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Shear Comfort®

Information Document



Shear Comfort®

Pressure Care and  
Foot Care Range

Shear Comfort® Medical Products is manufactured and distributed by Healthcare Innovations Australia Pty Ltd, based in Adelaide South Australia.

Shear Comfort® products provide a cost effective total body solution for the prevention of pressure ulcers and wound care, providing reassurance and comfort in a wide variety of settings.

Whilst other products on the market only address the issue of pressure reduction, Shear Comfort's innovative range of products address all factors contributing to tissue damage

- ✓ Shear
- ✓ Friction
- ✓ Pressure
- ✓ Moisture
- ✓ Temperature

Our products are also inherently anti-microbial and anti-bacterial therefore a natural odour suppressant. Lightweight, easily maintained and durable the Shear Comfort® range comes individually packaged, is machine washable and covered by a full replacement warranty.

*'Many Clinicians mistakenly believe that pressure is the only cause of decubitus ulcers (pressure ulcers). In fact, there is not one study that points to pressure as the only cause. Effective prevention case and wound care protocols should address Shear, Moisture, Friction and Pressure. I have found Shear Comfort® to be an effective choice and the most cost effective option available'.*

**Tal Ellis Director, Wound Heal Australia**

Pressure Ulcers are common in many healthcare settings across the world, affecting all age groups, and are costly both in terms of human suffering and use of resources. Shear Comfort® is a unique manufacturer of Medical Sheepskin Pressure Care Products designed to assist both young and old. We are part of one of the world's leading wool processing companies with over 130 years of market and product knowledge.

With an aging population and a focus in the Primary Care Sector on preventative treatment, products that play a role in prevention of disease states or conditions are highly regarded. In recent years, the focus of clinicians, institutions and government bodies on the risk assessment, prevention and treatment of pressure ulcers has intensified. This is demonstrated particularly through recent clinical trials (PRIME) and the initiation of the auditing program as a result of PUPPS (Pressure Ulcer Point Prevalence Survey) nationally in hospitals and health care settings.

The ability of manufacturers and suppliers to be 'solution providers' in this initiative is integral to being seen as a true health care partner by their customers, and the inclusion of the Shear Comfort range of Pressure Care and Foot Care products to pressure prevention protocol allows us to build that partnership.



From operating theatres to neonatal intensive care units, general wards, aged care facilities, palliative care units and community care, patients at risk of developing pressure ulcers can be found. In fact any setting that cares for people with reduced mobility needs to address pressure prevention to some degree. Age and fragility enhance the vulnerability of patients, as do co-morbidities such as disease states and poor nutrition and the extrinsic factors of pressure, shear, friction and moisture.

What we do know about Pressure Ulcer prevalence in Australia is that in acute care facilities it has been shown to be as high as 27% (Prentice et al 2001) and 26% in high level aged care facilities (Santamaria et al 2005).

When we look at the expenditure on pressure ulcer *prevention* vs pressure ulcer *treatment* the figures are quite staggering. In excess of US\$50 billion is spent each year on the *treatment* of pressure ulcers and yet only a staggering US\$20million on the *prevention* of the same condition. As Prentice & Stacey stated in 2001, "the most notable feature of pressure ulcers is that most are preventable". Given the Primary Care initiative of prevention across all disease states and conditions, the role of products that contribute to the prevention of pressure ulcers occurring and, therefore, substantial reductions in the cost to treatment, should be of great interest to all clinicians working in this area.



The availability of clinical data to support product claims is an integral part of evidence based medicine. There are three substantial trials that we use to support the inclusion of the Shear Comfort range into the Pressure Prevention protocol of institutions and facilities. These studies not only give confidence to clinicians using our product but also validate their inclusion where decision makers are required to justify protocol.

1. "Preventing pressure ulcers with the Australian Medical Sheepskin": an open-label randomised controlled trial. Jolley et al 2000
2. "Evaluation- Pressure Reducing Overlays" MHRA 04101-0 - 2004  
Medicines and Healthcare products Regulatory Agency (MHRA) U.K
3. "The role of sheepskins in preventing pressure ulcers in elderly orthopaedic patients".  
McGowan et al 1998

A copy of each of these follows with a brief summation of the trials key points and suggestions on its use / target audience. Study 1- Preventing pressure ulcers with the Australian Medical Sheepskin is available as a reprint.



## **“Preventing pressure ulcers with the Australian Medical Sheepskin: an open-label randomised controlled trial”**

Damien J Jolley, Robyn Wright, Sunita McGowan, Mark B Hickey, Don A Campbell, Rodney D Sinclair and Kenneth C Montgomery

This trial was conducted at the Royal Melbourne Hospital, Melbourne, Victoria in 2000. The objective stated was "To estimate the effectiveness of a new high-performance Australian sheepskin (meeting Australian Standard 4480.1-1998) in preventing pressure ulcers in a general hospital population at low to moderate risk of these ulcers"

### Points of note:

1. This study showed that the Australian Standard Medical Sheepskin (AS4480.1) overlay reduced the incidence of Stage 1 & 2 pressure ulcers by 58% when compared to standard nursing care in general hospital inpatients at low to moderate risk. These results support the inclusion of AS4480.1 as standard practice in an acute care setting.
2. Only Australian Standard Medical Sheepskins were used in this trial and therefore there is no data to support the use of non-standard products in pressure prevention protocol. A strong support when making the distinction between the large range of sheepskin products available.
3. The data was analysed excluding Stage 1 Pressure Ulcers (to negate concerns about inaccurate assessment) there was still a reduction of 46% in Stage 2 Pressure Ulcers. This further supports the validity of the study results.
4. The use of a AS4480.1 overlay may prevent one new Stage 1 or 2 Pressure Ulcer every 46 bed days for patients at low to moderate risk, a valuable link for this study to aged care facilities where length of stay is longer than acute care.



