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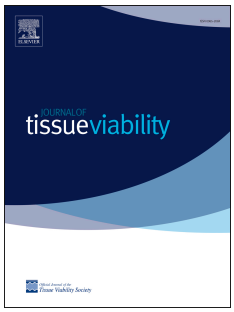

Pressure signatures can influence tissue response for individuals supported on an alternating pressure mattress

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Pressure signatures can influence tissue response for individuals supported on an alternating pressure mattress

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ABSTRACT

Prolonged mechanical loading can lead to the breakdown of skin and underlying tissues which can, in turn, develop into a pressure ulcer. The benefits of pressure relief and/or redistribution to minimise risk have been well documented. Manufacturers have developed alternating air pressure mattresses (APAMs) to provide periodic relief for individuals on prolonged bed-rest. The present study describes the development of a control system, termed Pneumatic Manager which can vary the signature of an APAM, namely its pressure amplitude, cell profile and cycle period. An experimental array was designed to investigate the effects of varying these parameters, particularly with respect to its ability to maintain skin viability in a group of five healthy volunteers lying in a supine position. Transcutaneous gas (T_cPO_2/T_cPCO_2) tensions at the sacrum were monitored. In addition, pressures and microclimate parameters at the loaded support interface were also measured.

In the majority of test conditions the alternating support produced sacral T_cPO_2 values, which either remained relatively high or fluctuated in concert with cycle period providing adequate viability. However, in 46% of cases at the extreme pressure amplitude of 100/0 mmHg, there was compromise to the skin viability at the sacrum, as reflected in depressed T_cPO_2 levels associated with an elevation of T_cPCO_2 levels above the normal range. In all cases, both the humidity and temperature levels increased during the test period. It is interesting to note that interface pressures at the sacrum rarely exceeded 60 mmHg. Although such studies need to be extended to involve bed-bound individuals, the results provide a design template for the optimum pressure signatures of APAM systems to ensure maintenance of skin viability during pronged loading.

Key Words: Pressure ulcers; Tissue viability; Alternating Pressure signatures; Supine lying; Microclimate

Highlights

- A control system has been designed to vary the pressure relief features in an APAM system
- The magnitude of pressure amplitude influences the physiological response of sacral tissues
- Optimum design features of APAM systems should match the individual response

1. Introduction

Prolonged mechanical loading of skin and underlying tissues can lead to a reduction in perfusion and subsequent delivery of vital nutrients to local cells, which affects tissue remodelling and can result in the development of pressure ulcers (PUs) [1]. In addition to local ischaemia, research has revealed other mechanisms associated with pressure ulcer formation namely, impaired lymphatic drainage, reperfusion injury and direct cell damage resulting from high deformations [2]. This disabling condition, which has been implicated as a key indicator of Patient Safety and Quality of Care, particularly affects immobile and insensate individuals who spend much of the day bed or chair-bound. The benefits of pressure relief and/or redistribution have been documented in international guidelines for the prevention and treatment of pressure ulcers for many sub-groups of patients deemed to be at high risk of developing PUs [3]. Thus a number of management strategies are available ranging from regular turning of the patient, which is labour intensive and not always strictly adhered to [4], to active support surfaces including a number of commercial alternating pressure air mattresses (APAMs). These systems tend to be prescribed to high risk individuals to reduce the effects of prolonged load-induced ischaemia on vulnerable soft tissues overlying bony prominences, typically at the sacrum and heels. The main evidence for their effectiveness derives from a large cohort study in which their use reduced the number of PUs at the heels when compared to a control group supported on a viscoelastic foam mattress [5]. In order to provide sequential offloading of vulnerable tissues manufacturers of APAM systems utilise pressure profiles, whereby the cells within the device inflate and deflate to a prescribed internal pressure along different zones of the support surface. However, there is considerable variation in the pressure profiles or signatures adopted in commercial APAM systems, the characteristics of which have been discussed in a consensus document [6]. These are often determined by practical issues, such as the characteristics of the incorporated pumps, as opposed to considerations related to maintaining tissue viability or status of the supported individual.

Only a few studies have evaluated the features which determine the pressure signature associated with APAM systems. In one such study, the effects of different pressure relief profiles (pressure range of

0-20 and 10-20 mmHg for cycle times of 5, 10 and 20minutes) were evaluated by monitoring skin blood perfusion in the heel supported by a single air cell of an experimental mattress [7]. Their findings revealed that the average skin perfusion could be maintained with the pressure relief profiles for healthy subjects. Using a similar approach, Goossens and Rithalia [8] examined the performance of three APAMs (peak internal pressures ranging from 28-49mmHg for cycle time of 10 minutes) and indicated differences in physiological responses, as assessed by gas tension recovery and tissue perfusion, at the heel of an able-bodied cohort. However, no statistical differences in maximum interface pressures between the three APAMs were observed. In a recent study the present authors evaluated the performance of a prototype APAM with an in-built pressure sensor, where the internal pressures of the sacral section could be adjusted to subject morphology and BMI [9]. Internal mattress pressures and transcutaneous gas tensions ($TcPO_2$ and $TcPO_2$) at the sacrum and a control site, the scapula, were monitored. The skin response to alternating support pressures in a cohort of healthy volunteers were divided conveniently into three distinct categories (1-3), as defined in Table 1.

Insert Table 1 here

In the majority of test conditions the internal support produced sacral T_cPO_2 values which provided adequate viability, either remaining similar to those at the control site (Category 1) or fluctuating in concert with the cycles of alternating support pressures (Category 2). In both cases, the associated T_cPCO_2 levels remained within the normal range of 35-45 mmHg [9-10]. However, in a few cases when the head of bed (HOB) was raised ($\geq 45^o$), there was compromise to the skin viability at the sacrum, as reflected in depressed T_cPO_2 levels associated with an elevation of T_cPCO_2 levels above the normal range (Category 3). In all cases, interface pressures at the sacrum rarely exceeded 8kPa (60 mmHg). The transcutaneous categorisation was also adopted in a recent publication examining the differences between lateral rotation provided by an active mattress system and the manual repositioning performed by a clinician [4]. Recent studies evaluating support surface performance have also incorporated temperature and humidity sensing [11], motivated by the increasing evidence

that thermodynamic conditions within and around skin tissue strongly influence the susceptibility of skin to pressure ulcers [12]. As an example, elevated interface temperatures increase the metabolic demands of the tissue and excessive moisture can lead to skin maceration.

