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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

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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).

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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.

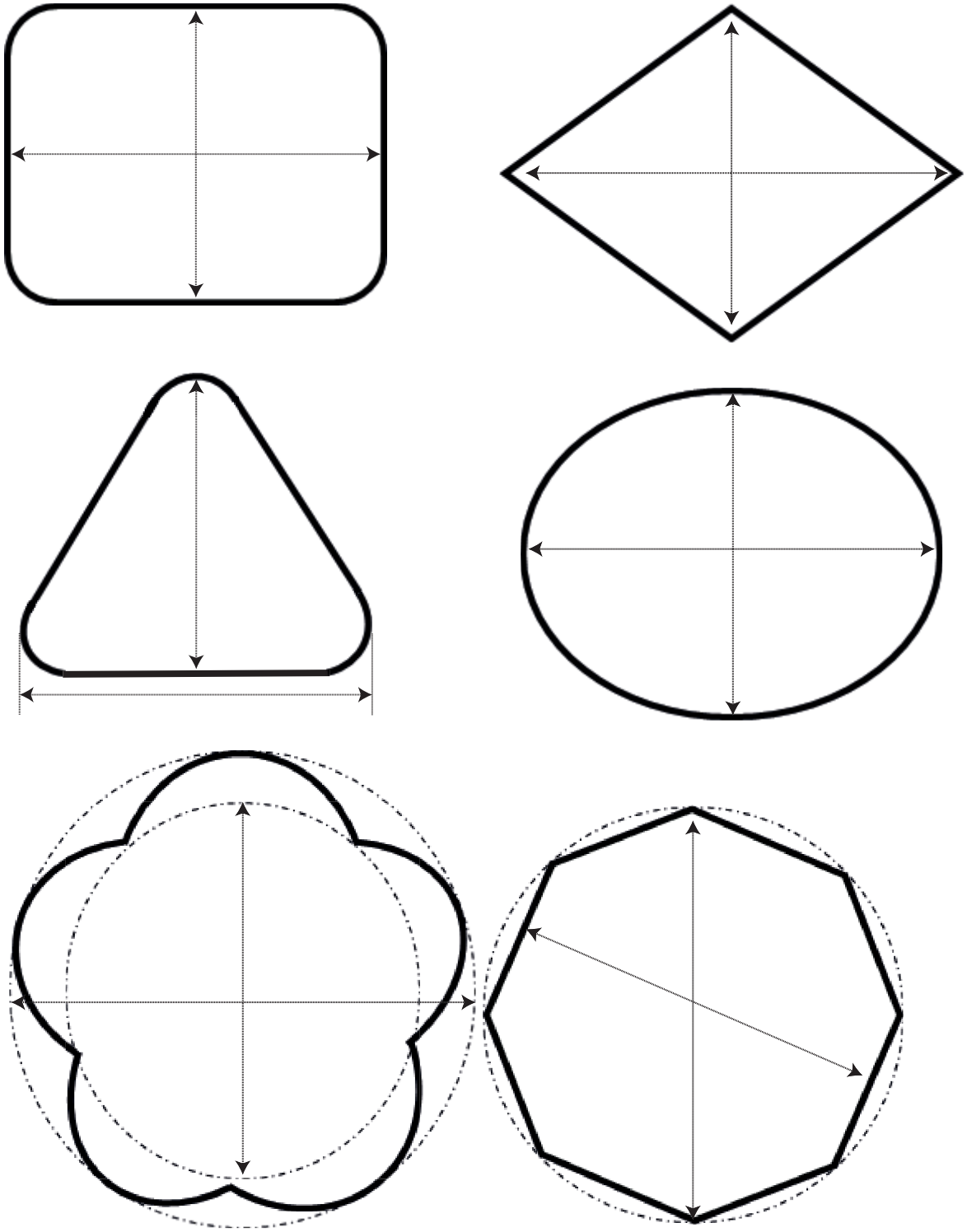
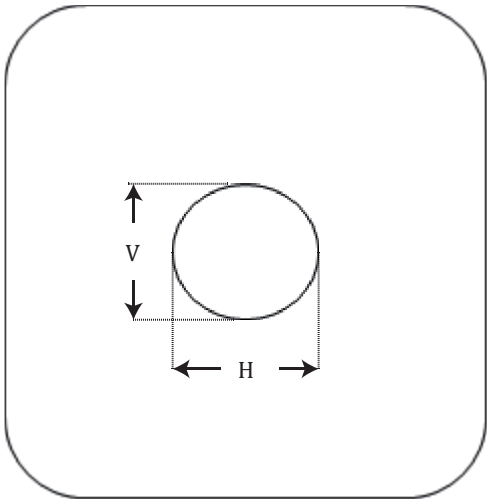