## **“Evaluation – MHRA 04101-0 Pressure Reducing Overlays”**

Duncan Bain, Martin Ferguson-Pell, Graham Nicholson

This paper is a review of Pressure Reducing Overlays conducted by the Department of Health's Medicine and Healthcare Products Regulatory Agency (MHRA) – UK in 2004. The stated aim was to “establish a broadly acceptable set of criteria and test methods for pressure reducing mattresses and overlays to reflect the interests of the very diverse set of interested parties.”

Pressure reducing overlays were defined as “supplementary mattresses designed for use on top of a standard mattress with no actively powered parts”. The protocol was established in consultation with health professionals including tissue viability nurses, physicians and biomedical engineers with an interest in pressure ulcers as well as representatives from manufacturers, hospital purchasing agencies and consumers. The study measured the performance of 12 products in relation to peak interface pressure (pressure distributive properties), vapour transfer rate, heat transfer rate and fatigue longevity (durability).

Of these four criteria the Shear Comfort® Overlay clearly demonstrated superior properties in the areas of Vapour transfer rate and Heat transfer rate and equivalent effectiveness in pressure distributive properties compared to ‘market leading products’. In the fourth area, durability, the testing and results of the Shear Comfort® overlay was compromised by the lack of laundering during testing and is not reflective of clinical use.

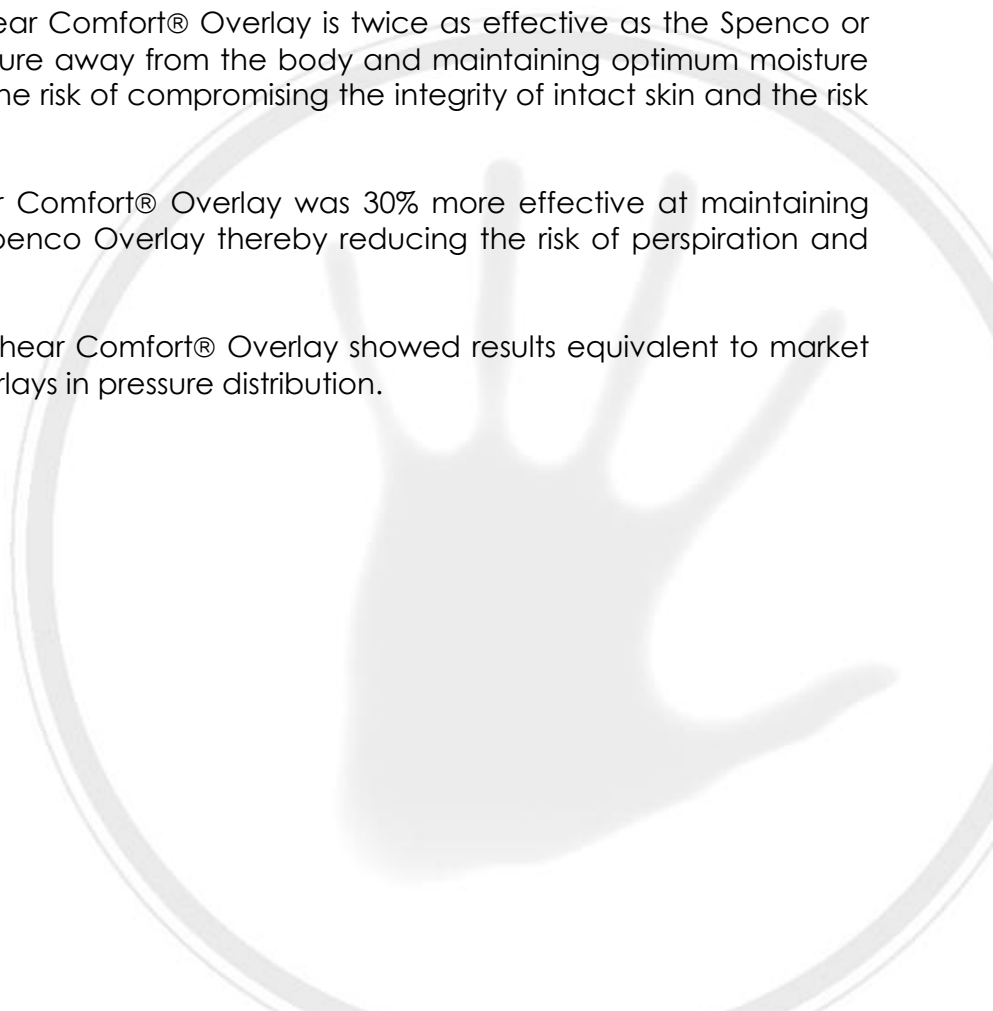
Considering that the extrinsic risk factors for pressure ulcers are pressure, shear, friction and moisture and that by its nature the Shear Comfort® range clearly addresses shear and friction, then the results of this paper highlight Shear Comforts ability to provide a holistic solution for patients at low to moderate risk of developing pressure ulcers.

The results of importance are as follows- (see attached graph also)

Vapour Transfer Rate – The Shear Comfort® Overlay is twice as effective as the Spenco or Roho overlay at drawing moisture away from the body and maintaining optimum moisture levels of the skin. This reduces the risk of compromising the integrity of intact skin and the risk of maceration.

Heat Transfer Rate - The Shear Comfort® Overlay was 30% more effective at maintaining body temperature than the Spenco Overlay thereby reducing the risk of perspiration and increased moisture.

Peak Interface Pressure - The Shear Comfort® Overlay showed results equivalent to market leaders Spenco and Roho Overlays in pressure distribution.



