Domus Auto

Alternating Pressure Redistribution System

Clinical Practice Guideline

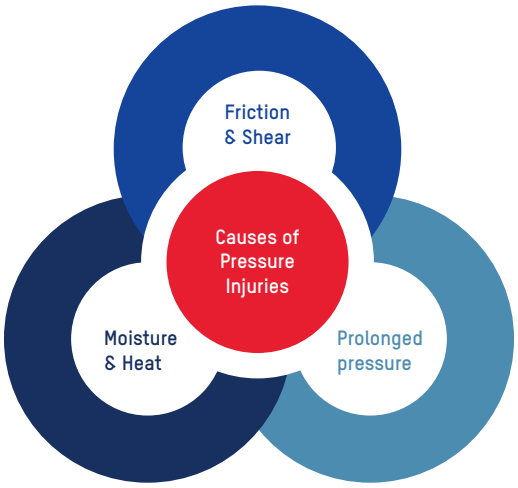
Care for a Healthy Life

APEX

Index

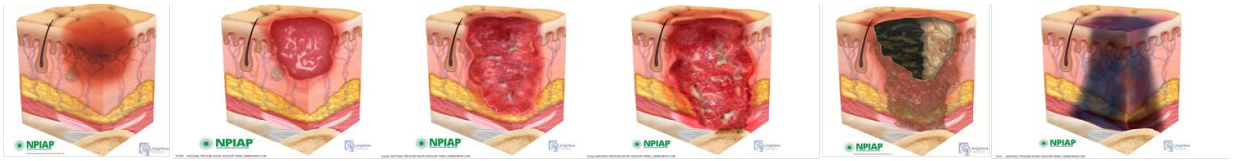
Risk Factors and Development of Pressure Injuries

Pressure Injuries commonly occur as a result of tissue being exposed to prolonged pressure or pressure associated with friction & shear, or the weaker tissue caused by moisture. [1]



Common Risk Factors of Pressure Injuries

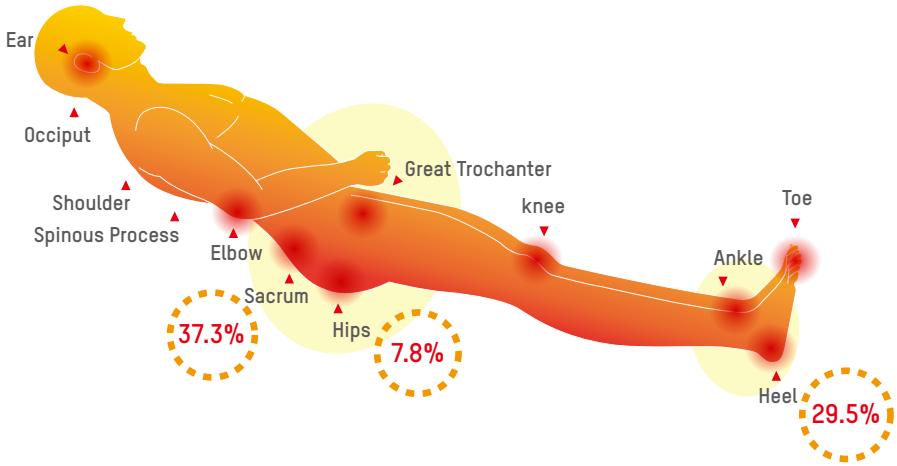
Pressure injuries are categorized into 6 stages[2]: Stage I with a non-blanchable erythema of intact skin; Stage II with a partial-thickness skin loss with exposed dermis; Stage III with a full-thickness skin loss; Stage IV with a full-thickness skin and tissue loss; Unstageable pressure injury is defined as obscured full-thickness skin and tissue loss; And last, Deep tissue pressure injury is the persistent non-blanchable deep red, maroon or purple discoloration of the skin.



