
Skin barrier for ostomy aids — Test methods —

Part 2:

Wet integrity and adhesive strength

Barrière cutanée pour appareillages stomiques — Méthodes d'essai —

Partie 2: Résistance des adhésifs et intégrité une fois mouillés



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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 World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

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 stoma effluent 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, 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, based on laboratory and clinical testing. But despite the efforts and improvements made, there are still problems for the user of the products; trial and error may still be the prime method to find an adequate product.

The problem that we primarily focus upon is the ability 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 are flexible, erosion-resistant, skin-friendly and have adhesion properties that allow the bag to stay in place during use and be removed following use. 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 for adhesive products were not developed for skin barriers but for industrial tapes. The test methods found in this part of ISO 12505 cover the evaluation of wet integrity and adhesion. The methods have been specifically designed for skin barriers for ostomy aids.

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Skin barrier for ostomy aids — Test methods —

Part 2:

Wet integrity and adhesive strength

CAUTION — These test methods may not provide design information as there may be no direct relationship between laboratory test results and functional requirements. Data shall not be interpreted as applying to clinical use of the skin barrier because of variations in the skin and in the user's pouching techniques.

1 Scope

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

This part of ISO 12505 does not cover medical properties (cytotoxicity, sensitization, irritation/intracutaneous reactivity, buffering effect, microbiological effects, 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 24214, *Skin barrier for ostomy aids — Vocabulary*

ISO 12505-1, *Skin barrier for ostomy aids — Test methods — Part 1: Size, surface pH and water-absorbency*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 24214, ISO 12505-1 and the following apply.

3.1

wet integrity

ability of a skin barrier to maintain its physical form when exposed to fluid

3.2

adhesive strength

force required to peel a skin substitute from the surface of a skin barrier specimen

3.3

specimen

single typical part or example taken from the trial sample sheet as a test piece

4 Evaluation of skin barriers

4.1 General

This part contains the following tests/measurements:

Wet integrity test and adhesive strength (resistance upon removal) test.

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. The test methods, however, shall be utilized for the market need to fulfil the product property of the skin barrier.

4.2 General conditions of test

4.2.1 Standard conditions of test place: The preferred standard test conditions shall be a temperature of $(23 \pm 2) ^\circ\text{C}$ and a relative humidity of $(50 \pm 5) \%$. If not available, state the used conditions 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 ^a
Wet-integrity (mm)	One digit after decimal point
Adhesive-strength (N/cm)	Two digits after decimal point
^a Integer number position in all.	

4.3 Wet integrity

4.3.1 Principle

Because skin barriers absorb water, deform and collapse over time, the test is used to measure such reaction as the swelling and/or erosion in simulated use. It is measured at the centre of the skin barrier where a stoma hole of 25 mm diameter is punched out, under the influence of physiological saline solution, which is rotated by using a magnetic stirrer process in 24 h incubation at 37 °C. Such change is observed as discoloration of erosion/swelling around the centre hole and defined as follows.

- Inner diameter (D1) of the hole after test > 25 mm = outward erosion.
- Inner diameter (D1) of the hole after test < 25 mm = inward swelling.
- Outer diameter (D2) = the outer edge of the discoloured area = collapsed border.

4.3.2 Apparatus

4.3.2.1 Test solution, saline or 0,9 % NaCl solution. Test solution shall be pre-warmed to 37 °C.

4.3.2.2 Stirrer table, magnetic stirrers ([4.3.2.3](#)) being able to run from 300 rpm to 600 rpm. Rotation speeds shall be within calibration specifications.

4.3.2.3 Magnetic stirrer, glass-coated, 8 mm diameter × 40 mm length. Do not use Teflon-coated¹⁾ stirrers in order to reduce wear and to prevent the washed-out adhesive from sticking to the bar.

4.3.2.4 Plastic container/cup, translucent, 365 ml in capacity, 95 mm in diameter.

4.3.2.5 Lid to cup, translucent, 95 mm in diameter, with an 8 mm diameter centre hole and a 2 mm diameter air vent.

1) Teflon is an example of a suitable product available commercially. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of this product.

