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

Title: **Wound Dressing Testing - New Allevyn**

Date: **25th April 2007**

Other Keywords:

Report No: **07/2402/1**

Author(s)
Alex Hallett

Location
Princess of Wales

Extension

Charging\ Case: **07/2402/1**
Filing\ Case:

Pages Text: 12	Other: 0	Total: 12
No. Figures: 6	No. Tables: 4	No. Refs.: 0

SURGICAL MATERIAL TESTING LABORATORY, PRINCESS OF WALES HOSPITAL, COITY ROAD, BRIDGEND. TEL: 01656-752820 FAX:01656-752830

CONTENTS

1. Name & Address of Client/Requesting Authority. 1
2. Introduction 1
3. Test Product(s)/Sample(s) 1
   3.1 Departures/Abnormalities of Sample Condition 2
4. Date of Testing 2
5. Testing Details 2
   5.1 Test Method 2
   5.2 Moisture vapour permeability 2
   5.3 Fluid handling properties 2
   5.4 List of SMTL Test Methods Used. 3
   5.5 Standards relevant to the test method. 3
   5.6 Deviations/exclusions from, and additions to standard methods. 3
   5.7 Sampling Details 3
   5.8 Sample Preparation 3
6. Results 4
   6.1 Moisture Vapour Transmission Rate 4
   6.2 Fluid Handling Properties 8

RCS Version Info: $Header: /projects/2402/Reports/rep2402,v 1.4 2007/04/25 15:38:14 gavin Exp $

LIST OF FIGURES

Figure 1. Allevyn Moisture Vapour Transmission - Run 1 4
Figure 2. Allevyn Moisture Vapour Transmission - Run 2 5
Figure 3. Allevyn Moisture Vapour Transmission - Run 3 5
Figure 4. Product A Moisture Vapour Transmission - Run 1 6
Figure 5. Product A Moisture Vapour Transmission - Run 2 7
Figure 6. Product A Moisture Vapour Transmission - Run 3 7

RCS Version Info: $Header: /projects/2402/Reports/rep2402,v 1.4 2007/04/25 15:38:14 gavin Exp $

LIST OF TABLES

TABLE 1. Test Product(s)/Sample(s) tested by SMTL. 1
TABLE 2. Allevyn Moisture Vapour Transmission Rate over 24 hours 4
TABLE 3. Product A Moisture Vapour Transmission Rate over 24 hours 6
TABLE 4. Fluid Handling Properties of Allevyn Adhesive and Product A - 24 hours incubation 8

RCS Version Info: $Header: /projects/2402/Reports/rep2402,v 1.4 2007/04/25 15:38:14 gavin Exp $

UKAS TESTING 1492

S . M . T . L .

subject: **Wound Dressing Testing - New Allevyn**

date: **25th April 2007**

from: **Alex Hallett**
Princess of Wales
Tel: +44-1656-752820

Report No: 07/2402/1

Test Report

07/2402/1

1. Name & Address of Client/Requesting Authority.

Ed Walton
Clinical Project Manager
Healthcare Ltd
Healthcare House
Goulton Street
Hull
HU3 4DJ

Email: ed.walton@smith-nephew.com

2. Introduction

The SMTL were requested by the client to perform moisture vapour transmission rate and fluid handling testing over 24 hours on the new Allevyn Adhesive and Competitor A Island Dressings. The fluid handling testing was performed in accordance with BS EN 13726-1:2002[1]

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
Smith & Nephew	Allevyn Adhesive	66000599	0637	10	4/10/2006
Competitor A	Product A Foam Island Dressing	xxxxxxxx	xxxxx	10	4/10/2006

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

RCS Version Info: $Header: /projects/2402/Reports/rep2402,v 1.4 2007/04/25 15:38:14 gavin Exp $

3.1 Departures/Abnormalities of Sample Condition

None.

4. Date of Testing

March 2007.

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.[2]

In this test, a sample of dressing is applied to a Paddington cup (a modified Payne 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 film) in an incubator set at 37±2°C upon the pan of a top loading balance. 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[3] 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

† 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.

RCS Version Info: $Header: /projects/2402/Reports/rep2402,v 1.4 2007/04/25 15:38:14 gavin Exp $

once again and the weight of fluid retained by the dressing calculated by difference.

