



**Independent Clinical Evaluation**  
Pure Air 8 & Simpulse 8

# Select Medical Introduction, Background to the Research and Objectives

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## **Introduction**

Select Medical are pressure area care specialists. We research, develop and manufacture a range of pressure relieving mattresses and cushions. As part of the ethos of the Company, to provide a better everyday life for people, we continually strive to bring the cared for, carer and care provider the very best and latest developments in pressure area care equipment.

## **Background to the Research**

As part of our on-going commitment to you, we interact with key stakeholders, interpreting the collected insights and integrating them into our product development. To more fully understand how our mattresses perform in real-life situations, we commissioned Wound Care Consultants Ltd to undertake some independent research into our Pure Air 8 and Simpulse 8 pressure relieving mattresses. Whilst commissioned by Select Medical, Wound Care Consultants are an independent company led by highly regarded and experienced Tissue Viability Nurses, Sylvie Hampton and Sarah Gray. Their report is reproduced here, in full with no amendments.

## **Objectives**

The main objective was to gather an independent evaluation as to the clinical efficacy of the mattress systems. Other areas for evaluation were the comfort of the systems and cost saving potentials. We wanted to gain insights into how Pure Air 8 & Simpulse 8 performed from both a patient and carer perspective.



# Wound Care Consultants

Knowledge, Experience in Healing Wounds

Wound Care; Audit; Report Writing; Advice on Product Development

## Introduction

Preventing pressure ulcers has been a nursing concern over centuries and Florence Nightingale (1859, page 8) wrote, "*If he has a bedsore, it's generally not the fault of the disease, but of the nursing.*" However, pressure ulcer development is far more complex than simply repositioning (Dealey, 1992) and these ulcers are often acute injuries which develop rapidly when compression of tissues causes ischaemia and necrosis during serious illness and trauma, including surgery (Bader, 1990). There is, of course, a greater emphasis today on the 'well' person such as those undergoing epidurals (i.e. mothers giving birth), as these patients are particularly vulnerable to pressure ulcers even though they remain well (Alfirevic et al. 2004).

This report will review the use of mattresses in prevention or treatment of pressure ulcers.

### Definition of pressure ulcer:

**Pressure:** The exertion of force by one body on the surface of another. Can cause wounds that expose bone (down to Grade 4).

**Ulcer:** *Webster's New Riverside University Dictionary* defines an ulcer as "an inflammatory, often suppurating lesion on the skin or an internal mucosal surface of the body, as in the duodenum, resulting in necrosis of the tissue."

**Shear:** Shear arises when pressure is applied at the surface of the skin and causing distortion of underlying structures. This can lead to the compression or stretching of blood vessels, which in turn can result in blood clots or tearing of the vessels (National Pressure Ulcer Advisory Panel, 2010). Causes wounds that can be as deep as bone (Grade 4) and also can extend under the skin creating a 'pocket' or 'undermining'. This is more dangerous than pressure alone.

**Friction:** A force between two surfaces that are sliding, or trying to slide, across each other. In the case of skin, the top layers of the skin can be worn away causing exposure of the dermis. This is a Grade 2 and can be rapidly healed.

Shear and friction are causative factors and not the cause of pressure ulcers. They are only able to injure the skin if pressure is present.

Despite considerable efforts to prevent pressure ulcers, data on prevalence of these ulcers continues to be unacceptably high (Bouten et al. 2003) and there is a trend toward increasing pressure ulcer prevalence in recent years (Chen et al. 2005). Data from the US and Europe confirms that pressure ulcer rates have failed to respond to prevention strategies (Gallagher et al, 2008; Van Gilder et al, 2008; Schoonhoven et al, 2007; Vanderwee et al, 2007) and incidence is actually increasing in long term care (Horn et al. 2004). This increase can at least partly be attributed to limited knowledge of the aetiology of the clinical condition and the fact that identification and prevention of pressure ulcers mainly focus on skin tissue, even though the underlying muscle tissue may be more susceptible to mechanical loading (Bouten et al. 2003).

Pressure ulcers can develop very quickly in some people if the person is unable to move for even a very short time – sometimes within an hour (NICE 2005) and are associated with significant morbidity and increased health care costs (Reddy, 2006; National Pressure Ulcer Advisory Panel 2001; Allman et al. 1999).