The relative paucity of literature provides motivation for the present study, which examines whether there is an optimal internal mattress pressure signature, which maintains tissue viability of individuals supported on an APAM system. This is achieved with the following objectives, namely to,

i) Design and develop a versatile controller for a commercial APAM system.

ii) Design an experimental test matrix, which enables a comparison of pressure signatures imposed on a small cohort of young healthy volunteers.

iii) Evaluate a range of test conditions on the physiological responses, interface pressure and microenvironment at the subject support interface

2. Material and Methods

2.1 Control of Support Mattress

The alternating pressure air mattress used in this study was a commercial system, Model Duo 2, which was loaned by the Research and Development Department of an international support surface manufacturer (HillRom, France). The system has a default operation in which the two distinct sets of cells along the long axis of the mattress are alternatively inflated and deflated (Table 2). The pressure signature associated with the APAM support systems can be defined by a number of variables, as discussed in a consensus document [5]. Their combination will determine the nature of the support afforded to the lying individual. The present study examined the influence of three of the critical parameters, namely pressure amplitude, cell profile and cycle period (Table 1).

The various configurations were achieved with a custom-made control system, termed Pneumatic Manager. To control the inflation phase, three-way pneumatic solenoid valves (Type 141, Hycontrol, Redditch, UK) were used to control air into the cells from a compressed air source. In the deflated state the cells were exhausted to atmosphere (Figure 1). To control the pressure difference between inflated and deflated cells, the pressures of the air source and the exhaust manifold were each

manipulated via means of a variable pressure regulator (Type 700 high flow, Control Air, US). The time-based functions and multiple outputs of a logic control unit (Millennium II Plus, Crouzet, France) were employed to inflate and deflate the individual cells in different configurations, at specified cycle periods. The cyclic timer prescribes the period at which a particular cam stage was maintained. The cam prescribed the cell profile arrangement (1:2 or 1:4) for each stage for the solenoid valves.

Insert Figure 1 here

Values for the three variables were selected based on a number of factors, including compatibility with existing commercial APAM systems, as well as practical time considerations for individuals involved in the testing. Accordingly, values were assigned to each variable, as summarized in Table 2.

Insert Table 2 here

2.2 Subject Group

The study was approved by the local Ethics committee of Queen Mary University of London (QMUL) (Ref no. QMREC 2009/43) and informed consent was obtained from each subject prior to testing. Exclusion criteria included any history of skin-related conditions. The study recruited five healthy participants (4 male, 1 female) from the local University student population. Participants were aged between 20 and 26 years of age with a mean height of 1.73m (range 1.64 -1.81m), a mean mass of 68.6kg (range 55-80 kg) and a corresponding mean BMI of 22.9 kgm^2 (range 18.9 – 27.0 kgm^{-2}). All tests were performed in the Biomechanical Performance Laboratory at QMUL, which was maintained at a temperature of 26 $\pm$ 2ºC. The participants were tested on separate occasions for each of the three pressure amplitudes, allocated in a random order. On each occasion 2 cell profiles and 3 cell periods were tested resulting in a total of 18 test conditions (Table 2).

2.3 Test Protocols

During the set-up phase, the support surface was actuated with Pneumatic Manager. A transcutaneous gas electrode (Model 841, Radiometer, Denmark), set at a temperature of 44^{o}C to ensure maximum vasodilatation [10], was attached to the mid-region of the sacrum. The volunteers adopted a sitting position during an acclimatization period to establish basal unloaded tissue gas values (T_cPO_2/T_cPCO_2) prior to them assuming a supine position on the support surface. A thin sheet incorporating a 96 cell array positioned on the top surface of the mattress was used to measure interface pressure via a monitoring system (Mark III, Talley Medical Group, Romsey, UK). This pressure mapping array included two 12-sensor arrays, located under the sacral and the left heel, at a corresponding spatial resolution of 30 mm in both directions. The remaining 72 sensors were positioned along the body with a spatial resolution of 50 mm across the body width and 120 mm along the body length.

The interface pressures were recorded over three cycles, each of approximately 4 minutes duration, before and after each of the 30 minute test phases. The internal pressures within the four cells (P1-P4) of the mattress and transcutaneous gas tensions (T_cPO_2/T_cPCO_2) were recorded continuously throughout the test period. All outputs processed using appropriate PC software.

Sensors were used for microclimate measurements at the subject-support interface. Both the humidity (HIH-4000-001 Honeywell Inc.) and temperature (Thermocouple-type) sensors were incorporated in two perforated stainless steel cages, one located at the sacrum and one at the heel. Outputs from the sensors were recorded by the data logger and displayed on a computer (Pico Technology Ltd., Cambs., UK)

2.4 Data Analysis

The skin response in terms of transcutaneous gas tensions (T_cPO_2/T_cPCO_2), to alternating support pressures were divided into the three distinct categories, which have been previously established by the authors [9] and defined in Table 1. The mean $\pm$ standard deviation of peak interface pressures values at the sacrum were estimated for each of the 18 test conditions. Chi squared analyses were conducted on the pooled transcutaneous categorical responses to compare between the pressure

amplitudes (100/0, 60/40 and 30/20mmHg). Transcutaneous categories during the two cell profiles (1:2 or 1:4) were compared using a Wilcoxon Rank test. A level of 5% was considered statistically significant (*$p \leqslant 0.05$).

3. Results

The performance of Pneumatic Manager was deemed to match design requirements, as indicated in a typical temporal response for a pressure amplitude of 100/0 mmHg with a cell profile of 1:4 in Figure 2.

