

# MEDITEC PRO 2000 & MEDIAIR

## Evaluation of Alternating Pressure Relief Mattress Systems

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## 1 Introduction

Alternating Pressure Air Mattresses (APAMs) are designed to prevent or treat pressure ulcers by a different principle from conventional support surfaces. Conventional “pressure reducing” support surfaces seek to achieve lower values of maximal interface pressures on the skin, by means of even distribution of pressure over the supported area. The aim is thus to bring interface pressures down to a continuously tolerable level. In contrast to this approach, APAMs are designed to provide cyclic loading to the skin, so that each area of skin experiences pressure only intermittently. Correct functioning of the APAM therefore relies on pressures **not** being evenly distributed. Pressure differentials between adjacent regions must be created to provide cyclic loading. For this reason, evaluation of APAMs cannot adopt the approach (commonly used for conventional support surfaces) of simply measuring maximum values of interface pressure at a given moment, but must characterise the time-varying behaviour.

Performance measures have been proposed<sup>1, 2</sup> in the scientific literature for quantifying the “pressure relief” behaviour of APAM systems. These measures are based on the proportion of the cycle time during which the skin interface pressure at a given location is maintained below a threshold value. The threshold value is arbitrary, and has variously been set at 10mmHg, 20mmHg, and 30mmHg.

It has also been shown<sup>2</sup> that the pressure profile can be improved by adjusting the air pressure according to the body mass of the bed occupant.

More recently, concerns have arisen over the use of APAM systems when the backrest of the bed is elevated, or in the “gatch” position, where the backrest is elevated and the thigh section is also raised to resist sliding towards the foot of the bed. As mentioned previously, APAMS rely for their effective operation on the maintenance of pressure differentials between adjacent areas of skin. If pressure differentials are not maintained, alternating behaviour is lost, and the skin does not experience an off-loaded part of the cycle where reperfusion may take place. In the backrest-elevated or gatched positions, air cells are often squeezed together, potentially causing equalisation of pressure between cells. Questions have been raised as to which geometries and arrangements of cells will be most susceptible to this problem.

It is thought that deep-cell systems will be more susceptible to this problem than shallower cell systems such as alternating overlays.

## **2 Aims**

The aims of this study are as follows:

- 1) To examine the performance of the Meditec Pro 2000 and of the Meditec Pneu-Air, set up according to the prescribed settings. 10 subjects of different body weights will be used. Evaluation will be based on a pressure- and time-based performance index to be defined in the “methods” section. The Meditec products will be compared with the Huntleigh Nimbus 3, which is a full mattress replacement APAM and has been shown by randomised controlled trials to be clinically effective in reducing pressure ulcer incidence.
  
- 2) To examine changes in the alternating behaviour in the profiled position, using subjects of different body weights, to determine if correct function is maintained in this position.

### 3 **Methods**

#### **APAM Performance Index (API)**

Understanding of the aetiology of pressure ulcers is as yet at a very simplistic stage. Gross assumptions have therefore been made in deriving a performance index, and it must be noted that performance measured in this way can not necessarily be extrapolated to clinical outcome. However, randomised controlled trials to examine clinical outcome are almost prohibitively large undertakings for this category of product, and therefore simple efficacy measures are appropriate as long as the limitations of the study are understood.

The assumptions made in using this performance index are as follows:

- 1) It is unimportant how high the interface pressure is on an area of tissue during the loaded part of the cycle. We assume for these purposes that occlusion to blood is total while loaded, and that higher loading will not produce greater occlusion.
- 2) During the “unloaded” part of the cycle, longer duration at lower pressure is better.
- 3) No attempt is made to accommodate second-order effects such as reperfusion injury in the index.
- 4) The performance of the system as a whole is determined by that region on the pressure map showing the worst performance throughout the cycle

Considering a hypothetical loading cycle on a single body location as shown in figure 1: Interface pressure hypothetically measured in mmHg is plotted against time in minutes, giving an idealised sinusoidal waveform. We can see from this graph the cycle time of the pressure profile, as illustrated. 3 threshold levels, 10mmHg, 20mmHg, and 30mmHg are shown on the graph, and we can see the regions of the loading cycle where the pressure falls below these thresholds.

One option for creating an index of performance is to cite the time duration during which the pressure is measured to be lower than a particular threshold, eg 30mmHg. However, this approach fails to identify benefits of dropping far below the threshold value, as opposed to dropping just below the threshold value. For example, the profile shown in figure 2, having a similar duration below the threshold, would be seen to perform as well as that in figure 1, which falls well below the threshold for much of that duration.

One means of addressing this shortcoming is to cite durations at several different thresholds, and summing them or weighting them to give a compound value. Thus, values would be cited for time below 30mmHg, time below 20mmHg, and time below 10mmHg.

Alternatively, a compound value may be calculated by taking the area of the loading cycle beneath the threshold value, shown as the shaded area A30 in the figures. This area takes into account both the duration (width of the shape) and the degree of pressure reduction below the threshold (height of the shape). These are (expressed in mmHg x minutes) may then be divided by the cycle time, to give a value of pressure relief below threshold expressed in mmHg.

So we define API :