Select Medical have mattresses that will address these problems and ensure time for appropriate nursing care. Two Simpulse 8 Dynamic mattresses and two Pure Air 8 Dynamic mattresses were provided to a Residential Care Home in Eastbourne. The Nurse in Charge and the Tissue Viability Care Assistant agreed to monitor the mattresses for a four week In-service Evaluation.

The mattresses provided:

### Simpulse 8 Dynamic mattress

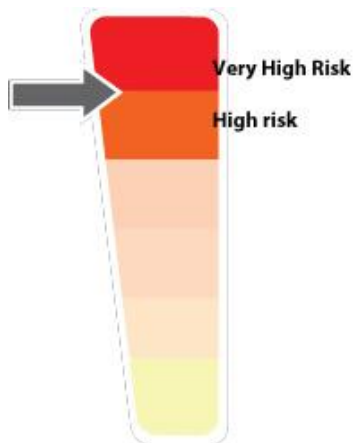
The Simpulse 8 Dynamic mattress has a one in two cell-cycle design of 10 to 15 minutes. There is also a static function with automatic return to the cell-cycle which is a vital function. Mattresses that do not have automatic return can be accidentally left on static and this is extremely dangerous and patients can develop pressure ulcers due to the firmness of the mattress in this setting.



Figure 1 Simpulse 8 Dynamic mattress



Figure 2 Electric pump for Simpulse 8



The Simpulse 8 Dynamic mattress is for patients/residents who are at high or very high risk of developing pressure ulcers.

Figure 3

## Pure Air 8 Dynamic mattress



Figure 4 Pure Air 8 Dynamic mattress



Figure 5 Electric Pump for Pure Air 8 Dynamic mattress



Figure 6. The internal cells of the mattress

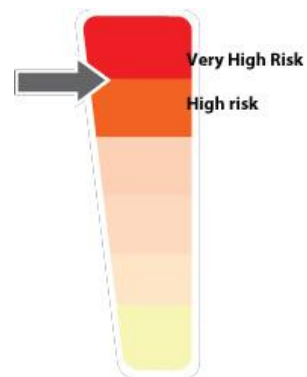


Figure 7 For patients/residents who are at high or very high risk of developing pressure ulcers.

The Pure Air 8 Dynamic mattress has a one in two cell-cycle design with a silent running pump and an optional 10 to 15 mins cycle time. There is a DARTEX multi-stretch waterproof and vapour permeable cover which can be laundered up to 95°C. There is also the static function with the essential auto-return.

# Results:

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The mattresses were provided to 4 residents in the residential Care Home. Each resident consented to take part. Each resident was elderly and at high risk of developing a pressure ulcer.

## **The Simpulse 8 Dynamic mattress**

The Simpulse 8 Dynamic mattress was used by 2 residents.

The first was placed on the mattress as she had suddenly become very unwell and was not eating and drinking very little. There was no redness apparent on any of the bony prominences at commencement of the In-service evaluation.

The second resident was at high risk of pressure injury but had no injury on entrance to the In-service evaluation.

The mattress was found to be very simple to set up and no difficulties were noted in using the mattress.

## **Comfort**

Comfort was judged on a scale of 1 to 10, 1 being the most comfortable. The first resident found it difficult to use the mattress for the first few days as she adjusted to the cell movements but then, when she did adjust, she found the mattress extremely comfortable.

The second resident found it extremely comfortable from the beginning of the evaluation.

## **Repositioning and cost saving**

Prior to the mattress being provided, the residents were being repositioned every 2 to 3 hours. During the use of the mattress, the residents were positioned every 3 to 4 hours. This means there was a potential to reduce the number of repositioning times in the day from 8 or 12 times to 6. That has a potential cost saving value to any care

home when there are several residents who require regular repositioning and it also releases carers to provide valuable time to all residents.

Given there may be 4 residents in any care home that require repositioning every 2 hours (commonly used repositioning regime) and, given each repositioning takes 10 minutes to ensure the comfort of the resident, then the time taken during the day for repositioning these residents is 120 minutes. Also, as it is two carers required for safe repositioning, then that is 240 minutes or 4 hours of carers time taken up during the day by repositioning.

