Citadel Patient Care System

A New Era of Performance

GETINGE GROUP

Figure 1

The Citadel™ Patient Care System (Figure 1) provides the user with a choice of pressure redistributing support surfaces integrated with the *Citadel* Bed Frame System.

The *Citadel* Patient Therapy System C100 is a 'reactive' support surface that optimises pressure redistribution using pre defined patient height/weight pre-sets which can be further customised across four anatomical pressure zones. The head and seat sections can be independently deflated and a full-length 'firm' mode can also be used to assist nursing interventions.

The *Citadel* Patient Therapy System C200 has similar features to the C100 support surface, but also offers the option of multiple 'active' therapeutic modes: 1 in 2 alternation and 3 levels of pulsation, and also includes a manual and automatic 'patient turn' mode to assist with repositioning.

Key Points

- Exposure to prolonged or extreme pressure results in pressure injury; tissue damage can be rapid
- Physical immobility, or factors that affect a patients ability to sense or respond to a stimulus to move, are recognised as critical risk factors
- Timely pressure redistribution through regular repositioning is key to pressure ulcer prevention and management
- Therapeutic support surfaces with effective pressure redistribution can complement repositioning regimens
- The *Citadel* C100 support surface delivers a constant low pressure environment that is equal to, or better than, comparator support surfaces

The *Citadel* C200 support surface delivers exceptionally low tissue/surface interface pressures during active therapy (lower for longer), while providing a semi-immersive environment over the heel: **performance that captures the therapeutic benefit of an Active and Reactive environment.**

Introduction:

Clinical context

The international pressure injury prevention guideline, published in 2014, represents a global consensus of, amongst others, clinicians, scientists, engineers and professions allied to medicine. This expert group concluded, without question, that immobility, resulting in exposure to prolonged pressure is the primary pathology behind tissue damage[1].

Time is also important in the evolution of a pressure injury. Tissues are generally able to tolerate lower pressures for longer periods whilst being naturally tolerant of higher pressures providing they are regularly relieved; for example, through spontaneous movement, routine repositioning or periodic off-loading. Where pressure deformation is sufficient to occlude the microcirculation, critical tissue hypoxia may result in irreversible changes and necrosis can occur within less than 2-hours[2 3]. With excessive tissue deformation and disruption to the cytoskeleton, damage can occur within minutes[1].

As a binary model (Figure 2), it is clear that the ability of tissue to withstand pressure (tissue tolerance) is also highly significant, although this varies between individuals, anatomical locations and even within individual patients over time[4 5]. Tissue tolerance is dependent upon the mechanical properties of the tissue layers and the impact of associated intrinsic and extrinsic risk factors. These factors are often complex to address and cannot always be mitigated quickly or completely; as a result, interventions that reduce exposure to pressure should be considered a clinical priority[6 7].

Pathology of Pressure Injury

Adapted from NPUAP 2014[1]

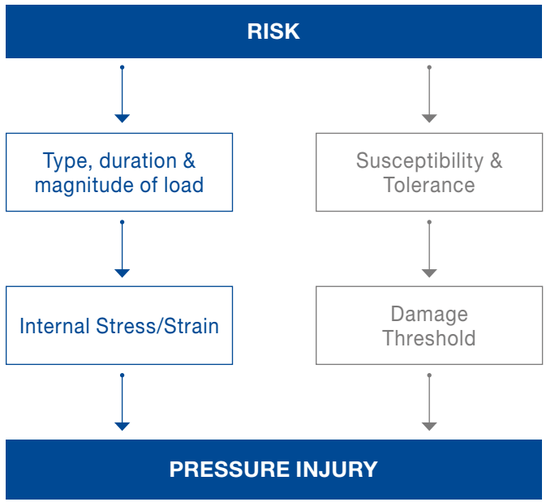


Figure 2

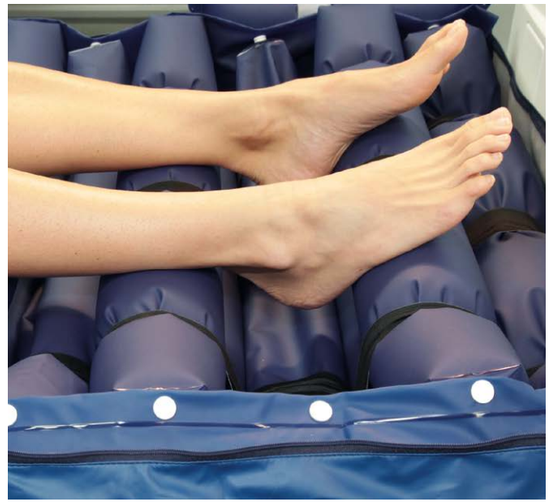
Managing the duration and magnitude of pressure

Normal spontaneous movement is the natural protective mechanism to relieve pressure; individuals subconsciously change their position several times each hour.
The physiological stimuli to move are triggered by periods of [relatively] high pressure, experienced as an individual stands, sits and/or lies in a relatively fixed position.