4.3.2.6 Punching tools, cutting two holes in lid (4.3.2.5); 8 mm and 2 mm in diameter, and cutting out a 65 mm diameter plate (4.3.2.9) with an 8 mm diameter centre hole, a 65 mm outer diameter and 45 mm inner diameter ring of foam (4.3.2.11), and a 55 mm outer diameter and 25 mm inner diameter ring-formed specimen of skin barrier.

4.3.2.7 Distance tube, fixing tube with a distance between the lid (4.3.2.5) and the plate (4.3.2.9). For example, Quick Star push-in fittings QSH-10-50 130726²⁾ by Festo Co.

4.3.2.8 Fasteners, auto cover clips, plastic (7 × 22) mm axis and 18 mm diameter head. The head shall not exceed 18 mm diameter. For example, Art.nr. 05009405³⁾ by Würth-Danmark A/S.

4.3.2.9 Mounting disc plate, APET (Amorphous Polyethylene Terephthalate) disk of 0.8 mm thickness, 65 mm diameter with an 8 mm diameter centre hole (for example, Axpert^{®4)} by Bayer Material Science AG).

4.3.2.10 Insulating material, used between the bottom of the plastic container (4.3.2.4) and the magnetic stirrer (4.3.2.3) to maintain the specified temperature constant and to keep the stirring function intact. The material, thickness and shape are up to the test person (for example, fabric or expanded polystyrene disk).

4.3.2.11 Waterproof ring-shaped foam, backed with adhesive, 65 mm diameter with a centre hole of 45 mm diameter, and used to prevent the outer rim of the skin barrier specimen from getting washed out by the salt water. It can be any tape that is good enough to stay on the specimen during the testing period.

4.3.2.12 Measuring template, circles with diameters between 15 mm and 45 mm at 1 mm increments printed on a transparent film, for measuring the inner and outer diameters after test. The diameters of the circles on the template shall be measured using a calibrated measuring tool before the template is used.

4.3.2.13 Oven or incubator, having a circulating fan and capable of maintaining the temperature of the test solution within an accuracy of $\pm 0,75$ °C and designed to distribute the air evenly throughout the oven or incubator.

4.3.3 Procedures

See [Figure 1](#).

- a) Prepare the required mounting disc plate of 65 mm diameter with an 8 mm diameter centre hole, the lid with an 8 mm diameter centre hole and a 2 mm diameter air vent hole, the adhesive foam ring of 65 mm outer diameter/45 mm inner diameter, and the required skin barrier ring specimen of 25 mm inner diameter/55 mm outer diameter, by punching out each hole.
- b) Remove the release liner from the skin barrier specimen but not the backing; the removed side is adhesive, and the adhesive side shall be attached to the disc plate.
- c) Place the specimen on the mounting disc plate centred around the 8 mm diameter hole in an upside-down position to avoid stretching of the adhesive, which could lead to non-circular centre holes after testing.
- d) Place the punched foam on top of the specimen centred around the outer edge.

2) Quick Star push-in fittings QSH-10-50 130726 is an example of a suitable product available commercially. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of this product.

3) Art.nr. 05009405 is an example of a suitable product available commercially. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of this product.

4) Axpert[®] is an example of a suitable product available commercially. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of this product.

- e) Assemble the lid and the disc plate of the specimen by using a distance tube and two auto clips at each edge.
- f) Place the magnetic stirrer in the cup and fill with 170 ml of pre-warmed 0,9 % NaCl solution. Use an insulating material between the container bottom and the magnetic stirrer to control temperature of the test sample constantly.
- g) Attach the lid assembly to the cup.

NOTE 1 Ensure that the skin barrier specimen is placed correctly, meaning, its backing side or non-adhesive side is faced toward the magnetic stirrer in the bottom of the plastic container.

- h) Place 6 specimen cups on the stirrer table and adjust the speed to 400 rpm.
- i) 6 containers with lid assembly shall be left on the stirrer table in the incubator for 24 h. It is important to control the solution (saline) temperature 37 °C within an accuracy of $\pm 0,75$ °C during the test. The temperature needs to be measured using a calibrated thermometer 1 h after the start and at the end of the test. The thermometer can be introduced through the air vent in each lid.
- j) Remove all containers with lid assembly from the incubator slowly enough to avoid further deformation of the specimens. Remove each lid assembly from each container and leave it upside-down (specimen in top and lid in down position) at room temperature, completing the diameter measurements within 10 min.
- k) Carefully apply the measuring template over the specimen at the centre hole and read its inner (D1) and outer (D2) diameters. The D1 diameter should be measured at the border of the central hole, while the D2 diameter should be measured at the outer edge of the discoloured area where the normal skin barrier colour has not changed.

