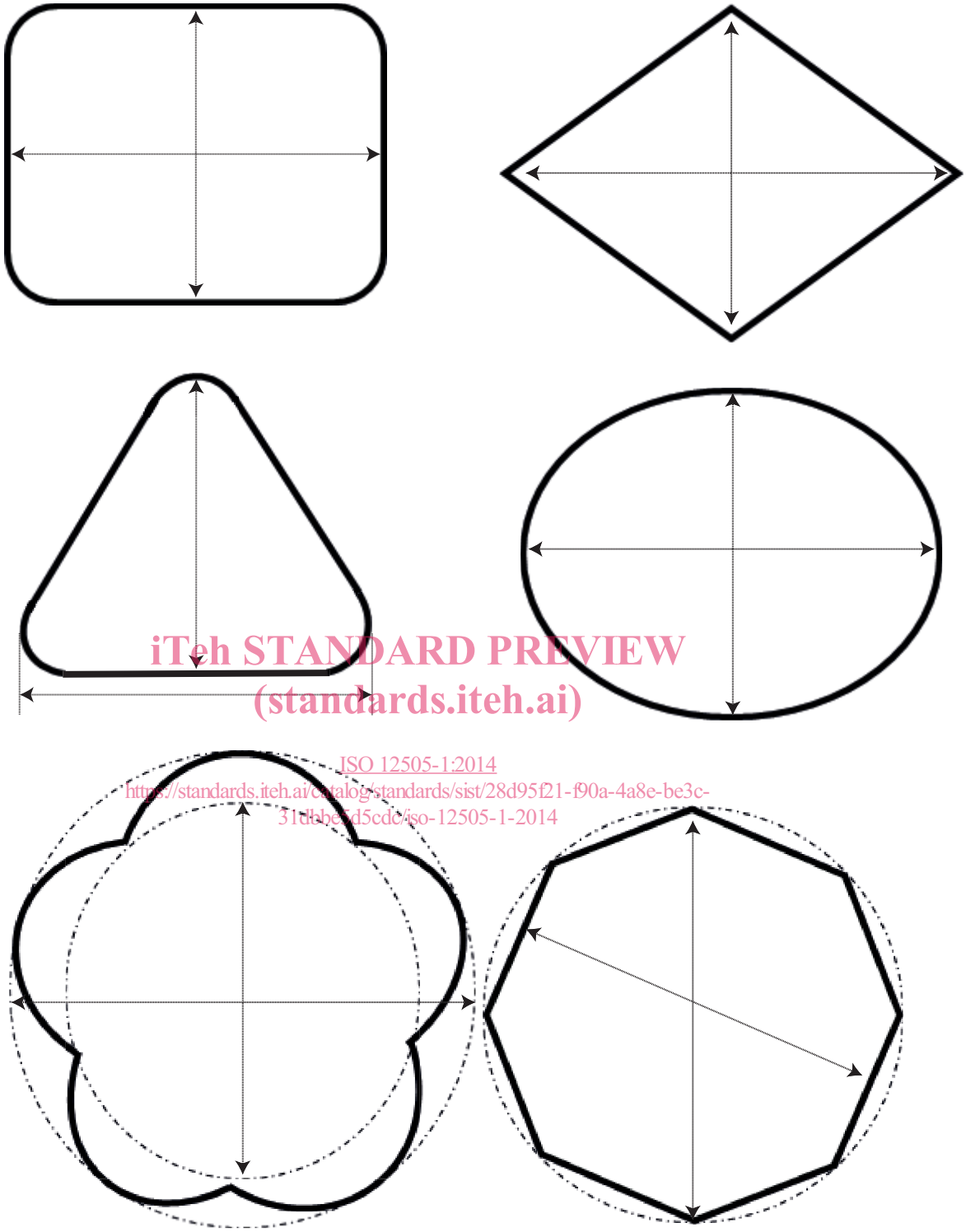

Figure 1 — Measurement map of sizes