S. M. T. L. Cover Sheet for Test Report

Title: **Wound Dressing Testing**

Date: **5th February 2008**

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UKAS TESTING 1492

S . M . T . L .

subject: **Wound Dressing Testing**

date: **5th February 2008**

from: **Paul Fram**
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Tel: +44-1656-752820

Report No: 07/2582/1

Test Report

07/2582/1

1. Name & Address of Client/Requesting Authority.

Mr Paul Mussert
UK Senior Brand Manager
Smith & Nephew
Healthcare House
Goulton Street
Hull
HU3 4DJ

Email: paul.mussert@smith-nephew.com

2. Introduction

The SMTL were requested by the client to perform comparative testing on two silver-impregnated foam dressings.

3. Test Product(s)/Sample(s)

TABLE 1. Test Product(s)/Sample(s) tested by SMTL.

Manufacturer	Item	Cat No	Batch/Lot No	Quantity	Date Received
Molnlycke Healthcare	Mepilex Ag Safetac Technology	287110	0740-8971	30	13-12-2007
Smith & Nephew	Allevyn Ag	66800086	0742	30	13-12-2007

NOTE: The test results in this report relate only to the test sample(s) analysed.

3.1 Departures/Abnormalities of Sample Condition

None.

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4. Date of Testing

December 2007 - January 2008.

5. Testing Details

5.1 Test Method

5.2 Moisture vapour permeability

The moisture vapour permeability of the dressings was determined using SMTL test method TM-8.[1]

In this test, a sample of dressing is applied to a Paddington cup to which is added 20 ml of a solution of sodium and calcium chloride containing 142 mmoles/litre of sodium ions and 2.5 mmoles/litre of calcium ions.

The cup is placed in an inverted position (with the test solution in contact with the sample) upon the pan of a top loading balance located within an incubator set at 37±2°C . The balance is connected to an electronic data logging device which records changes in the weight of the cup resulting from the loss of moisture vapour through the dressing. A tray containing 1 kg of freshly dried silica gel is placed in the bottom of the incubator to maintain a low relative humidity within the chamber.

At the end of the test the recorded data is down-loaded for examination.

5.3 Fluid handling properties

The fluid handling properties of the dressings were examined using SMTL test method TM-65[2] which is based on the method originally described in the *British Pharmacopoeia 1993 (Addendum 1996) Semipermeable hydrocolloid dressings* and recently adopted as a European Standard *BS EN 13726-1:2 2002 - Test methods for primary wound dressings; Aspects of absorbency*.

In this test five samples of each dressing of known weight are applied to Paddington cups (modified Payne cups) to which are added 20 ml of a solution of sodium/calcium chloride containing 142 mmol/litre of sodium ions and 2.5 mmol/litre of calcium ions. The cups are weighed and placed in an incubator at 37±0.5°C together with a tray containing 1kg of freshly regenerated self indicating silica gel for a period of 24 hours. At the end of the test the cups are removed from the incubator, allowed to equilibrate to room temperature and reweighed. From these weighings the loss in weight due to the passage of moisture vapour through the dressing is determined. The base of each cup is then removed and any remaining fluid allowed to drain.† The cup is then reweighed once again and the weight of fluid retained by the dressing calculated by difference.

† If there is an accumulation of test fluid between two components of the dressing, the inner component must be slit with a scalpel blade to allow free drainage of the entrapped fluid.

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5.4 Foam Absorbency Testing to BP Requirements

The absorbency of the dressings is determined using SMTL test method TM-366[3]

The weight of ten intact samples is determined prior to testing, and the dressings are then immersed in de-ionised water for 60 minutes before being drained on a draining board inclined at 45° for 5 minutes. The weight after draining is determined, and the individual increase in weight per sample is calculated. The increase in weight shall be greater or equal to 7.5 times the dry weight.

5.5 Standards relevant to the test method.

— *BS EN 13726-1:2002: Test methods for primary wound dressings. Aspects of absorbency. Section 3.3 Fluid handling capacity (plus moisture vapour transmission rate, liquid in contact)*[4]

— *British Pharmacopoeia 1993 Volume II, Polyurethane foam dressings*[5]

5.6 Deviations/exclusions from, and additions to standard methods.

The following deviations from the SMTL test method TM-65[2] were employed to ensure the dressings were tested to the requirements of BS EN 13726-1:2002[4]

— The testing was performed in a temperature/humidity controlled incubator to maintain an environment of 37°C (±2°C) and relative humidity below 20%. Therefore, the use of 1kg of silica gel was not required for this testing.