Insert Figure 2 here

In the sacral region, simultaneous measurements of transcutaneous gas tensions were performed for all test conditions. A typical set of data for one subject (male, BMI = 25.1 g/m^2) is presented in Figures 3-5, which includes both the four internal mattress pressures (P1-P4) and the oxygen (T_cPO_2) and carbon dioxide (T_cPCO_2) values at the sacrum over the monitoring period. It was evident from each response that after a period of time the internal pressures stabilise at the prescribed pressure amplitudes for each of the pressure profiles. It was also evident that the gas levels vary synchronously with the cycle periods for each of the pressure amplitudes. Nonetheless, the tissue response was variable in nature. In some cases, the T_cPO_2 changes minimally over the period (e.g. Figure 5c) while, in other cases, the T_cPO_2 fluctuates at a similar temporal profile to the internal mattress pressures (e.g. Figure 5a). In a few cases, the T_cPO_2 is depressed for a large proportion of the monitoring period (e.g. Figure 3c), with a corresponding increase in T_cPCO_2 levels above the normal range.

Insert Figures 3, 4 and 5 here

The complete series of responses in terms of Categories 1-3 (Table 1), are summarized in Table 3. There were significant differences in the sacral tissue responses when comparing the pressure

amplitude configurations during both 1:2 (p=0.001) and 1:4 (p=0.004) cell inflation profiles. In particular, in 14 of the 17 cases where a Category 3 response occurred, the support surface was prescribed a pressure amplitude of 100/0 mmHg (Figure 3). By contrast Category 1 responses occurred more predominantly with a cell profile of 1:4 with either pressure amplitudes of 60/40 mmHg (7/15 cases) or 30/20 mmHg (8/15 cases). The profile in which the cells were inflated (1:2 vs. 1:4) did not elicit a statistically significant change in category responses from the participants ($Z = -1.807$, $p = 0.071$).

Insert Table 3 here

The mean peak values of the interface pressures for each of the 18 test conditions indicate clear variations, as detailed in Table 4. In particular, the mean peak values are higher for the pressure amplitude of 100/0 mmHg when compared to the values corresponding to the other two pressure amplitudes, particularly 30/20 mmHg in the 1:4 cell profile, with a reduction in pressure of 30% or greater ($p>0.05$). A similar trend was observed for the group means of the heel pressures (data not shown), although the differences were again not statistically significant ($p>0.05$ in all cases). Close examination of the data revealed no consistent trends in the values of sacral or heel pressures with reference to changing either cell profile or cycle period of the APAM (Table 4).

Insert Table 4 here

The corresponding data for the humidity and temperature levels at both body sites for each subject were fairly consistent across the test conditions. In terms of relative humidity, the values increased on initial contact with the support surface from the initial ambient values of between 20-40% RH, followed by a slower increase. With many conditions, values reach 100% RH at the sacrum, whereas the humidity values at the heel more generally attained maximum values of between 60-80% over the test period. In a similar manner, the temperatures at both sacrum and heel increased dramatically and

then slowly reached a steady state value of between 35°C and 37°C. A typical result for one subject (male, BMI = 25.1 g/m^2) is presented in Figure 6.

Insert Figure 6 here

4. Discussion

This study incorporated the design of an experimental array to investigate the effects of varying three key parameters controlling an APAM support surface (Table 2). A cohort of five healthy subjects was tested in the supine position on three separate occasions. A series of measurements was conducted to assess the physiological tissue response, in terms of changes in transcutaneous levels of oxygen and carbon dioxide (Table 1), the interface pressures and the microenvironment (temperature and humidity) at the subject support interface.

The system, termed Pneumatic Manager, was designed to control the characteristics of a commercial APAM mattress (Figure 1). It proved successful in controlling three important parameters, namely pressure amplitude, profile and cycle period, associated with the pressure configuration within the APAM (Table 2). Close examination of the 1:4 profile for the 100/0 mmHg setting revealed a small transient decrease in pressure magnitude during the inflation phase, for each of the separate internal pressure measurements (Figure 2). This behaviour is attributed to the principles underlying Pneumatic Manager, which determines that when a cushion re-inflates from a deflated state, the solenoids permit its connection with the other two inflated rows, which remain inflated during the next phase of the cycle. The difference in pressure between the three rows of cells initiates a transient period in which air from the previously inflated cells supplies the deflated row in addition to the normal air supply. This transient behaviour is soon restored to the prescribed inflated maximum pressures (Figure 1). This feature was consistent in the 1:4 cell profile, but was not observed for the 1:2 cell profile, where cells are either in an inflated or deflated state.

A number of researchers have used transcutaneous gas measurements to estimate the viability of loaded tissues for both able-bodied and individuals with chronic conditions. Although the techniques necessitate an elevated electrode temperature of 44^{o}C, it is generally accepted that temporal monitoring of T_cPO_2 and T_cPCO_2 reflect relative changes in tissue viability [4, 9]. The present findings reveal a range of responses dependent on the internal characteristics of the mattress and, to a lesser extent, on the individual subject. However, for 81% (i.e. 73/90) of the individual test conditions, the T_cPO_2 levels either remained fairly stable during the loaded period or fluctuated at a periodicity equivalent to the cycle period of the APAM system (Table 3, Figure 5). In these cases, the T_cPCO_2 levels remained within the normal range of basal values. By contrast, in the remaining 19% of test conditions, there was a significant compromise to the T_cPO_2 levels during the loaded period, which was associated with an increase in T_cPCO_2 levels (Category 3). The majority of these cases (82%) coincided with an internal pressure amplitude of 100/0 mmHg (Table 3), with significantly more Category three responses observed during this extreme pressure amplitude. Close examination of the inter-subject data revealed that 41% of these cases (7/17) coincided with the response from subject 3 who presented with the lowest BMI (18.9 kg/m^2). This corresponds with previous research by the authors in which individuals with low BMI often present with a Category 3 response to sustained lying postures [11]. This suggests individuals with reduced tissue coverage over body prominences may be at increased risk of tissue ischaemia. It is important to note that oxygen debt per se, as in the case of a Category 2 response, does not reflect continued compromise to tissue viability. Indeed, it has been reported that there is a threshold level of tissue oxygen, representing a 60% reduction from unloaded basal values, below which there an accumulation in carbon dioxide levels within the loaded tissues [13]. In a recent paper involving a review of studies at different hierarchical levels, the authors have highlighted the importance of carbon dioxide levels and associated concentration of other metabolites, such as lactate and purines, in tissues subjected to prolonged mechanical-induced loading and subsequent reperfusion [14]. The authors reveal threshold levels of carbon dioxide, which might be indicative of early tissue damage during both mechanical-induced ischemia and subsequent reperfusion and suggest the need for a tissue sensor to monitor this process.