Stage 1	Stage 2	Stage 3	Stage 4	Unstageable Pressure Injury	Deep Tissue Pressure Injury
- Skin intact - Non-blanchable erythema	- Partial loss of dermis - Shallow open ulcers	- Full thickness skin loss - Fat exposed	- Full thickness skin loss - Exposed bone, muscle or tendon	- Covered with slough or eschar - Depth undetermined	- Purplish skin discoloration - Potential for deeper tissue damage

Images used with permission from https://npiap.com/page/PressureInjuryStages

They may be superficial injuries affecting the epidermis and dermis or they can extend into the subcutaneous tissues and involve muscle, tendon and bone. Pressure injuries typically occur over bony prominences with the lower trunk (sacrum, coccyx, trochanter and ischial tuberosity) and heels being the two most common anatomical locations.[3,4]



Locations in Risk of Pressure Injuries

Localized areas of tissues that have prolonged pressure cause the occlusion of blood flow, preventing the supply of nutrients and oxygen to the tissue, resulting in ischaemia and re-perfusion injury, leading to cell obliteration and eventually tissue death.[5]

From the information of the mechanism of pressure injuries above, additional risk factors that have been correlated with are age of 70 years and older, current smoking history, dry skin, low body mass index, impaired mobility, altered mental status (i.e., confusion), diabetes mellitus, peripheral vascular disease, urinary and fecal incontinence, malnutrition, physical restraints, malignancy, history of pressure injuries, and human race.

Pressure injuries can develop within 2 to 6 hours. Therefore, the key to preventing pressure injuries is to accurately identify at-risk individuals quickly, so that preventive measures may be implemented.[6] A major method of redistributing pressure is the use of support surfaces. Many researches had been conducted on the effectiveness of the use of support surfaces in reducing the incidence of pressure injuries. The concept of pressure redistribution has been embraced by the NPIAP.

“Support surfaces are: “Specialized devices for pressure redistribution”[7] “

“Support surfaces are specialized devices for pressure redistribution designed for management of tissue loads, microclimate, and/or other therapeutic functions (i.e., any mattress, integrated bed system, mattress replacement, overlay, or seat cushion, or seat cushion overlay)”.[7] In this context, pressure refers to the distribution of force on the individual’s body surface that is in contact with the device.

“Evaluate the individual’s comfort when using an alternating pressure air mattress or overlay[8] “

“Evaluate the individual’s comfort when using an alternating pressure air mattress or overlay. Powered alternating pressure air mattresses and overlays can be noisy and generate heat or motion that may be uncomfortable”.[8]

Support Surface Solution

Domus Auto is equipped with the following features to tackle the most common risk factors

Prolonged Pressure


Continuous Low Pressure (CLP)


Alternating Mode


Automatic Pressure Adjustment


Seat Inflation & Cell-on Cell Design


Heel Relief Function

Friction & Shear


4-way Stretch Top Cover with Low Friction & High MVTR

Moisture & Heat


Micro Low Air Loss

Pressure Mapping

By investigating the pressure mapping of Domus Auto, we can use the software to analyze the Pressure Area Index (PAI) and Pressure Redistribution Index (PRI) of different modes to see the performance of product, when threshold of interface pressure gets stricter, you can find out that Domus Auto can still offer good performance for prevention of pressure injuries.

Equipment Used: The XSENSOR X3 Display Medical Mattress System

Software Used: Xsensor X3 medical V6

Method: Each test is conducted over a 30-minute period during which the average, peak and minimum pressures are recorded.

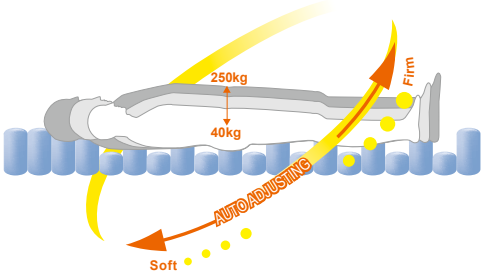
Pressure Area Index (PAI): Pressure Area Index (PAI) is a method used to measure the interface pressure of the surface. The PAI is calculated as the proportion of sensors that register interface pressure values.[9]

Pressure Redistribution Index (PRI): Pressure Redistribution Index (PRI) is a method to assess the ability of a dynamic support surface to sustain interface pressures below a chosen set of thresholds. The PRI is calculated as the ratio of the time during which the dynamic support surface interface pressure trace spends below the threshold and the total time of one inflation/deflation cycle.[10]

Product Therapy Modes and Performance

Automatic Pressure Adjustment

After completing initial inflation, Domus Auto will conduct automatic detection of patient weight and provide corresponding pressure to optimize mattress pressure relieving performance.
APEX will use pressure mapping test to verify the efficacy of this function.

