SLOVENSKI STANDARD
oSIST prEN 13726:2021

01-marec-2021

Preskusne metode za sanitetni material za oskrbo rane - Vidiki absorpcije in prepustnost za vodno paro, odpornost proti vodi ter ustreznost

Test methods for wound dressings - Aspects of absorbency and moisture vapour transmission, waterproofness and conformability

Prüfverfahren für Verbandstoffe (Wundauflagen) - Aspekte des Saugverhaltens, der Feuchtigkeitsdurchdringung, Wasserdichtheit und Anpassungsfähigkeit

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Méthodes d'essai pour pansements en contact avec la plaie - Absorption et perméabilité à la vapeur d'eau, imperméabilité à l'eau et conformabilité

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Ta slovenski standard je istoveten z: **prEN 13726**

ICS:

11.120.20	Sanitetni materiali, obveze in komprese	Wound dressings and compresses

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2003-01.Slovenski inštitut za standardizacijo. Razmnoževanje celote ali delov tega standarda ni dovoljeno.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

DRAFT
prEN 13726

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English Version

Test methods for wound dressings - Aspects of absorbency and moisture vapour transmission, waterproofness and conformability

Méthodes d'essai pour pansements en contact avec la plaie - Absorption et perméabilité à la vapeur d'eau, imperméabilité à l'eau et conformabilité

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This draft European Standard is submitted to CEN members for enquiry. It has been drawn up by the Technical Committee CEN/TC 205.

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European foreword

This document (prEN 13726:2021) has been prepared by Technical Committee CEN/TC 205 “Non-active medical devices”, the secretariat of which is held by DIN.

This document is currently submitted to the CEN Enquiry.

This document will supersede EN 13726-1:2002, EN 13726-2:2002, EN 13726-3:2003 and EN 13726-4:2003.

This document is a merger of the previously published EN 13726 series. Annex A has been included which outlines the rational for the major revisions of EN 13726 parts 1-4.

During the systematic review in 2012 it was apparent that no laboratory was performing the odour control method published in EN 13726-6, and therefore this standard has been withdrawn per CEN/BT decision c023/2020.

The test methods are listed as separate annexes and there are new methods covering Free-swell absorptive and fluid retention capacity (Annex C) and Absorbency under compression (Annex D).

Test methods which were infrequently used (Gelling Characteristics and Dispersion/solubility of hydrogel dressings) have been removed from the standard.

Modifications to previous methods have also been implemented to more closely simulate clinical use of the wound dressings (Annex G - Dispersion characteristics of gelling dressings), and to eliminate artefacts which have been introduced by the technical methods which would not be expected in the clinical setting (Annex E - Fluid handling capacity i.e. modifications to the test apparatus to eliminate dressing doming during testing which increases the test surface area leading to significant over-estimates of the dressings fluid handling capacity).

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EN 13726 now consists of a single part, under the general title Test methods for wound dressings: Aspects of Absorbency and Moisture Vapour Transmission, Waterproofness and Conformability.Scope

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1 Scope

This document specifies test methods for the evaluation of aspects of absorbency of wound dressings, test methods for the evaluation of moisture vapour transmission rate of permeable film wound and IV catheter dressings, and test methods to assess waterproofness and conformability.

Except for the requirements for waterproofness, this document does not contain performance requirements for test methods.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

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3.1
single absorbent layer dressing
dressing incorporating a single type of absorbing materials

Note 1 to entry: for example this could include a dressing one or both of a backing film and an adhesive layer

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3.2
multi absorbent layered dressing
dressing incorporating more than one type of absorbing material

Note 1 to entry: for example a dressing containing both a gelling fibre and foam layers

3.3
gelling dressing
single absorbent layer dressings that ‘gel’ freely when in contact with physiological fluid

Note 1 to entry: for example hydrogels, alginates and other gelling fibre dressings

3.4
foam dressing
single absorbent layer dressing incorporating an absorbent open cellular solid