Interface pressure measurements were performed at the end of the acclimatisation period and immediately after each of the test phases. There were clear inter-subject variations in peak pressures at the sacrum (Table 4). When pooled, however, the results were consistent in revealing that the highest mean peak pressures coincided with the internal pressure amplitude of 100/0 mmHg for both cell profiles. By contrast the configurations associated with the other two pressure amplitudes, yielded lower mean interface pressures at both sacrum and heel, more equivalent to those values measured with continuous low pressure air mattress [7]. It is tempting to relate the higher interface pressures associated with the maximum pressure amplitude (100/0 mmHg) with compromised tissue viability (Figure 3). However, there is considerable evidence to suggest that interface pressures per se cannot reliably assess individual risk of tissue compromise [7, 13, 15]. Accordingly the authors question the common practice, particularly in the commercial literature, to describe the performance of APAM systems in terms of pressure distribution data at single point in time.

The microenvironment measurements revealed increased levels of humidity often reaching saturation (100% RH), particularly under the supported sacrum, for a significant proportion of the monitoring period. This was associated with enhanced temperature values at the sacral region, often exceeding 35^{o}C, for each of the pressure signatures (e.g. Figure 6). There was, however, no systematic trend evident in this response with respect to the three pressure signatures. Indeed, there is increasing evidence that thermodynamic conditions within and around skin tissue strongly influence the susceptibility of skin to pressure ulcers, culminating in the use of the term “microclimate” to describe the local temperature and moisture conditions at the loaded skin-support interface [12, 16]. This has motivated the recent interest among support surface manufacturers to address this issue by designing mattresses and cushions which regulate the microclimate. As an example, technological advances in woven manufacturing techniques have given rise to new 3D spacer fabrics, which can be incorporated as overlays within support mattresses.

It is clear that the study is limited by the small number of participants, all of whom were young and healthy. Certain questions were not addressed in the present study, for example, whether the support

offered by continuous low air pressure might have proven sufficient to maintain tissue viability with no additional need for alternating air pressure support. In addition, the effectiveness of different pressure configurations in the APAM system needs to be examined for bed-bound subjects, who may be particularly susceptible to the development of pressure ulcers. It is evident that existing mattresses incorporating a single pressure profile will not accommodate the inter-subject variability with respect to morphology, BMI and other intrinsic factors [9]. The present approach offers the potential for a personalised support surface whose characteristics can be adjusted according to the needs of an individual morphology to maintain skin health during prolonged periods of bed-rest.

There is still much debate as to the comparable merits of APAM and continuous low pressure systems, with proponents of each in the clinical settings. The present work reaffirms that the support surfaces which incorporate alternating pressures, can have a major influence on both the physiological response of skin tissues, the interface biomechanics and the microclimate. However, the pressure amplitudes within APAMs are critical in determining these responses. Findings from the present study indicate that small variations in pressure amplitudes, namely 10 -20mmHg, generally provide sufficient pressure relief to maintain tissue viability. By contrast, when the pressure amplitudes are large as, for example, in the case of the 100/0 mmHg, then there is a tendency towards compromised tissue viability even in able-bodied subjects. These findings should be considered in the light of previous recommendations based on a RCT suggesting that both low pressure multi-stage and single stage inflation and deflation APAMs are equally effective in reducing the incidence of pressure ulcers to below 6% [3, 17].

In conclusion, the study describes the development of a versatile controller, which adjusts the pressure signatures of a commercial APAM system. The effects of varying pressure amplitude, cell profile and cycle period of the APAM device were demonstrated using physiological responses, interface pressures and microenvironment parameters at the support interface with a small cohort of able-bodied subjects. Results indicated that the pressure amplitude had the major effect on the physiological response such that, at extreme levels of 100/0 mmHg, there was a compromise to the

skin viability at the sacrum of many of the individuals, as reflected in depressed TcPO2 levels associated with an elevation of TcPCO2 levels above the normal range. The present approach needs to be extended to patients at risk of developing pressure ulcers. The present methodology provides a design template for optimising pressure signatures of APAM systems to ensure maintenance of skin viability during pronged loading.

REFERENCES

1. Gawlitta D, Li W, Oomens CWJ, Baaijens FPT, Bader DL, Bouten CVC. The relative contributions of compression and hypoxia to development of muscle tissue damage: an in vitro study. Ann. Biomed. Eng. 2007: 35(2):273-84

2. Bouten CVC, Oomens CWJ, Baaijens FPT, Bader DL The aetiology of pressure sores: Skin deep or muscle bound ? *Arch Phys Med Rehabil*. 2003; 84: 616-619

3. National Pressure Ulcer Advisory Panel- European Pressure Ulcer Advisory Panel-Pan-Pacific Pressure Injury Alliance (NPUAP-EPUAP-PPPIA). Prevention and Treatment of Pressure Ulcers: Clinical Practice Guidelines. Haesler E (Ed.) Cambridge Media: Osbourne Park, Australia 2014

4. Woodhouse M, Worsley PR, Voegeli D, Schoonhoven L, Bader DL. The physiological response of soft tissue to periodic repositioning as a strategy for pressure ulcer prevention. *Clin Biomechanics* 2015; 30:166-174

5. Vanderwee K, Grypdonck MH, Defloor T.Effectiveness of an alternating pressure air mattress for the prevention of pressure ulcers. *Age Ageing 2005:* 34(3): 261-7

6. Tissue Viability Society. Laboratory measurements of the interface pressures applied by active therapy surfaces: A consensus document. *Journal of Tissue Viability 2010;* 19(1): 2-6.