NOTE 2 Ensure the template is as closer as possible to the specimen and aligned parallel to the mounting disc plate.

- l) Report mean value and standard deviation of 6 specimens in D1 and D2 and the testing conditions (see [Table 2](#)).

Table 2 — Wet integrity testing conditions and results

	No. 1	No. 2	No. 3	No. 4	No. 5	No. 6	Mean	Standard deviation
Inner diameter (D1)							mm	mm
Outer diameter (D2)							mm	mm
Temperature^a after 1 h stirring							°C	°C
Temperature^a at the end of the test							°C	°C

^a Temperature of the test solution: See [4.3.3 i\)](#).

4.4 Adhesive strength (resistance upon removal)

4.4.1 Principle

The measurement of the peeling force by traction resistance against skin barrier is carried out by pulling up a skin-like film in the 180 degree direction to a skin barrier specimen that is fixed to a test plate.

The test result shall be highly reproducible without breaking and stretching of the test specimen during the test procedure. This is the reason why the test is to peel a non-adhesive, hydrophobic film off a thick and fragile specimen of skin barrier material which consists of a combination of hydrophilic and hydrophobic polymers.

The traction velocity is also available in two speeds.

NOTE This is not ideal but it is important to have a method that distinguishes between the higher adhesion level barriers with good confidence. There are markets in the world where users wear barriers for long periods (seven days or more) and want a barrier that has high initial adhesion.

Definition:

Low adhesion: peel measurement is smooth at low speed (30 mm/min or a slower value).

High adhesion: peel measurement is smooth at high speed (210 mm/min or a faster value).

This test method does not measure the adhesive power of a whole layer of skin barrier to the skin itself. Initial tackiness by probe tack, creep or holding power and other adhesive properties by tests may also be used to characterize skin barriers, but may not correlate perfectly with clinical performance because of the reasons mentioned in the Caution before the Scope.

4.4.2 Apparatus

4.4.2.1 Test plate, at least 33 mm wide and 100 mm long steel/aluminum, resistant to bending and stretching, and adhesive to the tape (4.4.2.2). For example, SUS304 or ISO 683/13 No.11, P.

4.4.2.2 Double-sided adhesive tape, for immobilization of specimen: at least 33 mm wide and 100 mm long with peeling strength sufficient to maintain adhesion of the test skin barrier or specimen to the test plate (4.4.2.1) during the peel force measurement.

4.4.2.3 Non-adhesive film, a test film used for adherend: a 25 mm wide and 200 mm long fluorocarbon polymer film (wide accuracy ± 1 mm) (50 μm or 2 mil thick with a dynamical friction coefficient 0.1 to 0.2). For example, PET-2/Nitoflon No.900UL.⁵⁾

NOTE It is important to keep track of the side of the film used in the peel test. In 4.4.3 f) and g), the inner surface of the film is applied to the specimen and the outer surface is reinforced with office tape in 4.4.2.5.

4.4.2.4 Rolling device, a rubber-covered ($2 \pm 0,05$) kg hand steel-roller or equivalent automated roller of (95 ± 5) mm in diameter and (30 ± 5) mm in width, coated with rubber approximately 6 mm thick, maintaining a spring hardness of (80 ± 5) Hs.

For example, a 2,05 kg roller with a steel core and a Shore scale A 80 durometer silicone rubber cover may be used. Two legs extend beyond the circumference of the roller to prevent flat spots from developing, according to PSTC Appendage B, PSTC/AFERA/ISO/JATMA Harmonized Test Methods.

4.4.2.5 Fixation tape, a standard single-sided 19 mm wide office tape, for example, Scotch⁶⁾ brand transparent tape. This tape is used to reinforce the fluorocarbon tape in 4.4.2.3 in order to prevent stretching during the test traction and to protect the bottom cut edge of the skin barrier specimen as described in 4.4.3 e).

4.4.2.6 Tensile testing machine, capable of measuring up to 50 N (5 kg) within a range of 20 % to 100 % by using a 5 kg load cell, as described in ISO 527-3:—, Clause 5. For example, Tensilon RTC1210⁷⁾ (autonomic) loading system: Closed-loop controlled digital servo machine, maximum capacity 1 kN by A&D Co. Ltd., or equivalent, may be used.