Note 1 to entry: for example polyurethane based foams

3.5
film dressing
single component dressing consisting of a non-absorbing material which can also include an adhesive layer

Note 1 to entry: for example semi-permeable film materials

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3.6
super absorbent dressing
single absorbent layer dressing incorporating super absorbent polymer particles

Note 1 to entry: for example a polyacrylate, that can absorb several times their weight in liquid

3.7
amorphous hydrogel dressing
semi-solid gel that contains hydrophilic polymers and water

3.8
free swell absorptive capacity
total absorptive capacity in the presence of excess test liquid and in the absence of any applied load expressed in g/cm² of the absorbent area

3.9
fluid retention
absorbed fluid retained following application of load expressed in g/cm² of the absorbent area

3.10
fluid absorbed (ABS)
fluid absorbed, expressed in g

3.11
moisture vapour loss (MVL)
fluid transpired through the dressing, expressed in g

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3.12
fluid handling capacity (FHC)
sum of the fluid absorbed (ABS) and the moisture vapour loss (MVL) expressed in g/cm²

3.13
moisture vapour transmission rate (MVTR)
general term used to describe the rate of permeability of materials to the passage of moisture vapour molecules from the skin contact side to the external atmosphere under controlled conditions of humidity and temperature expressed in g/cm² /24h

3.14
fluid donation of a wound dressing
ability to donate fluid to a simulated wound

3.15
waterproofness
ability to withstand a hydrostatic head of 500mm

3.16
conformability of a wound dressing
ability to adapt to the shape and movement off the body

3.17
extensibility
force needed to stretch a dressing to a known extension expressed in N/cm

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3.18
permanent set
increase in length of a sample after stretching and relaxing, expressed as a percentage (%) of the original length

4 Requirements

At present the value of the standard is in standardising the methods of assessing dressing performance, but the aim is to start to define performance requirements for different classes of dressings for future revisions. Therefore, we would welcome proposals from stakeholders once they have gained experience and test data from the revised methods.

5 Test methods

Where required, test conditions are specified in individual Annexes.

- Wound dressings that handle fluid via absorbency can be tested as per Annex B-D of this standard.
- Wound dressings that handle fluid via absorbency and moisture vapour loss (known as fluid handling capacity) should be tested as per Annex E of this standard.
- The fluid donation of amorphous hydrogels should be measured using Annex F of this standard.
- The dispersion characteristics of gelling dressings should be tested using Annex G of this standard.
- Wound dressings which do not have an absorbing function, but which handle fluid via moisture vapour transmission, should be tested to Annex H-I of this standard.
- Wound dressings that claim to be waterproof should be tested to Annex J of this standard.
- To assess a wound dressing conformability, measure the extensibility and permanent set using Annex K of this standard.
- The test solution used for absorbency, fluid handling capacity and MVTR is specified in Annex L.
- The test cylinder used for fluid handling capacity (Annex E) and moisture vapour transmission rate (Annexes H-I) is described in Annex M.
- Modifications of the test cylinder for testing multi-layer construction dressings that are prone to leakage is detailed in the informative Annex N.
- A method to remove entrapped air in dressings for fluid handling capacity testing is described in the informative Annex O.
- An informative section that discusses wound dressing size labelling on packaging and suggestions for greater clarity is presented in Annex P.
- Informative Annex Q is included that discusses possible future work programmes.

Any deviations from the test parameters listed in this standard shall be validated by the laboratory undertaking the test, and deviations noted in the test report.

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Annex A
(informative)

Rationale for revision of EN 13726 part 1-4

Since EN 13726 parts 1, 2, 3 and 4 were published, dressings technology has changed significantly. Test method parameters which seemed reasonable when the standard was first drafted are now causing operational difficulties for test houses, manufacturers and purchasers.

During the same period, European procurement legislation has also changed, and it is increasingly common for contracts to specify that data be provided in compliance with EN 13726. However, the technical issues now inherent in the standard mean that the usefulness of some of this data is questionable, and in fact can be misleading.

