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AtmosAir 9000X and AtmosAir Velaris® Adaptable Alternating Pressure System

Immersion, Envelopment, Horizontal Stiffness and Microclimate Testing

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Introduction & Clinical Context

Pressure injuries develop over time and are a consequence of a sequential and gradual deterioration of cell structures which are subjected to body weight or external forces^{1,2}. Although the underlying cause and formation of pressure injuries is complex and multifaceted, generally they cannot form without loading, or pressure on the tissues³.

Given that prolonged or unrelieved pressure is the primary causative factor³, the most appropriate interventions must be those designed to mitigate risk by reducing the exposure to the degree and duration of pressure. Interventions such as assisted repositioning regimens help to reduce risk and are most effective when used in combination with pressure redistributing support surfaces.

Support surface technologies reduce the interface pressure between the body and the support surface. The international pressure injury prevention and treatment guidelines⁴ view support surfaces as an important component in pressure injury prevention and treatment protocols, since they can help to prevent the effects of damaging tissue deformation and provide an environment that enhances perfusion of at risk or injured tissues⁵. They further recommend that the key characteristics to consider when selecting a support surface are those features that affect pressure redistribution, friction, shear force management and microclimate⁴.

These key characteristics however will vary substantially between the different support surface technologies available, and this can often make appropriate surface selection in the clinical setting challenging. Standard test methods that quantify performance characteristics have been developed with the aim of matching users' needs to support surface capabilities⁶. All Arjo support surfaces undergo rigorous bench testing to ensure they deliver the desired pressure redistribution under clinically relevant conditions. Our surfaces are also tested

in independent laboratories to the US national standard for support surfaces: ANSI/RESNA SS-1:2019⁷.

This document will provide a summary of the results of immersion, envelopment, horizontal stiffness (shear) and microclimate testing performed to this standard with the AtmosAir 9000X reactive pressure redistribution surface and the AtmosAir Velaris Adaptable Alternating Pressure System. All systems were tested both with and without the addition of the proprietary Arjo Skin IQ microclimate coverlet.

Surfaces Tested

The AtmosAir 9000X (Figure 1a) represents Arjo's new non-powered hybrid surface designed to provide reactive pressure redistribution while supporting patient comfort. The AA9000X contains nine foam filled air cells which are connected by a series of air tubes and check valves. This forms the ARM® (Air Redistribution Module), an open pressurised system which redistributes air between the cells in order to constantly maintain a predefined level of pressure.

The AA9000X is also designed with a 6° slope over the heel zone to further reduce pressure at the vulnerable heel area.

The AtmosAir Velaris (Figure 1b) is designed to meet the time critical challenges of pressure injury prevention. When used as a reactive surface, the Velaris uses ARM® (Air Redistribution Module) technology to constantly maintain a predefined level of pressure throughout the mattress. With the pump attached, it uses AltoVac® vacuum technology to deliver alternating pressure technology that is capable of delivering full pressure offloading, including from the vulnerable heel and sacral areas.

The Skin IQ (Figure 1c) is a coverlet designed for compatibility with pressure redistribution surfaces for managing microclimate.



Figure 1a: AtmosAir 9000X non-powered hybrid surface



Figure 1b: AtmosAir Velaris adaptable alternating pressure system



Figure 1c: Skin IQ advanced microclimate coverlet

Immersion & Envelopment Testing – Hemispherical Indenter: SS-1:2019 Section 6

Test Overview:

Immersion Testing: provides one measure of the pressure redistribution properties of a surface, by measuring how far a load sinks into a surface. Increased immersion can lead to an increase in envelopment.

Envelopment Testing: is designed to assess or measure how well a support surface conforms around the irregularities of the body to redistribute pressure.

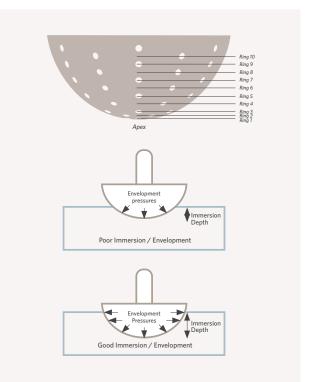
Method: Testing was performed to ANSI/RESNA SS-1:2019 section 6⁷. A half sphere indenter containing pressure sensors, was applied to the surface (Figure 2a), to measure the immersion and envelopment properties of each mattress, both with and without the addition of the Skin IQ coverlet to the surface. Immersion levels were measured by the distance the indenter sunk into each surface, whilst envelopment was measured to establish how well each surface conformed around the indenter (Figure 2b).