Figure 1 — Measurement map of sizes



Key

V vertical length

H horizontal length

NOTE Arrows show the length (mm) and direction to be measured

Figure 2 — Measurement map of stoma hole or starter hole

NOTE Arrows show the length (mm) and direction to be measured

4.3.3.3 Thickness

The thickness shall be measured with the release liner in place, which thickness is then subtracted. See Figure 3.

The thickness shall be measured at centre or around the stoma hole and 5 mm from the outer edge.

NOTE This is only a measurement of the skin barrier thickness and not the height of the convexity.

Measure the thickness by placing the skin barrier test between the jaws of the thickness gage. Lower the moving pressure foot gently on to the surface of the sample and take the reading on the gage within 2 s. Record this as the total thickness.

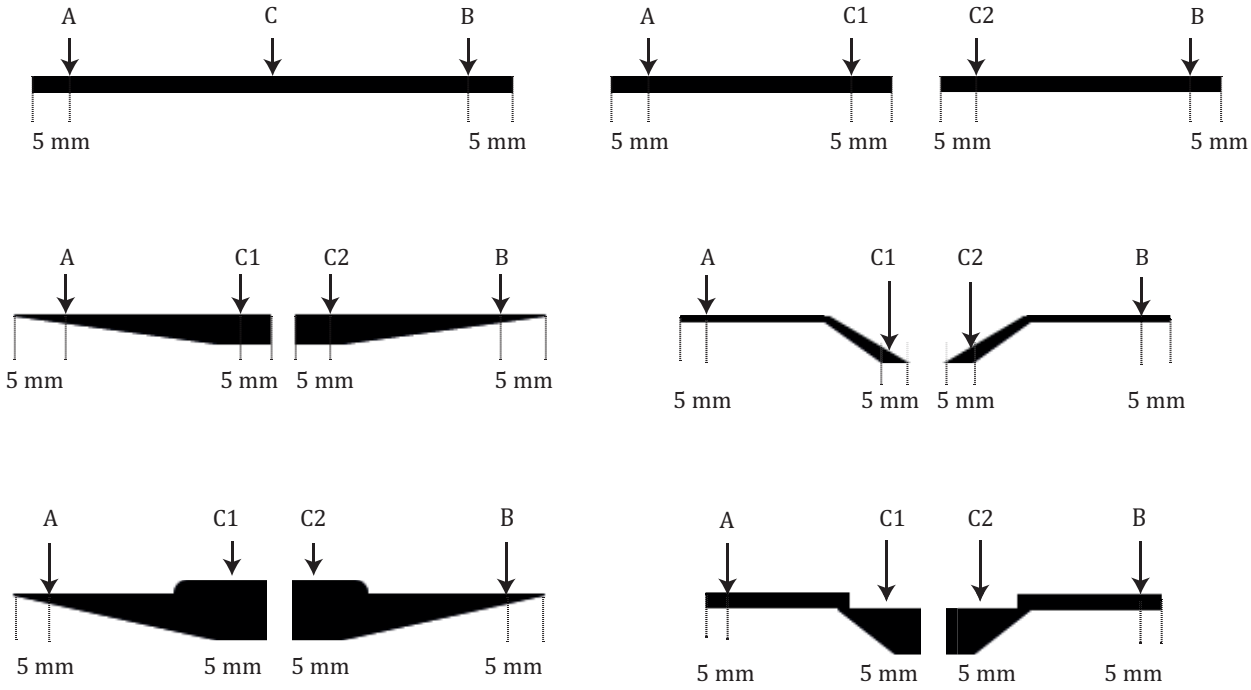
Remove the release liner and measure it in the same way. Record this as the thickness of the release liner.

Report the thickness of the skin barrier by subtracting the thickness of the release liner from the total thickness to the nearest 0,1 mm.

As skin barriers come in different shapes, like for example, convex plates, it might be necessary to measure several thicknesses in order to describe the product. These measurements shall then be reported in the test report.

Measure thickness including the backing or any cover if united by heat-seal or too tight to separate, but its inclusion shall be described in the measurement report.

Repeat the procedure in at least three samples, and take the average value.