## **“The role of sheepskins in preventing pressure ulcers in elderly orthopaedic patients”**

Sunita McGowan, Ken Montgomery, Damien Jolley, Robyn Wright

This trial was conducted in two Western Australian Hospitals, Fremantle Hospital and Hollywood Hospital in 1998. The objective stated was “To estimate the relative incidence of hospital acquired pressure ulcers among elderly orthopaedic patients nursed on a standard hospital mattress plus and Australian Medical Sheepskin overlay, compared to those nursed on either a standard mattress alone or a standard mattress with other low technology constant pressure supports.”

### Points of note:

Estimated that for each full thickness (Stage 4) sacral pressure ulcer that is prevented, it is possible to undertake 16 total hip replacements.

Lab testing supports at least 50 washes of the AS4480.1 product without degradation to the leather or wool. The Mercy Private Hospital laundry in Victoria has successfully washed the skins up to 65 times with no deterioration.

The overlay was changed every 3 – 4 days unless otherwise soiled.

Some patients in control group (No AS4480.1) developed > 2 pressure ulcers and pressure ulcers > Stage 1. No patients in experimental group (with AS4480.1) developed > 2 pressure ulcers and no patients in this group developed greater than Stage 1 Pressure Ulcers.

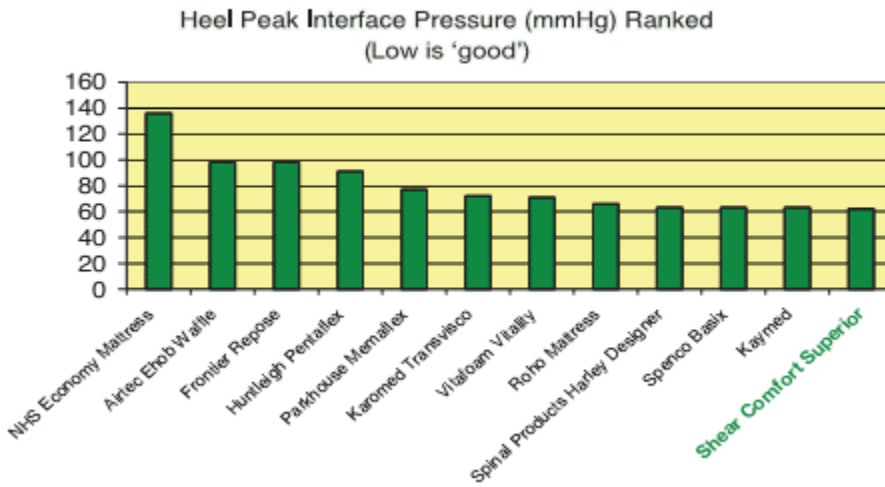
Thermal disinfection was confirmed by measuring median colony count at the start of the trial, at the 6 week point and again on completion of the trial at 13 weeks.

### Quote from trials:

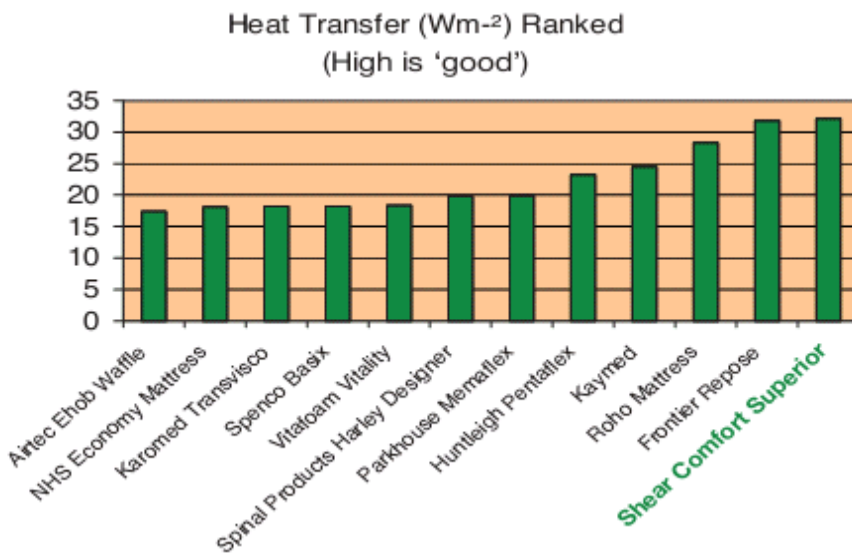
“The Australian Medical Sheepskin overlay is a simple. Low cost. Easy to use product that, unlike other support surfaces (eg foam or fibre filled mattresses) can be used on beds, chairs and trolleys for patients at risk of developing hospital acquired pressure ulcers. The sheepskin does not impede patient care, has a demonstrated longevity of at least 50 washes and it is easy to identify deterioration”



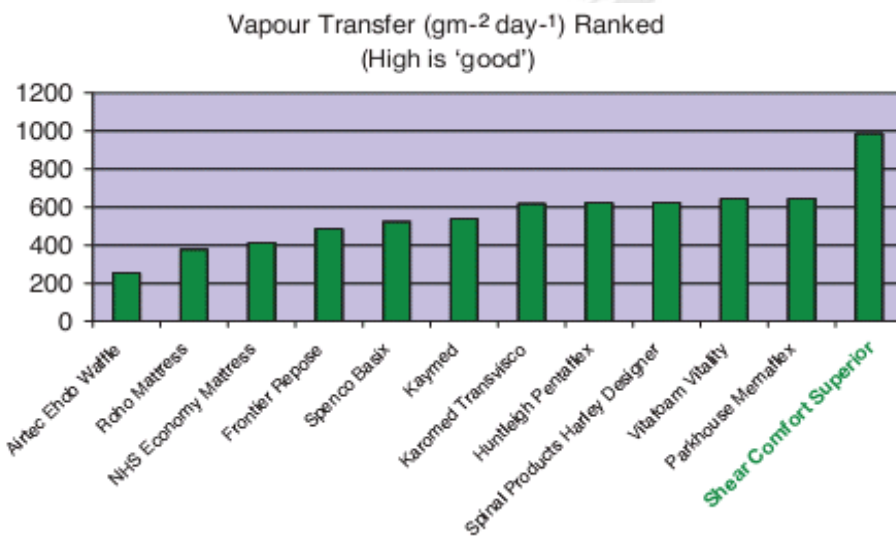
## Pressure Reducing Overlays: Shear Comfort® out-performs the rest.