5) PET-2/Nitoflon No.900UL is an example of a suitable product available commercially. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of this product.

6) Scotch is an example of a suitable product available commercially. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of this product.

7) Tensilon RTC1210 is an example of a suitable product available commercially. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of this product.

4.4.2.7 Oven or incubator, having a circulating fan and capable of maintaining the temperature of the test solution within an accuracy of $\pm 0,75$ °C and designed to distribute the air evenly throughout the oven or incubator.

4.4.3 Procedures

See [Figure 2](#).

- a) After a sample is kept under the pretreatment condition ($[23 \pm 2]$ °C and humidity $[50 \pm 5]$ %) for at least 12 h, 6 test fragments shall be cut out of the skin barrier sample, making specimens of 30 mm wide and at least 50 mm long, up to a maximum 100 mm long (without a hole or defect), in full thickness, including its backing but eliminating flange. The backing and the release liner shall not be eliminated before step d) below.

A specimen may be best taken from the sample of plain wafer without a starter hole or a hole in the centre, but if impossible, may be made by joining the bilateral parts beyond a hole without any space at the joint.

- b) Cleanse surface of a metal test plate.
- c) Adhere one surface of the double-sided tape to the surface of the test plate. The tape shall be as long as or longer than the skin barrier specimen. Apply the backing side of the specimen to the other adhesive surface of the double-sided tape, avoiding air between the specimen and the test plate, wrinkles and overstretching of the specimen, aligning the bottom cut edge of the specimen parallel to the lower edge of the test plate, and placing the specimen in the middle of the test plate in the width direction (leaving the specimen release liner in place).
- d) Remove the release liner from the specimen and cut the liner in halves longitudinally at the centre. Using this cut liner or another release liner, cover the exposed surface of the double-sided adhesive at both sides of the specimen or if the double-sided adhesive tape is longer than the test barrier specimen, in order to prevent contact between the exposed adhesive surface and the fluorocarbon tape/non-adhesive tape or the roller wheel used as step h) below.
- e) Cover 2 mm of the bottom edge, where the peel begins, with office tape to protect the cut edge of the skin barrier specimen during the initial peel.
- f) Reinforce the fluorocarbon film by applying a length of office tape to the outer surface side of the film. The office tape should be applied parallel to the direction of the fluorocarbon film and at least as long as the fluorocarbon film tape. Cut off any excess length of office tape.
- g) Apply the inner surface of the reinforced film of step f) above to the adhesive surface of the skin barrier specimen. Align the edge of the fluorocarbon film tape with the upper edge of the specimen so that it fully contacts the surface of the specimen, but do not apply pressure to the film.
- h) Then apply pressure with a standard roller traveling along the entire surface, starting from the upper edge to the lower one and reversing to roll from the lower edge upward at a velocity of 5 mm/sec.
- i) Place the test plate assembly in the oven of 37 °C for (30 ± 1) min.
- j) Remove the test plate assembly from the oven and immediately roll the specimen a second time, once in each direction as described in step h) above.
- k) Immediately after rolling, clamp the assembled test plate in the lower jaw of the tensile tester, ensuring it is aligned parallel to the direction of the peel.
- l) Set the upper jaw of the tensile tester as close as possible to the upper edge of the test plate while allowing convenient securing of the test film in the jaw. Clamp the free end of the tape-reinforced fluorocarbon film in the upper jaw of the tensile tester.

- m) Apply traction force at a uniform velocity of 30 mm/min in the upward direction at room temperature, recording the peeling resistance against the specimen (traction resistance). Continue the peeling up to the maximum height of the film on the skin barrier specimen.

Once peeling is started, record the peel force to determine the average value of the force between 20 % and 80 % of the peeling distance. Record the rate of grip separation or the head speed.

Note the type of failure: Some skin barriers with high adhesion levels may demonstrate cohesive failure in addition to clean adhesive failure, where the barrier material separates from the specimen surface and adheres to the fluorocarbon film, leaving its visible residues on the film. In these cases, the graph of the peel force will also show broad ranges of higher peel force where the barrier material is breaking. This failure is distinguished from the presence of an air bubble between the barrier surface and the fluorocarbon film, which produces a sharp, short duration peak in the peel force. [Figure 3](#) shows acceptable cases, air bubble cases and cohesion cases as reference graphs.