$$\text{API (mmHg)} = \frac{\int_{P=30}^{P=30} (\text{pressure} - 30) dt}{T_c}$$

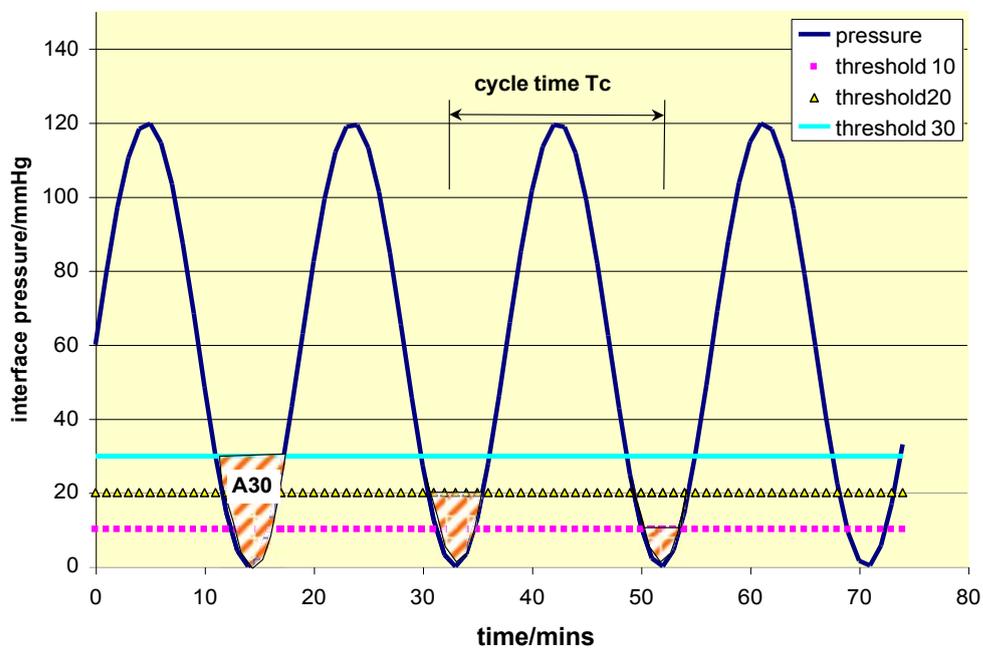


Figure 1: Hypothetical loading cycle at a single body location

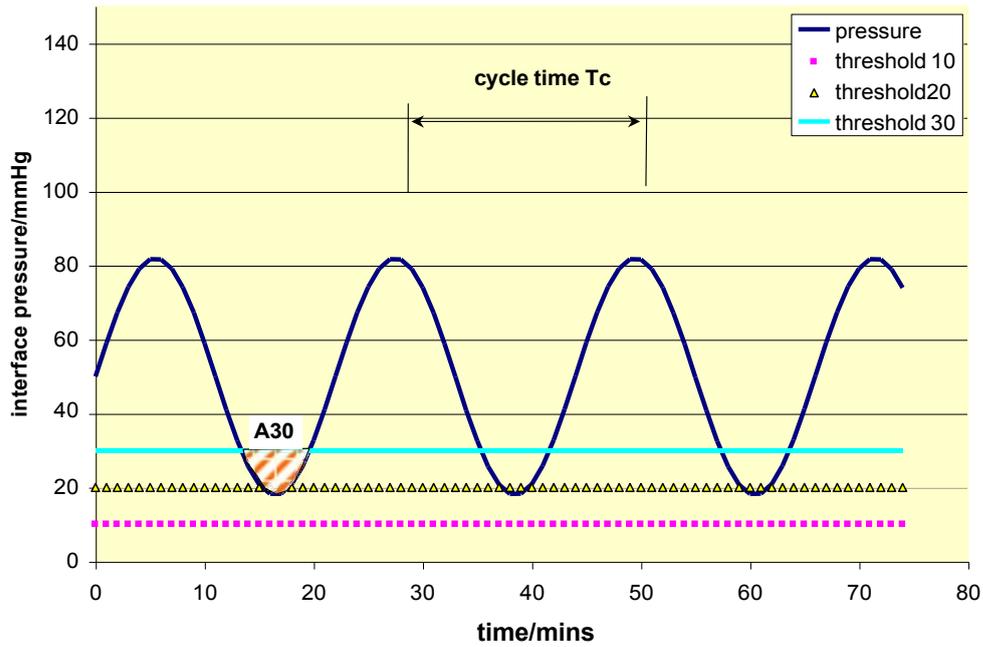


Figure 2: Alternative hypothetical loading cycle at same body location

### Instrumentation

An Xsensor pressure mapping array was used for this study, on the basis that it is relatively flexible compared to most pressure mapping systems. One concern with pressure mappers is that the presence of the mat in the system will introduce mechanical artefacts to the system being measured, and these concerns are mitigated somewhat by the flexibility of the mat.

## Subjects

10 healthy experimental subjects were chosen, each giving informed consent.

**Table 1: Subject group anthropometrics:**

<b>ID code</b>	<b>Age</b>	<b>Height</b>	<b>Weight</b>
<b>ID01</b>	39	1.80m	74 kg
<b>ID02</b>	63	1.58m	95kg
<b>ID03</b>	60	1.66m	52kg
<b>ID04</b>	60	1.65 m	49 kg
<b>ID05</b>	22	1.62m	103 kg
<b>ID06</b>	33	1.65	55 kg
<b>ID07</b>	26	1.67m	63 kg
<b>ID08</b>	28	1.64m	45 kg
<b>ID09</b>	18	1.75m	75 kg
<b>ID10</b>	41	1.82m	79 kg

### **Procedure: Comparison with Nimbus 3 when flat**

- 1) Each APAM was set up on the bed as with a flat sheet, and nominally inflated
- 2) The Xsensor (calibrated daily) was placed on the mattress
- 3) A TRS sensor was taped to the subjects skin on the sacrum.
- 4) A baseline reading of skin blood content (IHB) was taken.
- 5) A total skin blanch was effected to obtain a “biological” zero for the IHB measurement.
- 6) The subject lay supine on the mattress with the Xsensor array aligned with the pelvic area, showing the lower back to the upper thigh.
- 7) Pressure was set as instructed by the manufacturer according to body weight.
- 8) After 5 equilibration cycles, pressure was mapped over 3 pressure cycles.
- 9) Simultaneously, skin blood content was monitored, and scaled to the baseline level.
- 10) Average API was calculated over the 3 cycles, for every point on the map.
- 11) The point with the lowest value of API (averaged over 3 cycles) was recorded.
- 12) This was repeated 3 times to give a median and range value for each subject.
- 13) This was repeated for all 10 subjects

### **Procedure: examination of alternating function with elevated backrest**

- 1) Using the inflation pressures as specified, each subject was pressure mapped with the bed profiled so that the backrest was at 45 degrees, and the thigh section at approximately 15 degrees.
- 2) API was calculated in the new configuration.
- 3) Variation in skin blood content was also monitored in this position.