7. Mayrovitz HN, Sims N. Effects of different cyclic pressurization and relief patterns on heel skin blood perfusion. *Advanced Skin Wound Care* 2002; 15(4): 158-64

8. Goossens RH, Rithalia SV. Physiological response of the heel tissue on pressure relief between three alternating pressure air mattresses. *Journal of Tissue Viability* 2008; 17(10): 10-14

9. Chai CY, Bader DL. The physiological response of skin tissues to alternating support pressures in able-bodied subjects. *J Mech Behav Biomed Mater*. 2013; 28: 427-35.

10. Bogie KM, Nuseibeh I, Bader DL. Early progressive changes in tissue viability in the seated spinal cord injured subject. *Paraplegia* 1995; 33: 1441-47

11. Worsley PR, Parsons B, Bader DL. An evaluation of fluid immersion therapy for the prevention of pressure ulcers. *Clin Biomechanics* 2016; 40(12):27-32

12. Clark M, Romanelli M, Reger S, Ranganathan V, Black J, Dealey C. Microclimate in context. In: International guidelines. Pressure ulcer prevention: pressure, shear, friction and microclimate in context. A consensus document. London: *Wounds International.* 2010; 19–25.

13. Knight SL, Taylor RP, Polliack AA, Bader DL. Establishing predictive indicators for the status of soft tissues. *Journal of Applied Physiology* 2001; 90: 2231-2237

14. Mirtaheri P, Gjøvaag T, Worsley PR, Bader DL. A review of the role of the partial pressure of carbon dioxide in mechanically loaded tissues: The canary in the cage singing in tune with the pressure ulcer mantra. *Ann Biomed Eng.2015;* 43(2): 336-347

15. Bader DL. The recovery characteristics of soft tissue following repeated loading. *J.Rehab. Res. Dev.* 1990; 27:141-50

16. Ferguson-Pell M, Hirose H, Nicholson G, Call E Thermodynamic rigid cushion loading indenter: a buttock-shaped temperature and humidity measurement system for cushioning surfaces under anatomical compression conditions. *J Rehabil Res Dev.* 2009; 46(7):945-56.

17. Demarre´ L, Beeckman D, Vanderwee K, Defloor T, Grypdonck M, Verhaeghe S Multi-stage versus single-stage inflation and deflation cycle for alternating low pressure air mattresses to prevent pressure ulcers in hospitalised patients: A randomised-controlled clinical trial. *International Journal of Nursing Studies* 2012; 49: 416–426

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Table 1: Characterization response of transcutaneous oxygen and carbon dioxide tensions in human skin exposed to mechanical loading (Based on [9]).

Category	Changes in transcutaneous oxygen($TcPO_2$) and carbon dioxide ($TcPO_2$) tensions
1	Minimal changes in both $TcPO_2$ and $TcPCO_2$ from basal unloaded values.
2	>25% Decrease in $TcPO_2$ with minimal change in $TcPCO_2$
3	>25% Decrease in $TcPO_2$ associated with a >25% increase in $TcPCO_2$

Table 2: Variability of pressure signatures with APAM support surface.

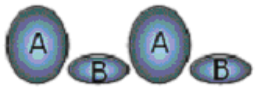
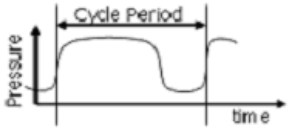
APAM variable				**Representation of the various states**
Pressure Amplitude (mmHg)	**100 / 0**	**60 / 40**	**30 / 20**	
Cell Profile	**1:2 or**	**1:4**		
Cycle Period (min)	**3 or**	**9 or**	**15**	

Table 3: Percentage of subjects which exhibited a tissue response for each of 18 test conditions based on categorisation of transcutaneous gas tensions (Based on [9]).

Pressure Amplitude mmHg	**100/0**			**60/40**			**30/20**		
Cycle period minute	**3**	**9**	**15**	**3**	**9**	**15**	**3**	**9**	**15**
Cell Profile	**1:2**			**1:2**			**1:2**		
CAT. 3	0%	80%	100 %	0%	0%	0%	0%	20%	20%
CAT. 2	80%	20%	0%	100%	80%	100%	80%	60%	40%
CAT. 1	20%	0%	0%	0%	20%	0%	20%	20%	40%
Cell Profile	**1:4**			**1:4**			**1:4**		
CAT. 3	0%	40%	60%	20%	0%	0%	0%	0%	0%
CAT. 2	100 %	60%	40%	40%	60%	40%	60%	40%	40%
CAT. 1	0%	0%	0%	40%	40%	60%	40%	60%	60%

Table 4: The mean values for the peak interface pressures at the sacrum across cohort group measured for all 18 test conditions.

Pressure Amplitude mmHg	**100/0**			**60/40**			**30/20**		
Cycle period minute	**3**	**9**	**15**	**3**	**9**	**15**	**3**	**9**	**15**
Cell Profile	**1 :2**			**1 :2**			**1 :2**		
Mean Peak	72.8	78.5	83.0	61.0	61.8	60.0	37.0	46.4	49.2
SD	21.6	37.8	22.0	7.4	19.9	25.8	5.0	5.0	12.6
mmHg									
Cell Profile	**1:4**			**1:4**			**1:4**		
Mean Peak	73.8	70.6	59.0	56.6	60.8	65.2	54.5	50.3	41.0
SD	24.0	22.4	15.2	6.2	19.2	8.4	11.4	13.9	1.8
mmHg									