- n) The test shall be repeated 6 times for each sample; 6 new specimens for each sample are tested, recording the average peel force.

NOTE Individual specimens can be prepared at 5 min intervals to allow enough time to roll and peel each individual specimen after it is removed from the oven while minimizing total test time. Each assembled test plate can be incubated for 30 min every 5 min. Do not incubate all plates at the same time but incubate one by one.

- o) For each sample, report the average peel force for each specimen, and the arithmetic mean value of 6 average peel forces. Record the type of instrument used and any deviation from the procedure specified that may have affected the result and the type of failure for each specimen (see [Table 3](#)).
- p) If peeling is smooth and consistent, stop further test and use this data.
- q) If the peel is not smooth and shows the cohesion issue, repeat steps a) to o) by the traction velocity at 210 mm/min in step m). If the peel is not smooth at this higher speed, repeat steps a) to o) by the traction velocity at 300 mm/min in step m) or 400 mm/min, if necessary, to obtain a smooth peel. If a smooth peel is not obtained even at the highest speed (400 mm/min), stop and report that no peel data were obtained.

Table 3 — Peeling force testing results

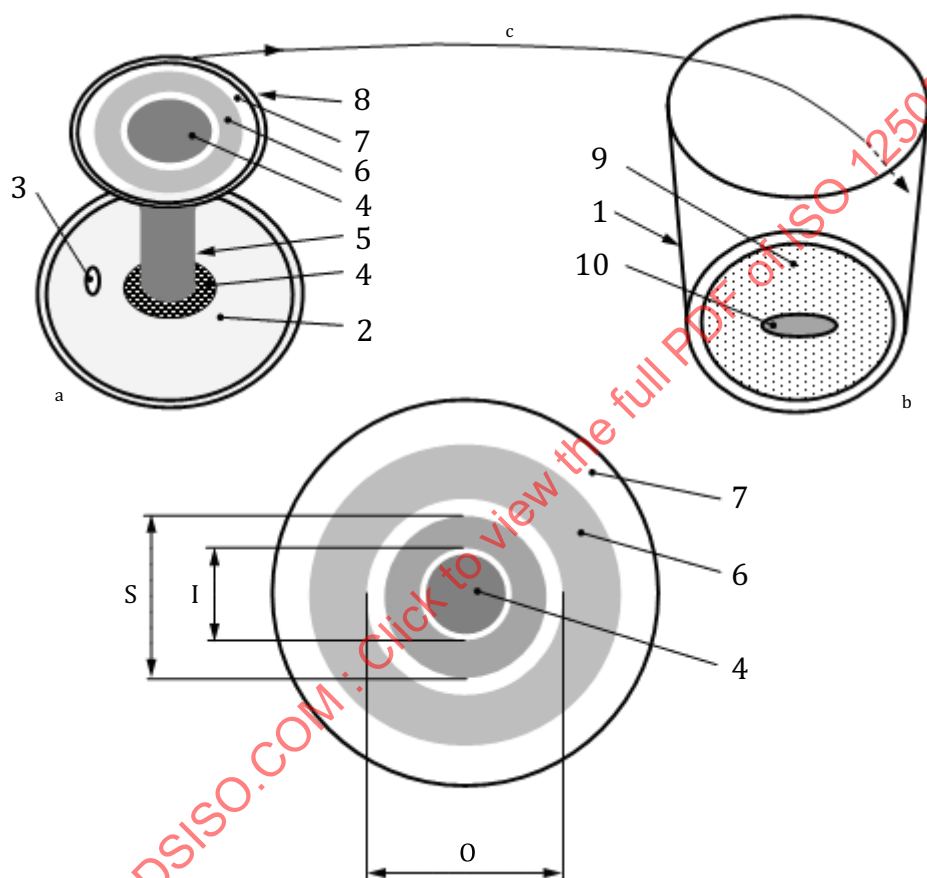
Specimen	Average Peel Force ^a (N/cm)		Note
No. 1	S	F	
No. 2			
No. 3			
No. 4			
No. 5			
No. 6			
Mean			
Standard deviation			
^a For a failure case, do not enter peel force, and describe failure type or explain reason for exclusion in the Note. S At the slower velocity of 30 mm/min. F At the faster velocity of 210 mm/min or more.			