Although the SS-1:2019 hemispherical indenter test is designed to assess reactive full body support surfaces. For the purpose of this testing the AtmosAir Velaris was tested in both reactive and active mode (alternating periods of high and low pressure), which represents a practical application of the this standard for this type of surface. This additional testing is not included in the current revision of the SS-1 standard, but in the absence of a full alternating section within the standard, this test method was used to give an indication of the performance of the surface in the alternating mode. Additional Pressure Redistribution Index (PRI) test data for Velaris in the active (alternating) mode is also available, to demonstrate the full offloading capabilities of the surface8.

Clinical Relevance of Immersion & Envelopment Testing: Higher levels of immersion and envelopment equate to lower interface pressure and more potential for pressure redistribution⁶.



Figure 2a: Hemispherical Indentor, ANSI/RESNA SS-1:2019 section 6. Image for illustration purposes, not actual test rig used.



Immersion is measured as the total distance the indenter travelled through the top of the mattress

Contact Depth is measured by counting the 'active' rings on the indenter. A ring is considered 'active' if the average pressure of sensors across that ring exceeds 1 mmHg. The aim is to activate as many rings as possible.

Envelopment is calculated as a percentage of contact depth divided by immersion.

Figure 2b

Immersion & Envelopment Results: Reactive Pressure Redistribution

Graphical representation of the AtmosAir Velaris and AA9000X in reactive mode in terms of immersion, envelopment, contact depth and peak pressure performance both with and without the addition of the Skin IQ is provided in Figures 3a-3d below. An interpretation of these results is provided in Box 1.

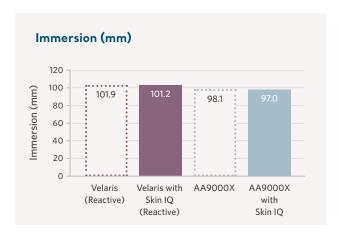


Figure 3a: Immersion data for AtmosAir Velaris in reactive mode and the AA9000X with and without the addition of Skin IQ to the surface

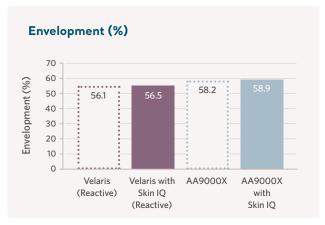


Figure 3b: Envelopment data for AtmosAir Velaris in reactive mode and the AA9000X with and without the addition of Skin IQ to the surface

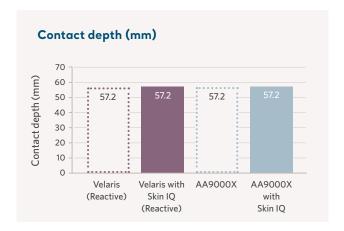


Figure 3c: Contact depth data (see Figure 2b) for AtmosAir Velaris in reactive mode & the AA9000X with and without the addition of Skin IQ to the surface

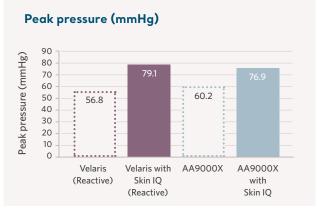


Figure 3d: Peak Pressure data for AtmosAir Velaris in reactive mode & the AA9000X with and without the addition of Skin IQ to the surface

Box 1

Interpretation of Immersion & Envelopment Performance Results for AtmosAir Velaris (in reactive mode) & AtmosAir 9000X

- Immersion, envelopment and peak pressures are equivalent between AA9000X and Velaris in reactive mode.
- Immersion, envelopment and contact depth are not significantly affected by the addition of the Skin IQ coverlet
 to each surface.
- There was an increase in peak pressures observed in both the AA9000X and Velaris with the addition of the Skin IQ coverlet. This increase in pressure is likely to be off-set by the large increase in microclimate performance gained from adding the Skin IQ coverlet to the surface.

Immersion & Envelopment Results: AtmosAir Velaris in Active (alternating) Mode

Although assessment of active alternating surfaces is currently not part of the SS-1 standard, the AtmosAir Velaris was tested in the active mode of operation using a modified method to investigate the performance with respect to immersion and envelopment. Readings were taken at both

the high point and low point of the cycle to represent the extremes of immersion and envelopment, as the surface moved through its alternating cycle. The results from this method in terms of immersion, envelopment, contact depth and peak pressure performance are shown in graphical representation in Figures 4a-4d below. An interpretation of these results is provided in Box 2.