#### 4 Results: dynamic pressure distribution

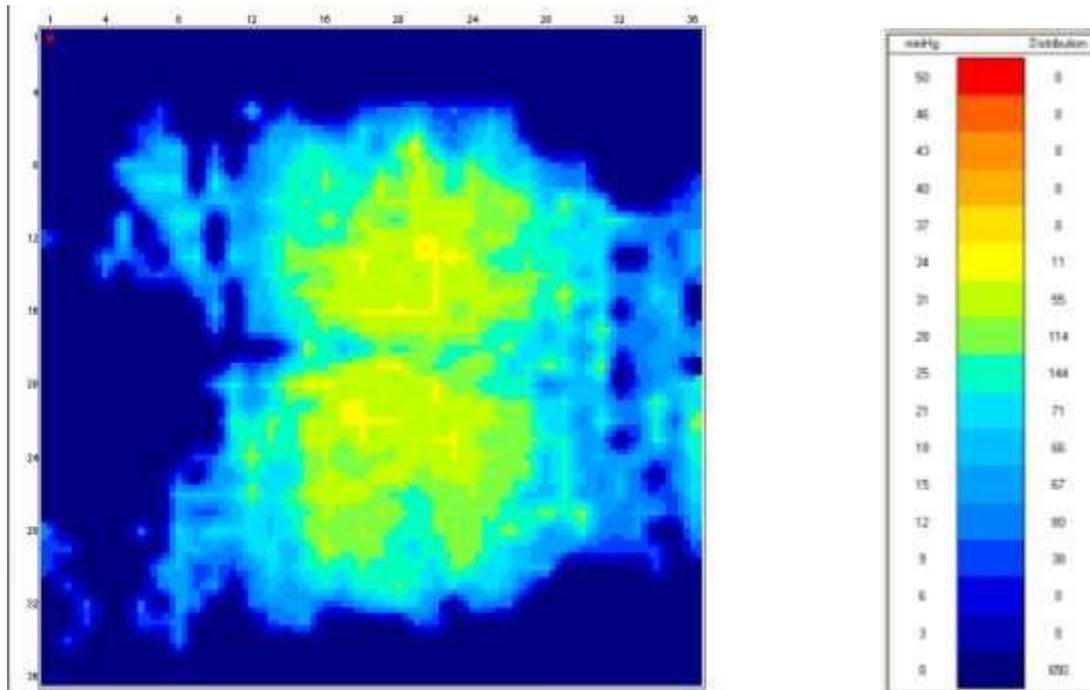


Figure 3A Pro 2000

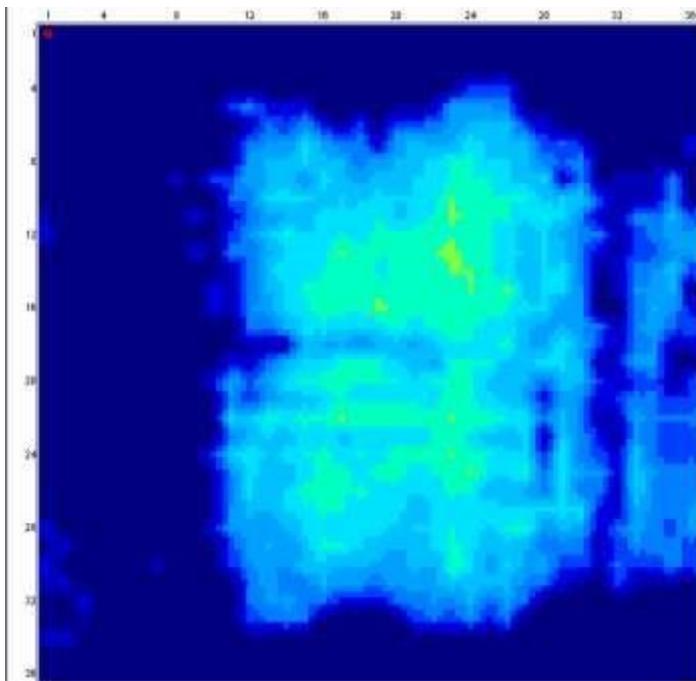


Figure 3B Pneu-care Pro 2000

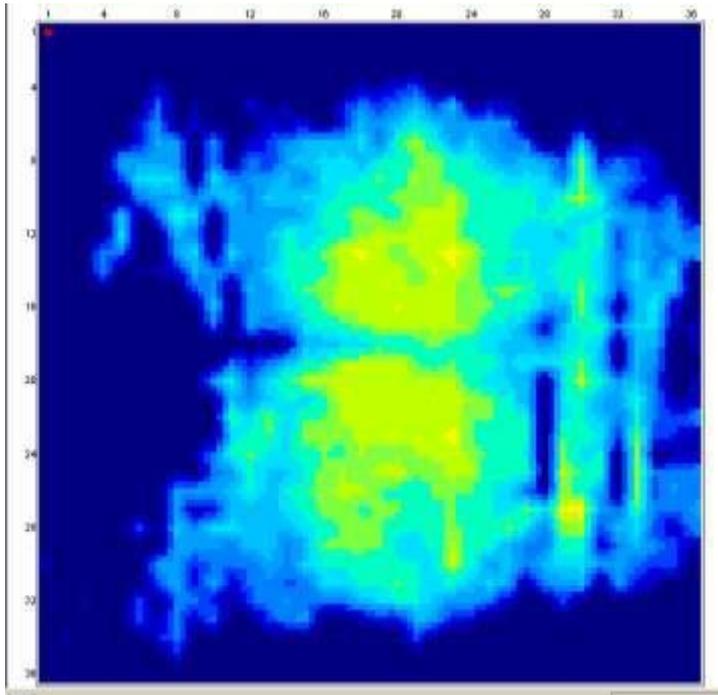


Figure 3C Pro 2000

**Figure 3 A-C: Example snapshots during cycle, Subject 1 . Pro 2000**

Figure 3 shows 7 snapshots of the pressure distribution at various times throughout the cycle, with the bed in the flat position, for a single subject on the Pro 2000 system. It can be seen that the loci of highest pressures move throughout the cycle. This was typical of all subjects. Pressure on the loaded areas are smoothly distributed, giving no pronounced peak pressures over bony prominences.