4.5 Test report

The test report shall contain the following information:

- a) a reference to this part of ISO 12505, i.e. ISO 12505-2;

- b) the date, place, room temperature and humidity, and conditions of testing;
- c) the name of the measuring equipment used and the maker;
- d) an identification of the skin barrier tested: manufacturer's code number, batch or lot number, type, etc.;
- e) the wet integrity by mean value of the diameter D1 and D2 in mm with standard deviation;
- f) the adhesive strength by 180° peeling in N/cm: the arithmetic mean and standard deviation with the peeling velocity;
- g) any deviation from the specified procedures and any specific failure.



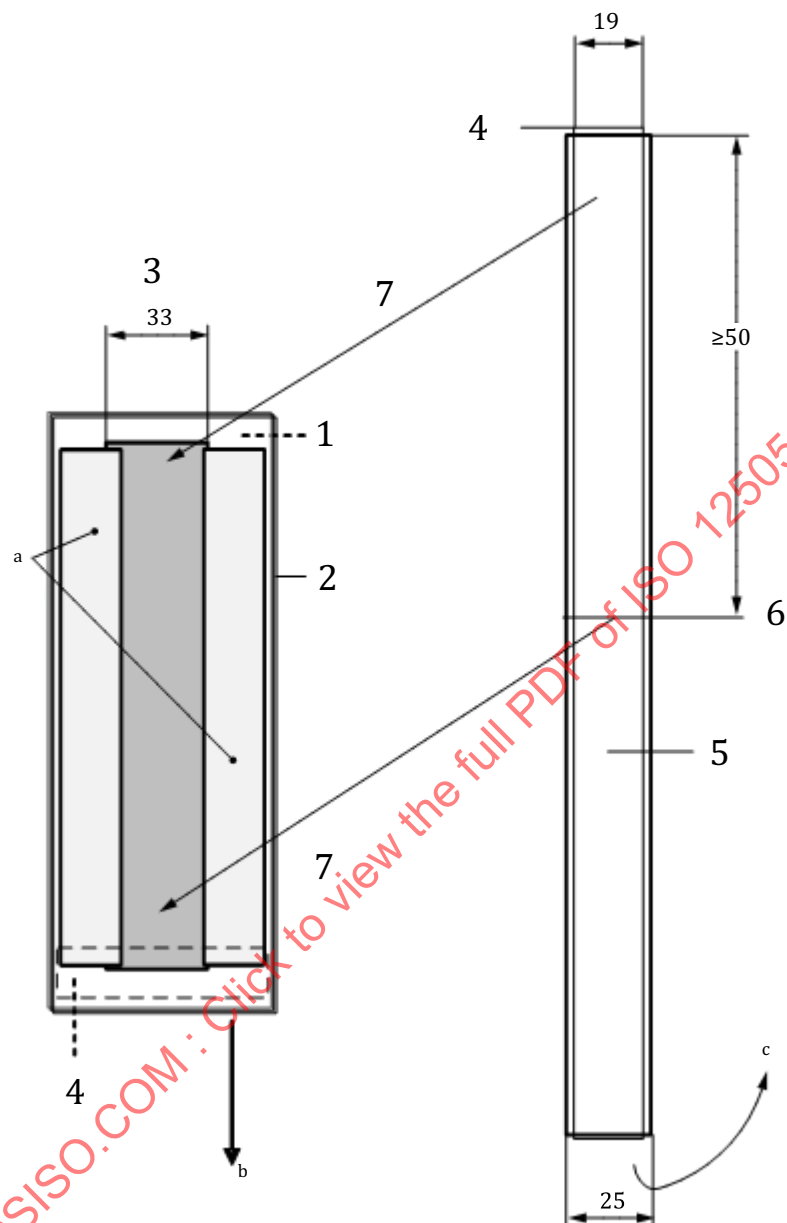
Key

- | | |
|---------------------------------------|--|
| 1 cup, translucent | 9 insulating material |
| 2 lid to cup, translucent | 10 magnetic stirrer |
| 3 air vent | S starting hole |
| 4 auto-clips: fastener | I inner diameter |
| 5 distance tube, fixing | O outer diameter |
| 6 skin barrier specimen | a Lid assembly. |
| 7 foam with adhesive: waterproof tape | b Cup. |
| 8 APET: mounting plate | c The lid assembly will be attached upside-down. |

NOTE The lower middle shows test measurement of the specimen on the mounting disc plate.