The effectiveness of this natural protective mechanism relies upon them having intact sensory, motor and cognitive functions. Some or all of these processes can be compromised during periods of ill-health, during medical treatment or following trauma.

When patients do not sense the stimulus to move or cannot physically move, routine and regular repositioning, though no doubt effective in most cases, can also be labour intensive and increases the risk of injury to caregivers[8]. Such interventions also interrupt rest and sleep patterns and may cause discomfort or distress[9].

To match clinical need with comfort, repositioning is often complemented, but not replaced by, the prescription for the use of a pressure-redistributing support surface designed to reduce the magnitude and/or duration of pressure applied; this allows repositioning intervals to be individualised according to their need. For the most vulnerable areas, such as the heels, the use of additional off-loading devices may enable complete pressure off-loading or ‘floatation’.



Therapeutic Support Surface characteristics

Therapeutic Support surfaces are defined by their primary mode of action (how they redistribute pressure) and by the addition of supplemental functionality to manage the microclimate, rotation and/or shear.

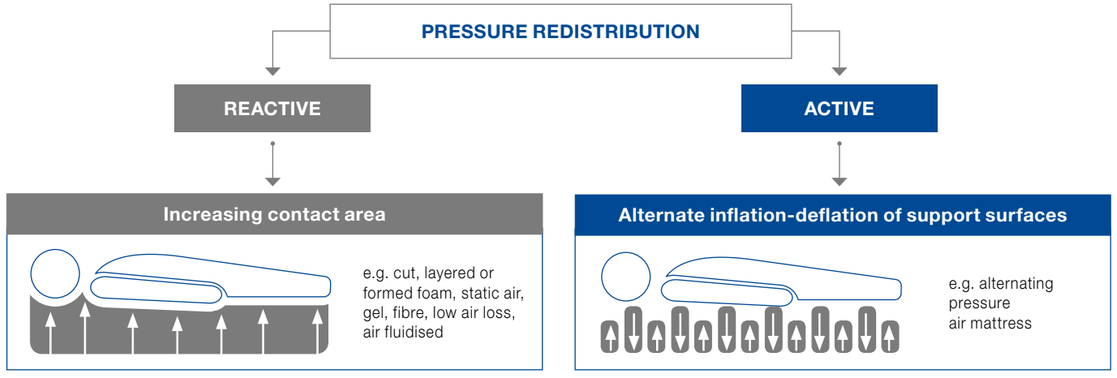


Figure 3

REACTIVE SUPPORT SURFACES:

e.g. foam, gel, low air loss, air fluidized

Reactive[1] Support Surfaces are typically constructed of air, foam, gel or a combination of one or more of these components; they may be powered or unpowered.

Pressure is redistributed across the surface of the body as it lowers into the supporting medium.

Reactive surfaces frequently incorporate additional features such as low-air-loss; this is clinically indicated in patients who might benefit from the active management of heat and moisture (microclimate) at the skin-mattress interface[1].

Key performance indicators are related to the degree of ‘immersion’ and ‘envelopment’.

ACTIVE SUPPORT SURFACES:

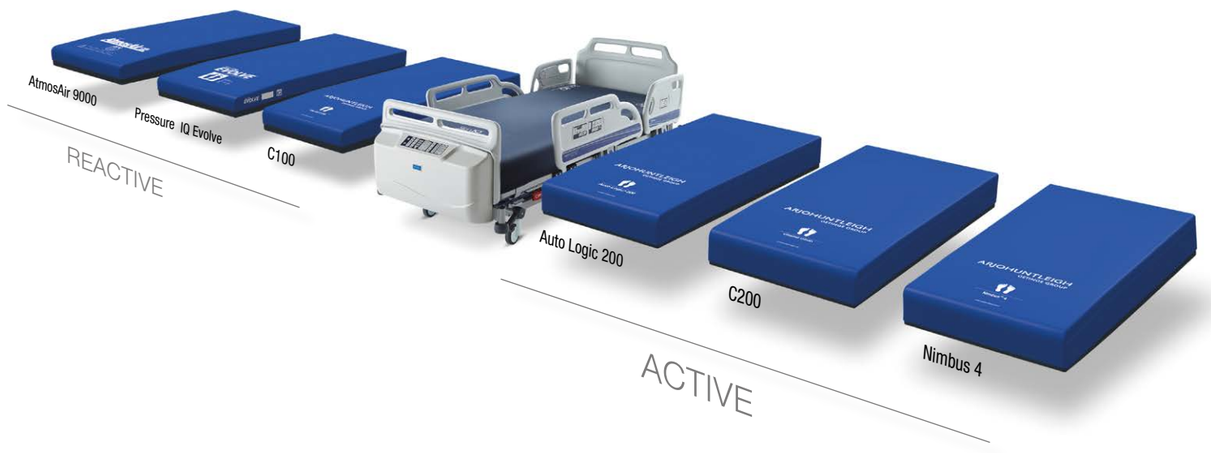
Also known as alternating pressure

An active[1] support surface redistributes pressure, most commonly, by the alternate inflation and deflation of air cells.

The principal design goal is to mimic the protective effect of spontaneous physiologic or assisted repositioning, by periodically reducing tissue contact with the support surface to a level that is **as low as is practically achievable and for as long as possible.** This is often the modality of choice for patients who cannot be regularly repositioned manually.[1]

Key performance indicators are; cycle frequency & duration; cycle amplitude and the rate of change between the inflate and deflate conditions[1].

As each patient presents with a unique and changing risk profile, it is not possible to determine universally ‘safe’ pressure thresholds and any residual pressure may still be sufficient to occlude the vessels.



Measuring performance

The physical appearance of surfaces belies the fact that each will have a unique set of characteristics; only when these are clearly defined and understood can each product be best aligned to clinical need. This is particularly important, as performance cannot be determined by appearance alone and, unlike in the pharmaceutical industry, there is currently no requirement for manufacturers to demonstrate clinical efficacy in patients.

This position has resulted in a lack of contemporary primary evidence and has driven the demand for, as a minimum, standardised tests to measure and report key performance metrics, such as interface pressure. Such test models are well advanced for reactive surfaces and a draft standard has been submitted to the International Standards Organisation (ISO) by a subgroup of the National Pressure Ulcer Advisory Panel (USA) with the intention that this becomes an international reference point. Work on an active surface standard is at an advanced stage[10] and will follow.

Anatomical zones

Choosing target anatomical locations for key performance measurements are logically driven by two considerations.

Firstly, the sacrum and heel are the two locations that consistently report the most common and most severe injuries. Secondly, many surfaces are now zoned, with their performance tailored to the unique requirements for support and off-loading over these different anatomical structures.

Human vs. mannequin test subject

Although the technical performance of a surface cannot be considered as a direct indicator of expected clinical outcome[11], it is possible to illustrate how each device redistributes pressure and draw comparisons with predicate devices that have proven efficacious in clinical trials.

This demands that data that is both valid and reliable (with repeatable results), which rules out the use of human test subjects, as was common practice in the past. Whilst using a human volunteer to test support surfaces may seem the obvious choice, it does not represent a 'repeatable standard' nor does it represent any individual patient, as the natural variation in morphology and body mass distribution is infinite.

Unfortunately, this also means that it is neither valid nor helpful to compare human test data from one laboratory or manufacturer to that of another, as even subtle changes can produce significant differences. This lack of repeatability, and the lack of an absolute reference to any individual patient, renders human test data inadmissible for comparative analysis.

With advances in measurement technology, new test methods have emerged. Consensus now recommends the use of published anthropomorphic data[12] to construct a standardised human analogue, or 'test dummy'. These models are typically of similar proportion and weight distribution to a 50th percentile human subject[11] (Figure 4), with volunteers increasingly reserved for *in vivo* physiological studies, such as tissue perfusion.