Key

A and B	Site to be measured for bilateral peripheral thickness
C, C1, and C2	Site to be measured for central thickness

Figure 3 — Measurement map of thickness

4.4 Measurement of surface pH

4.4.1 Principle

The pH of the saline immersion surface of skin barrier is determined after 4 h immersion by using a pH meter and a flat electrode.

4.4.2 Apparatus

4.4.2.1 pH meter.

4.4.2.2 Flat electrode, for example, Horiba pH electrode 6261-10c, etc.

4.4.2.3 Test solution, saline or 0,9 % w/w NaCl solution.

4.4.2.4 Deionized water.

4.4.2.5 Standard buffer solutions, at pH 4,0 ± 0,02 and pH 7,0 ± 0,02.

4.4.2.6 Shallow container, Petri dish with a cover, wide enough to contain a sample about 10 cm^2.

4.4.2.7 Double-sided adhesive, a waterproof tape at least 3 cm wide: ex. Nitto #5000, etc.

4.4.2.8 Oven or incubator, having a circulating fan and capable of maintaining a temperature of (37 ± 1) °C, and being of a design to distribute the air evenly throughout the oven or incubator.

4.4.3 Procedures

It shall be measured according to ISO 10523. However, electrodes used for the measurement shall be flat in shape to make a sufficient contact with skin side (adhesive face) of the skin barrier. Three pieces of sample shall be measured and take the average.

a) Remove the skin barrier from an ostomy bag and a flange by cutting. Take the sample from the centre, or immediately adjacent to the stoma hole. The sample shall have a dimension of 10 cm^2 (discus of 3,57 cm diameter; square of 3,17 cm length) without hole.

b) Put a sample in a shallow container (Petri dish), fixing the back of the sample to the bottom of the dish by using double-sided adhesive, and remove the release liner.

c) Pour physiological saline solution 1 cm high above the sample into the Petri dish.

d) Leave the container at 37 °C for 4 h before opening the cover. Remove the container from the oven and maintain at room temperature for at least 1 h before measuring.

e) Standardize the pH electrode using pH 4,0 and 7,0 standard buffer solutions according to the operating instructions provided by the manufacturer.

f) Rinse the electrode with deionized water and carefully blot the electrode dry with a soft, absorbent tissue.

g) Open the cover in d), and record the pH by putting the flat electrode perpendicularly by its own weight on the immersed surface of the test sample at the centre part.

h) Repeat a) to g) in three samples, and take the average value.

4.5 Water absorbency test

4.5.1 Principle

This test is intended to assess the fluid absorption capacity of skin barriers through the skin contact surface by using a cylinder containing normal saline solution under the test condition for 6 h duration.

NOTE The test is modified from EN 13726–1:2002, Test methods for primary wound dressings - Part 1: Aspects of absorbency, 3.3 Fluid handling capacity.[1]

4.5.2 Apparatus

4.5.2.1 Five clean, dry cylinder containers, with a retaining ring or a flange at the open end of the cylinder, made of corrosion-resistant material with an internal diameter of (15 ± 1) mm having a flange at open-end and able to accommodate 10 ml of test solution.

A syringe of 10 ml-capacity without plunger nor needle by ISO 7886-1:1993 shall be used. The syringe shall be checked for circularity. The inner diameter should not differ by more than 0,2 mm in circularity.

4.5.2.2 Test solution, saline or 0,9 % NaCl solution.

4.5.2.3 Calibrated pipette, or a syringe with plunger for 10 ml.

4.5.2.4 Oven or incubator, having a circulating fan and capable of maintaining a temperature of (37 ± 1) °C, and being of a design to distribute the air evenly throughout the oven or incubator.

4.5.2.5 Balance, capable of weighing to the nearest 1 mg.

4.5.2.6 Piece of absorbent paper towel.

4.5.2.7 Closure of container, such as PARAFILM during incubation.

4.5.2.8 Test tube stand, or rack able to hang five container assemblies separately.

4.5.3 Procedures

See Figure 4.

a) Cut a circular sample of skin barrier 24 mm ± 1 mm suitable to be clamped over the test apparatus of cylinder to prevent leakage. If appropriate, remove the release liner from the skin contact surface facing inwards. Invert the container and press it on the sample tightly enough to prevent leakage. Achieving a good seal to the skin barrier surface require slight rocking or twisting the container against the barrier surface.

b) Weigh (mg) each container holding the sample (W1). In case of syringe, however, cut inlet or nozzle part off before weighing.

c) Using a suitable pipette, add 5 ml of saline solution. Repeat the procedures four times so as to prepare five samples. If leakage is present, repeat the procedure starting a). Close the inlet of cylinder or syringe with parafilm.

d) Place the assembled cylinders in the incubator of 37 °C.

e) After 6 h, remove the assembled cylinders from the incubator, remove the parafilm closure, and pour out saline solution. In order to exclude excess water around the container including the backing of the samples, allow them in upright position with open-end upward on a piece of absorbent paper towel at room temperature for 15 min.

