Clinical evaluation report

on LINET 3-cell Alternating Pressure Mattress products

Evidence of clinical effectiveness

and product equivalence to show use as an accepted intervention in the prevention and treatment of pressure ulcers

1 Report Prepared By:

1.1 Type of soiling

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Mark has spent the last 15 years working in the pressure area care arena with market leading company's in a clinical education and research position.

Main areas of work:

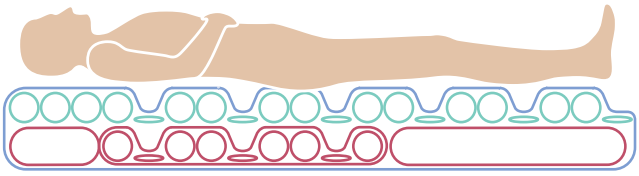
- Gathering, analysis and dissemination of clinical literature
- Carrying out and reporting on clinical investigations
- Clinical and company education
- Clinical and resource audit
- Wound care support to Tissue Viability colleagues

2 Product Description

For the past four decades Alternating Pressure Air Mattresses (also called Dynamic Mattresses), have played key roles in the prevention and management of pressure ulcers. There are now many different forms of dynamic mattress available some to replace the bed mattress others to supplement the basic mattress. While these devices vary greatly in size, depth, inflation time and appearance, the vast majority operate by inflating one air cell and deflating the adjacent cell. This is two-cell cycle technology and has been shown, in some cases, to be an effective tactic in both pressure ulcer prevention and treatment.

While two-cell cycle dynamic mattresses are undoubtedly effective, there is an advanced option known as three-cell cycle, a version of which is available from Linet UK. In this modality, two inflated cells are adjacent to a totally deflated cell (Figure 1).

This three-cell cycle allows more of the body to be supported at any given moment while the fully inflated cells around a deflated cell allows total pressure elimination at frequent intervals at all body sites. This total pressure elimination also known as 'zero pressure' has been at the heart of a small number of products for over 20 years dating back to the grandfather of alternating pressure in 1985 the 'Airwave System', 2008 sees the continued success of pressure ulcer prevention and management maintained through the 3-cell cycle zero pressure system from Linet called the 'Virtuoso'.



3 Supporting Literature

This section of the report shows the literature available to support alternating pressure as an accepted principle in pressure area management.

3.1 Concepts/principles

- Le, KM et al. An in-depth look at pressure sores using monolithic silicone pressure sensors. *Plastic Reconstruct Surg.* 1984; 74: 745–754.
- Kosiak, M. Aetiology of decubitus ulcers. *Arch Phys Med Rehabil.* 1961; 41: 19–29.

This study was performed to determine the effect of constant and alternating pressure on both normal and enervated muscle. Localised pressure was applied over muscle tissue and the relationship between microscopic changes in the muscle and time and intensity of pressure were recorded.

In both groups a range of pressure and applied time were used.

- Pressures applied ranged from 35 – 240mmHg.
- Pressures were applied for periods of one to four hours.
- Alternating pressure was applied at 5 minutes intervals.

"The application of alternating pressures, whereby the tissue was completely free of pressure for five minute intervals, showed consistently less change or no change when compared with tissue subjected to an equivalent amount of constant pressure. This was true even at pressures as high as 240mmHg for three hours."

- Landis, ME. Micro-injection studies of capillary blood pressure in human skin. *Heart*. 1931; VXV: 209–228.
- Williams, SA et al. Dynamic measurement of human capillary blood pressure. *Clin Sci.* 1988; 74: 507–512.

3.2 General evidence of alternating pressure as an accepted intervention

- National Institute for Clinical Excellence. Clinical Guideline 29 *The prevention and treatment of pressure ulcers.* Sept 2005
- European Pressure Ulcer Advisory Panel. *Pressure Ulcer treatment Guidelines. EPUAP Review* 1999 1(2) 31–33
- Young, JB, Dobrzanski S. Pressure sores: Epidemiology and current management concepts. *Drugs & Ageing*. 1992; 2 (1): 42–57.

3.3 Specific 3 cell cycle evidence of product effectiveness

- Brem, H. Decreased incidence of stage IV heel ulcers in patients treated on pressure ulcer protocol, *Poster presentation at 11th European Tissue Repair Society Conference*, Cardiff, September 2001
- Brem, H. Establishment of rate of healing for pressure ulcers. *Poster presentation at 11th European Tissue Repair Society Conference*, Cardiff , September 2001
- Brem, H. Pressure ulcers will heal despite low albumin levels. *Poster presentation at 11th European Tissue Repair Society Conference*, Cardiff, September 2001
- Exton-Smith, A. N., Overstall, P. W., Wedgwood, J., et al. Use of the ‚Airwave System' to prevent pressure sores in hospital. *The Lancet*, 1982, i:1288–1290.
- Gunther, R.A. & Clark, M. The effect of a dynamic pressure redistributing bed support Surface upon systemic lymph flow and composition. *Journal of Tissue Viability*. (suppl.) 2000:10(3); 10–15
- Knowles, C. Pressure ulceration and the morbidly obese. Presented at European Pressure Ulcer Advisory Panel Conference. 2000