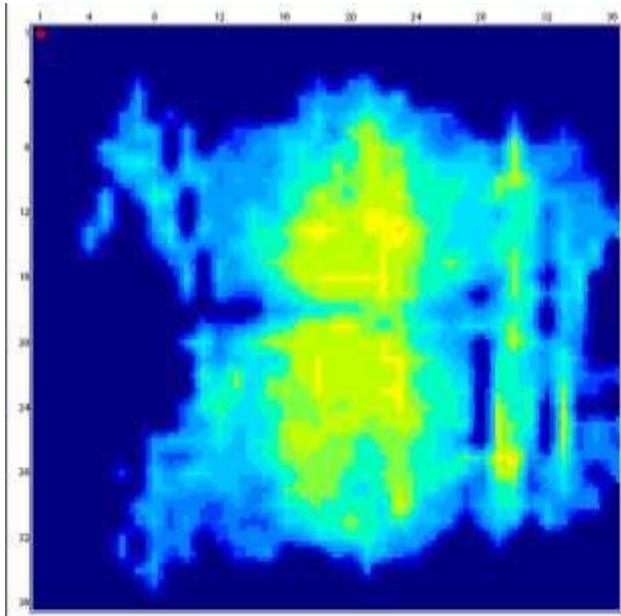


Figure 4A Pneu-air

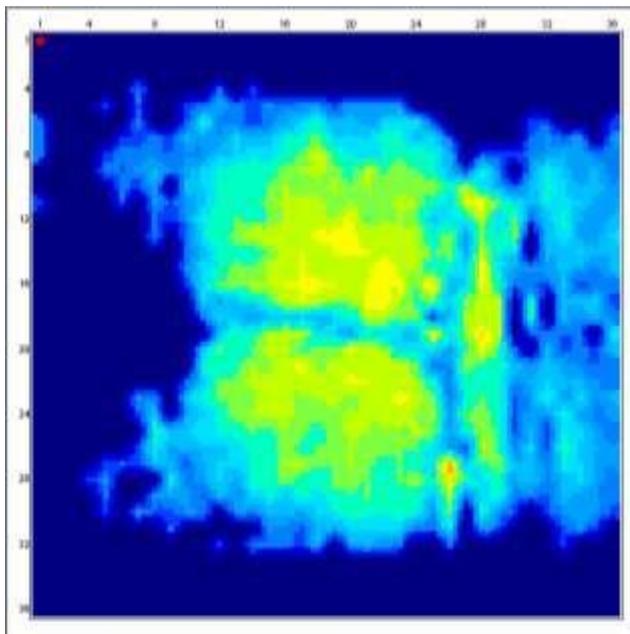


Figure 4B Pneu-air

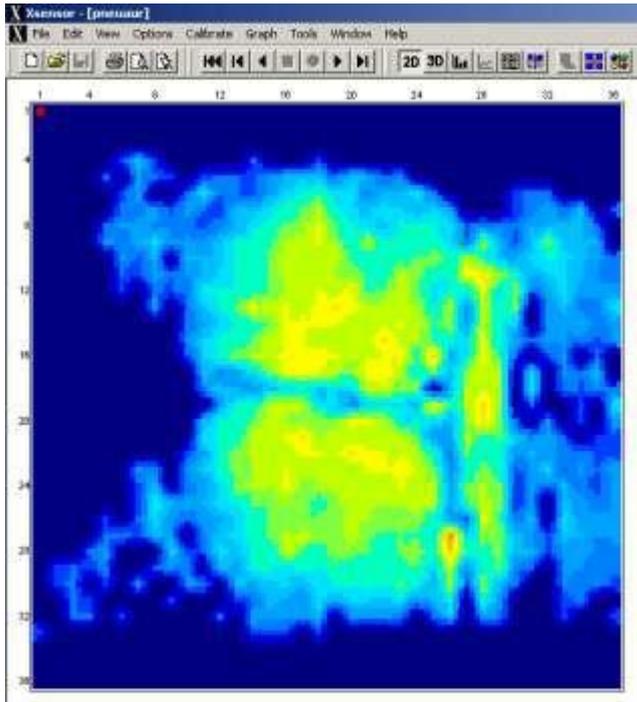


Figure 4C Pneu-air

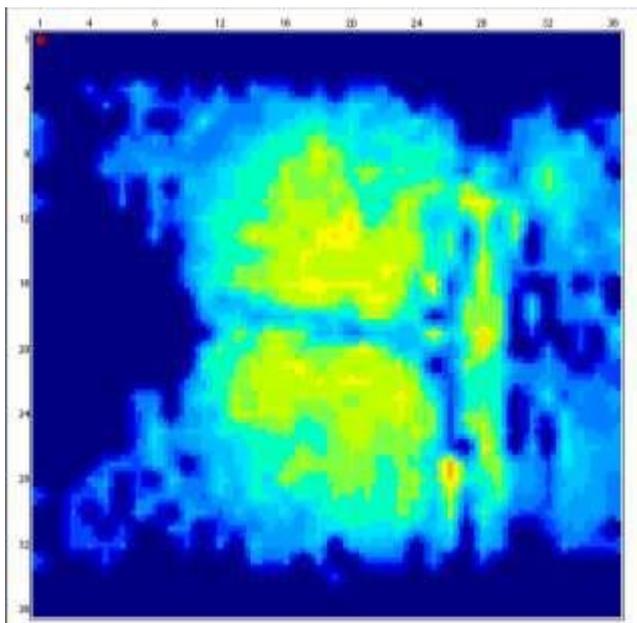


Figure 4D Pneu-air

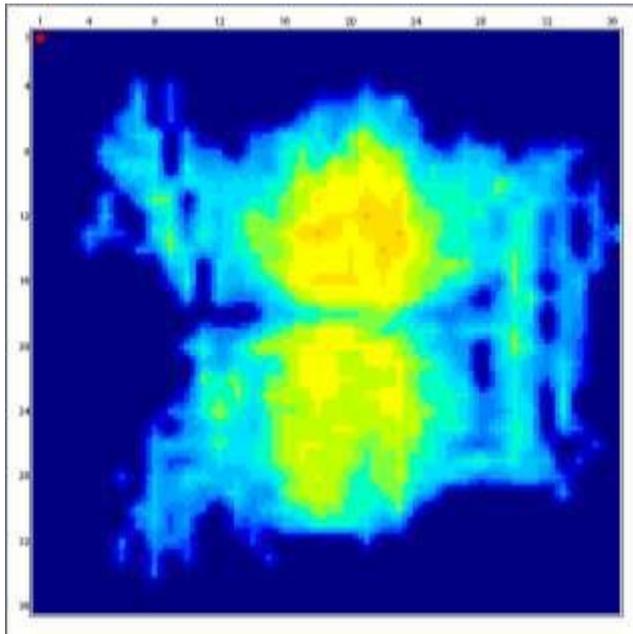
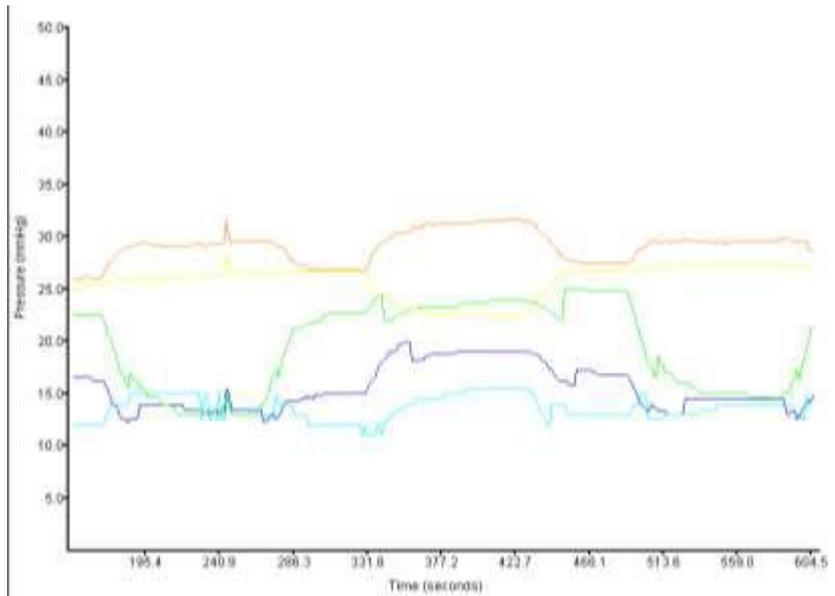


