SLOVENSKI STANDARD
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Preskusne metode za sanitetni material za primarno oskrbo rane - 1. del: Vidiki absorpcije

Test methods for primary wound dressings - Part 1: Aspects of absorbency

Prüfverfahren für primäre Verbandstoffe (Wundauflagen) - Teil 1: Aspekte des Saugverhaltens (Absorption)

Méthodes d'essai pour pansements primaires - Partie 1: Absorption

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Test methods for primary wound dressings - Part 1: Aspects of absorbency

Méthodes d'essai pour les pansements primaires en contact avec la plaie - Partie 1: Absorption

Prüfverfahren für primäre Verbandstoffe (Wundauflagen) - Teil 1: Aspekte des Saugverhaltens (Absorption)

This European Standard was approved by CEN on 25 February 2002.

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This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Management Centre has the same status as the official versions.

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Foreword

This document EN 13726-1:2002 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of an identical text or by endorsement, at the latest by September 2002, and conflicting national standards shall be withdrawn at the latest by September 2002.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

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Introduction

EN 13726 specifies test methods and does not contain performance requirements. Part 1 of this standard describes test methods for different aspects of absorbency.

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

1 Scope

Part 1 of EN 13726 specifies test methods recommended for the evaluation of some aspects of absorbency of primary wound dressings.

2 Terms and definitions

For the purposes of this European Standard the following terms and definitions apply.

2.1
alginate dressing
dressing containing salts of alginic acids which interact with physiological fluids to form a gel

2.2
amorphous hydrogel
semi-solid gel that contains hydrophilic polymers and water

2.3
fluid affinity of a wound dressing
ability to absorb fluid from or donate fluid to a simulated wound

2.4
fluid handling capacity
sum of the fluid absorbed and the fluid transpired through the dressing

2.5
free swell absorptive capacity
total absorptive capacity in the presence of excess test liquid and in the absence of any applied load

2.6
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 absorbency

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 Free swell absorptive capacity

3.2.1 Significance and use

The test is intended to assess the performance of dressings, typically used on moderately to heavily exuding wounds, where total absorptive capacity is an important feature.

It is only appropriate for dressings which will stay physically intact and which will reach their maximum absorptive capacity within 30 min, under the test conditions.

NOTE The test is suitable for use with, for example, most types of alginate dressings in either the sheet or rope (packing) form. In the case of alginate dressings, the ratio of test liquid to sample weight is an important factor due to the interaction which takes place.

3.2.2 Equipment

3.2.2.1 **Petri dishes,** (90 ± 5) mm in diameter.

3.2.2.2 **Laboratory oven**, with forced air circulation, capable of maintaining a temperature of (37 ± 1) °C.

3.2.2.3 **Test solution A**, consisting of sodium chloride and calcium chloride solution containing 142 mmol of sodium ions and 2,5 mmol of calcium ions as the chloride salts. This solution has an ionic composition comparable to human serum or wound exudate. It is prepared by dissolving 8,298 g of sodium chloride and 0,368 g of calcium chloride dihydrate in deionised water and making up to 1 litre in a volumetric flask.

3.2.2.4 **Balance**, capable of weighing 100 g with to the nearest 0,000 1 g.

3.2.3 Procedure

3.2.3.1 Place a single, weighed 5 cm x 5 cm (as presented to the wound) or 0,2 g (for cavity dressing) sample in a Petri dish.

3.2.3.2 Add a quantity of test solution warmed to (37 ± 1) °C corresponding to 40 times the mass of sample being examined, ± 0,5 g.

3.2.3.3 Transfer to the oven and allow to stand for 30 min at (37 ± 1) °C.

3.2.3.4 Using forceps suspend the sample being examined, either by one corner or by one end as appropriate, for 30 s and then weigh it.

3.2.3.5 Repeat 3.2.3.1 to 3.2.3.4 with a further nine samples

3.2.4 Calculation of results

Express absorptive capacity as the average mass of solution retained per 100 cm^2 (as presented to the wound) or per gram of sample (for cavity dressing).

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 absorptive capacity results;

d) date of test;

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

3.3 Fluid handling capacity (absorbency plus moisture vapour transmission rate, liquid in contact)

3.3.1 Significance and use

This test is intended to assess the fluid handling capacity of waterproof wound dressings typically used for more than 24 h and when absorption of exudate and management of the micro-environment are important.

3.3.2 Equipment

3.3.2.1 **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 test solution. (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. To prevent transpiration through the edges of the dressing an impermeable tape or alternative sealant may be used in this area. 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.

3.3.2.2 **Test solution A,** as specified in 3.2.2.3.

3.3.2.3 **A calibrated pipette.**

3.3.2.4 **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 relative humidity at less than 20 % RH throughout the test.

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

3.3.2.6 **Balance**, as specified in 3.2.2.4.

3.3.3 Procedure

3.3.3.1 Cut a circular sample of dressing suitable to be clamped over the test apparatus to prevent leakage. If appropriate, remove the release liner and affix to the upper flange of a cylinder with the wound contact surface facing inwards.

3.3.3.2 Place the retaining ring on the outer surface of the dressing and fasten in place.

3.3.3.3 Weigh the cylinder together with the base and clamps (W_1). Invert the cylinder and, using a suitable pipette, add approximately 20 ml of test solution A. Fix the solid plate in position and reweigh (W_2). Repeat the procedure four times so as to prepare five samples.

3.3.3.4 Place the assembled cylinder in the incubator.

3.3.3.5 After 24 h, remove the cylinders from the incubator, allow them to equilibrate at room temperature for 30 min and reweigh *(W_3)*.

3.3.3.6 Remove the solid plate from each cylinder, gently pour out any excess fluid and leave the cylinder to drain in the inverted position for (15 ± 2) min.

Reweigh the cylinder and all its associated components, including the dressing *(W_4)*.

3.3.3.7 Repeat steps 3.3.3.1 to 3.3.3.6 using fresh samples for a contact time of 48 h.

3.3.4 Calculation of results

3.3.4.1 Calculate the mass of moisture vapour lost through the dressing *(W_2-W_3)* and the mass of fluid absorbed by the material *(W_4-W_1)* for the 24 h and the 48 h periods.