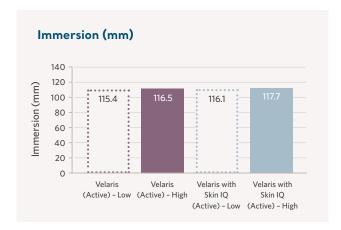


Figure 4a: Immersion data for AtmosAir Velaris in active (alternating) mode with and without the addition of Skin IQ to the surface

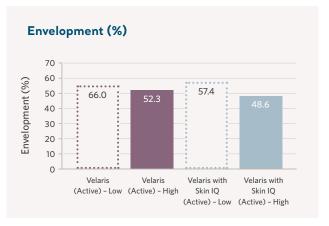


Figure 4b: Envelopment data for AtmosAir Velaris in active (alternating) mode with and without the addition of Skin IQ to the surface

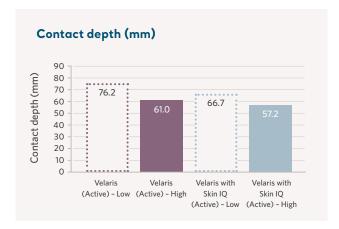


Figure 4c: Contact depth data for AtmosAir Velaris in active (alternating) mode with and without the addition of Skin IQ to the surface

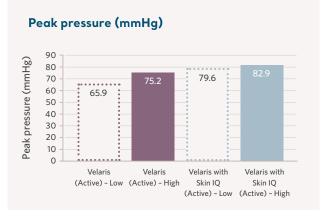


Figure 4d: Peak Pressure data for AtmosAir Velaris in active (alternating) mode with and without the addition of Skin IQ to the surface

Box 2

Interpretation of Immersion & Envelopment Performance Results for AtmosAir Velaris in Active (Alternating) Mode

Performance characteristics in terms of immersion, envelopment and contact depth pressures are broadly equivalent in each mode of operation – reactive and active (alternating).

The Velaris in active (alternating) mode shows a slight increase in immersion compared to reactive mode. However in the active mode only half of the cells are in contact with the patient at any one time, and this must be considered when assessing levels of immersion for the active (alternating) component of the Velaris system.

Peak pressures in the active (alternating) mode of the Velaris are higher than those in reactive mode; this is as a result of the deflated cells offloading the patient during the deflation cycle.

Horizontal Stiffness (Shear) Testing – SS1-2019: Section 5

Test Overview: The purpose of this test is to simulate shear forces that occur with support surfaces when patient movement occurs on the surface. The test can be used to allow for comparison between different support surfaces of the shear forces that are present with a simulated patient.

Method: A pelvic indenter representing the trunk and pelvic area of a 50th percentile male is pulled horizontally on a support surface toward the foot end, simulating patient movement. Comparison tests were performed between the AtmosAir 9000X and the AtmosAir Velaris in both active and reactive modes of operation. Each surface was also tested both with and without the addition of a Skin IQ coverlet.

Clinical Relevance: Mechanical loading and tissue compression from external forces deform the skin, creating stress within the tissues. While pressure may be applied to the skin and deeper tissues, the effects of pressure are frequently exacerbated by lateral shear forces. This causes deep horizontal stress by stretching and distorting tissues and blood vessels. Minimizing the effects of shear is an important element in pressure injury prevention and support surface design.

Horizontal Stiffness Results for AtmosAir 9000X & AtmosAir Velaris

A graphical summary representation of the average shear forces over time for the AtmosAir 9000X and Velaris in active and reactive modes both with and without the addition of the Skin IQ coverlet is represented in Figure 5 below. An interpretation of these results is provided in Box 3.

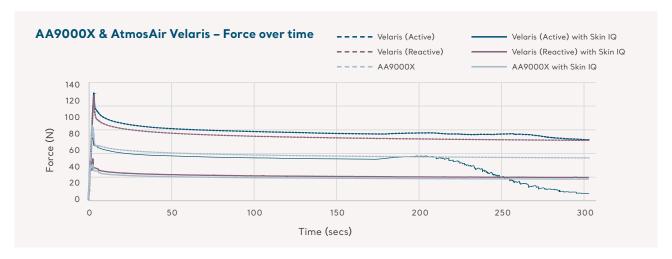


Figure 5: Horizontal Stiffness (Shear) data for AtmosAir Velaris & AtmosAir 9000X

Box 3

Results Interpretation:

The initial point (at t=0) on the graph (Figure 5) shows the static force that prevents the movement of the mannequin (patient) which has to be overcome for movement to occur. Once movement starts, the force is then known as dynamic force, which causes the indenter to move by 10mm at which point the force reaches a peak. After this, static forces resume and the response is comparable to forces after repositioning and in-bed movements.