Figure 4E Pneu-air

**Figure 4 A-E: Example snapshots during cycle, Subject 1 . Pneu-air.**

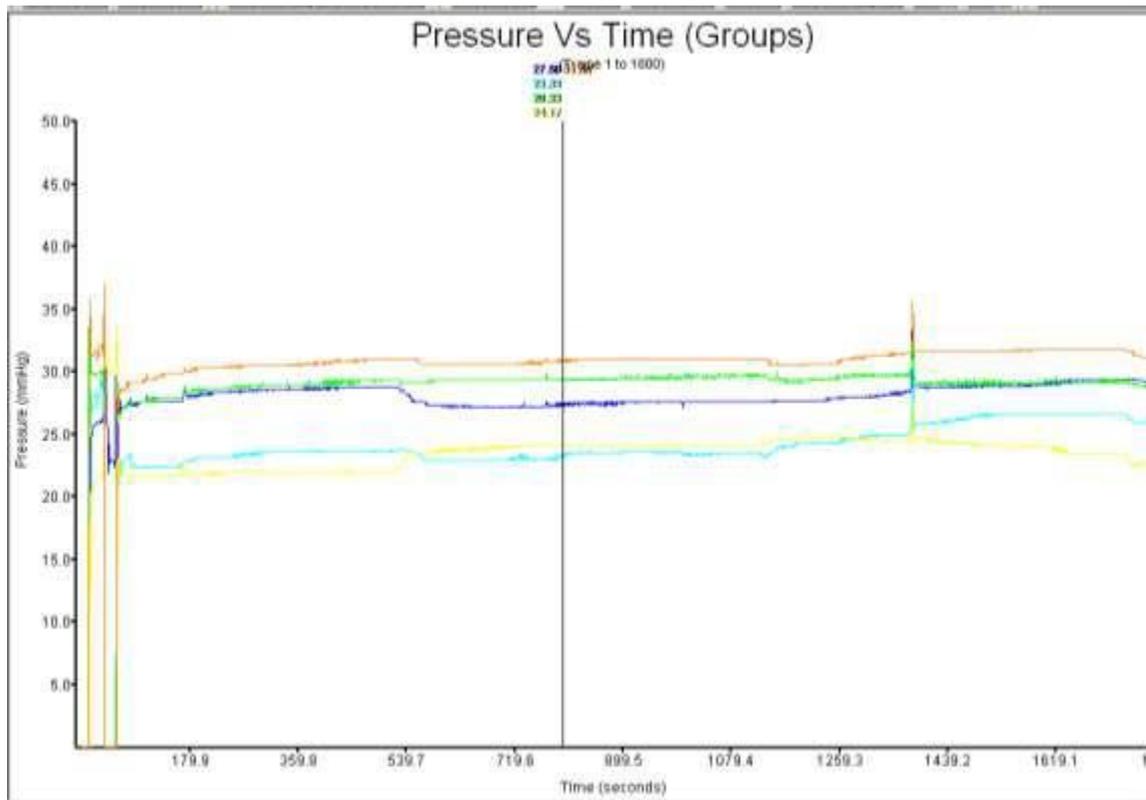
Figure 4 shows 7 snapshots at various stages throughout the cycle for the Pneu-air system. Although the distribution clearly changes, it is apparent (in this example) that the changes are less pronounced than on the Pro 2000. Smooth distribution of pressure over the loaded areas is also observed here, with peak pressures generally not exceeding 40mmHg.

A trace of a similar nature to those shown in figures 1 & 2 can be drawn for a single sensor cell, and the API for that cell calculated. Similarly, API can be calculated for any cell on the map.



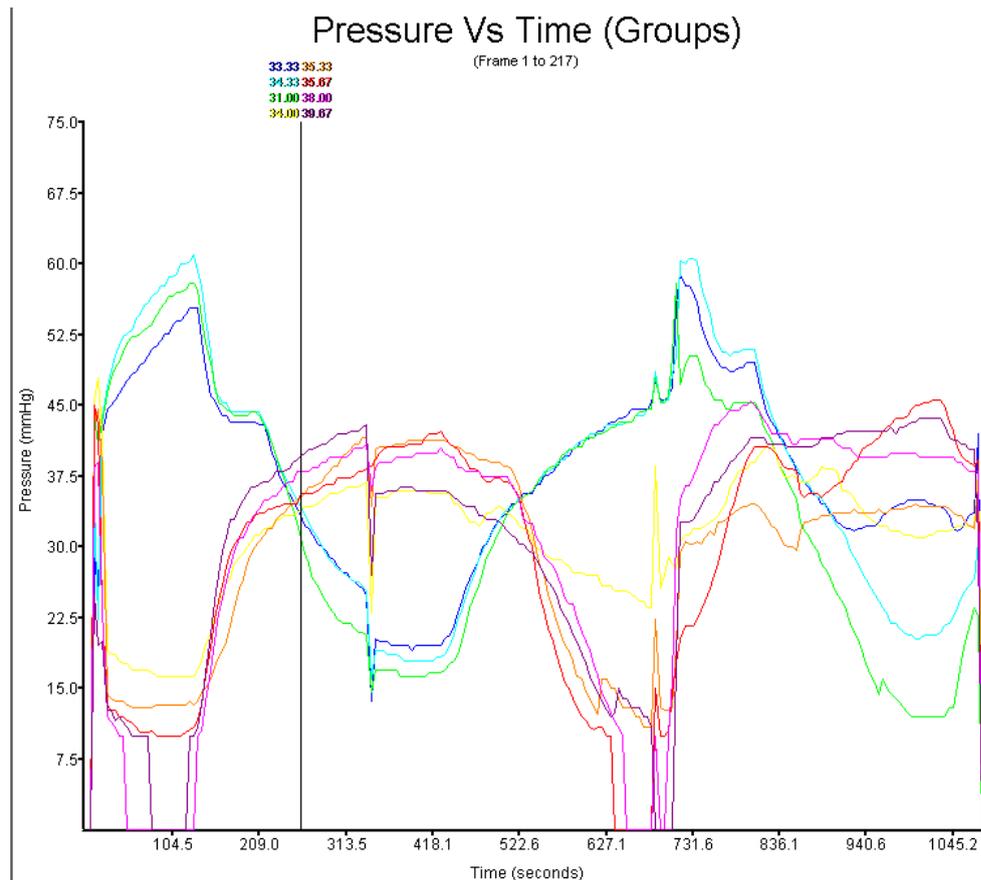
**Figure 5 Pressure profile at sample points, Subject 1, Meditec Pneu-Care Pro 2000**

An example pressure vs time trace taken at various points on the map for the Pro 2000 is shown in figure 5. Each different coloured line represents a different point on the surface of the mattress. For each different coloured line, API can be calculated as the integral of pressure.time below 30mmHg. Note that the orange traces will give a lower ( less effective) value of API than the other traces. In this evaluation, the value for the orange trace (least effective) would give the API recorded for this case.