Shear Comfort® reduced the pressure by 41% under the pelvis and 54% under the heels. (Producing the lowest mean pressure reading of the 11 overlays tested.)



Shear Comfort® heat transfer properties were the best of all overlays tested, with a 77% improvement as compared with the standard mattress

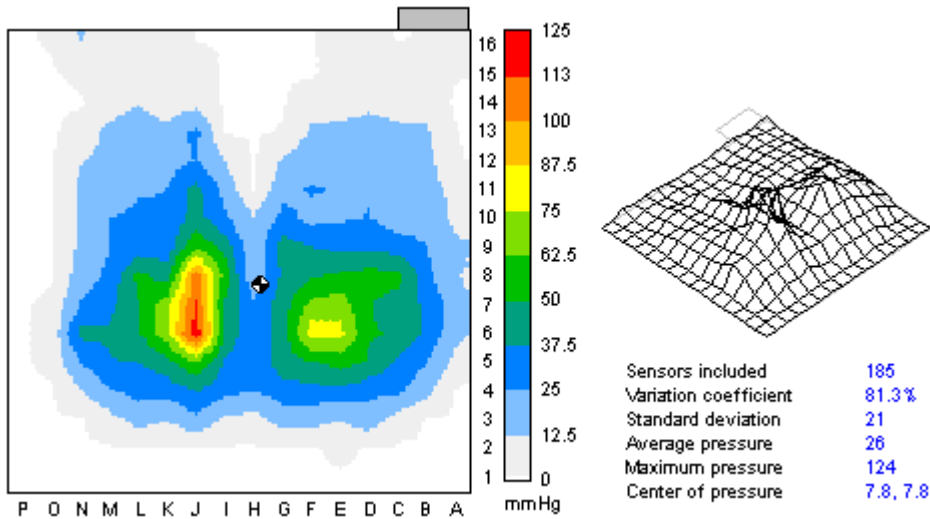


Vapour dissipation is very important for skin health: if moisture builds up the skin is at risk of maceration. Of the 11 overlays Shear Comfort® was by far the best surface for vapour transfer and 139% better than a standard mattress.

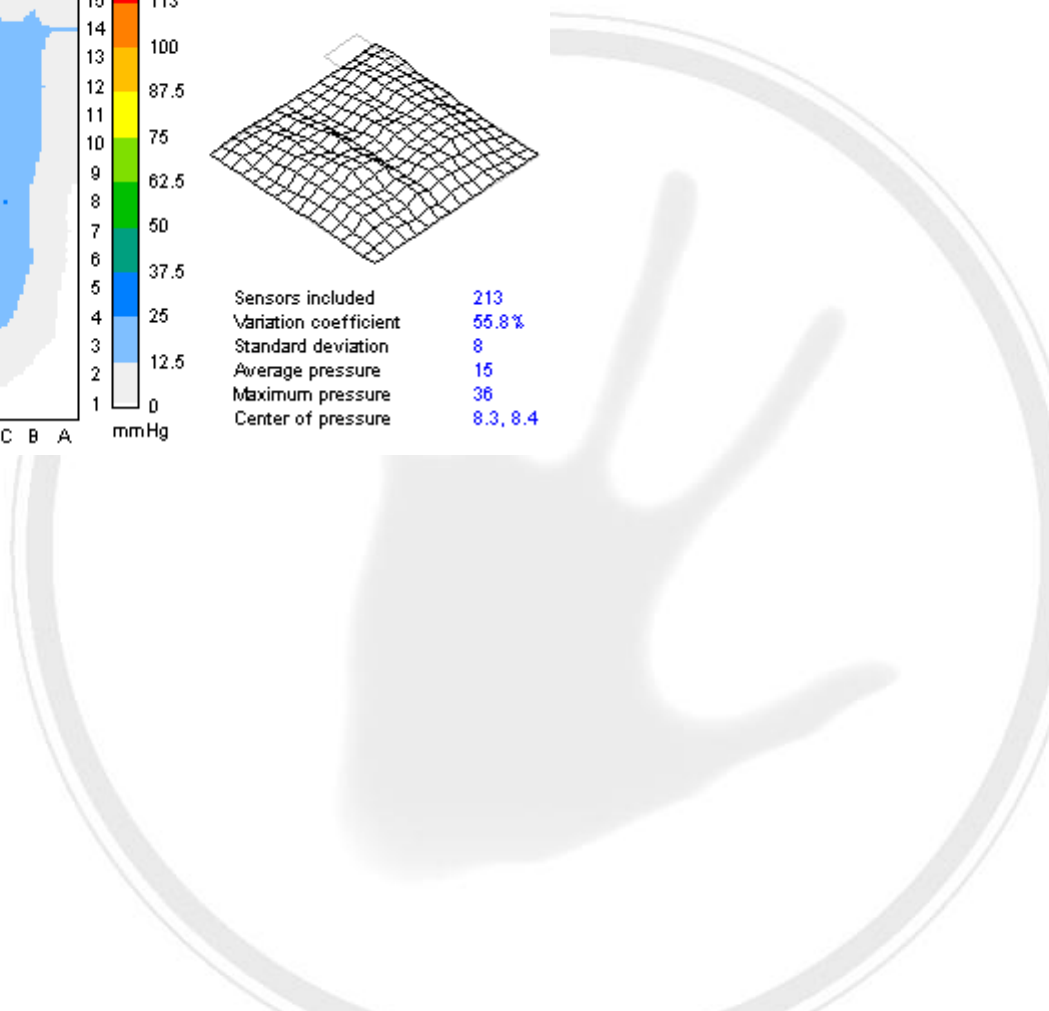
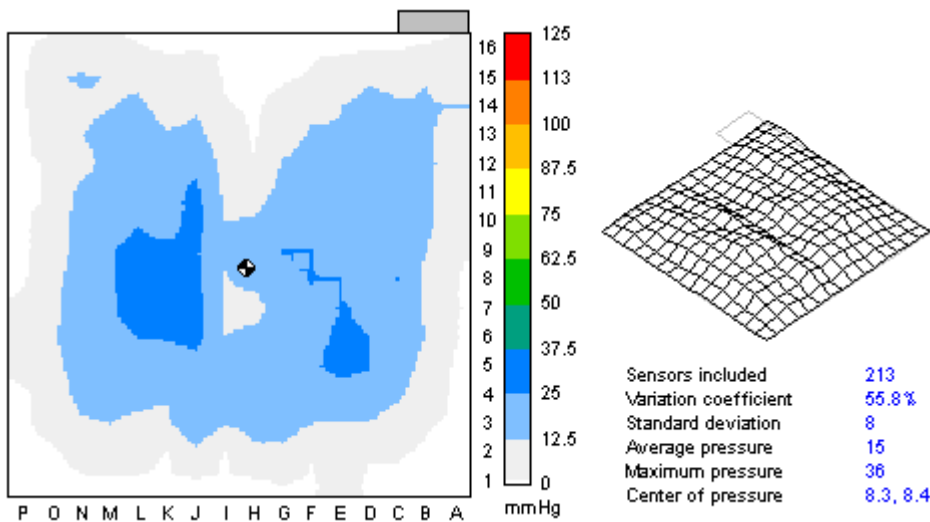
## Pressure reduction using Shear Comfort® Cushion-it™