Testing with the AtmosAir 9000X and Velaris system in reactive mode, during the pull of the indenter, the reduction in force was consistent.

With the Velaris system in active mode the alternating characteristic of the AtmosAir Velaris system did cause the shear force to vary (Figure 5), however, it did not increase the shear force between the indenter and the support surface. This suggests that the alternating action of the cells in active mode does not pose an increased risk of shear on the skin and tissues.

The addition of the Skin IQ reduces the shear force by 40–60% for the AtmosAir 9000X and AtmosAir Velaris system in reactive mode. The lower initial static and dynamic forces measured when the Skin IQ coverlet is added to each surface, can be expected to reduce the shear effect and tissue strain on the patient when repositioned or during normal patient movement.

The addition of Skin IQ during testing in active mode reduced shear forces by 40%. After 5 minutes of alternation, the shear force had on average been reduced by 90%. The Skin IQ significantly reduces shear forces in active mode. This reduced force is an indication that patients will experience reduced shear and therefore is a positive factor in the prevention of pressure injuries.

Microclimate Management

An increasing body of evidence suggests that microclimate between the skin and the support surface plays a role in the development of pressure injuries. The term microclimate refers to the temperature and humidity next to the skin. Managing microclimate helps to improve tissue tolerance to pressure, friction and shear.

Heat & water dissipation characteristics for full body support surfaces – Sweating guarded hotplate (SGHP) method: SS-1:2019 Section 4

Test overview: The purpose of this test is to identify the ability of the support surface to remove heat and moisture from the patient interface.

Method: A heated moist indenter measures the flow of heat and humidity through a support surface simulating the interface between the skin and the support surface.

For the purpose of this evaluation, testing was performed with the addition of the Skin IQ microclimate coverlet to the surface, which the AA9000X and Velaris surfaces were designed to be compatible with. For the Velaris surface, testing was performed in both active and reactive modes of operation.

Clinical relevance: There is a growing appreciation of the role of microclimate management in helping to improve tissue tolerance to aid in pressure injury prevention and management, particularly in the presence of excessive moisture and elevated temperature at the skin surface interface. Any surface that is in contact with the skin has the potential to affect the microclimate. The overall affect is dependent on the nature of the support surface and the cover material.

The results for the sweating guarded hotplate testing in terms of dry heat flux, wet heat flux and evaporative capacity for the AA9000X and the AtmosAir Velaris with the addition of the Skin IQ coverlet are shown below in Figures 6-8. An interpretation of these results is provided in Box 4.

Sweating Guarded Hotplate Results for AA9000X & AtmosAir Velaris with Skin IQ coverlet added

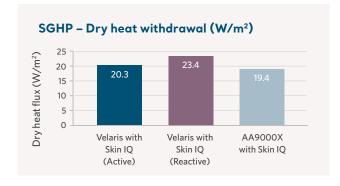


Figure 6: Dry Heat flux (Q-dry) data for AA9000X & AtmosAir Velaris with Skin IQ added to the surface

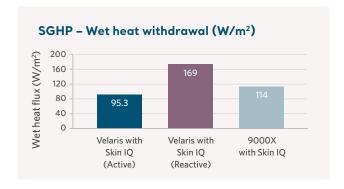


Figure 7: Wet Heat flux (Q-wet) data for AA9000X & AtmosAir Velaris with Skin IQ added to the surface

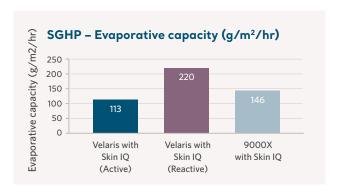


Figure 8: Evaporative Capacity (EvapCap) data for AA9000X & AtmosAir Velaris with Skin IQ added to the surface

Box 4

Microclimate Performance: Results Interpretation

The microclimate performance of both the AA9000X and Velaris (in active and reactive mode) with the addition of the Skin IQ coverlet to the surface is significant. This demonstrates the beneficial microclimate effect that could be present in a real life clinical situation.