**Figure 6 Pressure profile at sample points, Subject 1, Meditec Pneu-air**

Figure 6 shows the pressure /time trace for various points on the same subject, for the Pneu-air product. In this case, although the product shows impressively low peak pressures, dynamicl variation in pressure has a small amplitude in many places on the skin, with the lowest value of API being observed for the orange trace.



**Figure 7: Pressure profile at sample points, Subject 1, Nimbus 3.**

Referring to figure 7, it can be seen that the Nimbus 3 gives a relatively smooth pressure profile, with sensor cells falling into 2 easily recognisable groups on opposite cycles. In the case of this subject, although total pressure relief was observed by some of the cells in one part of the cycle (red and pink traces), those cells that were inflated in that part of the cycle do not fully deflate in the opposite part of the cycle (blue and green traces). This means that, for at least some body regions, “total pressure relief” does not occur. The effectiveness of this product clinically has been demonstrated quite convincingly clinically, backed up by much data.. This suggests that “total relief” is not a prerequisite for effectiveness.

Figure 8A gives an example of the incompletely deflated cells between inflated cells in mid-cycle.

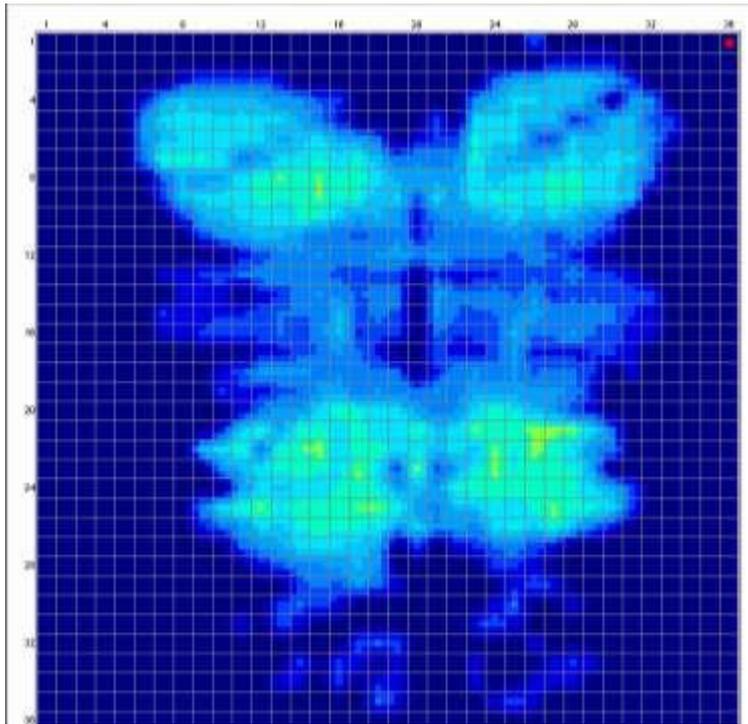


Figure 8A: Nimbus 3, Subject 1 , mid cycle

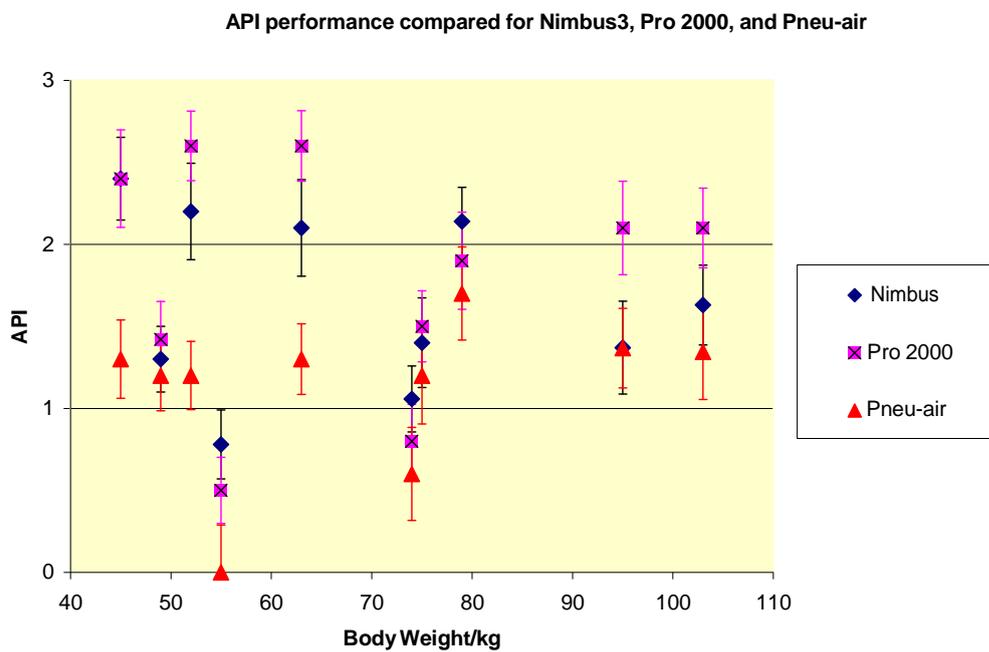


Figure 9: API performances compared for 3 subjects

Figure 9 shows the performance of the Nimbus 3 compared to that of the Pro 2000 and the Pneu-air products, for all subjects. In this graph, for each subject the API value given for the Nimbus 3 appears in blue, showing the median value with

whiskers to indicate range. Pro 2000 is shown in pink, and the Pneu-air in red, again with median and range marked.

Both the Nimbus 3 and the Pro 2000 performed significantly better than the Pneu-air overall ( $p < 0.05$ ).

It can be seen that for several subjects the Pro 2000 performed better than the Nimbus, with no intra-subject overlap. Paired Wilcoxon signed rank test shows a significantly higher API value overall for the Pro 2000 ( $p < 0.05$ ).