— Weighing was performed on a calibrated analytical balance.

— Following incubation, Paddington cups were allowed to acclimatise at room temperature for 30 minutes prior to weighing.

5.7 Sampling Details

All samples were selected and supplied by the client.

5.8 Sample Preparation

As stated in the SMTL test method.

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6. Results

6.1 Moisture Vapour Transmission Rate

Results from MVTR experiments are presented in Tables 2 and 3. Data is also expressed graphically in Figures 1 and 2.

TABLE 2. Mepilex Ag Moisture Vapour Transmission Rate over 24 hours

	MVTR (g/m^2/24Hrs)
Run 1	1785
Run 2	1574
Run 3	1540
Mean	1633

TABLE 3. Allevyn Ag Moisture Vapour Transmission Rate over 24 hours

	MVTR (g/m^2/24Hrs)
Run 1	16,107
Run 2	19,736
Run 3	12,045
Mean	15,963

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Figure 1. Mepilex Ag - Moisture Vapour Transmission

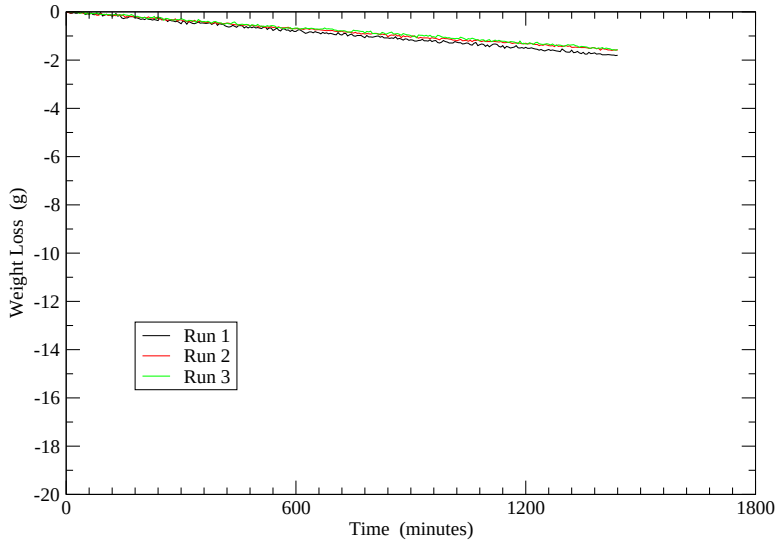
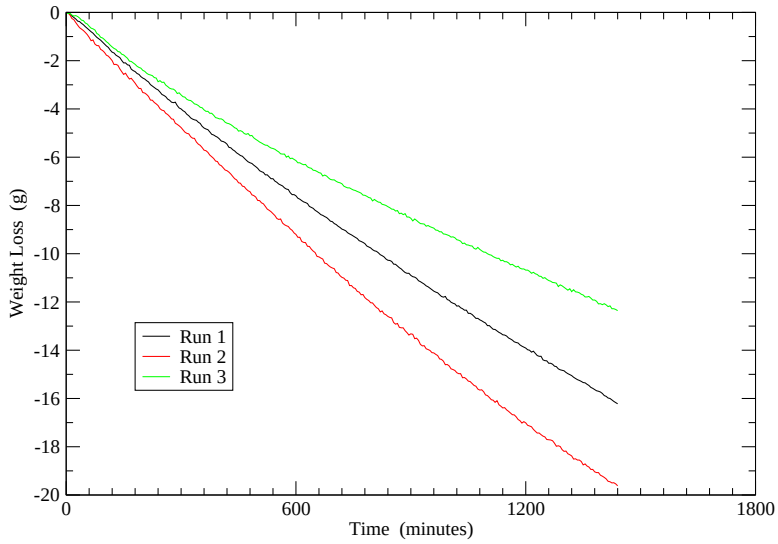


Figure 2. Allevyn Ag - Moisture Vapour Transmission



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6.2 Fluid Handling Testing

The results of the fluid handling testing are summarised in tables 4 to 6.