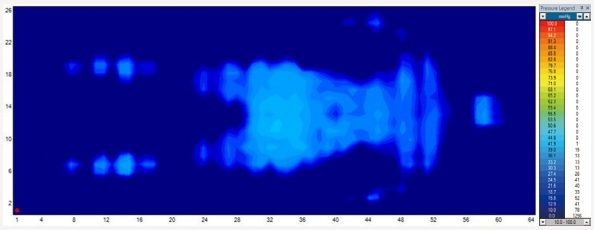


Continuous Low Pressure (CLP)

"Consider using a reactive air mattress or overlay for individuals at risk for developing pressure injuries[11] "

Reactive air mattresses redistribute pressure by deforming in response to an individual's weight on the surface.[12] Domus Auto offers a Continuous Low Pressure mode, which provides a stable surface with a pressure lower than the corresponding level when in the alternating mode. Also, this therapy mode is for the patients who are not fond of vibrations or alternating sensations.

Supine Position:



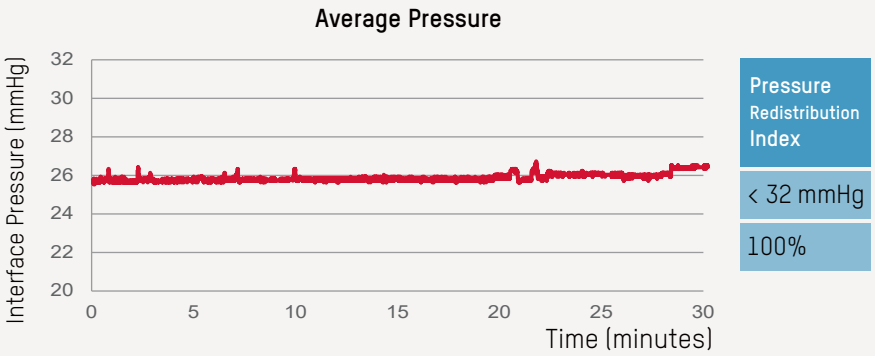
PAI & pressure mapping test of Domus Auto in the supine position for 30 minutes

User Height: 175 cm

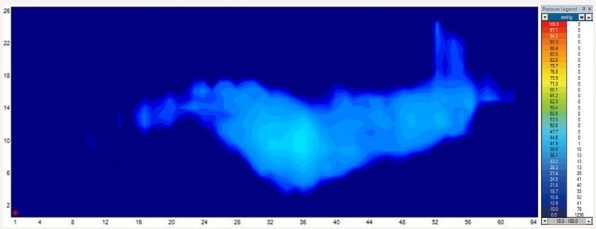
User Weight: 110 Kg

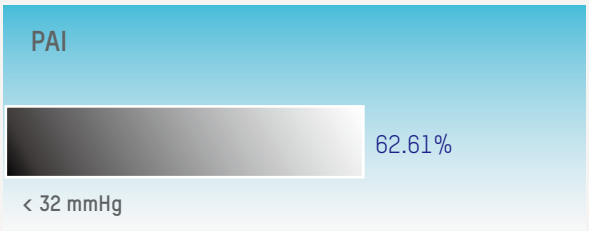
BMI: 35.9

Domus Auto (when used in Continuous Low Pressure mode) reaches a maximum of 26.7 mmHg and a minimum of 25.5 mmHg, and the 100% of interface pressures during its 30-minute cycle are all below 32 mmHg.



Lateral Position:





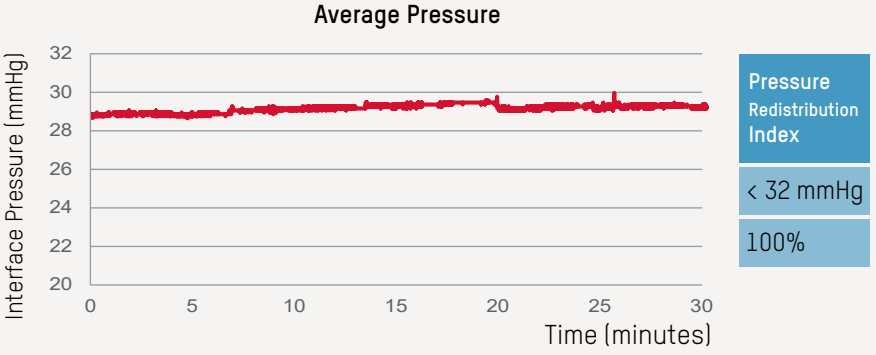
PAI & pressure mapping test of Domus Auto in the lateral position for 30 minutes