These two illustrations (Pressure maps) show the reduction in peak interface pressure points when incorporating a Shear Comfort® Cushion-it™ on a vinyl wheel chair sling seat. (51 yr old 90Kg male).

Without Shear Comfort®



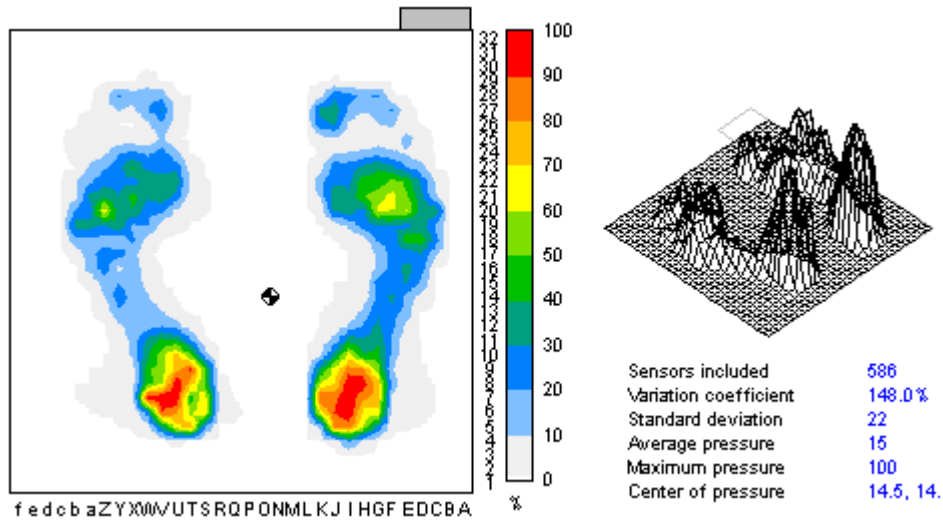
With Shear Comfort®



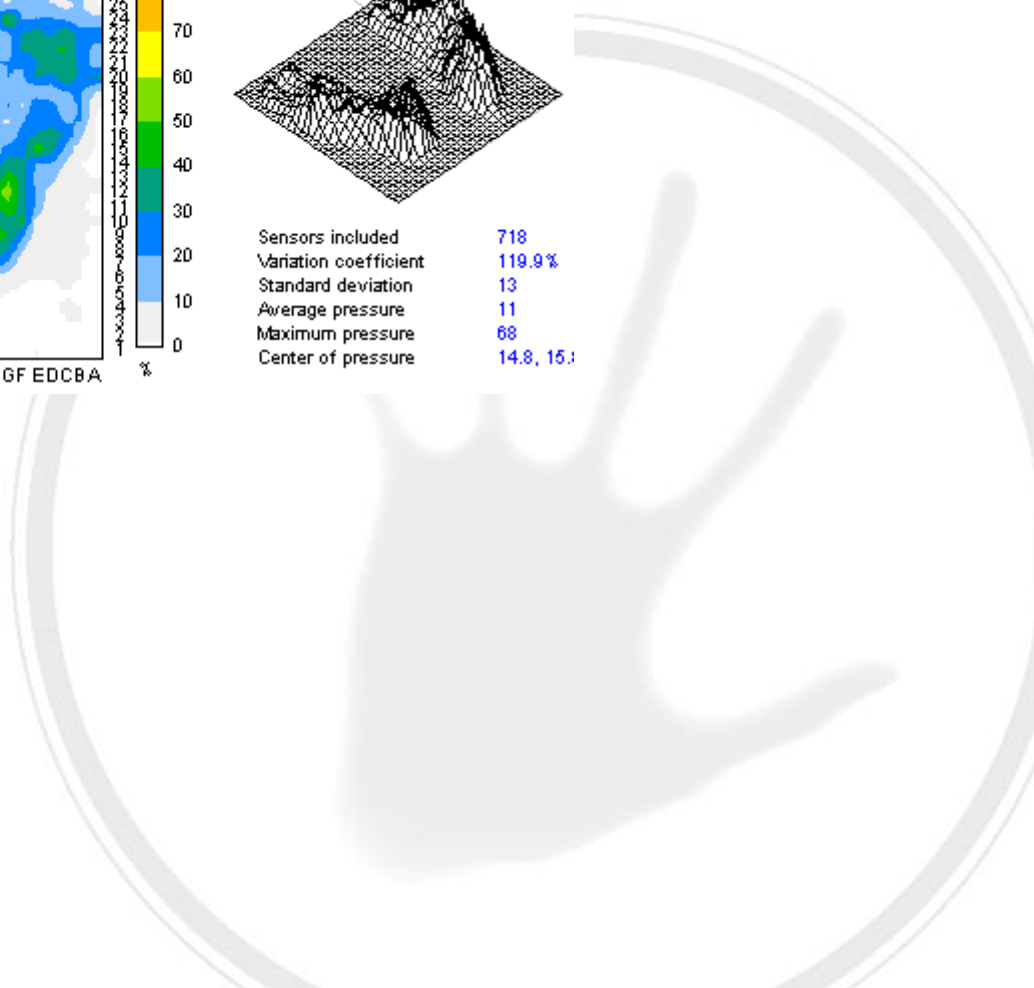
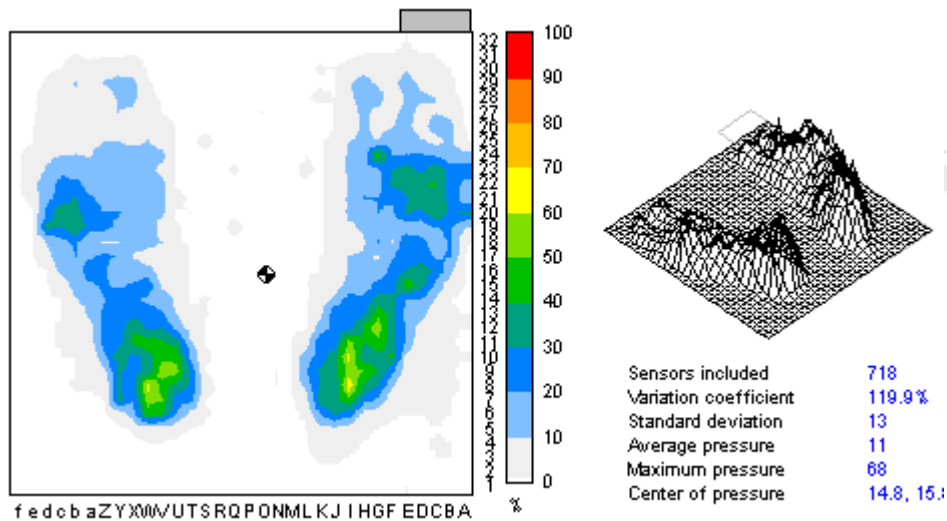
## Pressure reduction using Shear Comfort® Pressure Care Boots

These two pressure maps show the pressure distribution under the feet of a stockings 90kg individual, first on a normal surface and then with Shear Comfort® Pressure Care Boots.

Without Shear Comfort®



With Shear Comfort®





**CURRENT PRICING INFORMATION – FOB AUD / March - June 2008**



**SCOL – OVERLAY**

A complete skin to cover from the shoulders to the sacrum area. Providing reduction in pressure, friction and Shear whilst absorbing moisture and transferring heat away from the body. Measures approximately 92cm long and 63cm wide.

WHOLESALE	RRP	
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**PALM PROTECTOR**

For persons with contractures of the hand due to CVA (stroke), arthritis or other conditions, resulting in paralysis of the hand. Velcro back strap for easy use. Please order in left or right.

WHOLESALE	RRP	
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**Bed Overlay**