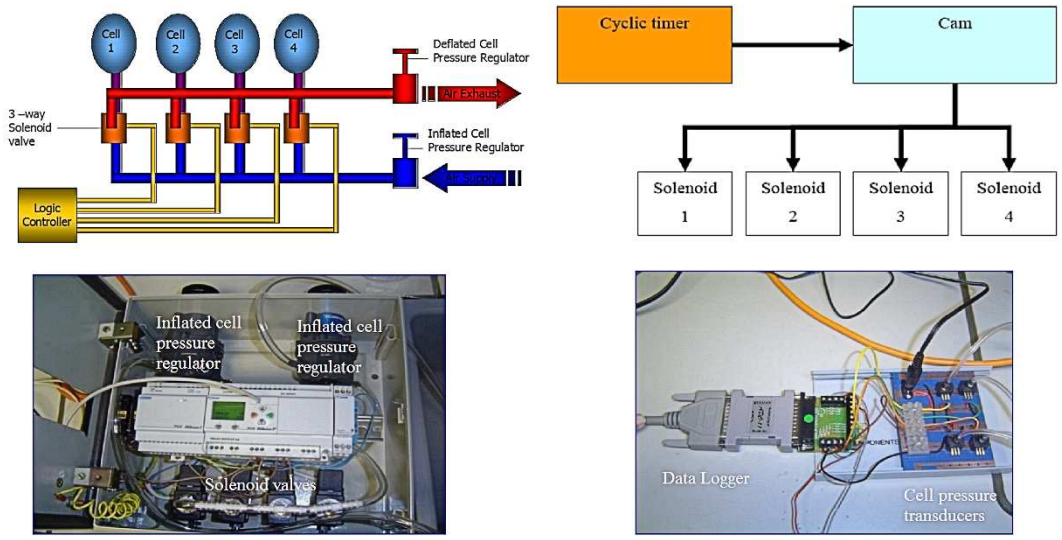


Figure 1: (Top row) General assembly and Layout of the Logic controller function for Pneumatic manager. (Bottom row) Images of logic controller and data logger

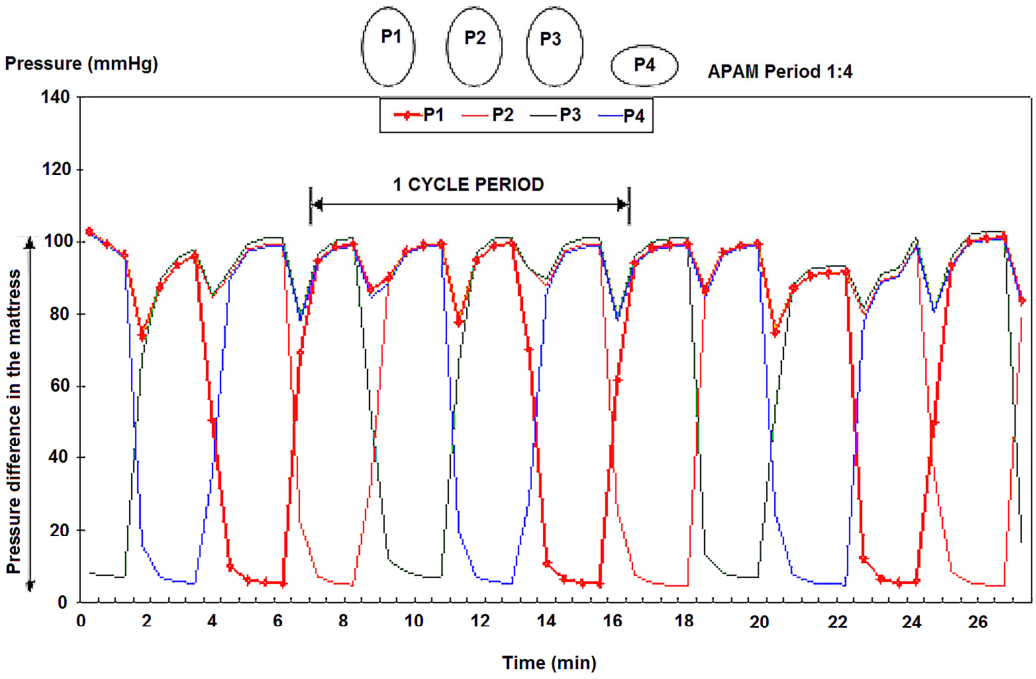


Figure 2: An example of the performance of Pneumatic Manager in controlling APAM support surface at a pressure amplitude of 100/0 mmHg, a cell profile of 1:4, and a cycle time of 9 min. P1-P4 represents the individual internal pressure values in a set of four cells.