User Height: 175 cm

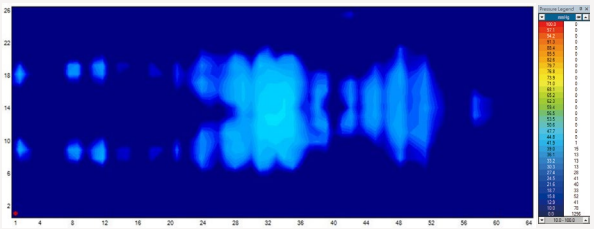
User Weight: 110 Kg

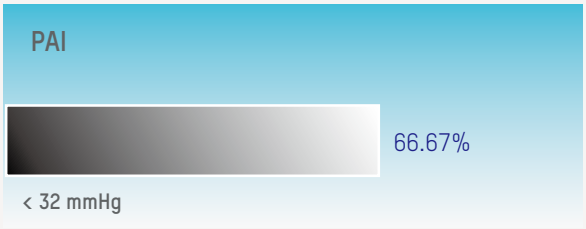
BMI: 35.9

Domus Auto (when used in Continuous Low Pressure mode) reaches a maximum of 29.9 mmHg and a minimum of 28.6 mmHg, and the 100% of interface pressures during its 30-minute cycle are all below 32 mmHg.



Sitting Position:





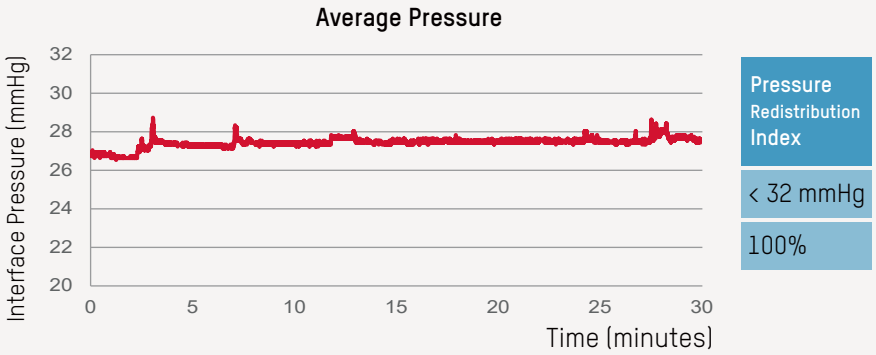
PAI & pressure mapping test of Domus Auto in the sitting position for 30 minutes

User Height: 175 cm

User Weight: 110 Kg

BMI: 35.9

Domus Auto (when used in Continuous Low Pressure mode) reaches a maximum of 28.6 mmHg and a minimum of 26.4 mmHg, and the 100% of interface pressures during its 30-minute cycle are all below 32 mmHg.

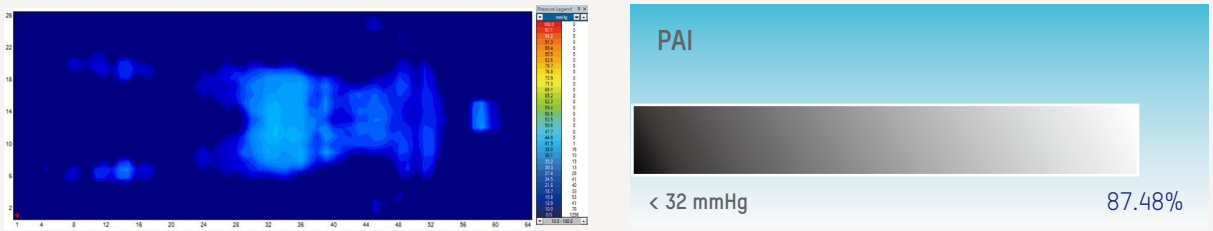


Alternating Mode

"Assess the relative benefits of using an alternating pressure air mattress or overlay for individuals at risk of pressure injuries[13] "

Domus Auto offers an alternating mode, which continuously and sequentially inflate and deflate air cells (1-in-2 alternating) to avoid long term pressurization of tissue.