The technical issues include the following:

1. The term primary has been removed as the tests are applicable to both primary (direct contact with wound) and secondary (indirect contact with wound) dressings. A good example would be film dressings, which are often used on top of an absorbent layer.

2. There is similarity between EN 13726 parts 1 and 2, and therefore both parts have been merged into a single document. Individual tests are now presented as separate Annexes.

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3. Many dressings are now designed to be used under compression bandages/hosiery, and have the ability to absorb under compression, but EN 13726 had no option to test in this manner. The revised standard now includes additional tests assessing Free-Swell Absorptive /Fluid Retention Capacity (Annex C – this test simulates a dressing which has absorbed and then exposed to pressure such as a patient rolling over onto the dressing e.g. sacral or thigh wound) and Absorbency Under Compression (Annex D – simulate a dressing under pressure before absorbing fluid e.g. dressings under compression bandages).

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4. Some of the test methods in the standard were being used for classes of dressings where they are inappropriate (for example, the free swell test is being used for super-absorbents). This requires sectioning of the dressings which can cause leaching of the super-absorbent from the dressing and thus lower than expected absorbency results. New test methods detailing Free-Swell Absorptive/Fluid Retention Capacity and Absorbency Under Compression of intact dressings are detailed in Annex C and D respectively.

5. Incubation times (30 mins) for Annex C and D are based on previous work the UK has undertaken and a report is available online see [1] in bibliography.

6. The temperature requirements for Annexes B, C and D relate to measurement of air temperature in the incubator rather than test fluid temperature. Testing performed by members of the working group has shown no statistical difference in dressing absorbency when testing is performed at ambient room temperature and 37°C, however for consistency it was agreed to specify the operational conditions of the incubator for these tests.

7. The dressing is now placed into the test solution obliquely (edgeways on) for testing to Annexes B and C. Testing undertaken by the working group has shown that this minimises the possibility of air pockets forming on the dressing surface during testing.

8. Results from Annex C and Annex D should be evaluated with caution in particular for foam dressings and multi-layered dressings, since this test is based on full saturation of wound pad (see relevant Annexes for

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further information). These methods are purely informative at present as inter-laboratory experiments have shown unexplained variation, especially between laboratories.

9. Foams and super-absorbent dressings are now common in wound care, but test parameters needed to be revised to make the tests appropriate. Definitions have been added for these products.

10. Fluid handling capacity (Annex E) of some dressings is now so high that they create a partial vacuum in the test chamber, distorting the dressing and causing inverse doming. This can stretch the dressing, thereby increasing the surface area of the dressing leading to significant over-estimates of the dressings fluid handling capacity. In addition, challenge volumes are too low for some dressings, resulting in misleading results. The UK have undertaken inter-laboratory investigations which show that this issue can be resolved through the use of a plate including a small vent hole (0.25mm diameter) which allows pressure to equalise, thus stopping dressing doming. A copy of this report is available online see [2] in bibliography.

11. The test cylinder used in Fluid Handling Capacity (Annex E) and MVTR (Annex H and I) is listed separately in Annex M. The design of the test cylinder has been updated to include the use of a vented lid, where appropriate (Annex E and I testing), and the use of M4 hex bolts which are tightened to 2Nm torque to provide more consistency in sealing the assembly.

12. An air gap of 2 to 3cm between the surface of the samples and the surface of the incubator shelf to has been standardised for Fluid Handling Capacity (Annex E) and MVTR (Annex H and I) testing. Testing performed by the working group showed that this distance had no significant effect on moisture vapour component and ensured unobstructed airflow across the surface of the samples.

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13. A modification of the test cylinder to accommodate testing multi-layer construction dressings that are prone to leakage using a gasket is detailed in the informative Annex N. This is based on round robin experiments performed by the working group.

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14. The test solution (Solution A) used for Absorbency, Fluid Handling Capacity and MVTR testing is defined separately in Annex L. The working group recognise that laboratories wish to use other test fluids that simulate wound exudate. If using alternative test fluids, then this is noted as a deviation to the method and include the rationale for selection of that particular fluid. However, in cases of dispute the reference Test Solution A shall be used.