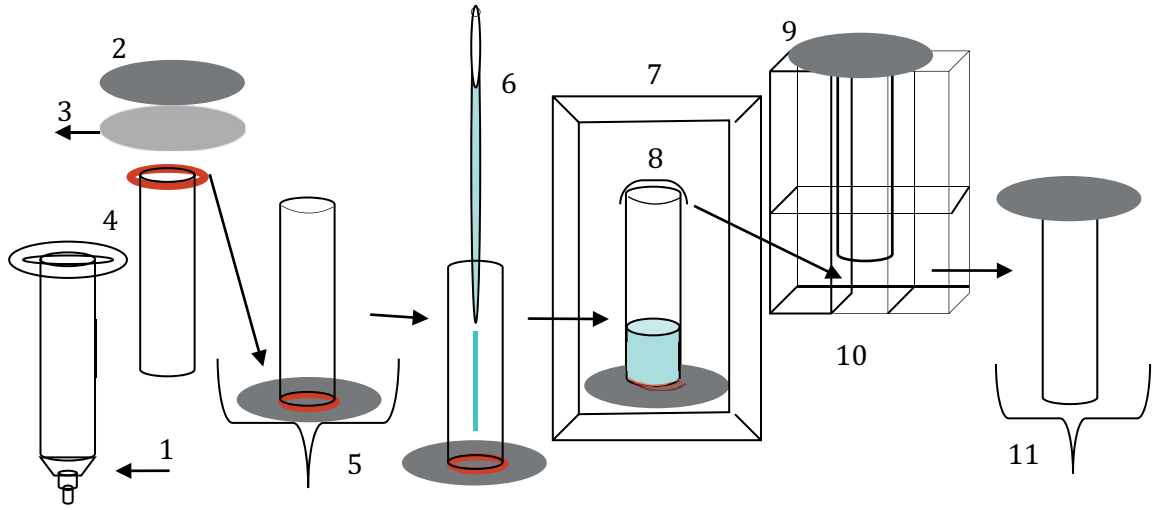
f) Shake off water-drops from the inner wall and hang the assembled container upside down on a rack in free air to drain out any excess fluid for (15 ± 2) min.

g) Reweigh the container with all its associated components including the sample (W2).

h) Calculate the mass of fluid absorbed during incubation by the sample material (W2 - W1).

i) Record a fluid quantity absorbed by the barrier and a diameter of the container. Divide the mass of fluid absorbed by the cross sectional area of the container to convert to mg absorbed per cm^2: Mean(W2-W1) / $\pi(C/2)^2$ mg/cm^2. C: inner diameter (cm) of the container.

j) Repeat a) to i) until at least five samples have been tested, and take the average value.



Key

1 cut off
2 skin barrier
3 release liner
4 syringe or cylinder with retaining ring or flange
5 balance (W1)
6 saline into container
7 incubator
8 closure
9 bottom up to empty
10 rack in free air
11 balance (W2)

Figure 4 — Water absorbency test

4.6 Test report

The test report shall contain the following information, and report all individual digital values together with their mean and standard deviation:

a) a reference to ISO 12505;

b) date, place, room temperature and humidity, and conditions of testing;

c) the measuring equipment used and their makers;

d) identification of the skin barrier tested: manufacturer's code number, batch or lot number, type, etc.;

e) shape and sizes of the skin barrier: length and width, or diameter, thickness (inclusion of backing or any attachments shall be described if so), and others if necessary; diameter of the starter hole and of the flange with the maximum diameter to which it can be cut if applicable, and surface area of the skin barrier;

f) surface pH of the skin barrier after 4 h in saline solution;

g) weight change (mg) per square cm in 6 h in water absorbency test of the skin barrier;

h) any deviation from the specified procedures and specific failure.

Bibliography

[1] EN 13726-1:2002, *Test methods for primary wound dressings — Part 1: Aspects of absorbency, 3.3 Fluid handling capacity*

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