50th percentile male:
body weight 86 kg

6% body weight over the heel:
5 kg

50% body weight located over the trunk:
43 kg

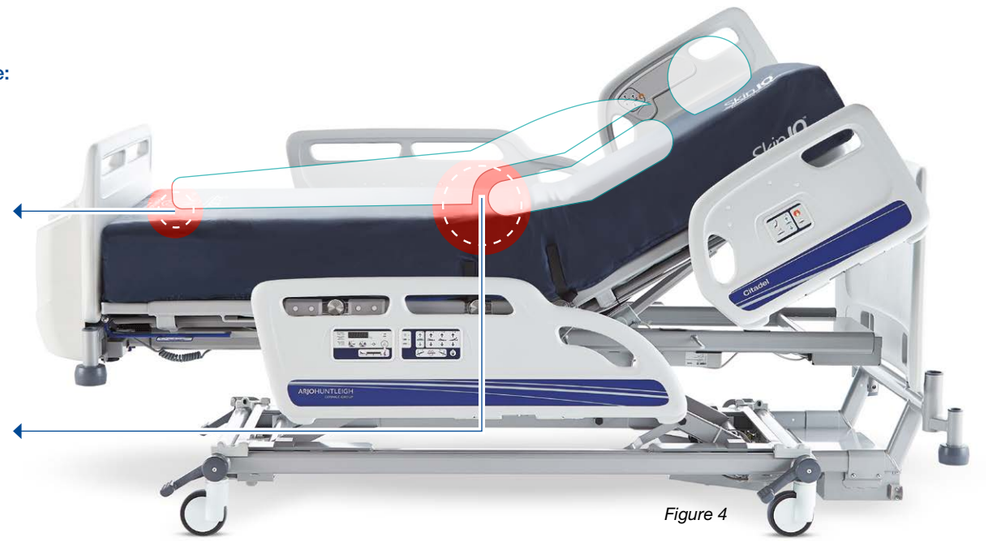


Figure 4

Performance measurement:

The *Citadel* Patient Therapy System in **REACTIVE** Mode

The ability of the *Citadel* Patient Therapy System to manage mechanical load (pressure) was measured in a series of laboratory tests. The first investigation looked at the ability of the mattress to redistribute pressure though immersion and envelopment: i.e. in reactive mode.

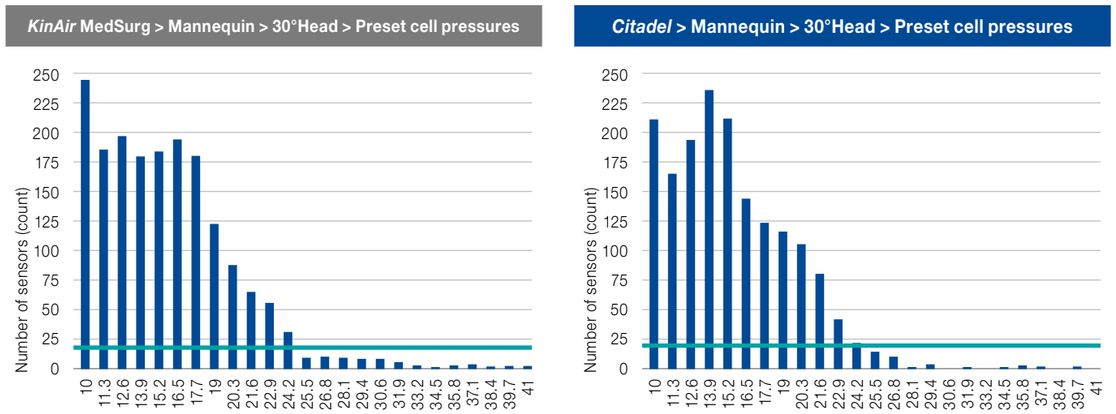
The support surface was loaded with an anatomically weighted, 50th percentile, test mannequin (Figure 4), the correct (weight-derived) pressure pre-set was selected and the head of the bed was elevated to 30 degrees.

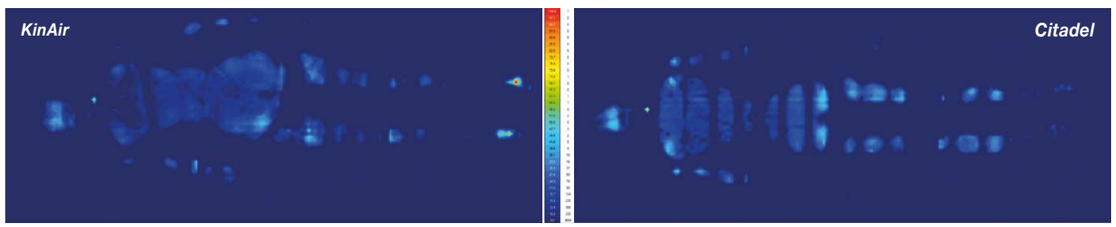
As performance for a reactive surface is defined by the redistribution of pressure through immersion and envelopment, interface pressure was measured using a full bed-sized, calibrated, pressure-mapping array (XSensor® Technology Corporation).