15. The incubation time for Fluid Handling Capacity (Annex E) has been standardised to 24h with the option to perform the test over longer periods if needed. The requirement to allow the cylinders to acclimatise before weighing has been removed as recent work has shown that the difference is negligible. A copy of this report is available online see [3] in bibliography.

16. The temperature and relative humidity for Fluid Handling Capacity (Annex E) and MVTR (Annex H and I) testing has remained at 37 ± 2°C and 0 to 20% RH. The working group discussed the performance of dressings at other temperatures and humidities and noted that a paper to predict moisture vapour performance under different conditions has been previously published, see [4] in bibliography.

17. When some wound dressings are tested for fluid handling capacity, there is evidence of delamination of the dressing layers which results in accumulation of trapped fluid trapped between layers. This is an artefact of the test presumably due to clamping of the dressing in the test apparatus which would not occur in clinical use. This results in artificially high absorbency figures, and therefore advice on how to free this fluid prior to measurement by splitting the dressing sample is included.

18. An informative Annex O has been included which outlines a method to remove entrapped air in dressings has been proposed for Fluid Handling Capacity testing (Annex E).

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19. Amorphous hydrogels are primarily used in clinical practise to donate moisture to dry tissue. As such the Annex F Fluid affinity of amorphous hydrogels has been amended to only assess the ability of the dressing to donate fluid i.e. fluid absorption using agar substrate has been removed. The associated example classification table has also been removed. The title of the Annex F has been changed to Fluid Donation of Amorphous Hydrogels.

20. Some consumables had been specified too tightly, leading to supply issues and an inability to follow the standard, even though there is no affect on the test results. A note has been included in Annex F Fluid Donation of Amorphous Hydrogels to validate the performance of different bloom gelatine before use.

21. During the standard review it was apparent that the Gelling characteristics (previously section 3.5) and Dispersion/Solubility of Hydrogel Dressings (previously section 3.7) test methods are infrequently used, and therefore these have been removed from the standard.

22. The Dispersion Characteristics of Gelling Dressings method (Annex G) has been modified to more closely simulate clinical use of the wound dressings e.g. incubation temperature and incubation period amended.

23. Amorphous hydrogels are often use to debride dry necrotic wounds. The surface temperature of the dead tissue can be considerably lower than an open wound, and therefore the test is performed at a temperature (25°C) which is recognisably lower than body temperature.

24. The number of replicates used in each test has been standardised.

25. The units used for reporting absorbency, MVL, fluid handling capacity and MVTR results have been standardised to mass of solution (g) per cm^2 of dressing. The Project Group thought that reporting per cm^2 of dressing would enable users to perform a simple calculation to estimate results for different size dressings. For example multiplying a result by 100 would equate to a 10 x 10cm dressing. Example calculations have also been included where appropriate.

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26. Definitions for MVL and MVTR have been added to enable reports and discussions to be more specific when assessing dressings performance, and reduce confusion.

27. Fluid Handling Capacity (Annex E) and MVTR (Annexes H and I) measure the MVL 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.

28. Fluid Handling Capacity (Annex E) and MVTR (Annexes H and I) have an added check for test validity if the chamber dries out in Fluid Handling Capacity and MVTR tests.

29. Information clarifying the mode of action of exudate handling and which tests are appropriate for dressings are included in Fluid Handling Capacity (Annex E) and MVTR (Annexes H and I).

30. Limits for the incubation times for relevant tests have been included.

31. The volume of test solution used in MVTR In Contact with Vapour test in Annex H has been specified as approximately 20ml. This is to minimise accidental fluid contact with the dressing which can produce erroneously higher MVT results i.e. the 20ml volume has been shown to be sufficient when used with the test cylinder specified in Annex M.