Supine Position:



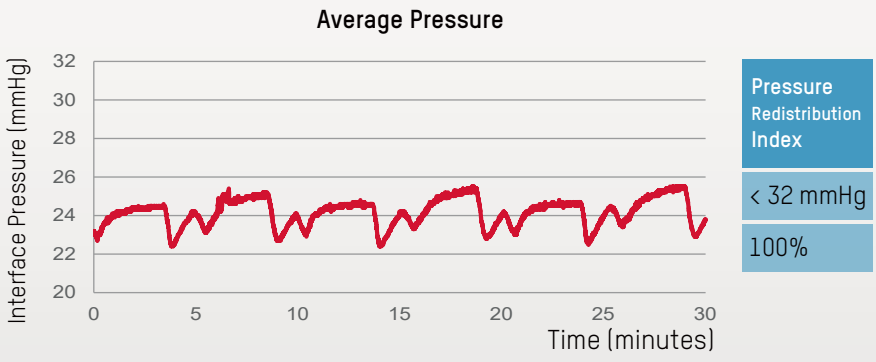
PAI & pressure mapping test of Domus Auto in the supine position for 30 minutes

User Height: 175 cm

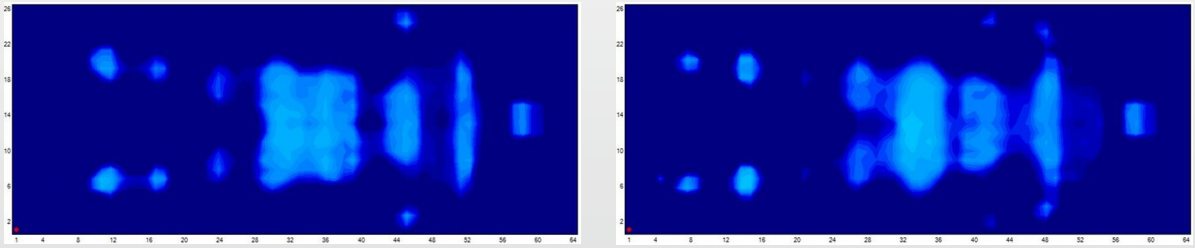
User Weight: 110 Kg

BMI: 35.9

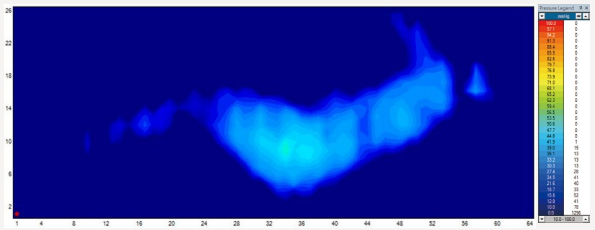
Domus Auto (when used in alternating mode) reaches a maximum of 25.5 mmHg and a minimum of 22.4 mmHg, and the 100% of interface pressures during its 30-minute cycle are all below 32 mmHg.



From the pressure mapping images you can easily observe the alternating situation in the supine position:



Lateral Position:



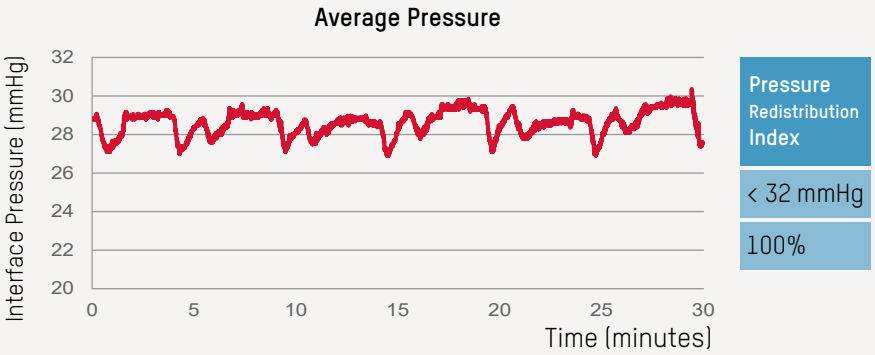
PAI & pressure mapping test of Domus Auto in the lateral position for 30 minutes