**5 Results: examination of alternating function with elevated backrest**

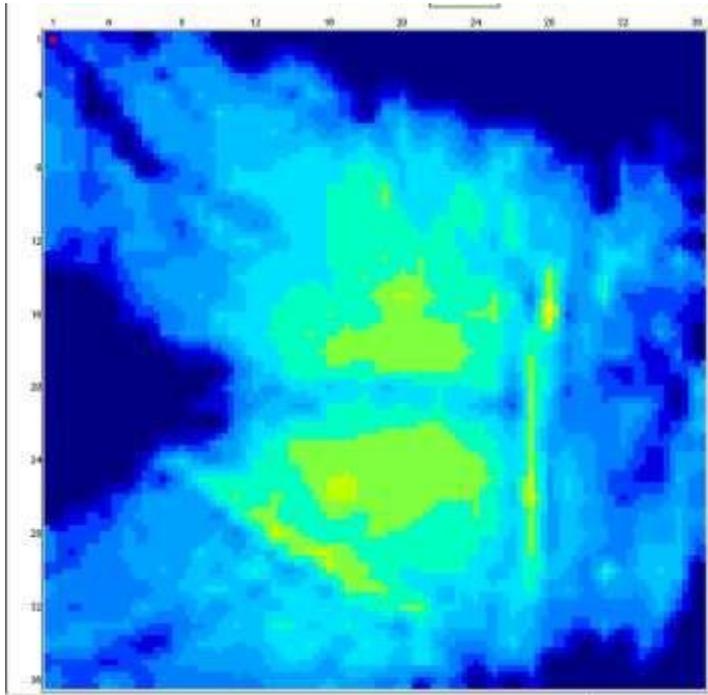


Figure 10: Pro 2000 subject1 elevated backrest and gatch, mid-cycle

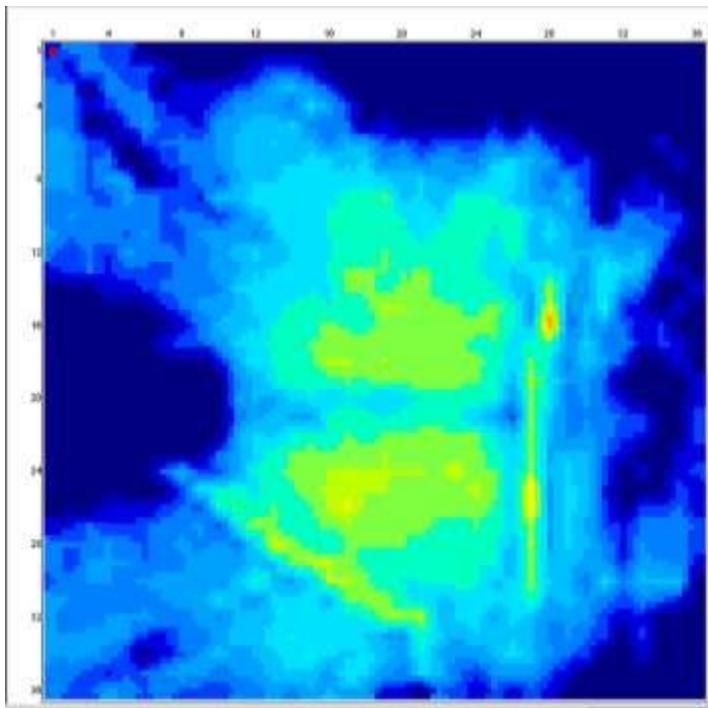


Figure 11: Pro 2000 subject1 elevated backrest and gatch, opposite cycle

On both APAM systems, the API value was zero for all three subjects in the profiled position. Example pressure maps showing different stages of the inflation cycle are shown.

Referring to figures 10 and 11, it can be seen that the pressurised regions are brought much closer together, and cause some encroachment of the deflated areas. This encroachment was sufficient to give zero API values in all cases at the predicted pressure setting. Movement can be seen in the margins of the pressure distribution defining the overall imprint of the body, but the more heavily loaded areas under the pelvis remain more static.

However, it can be seen that although alternating behaviour is greatly impaired by the squeezing together of sacks, some pressure differential is maintained between inflated and deflated regions, so some alternating behaviour is maintained. It may be that the 30mmHg threshold is unreasonable for the sitting position, since more of the body weight is being applied to the pelvis.