Given that carers may receive an average pay of £9 per hour, then this is £36 per day spent on repositioning or £13,140 per year. Therefore, the cost of the mattress can be offset by halving the cost of repositioning to £6,750 per year saved on repositioning times. Although the carers still require to be paid for the full day, they are then able to provide increased attention to other residents.

### **Potential for pressure ulcer formation**

These residents were unwell and remained on bed rest during the evaluation. Neither resident developed any pressure injury or redness over any bony prominence while using this mattress.

### **Opinion of those using the mattress**

The carers found it very easy to use. It did not alarm once, was very quiet and was enjoyed by both residents. No difficulties were noted with either mattress.

The automatic static return function was excellent and gave peace of mind that it would not matter if the carer forgot to return the automatic function once the static was no longer required.



## The Pure Air 8 Dynamic mattress

The Pure Air 8 Dynamic mattress was used by 2 residents. One had an established grade 2 pressure ulcer over the sacrum and a reddened heel on admission to the evaluation.

The carers found the mattress extremely simple to use and very quiet.

### Repositioning and cost saving

The repositioning times and the outcome of using this mattress is exactly the same as the Simpulse 8 Dynamic mattress:

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## Potential for pressure ulcer formation

One resident had redness over the heels and a broken area on the sacrum on the 31<sup>st</sup> July. These were photographed and placed on the Care Home computer. Unfortunately, the carers had to obey data protection laws and they removed the images from the camera. This means that the images have to be downloaded for the computer which does not provide good reproduction or quality photographs.

Although poor quality, these photographs show the progress of the pressure areas from broken and reddened to healed.

James  
31-7-17



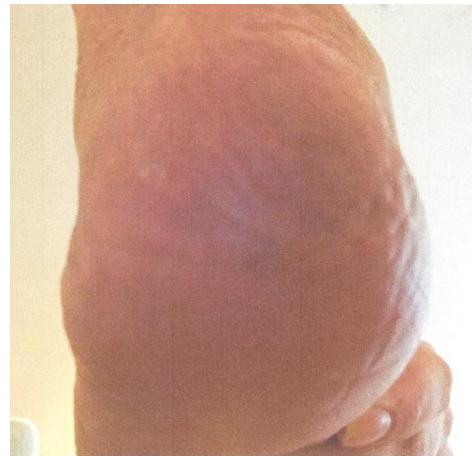
JAMES  
22-8-17



There was an open wound on the sacrum on the 31<sup>st</sup> July that had healed by the 22<sup>nd</sup> August.



James 22<sup>nd</sup> 8.17



This picture is of the right heel. Although the photograph is not high quality, it can be clearly seen that there is no redness on the bony prominence following 4 weeks use of the Pure Air mattress.

James 22.8.17

## Discussion

The carers found the two mattresses great value in their care of the residents. They described them as *"Really good mattresses that were easy to put up with no alarms occurring during the period of use of 12 weeks."*

*"The residents slept very well on all 4 mattresses and there were no sores developed over the 12 week period."*

One of the problems associated with prevention of pressure ulcers is the time it takes to reposition patients/residents. NICE Guidelines recommend repositioning every 6 hours, but the carers are aware that any time greater than 2 to 3 hours between repositioning does increase the risk of pressure ulcer development. That takes up a considerable time during the day – time that could be spent increasing residents mobility and quality of life.

None of the residents developed pressure ulcers in the 12 weeks that the products were used. One resident had a grade 2 pressure injury to the sacrum and Grade 1 to his heel on entry to the evaluation, but that healed within the 4 week period.

## Conclusion

Both the two Simpulse 8 Dynamic mattresses and two Pure Air 8 Dynamic mattresses evaluated extremely well. They were popular with both carers and residents. There have been no problems arising from their use; they were quiet, comfortable and easy to use.

This simple In-service evaluation demonstrated the potential for time and cost saving and were shown as a very useful tool in the prevention of pressure ulcers.

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Sylvie Hampton. Independent Tissue Viability Nurse Consultant.

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Wound Care Consultants Ltd.