5.4 List of SMTL Test Methods Used.

— TM-8 - Moisture Vapour Transmission Rate from Dressings by Electronic Data Capture Method.[2]

— TM-65 - Fluid Handling Properties of Wound Management Dressings.[3]

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)*[1]

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

The following deviation from the SMTL test method TM-8[2] was employed.

— The dressing was tested for a period of 6 hours with it not being in contact with the fluid and then for a period of 18 hours with the dressing in contact.

The following deviations from the SMTL test method TM-65[3] were employed to ensure the dressings were tested to the requirements of BS EN 13726-1:2002[1]

— The testing was performed in a temperature/humidity controlled incubator to maintain an environment of 37°C (±1°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.

RCS Version Info: $Header: /projects/2402/Reports/rep2402,v 1.4 2007/04/25 15:38:14 gavin Exp $

6. Results

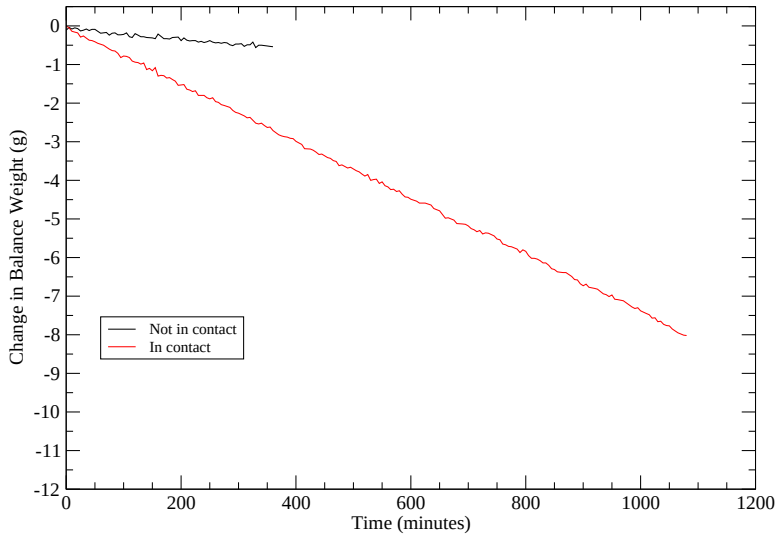
6.1 Moisture Vapour Transmission Rate

Results from MVTR experiments are presented in Tables 2 and 3. Data is also expressed graphically in Figures 1, 2, 3, 4, 5 and 6.

TABLE 2. Allevyn Moisture Vapour Transmission Rate over 24 hours

	Maximum MVTR (g/m^2/24Hrs)	
	Not in contact	In contact
Run 1	1915	10,581
Run 2	1568	12,595
Run 3	2247	13,303
Mean	1910	12,160

Figure 1. Allevyn Moisture Vapour Transmission - Run 1



RCS Version Info: $Header: /projects/2402/Reports/rep2402,v 1.4 2007/04/25 15:38:14 gavin Exp $