Figure 1 — Apparatus and procedure of wet integrity test

Dimensions in millimetres

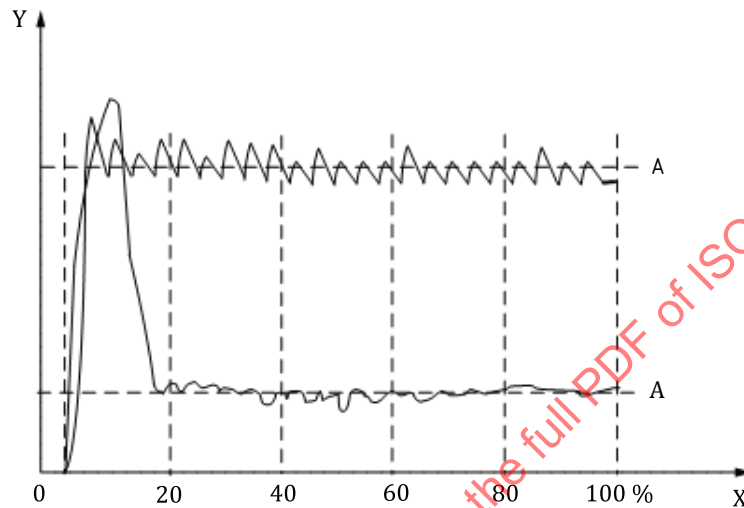


Key

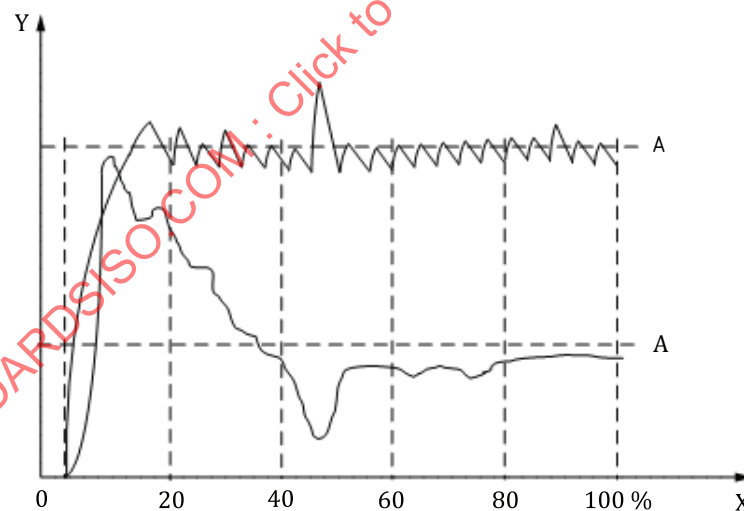
- 1 test plate (33 mm × 100 mm)
- 2 double-sided adhesive tape (33 mm × 100 mm)
- 3 specimen of skin barrier
- 4 office tape (cover the bottom 2 mm of the specimen)
- 5 non-adhesive film, enforced with office tape
- 6 to the bottom edge of the specimen
- 7 rolling pressure after attaching the non-adhesive film on the specimen
- a Cover the exposed surface of the taped plate(2) by using the release liner after applying the specimen.
- b To the lower jaw of the tensile testing machine.
- c To the upper jaw of the tensile testing machine.

Figure 2 — Fixation of skin barrier sample for adhesive strength test

- a) Preparation is carried out under the condition of $(23 \pm 2) ^\circ\text{C}$ and humidity of $(50 \pm 5) \%$.
- b) Press a test film to the specimen on a test plate with a roller travelling along the entire surface, starting from the upper edge to the lower one and reversing upward.
- c) Place the test plate assembly in the $37 ^\circ\text{C}$ oven for $(30 \pm 1) \text{ min}$.
- d) After removing the specimen from the oven, immediately roll the specimen a second time, once from the top edge to the bottom edge and reversing to roll upward.
- e) Immediately mount the test plate in the tensile tester and start the peel.



a) Acceptable cases



b) Failure cases with air/crack in middle