A full bed overlay, designed to cover head to toe. Suitable for long term patients, where shear and friction are a concern.

Available for - single, double and queen size beds.

WHOLESALE - Single Bed	RRP	
WHOLESALE - Double Bed	RRP	
WHOLESALE - Queen Bed	RRP	



**SCEP – ELBOW PROTECTOR S, L**

The elbow is a common problem point for pressure ulceration and with its limited blood supply is a slow repair. Good for use in bed or in a wheelchair. Sold in pairs.

WHOLESALE	RRP	
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**SBSB – SHORT SLIPPER BOOT XS, S, M, L, XL**

Ideal for bed and indoor use to protect the heel and foot. The large toe-to-ankle tongue and generous Velcro straps allow for easy on and off, and for use with swollen feet. Sold in pairs.

WHOLESALE	RRP	
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**PCA – PRESSURE CARE ASSIST**

A 70cm x 30cm strip of sheep skin covering a width of a single bed with linen flaps to tuck under the mattress. For a person at risk of ulceration to the sacrum, heels, shoulders or head.

WHOLESALE	RRP	
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**SBHP – HEEL PROTECTOR S, L**

20% of all pressure ulcers occurs at the heels. The Shear Comfort Heel Protector protects the heels wherever the feet are placed. Sold in pairs.

