BRITISH STANDARD

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13726-2:2002

Test methods for primary wound dressings —

Part 2: Moisture vapour transmission rate of permeable film dressings

The European Standard EN 13726-2:2002 has the status of a British Standard

ICS 11.120.20

National foreword

This British Standard is the official English language version of EN 13726-2:2002.

The UK participation in its preparation was entrusted by Technical Committee CH/117, Medical textiles, to Subcommittee CH/117/1, Test methods for non-wovens for use in compresses, which has the responsibility to:

— aid enquirers to understand the text;

— present to the responsible European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;

— monitor related international and European developments and promulgate them in the UK.

A list of organizations represented on this subcommittee can be obtained on request to its secretary.

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This British Standard, having been prepared under the direction of the Health and Environment Sector Policy and Strategy Committee, was published under the authority of the Standards Policy and Strategy Committee on 15 April 2002

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English version

Test methods for primary wound dressings - Part 2: Moisture vapour transmission rate of permeable film dressings

M6thodes d'essai pour les pansements primaires en contact avec la plaie - Partie 2: Perm6abilit6 & la vapeur d'eau des pansements comprenant un film permeable

Prufverfahren fur primare Verbandstoffe (Wundauflagen) - Teil 2: Feuchtigkeitsdurchdringungsrate durchlassiger Folienverbande

This European Standard was approved by CEN on 22 February 2002.

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Foreword

This document EN 13726-2:2002 has been prepared by Technical Committee CEN/TC 205 "Non-active medical devices", the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by September 2002, and conflicting national standards shall be withdrawn at the latest by September 2002.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

EN 13726 will consist of the following parts under the general title Test methods for primary wound dressings:

- Part 1 : Aspects of absorbency
- Part 2 : Moisture vapour transmission rate of permeable film dressings
- Part 3 : Waterproofness
- Part 4 : Conformability
- Part 5 : Bacterial barrier properties
- Part 6 : Odour control

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Introduction

EN 13726 specifies test methods and does not contain performance requirements. Part 2 of this standard describes test methods for the determination of the moisture vapour transmission rate of permeable film dressings.

Test methods for other aspects of primary wound dressings are described in other parts of EN 13726.

1 Scope

Part 2 of EN 13726 describes test methods recommended for the evaluation of moisture vapour transmission rate of permeable film primary wound dressings.

2 Terms and definitions

For the purposes of this standard the following terms and definitions apply.

2.1
moisture vapour transmission rate (MTVR)
permeability of materials to the passage of water molecules from the skin contact side to the external atmosphere under controlled conditions of humidity and temperature

2.2
permeable wound dressing

wound dressing that permits water vapour to pass from the skin or wound through it to the external atmosphere

2.3
primary wound dressing
material or combination of materials, in any shape, form or size that is intended to remain in direct contact with a wound

NOTE Primary wound dressings are used as mechanical barriers, for the absorption or transmission of exudates, to manage the micro-environment of the wound, and can enable the wound to heal by primary or secondary intent. Devices which have a metabolic, pharmacological or immunological interaction as their primary intent are excluded.

3 Test methods for moisture vapour transmission rate (MVTR)

3.1 Test conditions

Unless otherwise stated, condition the test samples and carry out the tests at a temperature of (21 ± 2) °C and a relative humidity of 60 % RH ± 15 % RH.

3.2 MVTR of a wound dressing when in contact with water vapour

3.2.1 Significance and use

The test is intended for the evaluation of the MVTR of a wound dressing when it is in contact with water vapour.

This test measures moisture vapour transmission through dressings by mass differential. Entrapment of fluid can lead to serious consequences for skin integrity. Dressings should have sufficient permeability to moisture vapour to prevent fluid collecting under the dressings.

NOTE The test is suitable for use with, for example, thin film wound dressings.

3.2.2 Equipment

3.2.2.1 Five clean, dry cylinders, made of corrosion-resistant material with an internal diameter of (35,7 ± 0,1) mm (cross-sectional area 10 cm^2) having a flange at each end and able each to accommodate 20 ml of deionised water. (An example of a cylinder that has been found to be adequate is given in Figure 1).