This approach enables 'whole body' visualisation of interface pressure, with data reported as an average (mean) pressure across the body plus 'hot spot' analysis: areas of higher pressures, usually over bony prominences.

To provide a clinically appropriate reference point, the study support surface was contemporaneously compared to a predicate device routinely used in the care of very high-risk patients (KinAir™ Med-Surg, ArjoHuntleigh Getinge Group).

Figure 5. Interface Pressure (mmHg)





Average pressure 17.9 mmHg	**COMPARABLE** Average (mean) pressures are similar	Average pressure 21.5 mmHg
83% below 20 mmHg	**EQUIVALENT** 83% of the body experiences pressure < 20mmHg	83% below 20 mmHg
Peak Press: 131.6 mmHg	**ENHANCED** Citadel C200 support surface produces lower peak pressures over especially vulnerable areas such as the heel	Peak Press: 88.9 mmHg

Results: The tests demonstrate that the *Citadel* Patient Therapy System delivers pressure redistribution that is equivalent or superior when compared to its predecessor.

Performance measurement:

The *Citadel* Patient Therapy System (C200) in **ACTIVE** (Alternating) Mode

The *Citadel* C200 support surface provides a choice of four active modes. The highest amplitude cycle delivers a noticeable difference between the highest and lowest pressures within the cells; this aligns with the functionality of traditional alternating support surfaces. The most subtle pressure differences are characteristic of the 'pulsation' mode, which combines both active and reactive characteristics by means of a lower-amplitude, part immersion, alternating cycle.

As the inflation pressures in all active states need to be sufficient to hold the patient clear of the deflating cell, internal air pressures are proportionally elevated beyond those used to support the patient in the reactive mode (Figure 6).

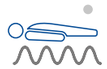
Symbol	Therapy description	Pressure Target in Increased Bladders, (% of Set Pressure)	Pressure Target in Decreased Bladders, (% of Set Pressure)
	Alternating Pressure	↗ 125%	↙ 0%
	High Pulsation	↗ 148%	↙ 42%
	Medium Pulsation	↗ 128%	↙ 55%
	Low Pulsation	↗ 115%	↙ 75%

Figure 6

As an active support surface is designed to deliver cyclical pressure application and removal, the methodology for performance measurement differs from that of reactive surfaces by capturing the time sequence of loading and off-loading. A similar, anatomically weighted, test mannequin was used but, this time, a small, focussed sensor array (IScan™, XSensor® Technology Corporation) was placed over a convex reference point located in the region of the sacrum and heel.

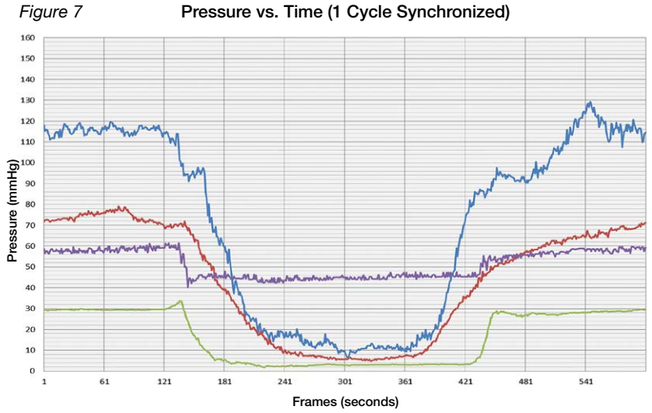
The mannequin was then positioned so that the sensor rested over the apex of an air-cell. The support surface was set to its maximum-amplitude cycle and allowed to run until a stable state was reached (steady inflation-deflation profile) at which point a 10-minute pressure-time trace was captured. The test was repeated with the support surface in its lowest amplitude (pulsation) cycle for comparison: data were captured for both sacrum and heel.