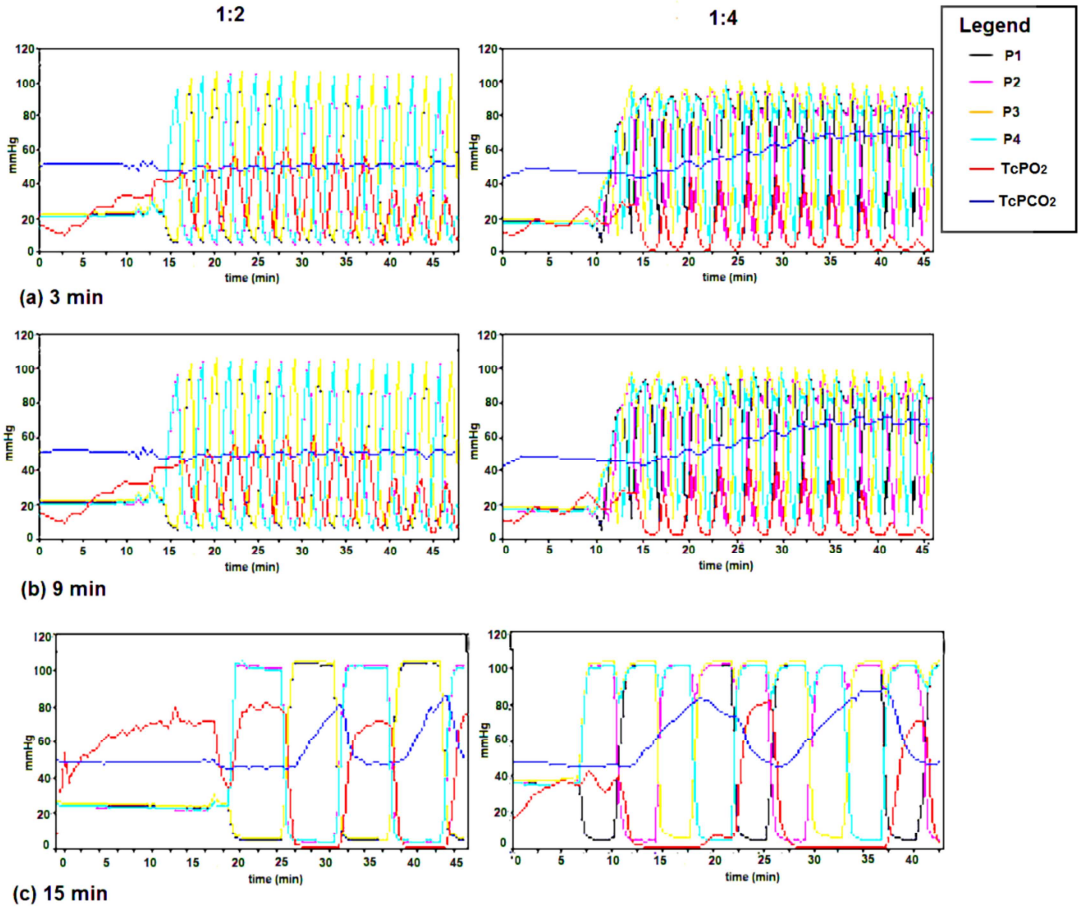


Figure 3: A complete data set for one participant (male, BMI= 25.1 kgm^{-2}) incorporating six combinations of cell profile and cycle period with a pressure amplitude of 100/0 mmHg. P1-P4 represents the individual internal pressure values in a set of four cells.

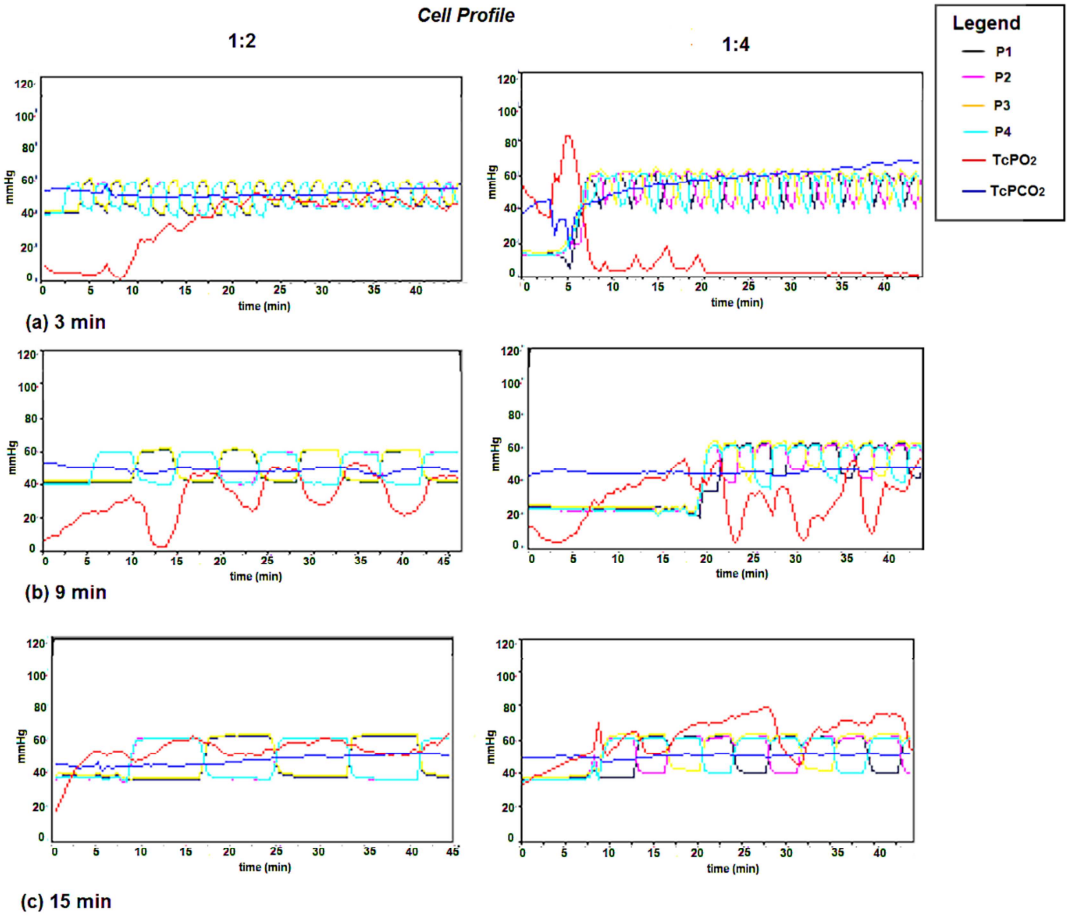


Figure 4: A complete data set for one participant (male, BMI= 25.1 kgm^{-2}) incorporating six combinations of cell profile and cycle period with a pressure amplitude of 60/40 mmHg. P1-P4 represents the individual internal pressure values in a set of four cells.