At one end of the cylinder is an annular clamping plate with an orifice area of 10 cm^2. At the other end of the cylinder is a solid metal plate the full diameter of the flange. A sealing ring is also advisable to ensure an effective seal against the flange. The plates at both ends are clamped in position against the flanges.

3.2.2.2 **Balance,** capable of weighing 100 g with an accuracy of 0,000 1 g.

3.2.2.3 **Humidity meter,** capable of detecting whether or not the 20 % RH limit has been exceeded.

3.2.2.4 **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 so as to maintain humidity at less than 20 % RH throughout the test.

3.2.2.5 **Scalpel,** or alternative cutting equipment.

3.2.3 Procedure

3.2.3.1 Using the flange of clamping plate as a template, cut out a sample of the material to be tested.

3.2.3.2 Add sufficient deionised water at room temperature (minimum 20 °C) to leave an air gap of (5 ± 1) mm between the liquid surface and the sample when clamped in place.

3.2.3.3 Place the circular sample exactly over the flange of the test container. Clamp it in place without stretching the sample, using the clamping plate / clamps to give a watertight seal. If the specimen has an adhesive coated surface, place the adhesive side to the cylinder flange. For non-adhesive or pattern coated materials, take care to ensure a complete seal. Repeat the procedure four times so as to prepare five samples.

NOTE To ensure a good seal a small amount of sealant such as petrolatum can be applied to the flange.

3.2.3.4 Weigh and record the mass of the container, sample and liquid (V^) to the nearest 0,000 1 g.

3.2.3.5 Place the container in the oven / incubator at temperature of (37 ± 1) °C with the sample uppermost.

3.2.3.6 After 18 h to 24 h remove the container from the oven / incubator and record the test period (7) to the nearest 5 min.

3.2.3.7 Immediately reweigh the container and sample and liquid and record the mass (W_2) to the nearest 0,000 1 g.

3.2.4 Calculation of results

3.2.4.1 Calculate the MTVR using the formula:

$$X = (W_1 - W_2) \times 1\,000 \times 24/T$$

where

X is MVTR ($g.m^{-2}\text{-}24\ h^{-1}$);

W_1 is the mass of the container, sample and liquid;

W_2 is the mass of the container, sample and liquid after test period;

T is the test period in hours.

3.2.4.2 Calculate the mean result of at least five samples.

3.2.4.3 Discard values differing by more than 20 % from the mean and repeat the test.

3.2.4.4 The test is invalid if the humidity levels within the oven / incubator rise to more than 20 % RH during the test period.

3.2.5 Test report

The report shall include at least the following information:

a) type of dressing, including lot number;

b) any deviations from the test method;

c) individual and average results;

d) date of test;

e) identity of the person(s) who carried out the test.

3.3 MVTR of a wound dressing when in contact with liquid

3.3.1 Significance and use

This test is intended for the evaluation of the MVTR of a waterproof wound dressing when it is in contact with liquid. It measures the MVTR through dressings by mass differential. Entrapment of liquid can lead to serious consequences for skin integrity.

3.3.2 Equipment

3.3.2.1 **Five clean, dry cylinders,** as specified in 3.2.2.1.

3.3.2.2 **Balance,** as specified in 3.2.2.2.

3.3.2.3 **Humidity meter,** as specified in 3.2.2.3.

3.3.2.4 **Oven or incubator,** as specified in 3.2.2.4.

3.3.2.5 **Cutting equipment,** as specified in 3.2.2.5.

3.3.3 Procedure

3.3.3.1 Perform the procedures described in 3.2.3.1 to 3.2.3.4.

3.3.3.2 Invert the container and place it in the oven / incubator at temperature of (37 ± 1) °C so that the deionised water is in contact with the sample. Ensure there is a sufficient gap between the surface of the sample and the surface of the oven/incubator shelf to allow good airflow across the surface of the sample.

3.3.3.3 After approximately 4 h remove the container from the oven / incubator and record the test period (T) to the nearest 5 min.