WHOLESALE	RRP	
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**SCCI – CUSHION IT**

Cushion It™ can be used directly on a seat or back of a standard wheelchair. It can also be placed over standard foam cushions to increase pressure care, and absorb perspiration.

WHOLESALE	RRP	
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**SBSNUG – SOVEREIGN SNUG XS, S, M, L**

Attractive, lightweight suede sole slipper for indoor use. Sold in pairs.

WHOLESALE	RRP	
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**SCCALF – CALF PLATE PROTECTOR**

Designed to ease pressure areas for wheelchair patients, Shear Comfort Calf Plate Protectors are adaptable for a range of practical applications. Sold in pairs.

WHOLESALE	RRP	
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**PCB – PRESSURE CARE BOOT EX, S, M, L, XL**

For those at risk of leg and foot ulcers as a consequence of diabetes. Foot swelling, such as with oedema, can also be readily accommodated. The open toe design allows toe inspection without the need to remove the boot. Sold in pairs.

WHOLESALE	RRP	
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**SCFOOT – FOOT PLATE PROTECTOR**

Designed to ease pressure areas for wheelchair patients, Shear Comfort Foot Plate Protectors are adaptable for a range of practical applications including skin tears. Sold in pairs.

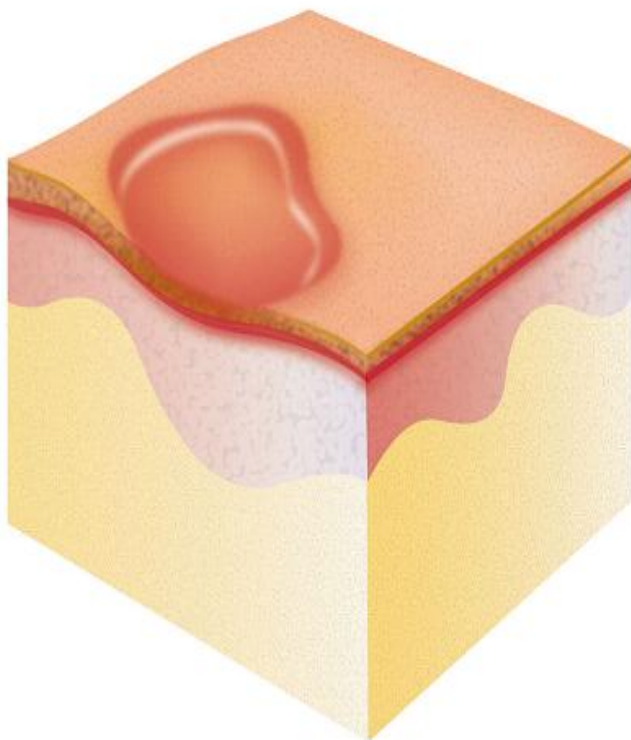
WHOLESALE	RRP	
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**WAB – WRAP AROUND BOOT XS, S, M, L, XL**

Shares many of the special properties of Pressure Care Boots™, with the key difference being that the toes are enclosed and therefore protected by the sheepskin at the front. This design also offers generous Velcro straps for easy closure and Shear Comforts unique rubber soles for outdoor as well as indoor use. Sold in pairs.

WHOLESALE	RRP	
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# What the Experts Say About the Financial Implications of Pressure Ulcers

"The average hospital incurs \$400,000 to \$700,000 in direct costs to treat pressure ulcers annually. Most of that cost is not reimbursable. It is estimated that 20 minutes/day/patient of nursing time is related to services for pressure ulcers."

*Robinson C, et al., "Determining the efficacy of a pressure ulcer prevention program by collecting prevalence and incidence data: A unit-based effort," Ostomy/Wound Management. May 2003;49(5):44-51.*

"Pressure ulcers are estimated to affect 1 million people each year, leading to an annual cost of approximately \$1.6 billion."

*Whittington K, Patrick M, and Roberts JL, "A national study of pressure ulcer prevalence and incidence in acute care hospitals," Journal of Wound, Ostomy and Continence Nursing. July 2000;27(4):209-215.*

"A study—limited to patients over age 55, length of stay at least 5 days, confined to a bed or chair, from 1988 to 1992 in an acute care hospital—found that the mean cost of caring for a patient who developed a pressure ulcer was \$37,000 versus \$13,924 for a patient without one."

*Allman RM, "The impact of pressure ulcers on healthcare costs and mortality," Advances in Wound Care. May/June 1998 Supplement;11(3):2.*

"A study was performed to calculate the cost of a pressure ulcer from time of development to time of healing. There were 45 ulcers treated for a total of 5200 days and a total cost of \$122,887. The mean cost per pressure ulcer was \$2,731."

*Xokellis GC and Frantz R, "The cost of healing pressure ulcers across multiple health care settings," Advances in Wound Care. November/December 1996;9(6):18-22.*

"Although the cost of pressure ulcer prevention remains elusive, costs associated with their treatment have been conservatively estimated to range from \$500 to \$50,000 per ulcer, with more severe wounds being significantly more expensive to manage than less severe ulcers....Presently, approximately 1.5 to 3 million adults suffer with pressure ulcers."

*Lyder GH, et al., "A comprehensive program to prevent pressure ulcers in long-term care: Exploring costs and outcomes," Ostomy/Wound Management. April 2002;48(4):52-62.*

"Once a pressure ulcer develops, longer hospitalization and more nursing time are required, resulting in higher costs. Pressure ulcers tracked across multiple healthcare settings cost, on average, between \$1,119 and \$10,185 to treat while the management of severe wounds may cost as much as \$55,000."