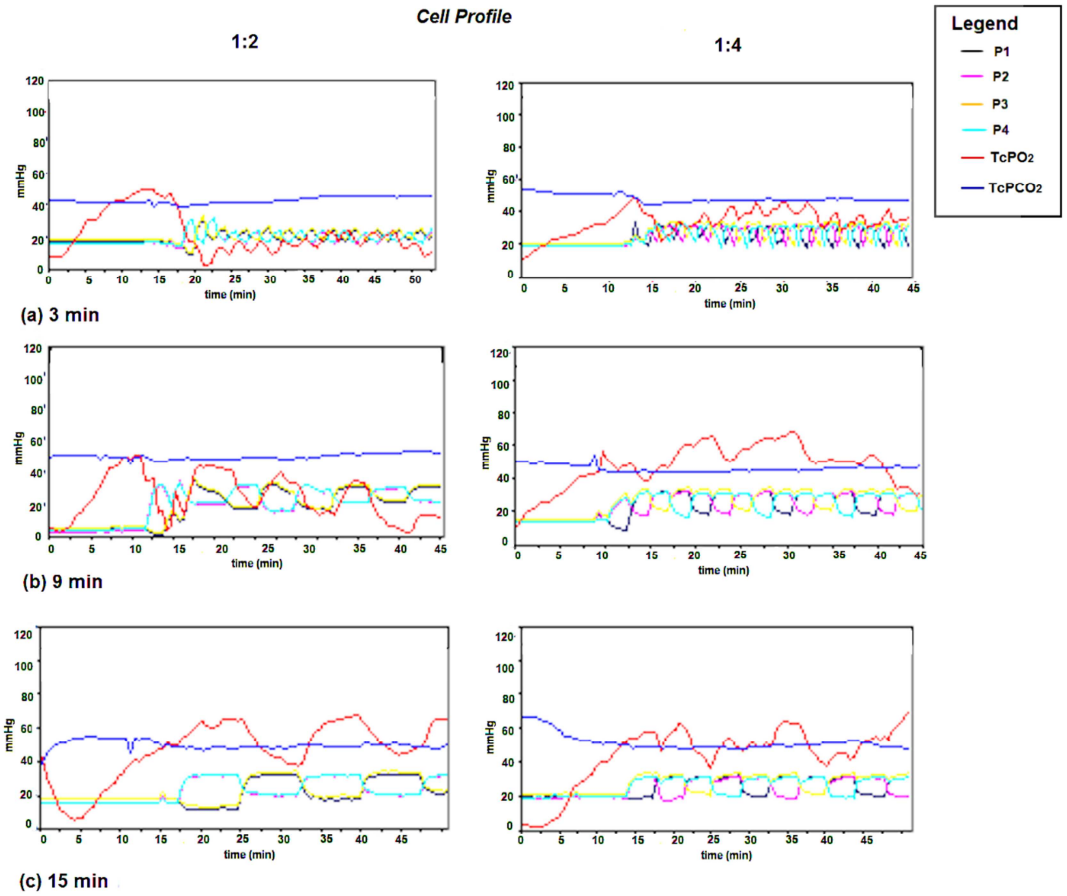


Figure 5: A complete data set for one participant (male, BMI= 25.1 kgm^{-2}) incorporating six combinations of cell profile and cycle period with a pressure amplitude of 30/20 mmHg. P1-P4 represents the individual internal pressure values in a set of four cells.

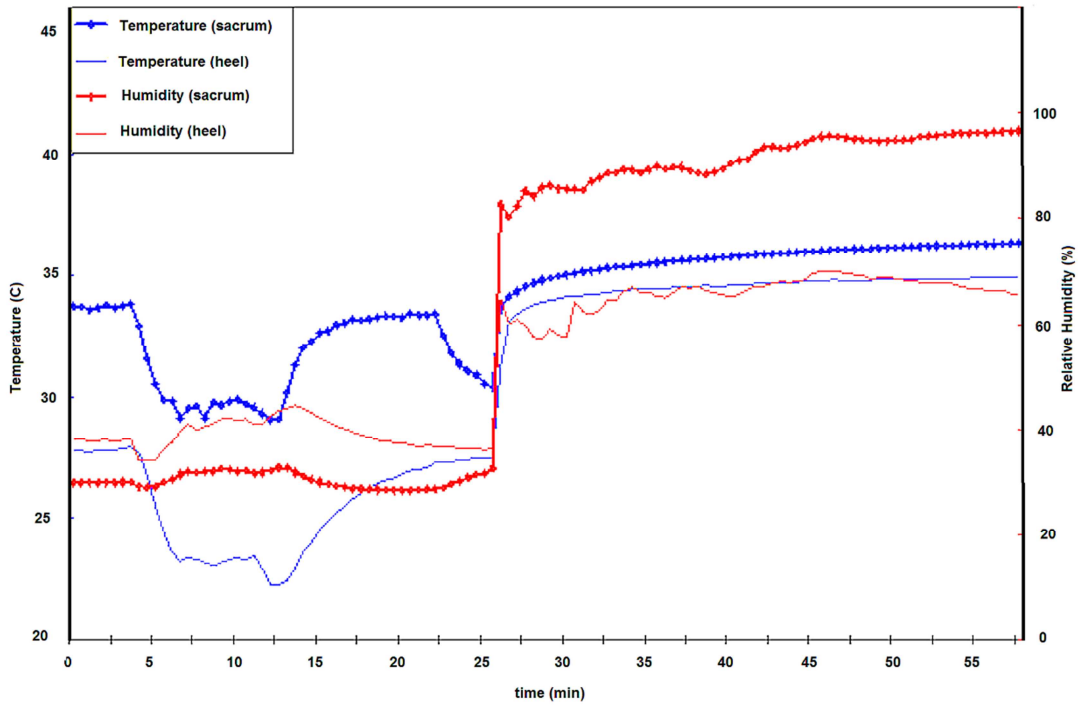


Figure 6: An example of the performance of the temperature and humidity changes on a single subject (male, BMI 25.1 kgm^{-2}) supported on the APAM support surface controlled at a pressure amplitude of 60/40 mmHg, a cell profile of 1:4, and a cycle time of 9 min.

Conflicts of interest statement:

The authors declare that the submitted article is absent of any commercial or financial relationships that could pose as a potential conflict of interest.

Role of funding source

The funding source had no involvement in the study design, in the collection, analysis and interpretation of data, in the writing of the report, or in the decision to submit the paper for publication.