- Marin, E.M. A prospective clinical outcome study of the effectiveness of a dynamic mattress replacement system in the critically ill patient. *Presented at European Wound Management Association Conference*. 2002
- Phillips L. Pressure relief and the critically ill Bariatric patient. *Poster presentation at Innovations in Wound Care conference*. September 2001
- Phillips, L. Cost-effective Strategy for Managing Pressure Ulcers in Critical Care: A Prospective, non-randomised, Cohort Study. *Journal of Tissue Viability (Supplement)*. July 2000, 2–6.
- Phillips, L. Pressure relief and the obese patient: translating technical specification into clinical outcome. *Presented at Australian Wound Management Association conference*. 2002
- Schregel, W. et al Static and dynamic anti-decubitus systems for ITU care patients. *Journal of Tissue Viability*. 1993: 3(4); 9–14
- Taylor, L. Evaluating the Pegasus Trinova: a data hierarchy approach. *British Journal of Nursing*, 1999. 8(12): 771–778.
- Lynn Taylor, *British Journal of Nursing*, Vol. 8, Iss. 12, 24 Jun 1999, pp 771–778

Understanding the efficacy of patient support surfaces is essential if pressure sore management is to be both efficient and effective. However, laboratory and clinical studies in this area are fraught with well recognized problems. This investigation reports a combination of laboratory, randomised controlled trial (efficacy data) and measures of effectiveness to illustrate the beneficial role of a new dynamic integrated mattress and seat cushion system: the Pegasus Trinova. Successful prevention of sores among a vulnerable patient population, along with positive comments regarding the system's comfort and 'user-friendliness' are supported by laboratory measures of interface pressure to provide a hierarchy of data. Such an approach may present one solution to the lack of timeliness of most mattress clinical trials, thus allowing decisions regarding new support surfaces to be made upon the basis of evidence, not on anecdote or solely upon marketing claims.

- Thompson, G. Wound healing in a critically ill Bariatric patient using the combined facilities of the Cairwave Therapy System and the Multicare Bed Frame. *Presented at Innovations in Wound Care Conference*, Cardiff. 2001
- West J. et al The effects of a unique alternating pressure mattress on tissue perfusion and temperature. *Presented at the European Tissue Repair Society Conference*. 1995
- Clark, M. et al. Collecting pressure ulcer prevention and management outcomes. Part 1. *British Journal of Nursing. 2002*: 11(4); 230–238
- Clark, M. et al. Collecting pressure ulcer prevention and management outcomes. Part 2. *British Journal of Nursing*. 2002: 11(5); 310–314
- Clark, M. Models of pressure ulcer care: costs and outcomes. *British Journal of Healthcare Management*. 2001: 7(10); 412–416
- Clark, M. Modelling the outcomes of pressure area care. *Presented at Innovations in WoundCare conference*, Cardiff. 2001

4 Evidence of equivalence

4.1 Manufacture

The processes used in the production of these products are the same as have been successful employed in the manufacture of this type of active air mattress product by all the main European & North American manufacturers for many years.

The quality of these processes and the materials used is assured by a manufacturing quality system that is external assessed & approved in accordance with ISO13485 & ISO9001.

4.2 Design

The design of these products is based upon the same basic functionalities and their embodiment as have been successful employed in this type of active air mattress product by all the main European & North American manufacturers for many years.

The differences exist at the ergonomic and functional levels and have no effect on the core clinical performance provided.

4.3 Cycle

The 7.5 minute 3 cell cycle is faithfully reproduced in the products in order to achieve the same performance and outcomes as early products based on the principle (see section 3.3)

4.4 Interface pressure comparison

Interface pressure measurement is recognised as a key method for determining the potential clinical performance of pressure area care products. Interface pressure measurements have been performed by PSP technology clinical & technical staff using an industry standard measurement device. These tests were performed using a clinical manikin & a range of healthy volunteers.

By direct comparison of the results so obtained both by measurement of competitor equipment that has proven clinical outcomes and published data. It is possible to state that from this analysis the pressure maps recorded on the Linet products are in all cases at least equivalent to other products already on the market and in most cases achieve longer periods of zero pressure and thus indicate to have superior clinical performance.

4.5 Clinical evaluation

Practical Clinical evaluation has been achieved by the performance of user trials carried out in UK , French & Czech healthcare establishments using real patients of the pressure sore risk categories that these products are intended for use with.

These trials were performed by the independent clinical professionals employed at the various health care facilities and the results collated by the author of this report.

The details of these trials can be read in the individual reports & other clinical literature written by LINET & available separately from this document.

The summary of these reports is that no patient using the products suffered any injury or reduction in their state of health due to the use of these products and in all cases the patient either remained free from new pressure ulcers, or had the state of their existing ulcers stabilised or improved.

5 Risk analysis

A risk analysis was performed on this product in accordance with ISO14971:2007 and EN62304:2006 and no significant risks were identified (see Risk management files for individual models of this type of 3 cell APM product)

6 Conclusion

The review concluded that, based on the clinical evidence compiled within this report, this type of product is safe for use in the clinical environment as an effective method for prevention & treatment of pressure ulcers.

Customers must however always be made aware through means of the literature & training provided by Linet of the individual limitations of use, patient weight limits, contraindications etc, of the different models that are available.

7 Authorisation & Sign off

The contents of this evaluation was reviewed & approved for use by:

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8 Combined References

- Brem, H. Decreased incidence of stage IV heel ulcers in patients treated on pressure ulcer protocol, *Poster presentation at 11th European Tissue Repair Society Conference*, Cardiff, September 2001
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