Figure 2. Allevyn Moisture Vapour Transmission - Run 2

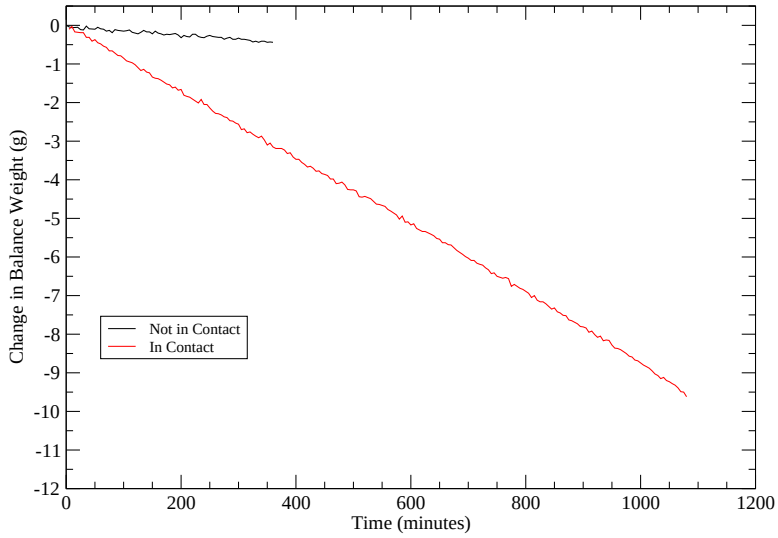
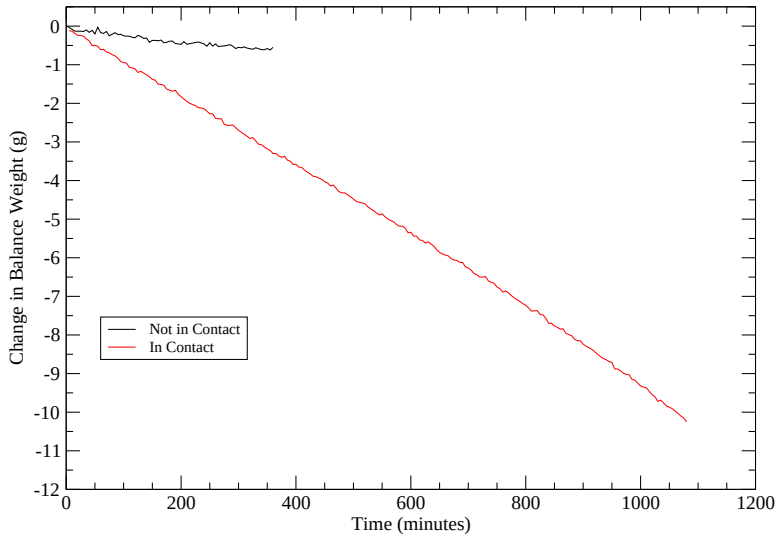


Figure 3. Allevyn Moisture Vapour Transmission - Run 3

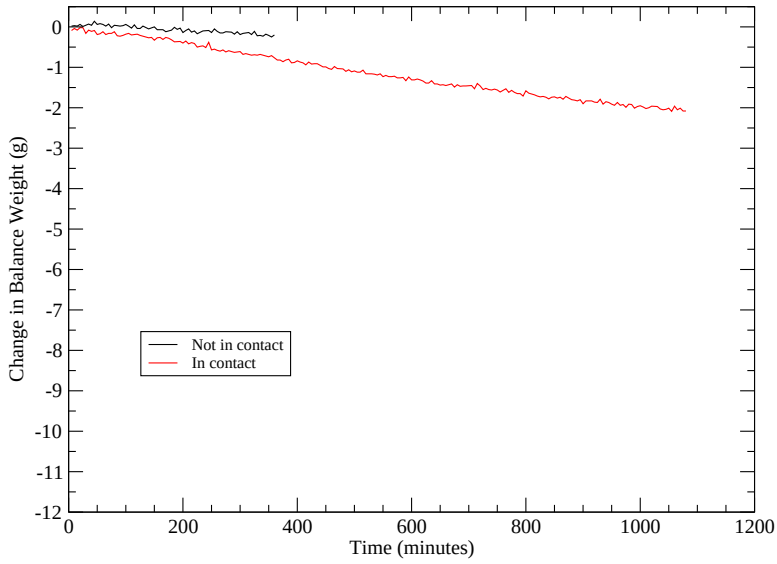


RCS Version Info: $Header: /projects/2402/Reports/rep2402,v 1.4 2007/04/25 15:38:14 gavin Exp $

TABLE 3. Product A Moisture Vapour Transmission Rate over 24 hours

	Maximum MVTR ($g/m^2/24Hrs$)	
	Not in contact	In contact
Run 1	1177	2859
Run 2	1270	1906
Run 3	1206	1895
Mean	1218	2220

Figure 4. Product A Moisture Vapour Transmission - Run 1



RCS Version Info: $Header: /projects/2402/Reports/rep2402,v 1.4 2007/04/25 15:38:14 gavin Exp $