TABLE 4. Fluid handling properties following 24 hours incubation

Dressing	Moisture Vapour Loss ($g/10cm^2$)	Absorbency ($g/10cm^2$)	Fluid Handling Capacity ($g/10cm^2$)
Mepilex Ag	1.647 (0.0903)	5.560 (0.2503)	7.208 (0.2179)
Allevyn Ag †	18.356 (0.6330)	1.651 (0.6153)	20.007 (0.0200)

Note:
† These dressings retained no fluid at the end of the testing period. There was no evidence of leakage during the test period and the dressings appear to handle all of the fluid during the test. These results are an indication of the amount of fluid applied and not necessarily the fluid handling capacity of the dressing.

- The results are the mean of 5 determinations
- Figures in brackets denote standard deviations

TABLE 5. Fluid handling properties following 48 hours incubation

Dressing	Moisture Vapour Loss ($g/10cm^2$)	Absorbency ($g/10cm^2$)	Fluid Handling Capacity ($g/10cm^2$)
Mepilex Ag	3.156 (0.1621)	5.766 (0.4196)	8.921 (0.4828)
Allevyn Ag †	19.807 (0.0478)	0.204 (0.0083)	20.011 (0.0457)

Note:
† These dressings retained no fluid at the end of the testing period. There was no evidence of leakage during the test period and the dressings appear to handle all of the fluid during the test. These results are an indication of the amount of fluid applied and not necessarily the fluid handling capacity of the dressing.

- The results are the mean of 5 determinations
- Figures in brackets denote standard deviations

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TABLE 6. Fluid handling properties following 72 hours incubation

Dressing	Moisture Vapour Loss ($g/10cm^2$)	Absorbency ($g/10cm^2$)	Fluid Handling Capacity ($g/10cm^2$)
Mepilex Ag	5.000 (0.1790)	5.724 (0.1637)	10.725 (0.2966)
Allevyn Ag †	19.859 (0.0114)	0.168 (0.0028)	20.027 (0.0135)

Note:
† These dressings retained no fluid at the end of the testing period. There was no evidence of leakage during the test period and the dressings appear to handle all of the fluid during the test. These results are an indication of the amount of fluid applied and not necessarily the fluid handling capacity of the dressing.

- The results are the mean of 5 determinations
- Figures in brackets denote standard deviations

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6.3 Absorbency

The results from the absorbency determination are summarised in Tables 7 and8 below.

TABLE 7. Absorbency of Mepilex Ag dressings

Sample No.	Sample weight (g)	Final Weight (g)	Weight increase Factor	Complies/ Does not comply †
1	1.76	22.44	11.75	Complies
2	1.57	18.54	10.81	Complies
3	1.80	22.46	11.48	Complies
4	1.81	22.56	11.46	Complies
5	1.59	19.44	11.23	Complies
6	1.66	20.42	11.30	Complies
7	1.66	20.60	11.41	Complies
8	1.61	19.55	11.14	Complies
9	1.65	19.14	10.60	Complies
10	1.62	19.50	11.04	Complies

Note:
†Weight increase factor shall be greater or equal to 7.5 times the dry weight.

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TABLE 8. Absorbency of Allevyn Ag dressings

Sample No.	Sample weight (g)	Final Weight (g)	Weight increase Factor	Complies/ Does not comply †
1	1.70	23.27	12.69	Complies
2	1.62	21.62	12.35	Complies
3	1.68	23.77	13.15	Complies
4	1.63	23.92	13.67	Complies
5	1.68	24.12	13.36	Complies
6	1.63	23.40	13.36	Complies
7	1.66	23.97	13.44	Complies
8	1.66	22.56	12.59	Complies
9	1.66	23.27	13.02	Complies
10	1.67	24.67	13.77	Complies

Note:
†Weight increase factor shall be greater or equal to 7.5 times the dry weight.

Authorised by: Peter Phillips
Acting Director, SMTL
22nd February 2008

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1. Surgical Materials Testing Lab., "Moisture Vapour Transmission Rate from Dressings by Electronic Data Capture Method.," TM-8 ().
2. Surgical Materials Testing Lab., "Fluid Handling Properties of Wound Management Dressings.," TM-65 ().
3. Surgical Materials Testing Lab., "Foam Absorbency Testing to BP Requirements," TM-366 ().
4. "Test methods for primary wound dressings. Part 1; Aspects of absorbency. Section 3.3 - Fluid Handling Capacity (absorbency plus moisture vapour transmission rate, liquid in contact).," *BS EN 13726-1 Section 3.3*, British Standards Institution, (2002).
5. "Surgical Dressings: Polyurethan Foam Dressings.," *BP 1993 Volume II*, British Pharmacopoeia, (1993 Vol II).

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