To provide a clinically appropriate reference point, results were compared to the Nimbus™ 4 and Auto Logic™ 200 support surfaces (ArjoHuntleigh, Getinge Group): both have a clear clinical efficacy as established through clinical field trials and, for the *Auto Logic* mattress in particular, clearly demonstrates the important relationship between the degree and duration of off-loading and tissue perfusion[14]. Results for each 10-minute test series were overlaid to provide a visual comparison.

Results: HEEL

The *Citadel* Patient Therapy System delivered enhanced off-loading (duration and extent) over the heel compared to the comparator mattresses (Figure 7), while also providing relatively low maximum pressures.

Figure 7 **Pressure vs. Time (1 Cycle Synchronized)**



Auto Logic 200
Typical cycle profile with relatively higher pressures during inflation followed by rapid deflation to hold low pressure as long as possible

Nimbus 4
Different cell design results in lower maximum pressures than the Auto Logic 200 system, while the 'Power Down' heel straps result in more time at lower pressure

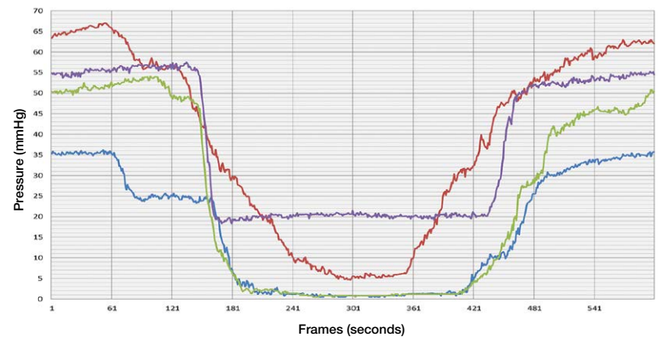
***Citadel* in Pulsation Mode**
A lower-amplitude cycle that offers gentle alternation in a 'reactive' (immersion & envelopment) environment

***Citadel* in Alternating Mode**
Achieves a prolonged low pressure interval with maximum pressures close to 30mmHg

Results: SACRUM

Similar results were seen for the sacral zone, where the mattress supports the bulk of the body weight. Alternating pressure characteristics were within the range of that demonstrated by predicate devices (Figure 8), with pressures held below 30mmHg for at least one third of each 10-minute cycle. For three of the four conditions pressure dropped below 10mmHg for at least 20% of each cycle; the exception being *Citadel* Patient Therapy System in pulsation mode.

Figure 8 **Pressure vs. Time (1 Cycle Synchronized)**



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Different cell design results in lower maximum pressures than the Auto Logic 200 system, while the 'Power Down' heel straps result in more time at lower pressure

***Citadel* in Pulsation Mode**
A lower-amplitude cycle that offers gentle alternation in a 'reactive' (immersion & envelopment) environment

***Citadel* in Alternating Mode**
Delivers a prolonged low pressure environment (≤ 30mmHg) virtually identical to that delivered by the Auto Logic 200 mattress

Interpretation and Clinical Relevance

There are a number of features of the *Citadel* Patient Therapy System that have clinical importance and can be illustrated using this performance data. One example is the benefit of delivering 'zoned' pressure redistribution over the most vulnerable heel and sacral regions.

In order to prevent 'bottoming out' (in reactive mode) and to support the patient clear of the deflating cell in active (alternation/pulsation) mode, there are higher inter-cell pressures in the upper region of the mattress. When in active mode these higher cell pressures, though necessary to adequately support the weight of the patient, are regularly relieved to restore blood flow and reperfuse the tissue.

In contrast to the sacrum, the heel is perhaps more vulnerable to blood vessel occlusion particularly given the prevalence of confounding risk factors such as diabetes, peripheral vascular disease and medication (e.g. inotropes); conditions known to compromise or delay reperfusion in the lower limb. As the heel zone of the mattress is required to support less weight than the body of the mattress, the maximum cell inflation pressures can be reduced.

As a result, the heel can benefit from a lower pressure environment, predominantly governed by immersion and envelopment. In addition, as less pressure is required to lift the heel, it is possible to add a regular off-loading cycle to enable this most vulnerable area to experience a very low pressure for as long as possible during deflation. **This creates an active (alternating) therapy environment that has been shown in studies of both normal volunteers[13] and diabetics[14] to significantly increase tissue perfusion compared to mattresses that otherwise look very similar.**

Measuring performance against an established device in this way provides clinicians with an indication, as a minimum, that the product might deliver similar performance in the field, although uncertainties surrounding the patient and his/her environment means that this cannot be guaranteed.
That said, such data can aid clinical decision making by matching product selection to clinical need; this is in contrast to the many procurement decisions that may be made entirely blinded to the product's wider performance and based upon less relevant non-clinical technical specifications such as size, power and weight limit.