3.3.3.4 Immediately reweigh the container and sample and record the mass (W_2) to the nearest 0,000 1 g.

3.3.4 Calculation of results

3.3.4.1 Calculate the results as described in 3.2.4.1 to 3.2.4.4.

3.3.4.2 If the MVTR of the test sample is less than 1 000 $gm^{-2}\,24h^{-1}$, repeat the test using a time of 18 h to 24 h in 3.3.3.3.

3.3.5 Test report

The report shall include at least the following information:

a) type of dressing, including lot number;

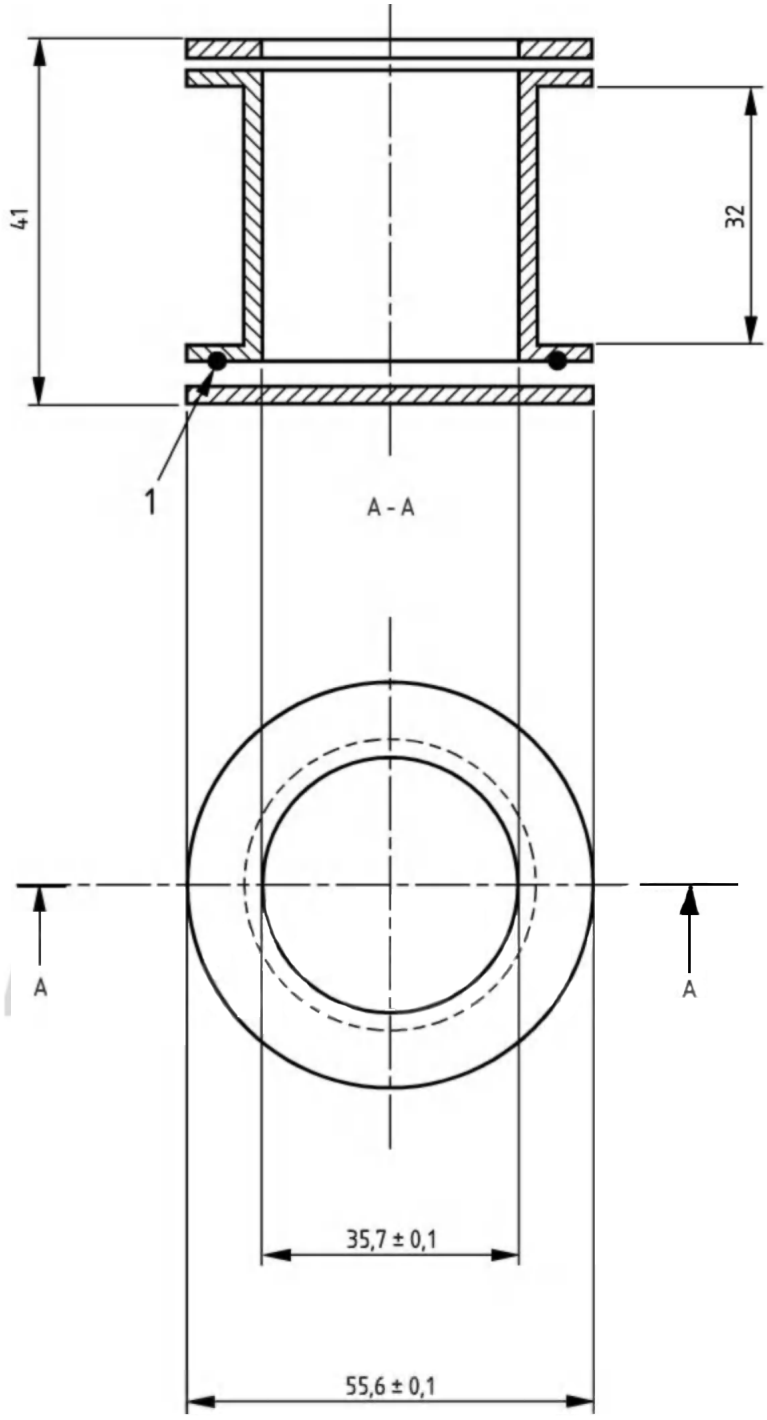
b) any deviations from the test method;

c) individual and average results;

d) date of test;

e) **identity of the person(s) who carried out the test**.

Dimensions in millimetres



Key

1 Sealing ring

Figure 1 - Example of a cylinder that has been found to be adequate

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