32. The MVTR In Contact with Liquid test in Annex I test has been amended so that the test is performed only over 24h, as recent data suggests that the majority of semi-permeable film dressings have MVTR of below 1000g/m^2/24h. The test is performed with 30ml of test solution. For high MVTR film products in which the test solution within the cylinder can dry out during the incubation period, it may be appropriate to decrease

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the duration of the test. It is recognised that the MVTR for film dressings is linear over time and therefore it is acceptable to use a shortened time period and extrapolate the results to predict MVTR over 24h. It is not acceptable to use a taller test cylinder with a higher volume of test solution, as the extra volume may deform the film under test leading to a larger surface area and therefore a larger than expected MVTR result.

33. The Waterproofness test in Annex J has been amended so that a different test solution (e.g. test solution A) could be used, and also that the test duration could be increased. If the conditions are changed then this needs to be reported as a deviation in the test report.

34. The Conformabilty test in Annex K has been amended to clarify which areas of the dressing are tested, where to clamp/grip the dressing and also the requirement to state the size of the dressing sample tested.

35. Informative Annex Q is included that discusses test result requirements. It is acknowledged that the majority of tests in this standard do not have performance requirements, however the aim is to start to define performance requirements for different classes of dressings in the next revision. Therefore, we would welcome proposals from stakeholders once they have gained experience and test data from the revised methods.

36. An informative Annex P discussing wound dressing size labelling on packaging and discrepancies in size when compared to actual dressing sizes is included. This is important as EN 13726 requires masses to be placed onto dressings to apply specific pressure during tests. It also requires calculations of the area of the dressing so that results can be reported in terms of, for example, g/cm^2. For example, in Annex C (Free-swell absorptive and fluid retention capacity) and Annex D (Absorbency under compression), a mass is required to be placed onto the dressing to exert 40 mmHg pressure onto the raised absorbent padded area of the dressing. The Project Group agree that it would be helpful for manufacturers to state the size of the active area on their packaging as well as the descriptive size, but at present the standard does not require this. The Project Group would be interested to hear views on this from healthcare workers and the dressings industry.

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37. This version of the standard does not currently have a test to assess adhesiveness of wound dressings. See Annex Q for future work.

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Annex B
(normative)

Free swell absorptive capacity

B.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 minutes, under the test conditions.

NOTE 1 The test is suitable for use with, for example, most types of fibrous absorbents including alginate, and other gelling fibre dressings in either the sheet or rope (packing) form, and foams.

This test could also be performed using intact dressings.

B.2 Equipment

1. Petri dishes, 90 mm ± 5 mm in diameter (An alternative absorption tank/containers large enough to contain the dressing may also be used).

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2. Laboratory incubator, or an equivalent technique of controlling temperature (e.g. water bath), capable of maintaining a temperature of 37 °C ± 2 °C.

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3. Temperature datalogger, or other suitable equipment, able to detect whether the 37 °C ± 2 °C has been exceeded during the test.

4. Test solution A as defined in Annex L.

5. Balance, capable of weighing 500 g with to the nearest 0,01 g.

6. Forceps

7. Perforated disc or plate (Optional). The perforated disc/plate fits inside the Petri dish/absorption tank which has legs elevating the face of the plate off the bottom of the incubation tank. The plate shall be large enough to contain the dressings under test.

NOTE 1 The plate is used to support the wound dressing under test. The plate is typically perforated with circular holes, 3,0 mm to 5,0 mm in diameter, evenly spaced, and with an open area of 50 % ±10 %, approximately 2 mm thick, made of corrosion-resistant material. Stainless steel is a suitable material. Suitable perforated material is available from RS, Cat No 182-8398 (Perforated steel sheet, 4,8 mm diameter hole, Pattern 6)[1]

NOTE 2 Use of the disk is only necessary if the dressings disintegrates when held with forceps. Self-tensioning forceps can be useful

1 RS, Cat No 182-8398 is the name of a product supplied by RS Components. This information is given for the convenience of users of this document and does not constitute an endorsement by CEN/CENELEC of the product named. Equivalent products may be used if they can be shown to lead to the same results.