User Height: 175 cm

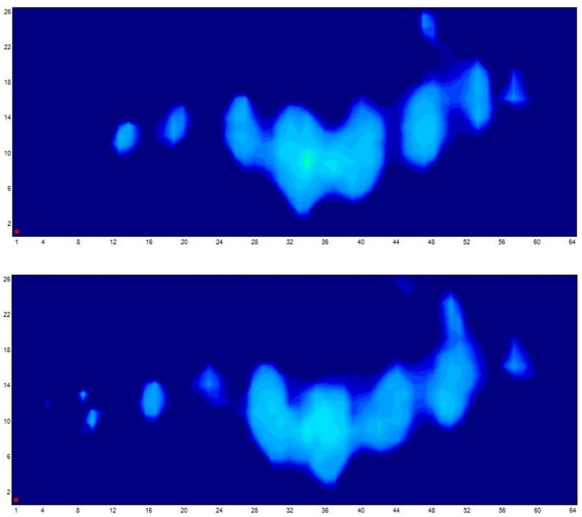
User Weight: 110 Kg

BMI: 35.9

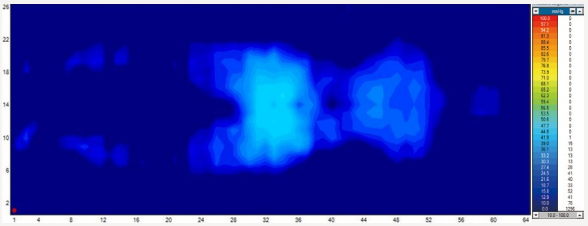
Domus Auto (when used in Alternating low pressure mode) reaches a maximum of 30.4 mmHg and a minimum of 26.9 mmHg, and the 100% of interface pressures during its 30-minute cycle are all below 32 mmHg.



From the pressure mapping images you can easily observe the alternating situation in the lateral position:



Sitting Position:



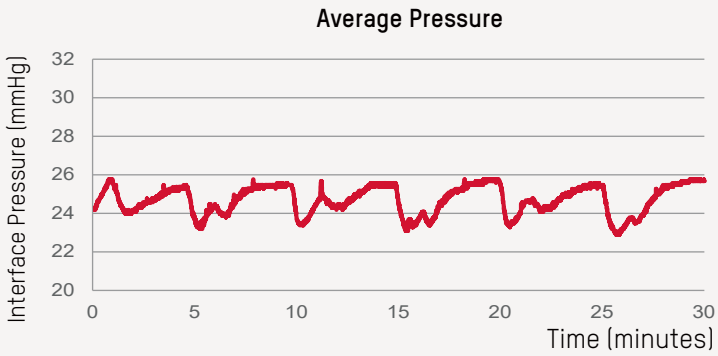
PAI & pressure mapping test of Domus Auto in the sitting position for 30 minutes

User Height: 175 cm

User Weight: 110 Kg

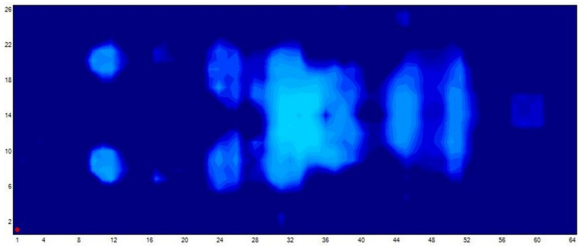
BMI: 35.9

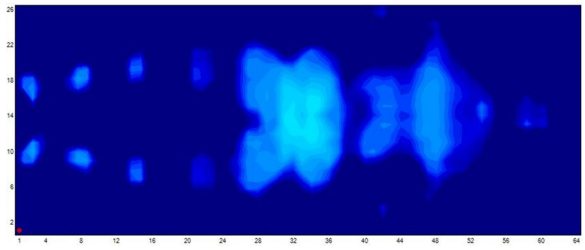
Domus Auto (when used in Alternating low pressure mode) reaches a maximum of 25.7 mmHg and a minimum of 22.8 mmHg, and the 100% of interface pressures during its 30-minute cycle are all below 32 mmHg.

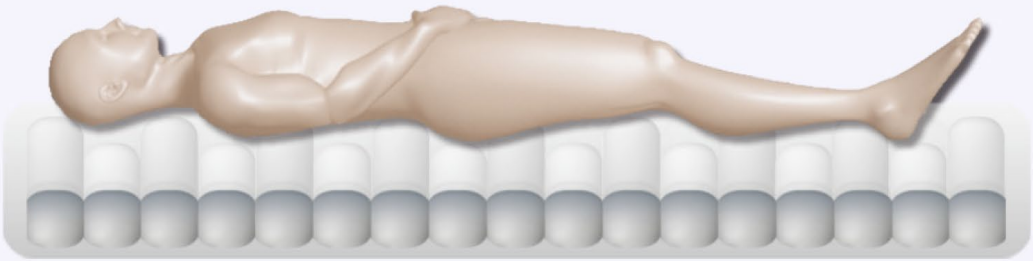


Pressure Redistribution Index
< 32 mmHg
100%

From the pressure mapping images you can easily observe the alternating situation in the sitting position:







Design of Mattress

Seat Inflation & Cell-on-Cell Design

"For individuals with a pressure injury, consider changing to a specialty support surface when the individual: 'Bottoms out' on the current support surface [14] "

To avoid the situation of bottoming out, Domus Auto offers an extra support in sacral area during sitting position. It will increase pressure of the whole mattress when patient is in a fowler's position for steady support. It can be used with continuous low pressure (CLP) or alternating mode.
The cell-on cell design also prevents the patient from bottoming out in case of power failure.