Figure 5. Product A Moisture Vapour Transmission - Run 2

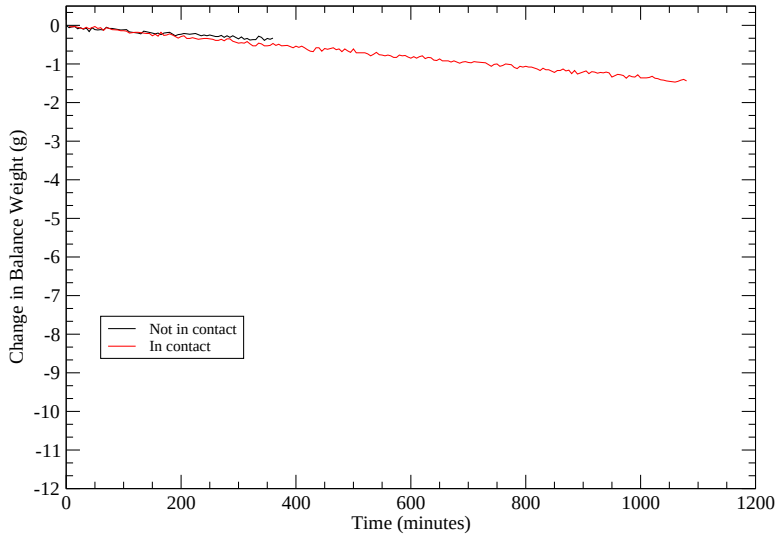
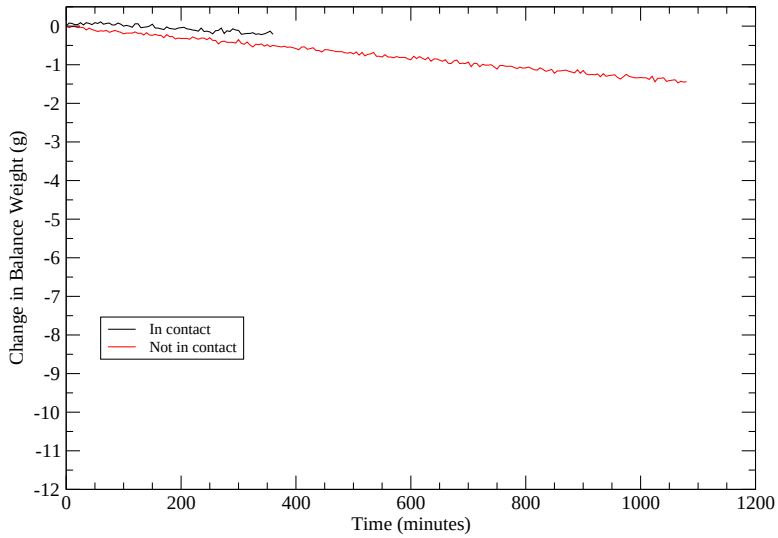


Figure 6. Product A Moisture Vapour Transmission - Run 3



RCS Version Info: $Header: /projects/2402/Reports/rep2402,v 1.4 2007/04/25 15:38:14 gavin Exp $

6.2 Fluid Handling Properties

The results of the fluid handling tests are presented in Table 4.

TABLE 4. Fluid Handling Properties of Allevyn Adhesive and Product A - 24 hours incubation

Dressing	Moisture Vapour Loss ($g/10cm^2$)	Absorbency ($g/10cm^2$)	Fluid Handling Capacity ($g/10cm^2$)
Allevyn Adhesive	1.5590 (0.0328)	0.3206 (0.0952)	1.8796 (0.1041)
Product A	1.1967 (0.1747)	2.2037 (0.5099)	3.4004 (0.5985)

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

Authorised by: Peter Phillips
Acting Director, SMTL
April 2007

RCS Version Info: $Header: /projects/2402/Reports/rep2402,v 1.4 2007/04/25 15:38:14 gavin Exp $

References

1. "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).

2. Surgical Materials Testing Lab., , "Moisture Vapour Transmission Rate from Dressings by Electronic Data Capture Method.," TM-8 ().

3. Surgical Materials Testing Lab., "Fluid Handling Properties of Wound Management Dressings.," TM-65 ().

RCS Version Info: $Header: /projects/2402/Reports/rep2402,v 1.4 2007/04/25 15:38:14 gavin Exp $