When the Velaris is used in active (alternating) mode there is a slight decrease in performance in terms of dry heat flux (Q-dry), Wet heat flux (Q-wet) and evaporative capacity (EvapCap), when compared to the reactive mode of operation. This is more pronounced in the wet heat flux (Q-wet) condition. Overall however the Skin IQ still gives significant performance in the active mode.

In this testing the AtmosAir Velaris in reactive mode demonstrates better performance results than the AA9000X, in terms of dry heat flux (Q-dry), wet heat flux (Q-wet) and Evaporative capacity (EvapCap), although this may be due to experimental variation rather than any specific product differences.

Body Analog Method: SS-1:2019 Section 3

Test Overview: This method measures the heat and moisture dissipation properties of the support surface by creating a test indentor comparable to the human body lying on a support surface. This test also includes a simulated repositioning event (shown at 180 minutes) to assess the ability of the surface to return to its original state prior to loading.

Method: A Thermodynamic Rigid Cushion Loading Indenter (TRCL) is used to generate, control and measure the environmental conditions of temperature and relative humidity (%RH) at the patient interface.

Clinical Relevance: Humidity can have an adverse effect on tissue viability and often results in moisture being condensed and trapped under the patient's body. Products that provide less resistance to heat flow and more breathability will have RH closer to 50% with lower temperature.

Body Analog results for AtmosAir 9000X and AtmosAir Velaris

Graphical representation of each surface performance in terms of temperature and relative humidity are shown in Figure 9 and Figure 10. An interpretation of these results is provided in Box 5.

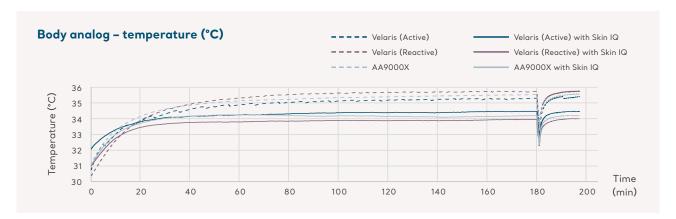


Figure 9: Body Analog - Temperature data for AtmosAir Velaris & AtmosAir 9000X

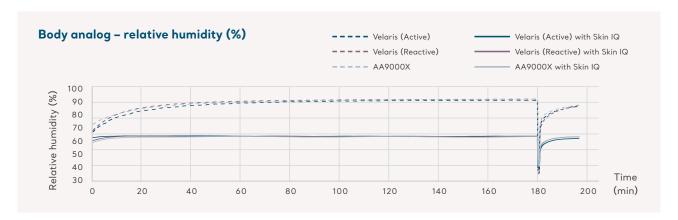


Figure 10: Body Analog - Relative Humidity data for AtmosAir Velaris & AtmosAir 9000X

Box 5

Results Interpretation:

In terms of temperature and relative humidity (%RH) measurements, the performance between the Velaris system (in both reactive and active mode) and the AA9000X is similar.

The addition of the Skin IQ to both surfaces reduces average temperatures by 1.1 to 1.5 °C and relative humidity at the surface interface by 25%. These reductions are significant in respect of microclimate management and in keeping the patient cool and dry.

The Velaris in active mode gave the lowest temperature and humidity values with no Skin IQ fitted, this is likely a result from the alternation of the air cells allowing air to flow more freely underneath the test indentor (patient).

Summary & Conclusion

These tests are designed to measure and assess support surface performance characteristics in order to provide clinically meaningful metrics for comparison; they are not intended to assess the impact directly on individual patients. The results of this independent testing demonstrate that:

- In terms of immersion and envelopment, the AA 9000X and AtmosAir Velaris system both demonstrated similar
 and consistent performance in every position tested. The addition of a Skin IQ coverlet to the devices makes no
 significant difference to the surface performance in terms of immersion and envelopment characteristics.
- No significant difference in shear force was noted when the Velaris is in the active (alternating) or reactive modes
 of operation.
- The addition of the Skin IQ to the performance of the AA9000X and Velaris (in both active and reactive) in terms of heat and water dissipation characteristics is significant.

These results can help to inform clinical decision making and surface selection at the bedside. However, the test results only form part of an individual patient risk assessment, which should be carried out by the responsible clinician. When selecting an appropriate support surface the following factors should also be taken into consideration:

- The individual clinical condition and needs of the patient
- The efficacy of the existing surface they have been allocated
- · Level of mobility
- The need for repositioning
- Other factors influencing the risk of pressure injury e.g. temperature and microclimate

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