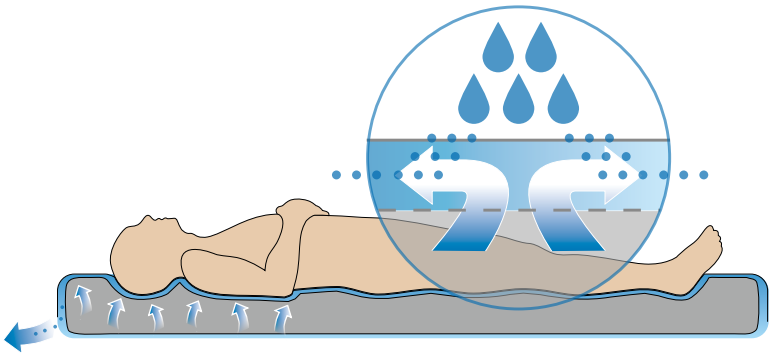
Heel Relief Function

"The heel is one of the two most common anatomical sites for pressure injuries. In a European survey on pressure injury prevalence, almost 80% of all Category/Stage IV pressure injuries were found at the sacrum and heels[15] "

APEX Heel Relief Function is a simple and easy way to prevent and assist in treating heel pressure injuries by eliminating interface pressure from heels as if they are suspended in air. The heel is typically reported as the second most common sites for pressure injury development.[15]
With the Heel-Relief quick connectors on the last five cells from the foot end, regardless of patients' height, the caregivers can always deflate the cell directly underneath the heel to achieve zero pressure.

Microclimate Management

"An increasing body of evidence suggests that the microclimate between skin and the supporting surface plays a role in the development of pressure injuries.[16]"



As for the microclimate control, Domus Auto offers micro low air loss function; it provides good ventilation and reduces the accumulation of heat and moisture.

Information of Top Cover

"Consider using textiles with low friction coefficients for individuals with or at risk of pressure injuries[17] "

Domus Auto alternating pressure redistribution system is provided with a standard cover (sanitary cover sheet) with high-performance technical material which covers them completely and is biocompatible, with low friction (μ = 0.21 (static), μ = 0.17 (dynamic)) & shear forces, water resistant and highly vapor permeable.

The Moisture vapor transmission rate (MVTR) is 2315 g/24hrs/ m^2 according to ASTM E96 Procedure BW.

Clinical Study

General Outline

Prospective observational study

Study location: France (4 nursing homes and 1 geriatric long-stay center)

Number of patients: 86 patients

Follow-up: 35 days

Main objective

To determine the clinical interest in the use of Domus 4 / Auto mattress for the prevention of pressure injuries in patients at medium to high risk of pressure injuries (Braden Scale).

Secondary objectives

(1) Patient comfort

(2) The satisfaction of the nursing staff

(3) The sound level of the mattress

(4) The safety of the mattress

(5) The maceration score

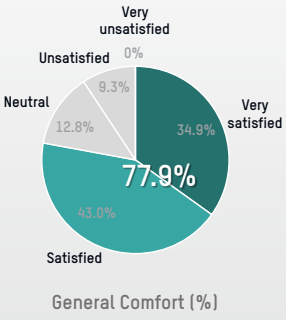
Results:

Primary Endpoint: 0% of patients developed a pressure injury of the sacrum, spine dorsal or heel during the 35-day trial.

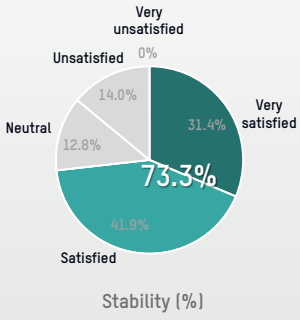
Secondary Endpoints:

Patient's assessment of mattress comfort and stability were measured on a 5-point scale on the parameters. The patients were satisfied or very satisfied in the majority of cases (Tab. 1).