Conclusion:

The two support surfaces provided with the *Citadel* Patient Care System, the C100 or C200, are examples of contemporary support surface design that uses advanced technologies to deliver both active and reactive pressure redistribution and does so with performance that equals or surpasses long-established products with proven clinical value.

The ability to deliver both modalities within a single surface provides the ultimate flexibility for clinicians and having a low-pressure environment with an 'active' (alternating) mode might be considered the best of both worlds.

References:

1. National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel and Pan Pacific Pressure Injury Alliance. Prevention and Treatment of Pressure Ulcers: Clinical Practice Guideline. Emily Haesler (Ed.). Cambridge Media: Osborne Park, Western Australia; 2014.
2. Oomens C, Bader D, Loerakker S et al. Pressure induced deep tissue injury explained. Annals of Biomedical Engineering. 2015; 43(2): 297-305
3. Gefen A. How much time does it take to get a pressure ulcer? Integrated evidence from human, animal, and in vitro studies. Ostomy Wound Manage. 2008; 54(10): 26–8, 30–5
4. Coleman S, Nixon J, Keen J et al. A new pressure ulcer conceptual framework. Journal of Advanced Nursing. 2014; 70(10): 2222-34
5. Loerakker S, Manders E, Strijkers GJ et al. The effects of deformation, ischemia, and reperfusion on the development of muscle damage during prolonged loading. J Appl Physiol. 2011; 111(4): 1168–77
6. Black J, Edsburg L, Baharestani M et al. Pressure ulcers: avoidable or unavoidable? Results of the National Pressure Ulcer Advisory Panel Consensus Conference. Ostomy Wound Management. 2011; 57(2): 24-37
7. Phillips L. Taking the pressure out of pressure ulcers. Suppl. 2014. British Journal Nursing. MA Healthcare, London
8. Bureau of Labor Statistics, US Department of Labor. Non-fatal occupational injuries and illnesses requiring days away from work – 2012. USDL-2-2257. 2013. www.bls.gov/news.release/pdf/osh2.pdf accessed August 2016
9. Faigeles B, Howie-Esquivel J, Miaskowski C et al. Predictors and use of nonpharmacological interventions for procedural pain associated with turning among hospitalized adults. Pain Manag Nurs. 2013; 14(2): 85-93
10. Phillips L, Goossens R, Takahashi M, Clark M. Defining 'active' pressure redistribution. Wounds International. 2012; 3(3): 52-56
11. Tissue Viability Society. Laboratory measurement of the interface pressures applied by active therapy support surfaces: a consensus document. J Tissue Viability. 2010; 19(1): 2-6
12. Fryar CD, Gu Q, Ogden CL. Anthropometric reference data for children and adults: United States, 2007–2010. National Center for Health Statistics. Vital Health Stat 11. 2012; 252
13. Goossens RH1, Rithalia SV. Physiological response of the heel tissue on pressure relief between three alternating pressure air mattresses. J Tissue Viability. 2008; 17(1): 10-4.
14. Van Schie C, Ragunathan S, Rithalia S, et al. Manchester Diabetes Centre, Manchester Royal Infirmary, Diabetes Foot Clinic, Disablement Services Centre, Withington Hospital, School of Health Care Professions, University of Salford. 2004
15. Support Surfaces Standardisation Initiative: http://www.npuap.org/resources/educational-and-clinical-resources/support-surface-standards-initiative-s3i/ accessed August

About the author

The author is a registered nurse with more than 20-years experience in the design, testing and clinical application of pressure redistributing mattresses and cushions. As an active participant in international standards groups for the measurement of support surfaces; including the Support Surfaces Standards Initiative[15] (founded in 2001); the Shear Force Initiative (founded 2005) and as a founder member of the 'Active (alternating) Surfaces Standard Group, she has expertise in developing test protocols to measure support surface performance and in establishing clinical relevance.

Note: Previously reported interface pressure data will have been gathered using substantially different methodology and will differ from that represented here.

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