*Cleaver K, et al., "Evaluating the efficacy of a uniquely delivered skin protectant and its effect on the formation of sacral/buttock pressure ulcers," Ostomy/Wound Management. December 2002;48(12):60-67.*

"Most recently, the U.S. Centers for Medicare and Medicaid Services (formerly the Health Care Financing Administration) included pressure ulcers as one of three sentinel events for long-term care; therefore, the formation of a pressure ulcer or subsequent deterioration of a pressure ulcer can lead to significant monetary penalties (maximum \$10,000/day) in long-term care."

*Lyder GH, et al., "A comprehensive program to prevent pressure ulcers in long-term care: Exploring costs and outcomes," Ostomy/Wound Management. April 2002;48(4):52-62.*

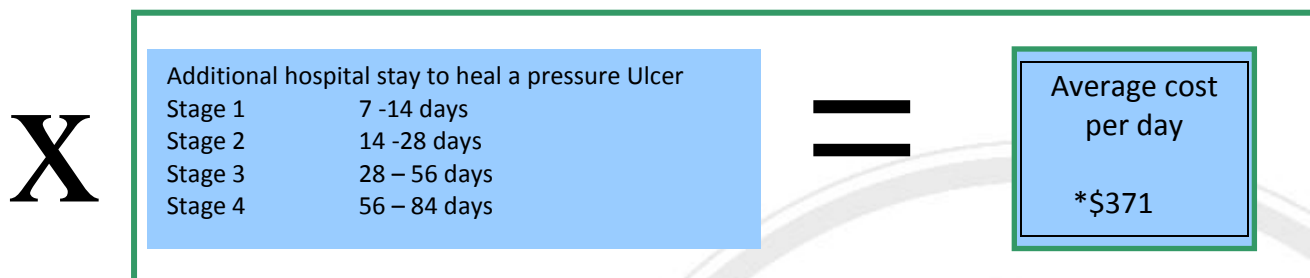
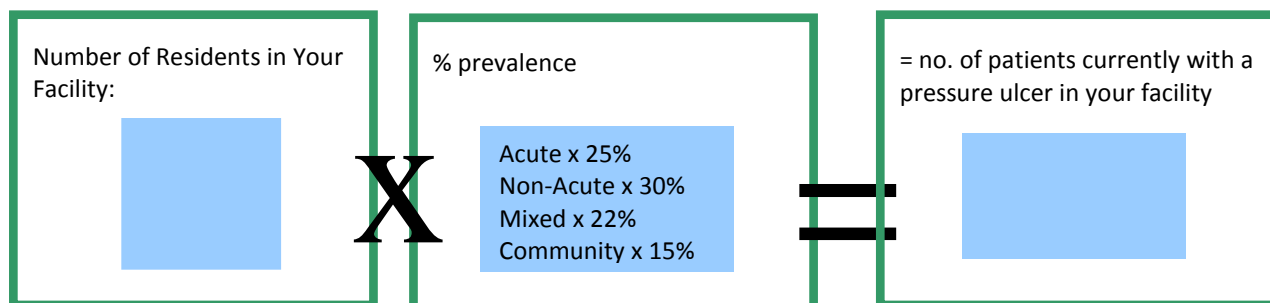


Shear Comfort®

Pressure Care and  
Foot Care Range

## HOW MUCH ARE PRESSURE ULCERS COSTING YOUR FACILITY?

Use the guide below to calculate:



### EXAMPLE:

100 Residents x 25% Prevalence = 25 Patients

**Multiplied by \$371 day = \$9275.00 day additional cost!**

\* Source: Australian Institute of Health and Welfare (2003),  
*Health Expenditure Australia 2001-02* and  
1998-2003 Australian Health Care Agreements

## FREQUENTLY ASKED QUESTIONS

<p><b>1. Why is Shear Comfort® different to other sheepskins?</b></p>	<p>All Shear Comfort® products are made from specially selected sheepskins, with a 30 mm wool height providing density not seen in inferior and synthetic products</p>
<p><b>2. I have heard the term U.R mentioned, what does this mean?</b></p>	<p>U. R is simply a common term for urine resistant.</p>
<p><b>3. What does high temp mean and why is this important?</b></p>	<p>High Temp means that all Shear Comfort® products can be washed in up to 80°C or 176°F water temperature. Clinical data indicates that thermal disinfection occurs around this temperature. This is particularly important when using within a medical facility as it allows multi patient use of the products</p>
<p><b>5. So why green or blue?</b></p>	<p>The most recognisable medical colours are Green and Blue and to differentiate medical grade sheepskins from others in the market the AS4480.1 standard recommends that only Green or Blue are incorporated.</p>
<p><b>6. How often do I wash the product and do I put it under the bed sheet?</b></p>	<p>The product can be laundered as required.</p> <p>Shear Comfort® products are most effective at the skin interface therefore it is recommended that all products should have skin contact</p>
<p><b>7. I consistently hear reference made to the Australian standard, what does this mean?</b></p> <ul style="list-style-type: none"> <li>• <b>TGA ACCEPTED</b></li> <li>• <b>CE MARK APPROVED</b></li> <li>• <b>AUSTRALIAN STANDARD 4480.1 1998</b></li> </ul>	<p>AS4480.1 was established in response to a new method of tanning sheepskin that allows the product to withstand laundering to high temperatures.</p> <p>Shear Comfort® implement quality assure guidelines in accordance with ISO 13485 which allows the range to be sold in Europe with a CE marking.</p> <p>In 2005 Shear Comfort® gained FDA approval and TGA acceptance as a medical device.</p>



# AS 4480-1



Australian Government  
Department of Health and Ageing  
Therapeutic Goods Administration



Shear Comfort® is a registered Trade Mark



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