	General comfort	Stability
Very satisfied	30	27
Satisfied	37	36
Neutral	11	11
Unsatisfied	8	12
Very unsatisfied	0	0



General Comfort (%)



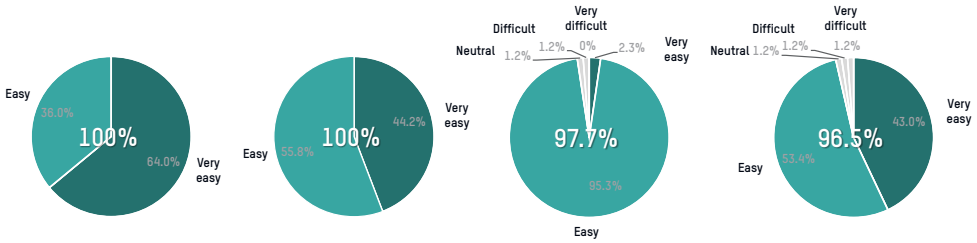
Stability (%)

Table 1. Patient's assessment of mattress comfort - N = 86

Assessment of the equipment by the nursing staff on a 5-point scale on the following parameters: ease of implementation, easy maintenance, ease of use in terms of turning patients and ease of use in terms of moving patient into a sitting position. The care team evaluated the implementation very easy or easy in the majority of cases mattress (100%), maintenance (100%), use in terms of repositioning patients (97.7%), use in terms of moving patient into a sitting position (96.5%) (Tab. 2).

	Ease of implementation	Easy maintenance	Use in terms of repositioning patients	Use in terms of moving patient into a sitting position
Very easy	55	38	2	37
Easy	31	48	82	46
Neutral	0	0	1	1
Difficult	0	0	1	1
Very difficult	0	0	0	1

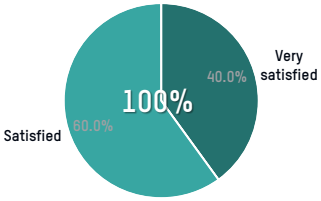
Table 2. Assessment of the equipment by the nursing staff - N = 86



The sound level of the mattress was evaluated by the patients and the results were satisfied or very satisfied in the majority of cases (Tab. 3).

	Sound level
Very satisfied	34
Satisfied	51
Neutral	0
Unsatisfied	0
Very unsatisfied	0

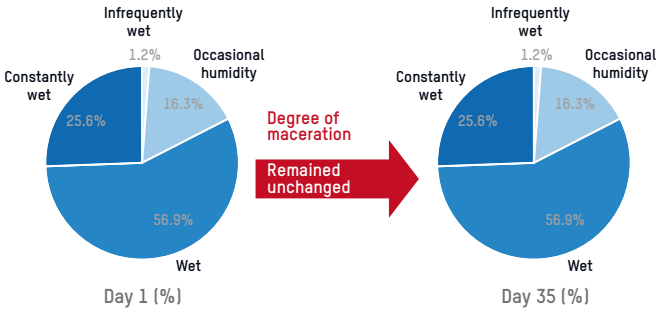
Table 3. Patient's assessment of the sound level of the mattress - N = 85 * (* 1 patient did not answer this question)



On day 35, the maceration score was compared to that of day 1 and the degree of maceration has not changed. The maceration score was 1.9 ± 0.7 on a score of 1 to 4 (Tab. 4).

	Day 0	Day 35
Infrequently wet	1	1
Occasional humidity	14	14
Wet	49	49
Constantly wet	22	22

Table 4. Degree of maceration - N = 86



Conclusion:

To conclude, Domus 4 / Auto has proven to be effective in preventing pressure injury and gained great customer satisfaction based on a 35-day clinical study in France.

FAQ

(1) How long does it take for the mattress to deflate when the CPR system is triggered?

It takes less than 20 seconds for the mattress to be deflated for performing CPR

(2) How long does it take to fully inflate the mattress?

It takes less than 30 minutes to fully inflate the mattress.

(3) The new Domus Auto replaces "Static" mode with "CLP" mode. What are the differences? What is the reason behind the change?

In Domus 4/Auto, "Static" mode & "CLP" mode are the same. Apex redefined the terms to differentiate "Static" mode for non-digital pump (Domus 3) from "CLP" mode for digital pump (Domus 4, Domus Auto).

"CLP" - Provides patient a stable static surface with a relatively low pressure (2/3 of the chosen alternating pressure).

"Static" - Provides patient a static surface with the same pressure as the chosen alternating pressure.

(4) When is Continuous Low Pressure (CLP) mode used? What are the benefits of CLP comparing to Alternating Mode?

When clinically indicated, CLP can be activated for better patient immersion, envelopment and comfort.

References

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7. Section 10: Support Surfaces. **Page 155**
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