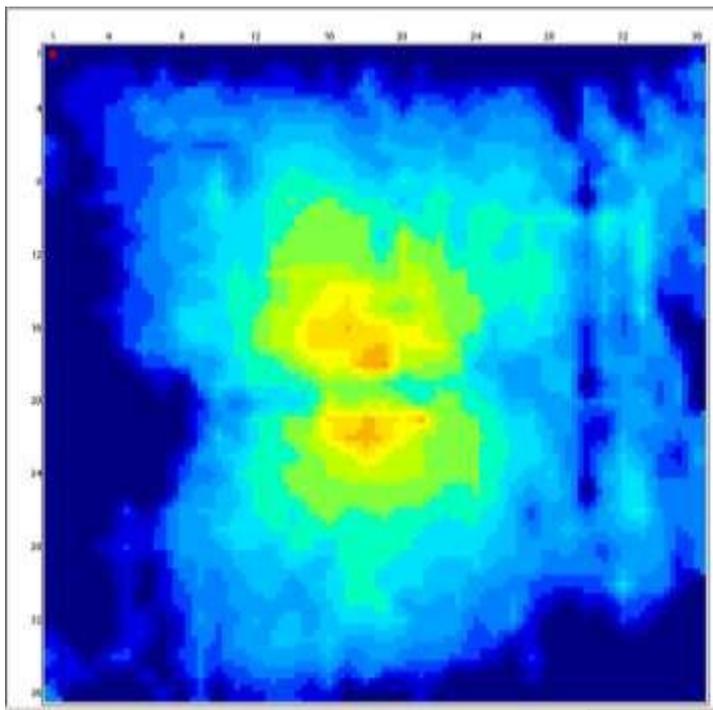


Figure 12: Pneu-air subject1 elevated backrest and gatch, mid-cycle

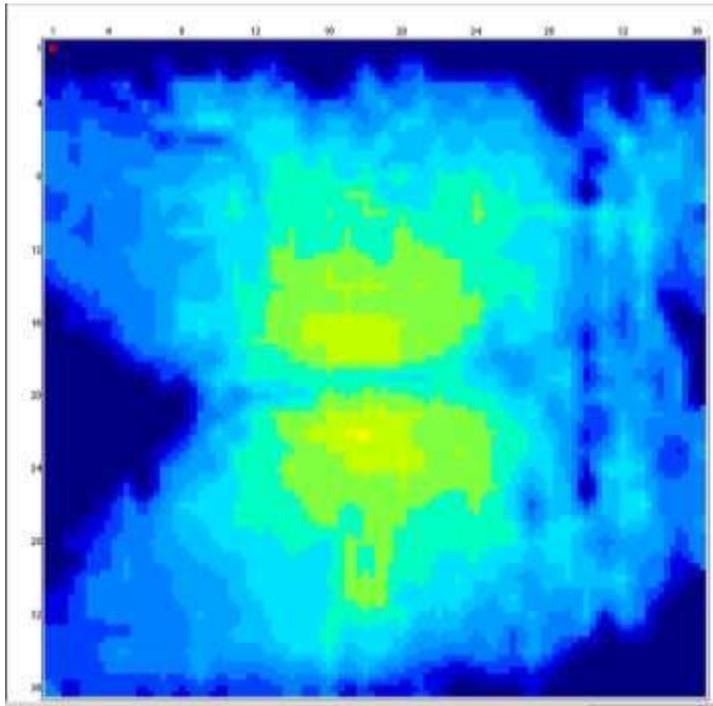


Figure 13: Pneu-aire subject1 elevated backrest and gatch, opposite cycle

Referring to figures 12 and 13, much the same phenomenon can be seen. Movement is observed around the margins defining the shape of imprint, but less movement is observed in the loaded areas, although fluctuations in amplitude (rather than location) of peak pressures is observed.

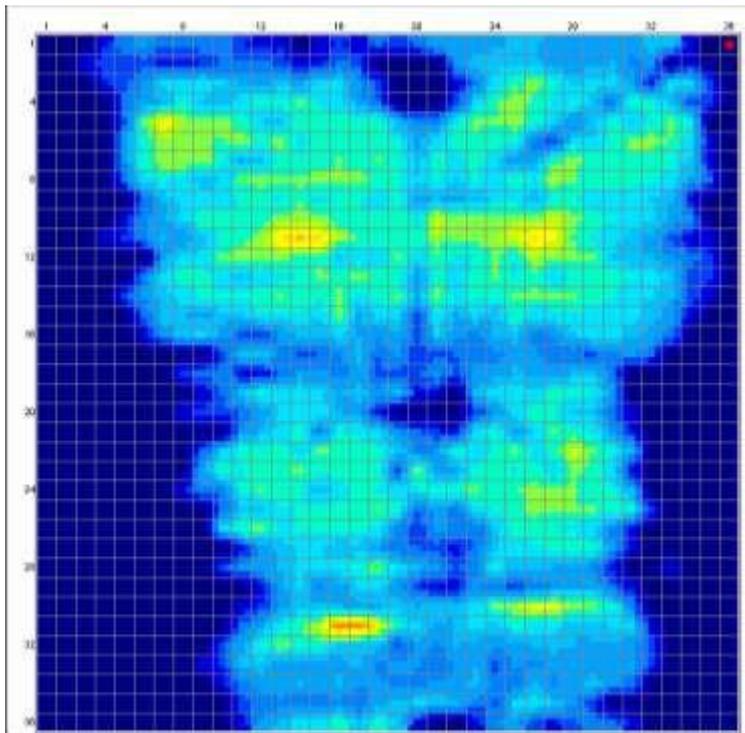


Figure 14: Nimbus 3, subject 1, elevated backrest and gatch, mid cycle

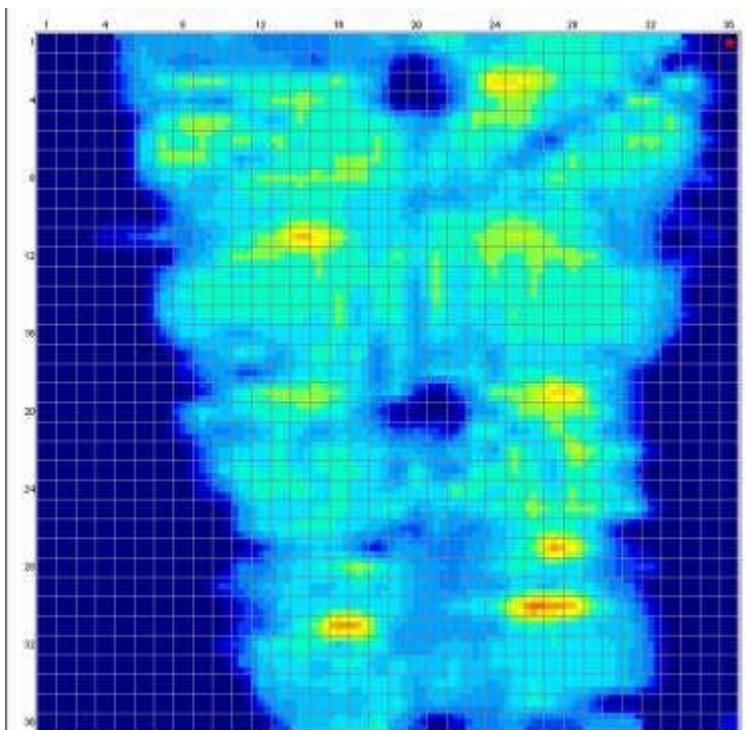


Figure 15: Nimbus 3, subject 1, elevated backrest and gatch, opposite cycle

Referring to figures 14 and 15, it is apparent that the Nimbus 3 also suffers from dramatically reduced intervals between cells in the profiled position. For much of the cycle, pressure differentials are not maintained between adjacent cells, and API was zero in every case. Once again, this may partly reflect the increased loading on the pelvis in this position.

## Conclusions

Performance of the Meditec Pro 2000, when flat, was comparable in these studies to the Nimbus 3 over a broad range of body weights. The Pro 2000 performed significantly better than the Nimbus in a performance index representing dynamic pressure redistribution, or in a performance index representing skin blood perfusion.

Both the Pro 2000 and the Nimbus 3 performed significantly better than the Pneu-air according to both performance indices.

In the profiled position, all 3 systems exhibited some degree of impaired performance, showing some failure to maintain pressure differentials between adjacent cells in the pelvic area. Encroachment of cells into adjacent spaces was visible in both cases. A solution to this problem, which may be present in all current APAM systems, would be of great value.

It must be stressed that this report has certain limitations. The study consisted purely of laboratory evaluations, and no clinical outcomes data is presented.

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## REFERENCES

<sup>1</sup> Rithalia SV, Heath GH, Gonsalkorale M. Assessment of alternating-pressure air mattresses using a time-based pressure threshold technique and continuous measurements of transcutaneous gases J Tissue Viability. 2000 Jan;10(1):13-20.

<sup>2</sup> Rithalia SV, Evaluation of alternating pressure air mattresses: one laboratory-based strategy J Tissue Viability. 2004 Apr;14(2):51-8.